STANDING FRAME



Use and Maintenance Instruction



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.

Producer's identification number in the Registration Department of Healing Products, Medical Products and Biocide Products:

PL/CA01 04088/W





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..

Daily patient's upright standing is a vital element of the process of rehabilitation and it has a positive influence on mental state of disabled person.

Static standing frame Lifter is a modern rehabilitation device recommended to use during the process of prolonged rehabilitation for patients with serious paraparesis and paraplegia as well as tetraplegia. The adoption of standing position is a vital element of daily rehabilitation, especially at home conditions. Technical solutions applied in this device make it possible for disabled person to adopt and keep an upright position single-handedly. Furthermore, it has a significant influence on patient's mental state due to increasing of his independence and decreasing of dependence on environment. It goes without saying that it helps him to perform activities which were impossible earlier (opening the window, removing the book from a shelf etc.) In brief, it improves the quality and comfort of life.

Stability of the whole construction that gives sense of security, ease of regulation that makes it possible to tailor person to the correct upright position, simplicity of control – there are another advantages of our product.

Please read the instruction carefully. You will find information about our product and you will find out about how to use it effectively and safely.

If you have any questions or comments, please contact the medical consultant of our company (ph.+48 508-382-509) or contact directly with our office (ph. +48 17 864 04 70).



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1. Upright standing as essential element of the process of rehabilitation

Clinical research show that it is very important to adopt an upright position by the patient for correct functioning of the body. Moreover, systematic and daily upright position is a remarkably vital element in a comprehensive rehabilitation process – it has a positive impact on a work of many organs and systems because it:

- improves functions of Cardiovascular system
- improves ventilation of lungs and prevents pneumonia
- prevents and facilitates treatment for muscle and joint contractures, improves movability of joints
- guards against muscle atrophy (especially postural)
- prevents and treats Osteoporosis
- improves intestinal peristalsis
- prevents and facilitates treatment for venous stasis, decreases the risk of pulmonary embolism
- prevents and facilitates treatment for urinary tract blockage, helps in re-education of neurogenic bladder
- guards against forming bed sores and it facilitates its treatment
- fundamentally affects improvement of patient's mental state

Passive upright position of the patient usually is only a stage of the rehabilitation process which precedes the study of walking and obtaining more and more independence.

2. Indications for use Lifter standing frame



Decision about Lifter's application and time of upright position is always made by referring doctor.

- a) as rehabilitation device for using during the period of early, intensive rehabilitation.
- after backbone injuries with spinal cord injury with tetrapareza beside paraplegia (as the stage of the rehabilitation process or permanent orthopaedic supply
- in case of lower limb paresis and paralysis, usually at the stage of early rehabilitation or as permanent supply
- tetraplegia after recent craniocerebral trauma as the stage of the rehabilitation process (possible return of motion functions) or as permanent supply.

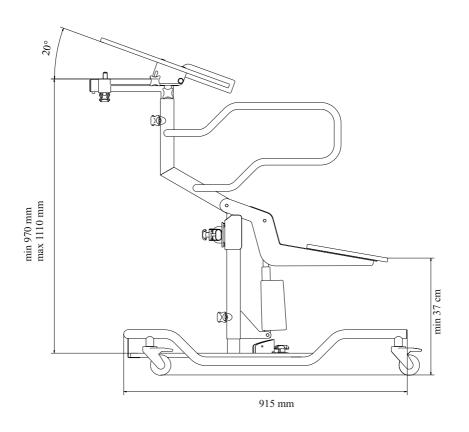


- pathogenic or vascular brain injury and spinal cord injury with limb paresis, serious balance disorders and coordination.
- b) as an individual device for upright standing during prolonged rehabilitation (permanent supply)
- during perpetuated paralysis, serious paraparesis and tetraplegia
- advanced demyelinization (multiple sclerosis, amyotrophic lateral sclerosis)
- infantile cerebral palsy
- meningomyelocele

