



PO Box 302 250
North Harbour
Auckland



0800 31 61 81
www.alliedmedical.co.nz

**ALLIED
MEDICAL**
LIMITED

Totstander

User Manual



Supporting
Children



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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

Totstander has been designed for used at home or in school for upright standing. The stander is available in one size catering for the needs of children from the age of 1-5. The maximum user weight is 22kg. Suitable for:

- Children 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 Totstander 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, Medical 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

- **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.
- **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.
- **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.
- **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.
- **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.
- **Caution Trip Hazard with Powered Chassis:**
 - Before moving a powered stander ensure that battery charging connection is removed.
- **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.
- **Caution Cleaning Power Washer/ Hoses:**
 - Hoses and power washers are not to be used to clean the product. Stander with the electric lift system are not sealed against running water and may be damaged by water ingress.

See section Cleaning & care information.

- **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-authorized personnel.
- **Caution Disposal:**
 - When disposing of the product using a community waste disposal site, the frame and any electrical components should be disposed of separately.
- **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 10 Product Care

Section 11 Cleaning and Care Information

Section 12 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.
3. Only use Leckey approve 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 Totstander 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.
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. 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.
14. 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°.

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 life-sustaining 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 Totstander. When you receive your Totstander it will be boxed and wrapped in one parcel. Your Totstander comes as standard with chest support, knee plate, knee cups, pelvic strap, wooden base, inner poles and sandals.

Carefully remove all the parcels from the box and check you have all the parts you have ordered.



Keep polythene bags away from children

SECTION 10: PRODUCT CARE

Clinical Set-up

Adjusting the height

To adjust the height of the Totstander, loosen the lowest knobs **A** on the upright bars, adjust to the desired height and retighten.

Adjusting the height of the knee cups. Loosen the knobs **B** (see photo below), set knee cups to desired and retighten knobs.



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: CLEANING & CARE INFORMATION

How to Maintain

When cleaning the product, we recommend that you use only warm water and a non-abrasive detergent. Never use organic solvents or dry cleaning fluids.

Upholstery and fabrics

1. The upholstery and fabrics can be cleaned by hand whilst in place.
2. Remove spillage promptly with an absorbent dry cloth.
3. Vacuum and wipe clean regularly with a damp cloth to remove dust particles and prevent build-up of soiling.
4. If necessary, use a mild disinfectant or bleach diluted to 3 part per 100.
5. For heavily soiling use a mild liquid soap.
6. Remove bodily fluids promptly (within 15 minutes) with cold water and clean as above.
7. Do not machine wash, full immerse, dry clean or apply other chemicals / stain removers.
8. 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.
3. 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 12: 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 Velcro strips and brush fluff to ensure straps secure firmly.
2. 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.
3. 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 services department or your local dealer as soon as possible.

SECTION 13 : 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.

1. Check all knobs, nuts, bolts and plastic buckles are in place, replacing any missing items.



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 : 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 re-issued 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 13 for the required checks to be carried out.

Before re-issuing a product, it is recommended that it is disinfected using one of the following procedures:

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

1. 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.
2. 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 service department or your local dealer as soon as possible.

SECTION 15 : 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 16: TECHNICAL INFORMATION

















Product Code **LFS/T-MW**

The Totstander comes with Meadow Fabric as the sole option.

Totstander		
Chest Band Height		
min	470	18,5
max	680	27
Base		
min	450	18
max	450	18

For more information please visit **leckey.com**

Table of Symbols

Symbol	Meaning
	Medical Device
	Read the Instructions for Use
	CE mark
	Warning
	Manufacturer
	Serial number
	Product code
	Max occupancy weight
	Date of Manufacture
	For indoor use only
	Latex free
	Unique Device Identification
	Machine wash- water temperature 50°C
	Tumble dry- low heat
	Cool iron
	Do not dry-clean