STANDING FRAME

GENIUS®

USER MANUAL

CE

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!

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

MEDICAL DEVICE CLASS 1 WYRÓB MEDYCZNY KLASA 1

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.

CERTYFIKACJA SYSTEMU JAKOŚCI DNV·GL ISO 13485

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

The **GENIUS®** standing frame has been created for the most demanding customers. Its well thought-out design gives you infinite adjustment possibilities of all the independent elements in every plane so the standing frame can be perfectly adjusted depending on the user's needs.

Every element is thoroughly designed and the materials used are of very high quality – all these factors make the standing frame comfortable and safe for the user. Rehabilitation of people with spinal, pelvic or knee joint dysfunctions does not have to be complicated – with the **GENIUS®** standing frame it is much more effective and its effects are long-lasting.

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 +48 516 183 883*
Akces-MED. Sp. z o.o.: *tel. +48 17 864 04 77*
e-mail: *export@akces-med.com*

Thank you for purchasing our product!

Before using the stander, read this user manual which is essential for proper and safe usage 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 **GENIUS®** standing frame, user is obliged to familiarize himself/herself with user manual.

2. INDICATIONS FOR USE

It is recommended for users in the following cases:

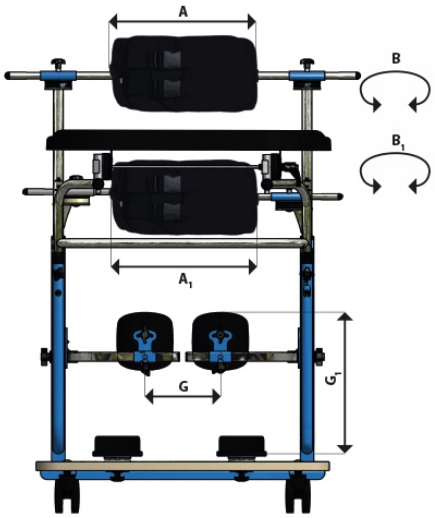
- cerebral palsy – various types and forms,
- brain and spinal cord injuries with lower limbs paralysis and weakness, balance and motor coordination disorders with different etiology,
- demyelinating disease (e.g. multiple sclerosis – SM),
- meningocele,
- muscles diseases with weakness and paralysis (dystrophy, myasthenia gravis, myositis),
- genetic disorders,
- 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.

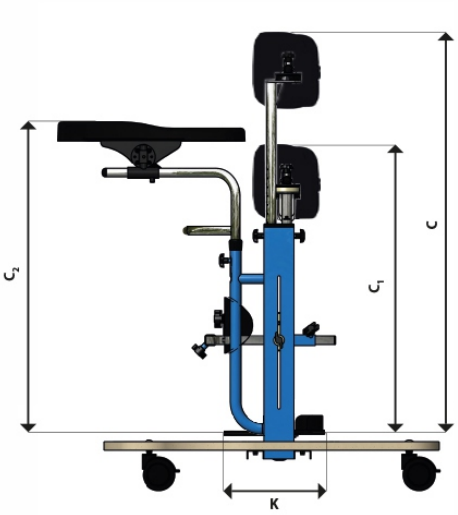
3. GENERAL CHARACTERISTIC

3.1 Standard equipment

1. Frame
2. Mobile base with wheels with brakes
3. Sandals with the adduction and abduction function, equipped with feet stabilizing belts
4. Independently adjustable knee supports
5. Pelvic belt with pelvic rotation function
6. Chest belt with chest rotation function
7. Tray

4. SIZE TABLE





SIZE TABLE

Symbol	Measurement	Unit	Size 1	Size 2	Size 3
	indicative user height*	**[cm]**	**75 - 100**	**95 - 125**	**120 - 150**
A/A_1	**chest/pelvic support width**	**[cm]**	**10 - 24**	**12 - 24**	**20 - 33**
C	**chest support height****	**[cm]**	**55 - 67**	**72 - 89**	**83 - 107**
C_1	**pelvic support height****	**[cm]**	**45 - 55**	**56 - 69**	**67 - 87**
B/B_1	chest/pelvic support perimeter	[cm]	43 - 67	50 - 77	66 - 100
C_2	tray height**	[cm]	54 - 70	64 - 90	73 - 100
G	knee supports width	[cm]	6 - 25	6 - 30	6 - 35
G_1	knee supports height**	[cm]	25 - 35	23 - 43	37 - 53
K	footer length	[cm]	17	20	23
	max. user weight	[kg]	35	45	55

	Weight and dimensions		Size 1	Size 2	Size 3
	Width	[cm]	56	60	66
	Length	[cm]	72	80	88
	Height	[cm]	66	83	95
	Weight	[kg]	20	24	27

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

5. DESCRIPTION HOW TO USE STANDING FRAME

KEY

Info icon - appears in the manual when you need to read the additional information.

