

STANDER

CAT II INVENTO[™]



USER MANUAL

CE

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.







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INTRODUCTION

Standing frame **CAT II INVENTO™** was designed to help during rehabilitation of children with paresis of lower limbs and trunk in order to enable those children taking the upright position. It is designed for active rehabilitation of handicap children. It enables independent (with supervision), safe standing, play and education.

Thanks to its simplicity **CAT II INVENTO™** is a valuable device in rehabilitation of handicap children at home, hospitals, rehabilitation centers. Used properly may significantly improve the quality of life of children.

Due to the usage of wood, colorful upholstery, bright colors and nice figure of cat children tend to treat the device more like a toy than the rehabilitation device.

It is a very universal device, very flaccid children can be put in it in upright position as well as children with huge muscle tone. Its universal character comes from wide range of proposed adjustments.

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



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 **CAT II INVENTO™** standing frame, user is obliged to familiarize himself/herself with user manual.

2 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.





3 GENERAL CHARACTERISTICS OF STANDER

3.1 Standard equipment

- 1. Foot rest with street castors with gas spring
- 2. Foot stabilization
- 3. Knee stabilization
- 4. Pelvis supports
- 5. Chest supports
- 6. Pelvis stabilizing belt
- 7. Chest stabilizing belt
- 8. Head rest (used during supine standing)
- 9. Tray







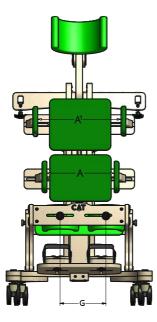
3.2. Additional equipment

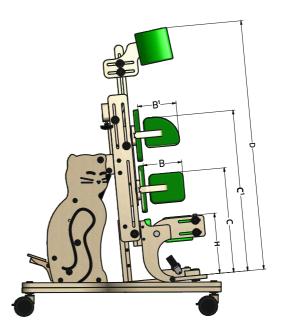






SIZE TABLE





C	ol Measurement	Unit	Size 1		Size 2	
Symbo		onit	Supine	Prone	Supine	Prone
A	Hip support width	[cm]	14-27	14-27	18-31	18-31
В	Hip support depth	[cm]	15	15	15	15
с	Foot rest to top of hip support	[cm]	30-59	34-59	27-78	40-78
A1	Chest support width	[cm]	14-27	14-27	18-31	18-31
B1	Chest support depth	[cm]	15	15	15	15
C1	Foot rest to top of chest support	[cm]	46-75	50-75	50-97	65-97
D	Foot rest to top of head rest	[cm]	72-106	-	80-135	-
G	Knee support width	[cm]	14-23	14-23	14-23	14-23
н	Foot rest to knee support	[cm]	15-31	15-54	15-54	15-54
	Upright position angle	[°]	0-9	0	0-9	90
	Maximum user weight	[kg]	35	i	4	5
	Weight and dimensions of the device	Unit				
	Product width	[cm]	60		60	
	Product length	[cm]	81		81	
	Product height	[cm]	85		90	
	Product weight	[kg]	21		21	

Note: Dimensional tolerance in the table is +1/-1 cm.



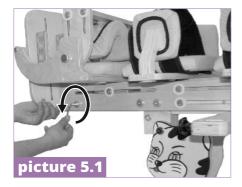


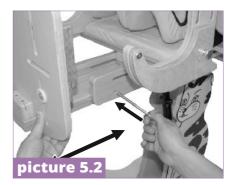
5 DESRIPTION HOW TO USE STANDER

5.1 Adjustment of the foot rest

This is the main adjustment to the height of the user. In order to do that it is necessary to:

- remove the screw located in the lower part of the standing frame using the 5mm key (point 11 page 6) included with the device (picture 5.1)
- place the foot rest in the required position (picture 5.2)
- insert the screw into the whole and tighten it with the key (picture 5.2)





