
ELLA STANDER



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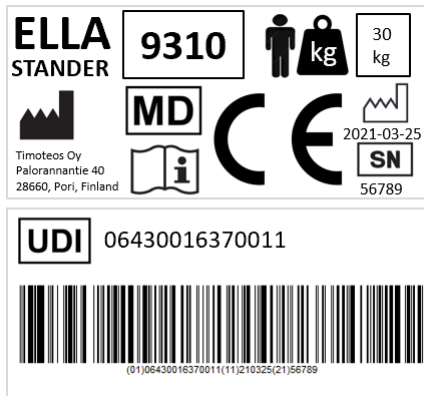
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Package content

- ELLA Stander according to ordered configuration.
- Charger (CH01) for battery when powered version is ordered.
- 5mm Allen Key
- Instructions for Use

Symbols used in Labels

This product label is an illustrative example used in explaining the symbols.



XXXX	Product identifier 9310: Size 1 (3-in-1), Manual Tilt 9320: Size 2 (3-in-1), Manual Tilt 9330: Size 3 (3-in-1), Manual Tilt 9311: Size 1 (3-in-1), Powered Tilt 9321: Size 2 (3-in-1), Powered Tilt 9331: Size 3 (3-in-1), Powered Tilt 9341: Size 4 (3-in-1), Powered Tilt Product identifier 9310+: Size 1 (4-in-1), Manual Tilt 9320+: Size 2 and 2+ (4-in-1), Manual Tilt 9330+: Size 3 (4-in-1), Manual Tilt 9311+: Size 1 (4-in-1), Powered Tilt 9321+: Size 2+ (4-in-1), Powered Tilt 9331+: Size 3 (4-in-1), Powered Tilt 9341+: Size 4 (4-in-1), Powered Tilt	CE CE-mark symbol
MD	Medical device symbol	MD
2021-03-25	Date of manufacture Year-Month-Day	2021-03-25
30 kg	Maximum user weight Kilograms	30 kg
i	Consult instructions for use	i
UDI	Unique device identification number	UDI
SN 12345	Serial number	SN
Factory icon	Manufacturer Name and address	Factory icon
Warning icon	Caution Attention	Warning icon

Power Unit Labels



1. INTENDED USE

ELLA stander are mainly used with children, teenagers and young adults suffering of for example Cerebral Palsy (CP), muscular dystrophy, spina bifida and/or spinal cord injuries. It is possible to use ELLA Stander in any similar cases where the rehabilitation of individual requires or individual benefits of assisted standing. The conditions where ELLA Stander is used are to be determined by specialized health care experts such as doctors and physiotherapists. ELLA Stander can be used in medical facilities or Schools and Day Care facilities or in the home environment by a private carer, e.g. a relative, who has been instructed in the use of the standing device by a healthcare professional.

ELLA Stander is a module based stander for Prone, Supine and Upright postures. Each module comes in different sizing to accommodate perfectly to end user body measures and creating a stable posture. All modules in any size can be combined with any ELLA stander size. ELLA Stander are available in four sizes. Sizes available can be found from "Technical Information" sheet under section 13. ELLA Stander are available with manual and powered tilt and as 3-in-1 or 4-in-1 version. The essential performance of the tilt is to safely transfer the end user between horizontal and vertical positions.

With ELLA standers it is possible to perform standing therapy in upright, prone and supine postures. All postures are possible to apply with or without hip abduction. When user requires hip abduction on the right, left or both sides, the 4-in-1 version should be used. Switching between postures is made easy and no additional modules or components is needed when switching from supine to prone and back. Change from Prone or Supine posture to Upright posture is made by changing the tilt angle to vertical (upright) position. ELLA Stander are designed so that all its functions can be operated by using one 5mm hex tool or fingers. It is not necessary to remove any modules or upholsteries to make adjustments. Tool is included to Stander.

All ELLA Stander functions are bilateral, individually adjustable and stepless. This allows the end user standing posture to be set independently for both right and left side. This feature enables the optimal set up for example to different leg lengths. ELLA Stander is available as a 3-in-1 and 4-in-1 version. Both versions offer the option of tilting in prone and supine postures. The 4-in-1 version also offers the option of adjusting the leg position in abduction.

Available versions

The ELLA stander is available as a 3-in-1 or 4-in-1 version. The decision on which version to use depends on whether the user requires hip abduction for correct positioning of hips and legs. If the user requires hip abduction on the left or right side or on both sides, the 4-in-1 version of the ELLA Stander should be chosen. The decision which version to be used should be made by specialized health care expert such as doctor or physiotherapist.

The minimum abduction angle is 0°. The maximum abduction angle for the 4-in-1 version depends on the size of the ELLA Stander and on the height of the user. The maximum

abduction angles of the different ELLA Stander sizes are listed in the table below. The maximum angles are given as the combined maximum angles of both legs.

ELLA Stander 4-in-1 Size	User Height	Maximum Abduction angle
Size 1	60 cm	90°
Size 1	95 cm	67°
Size 2	90 cm	68°
Size 2	130 cm	45°
Size 2+	90 cm	90°
Size 2+	130 cm	55°
Size 3	120 cm	60°
Size 3	155 cm	43°
Size 4	130 cm	55°
Size 4	180 cm	35°

Chapter 6 of these instructions for use describes how to set or readjust the ELLA Stander to the desired abduction angle. The decision of which abduction angle to set must be made by specialized health care expert such as doctor or physiotherapist.

2. CONFORMITY

Declaration of Conformity

Timoteos Oy as manufacturer declares that the ELLA Stander as Class I medical device conforms to the Medical Device Regulation (2017/745) .

Electrical Safety and EMC

This product complies with EN 60601-1:2007 General Requirements for basic safety and essential performance and EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

3. TERMS OF WARRANTY

A two year warranty applies to Timoteos products and modules from the date of purchase from Timoteos Oy. The warranty applies only when the product is used according to the specified conditions and for the intended purposes, following manufacturer's recommendations.

