This user guide contains important information on correct usage, handling, cleaning and decontamination. Please read carefully prior to use.

! IMPORTANT - Indicates a hazardous situation that could result in damage to property if it is not avoided.

Toto® Lateral Turning System Labelling

- 65°C for 10 minutes or 73°C for 3 minutes
- Bleaching agent allowed
- Max user weight
- Do not pierce or cut
- Line dry
- Do not iron
- CE conform
- Refer to user manual
- CE marking (European Union New Approach Directives)
- Type BF applied part
- Class II equipment
- Caution symbol
- Disposal: do not dispose of this product as unsorted domestic waste. It must be sent to a separate collection facility for recovery and recycling.
- Keep dry
- Operating instructions
Kit Contents

Before you start please ensure you have all the necessary components, if any are absent, or in case of doubt, please contact Frontier Therapeutics Ltd Customer Services on 0044 (0) 1495 235800.

Toto Lateral Turning System Control Unit

• 1x Toto lateral turning system control unit.
• 1x Control unit power lead.
• 1x Instructions for use.

Toto Lateral Turning System Platform

• 1x Platform.
• 1x Platform cover.
• 1x CPR deflation valve and tubing set.
• 1x Pair of air cells with quick connectors.

Toto Control Unit Labelling

• **Power** - Starts or stops the control unit.
• **Inflate time** - Controls the length of time the patient is on one side.
• **Rest time** - Controls the length of time the patients is supine.
• **Alarm** - Visual LED indication.
Product Specifications

Toto Lateral Turning System - Standard: Fully customisable control unit with a 30 degree tilt.

Toto Lateral Turning System - 45: Fully customisable control unit with a 45 degree tilt.

Toto Lateral Turning System - XL: Fully customisable control unit, with an extra wide platform suitable for bariatric patients.

Toto Platform

<table>
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<tr>
<th>Product</th>
<th>Weight (kg)</th>
<th>Maximum User Weight (kg)</th>
<th>Width (mm)</th>
<th>Length (mm)</th>
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<tbody>
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<td>Standard</td>
<td>18</td>
<td>190</td>
<td>745</td>
<td>1850</td>
</tr>
<tr>
<td>45</td>
<td>18</td>
<td>190</td>
<td>745</td>
<td>1850</td>
</tr>
<tr>
<td>XL</td>
<td>23</td>
<td>190</td>
<td>1067</td>
<td>1850</td>
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<table>
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<tr>
<th>Product</th>
<th>Depth (flat position - air cells empty) (mm)</th>
<th>Depth (raised position - air cells inflated) (mm)</th>
<th>CPR Deflation Valve</th>
<th>Angle of Tilt (°)</th>
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<td>Standard</td>
<td>35</td>
<td>185</td>
<td>Quick Release Pull Tag</td>
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<td>45</td>
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<tr>
<td>XL</td>
<td>35</td>
<td>271</td>
<td>Quick Release Pull Tag</td>
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Toto Control Unit

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Dimensions (mm)</th>
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<tr>
<td></td>
<td>Width</td>
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<td>3</td>
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<table>
<thead>
<tr>
<th>Maximum Current</th>
<th>Voltage (AC)</th>
<th>Air Output (LPM)</th>
<th>Fuse Rating</th>
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</thead>
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<tr>
<td>0.2A/0.3A Frequency 50Hz</td>
<td>230</td>
<td>6.5</td>
<td>1A/250v (slow blow type fuse)</td>
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</table>
**Product Description**

Toto is an automated lateral turning system which consists of a powered control unit and a turning platform with cover.

Designed to assist with patient turning and pressure injury prevention plans, the system is based on inflating alternating air cells within the platform. These turn patients laterally via the mattress surface to a maximum of either 30 or 45 degrees depending on which version is used.

The programmable control unit provides customised care with user determined inflation and rest durations. This should be based upon the patient’s main risk factors and their ability to reposition themselves.