3. Technical specifications

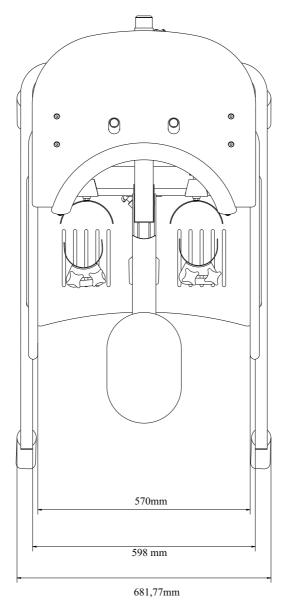
Lifter standing frame is an individual device and it will satisfy all of its functions if it is correctly adapted to height and body weight of the patient and pelottes are matched to measurements (regarding hips and chest) on the specific levels. Authorized repairer or therapist are the only one who are responsible for regulation and adjustment which is aimed at securing maximum comfort and security for disabled person.







Top view of device





4. Safety measures

- 1. Lifter standing frame should be used according to recommendations of the present instruction.
- 2. Before every use of Lifter it is necessary to:
- make sure whether all parts are efficient as well as fitted in a proper way and if device does not show trails of cracks and deformities,
- check whether bolts and nuts did not loosen,
- check the operation of brakes and castors,
- make sure that movable parts are stable and stuck,
- adapt and tailor standing frame to the patient.
- 3. Device cannot be jolted and turned over, especially when the patient is inside the device.
- 4. Lifter should not be used if there is no trained family member or entitled person nearby.
- 5. Lifter should not be used on a shaky ground, stairs or steep slopes as well as it cannot be left on a sloping area.
- 6. Lifter should not be used if it is damaged or is short of some part.
- 7. Despite the fact that device, including upholstery, is made of non-flammable and not supported burning materials, it is necessary to pay attention on coming closer to source of fire or source of high temperature.
- 8. Patients are strictly forbidden to use the device when they are under the influence of alcohol, intoxicants, drugs and another medications which can have a negative impact on sense of balance.

AKCES-MED Sp. z o.o. sells the product technically in proper working condition, free of defects: design, manufacture and material etc. There is 24 months guarantee on Lifter standing frame, starting on the day of purchasing.



The producer takes no responsibility for damages in following cases:

- damages happened as a result of usage of Lifter by untrained staff
- usage of Lifter without assistance of trained staff
- incorrect assembly of parts and accessories
- selfmodification of parts
- usage of unoriginal parts and accessories
- natural signs of wear and usage of parts (upholstery, castors etc)
- damages resulting from incorrect usage (regarding unsuitable weight and selection of standing frame's size to patient)
- not following the rules included in the present instruction

Detailed rules of guarantee are included in a guarantee card attached to standing frame.

WARNINGS:

- it is advisable to be careful during unwrapping of device (cutting of wrapping) in order not to damage upholstery
- assembly of standing frame is performed by entitled person (salesman, dealer) or medical staff which is properly trained
- Lifter static standing frame is a device for individual use
- Lifter should be used by people who accurately familiarized with the present instructions
- Lifter should be operated by people who are entitled such as: therapists, doctors and qualified staff after training
- Lifter can be used not only in rehabilitation wards but also at home exclusively in the presence of properly trained people

ADITIONAL INFORMATION:

- cleaning should be done according to 'Maintenance and cleaning' instruction
- in case of accidents and damages it is necessary to contact with dealer who sold you the product



5. Upright position of the patient



First upright position of the patient usually occurs in a rehabilitation, neurology, neurosurgery or orthopaedics ward. Upright position is performed by a doctor together with a physiotherapist for the sake of medical problems which can appear during first treatments e.g.: fainting, syncope, drop in blood pressure, dizziness and others. Upright position is continued at home conditions by: qualified staff after training (rehabilitation technician, health visitor, trained family members)



Lifter standing frame should be used according to recommendations of the present instruction. Before every use of Lifter it is necessary to prepare patient and device.

The preparation of the patient:

- 1. Patient should wear light clothes which do not constrain patient's movements, shoes should be comfortable, well stabilizing ankle joint (due to hygienic reasons and with the aim of counteract abrasions it is necessary to exercise in the device with clothes that shade body in places of regular contact with upholstery)
- 2. In case of indications for use orthopedic supply (collar, chest support, orthosis, orthopedic shoes) it should be putted on before upright position. Decision about usage of definite orthopedic supply are made by the leading doctor.
- 3. Any drains, bags, catheters etc. if used, must be protected from falling out, tightening in order not to disturb during upright position.
- 4. All exercises must be done exclusively in the presence of trained people.