Availability of Spare Parts

Timoteos will supply spare parts to its products for 5 years after the product is manufactured. Manufacturing date is shown on the product label.

4. IMPORTANT INFORMATION

ELLA Stander is a multi-adjustable and versatile standing device for children, teenagers and young adults, that helps to achieve a specific and individual, comfortable standing posture. Product is to be used only in situations described in chapter 1 “Intended Use”.



- 4.1. Always read instructions carefully before use.
- 4.2. Ensure the product is fully assembled following instructions before use. Contact your local distributor if need advice at this stage.
- 4.3. Users should not be left unattended at any time whilst using Timoteos product.
- 4.4. Do not allow other individuals to use, play with, stand on, ride on or run around the ELLA Stander. ELLA Standers should only be used for its intended purpose.
- 4.5. Only use Timoteos approved components with your product. Never modify the product in any way. In case modification is needed always consult Timoteos before making modifications. Service or repair should only be carried out by a Timoteos authorized service person. All services, inspections and possible modifications should be recorded. Failure to follow instructions may put the user or carer at risk and will invalidate the warranty of the product. Timoteos cannot accept any liability for injury or damage caused by unauthorized modification or unapproved components.
- 4.6. If in any doubt as to the continued safe use of your product or if any parts should fail, please cease using the product and contact Timoteos directly or your local distributor immediately.
- 4.7. Carry out all positional adjustments and ensure that they are securely fastened before you put the user into this product. Some adjustments may require the use of a tool which is provided with each product and is available as spare part if required. To use the tool, nothing needs to be removed from the stander, as all adjustment options are located outside the stander. Some adjustments of ELLA Stander can also be made without the tool, such as adjusting the lateral supports. Keep all tools out of reach of children and other people who has no need for using the tool.
- 4.8. All positional adjustments should be carried out by therapist or other technically competent person who has been trained to use of this product and has received instructions for the correct settings for individual user from the therapist. Timoteos recommends that a written record is maintained of all people trained to the use of this product.

- 4.9. This device should have been prescribed by a doctor or a therapist who has previously examined the user and determined that ELLA Stander is suitable for achieving the user's individual therapy goals. The doctor or the therapist has also determined the suitability of the product in terms of dimensions, weight and the needs to be met. The adjustments of ELLA Stander to meet the user needs are carried out by a therapist, doctor or a trained person. If ELLA Stander has not been adjusted by such person, do not use ELLA Stander and contact one of the above-mentioned persons.



- 4.10. When placing the user into the ELLA Stander, for safety reasons, always secure the pelvic and trunk belts first. The knee supports should then be fastened and lastly secure the foot straps. When used in any position it is important to ensure that all belts and straps are fastened securely before making other adjustments or angling the stander to upright position. Always check that Buckle clips and Velcro's are fully engaged. If the user is wearing sandals or light footwear, short sleeve shirts or short sleeve trousers check the straps to make sure the webbing does not irritate the skin.

- 4.11. Always check with your therapist as to the correct tension of the straps for a particular end user as too much force could cause injury. Always use all positioning straps provided.

- 4.12. Fine positional adjustments may be carried out safely when the user is in the product. It is important to support all pads, straps and belts when adjusting them while user is in the Stander.

- 4.13. When doing a hoist transfer, please ensure that the hoist sling, or any part of hoist, is not caught on any part of the stander.



- 4.14. Always keep the tilt mechanism secured with tilt locking pin when tilt angle is not being changed. Always make sure the tilt mechanism is working properly and the pedal is not bent as instructed in Chapter 9. Product Inspections.



- 4.15. Although the ELLA Stander is fitted with castors it is not a mobility device. Always ensure that the castor brakes are locked at all times when the Stander is in use, being adjusted or even just stored. However it is possible to move the ELLA Stander while user is on the stander. Moving the Stander with user should be done only when necessary and with extreme care. Moving is possible only slowly and only for short distance on even surface. It is not allowed to cross any obstacles while moving the stander with user. Before moving the Stander with user, the Stander should be placed in 20-30° angle (0° equals vertical). When moving the Stander, hold the Stander with both hands and make sure one hand is holding the upright column behind the thoracic pad. Never

move the Stander sideways and always lock the castor breaks before releasing your crib from the Stander. Always make sure all the straps and supports are firmly secured as instructed in this manual.

- 4.16. When using the ELLA Stander, especially when tilting the Stander, ensure that the user and all parts of the product are well clear of surroundings furnishings to avoid potential collisions.
- 4.17. Never leave or use the product on a sloping or rough surface or stairs. Always remember to lock all the castors.
- 4.18. The product contains components that are removable even not intended to remove and which could present a choking hazard to small children. Always check that knobs, bolts, washers and wingnuts are in place, tightened and secured at all times.
- 4.19. Product should be kept away from all direct sources of heat including naked flames, cigarettes, open fires, electric and gas heaters etc.
- 4.20. Never place hot items on the Tray as they may damage the plastic and can put the user or carer at risk of burn.
- 4.21. Never use the Tray to steer or push the Stander.
- 4.22. Ensure the Tray is always in place when using the Stander in Prone. Tray is for the use of the user only. Do not lean or place heavy objects on the Tray.
- 4.23. Clean the product regularly. Do not use abrasive cleaners. Carry out maintenance checks on a regular basis to ensure your product is in good working condition.
- 4.24. Do not carry out any maintenance or service to the product while product is in use.
- 4.25. Product is intended for indoor use. When not in use product should be stored in dry place.
- 4.26. Manufacturer Product Serial Number can be found from the mobile base. Refer to that number in any correspondence. Product Serial Number is used to identify a single product and to track the content of the product configuration.
- 4.27. Before using ELLA Stander with electrical actuator for the first time, please charge the battery for 12 hours. Batteries should be charged overnight once every week to maintain optimum life of battery.
- 4.28. Do not operate the electrical tilt while charging the battery to avoid potential EM disturbance.