The system is compatible with profiling beds and both standard and alternating pressure relieving equipment. It is also compatible with domestic mattress with the exception of pocket sprung.

**Indications**

The Toto lateral turning system is suitable for the prevention of pressure ulcers for the following patients:

- Identified as being at moderate to high risk of developing pressure ulcers as defined by commonly used assessment tools.
- Weighing up to 190kg (415lbs).
- Who are unable to change their position without assistance.
- Identified as requiring regular turning and who are non-compliant with manual turning schedules.

**Contraindications**

- Do not use with patients with unstable spinal cord injuries or who are undergoing traction.
- Do not use with patients with equilibrium disturbances.
- Not to be used where patients must be supported by wedges or pillows etc.
Warnings and Precautions

Individual patient assessments should be made prior to use. Please note the following:

• Caution is advised when using with patients with underlying neurological disorders which may lead to increased anxiety.

• Unusual body shapes, body postures and other medical devices should be assessed for suitability.

• Toto lateral turning system should be fully deflated when attempting to leave the bed.

• Ensure that the Toto lateral turning system is discontinued for feeding times to avoid the risk of spillages.

• When elevating a profiling bed back rest, raise the knee break first.

• Ensure that the surface of the bed frame is clear from debris before placing the Toto lateral turning system platform, as this can damage the coating of the cover.

• The system should not be used without a mattress.

• Do not strap the mattress to the bed frame as this will prevent Toto lateral turning system from operating.

• If mattress overlays are being used, these must be securely fastened to the mattress, not the Toto lateral turning system platform.

• The Toto lateral turning system can be used with positioning systems, bed levers and linen cradles as long as their support frame fits horizontally across the bed. These must be positioned under the Toto lateral turning system platform.

• Evacuation hammocks must be placed between the Toto lateral turning system platform and the mattress.

• If using bed sides, check for clearance from the top of the mattress to the bottom of the bed side (minimum of 185mm) and assess for risk of entrapment.

• If using foot board protectors, and assess for compatibility.

• Do not place the control unit underneath the bed frame if placing on the floor.

• The Toto control unit must only be connected to mains supply which has a protective earth.

• Do not use if mains lead or plug is damaged.
Platform Installation and Operating Guide

To ensure the system is correctly installed and functions smoothly, please follow this step-by-step guide.

1. Remove all items from the packaging and inspect for damage.
2. The platform should be placed directly onto the bed frame and underneath the existing mattress. DO NOT strap or fasten the mattress to the bed frame. (A)
3. If installing the platform for the first time, inspect the platform for any visible signs of damage. If it is for repeated use, unzip the cover and inspect for any visible signs of damage. (B)
4. Ensure the air cells within the platform are secured in position via the Velcro® strap.
5. Replace and re-zip the cover, ensuring that the air cell hoses are fed through the apertures at the foot end of the cover.
   Note: The platform cover should be free to move, allowing each side of the platform unrestricted room to inflate.
6. Using the quick connectors, connect the inflation hoses to the air cell hoses - 'Red to Red' - ensuring the hoses are not twisted or kinked. (C)
7. Check the CPR deflation valves are securely in place to ensure no air leaks. (D)
8. Using the bed hooks, hang the control unit on footboard of the bed. (E)
9. Using the quick connectors, connect the air cell hoses to the control unit - 'Black to control unit' - ensuring the hoses are not twisted or kinked. (F)
10. Connect the control unit to the mains power via the cable supplied. (G)

A. The platform should be placed directly onto the bed frame and underneath the existing mattress.
B. Inspect the platform for visible signs of damage. Remove the cover if required.
C. Using the quick connectors, connect the inflation hoses to the air cell hoses - 'Red to Red' - ensuring the hoses are not twisted or kinked.
D. Check the CPR deflation valves are securely in place to ensure no air leaks.
E. Using the bed hooks, hang the control unit on footboard of the bed.
F. Using the quick connectors, connect the air cell hoses to the control unit 'Black to control unit' - ensuring the hoses are not twisted or kinked.
G. Connect the control unit to the mains power via the cable supplied.
Instructions For Use

