

SMART TM STANDING FRAME



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USER MANUAL

Our passion – your independence!











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

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

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

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







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INTRODUCTION

SMART™ is a solid device which makes it possible for patient to adopt passive upright position. The product is easy in use thanks to which family as well as hospital staff find it easy to look after patient. Furthermore, smart is equipped with the system of precautions. It is highly beneficial due to the fact that patient feels safe and comfortable regarding his upper limbs. Both chest and pelvic brace perfectly adjust to patient's body which has an influence on his upright position. The product is equipped with castors which make it easy for patient to relocate. What is more, its construction is well planned because of which it eliminates barriers which patient may come across. Additionally, it exerts a positive influence on patient's mood and motivates him to overcome any difficulties with regard to injury or diseases.

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

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

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Thank you for purchasing our product.



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





1 THE PURPOSE OF USER MANUAL

The present user manual contains basic information which is essential for proper usage, preparation, maintenance, cleaning and guarantee conditions $\mathbf{SMART}^\mathsf{TM}$ static standing frame.

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



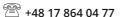
CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual.

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

2 INDICATIONS FOR USE

The device is recommended for people in the following cases:

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







GENERAL CHARACTERISTICS OF STANDING FRAME

3.1. Standard equipment

- 1. Frame with castors and brakes
- 2. Pelvic pelotte with pelvic belt
- 3. Chest pelotte with chest belt
- 4. Knee support with pelottes
- 5. Foot support with pelottes
- 6. Tray



3.2. Additional equipment





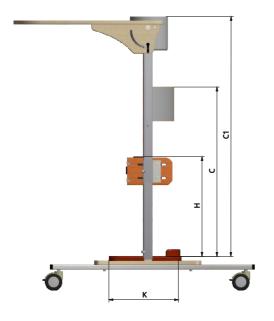








SIZE TABLE





Symbol	Measurement	Unit	Size							
			0a	1	1a	2	2a	3	3a	4
Α	Pelvic support width	[cm]	22	22	28	28	37	37	44	44
C	Pelvic support length	[cm]	18-44	18-65	24-68	28-86	28-92	30-107	30-110	33-129
A1	Chest support width	[cm]	20	20	26	26	35	35	42	42
C1	Chest support length	[cm]	41-56	58-76	55-80	70-96	72-107	86-121	86-126	106-145
	Chest support circuit	[cm]	50-64	50-64	64-76	64-76	80-105	80-105	95-125	95-125
G	Knee supports spacing	[cm]	8-10,5	8-10,5	11-14	11-14	14-20	14-20	16,5-25	16,5-25
Н	Knee supports length*	[cm]	11-35	11-55	12-57	13-72	14-78	14-88	14-96	14-98
K	Footplate length	[cm]	17	17	20	20	24	24	30	30
	Maximum user weight	[kg]	35	35	55	55	75	75	95	95
Weight and dimensions of the device		ice	0a	1	1a	2	2a	3	3a	4
	width	[cm]	50	50	60	60	70	70	78	78
	length	[cm]	63	63	70	70	87	87	91	91
	height	[cm]	55	70	70	75	75	92	92	110

10

12

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



weight



[kg]

10



13

19,8

20

24,4

26

^{*}Knee supports height depends on the height of the tray.

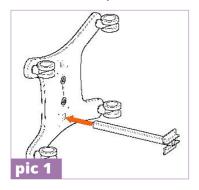


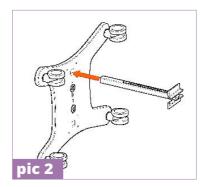


DESRIPTION HOW TO ASSEMBLY STANDING FRAME

5.1 Follow these rules so as to assembly **SMART™** standing frame in size 1 and 2:

STEP 1. Insert posts into holes in the frame so as that mesure is placed towards the outside of the device (pic. 1, 2)

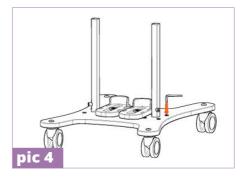




STEP 2. Fasten posts to the frame with the aid of eight screws (pic 3).

