

Pronestander

User Manual



Supporting Children



The Leckey Pronestander 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 the functions. The instructions on the safety and maintenance of the product will ensure that you will enjoy the use of this product 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

Pronestander has been designed for use at home or school. The range of prone angles available allow the gradual increases of weight bearing as tolerance increases. Pronestander is intended for children from the ages 1-17 years. 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: DECLARATION OF CONFORMITY

The Pronestander is classified as a Class I Medical Device under EU and UK regulations. James Leckey Design Ltd as manufacturer with sole responsibility declares that the Leckev Pronestander conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2017, UK Medical Devices Regulation 2002 and EN 12182 Technical aids for disabled persons 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 userserviceable. Servicing and repairs are only to be carried out by Leckeyauthorised 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.
- To improve we recommend that 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 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.
- 5. We recommend that users are never transferred straight from the seating to standing without preperation and stretching. This is best done whilst lying on a mat but can be carried out in a wheelchair or a 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 all castors are locked and facing away from the base as this will improve product stability.
- 9. Never adjust either the angle of the Pronestander or overall height of the chestplate 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 on the tray greater than 40 degrees
- 14. 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.
- 16. 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 Pronestander. When you receive your Pronestander it will be boxed and packed flat. The tray will be in a separate parcel. The Pronestander will come as standard with chest plate including flexible laterals, knee plate, pelvic plate including belt, hinged foot plate, sandals and activity tray including bowl.

Assembling the Pronestander

To assemble the Pronestander, two people should firstly lift the Pronestander out of its box or alternatively remove the packaging and wheel the Pronestander out on its castors. The castors should then be locked into position, facing out of the frame at 45 degrees.



Safety first

Keep polythene bags away from children.

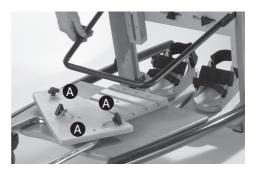
Ensure angle adjuster bar is secure before placing the user in the Pronestander.

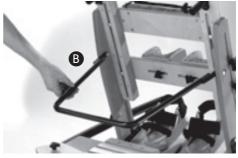
9.1 SETTING THE **ANGLE**

In order to fix the Pronestander at the desired angle, you should firstly hold the chest plate and gently swing the main frame of the stander upright. Then loosen the three bolts A as shown and the angle adjuster bar **B** can then be positioned to the desired angle. The plate should then be placed back into position and the three bolts A re-attached and tightened securely.



Never attempt to adjust the angle of the Pronestander when the frame is in use.





9.2 ATTACHING THE **TRAY**

The Pronestander tray is attached by sliding the outer poles already attached to the tray over the inner poles already attached to the frame and then tightening the bolts . The tray is then secured with a tray pin into one of the slots on the side of the frame.



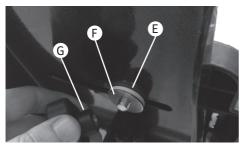


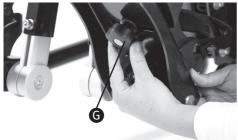
9.3 ATTACHING THE **SANDALS**

Insert the required attachment bolt A along with the retention plate B Place a rubber lid **(** 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.



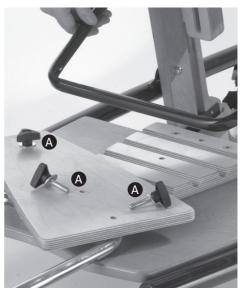
Place the sandal so that the attachment bolt goes through the slot in the footplate. To secure, on the underside of the footplate place the rubber washer **(E)**, followed by the metal washer **(F)** and then the knob **G** onto the attachment bolt. To position the sandals simply loosen the knob **G** 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 SETTING THE ANGLE

There is a choice of five different angle positions on the Pronestander. Depending on the user's tolerance to standing, you can choose to position them anywhere from a very prone angle to almost upright.

Once you have selected the desired angle, you can set up the rest of the Pronestander to suit the user.



Ensure angle adjuster bar is secure before placing user in the Pronestander.



10.2 ADJUSTING THE HEIGHT OF THE CHEST **PLATE**

You should firstly measure the distance from the user's feet to just under their arms. This is best done where practical in a lying down position on a mat. The height between the top of the chest plate and sandals should be set to the equivalent of this distance. The height of the chest plate can then be altered by loosening the knobs on the side of the frame. Once loosened, this will allow the whole inner section (including chest plate, pelvic plate and knee plate) to move up and down. Once the required height is obtained, the knobs should be re-tightened securely.