Control Unit Operating Guide

There are two dials on the front of the control unit:

**Inflate time:** Controls the length of time the patient is on one side; minimum 10 minutes, maximum two hours.

**Rest time:** Controls the length of time the patient is supine; minimum 10 minutes, maximum two hours.

1. Set both dials to the required time as shown in the images below. *(A - B)*
2. Switch on the control unit; note the on/off switch back-lit green. *(C)*
3. After several minutes, the patient’s left hand air cell will inflate denoted by the illuminated white inflating light. The air cell will remain inflated for the length of time set during point (1).
4. Once the inflation time has elapsed, the control unit will automatically switch to ‘rest’ mode denoted by the illuminated blue ‘rest’ light. The system will remain at rest for the time period set in point (1).
5. The sequence will repeat when the opposite side inflates.

### Patient Positioning

Patients should be positioned along the centre line of the mattress by aligning the patient’s nose with the centre point of the head board. Ensure head and shoulders are supported to prevent neck roll and pivoting at the hips during use.

For patients lying on their side, if they can self-support and they are in the middle of the bed, Toto lateral turning system can be used.

If patients cannot control their limbs and bed sides are being used, padding or net infills are recommended.

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Centre Line
The Toto lateral turning system features a quick release CPR deflation valve which allows for rapid deflation for emergency procedures.

The CPR deflation valve can be found on the air hoses between the control unit and the platform, clearly marked with a yellow tab.

In the event of an emergency, firmly pull and release the yellow tab.

To re-inflate the system after the CPR tag has been removed, replace the CPR tag ensuring both sealing connectors are firmly attached, and restart the Toto control unit.

**Alarms**

Should either of the air-cells fail to inflate there will be an audible warning signal and visual alarm on the control unit.

In the event of an alarm, please check ALL connections and ensure CPR sealing connectors are pushed in fully.

If all connections are secure and correct, contact Frontier Therapeutics Ltd tel. 0044 (0) 1495 235800 for assistance.
Regular Care Checks

**Inspection**

Inspect the inner and outer surfaces of the cover and zip fasteners regularly for signs of damage. Damaged covers should be reported to the ward or department manager or relevant healthcare professional.

Torn covers should be withdrawn from service, and replacements sought.

Regularly inspect the interior and exterior of the platform, ensuring that the hinges and air cells remain intact.

The labels on the Toto lateral turning system cover, platform and control unit have a unique batch number which should be retained and used in the event of a warranty claim. NEVER remove the labels.

**Control Unit**

The Toto control unit is designed to be reliable and long lasting, with few parts requiring maintenance. Air filters should be cleaned at least once every 24 months and inspections should be undertaken noting any visible signs of damage.

In the event of product failure, please contact Frontier Therapeutics for advice and recommendations on service and repair.

Although there are no requirements for PAT testing, guideline recommendations indicate:

- Class 1 moveable equipment such as extension leads and portable electrical equipment should be tested every six months. This is the responsibility of the operator alone.

Please refer to local guidance.

**Cleaning Air Filters**

1. Switch off the power supply to the control unit.
2. Disconnect the power lead and air hoses.
3. Place the control unit on a flat surface with its back panel uppermost (place a soft cloth under the unit to prevent scratches).
4. Carefully remove the air filter covers located on the back panel of the control unit (x2).
5. Remove and clean the filters with clean water and allow to fully dry.
6. Refit the air filter cover to the control unit.
7. The control unit is now ready for re-use.
Platform
Regularly check that the platform has not drifted out of position and the hoses are not blocked, kinked or twisted.

Fitting / Replacing Damaged Air Cells
In the event of puncture or leak, it is possible to replace either or both air cells. Please contact Frontier Therapeutics Customer Services for replacement parts.