4.29. **WARNING!** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Use of accessories, transducers and cables other than those specified or provided by Timoteos could result in increased EM emission or decreased EM immunity of this equipment and result in improper operation. A power plug is supplied with this equipment. Please use the power plug suitable for your country. In case the supplied power plug is not suitable to your country, contact your local distributor for advice. Portable radio frequency (RF) communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ELLA Stander, including cables specified by Timoteos. Otherwise, degradation of the performance of this equipment could result. This equipment is not likely to cause any harmful interference in nearby equipment; however, it can be impaired by electromagnetic (EM) interference emitted by other equipment, which can lead to malfunctions. Do not use this equipment where there is a risk that other electrical and/or electronic equipment can interfere with this equipment.

4.30. The safety advice and directions in this manual cannot cover all eventualities and unforeseen situations that may occur. It must be understood that common sense, general caution and care are factors that cannot be built into this product. These are factors which the person using this product must assume responsibility for. In case the use of this product causes a severe incident this should be immediately informed to manufacturer of the product in writing as well as to the responsible institution in your country following the guidelines given by this institution.

4.31. When a product reaches the end of its lifetime, it should be separated by material type so that the parts can be recycled or disposed of properly (for material composition look "Materials used" under the chapter Technical Information). If required, please contact your local dealer for a precise description of each material. Please contact your local authorities to be informed of the options available for recycling in an environmental friendly way.

4.32. ELLA Standers size 1-3, with gas piston assisted tilt, are equipped with Fail Safe -mechanism preventing the Stander to fall into negative angle in case of accident.



A risk of finger trap exists when gas piston assisted Stander in size 1-3 is tilted towards horizontal posture.



5. INDICATIONS, CONTRAINDICATIONS AND APPLICATION RISKS

Indications

ELLA standers are used with children, teenagers and young adults suffering Paralysis of the lower extremities or muscle diseases, Cerebral Palsy (CP), muscular dystrophy, spina bifida and/or spinal cord injuries. It is possible to use ELLA Standers in any similar cases where the rehabilitation of individual requires or individual benefits of assisted standing. The conditions where ELLA Stander is used are to be determined by specialized health care experts such as doctors and physiotherapists.

Contraindications

Never use this product in any other condition than prescribed and determined by specialist healthcare expert.

In case user knee contracture is so severe that posture cannot be classified as standing posture, the product should not be used. The severity of each individual user knee contracture is to be determined by specialist healthcare expert.

To be able to use the product user must have adequate upper body control, such as head control, when product is used in Prone. Whether user has adequate upper body control is to be determined by specialist healthcare expert. In case user does not have adequate upper body control the product should be used in Supine posture only.

Application Risks

Never leave the user unattended to this product and do not allow other individuals to use, play with, stand on, ride on or run around the product. ELLA Stander should only be used for its intended purpose. Failing to follow this may create a risk of injury to user or to other individuals.

This product is not intended to be a mobility device. Do not move the product while user is using the product. Always make sure that all the castors are locked when product is in use, adjusted or stored. Failing to follow this may create a risk of injury to user or to other individuals.

This product is to be used only indoors on an even surface. Failing to follow this may create a risk of product falling over.

False operation of tilt, tilt adjustment pedal, tilt locking pin or failure in user securing may lead to a risk of an injury.

6. STANDER SET UP (ASSEMBLY) AND BASIC SETTINGS FOR USER

All postural adjustments and basic settings must be made by a therapist, doctor or other competent person who has been trained in the use of this product and has received instructions from the therapist or doctor on the correct settings for the individual user. Timoteos recommends keeping a written record of all persons who have been trained in the use of this product.

The basic settings and posture adjustments for the individual user usually only need to be made once at the start of therapy and not every day. However, if changes to the posture adjustments or basic settings are required, these must be made by the persons described above. The possible and necessary daily adjustments are described in chapter 7 "Adjustments in Daily Use".

As standard most of the ELLA Stander settings are adjusted with the use of 5mm hex tool. Tool is delivered with the product. It is possible to order a new ELLA Stander or retrofit an existing ELLA Stander with "Tool Free -kit" in order to have selected adjustments or all adjustments done without tool. Adjustments A – O can all be equipped with either clamping lever or wing nut and then used by fingers only.

- A. Knee Support height, depth, width and rotation adjustment.
- B. Lateral Support (trunk and pelvic) height, width and rotation adjustment.
- C. Head Rest rotation adjustment.
- D. Head Rest depth adjustment.
- E. Head Rest height adjustment.
- F. Trunk Support Pad height adjustment.
- G. Tray height adjustment.
- H. Pelvic Support Pad height adjustment.
- I. Gas Piston assisted tilt adjustment pedal.
- J. Gas Piston Assisted tilt locking pin. Always keep the tilt locked when angle is not changed.
- K. Castor locking pedal.
- L. Foot Rest height adjustment.
- M. Foot Rest width adjustment.
- N. Foot Rest depth adjustment.
- O. Rotational Trunk and Pelvic Support adjustment (2 bolts on both sides)



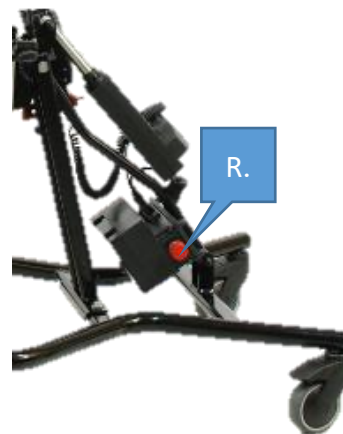
P. Handset HB-41 for electrical tilt operating from horizontal to vertical

Q. Charging port for battery charger.



Do not operate the electrical tilt while charging the battery.

