

Freestander

User Manual



The Leckey Freestander has been designed to promote weight bearing and mid line symmetry. This manual shows you how you can quickly and easily make use of all of the functions. The instructions on the safety and maintenance of the product will ensure that you will enjoy it for a long time.

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SECTION 01: INTENDED USE

Intended use

The devices are intended to assist children that cannot stand or maintain a standing position independently as part of a supported weight bearing program.

Indications for use

Freestander has been designed for used at home or in school for upright standing. The stander is available in three sizes catering for the needs of children from the age of 1-18. Size 1 has a maximum user weight a maximum user weight of 60kgs (132lbs), size 2 80kgs (176lbs) and the size 3 90kgs (198lbs). Suitable for:

- Children and adults with disabilities such as Cerebral Palsy, traumatic brain injuries, muscular dystrophy and other conditions where supported standing programs are encouraged.
- Children presenting with developmental delay who are currently non-ambulating.
- Children where early intervention is indicated.

SECTION 02: CERTIFICATION

The Freestander is classified as a Class I Medical Device under EU and UK regulations. As the manufacturer, James Leckey Design Limited, declares that this product conforms to the Medical Device Regulation (2017/745), UK Medical Device Regulations 2002, Medial Device Directive (93/42 EEC) and EN 12182:2012 Assistive products for persons with disability, general requirements and test methods.

Notice to the user and/or patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



NOTE: General user advice. Not following these instructions may result in physical injury, damage to the product or damage to the environment!

SECTION 03: WARNINGS AND CAUTIONS

1) WARNING TOPPLING HAZARD

- Never use the product on a sloping surface greater than 5 degrees.
- Always check operation of linear drives, gas struts, and motor drives before use.
- When adjusting the stander angle ensure there is adequate access space on all sides of the product.
- Always lock casters facing outwards before placing the user in the product.

2) WARNING FINGER TRAP HAZARD

- Ensure that the user or carer does not touch any moving joint or pivot that is not locked.
- While the user is in the product, the carer should strive to keep product adjustments to a minimum.

3) WARNING OCCUPANT SECURITY

- User transfers in and out of the product must be done with appropriate equipment and personnel.
- When transferring the user into the product, first use the pelvic band to secure the user.
- Ensure that all harnesses, sandal straps and chest pad are securely applied.
- If the user exhibits any form of distress, remove from the product as quickly as is safely possible.

4) CAUTION FINGER PINCH HAZARD

• While the user is in the product, the

carer should strive to keep product adjustments to a minimum.

- Take care when assembling or adjusting the position of the stander components that your fingers do not get pinched when positioning stander components and tightening mountings.
- During product assembly and adjustment, the carer should avoid finger pinching risk of the product's joints or pivots.
- During transfers and adjustments, the carer should avoid the finger pinching risk of over-centre buckles and latches.

5) CAUTION DAILY CHECKS

- The stander is to be checked daily before use to ensure that all harnesses and stander components are securely attached.
- Always check operation of linear drives, gas struts, and motor drives before use.

6) CAUTION TRIP HAZARD WITH POWERED CHASSIS

• Before moving a powered stander ensure that battery charging connection is removed.

7) CAUTION CLEANING

 Clean the stander regularly to prevent the build-up of dirt. Accumulated dirt can prematurely wear the fabric components and encourage corrosion on the stander. Only use non-abrasive household cleaners and moist cloths, do not use running water on the upholstery whilst it is still attached to the seat. See section Cleaning & Care Information.

8) CAUTION CLEANING POWER WASHERS/HOSES

• Hoses and power washers are not to be used to clean the product. Standers with the electric lift system are not sealed against running water and may be damaged by water ingress. See section Cleaning & Care Information.

9) CAUTION SERVICING/REPAIR OF ELECTRONIC COMPONENTS

• All electronic and electrical components are NOT user-serviceable. Servicing and repairs are only to be carried out by Leckey-authorised personnel.

10) CAUTION DISPOSAL

• When disposing of the product using a community waste disposal site, the frame and any electrical components should be disposed of separately.

11) CAUTION BRINGING INTO USE

• Before use, allow 2 hours for the product to acclimatise to room temperature.

SECTION 04: TERMS OF WARRANTY

The warranty applies only when the product is used according to the specified conditions and for the intended purposes, following all manufacturers' recommendations (also see general terms of sales, delivery and payment). A three year warranty is provided on all Leckey manufactured products and components.

