



STATIC STANDING FRAME

ASTRIDE™



USER MANUAL





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

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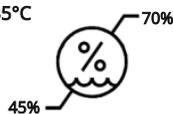
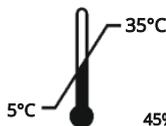


Product marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.



Akces-MED Ltd. 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

ASTRIDE™ is an advanced single-column standing frame with an abduction function. The design of the device allows for lower limb abduction so that the femoral head can be properly positioned in the acetabulum. This prevents hip dysplasia and ensures correct joint alignment in the frontal plane during upright standing. Rotating knee supports stabilize and secure the knee joint and allow the lower limbs to be positioned according to the clinical picture. Thoughtful design of the knee supports eliminates pressure on the knee cap during use of the product.

The correct standing position in **ASTRIDE™** is also possible due to the independently adjustable chest and hip belts. The central column allows the upright standing of people from 90 cm to 130 cm tall. Comfortable belts and support guarantee safety and comfort while using the product.

The **ASTRIDE™** single-column standing frame is highly recommended for children and adolescents at risk of hip dislocation. It is the control of proper leg abduction that significantly reduces the likelihood of hip joint injury.

A stable base equipped with wheels with independent brakes allows easy transfer of the standing frame between rooms. The practical table top facilitates therapy and everyday activities such as studying, playing and eating.

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:

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Before using the stander, read this user manual which is essential for proper and safe use of the stander.

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





1. 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 **ASTRIDE™** standing frame, user is obliged to familiarize himself / herself with user manual.

2. INDICATIONS AND CONTRAINDICATIONS 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.

It is recommended for users 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,
- degeneration 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 arrhythmias, 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.

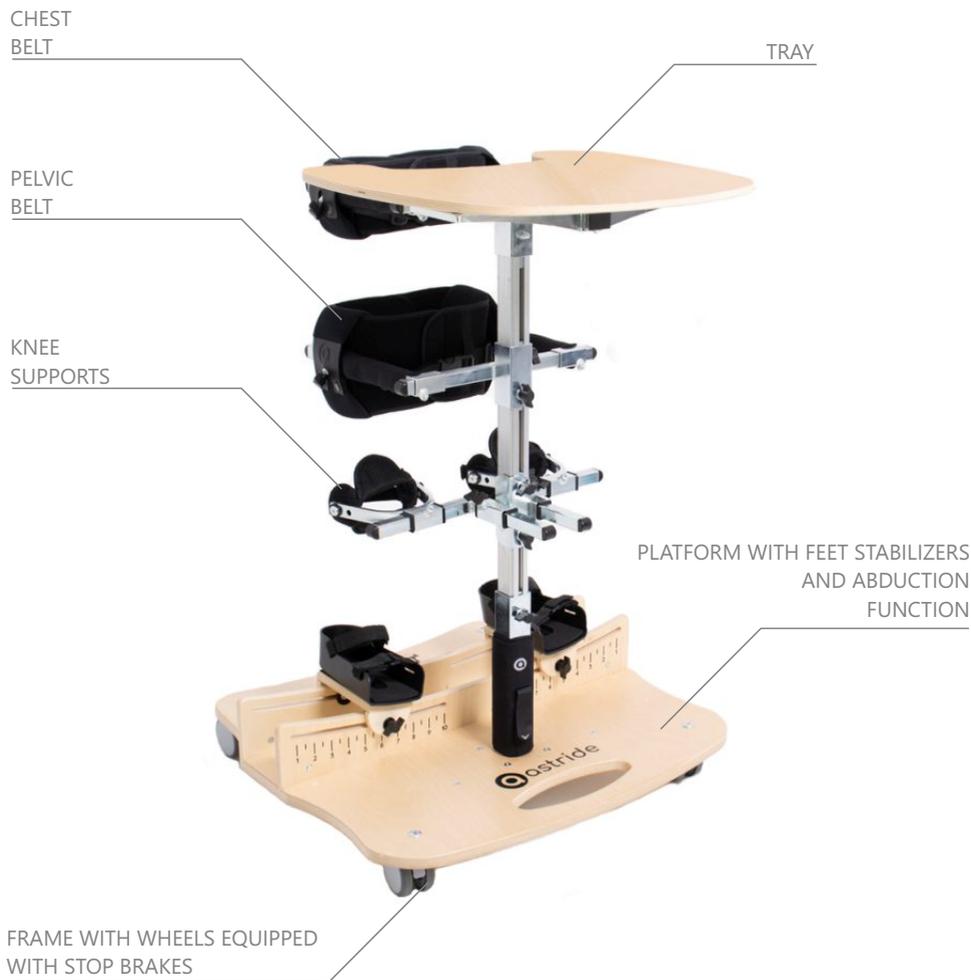
In case of people with impaired cardiovascular system (arterial hypertension at rest above 200/110 mmHg, pulmonary hypertension, cardiac arrhythmias, moderate heart valve disease); respiratory system (unstable asthma) and unstable metabolic disorders, it is necessary to monitor the user while standing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