1. Switch off the control unit and disconnect from mains.
2. Disconnect the air hoses to the platform using the quick connectors.
3. Unzip and pull back the cover revealing the platform.
4. Determine the faulty air cell and remove by unfastening the Velcro® straps.
5. Inspect the platform for other signs of damage, including what could have caused air cells to have become damaged.
6. Using the Velcro® straps, fit the new air cell in place ensuring it is in-line with the correct section.
7. Replace cover ensuring correct orientation and feed air cell hoses through apertures at the bottom of the cover.
8. Reattach hoses using the quick connectors - 'Red to Red' - ensuring they are not twisted or kinked.

Disposal
! IMPORTANT The disposal and recycling of used products and packaging must comply with the applicable legal regulations in each country.

Storage Guidance
When not in use, the Toto lateral turning system should be stored in a secure location away from the public.

It is recommended that the Toto platform is handled by a minimum of two people.
- Do not drag!
- Never store other items on top of the Toto platform.
- Place a protective covering over the platform and do not store directly on the floor.
- Do not store next to radiators or other heating devices.
- Do not allow sharp objects to penetrate the cover.
Cleaning

Toto Lateral Turning System Platform Cover
Keeping a cleaning record is recommended as the product is suitable for re-use.

Light Soiling

! IMPORTANT In the absence of gross contamination or unusual risk, the removal of dirt and spillages with a neutral detergent and warm water should be sufficient. A 0.1% hypochlorite solution (1000ppm) may also be used. Ensure that the cover is rinsed with clean water using a single use, non-abrasive cloth and thoroughly dried. Ensure adequate ventilation.

Heavy Soiling

! IMPORTANT In cases of gross contamination the Toto lateral turning system platform cover should be cleaned first with detergent and water and then with a 0.1% hypochlorite solution (1,000ppm). Rinse well with clean water and wipe down with a single use, non-abrasive cloth and thoroughly dry. Ensure adequate ventilation.

! IMPORTANT If required, a 1% hypochlorite solution (10,000ppm) and cold water may be applied for no more than two minutes.

Machine Washing Instructions

! IMPORTANT Disinfection may be achieved by laundering at temperatures not exceeding 65°C for 10 minutes or 73°C for three minutes.¹

¹Protect, Rinse and Dry - BHTA guidance on the care, cleaning and inspection of healthcare mattresses. (January 2012 - HHTA HM 0112)
**Warranty**

The Toto lateral turning system warranty is valid for one year from time of shipping. If a defect or fault is discovered, please contact Frontier Therapeutics Ltd Customer Services on tel: 0044 (0) 1495 235800 or email: info@frontier-group.co.uk immediately.

Frontier Therapeutics Ltd guarantees that the equipment is free from defects in material and workmanship, under normal use and service.

During the period of the warranty, any products that have become defective due to faulty workmanship or material will be renewed as deemed appropriate by Frontier Therapeutics Ltd, without charge for parts or labour. During this time, a loaned control unit will be made available if required.

If the product is damaged due to an accident, negligence or misuse the product warranty will be forfeited. No unauthorised alterations are permitted. Both warranty and fire retardancy certification will be null and void if non-Frontier Therapeutics Ltd spares or replacement parts are used.

Frontier Therapeutics Ltd will not accept responsibility for damage caused by misuse, negligence, accidental damage nor non-observance of the instruction set out within this document. This warranty does not affect your statutory rights.

**Fire Testing**

The Toto lateral turning system platform meets the requirements of ‘The Furniture & Furnishings (Fire) (Safety) Regulations 1988’. Meeting the requirements of BS 7175: 2008 for medium hazards.

**Standards and Regulation**

This Active Class 1 Device complies with the requirements of the MDD 93/42/EEC (as amended). The control unit is tested to EC Directive 2004/108/EEC and EN 55011. Manufactured to comply with EN 60601 and all relevant sub standards.

**Other Standards**

BS EN ISO 9001:2008 Quality Management Systems


No modification of this equipment is allowed.