Never attempt to adjust the height of the main frame when the stander is in use. Check adjustment knobs on the chest plate are secure before placing the user in the Pronestander.



10.3 ADJUSTING THE **PELVIC PLATE**

The height of the pelvic plate is set to the equivalent distance between the top of the user's pelvis and their feet. The pelvic plate is adjusted by loosening the bolt, on each side of the plate and sliding the padded plate into the required position. Once the required position is obtained, the bolts, A should be re-tightened securely.



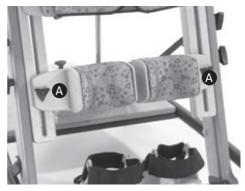
10.4 ADJUSTING THE **KNEE PLATE**

The height of the knee plate is adjusted by loosening the bolts (A) on each side of the knee plate, sliding the knee plate into the required position and then retightening the bolts A securely.



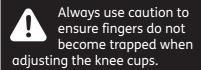
Minor adjustments to the knee and pelvic plate may be made during use.

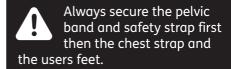
Always use caution to ensure fingers do not become trapped when adjusting the knee plate.



10.5 ADJUSTING THE **KNEE CUPS**

The knee cups can be moved from left to right and each knee cup is fixed by a single bolt at the back of the knee plate. To adjust the knee cup loosen the bolt, position the knee cup as required, then re-tighten the bolt A securely.







10.6 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 and the longer straps are slipped through the D-Rings on the pelvic plate and secured firmly behind the user with 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 ADJUSTMENTS 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**

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.



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

11.2 ADJUSTING THE SANDALS AND **FOOTPLATES**

The Pronestander footplate is split and hinged at the back of the footboard. This allows the sandals to be adjusted more easily and can facilitate transfer from a seating position, to a wheelchair for example. To position the sandals simply loosen the knob under the footplate (photo1), 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 (photo 2).

If the child is wearing sandals or light footwear check the straps to make sure the webbing does not irritate the skin.





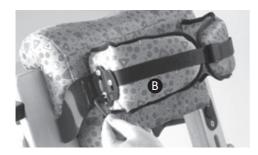
11.3 FLEXIBLE LATERAL SUPPORT **ADJUSTMENT**

The Propestander flexible lateral supports can be adjusted in and out by loosening the bolt on the back of the chest plate. Once this bolt has been loosened, the flexible lateral supports can be adjusted to the required position and once in position the bolts should be re-tightened securely. The flexible laterals also have a small amount of height adjustment. To alter the height loosen the allen bolts **B**, position the laterals 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 use caution to ensure fingers do not become trapped when adjusting the lateral supports.





11.4 ADJUSTING THE **TRAY**

The tray can be height and angle adjusted by loosening the bolts A on the tray poles, adjusting to the required position and then retightening 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.





11.5 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 slipped through the D-Rings on the pelvic plate and secured firmly behind the user with 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.



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



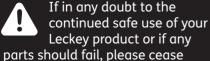
SECTION 12: CLEANING & CARE INFORMATION

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.

Metal, 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.



parts should fail, please cease using the product and contact our Customer Care team or your local dealer as soon as possible.

Upholstery and fabrics

- 1. 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.
- 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.
- 3. 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.
- 4. Wipe clean regularly with a microfibre cloth to remove dust particles and light soiling.
- 5. Remove spillages promptly with an absorbent dry cloth.
- For general soiling, use a microfibre cloth (taking care to avoid abrasive damage to the surface) and tepid soapy water (non alkaline).
- 7. Rinse clean with water and dry with an absorbent cloth.

- 8. Bodily fluids should be removed promptly within 15 minutes with cold water then cleaned as above.
- 9. Extreme soiling/infection control purposes use 5% sodium hydrochloride bleach solution, Haz Tabs or Chlorclean.
- 10. Steam cleaning is an effective sanitizer as are Haz Tabs and Chlorclean but is not a good cleaner. A wipe with a cloth, preferably microfibre, and water is more effective for actual cleaning. Steam and heat from steam cleaners actually seal in oily residues from bodily fluids, etc. If steam cleaning is essential, use infrequently for emergency infection control purposes only and in accordance with the machine manufacturer's recommendations. As we are unable to comment on the variety of machines in the marketplace or on the operator's handling, care should be taken for the sake of the upholstery fabric and we are unable to guarantee these.
- 11. Do not machine wash or dry clean.
- 12. Do not use furniture polish, stain remover or solvents.
- 13. Remove indigo dye from denim and canvas garments immediately as they will produce permanent staining if not dealt with promptly.
- 14. Do not use a felt tip or ball-point pen to mark.