SECTION 05: PRODUCT HISTORY RECORD

Your Leckey product is classified as a Class 1 Medical device and as such should only be prescribed, set up or reissued for use by a technically competent person who has been trained in the use of this product. Leckey recommend that a written record is maintained to provide details of all setups, reissue inspections and annual inspections of this product.

SECTION 06: PRODUCT TRAINING RECORD

(PARENTS, TEACHERS & CARERS)

Your Leckey product is a prescribed Class 1 Medical Device and as such Leckey recommend that parents, teachers and carers using the equipment should be made aware of the following sections of this user manual by a technically competent person.

SECTION 07 Safety Information SECTION 11 Frequent Adjustments for Daily Use SECTION 12 Cleaning and Care Information SECTION 13 Daily Product Inspection

Leckey recommend that a written record is maintained of all those who have been trained in the correct use of this product.

SECTION 07: SAFETY INFORMATION

- 1. Always read instructions fully before use.
- 2. Users should not be left unattended at any time whilst using Leckey equipment.
- Only use Leckey approved components with your product. Never modify the product in any way. Failure to follow instructions may put the user or carer at risk and will invalidate the warranty on the product.
- 4. If in any doubt to the continued safe use of your product or if any parts should fail, please cease using the product and contact our customer services department or local dealer as soon as possible.
- 5. We would recommend that users are never transferred straight from seating to standing without preparation and stretching. This is best done whilst lying on a mat but can be carried out in a wheelchair or seating system if required.
- 6. Carry out all positional adjustments and ensure that they are securely fastened before you put the user into this product.
- 7. When placing the user into a standing frame, for safety reasons, always secure the pelvic band first.

The chest and knee straps should then be fastened.

- 8. When the product is stationary ensure that all castors are locked and facing away from the base as this will improve product stability.
- 9. Never adjust the overall height of the Freestander while the frame is in use. Other finer positional adjustments may be carried out safely when the user is in the frame.
- 10. Never leave the product on a sloping surface, greater than 5 degrees. Always remember to lock all the castors.
- 11. The product contains components which could present a choking hazard to small children. Always check that locking knobs and bolts within the child's reach are tightened and secure at all times.
- 12. Leckey products comply with fire safety regulations in accordance with EN12182. However the product contains plastic components and therefore should be kept away from all direct sources of heat including naked flames, cigarettes, electric and gas heaters.
- 13. Do not place hot items of greater than 40 degrees onto the tray.

- 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.
- 15. The product is designed for indoor use and when not in use should be stored in a dry place that is not subjected to extremes of temperature. The safe operating temperature range of the product is +5 to +40 deg Celsius.

SECTION 08: PRECAUTIONS AND CONTRAINDICATIONS

Precautions

- Fixed spinal deformities such as scoliosis or kyphosis
- Severe muscle contractures
- Severe muscular or skeletal asymmetry including hip dislocation
- Progressive and muscle wasting conditions
- High risk or recent history of bone fractures
- High risk of pressure related injury or open sores
- Strong, uncontrolled movement patterns
- Poorly controlled seizure activity
- Children dependent on the use of percutaneous endoscopic gastrostomy
- Medical instability including compromised respiratory or cardiovascular function
- Dependant on 3rd party lifesustaining apparatus such as oxygen tanks
- Significant learning disabilities and/or behavioural issues

Contraindications

- Children experiencing pain or discomfort that cannot be resolved by adjustment of support/positioning
- Children with hip/ knee flexion contracture beyond the limits of the stander

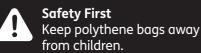
All precautions and contraindications are taken at the discretion of the prescribing clinician or parent. Leckey recommends a trained and experienced clinician to be present during all initial assessment, set ups, configurations, and reissues to minimise risk.

SECTION 09: HOW TO UNPACK AND ASSEMBLE

Check parts

Congratulations on purchasing your Leckey Freestander. When you receive your Freestander it will be boxed and wrapped in several parcels. Your Freestander comes as standard with chest plate including flexible laterals, knee plate, pelvic strap, activity tray and bowl, base with castors, inner poles and sandals.

The Totstander is supplied without castors, tray and with a chest strap instead of a solid chest plate. Carefully remove all the parcels from the box and check you have all the parts you have ordered.



9.1 ASSEMBLING THE FREESTANDER

To assemble your Freestander, firstly loosen the height adjustment bolt's on the outer upright poles and remove the inner poles.

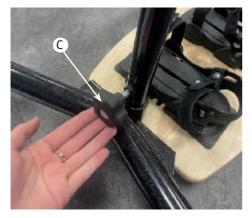
Insert the inner poles into place into the receiver tubes on the base castor frame. The allen key provided tighten the two small socket screws on each receiver tube securely **B**.