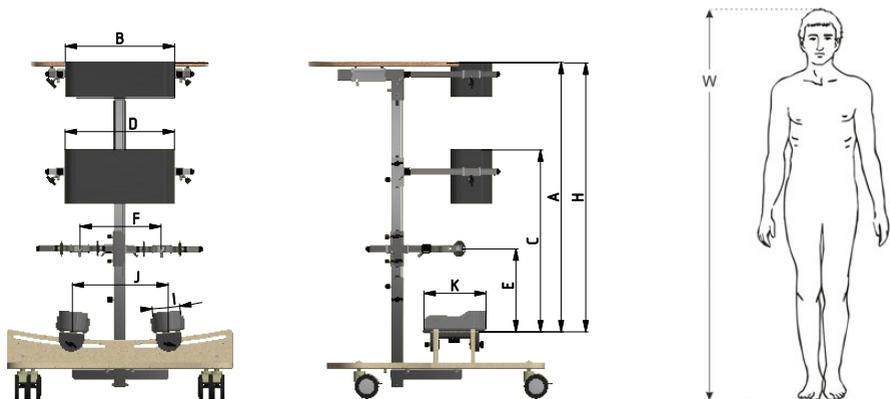
3. GENERAL CHARACTERISTIC

3.1 STANDARD EQUIPMENT





4. SIZE TABLE



Symbol	Measurement	Unit	Size 1
W	indicative user height*	[cm]	90 - 130
A	chest belt height	[cm]	61 - 83
B	chest belt width	[cm]	18 - 40
	chest belt perimeter	[cm]	56 - 96
C	pelvic belt height	[cm]	40 - 73
D	pelvic belt width	[cm]	18 - 40
	pelvic belt perimeter	[cm]	56 - 96
E	knee supports height	[cm]	22 - 54
F	knee supports width	[cm]	17 - 45
H	tray height	[cm]	63 - 85
I	footer width	[cm]	8 (size S) 10 (size M)**
J	footer spacing	[cm]	12 - 62
K	footer length	[cm]	19 (size S) 23 (size M)**
	max. user weight	[kg]	50

Note: Measurement tolerance range is +/- 1 cm / ½ in.
 * Height cannot be the main parameter while choosing the product size.

Weight and dimensions	Unit	Size 1
width	[cm]	70
length	[cm]	72 - 76
height	[cm]	82 - 104
weight	[kg]	21

Note: Measurement tolerance range is +/- 1 cm / ½ in.
Note: Approximate values, depending on the product configuration.





5. ASSEMBLY



During installation, the lower column of the upright should be installed first.

There is a locking device on one side of the column, preventing it from sliding out completely during adjustment.

The method of assembly is shown on page 10.





The column should be inserted so that the lock (fig. 2) is on the side of the lower adjustment knob, marked in fig. 1.





Make sure that plates (**fig. 5**) are lead in standing frame column properly (**fig. 6**).

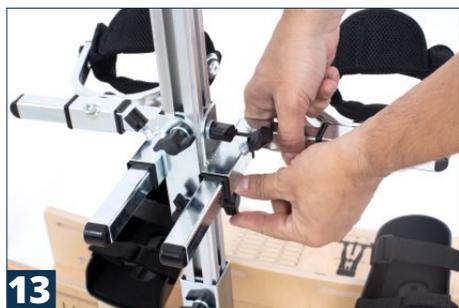


After the column assembly, make sure to tighten the knobs properly.





KNEE SUPPORTS



After the knee supports assembly, make sure to tighten the knobs properly.

PELVIC BELT





After the pelvic belt assembly, make sure to tighten the knobs properly.

TRAY WITH CHEST BELT



After the assembly, make sure to tighten the knobs properly.





6. DESCRIPTION HOW TO USE STANDING FRAME



Adjust the standing frame to the user before use.

6.1 HEIGHT ADJUSTMENT



To adjust the height of the standing frame use the knobs located on the column of the standing frame.

1. Loosen the knobs on the column.
2. Set the height of the standing frame - there is a scale on the column that makes it easier to set the desired height.
3. Tighten the knobs.