Info icon - appears in the manual when you need to use the tools indicated in the assembly description.

Warning icon - appears in the manual when you need to take **special precautions.**

5.1 CHEST AND PELVIC BELT ADJUSTMENT

5.1.1 HEIGHT ADJUSTMENT OF THE BELTS

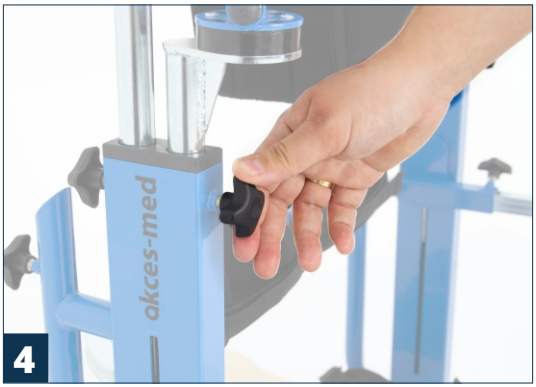
1

Use knobs (A) to adjust the height of the chest belt (**fig. 2 - 3**). Before adjusting the height, loosen both knobs.

2

3

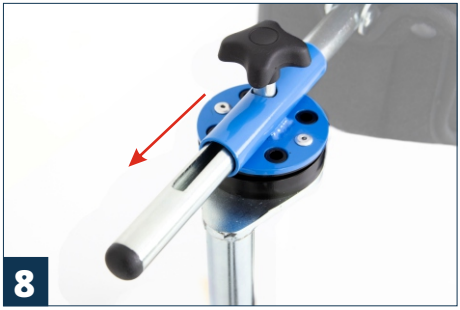
Use knobs (B) to adjust the height of the pelvic belt (**fig. 4 - 5**). Before adjusting the height, loosen both knobs.

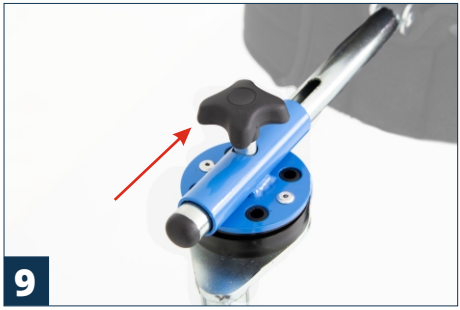


5.1.2 SETTING THE POSITION AND ADJUSTING THE WIDTH OF THE CHEST AND PELVIC BELTS

Use knobs (C) to adjust the width of the chest belt (**fig. 10 - 11**) and to position the belt laterally (**fig. 12 - 13**).

Use knobs (D) to adjust the width of the pelvic belt (**fig. 10 - 11**) and to position the belts laterally (**fig. 12 - 13**).





WIDTH ADJUSTMENT OF THE BELTS

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11

LATERAL ADJUSTMENT OF THE BELT

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13

5.1.3 DEPTH AND ROTATION ADJUSTMENT OF THE BELTS

Use knobs (C) to adjust the depth (**fig. 16 - 17**) and rotation (**fig. 21 - 24**) of the chest belt.

Use knobs (D) to adjust the depth (**fig. 16 - 17**) and rotation (**fig. 21 - 24**) of the pelvic belt.

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DEPTH ADJUSTMENT OF THE BELT

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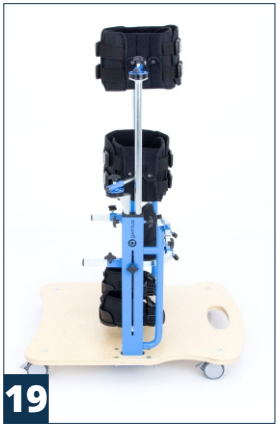
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ROTATION ADJUSTMENT OF THE BELT

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5.1.4 BELT SUPPORT

Both the chest and pelvic belts have a special support. The support helps to adjust the belts to the user's body.

5.1.5 CHEST AND PELVIC BELTS

The chest and pelvic belts can be adjusted to the circumference of the chest and pelvic with the use of the Velcro fastening. The fastening is located at the front and back of the belts.