R. Electrical tilt emergency stop



Change from Supine to Prone

1. Remove the Head Rest by loosening head rest height adjustment knob and pulling the head rest off the stander.
2. Insert the tray from the side of tilt mechanism (opposite to supine set up).
3. Turn the Sandals 180° by loosening the bolt underneath the Sandals.



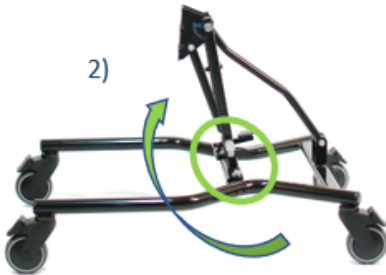
STANDER SET UP

3-in-1 and 4-in-1 Standers

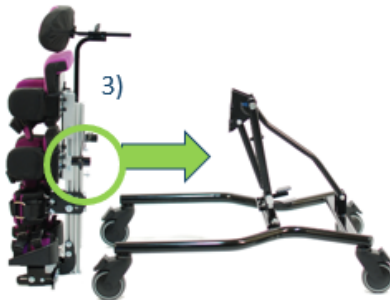
1)



2)



3)



4)



SETTING UP THE STANDER

- Remove the protective filling from the box and take the base (1) and frame (3) out of the box. Base is folded in the box, in Frame all the ordered modules are already attached.
- Lift the tilt / Frame holder up (2), place the two bolts into their slots and tighten the bolts to secure the tilt / Frame holder to its position. If the tilt / Frame holder does not slide into its place properly, loosen the bolts as long as tilt/ Frame holder slides into its place. It is not needed to remove the bolts off the base.
- Place the Frame on the Base (3) by placing the three bolts into their slots and tighten the upper bolt to secure the Frame locking on the Base. If the Frame does not slide into its place properly, loosen the upper bolt as long as Frame slides into its place. It is not needed to remove the bolts off the Frame.
- ELLA Stander is now ready (4) for initial, user specific, settings.

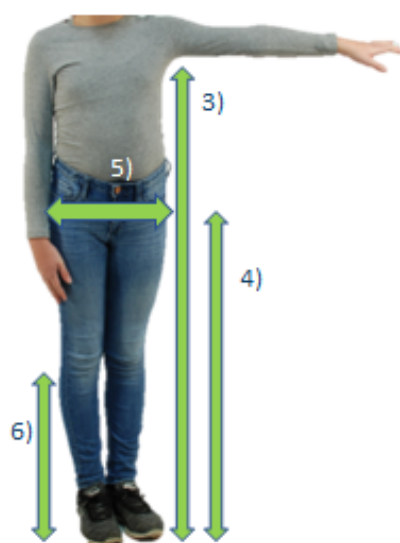
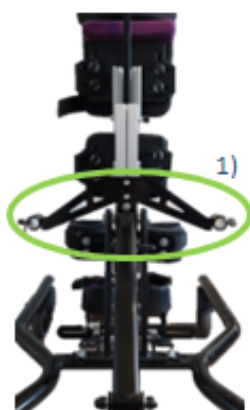
INITIAL SETTING FOR USER

60-72 cm in ELLA Size 1 and 90-105 cm in ELLA Size 2 and 2+
3-in-1 and 4-in-1 Standers

NOTICE

Following instruction, on this page apply only to ELLA 1 in user height range of 60-72 cm and ELLA 2 and 2+ in user height range of 90-105 cm.

Because of design that allows wider growth range the starting point of the initial setting of ELLA 1 and ELLA 2 and 2+ for small users is determined by the lowest tray table height where as normally the starting point is lowest foot plate height.



SETTING UP THE STANDER

- Place the tray holder and tray to its place in the lowest possible position (1).
 - Place the lower edge of the trunk lateral support (in its lowest position) to the same height with tray table top by adjusting the height of the trunk support.
 - Measure the width of the users trunk (2) and adjust the trunk lateral support to equal width.
 - Measure the height of the user from sole to armpit (3). Adjust the foot plate up or down so that measure from bottom of the foot plate to top edge of the trunk lateral support is equal.
 - Measure the height of user from sole to middle of pelvis (4). Adjust the pelvic support pad so that the measure from the bottom of the foot plate to middle of the pelvic support pad is equal.
 - Measure the width of the users hip (5) and adjust the pelvic lateral supports to equal width.
 - Measure the height of user from sole to right below patella (6). Adjust the knee support up or down so that the measure from the bottom of the sole to the upper edge of the knee support is equal.
 - Adjust Head Support to right height and angle for user.
- Notice that in ELLA Stander the user standing posture is possible to finalize when user is placed on stander and stander tilt in is in desired angle.

INITIAL SETTING FOR USER

All user heights in all 4 stander sizes except the ones instructed on previous page
3-in-1 and 4-in-1 Standers

NOTICE

Following instruction, on this page, apply to ELLA 1 in user height range of 73-95 cm, ELLA 2 and 2+ in user height range of 106-130 cm and all user heights in ELLA 3 and ELLA 4.

Because of design that allows wider growth range the starting point of the initial setting of ELLA 1 and ELLA 2 and 2+ for small users is determined by the lowest tray table height where as normally the starting point is lowest foot plate height. Set up for small users was presented on earlier page.



SETTING UP THE STANDER

- Place the foot plates (1) in to lowest position.
 - Measure the height of user from sole to right below patella (2) or right above patella in case knee support is wished to put on top of patella. Adjust the knee support up or down so that the measure from the bottom of the sole to the upper edge (or lower edge in case support will come above patella) of the knee support is equal.
 - Measure the height of user from sole to middle of pelvis (3). Adjust the pelvic support pad so that the measure from the bottom of the foot plate to middle of the pelvic support pad is equal.
 - Measure the width of the users hip (4) and adjust the pelvic lateral supports to equal width.
 - Measure the height of the user from sole to armpit (5). Adjust the trunk support pad up so that measure from bottom of the foot plate to top edge of the trunk lateral support is equal.
 - Measure the width of the users trunk (6) and adjust the trunk lateral support to equal width.
 - Adjust Head Support to right height and angle for user.
- Notice that in ELLA Standers the user standing posture is possible to finalize when user is placed on stander and stander tilt in is in desired angle.