STEP 3. Tighten all screws by means of Allen wrench (pic 4).





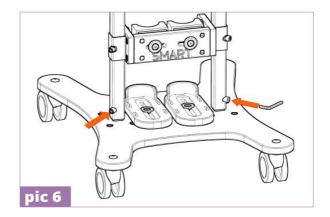
STEP 4. Place upper part of standing frame with belts, tray and knee support on frame with posts (pic 5).

STEP 5. Adjust the height at your discretion and tighten screws at posts with the aid of Allen wrench (pic 6).











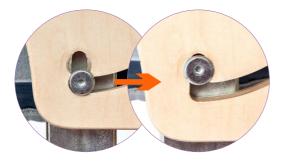
On the platform and tray, you can find yellow stickers showing the front side of the standing frame. In order to assemble the product properly, the arrows on the stickers should be pointing the same direction. After successful assembly of the standing frame, the stickers can be removed.



STEP 6. Standing frame is equipped with tray. In order to unfold tray it is necessary to:

- loosen four fastenings from tray which are placed on both sides with the aid of Allen wrench;
- Next, unfold tray's top (fig.1) and block it by pressing top (fig.2) and tightening tray's fastenings (fig. 3, fig. 4).















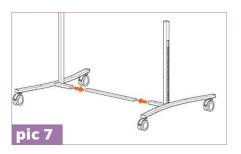


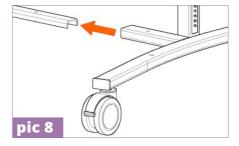




5.2. Follow these rules so as to assembly **SMART™** standing frame in size 3 and 4:

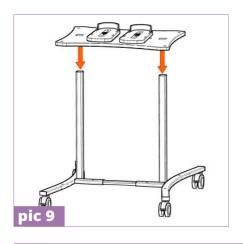
STEP 1. Insert transverse frame into profiles for frame (pic 7, 8).

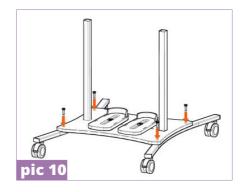




STEP 2. Put footplate on frame's posts with castors (pic 9).

STEP 3. Look at footplate, insert six screws with pads-four screws in the corners of base, two under footers (pic 10).









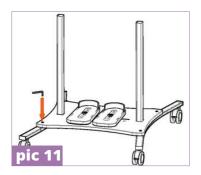


On the platform and tray, you can find yellow stickers showing the front side of the standing frame. In order to assemble the product properly, the arrows on the stickers should be pointing the same direction. After successful assembly of the standing frame, the stickers can be removed.

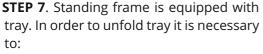


STEP 4. Tighten all screws with the aid of Allen wrench (pic 11).

STEP 5. Put upper part of Smart on frame (pic 12).

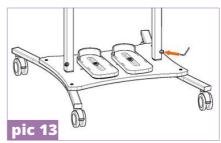


STEP 6. Tighten screws at frame's profile with the aid of Allen wrench (pic 13).



- loosen fastening from tray with the aid of Allen wrench,
- Next, unfold tray's top (fig.5) and block it by pressing top (fig.6) and tightening tray's fastenings (fig.7, fig.8).



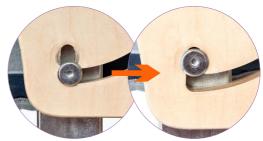




















DESRIPTION HOW TO USE STANDING FRAME

6.1. Pelvic and chest brace

6.1.1 Chest belt is fastened with the aid of Velcro tapes (fig.9).

Chest belt is equipped with stabilizing belts which are fastened by means of Velcro tapes. It is possible to choose either longer (fig.10) or shorter (fig.11) belts depending on patient's measurements.







6.1.2. Pelvic belt is fastened with the aid of Velcro tapes (fig. 12) Patient should be placed in pelvic belt as it is presented on photo (fig.13). Pelvic belt can be mounted on frame at any height. Belt stabilizes buttocks and makes it possible to adapt correct position in standing frame.