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5.2 TRAY

5.2.1 TRAY HEIGHT ADJUSTMENT

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Use knobs (E) to adjust the height of the tray (**fig. 31 - 33**). Before adjusting the height, loosen both knobs.

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5.2.2 TRAY DEPTH ADJUSTMENT

34

Use knobs (F) to adjust the depth of the tray (**fig. 34 - 36**). Before adjusting the depth, loosen both knobs.

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5.2.3 TRAY TILT ANGLE ADJUSTMENT

Use knobs (G) to adjust the tilt angle of the tray (**fig. 37 - 40**). Before adjusting the angle, loosen both knobs.

5.3 KNEE SUPPORTS

5.3.1 KNEE SUPPORTS HEIGHT ADJUSTMENT

41

Use knobs (K) to adjust the height of the knee supports (**fig. 41 - 43**). Each knee support can be adjusted independently.

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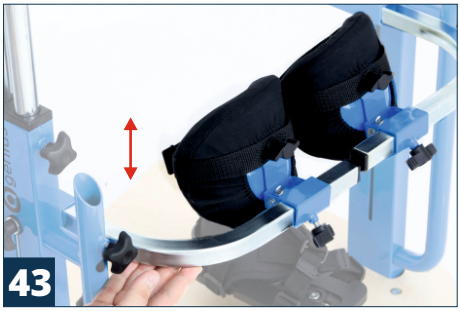

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5.3.2 KNEE SUPPORTS SPACING ADJUSTMENT

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Use knobs (H) to adjust the spacing of the knee supports (**fig. 44 - 48**).

You can adjust the knee supports according to the deformations within the knee joints – valgus or varus. Each knee support can be adjusted independently.

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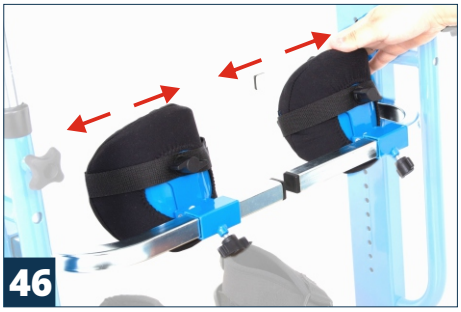
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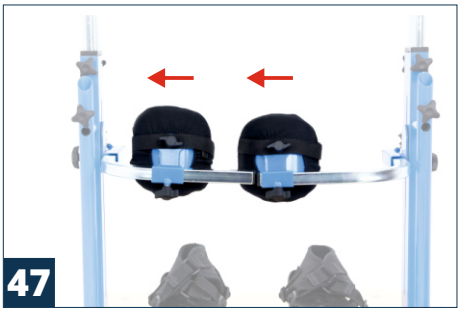
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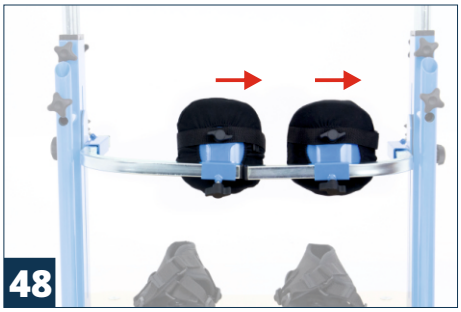
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5.3.3 FRONT-BACK KNEE SUPPORTS ADJUSTMENT

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Use knobs (J) to adjust the knee supports in the front-back plane (**fig. 49 - 53**).

You can adjust the knee supports depending on the needs and therapeutic indications, e.g. existing flexion contractures. Each knee support can be adjusted independently.

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5.3.4 KNEE SUPPORTS ANGLE ADJUSTMENT

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Use knobs (I) to adjust the rotation of the knee supports (**fig. 54 - 58**).

You can set the knee supports at the proper angle to achieve the desired positioning of the knee joint area.
Each knee support can be adjusted independently.