4-in-1 ADDITIONAL SETTINGS

Only 4-in-1 Standers

NOTICE

The following instructions apply only to ELLA standers which are bought as 4-in-1 or which has been upgraded with 4-in-1 Assembly Kit.



Setting the angle for abduction

- Download a free clinometer app or use manual clinometer.
 - Loosen the two bolts behind the knee support bracket to adjust the width of knee support.
 - Loosen the two bolts in front of the foot rest bracket to adjust the width of the foot rest.
 - Pre-Set the angle when stander frame is in vertical position by placing a bar or stick to simulate leg and measuring the angle with clinometer (2).
 - When angle is desired, tighten the bolts behind the knee support bracket and in front of foot rest bracket.
 - Repeat to other side.
- Notice that it is possible to adjust both legs individually even to different angles
-
- Once user is standing and set up is finalized, double check the angle by measuring it with clinometer from the user leg. Correct angle if needed.
 - Notice that small finalizing changes in angle are possible to do while user is in stander and stander frame is in vertical position. If the foot module is difficult to move, adjust the stander frame towards horizontal position to ease the pressure from the foot allowing the foot module to slide more easily.

PUTTING THE USER ON STANDER

3-in-1 and 4-in-1 Standers

NOTICE

It is recommended to use lift or hoist when placing the user to stander. If this is not possible it is advised to pay attention to user weight and proper ways of lifting to avoid injuries. It is recommended to put the user on stander while stander is in horizontal position. Always make sure when user is in the stander that all the belts and supports are in place and tightened. Do not leave child unattended to stander.



PUTTING THE USER ON STANDER

- Place the stander frame into horizontal position (1) and open all the straps and belts. It is advised to turn the belts and straps aside before placing the user on stander. Open and turn aside the possible swing-away lateral supports from the side where user will be lifted to stander.
- Notice there is small pieces of velcro to help the lateral support belts to stay aside.
- Fasten all the belts and straps and close all the swing-away supports
- Pay attention that belts on pelvis and trunk area are firmly in place and check there is no empty space between belt and body (2). This way the user posture in stander remains as stable as possible.
- Check that the knee support is correctly placed right under patella (3) or right above patella in cases where it is wished to put so.
- Lift the stander frame into desired angle (4).
- Notice it is normal that user slides downwards when angle of stander frame changes from horizontal towards vertical. This may impact to pre-set adjustments. Once the angle is set it is possible to finalize the adjustments of the modules while user is in stander and stander frame is in desired angle. Simply loosen the bolts of modules and finalize the location of the module.



Check how to operate the tilt functions under title “Operating the tilt”.

Fastening the belts

3-in-1 and 4-in-1 Standers



BELT / STRAP TYPES

- 1) Buckled strap in Flexible Swing-Away Lateral Supports.
- 2) Velcro enhanced buckle straps with cover in Standard Lateral Supports and Swing-Away Lateral Supports.
- 3) Buckled strap in knee support
- 4) Velcro strap in knee support
- 5) Buckled strap with cover in Foot Rest (Sandals)



Flexible Swing-Away

- 1) Pre-adjust the length of straps.
- 2) Close the Flexible Swing-Away Laterals
- 3) Fasten the buckle and tighten if needed by pulling the strap outwards.



Knee Support

- 1) Pre-adjust the length of straps.
- 2) Turn the knee pads over the leg
- 3) Slide the velcro through metal ring and tighten or fasten the buckle and tighten if needed by pulling the strap outwards.



Trunk and Pelvic Belts

- 1) Pre-adjust the length of straps. Notice the small piece of velcro outside the belt.
- 2) Turn the belt outside and use the small piece of velcro to fasten it to lateral support. This helps to keep the belts away when placing the user to stander.
- 3) Wrap the belts around user, fasten the buckle and tighten if needed by pulling the straps outwards.
- 4) Check that there is no empty space between the belt and body. Otherwise the upper body posture might not be as stable.

7. ADJUSTMENTS IN DAILY USE

All settings described in this chapter can be made without tools.

Operating tilt

Tilt is used to change the angle of the stander upright column between vertical and horizontal posture. This can be done whilst user is on the stander and function is stepless.

 Before adjusting the angle make sure the user is secured in the stander as advised in Chapter 6 and daily visual check is done as instructed in Chapter 9.

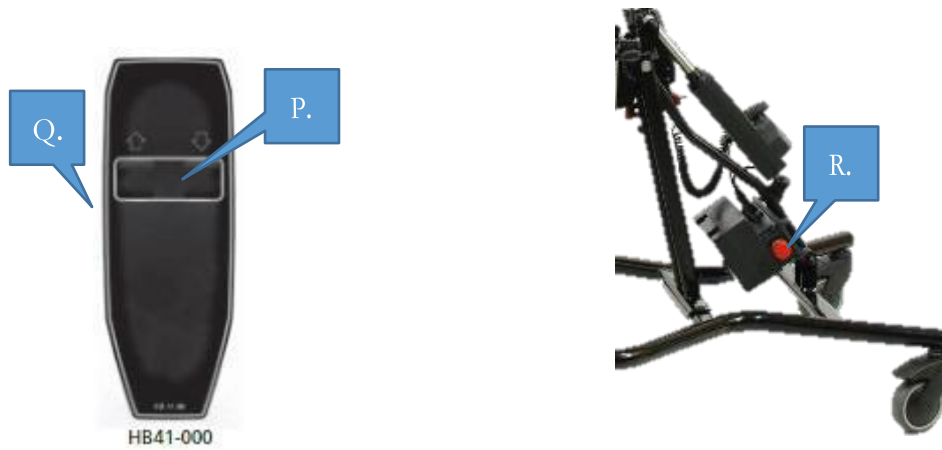
When adjusting the manual, gas piston assisted, tilt first unlock the tilt locking pin (J.) by pulling the pin outwards. This will release the tilt adjustment pedal (I.) for pressing. Do not press the pedal when pedal is locked with locking pin as this may damage the pedal and cause the tilt function not operating as it should and may lead to risk of an injury. After locking pin is unlocked hold the stander with your hands, from the upright column, behind the thoracic pad, and press the tilt adjustment pedal (I.) down with your foot. Carefully adjust the tilt into desired angle, tilt angle indicator is available as an accessory. When reached the desired angle take your foot off the pedal and lock the pedal by lifting it upwards with your foot or hand as long as the tilt locking pin slides inwards and locks the pedal into upright position. Make sure the pin slides fully inwards.