Please note that when you change the height of the column of the standing frame, the height of the tray, the hip belt and the chest belt also change.



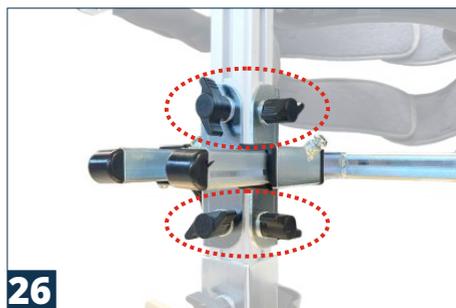


6.2 KNEE SUPPORTS ADJUSTMENT

6.2.1 KNEE SUPPORTS HEIGHT ADJUSTMENT



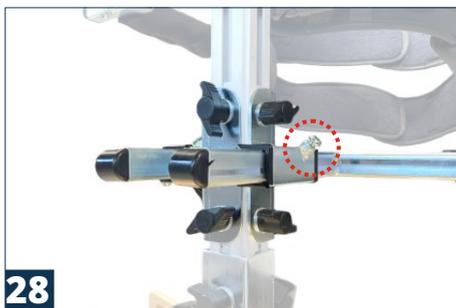
The height of the knee supports can adjusted independently. Each knee support has two height adjustment knobs - for one knee support the knobs are on the front side and for the other knee support the knobs are on the side of the column.



6.2.2 KNEE SUPPORTS DEPTH ADJUSTMENT



The depth of the knee supports is adjusted with the attached hex key and a clamping screw for each of the knee supports.





6.2.3 KNEE SUPPORTS SPACING ADJUSTMENT



The spacing of the knee supports is adjusted using the attached hex key and a clamping screw for each of the knee supports.

6.3 CHEST / PELVIC BELT ADJUSTMENT

6.3.1 ADJUSTMENT OF THE HEIGHT OF THE CHEST / PELVIC BELT



The height of the pelvic belt is adjusted with knobs **(fig. 30)**.
The height of the chest belt is adjusted together with the height of the standing frame.





6.3.2 ADJUSTMENT OF THE WIDTH OF THE CHEST / PELVIC BELT



The width of the belts is adjusting with the attached hex key and clamping screw located on chest and pelvic belt regulations.

The adjustment is done independently on the right and left side of the belts, allowing for lateral positioning of the user in the standing frame.

The width adjustment is also done with the use of Velcro straps placed on the belts.

The belts are additionally secured with a buckle.



6.3.3 ADJUSTMENT OF THE DEPTH AND ROTATION OF THE CHEST / PELVIC BELT



The depth of the belts is adjusted with the knobs (fig. 34, 35).

The adjustment is done independently on the right and left side of the belts, allowing for lateral positioning and rotation of the user in the standing frame.

The belts are additionally secured with a buckle.





6.4 TRAY ADJUSTMENT



To adjust the tray, use the attached hex key and clamping screw under the tray. The tray has a front - back adjustment to fit it to the user's needs.

6.5 FEET ADJUSTMENT

6.5.1 FEET SPACING ADJUSTMENT



Each feet stabilizer is blocked with two knobs. By loosening the knobs, you can set the user's feet in the proper position, including the abduction. Make sure to tighten the knobs properly.





6.5.2 ADJUSTMENT OF THE FRONT AND BACK MOVEMENT AND ROTATION OF THE FEET



Each feet stabilizer has a front - back and rotation adjustment.
The adjustment is possible after loosening the knobs located under the stabilizers.
Make sure to tighten the knobs properly.





7. THE USE OF STANDER



Before using the **ASTRIDE™** stander, read this user manual.
Before each use, prepare the user and the device!

7.1 PREPARATION OF THE USER

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

- user'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 user 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, orthosis, shoes) if it is recommended by doctor.



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

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





7.2 PREPARATION OF STANDING FRAME

1. How to prepare the standing frame for use:

- assemble the standing frame,
- place the standing frame on an even and flat surface, away from sources of fire and high temperature,
- make sure that all the elements are undamaged, properly mounted and stable;
- push the brakes,
- adjust the standing frame to the user's size and needs,
- unfasten the chest and pelvic belts in order to place the user in the standing frame,
- fasten the elements which stabilize the user - the chest and pelvic belts,
- mount the tray.



Before using the standing frame, make sure that all the belts and other elements have been properly adjusted, and all the knobs and fastenings of the adjustable elements are firmly tightened.