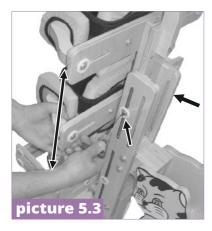


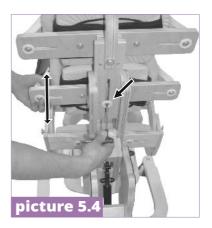


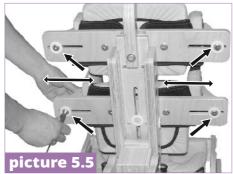
5.2 Adjustment of back stabilization

In order to properly adjust the back stabilization it is necessary to:

- remove the screws, place the back rest in the required position, insert the screws back into the wholes and tighten them (picture 5.3)
- adjust the pelvis supports (picture 5.4)
- adjust the distance between chest and pelvis supports (picture 5.5)









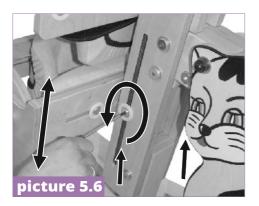


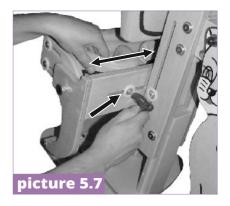


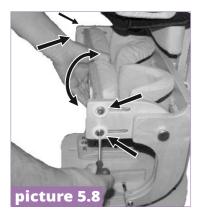
5.3 Adjustment of knee stabilization

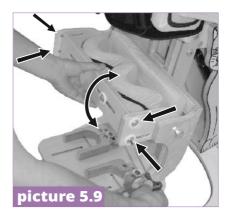
In order to properly adjust the knee stabilization it is necessary to:

- adjust the height of the knee stabilization (pict. 5.6)
- adjust the distance between the knee supports (pict. 5.7)
- place the knee cushion in the required position (pict. 5.8)
- to prepare the device to the supine position additionally the knee supports must be adjusted (pict. 5.9)













5.4 Adjustment of head rest

The head rest is used in supine position. The adjustment is presented in chapter 7

In order to properly adjust the head rest it is necessary to:

- adjust the correct height, angle of head position towards the body (pict. 5.10)
- shape the head rest to fit patient's head (pict. 5.11)





5.5 Adjustment of foot stabilization

a) heel stabilization

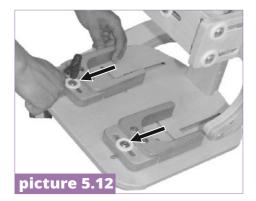
In order to properly adjust the heel stabilization it is necessary to:

- adjust the location and the distance between the heel stabilizations (pict. 5.12)
- adjust the width of heel stabilization to fit the shoes of the patient (pict. 5.13)







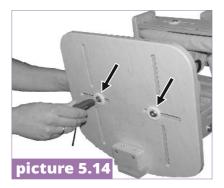


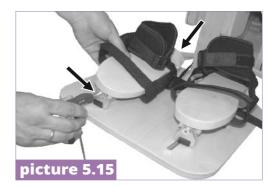


b) footers with 3D adjustment (optional equipment)

If the device is equipped with 3D footers you have to adjust:

- location and distance between the footers (pict. 5.14)
- lateral inclination of the footers (pict. 5.15)







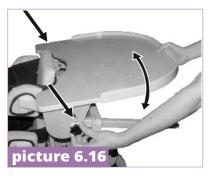


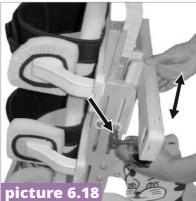
6 Additional equipment

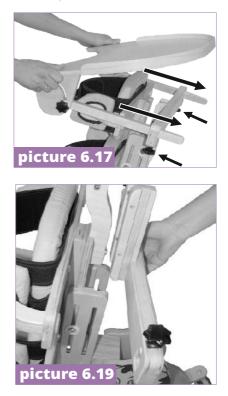
6.1 Adjustment of tray

The pictures 6.16, 5.17, and 6.18 present the way to adjust the height, assembly and tilting angle of the table.

If standing in the supine position additionally requires lowering the tray below the standard, turn the support as it is presented in the picture 6.19.