Then slide the main outer frame over the inner poles and tighten the two height adjustment bolts **G** at the desired height.









9.2 ATTACHING THE TRAY

The Freestander tray is attached by sliding the outer poles already attached to the tray over the inner poles already attached to the base and then tightening the bolts **(A**).

The tray is then secured with a tray pin into one of the slots on the side of the frame.











9.3 ATTACHING THE SANDALS

Insert the required attachment bolt (A) along with the retention plate (B) Place a rubber lid (C) on both the top and bottom of the sandal. Fasten using the four screws (D) provided. To remove or replace the attachment bolt, reverse this process. Place the sandal so that the attachment bolt goes through the slot in the footplate. To secure, on the underside of the footplate place the rubber washer (a), followed by the metal washer (b) and then the knob (c) onto the attachment bolt.

To position the sandals simply loosen the knob G under the footplate, select the position you require and re-fasten the knob.

SECTION 10: CLINICAL SETUP FOR POSTURAL MANAGEMENT

The clinical setup of the product should be completed by a technically and clinically competent person who has been trained in the use of the product. Leckey recommend a written record is maintained of all clinical setups for this product.

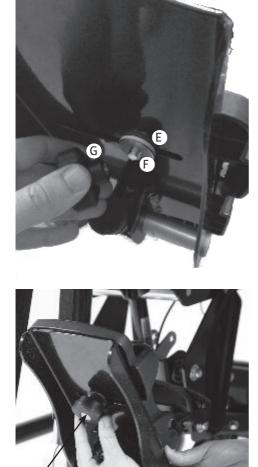
10.1 ADJUSTING THE CHEST PLATE

You should firstly measure the distance from the user's feet to just under the arms. This is best done where practical in a lying position, on a mat. The height between the top of the chest plate, and sandals should be set to the equivalent of this distance. This will always be the first adjustment you need to carry out.

To adjust the height of the chest plate, loosen the bolts (B), adjust to the required position, then re-tighten the bolt (A) securely.

The chest plate has a number of other adjustments that are carried out by loosening the bolts (A) at the side of the chest plate.

By loosening these bolts the chest plate can be moved:



- 1. Forwards and backwards for body profiling.
- 2. Up and down for finer, last minute adjustments to the height of the chest plate.
- To angle forwards/down or backwards/up slightly to assist in the positional management of extension or flexion respectively.

Never attempt to adjust the height of the main frame when the stander is in use.



10.1 ADJUSTING THE KNEE PLATE

The knee plate is adjusted in exactly the same way as the chest plate using the bolts **A**.



Always use caution to ensure fingers do not become trapped when adjusting the knee plate.



10.2 ADJUSTING THE KNEE CUPS

The knee cups are fixed with the bolts at the front of the knee block. When this bolt is loosened, the knee cup can be moved from left to right and rotated. Once the desired position is obtained the bolt A should be retightened securely.



Always use caution to ensure fingers do not become trapped when adjusting the knee cups.



10.3 ATTACHING THE PELVIC BAND

The pelvic belt should be attached to the user first, again if practical on a mat.

The pelvic straps are attached around the user's pelvis. The longer straps are then slipped through the outer poles of the frame and secured firmly behind the user with the Velcro on the belt. To ensure that you can easily identify the strap that goes around the user and the one that attaches to the frame, a Leckey label is sewn on to the one that goes around the frame.



SECTION 11: FREQUENT ADJUSTMENT FOR DAILY USE

Parents and carers should be shown how to make frequent adjustments and made aware of the safety checks in section 7 by a technically and clinically competent person who has been trained in the use of the product. Leckey recommend that a written record is maintained of all parent and carers who have been trained in the use of this product.

11.1 TRANSFERRING THE USER INTO AND OUT OF THE STANDER

11.2 ADJUSTING THE FLEXIBLE LATERALS

The Freestander flexible lateral

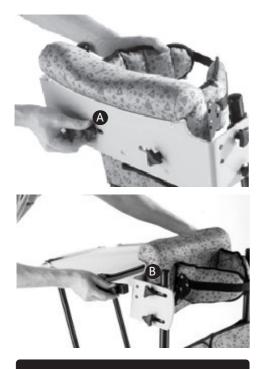
Before transferring the child into the stander carry out the daily product inspection as outlined in section 13 of this user manual.