VINYL MATERIAL

Cleaning and Care Information

- 1. Wipe clean routinely with a microfibre cloth, lightly dampened with cold water only. Then dry with a clean absorbent cloth.
- Soak up spillages as soon as 2. possible with an absorbent dry cloth to prevent staining. Clean with a microfibre cloth, lightly dampened with cold water.
 - Note dyes and pigments from indigo jeans, ball point and felt tip pens may permanently stain.
- 3. If soiling has accumulated use a mild soap (non-alkaline). Take care to remove all soap residues. Then dry with an absorbent cloth.
- Remove body fluids and extreme soiling immediately (within 15 minutes) with cold water. Apply your approved infection control protocol, a 10,000ppm sodium chloride bleach solution, Haz-Tabs or Chlor-Clean, Remove product residues and then dry with a clean absorbent cloth.

Note steam cleaning disinfects but the application of heat may fix staining substances and may result in permanent marks.

- 5. Do not apply solvent based cleaners or any other chemicals to the fabric.
- 6. Do not clean, tumble dry or fully immerse the fabric in water.

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 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 recommended daily checks are detailed below.

- 1. Ensure all adjustment knobs are in place and secure.
- 2. Check all upholstery and velcro 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.
- 5. Check adjustment knobs on the chest plate are secure before placing the user in the product.
- 6. Ensure angle adjuster bar is secure before placing the user in the product.

SECTION 14: ANNUAL PRODUCT INSPECTION

(Therapist, Technician, Leckey **Product Specialist, 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. 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 reissuina 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 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 "foager" 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.leckev.com

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

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.

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

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 17: TECHNICAL DATA

Product Sizing							
Size		1		2		3	
Age		1 – 5		4 - 9 1/2		9 – 17	
Codes		LPS/1		LPS/2		LPS/3	
	mm	inches	mm	inches	mm	inches	
Chest Plate Height							
min	470	18.5	680	27	975	38	
max	680	27	975	38	1350	53	
Base							
length	820	32	1070	42	1270	50	
width	600	24	650	26	700	28	
Activity Tray							
depth	400	16	450	18	500	20	
width	525	21	575	23	625	25	
User Weight							
max	30kg	66lbs	60kg	132lbs	100kg	220lbs	
Prone Angles from vertical	0° 10° 20°	30° 40°					

TABLE OF SYMBOLS

Symbol	Meaning
MD	Medical Device
(i)	Read the Instructions for Use
CE	CE mark
UK CA	UKCA mark
<u> </u>	Warning
•••	Manufacturer
SN	Serial number
REF	Product code
Max T	Max occupancy weight
	Date of Manufacture
	For indoor use only
TATES	Latex free

Symbol	Meaning				
UDI	Unique Device Identification				
500	Machine wash- water temperature 50°C				
\odot	Tumble dry- low heat				
a	Cool iron				
×	Do not dry-clean				
<u> </u>	Do not dispose in domestic waste				
\bowtie	Do not machine wash				
	Do not tumble dry				
\geqslant	Do not iron				
\bowtie	Do not bleach				
40°	Machine wash- water temperature 40°C				
70°	Machine wash- water temperature 70°C				
0	Tumble dry- low heat				



USA Distributor

Sunrise Medical (US) LLC North American Headquarters 12002 Volunteer Blvd.

Mount Juliet, TN 37122

T: 1-800-333-4000 **F:** 1-800-300-7502

E: customseating@sunmed.com

sunrisemedical.com

Canadian Distributor

Sunrise Medical Canada Inc. 1000 Creditstone Rd., Unit #2 Concord, ON, L4K 4P8

Canada

T: +1.800.263.3390 **F:** +1.800.561.5834

E: mkt.canada@sunmed.com

sunrisemedical.ca

Please visit leckey.com for a full list of Leckey distributors.



Leckey 19 Ballinderry Road Lisburn, BT28 2SA Northern Ireland

leckey.com

(+44) 28 9260 0750 hello@leckey.com