6.1.3. Pelvic belt is equipped with stabilizing belts which are fastened with the aid of Velcro tapes. It is possible to choose either longer (fig.14) or shorter (fig.15) belts depending on patient's measurements. Pelvic belt should be adjusted in a way that patient adopts upright position.





6.1.4. So as to adjust the suitable height of torso braces it is necessary to loosen screws which are situated at the frame (fig. 16). Activity should be repeated for the second frame.









6.2. Knee support

6.2.1. Loosen fastening situated on frame in order to change the height of knee support. Next, adjust the height of standing frame at your discretion and tighten firmly fastening (fig.17). Activity should be repeated for the second frame. Knee support can be adjusted either forwards or backwards. It is necessary to loosen four fastenings situated on the sides of standing frame (fig.18). Next, adjust standing frame at your discretion and fasten fastenings.



- 6.2.2. It is possible to adjust each pelotte from knee support individually. Loosen fastening situated at the front of knee support, adjust knee pelottes at your discretion and fasten fastening (fig.19). Regarding pelottes, they can be adjusted at any angle.
- 6.2.3. Concerning size 1 and 2, knee pelottes are equipped with belts which are fastened by means of Velcro tapes (fig. 20).











6.3. Foot support

6.3.1. Foot support is equipped with crisscrossed belts and heel counters (fig.21).



6.3.2. The adjustment of foot support can be easily changed. Loosen footer's fastening, adjust the position at your discretion and fasten fastening. It is possible to adjust at sides, forwards or backwards. Moreover, support can be adjusted at any angle (fig.22).





CAUTION! SMART™ standing frame should be used in compliance with guidelines in this user manual. Before using the product, it is highly important to prepare both patient and device.





ADDITIONAL EQUIPMENT

7.1 REF SMD_003 Soft cover for tray

So as to put soft cover for tray it is necessary to put it on tray and then fasten cover under top with the aid of Velcro tapes (fig.23, 24, 25).











THE USE OF STANDING FRAME



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

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. How to use SMART

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

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



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







8.3. Upright position

CAUTION!

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

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

- manipulation games
- educational games
- touch stimulation and others

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



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

CAUTION! It is forbidden to leave the patient unattended!

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





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



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







9 SAFETY RULES



CAUTION! Static standing frame **SMART™** 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 **SMART™** 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.
- 2. It is forbidden to use the device for different purposes that it is intended to.
- 3. It is forbidden to use the device when it is damaged or any part is missing.
- 4. It is forbidden to leave the patient unattended.
- 5. The device should be used only when there is someone who is trained and knowledgeable.







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

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

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



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

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







- 1) AKCES-MED Sp. z. o. o sells products free from manufacturing defects or faults.
- 2) Manufacturer gives the purchaser 24-month guarantee from the date of purchase. All defects revealed during warranty period will be repaired free of charge.
- 3) All defects which appear after warranty period can be repaired only when the user will pay for it. This rule doesn't apply to refunded products - user can ask National Health Refund for refund.
- 4) Manufacturer claims that the product can be used for 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 customer service (ph. 17/864 04 77)





10 MAINTENANCE AND CLEANING

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

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

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



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

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







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

Before using it is necessary to:

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



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

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















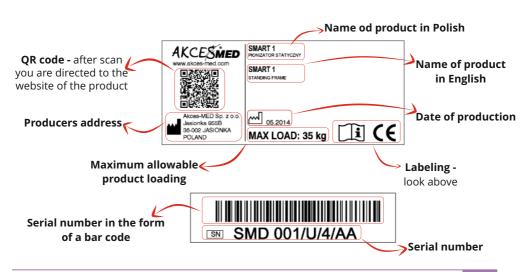


LABELLING

11.1. Symbols

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

11.2. Example of identification plate





ORTHOPAEDIC DEVICES MANUFACTURER



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Authorised Dealer					

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our passion - your independence!