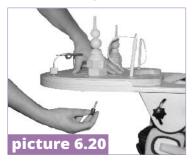
CAUTION! The adjustment of the tray in the supine position must be done after the patient is placed in the device. In case of prone position the tray is adjusted before the patient is placed in the device!





6.2 Table for manual therapy

The table for manual therapy is assembled after the patient is placed in the device. The table for manual therapy is placed on the normal table and fixed to it with 2 screws (pictures 6.20 and 6.21).



6.3 Head supporting belt

Head supporting belt is attached to the back of the head rest (picture 6.22). It is used only if the device is in supine position.

6.4 Soft cover for tray

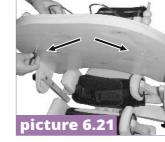
Please follow these steps so as to mount soft cover for tray:

- Adhere 5 adhesive Velcro tapes;
- Put soft cover in a way that its edges cover tray edges.









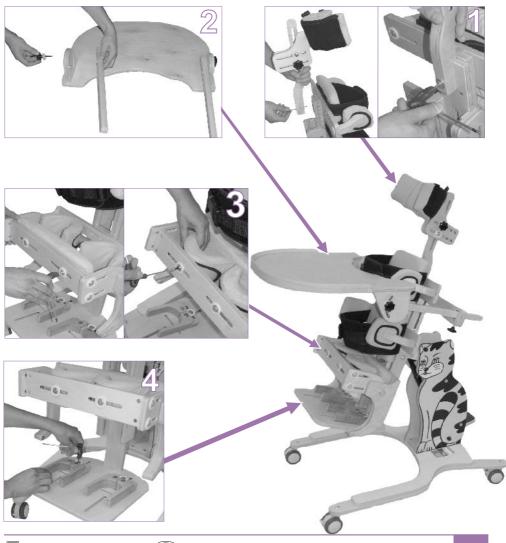




7 Adjustment of the device to the supine

In order to prepare the device for standing in supine position it is necessary to:

- 1- assemble the head rest
- 2- change position of the tray support
- 3- assemble knee supports on the other side of the knee stabilization
- 4- change position of the heel stabilization in the footers









8 THE USE OF STANDER



CAUTION! Stander **CAT II INVENTO**[™] 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.

8.1. 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!





8.2 Preparation of device before each use



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

- 1. Before use it is necessary to:
 - unfold the device;
 - place the device on even ground in a way that it is easy to reach standing frame and person who sits inside; remember to keep standing frame away from fire and high temperature
 - make sure that all parts are serviceable, correctly mounted and stable
 - check castors and brakes
 - lock brakes
 - press brakes so as to lock all castors

Regarding standard equipment, the device is created for upright position forwards. Chapter 7 clearly shows how to adjust the device for upright position backwards.



CAUTION! Decision regarding prone or supine position is taken by the leading doctor or therapist!

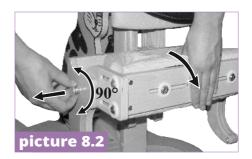
- adjust the device to the patient
- place the device in lying position pressing the pedal with your foot (pict. 8.1)
- undo the chest stabilizing belts, pelvis stabilizing belts and foot and head stabilizing belts (if the device is equipped)
- open the knee stabilization, releasing the catch hold and turning it by 90°(pict. 8.2)











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







8.3. Upright position

In order to have upright position it is necessary to:

1. Prepare place where upright position process will take place. It should be a place without any dangers (toys scattered all over the floor or any different objects).

2. Place standing frame as close as possible to the patient.

3. Lock castors from standing frame, stroller or any different device in which the patient is seated

4. Place patient in standing frame and make sure that all adjustment is correct. Make changes if necessary





5. Fasten the patient with the aid of all belts and close knee support. Make sure that all castors are situated in correct places (fig. 8.3)









6. Make sure that all belts and locking are correctly adjusted and fastened.

7. Unlock standing frame with the aid of pedal and hold patient as well as upper movable part of the device at the same time. Place the patient in proper position and then lock the device by releasing pedal.