Before transferring the child into the product lock all the castors, ensuring that they are facing outwards to maximise product stability. Make sure the straps on the chest, hip support harnesses and sandals are released and out of the way to facilitate transfer.

supports can be adjusted in and out by loosening the bolts A on the back of the chest plate. Once these bolts have been loosened, the flexible lateral supports can be adjusted to the required position and once in position the bolts should be retightened securely. The flexible laterals also have a small amount of height adjustment. To alter the height loosen the allen bolts **B**, position the lateral as required and then re- tighten the allen bolts **B** securely. The flexible lateral supports are secured around the user by tightening the safety strap into position. Fasten the safety strap immediately.



Always secure the pelvic band and safety strap first then the chest strap and the users feet.



Always use caution to ensure fingers do not become trapped when adjusting the lateral supports.

11.3 ADJUSTING THE KNEE CUPS

The knee cups are fixed with the bolts at the front of the knee block. When this bolt is loosened, the knee cup can be moved from left to right and rotated. Once the desired position is obtained the bolt A should be retightened securely.

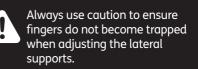


11.4 ADJUSTING THE SANDALS

To position the sandals simply loosen the knob under the footplate, select the position you require and re-fasten the knob. To position the user's feet in the sandals secure the Velcro straps provided so the foot is held in place. The straps should be placed over the bridge of the foot and over the toes. The front strap can be fed through one of two slots on either side of the sandals, depending on the size of the user's feet.







11.5 ADJUSTING THE TRAY

The tray can be height and angle adjusted by loosening the bolt (A) on the tray poles, adjusting to the required position and then re- tightening the bolts (A) securely.



The position of the tray can also be altered in relation to the chest plate. One of three positions can be selected to help facilitate good hand function. The tray will come complete with a tray cover and a bowl meaning that you can use the tray with a flat cover and use the bowl for play activities.



11.6 ATTACHING THE PELVIC BAND

The pelvic band should be attached to the user first, again if practical on a mat. The pelvic straps are attached around the user's pelvis, the longer straps are then slipped through the outer poles of the frame and secured firmly behind the user with the Velcro on the belt. To ensure that you can easily identify the strap that goes around the user and the one that attaches to the frame, a Leckey label is sewn on to the one that goes around the frame.



SECTION 12: CLEANING & CARE INFORMATION

How to maintain

When cleaning we recommend that you use only warm water and a nonabrasive detergent. Never use organic solvents or dry cleaning fluids.

Upholstery and fabrics

- The upholstery and fabrics can be cleaned by hand whilst in place. When cleaning we recommend that you use only warm water and a nonabrasive detergent.
- 2. The best cleaning method is a 'wipe & dry' technique.
- 3. Staining should be removed as quickly as possible with absorbent cloth, towels or a sponge. Routine soap and warm water sponging is effective for ordinary soiling and minor spills. Be careful not to over wet the fabric, as this will cause the staining to spread.
- 4. Antiseptic cleaning agents can be used on more stubborn stains. These may require a safe solvent such as Isopropyl Alcohol or Mineral Spirit. A half cup of household bleach to 5 litres of water can also be used as a useful disinfectant.
- 5. Always ensure the product is dry before use.

Metal and plastic and wooden components

- 1. Soap and water or antibacterial spray can be used for daily cleaning.
- 2. For deep cleaning a low pressure steam cleaner can be used.
- Do not use solvents to clean plastic, wooden or metal components.
- 4. Make sure the product is dry before use.
- 5. Check all wooden components regularly to ensure there are no cracks or splinters.

SECTION 13: DAILY PRODUCT INSPECTION

(Therapists, Parents & Carers)

We recommend that daily visual checks of the equipment are carried out by therapists, carers or parents to ensure the product is safe for use. The recommend daily checks are detailed below.

- 1. Ensure all adjustment knobs and bolts are in place and secure.
- 2. Check all upholstery for signs of wear and tear.
- 3. Check all castors are moving freely and lock securely.
- 4. Check all Velcro strips and brush fluff to ensure straps secure firmly.

If in any doubt to the continued safe use of your Leckey product or if any parts should fail, please cease using the product and contact our customer services department or your local dealer as soon as possible.

SECTION 14: ANNUAL PRODUCT INSPECTION

(Therapist, Technician, Leckey Product Advisor, Dealer)

Leckey recommend that each product should be subject to a detailed inspection at least once a year and every time the product is reissued for use. 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, replacing any missing items. Paying particular attention to the following items;
- Chest and hip height and angle adjustments
- Knee cups adjustment knobs
- 2. Lift the base to check each castor individually. Make sure they are moving freely and remove any dirt from the rubber wheels. Check that the brakes lock the wheels securely.