 Check that pedal is locked. If you notice any jamming in the movements of tilt locking pin or tilt adjustment pedal immediately stop using the product and contact to your local distributor.



 Do not press the pedal when pedal is locked with locking pin as this may damage the pedal and cause the tilt function not operating as it should and may lead to risk of an injury.

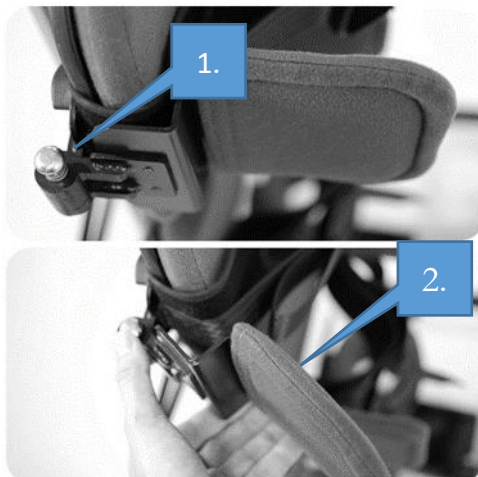
 When adjusting the electrically powered tilt first make sure the electrical tilt emergency stop button (R.) is not pressed in. If pressed in it will prevent the tilt from working. Use the handset (P.) to adjust the tilt into desired angle by pressing the buttons on the handset. Tilt angle indicator is available as an accessory. When reached the desired angle stop pressing the button on the handset. If you notice any jamming in the movements of tilt or handset immediately stop using the product and contact to your local distributor.



 False operation of tilt, tilt adjustment controls or failure in user securing may lead to a risk of an injury.

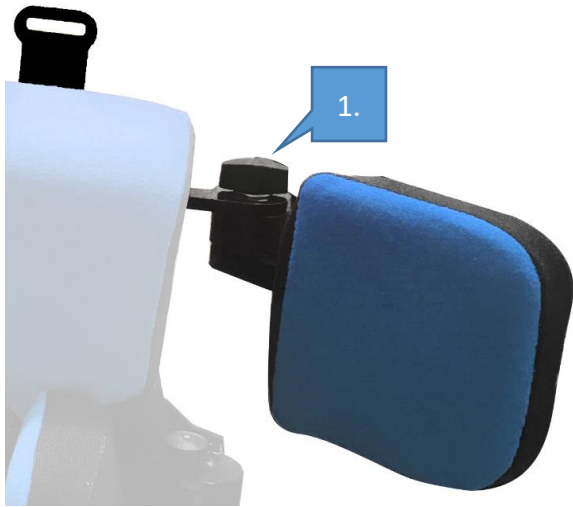
Swing-Away Laterals (including Flexible version)

1. Pull the knob up to release lock of Swing-Away Lateral Supports
2. Move the Lateral Support sideways.



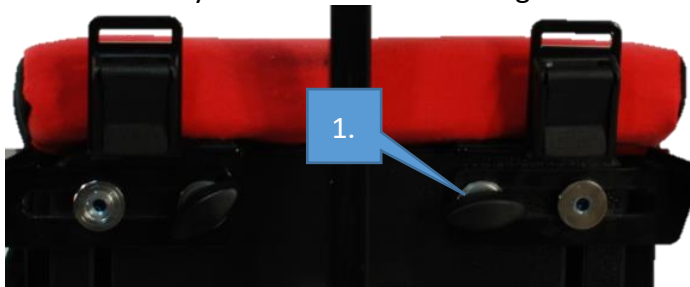
Shoulder Protraction Pads

1. Loosen the wingnut to release the lock of Protraction Pad. Move Pad to desired location and tighten the wingnut.



Harness Guides

1. Loosen the wingnut to release the lock of Harness Guide. Move the Guide sideways to desired width and tighten the wingnut. Adjust both sides separately.



8. CLEANING AND CARE

Cleaning

ELLA Stander upholsteries are both wipeable and removable. In daily cleaning of the product, in general, we recommend that you use warm water and a nonabrasive detergent when cleaning the metal and plastic parts and cushioning. Also standard household cleaning agents and household disinfectants can be used when wipe cleaning the product. Always follow disinfectant manufacturer's instructions for use and their safety measures. Never use organic solvents or dry-cleaning fluids. When more thorough cleaning is needed follow the instructions below.

The foam pads cannot be washed or disinfected. This is not necessary as the covers of the ELLA Stander are made of a material with a liquid barrier that prevents the foam pads from staining. However, if the foam pads stains, we recommend changing them. The foam used is a synthetic material that does not mould when it is kept dry.

Upholsteries

Staining should be removed from upholsteries as quickly as possible with absorbent cloth, wipe, towel or soft sponge. Soap and warm water sponging are effective for normal staining and minor spills. Be careful not to over wet the fabric as that might cause the stain to spread. Do not tumble dry the covers, but let them air dry.

For deep cleaning of upholstery, a low-pressure steam cleaner can be used in situ.