8. Fix table (concerning upright position backwards).

9. Do everything the other way around when it is necessary to take out the patient from the device

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

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.







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).

The ending of upright position

- 1. It is essential to prepare a place in which the patient 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 patient will be moved.
- 3. Block castors from a standing frame, orthopaedic bed or other device in which the patient will be situated.
- 4. When we stabilize the patient's body we should unblock the lever which protects a servo-motor. It is important to talk as well as have an eye contact with the patient during that action. After, we slowly place the patient in the direction of gradient. When we obtain a proper tilt angle, it is necessary to block the device by releasing the lever in order that a servomotor will be blocked.
- 5. Unfasten belts which stabilize foot, hips and chest.
- 6. Make sure that all belts and precautions do not block the patient.
- 7. Move the patient and place him on a prepared device.





SAFETY RULES

CAUTION! Stander **CAT II INVENTO™** 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 **CAT II INVENTO™** 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 e.g. the adjustment of pelottes , footplate etc.;
 - make sure that all movable parts and knobs for adjustments are stable and locked;
 - secure patient with the aid of elements such as vest, foot stabilizing belts, pelottes, abduction block, headrest. It is highly important to secure patient because it safeguards him/her from falling out. If abduction contracture occurs, it is recommended to use abduction block in order to prevent ulcers between knees.

CAT II invento



- 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.

11 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. 17/8640477)





10 MAINTENANCE AND CLEANING

The standing frame **CAT II INVENTO**[™], 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.





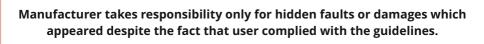


Remember that upholstery has to be always dry before using!

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.



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.	General condition of the product.	 Check: 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.
	Wheels and brakes.	 Check: 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.
	Fastening of the construction elements.		
	Upholstery elements.	 Check: 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.	Product cleaning.	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.	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 connec- tors (if applicable).	• if the wheels are rolling and if they are not loose. To maintain the wheels, apply a	discontinue the use of the product and contact your Supplier/Distributor or the
	Product construction con- nectors (welding, threading, soldering)	Check: • the condition of the product frame in the places of joining (welds, threads, soldering).	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Tires/innertubes (if appli- cable).	• tire wear condition. Check for visible	If the tire pressure is too low, inflate them to the correctlevel. In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
Once every 6 months.	Construction moving parts.	Check: • if the moving parts of the construction have not been damaged. Maintain them using a proper cleaning agent.	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
	Product labeling.	Check: if the marking and labels are readable. 	In case of any damage or defects, discontinue the use of the product and contact your Supplier/Distributor or the Manufacturer.
After the life time of the product finishes.	Detailed product check.	Check the product.	The manufacturer specifies the life time of the product, which is given in the user manual. After the given period, the user 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.

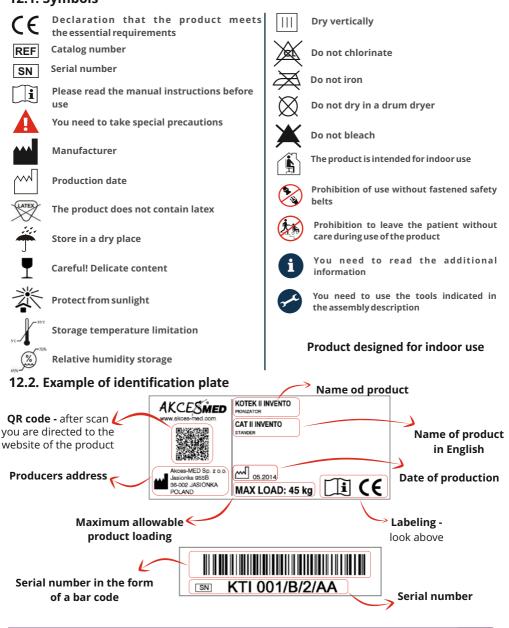
The list of all spare parts is available for download after selecting a product on www.akces-med.com.





12 LABELLING

12.1. Symbols



MANUFACTURER



Akces-MED Sp. z o.o.

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Authorised Dealer



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