- 3. Visually check the structure of the product, paying attention to weld points on the frame ensuring there are no signs of fatigue or cracking around the welds.
- 4. Leckey recommend that a written record is maintained of all annual product inspections.

If in any doubt to the continued safe use of your Leckey product or if any parts should fail, please cease using the product and contact our Customer Care Team or your local dealer as soon as possible.

SECTION 15: RE-ISSUING LECKEY PRODUCTS

Most Leckey products are assessed and ordered to meet the needs of an individual user. Before reissuing a product we recommend that the therapist prescribing the product has carried out an equipment compatibility check for the new user and has ensured that the product being reissued contains no modifications or special attachments.

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 and inspection of the product.

Please refer to **section 14** for the required checks to be carried out.

Before re-issuing a product, we recommend it is disinfected using the following procedure:

Note: Always clean the product first to remove accumulated soiling prior to disinfecting/sanitising

 Where possible, we recommend the use of an automated "fogger" disinfection system that is used to completely cover the product surfaces with a disinfectant agent. The manufacturer's instructions for the chosen system should be referred to prior to use and followed exactly. Where an automated disinfection system is not available, all product surfaces should be wiped over with disinfectant surface wipes or liquid disinfectant on a soft cloth. Suitable products are 70% IPA, 70% Alcohol or diluted bleach. The manufacturer's instructions for the chosen product should be followed. Product upholstery and fabrics should be cleaned thoroughly in accordance with section, Cleaning and Care Information, of this manual.

Ensure a copy of the user manual is supplied with the product. A copy can be downloaded from our website **www.leckey.com**

Leckey recommend that a written record is maintained of all product inspections carried out during the reissue of the product.

If in any doubt to the continued safe use of your Leckey product or if any parts should fail, please cease using the product and contact our Customer Care Team or your local dealer as soon as possible.

SECTION 16: PRODUCT SERVICING

Servicing of all Leckey products should only be carried out by technically competent persons who have been trained in the use of the product.

In the UK & ROI please contact the Leckey Service Centre on:

• UK 0800 318265 or ROI 1800 626020

and our customer service department will be delighted to assist you with your servicing requirements.

All international service enquiries should be directed to the appropriate Leckey distributor who will be delighted to assist you. For further information on Leckey distributors please visit our website : **www.leckey.com/contact**

SECTION 17: TECHNICAL DETAILS

| Technical Details | | | | | | |
|---------------------------|--------|--------|--------|--------|--------|--------|
| Size | Size 1 | | Size 2 | | Size 3 | |
| Age (Years Approx) | 1-5 | | 4 - 10 | | 9 - 18 | |
| Codes | LFS/1 | | LFS/2 | | LFS/3 | |
| | mm | Inches | mm | Inches | mm | Inches |
| Freestander | | | | | | |
| Chest Plate Height min | 470 | 18.5 | 680 | 27 | 975 | 38 |
| max | 680 | 27 | 975 | 38 | 1350 | 53 |
| Base length | 650 | 26 | 750 | 30 | 750 | 30 |
| width | 650 | 26 | 750 | 30 | 750 | 30 |
| Activity Tray depth | 400 | 16 | 425 | 18 | 470 | 20 |
| width | 540 | 21 | 590 | 23 | 644 | 25 |
| User Weight max | 60kg | 132lbs | 80kg | 176lbs | 90kg | 198lbs |
| Totstander | | | | | | |
| Chest Plate Height min | 470 | | | 18.5 | | |
| max | 680 | | | 27 | | |
| Base length | 450 | | | 18 | | |
| width | 450 | | | 18 | | |

TABLE OF SYMBOLS

| Symbol | Meaning |
|-------------|-------------------------------|
| MD | Medical Device |
| (ii) | Read the Instructions for Use |
| CE | CE mark |
| | Warning |
| | Manufacturer |
| SN | Serial number |
| REF | Product code |
| | Max occupancy weight |
| ~~~ | Date of Manufacture |
| \uparrow | For indoor use only |
| NUER | Latex free |

| Symbol | Meaning | | | |
|-----------|--------------------------------------|--|--|--|
| UDI | Unique Device Identification | | | |
| 50° | Machine wash- water temperature 50°C | | | |
| \odot | Tumble dry- low heat | | | |
| Ā | Cool iron | | | |
| \otimes | Do not dry-clean | | | |

NOTES

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