Some ELLA Stander upholsteries might not be machine washable. Washing Instructions label is sewn inside the upholsteries so pay attention to washing instruction given in label. ELLA Stander can be ordered with machine washable upholsteries that are washable up to 70°C. This is indicated in washing instruction label. Before washing in washing machine the foam pads should be removed. Behind the upholsteries you find zippers or rubber band enhanced folds for easy removal of padding.

Always ensure the upholsteries and paddings are dry before use.

Always replace broken or damaged upholsteries and cushions. Upholsteries and cushions are available as spare parts and we recommend contacting your local distributor for new ones.

Plastic and Metal parts

Wiping with soap and water, antibacterial spray or standard household cleaning agents and household disinfectants can be used in cleaning of metal and plastic components of ELLA Stander. For deep cleaning a low-pressure steam cleaner can be used. Do not use solvents or high pressure washer to clean plastic or metal components. Dry the cleaned parts with a cloth. Always ensure product is dry before use.

Disinfection

The covers can be disinfected by wiping with a commercially available disinfectant. The metal and plastic parts can be spray-disinfected with an antibacterial spray or wipe-disinfected with a commercially available disinfectant.

Always follow the disinfectant manufacturer's instructions for use and safety instructions.

Storage

Timoteos recommends the product is stored and transported in the temperature range of -10°C to +50°C, under relative humidity of 20% to 90% and under atmospheric pressure of 800 to 1060 hPa. Operating temperature range is +5°C to +40°C, relative humidity and atmospheric pressure as above.

Avoid storing the product for long time under extreme temperatures, temperature variations, in high humidity or in direct sunlight.

9. PRODUCT INSPECTIONS

We recommend that daily visual inspections of the product are carried out by therapist, carers or parents to ensure the product is safe for use. The recommended daily inspections are minimum as detailed below.

- Ensure all adjustment knobs and bolts are in place, tightened and secured.
- Check all upholstery for signs of wear and tear.
- Check all wheels are moving freely and lock securely.
- Check all Velcro straps and brush fluff to ensure secure firmly.
- Check all buckle straps to ensure the buckle functions and secure firmly.
- Check that tilt mechanism functions and the gas piston works properly.
- Check that the tilt locking pin locks securely and that tilt adjustment pedal in not bended.
- Check that all electrical connectors, components and cables are intact.

Timoteos recommend that each product should be subjected to a detailed inspection at least once a year and every time the product is reissued for use or any part is changed or replaced. This inspection should be carried out by a technically competent person who has been trained in the use of the product and should include the following checks as a minimum requirement.

- Check all knobs, nuts, bolts and plastic buckles are in place. Replace any missing items. Paying particular attention to the following items;
 - ✓ Buckles and Velcro bands and straps on pelvic and trunk, knee support straps, buckles and Velcro, and foot rest buckles and straps.
 - ✓ Trunk, Hip, Knee and Foot supports adjusts and locks securely.
 - ✓ Head Rest adjusts and locks securely.
- Lift the base and check each castor individually. Make sure they are moving freely and remove any dirt from the wheels. Check that the brakes lock the castors securely.
- Check that tilt mechanism functions and the gas piston works properly. Check that the tilt locking pin locks securely and that tilt adjustment pedal in not bended.
- Visually check the structure of the product ensuring there are no signs of fatigue or cracking around the welds.
- Visually check the plastic parts of the product ensuring there are no signs of fatigue or cracking.
- Check that all electrical connectors, components and cables are intact.

Timoteos recommends that a written record is maintained of all product inspections.

10. RE-ISSUING OF THE ELLA STANDER

ELLA Stander is manufactured from high-quality materials and is subject to constant quality control in our company. Due to this and the solid construction, the expected service life of our product is up to 5 years under normal, intended use, depending on the intensity of use.

Most Timoteos products are assessed and ordered to meet the needs of an individual user, however the re-use of the ELLA Stander is possible. Before re-issuing a product we recommend that the therapist prescribing (or other medical expert entitled to prescribe) the product has carried out an equipment compatibility check for the new user and has ensured that the product being re-issued contains no modifications or special attachments.

Additionally a detailed technical inspection should be carried on the product prior to re-issuing. This should be carried out by a technically competent person who has been trained in the use, inspection and maintenance of the product. At minimum the following measures must be taken:

- Thorough cleaning and disinfection in accordance with Chapter 8.
- Replacement of wearied parts.
- Detailed technical inspection and Maintenance according to chapter 9.
- Creation of accompanying documents and approval for reuse.

Ensure a copy of the user instructions is supplied with the product. A copy is available from Timoteos or from appointed Distributor upon request.

Timoteos recommends that a written record is maintained for product re-issuing.

11. PRODUCT SERVICING

Servicing of Timoteos products should only be carried out by technically competent persons who have been trained in the use of the product. All service enquiries should be directed to local Timoteos distributor who will assist you further. In case a local distributor is not available, please contact to Timoteos Oy directly for assistance. Timoteos recommends that a written record is maintained of all product services.

12. PRODUCT RECORDS

[illegible]