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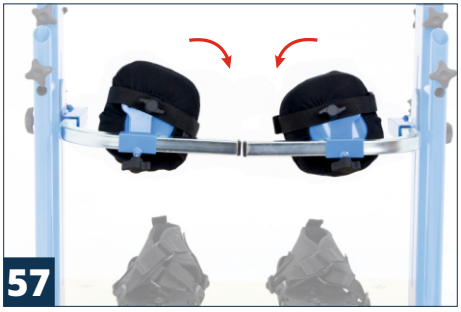
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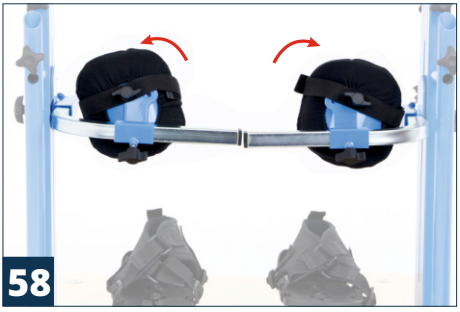
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5.3.5 FRONT-BACK KNEE SUPPORTS ANGLE ADJUSTMENT

With the additional joint, the knee supports automatically adjust to the user.

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5.4 SANDALS WITH FEET STABILIZING BELTS

The user of the stander must always wear proper footwear which provides stabilization of the ankle joints to minimize the risk of injury.

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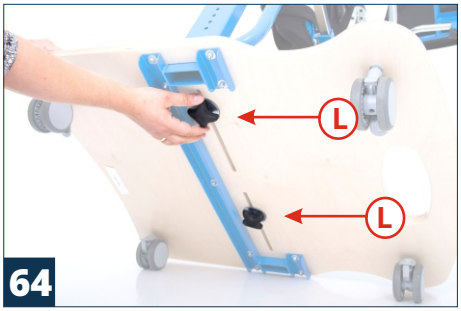
5.4.1 SANDALS SPACING ADJUSTMENT

Use knobs (L) to adjust the spacing of the sandals (**zdj. 64 - 66**).

Sandals can be set in a selected position conducive to the correct upright standing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L
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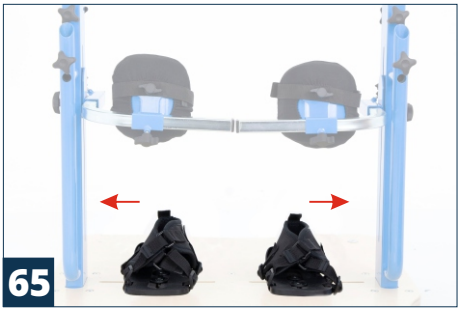
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6. THE USE OF STANDER

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

6.1 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, orthesis, 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!

6.2 THE 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.

6.3 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 fasteningsfrom adjustable elements are correctly adjusted andfastened!

It is forbidden to leave the patient 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.

7. SAFETY RULES

Stander **GENIUS®** 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 **GENIUS®** 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 to.

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.

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 uswith 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.

The weight of user should not be bigger than maximal weight described on page 7 where you will find information regarding this issue.

This device can be only used inside the buildings!

8. 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 stroller 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 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.
- If product is damaged, please contact our dealer or **Akces-MED Ltd.** customer service (ph. 17/864 04 77, e-mail: export@akces-med.com).

9. MAINTENANCE AND CLEANING

The standing frame **GENIUS®**, 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.

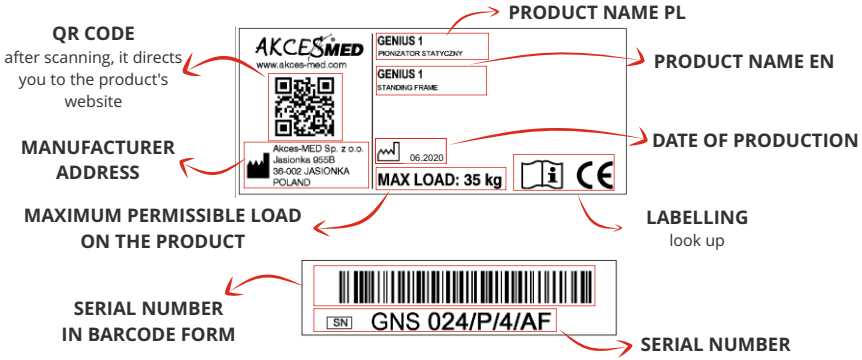
In case of any damages, it is essential to contact the person who sold you the product.

10. LABELLING

10.1 SYMBOLS

- Declaration that the product meets the essential requirements
- REF — Catalog number
- SN — Serial number
- Please read the manual instructions before use
- You need to take special precautions
- Manufacturer
- Production date
- LATEX — The product does not contain latex
- Store in a dry place
- Careful! Delicate content
- Protect from sunlight
- 5°C / 35°C — Storage temperature limitation
- 45% / 70% — 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

10.2 SAMPLE DATA PLATE



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