The standing frame will fulfil its function properly only when it is adjusted to the size and needs of the user. The most important thing, while adjusting the standing frame to the user, is to provide the user with the maximum feeling of safety. The improper use of the standing frame may lead to strengthening the incorrect posture patterns.

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





7.3 UPRIGHT POSITION

It is necessary to:

1. Prepare a place for upright standing. It is important to choose a room without any dangers (such as: strewn toys or other objects).
2. Move a standing frame closer to a place in which the user is situated.
3. Block castors from a standing frame, wheel chair or other device in which the user is sitting.
4. Move the user and place him in a standing frame. We ought to make sure that all alignments are preserved. Implement corrections if necessary.
5. Fasten belts stabilizing chest, hips and foot.
6. Make sure that all belts and precautions were correctly adjusted and fastened.

The length of time for upright position process is different for each user. 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 user'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 user 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 user unattended!

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 user 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.

The ending of upright position:

1. It is essential to prepare a place in which the user will be taken out from a standing place. It is important to choose a room without any dangers.
2. Move a standing frame closer to a place in which the user will be moved.
3. Block castors from a standing frame, orthopaedic bed or other device in which the user will be situated.
4. Unfasten belts which stabilize foot, hips and chest.
5. Make sure that all belts and precautions do not block the user.
6. Move the user and place him on a prepared device.





8. SAFETY RULES



Stander **ASTRIDE™** has to be used in compliance with guidelines in this user manual.
Before each use, prepare the user and the device.

It is highly important to consult either doctor or physiotherapist in order to make right decision concerning the choice of **ASTRIDE™** 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 user'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 the condition of the upholstery for any signs of damage,
 - 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 user's measurements and needs e.g. the adjustment of pelottes etc.,
 - make sure that all movable parts and knobs for adjustments are stable and locked,
 - secure the user with available stabilizing aids of the standing frame. It is highly important to secure patient because it safeguards him/her from falling out.
2. It is forbidden to use standing frame for different purposes that it is intended.
3. It is forbidden to use standing frame when it is damaged or any part is missing.
4. It is forbidden to leave the user unattended.
5. Stroller should be used only when there is someone who is trained and knowledgeable.
6. It is forbidden to leave standing frame and the user 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 user is placed in the device or not.





8. It is important to engage brake during getting into and getting out the standing frame.
9. Make sure that all limbs are not close to spokes or other adjustable elements.
10. The standing frame should be stored and used away from sources of fire or high temperature. Moreover, standing frame shouldn't be stored in rooms with high humidity.
11. Secure standing frame 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 standing frame, 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.

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

The device contains small parts which children may swallow.

Do not use a product that shows any signs of damage, destruction or wear. Only a fully functional product, used in accordance with the instructions for use, is safe for the user. If the product is damaged, discontinue use and contact us with 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 losing warranty.

The weight of user should not be bigger than maximal weight described on page 8 where you will find information regarding this issue.

This device can be only used inside the buildings!





9. TERMS OF WARRANTY

- Akces-MED Ltd. sells products free from manufacturing defects or faults.
- Manufacturer gives the purchaser 24-month guarantee from the date of purchase. All defects revealed during warranty period will be repaired free of charge.
- 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.
- The stander is covered by a 36-month warranty on the territory of Canada – the details of the rights resulting from the extended warranty are regulated by the warranty card.
- 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.
- If product is damaged, please contact our dealer or Akces-MED Ltd. customer service (ph. +48 17 864 04 77, e-mail: export@akces-med.com).





10. MAINTENANCE AND CLEANING

The standing frame **ASTRIDE™**, 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 Ltd.**, 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.





TECHNICAL INSPECTION

Technical inspections should be performed regularly. Before servicing, the product should be thoroughly cleaned to reveal any hidden damage.