The preparation of device:



First tailoring of standing frame to the patient is only performed by qualified staff.



- 1. Before proceeding to upright position it is necessary to stop castors by pressing the brake.
- 2. Draw up the front of the wheelchair to standing frame, it should place one leg on standing frame's floor and then help patient with change from wheelchair to saddle and protect its back by safety belt.
- 3. Place feet in handles which are designed for feet, fasten feet by belts, regulate the knee pellotes in order that a knee cap was situated in the centre of pellote.
- 4. We regulate table in order not to disturb the patient in adjustment, we regulate the height of the chest pellote if necessary (up and down or forwards and backwards)
- 5. During upright position we check if foot do not get out from belts which stabilize knees as well as knees should be propped against the knee pellotes.
- 6. The chest pellote should be fitted on level of the chest. Only then the patient can undergo the process of upright position.
- 7. We connect the standing frame to front and pin the security key to remote control and by pressing the button we proceed to stand the patient.
- 8. Upright position should be done slowly, during it we should take patient's pulse and check his pressure in order that it should not exceed rate suitable for age. We end upright position when the patient stands and is propped against saddle at the back on the level of hips and his chest is propped against the chest pellote.
- 9. Patient should stand in erect position, that is to say, the zero position is in knee and hip joints (if there are no contractures).
- 10. In case of contractures in knee or hip joints we should lift the patient to upright position to the contracture limit.
- 11. Smooth regulation of upright position is a very good effect in patients who have restrictions on movement and contractures in ankle, knee and hip joints.

Decision about the end of upright position is made by a doctor or therapist or when the patient voices any complaints caused by upright position. With the aid of remote control we move saddle lower in order that patient is lowered to sitting position. Next we unbuckle belts for feet, unbuckle the securing chest belt and we help the patient in change from standing fame to wheelchair, chair or bed.



6. Maintenance and cleaning

Standing frame – as an individual means of orthopaedic supply and medical device, should be kept in a proper cleanness and be used according to manufacturer's recommendations.

Device should be kept in clean, dry and ventilated room at a temperature of 15-35°C and relative humidity which does not exceed 80 %.

Maintenance and cleaning of device should be performed at least once a month. Periodic cleaning and maintenance of Lifter are indispensable in keeping its correct functionality and security.

Maintenance of castors

It is recommended to clean castors as well as remove hair, dirt, dust etc. at least once a month.

Maintenance of constructions and parts of upholstery

Construction as well as parts of upholstery should be cleaned with the help of soft cloth that is moistened in diluted alcohol. After cleaning it should be softly wiped with a dry cloth.

In case of using standing frame in hospitals, rehabilitation centres and another places by patients, and the rules of the abovementioned institutions are not different, hand handles should be disinfected before transferring it to next person (the best way is to wipe it with alcohol). Direct contact of the upholstery with uncovered patient's body is absolutely unacceptable.

Only in case of exact applying to recommendations, the producer takes responsibility for correct functionality of Lifter.



Cleaning, changing and maintenance of Lifter is not allowed while it is being used by patient. Any other activities with Lifter are performed on user's own responsibility.

Producer takes responsibility only for original defects or technical damages of product.

When some part needs to be changed or serviced, it is necessary to contact with dealer who sold you the product.



According to art.22, par. 1 and 2 of the Act about used-up electrical and electronic equipment (Journal of Laws No. 180 item 1495), placing, discarding and storing up is not allowed with other waste products.

Dangerous compounds included in electrical and electronic equipment demonstrate disadvantageous affecting plants, microorganisms and human.

Used-up equipment should be delivered to local Collection Point of used-up electrical devices which is registered in Inspectorate for Environmental Protection and leads selective waste collection.

Remember!!!

According to art.35 of the Act, person who uses equipment designed for household, after using this equipment is committed to return it to person who is responsible for collecting electrical and electronic equipment. Selective waste collection that come from household and its transforming contributes to environmental protection, reduces permeating of dangerous chemicals into the atmosphere and water.





ORTHOPAEDIC DEVICES MANUFACTURER



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Authorised Dealer			

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