13. TECHNICAL INFORMATION

ELLA STANDING FRAME	TECHNICAL INFORMATION									
	Size 1 (3-in-1 & 4-in-1)		Size 2 (3-in-1 & 4-in-1)		Size 2+ (4-in-1 only)		Size 3 (3-in-1 & 4-in-1)		Size 4 (3-in-1 & 4-in-1)	
	min	max	min	max	min	max	min	max	min	max
User approximate age (years)	0	4	3	7	3	7	6	12	11	18+
User height [mm]	600	950	900	1300	900	1300	1200	1550	1300	1800
Max user weight [kg]	30		40		40		55		80	
Power assisted tilt	Yes		Yes		Yes		Yes		Yes	
Manual assisted tilt	Yes		Yes		Yes		Yes		No	
Pivot width [mm]	1000		1000		1350		1350		1450	
Castor height (space for hoist skis) [mm]	140		140		140		140		140	
Castor diameter [mm]	100		100		100		100		100	
Height in upright position, floor to top of head rest [mm]	970	1100	1040	1430	1040	1430	1280	1630	1460	1880
Height in horizontal position to lateral support edge [mm]	810		890		890		940		950	
Height in horizontal position to trunk support pad surface [mm]	710		790		790		790		810	
Width [mm]	580		580		702		702		752	
Length in upright position [mm]	750		750		1000		1000		1080	
Length in lying position [mm]	870	1000	940	1330	940	1330	1180	1530	1360	1780
Foot plate to top of head rest [mm]	600	850	740	1300	740	1300	1040	1600	1075	1800
Foot plate to top of trunk pad [mm]	430	680	570	975	570	975	800	1280	900	1500
Foot plate to top of pelvic pad [mm]	300	540	475	785	475	785	500	1040	625	1225
Foot plate to top of knee cup [mm]	140	450	180	550	180	550	200	650	250	850
Foot plate to floor [mm]	135	-	135	-	135	-	150	-	150	-
Product weight with manual tilt, Standard Set up [kg]	28		29		31		32		-	
Product weight with powered tilt, Standard Set up [kg]	32		35		36		38		47	
Actuator Voltage (LA31, LA34)	24V (LA31)								24V (LA34)	
Integrated Lead Battery / Control Unit (CB8)	24V / 2,9 Ah (Control Box CB8)									
Operating noise with powered tilt	48 dB (LA31)								< 50 dB (LA34)	
Lifting Speed without / with load [mm/s]	8,2 / 5,4 (LA31)								10,8 / 7,9 (LA34)	
Battery charger (CH01)	Mains: 100 - 240 VAC / 50 - 60 Hz switch mode supply Charging Voltage: 27,6 VDC Charging Current: Max. 500 mA									
Battery charging time	6 hours									
IP Protection Class	IPX1 (Handset HB41) IPX4 (Actuator LA31, LA34)									
Duty Cycle	10%, Max. 2 min / 18 min (LA31, LA34, CB8)									
Emergency stop	Yes									
Power tilt components	ELLA 1 - 3: Actuator LA31, Control Box CB8, Charger CH01, Handset HB41 ELLA 4: Actuator LA34, Control Box CB8, Charger CH01, Handset HB41									

Testing for EM disturbances

Test modes during emission tests

1. Battery mode: Standby and moving
2. Use when charging: Standby

EM emission standards	Classification / levels
Conducted and radiated RF emissions CISPR 11	Group 1 Class B
Harmonic distortion IEC 61000-3-2	Class A
Voltage fluctuations and flicker IEC 61000-3-3	$d_{max} \leq 4 \%$

Test modes during immunity tests

1. Battery mode: Standby
2. Use when charging: Standby

EM immunity standards	IEC 60601-1-2:2014 test levels	
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communication equipment IEC 61000-4-3	Test frequency (MHz)	Test level (V/m)
	385	27
	450	28
	710	9
	745	
	780	
	810	
	870	28
	930	
	1720	
	1845	
	1970	
	2450	
	5240	9
	5500	
	5785	
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz	
Electrical fast transients / bursts IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges Line-to-line IEC 61000-4-5	$\pm 0,5$ kV, ± 1 kV	
Surges Line-to-ground IEC 61000-4-5	$\pm 0,5$ kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	
Voltage dips IEC 61000-4-11	0% U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70 % U_T ; 25 cycles at 0°	
Voltage interruptions IEC 61000-4-11	0 % U_T ; 250 cycles at 0°	

14. USED MATERIALS

Module name	Materials used in module
Mobile base (foldable base, castors, tilt mechanism, brackets for footrests, Brackets for knee supports, fasteners)	Powder coated steel in foldable base, tilt mechanism, knee support brackets and footrest brackets, anodized aluminum in upright column, zinc coated steel in fasteners, polyamide + soft polyurethane in castors
Footrests (sandals with straps, fasteners)	ABS plastic in sandals, zinc coated steel in fasteners, polypropylene straps, nylon buckles
Knee Supports (knee cups, pads, straps, fasteners)	Powder coated steel in knee cups, zinc coated steel in fasteners, polyester fabric, polyether pads, velcro, or nylon buckles, polypropylene straps
Pelvic Support (slider, back plate, pad, fasteners)	anodized aluminum in slider, zinc coated steel in fasteners, ABS plastic in back plate, polyether pads, polyester fabric
Trunk Support (slider, back plate, pad, fasteners)	anodized aluminum in slider, zinc coated steel in fasteners, ABS plastic in back plate, polyether pads, polyester fabric
Belts with velcro and buckle	Polypropylene straps, velcro, nylon buckles
Lateral Supports (hardware, pads, fasteners)	Powder coated steel in hardware, zinc coated steel in fasteners, polyether pads, polyester fabric
Tray (tray, tray bars, tray holders, fasteners)	ABS plastic in Tray, chrome plated steel tube in Tray, powder coated steel in tray holder, zinc coated steel in fasteners
Head rest (hardware, cushion, fasteners)	Powder coated steel in hardware, zinc coated steel in fasteners, polyether cushion, polyester fabric,
Shoulder protraction pads (hardware, pads, fasteners)	Powder coated steel in hardware, zinc coated steel in fasteners, polyether pads, polyester fabric
Harness fitting kit (brackets, cam locks, fasteners)	Powder coated steel in brackets, zinc coated steel in fasteners, ABS plastic in cam locks
Component position marker, CE label and other identification labels	Polyester sticker, marker back plate and other labels ABS plastic
Tilt angle indicator	PETG
Optional upholstery materials	Dartex: Polyurethane coated Polyester fabric Stirata: Polyester fabric

The ELLA Stander and its components do not contain any corrosive materials, are resistant to commercially available cleaning and disinfecting agents and can be cleaned or disinfected with these agents. The upholstery of the ELLA Stander is antibacterial, antifungal, water and dirt repellent, non-cytotoxic in accordance with ISO 10993-5 and flame retardant.

MANUFACTURER



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