Frequency	What should be checked? What should be done?	Remarks
Before each use.	<p>General condition of the product.</p> <p>Check:</p> <ul style="list-style-type: none"> the entire product for any visible damage, cracks or mechanical defects,, if the product complete, if all bolts, screws, knobs, nuts and other elements of the construction are complete and tightened.. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	<p>Wheels and brakes.</p> <p>Check:</p> <ul style="list-style-type: none"> if the wheels are properly mounted and if they are not damaged, if the brake is blocking the spinning wheel, if the wheels are not dirty. If necessary, clean the wheels. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	<p>Fastening of the construction elements.</p> <p>Check all the mechanisms of the product and its moving parts. Check in particular:</p> <ul style="list-style-type: none"> if the seat is properly mounted (if applicable), if the wheels are properly mounted (if applicable), if the elements securing the user are properly mounted and if they work well (if applicable), if all the moving parts are complete, work properly, do not jam, if the adjustment mechanisms of the following elements work properly (if applicable): headrest, backrest, seat, abduction block, armrests, footrests. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	<p>Upholstery elements.</p> <p>Check:</p> <ul style="list-style-type: none"> if there is any damage, tears, rips, loose seams or deformations on the upholstery elements, if the stabilizing straps, vests or safety belts are not frayed or twisted and if the buckles work properly, if the stabilizing straps, vests or safety belts work correctly and do not unfasten under pressure or when pulled. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
Once a week.	<p>Product cleaning.</p> <p>If the frame and upholstery get dirty (dusty, muddy, etc.) during everyday use, wipe them with a damp cloth without detergents. Remove dirt (e.g. hair, food remains, etc.) from the moving parts of the product.</p>	The product should be cleaned when necessary, but at least once a week. Do not use any chlorine based cleaners or methylated spirit. Before using the product, check if the upholstery is dry.





Frequency	What should be checked? What should be done?	Remarks	
Once a month.	Wheel axles, quick connectors (if applicable).	<p>Check:</p> <ul style="list-style-type: none"> if the wheels are rolling and if they are not loose. To maintain the wheels, apply a small amount of a preservative-lubricant between the axle and the wheel hub. Check if you can easily remove and attach the wheels. 	<p>Clean the wheels when dirty.</p> <p>In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.</p>
	Product construction connectors (welding, threading, soldering)	<p>Check:</p> <ul style="list-style-type: none"> the condition of the product frame in the places of joining (welds, threads, soldering). 	<p>In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.</p>
	Tires/innertubes (if applicable).	<p>Check:</p> <ul style="list-style-type: none"> tire wear condition. Check for visible damage. Check tire pressure (if applicable). 	<p>If the tire pressure is too low, inflate them to the correct level.</p> <p>In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.</p>
Once every 6 months.	Construction moving parts.	<p>Check:</p> <ul style="list-style-type: none"> if the moving parts of the construction have not been damaged. Maintain them using a proper cleaning agent. 	<p>In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.</p>
	Product labeling.	<p>Check:</p> <ul style="list-style-type: none"> if the marking and labels are readable. 	<p>In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.</p>
After the life time of the product finishes.	Detailed product check.	Check the product.	<p>The manufacturer specifies the life time of the product, which is given in the user manual. After the given period, the user may use the product only if it is sent back to the manufacturer to be checked first. After that, the manufacturer will re-define the life time of the product and the date of the next check.</p>

The list of all spare parts is available for download after selecting a product on www.akces-med.com.





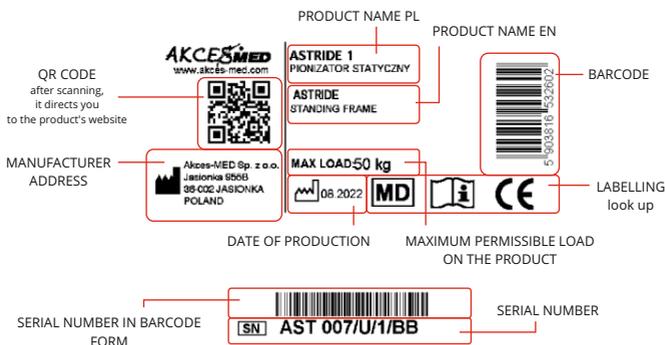
11. LABELLING

11.1 SYMBOLS

- Declaration that the product meets the essential requirements
- Catalog number
- Serial number
- Please read the manual instructions before use
- You need to take special precautions
- Manufacturer
- Production date
- The product does not contain latex
- Store in a dry place
- Careful! Delicate content
- Protect from sunlight
- Storage temperature limitation
- Relative humidity storage

- 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 belts
- 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
- Medical device

11.2 SAMPLE DATA PLATE

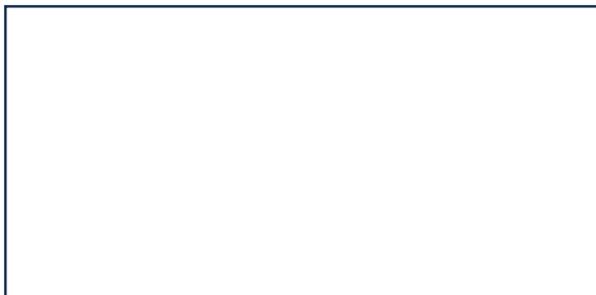


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Date of issue: 19.07.2021
The last update: 21.12.2022
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