easycare systems

frontiermedical group

toto® & toto® cradle

EN Toto® Lateral Turning System, with Toto® Touch Control Unit

Instructions for Use
Version 9.0 2023

www.easycaresystems.co.uk

toto® & toto® cradle

Instructions for Use

EN

English

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Contents

Toto® & Toto® Cradle Symbol Definitions

	Manufacturer		Temperature limitation	250 kg	Maximum user weight		Interface lock
EC REP	European authorised representative		Humidity limitation		Type BF applied part		Air leak
LOT	Lot number		Atmospheric pressure limitation		Do not pierce or cut		Recyclable
REF	Reference number		Disposal		Refer to instructions		This way up
SN	Serial number		Caution symbol		Class II electrical equipment	65	65°C for 10 minutes or 73°c for 3 minutes
	Importer		Patient information website	CE	CE Mark	< 1%	Bleaching agent allowes
	Distributor	MD	Medical device	UK CA	UKCA Mark		Do not iron
CHN	Date and country of manufacture	UDI	Unique device identifier		Air hoses blocked		Line dry
	Fragile handle with care	IP21	Ingress protection		Audio pause		Do not tumble dry
	Keep dry		Refer to user manual		Service interval		

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

Kit Contents

Before you start, please ensure that you have all the necessary components listed below. If any are absent, or in case of doubt, please contact Frontier Therapeutics Limited Customer Services on +44 (0) 330 460 6030.

Toto® Touch Control Unit

- 1x Toto® Touch control unit.
- 1x Control unit power lead.
- 1x User guide.

Product Codes	Product Description
4000000	Toto® Touch Control Unit (220V)
4100200	Toto® Touch Control Unit Transport Bag

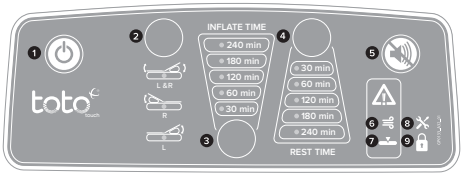
Toto® Touch Control Unit Labelling

1. Starts, stops and pauses the control unit.
2. Air Cell side selection.
3. Air Cell inflation time.
4. Air Cell rest time.
5. Alarm mute and interface lock mode.
6. Air leak alarm.
7. Blockage alarm.
8. Service indicator.
9. Interface lock indicator.

Toto® Platform

- 1x Platform or 1x Cradle Platform including a fitted cover.
- 1x Cardiopulmonary Resuscitation deflation valve and tubing set.
- 1x Pair of air cells with quick connectors.
- 1x Platform or 1x Cradle Platform Transport bag.

Product Codes	Product Description
4100000	Toto Platform (UK)
4100001	Toto® Platform (International)
4100300	Toto® Platform Transport Bag
5100000	Toto® Cradle Platform (UK)
5100001	Toto® Cradle Platform (International)
5100300	Toto® Cradle Platform Transport Bag



Product Specifications

Toto® Platform

Product	Weight - kg (lbs)	Maximum User Weight - kg (lbs)	Width - mm (Inches)	Length - mm (Inches)
Standard	6.7 (14.7)	250 (551)	745 (29)	1850 (73)
Cradle	8.0 (17.5)	250 (551)	745 (29)	1850 (73)

Product	Depth (flat position - air cells empty) mm (Inches)	Depth (raised position - air cells inflated) mm (Inches)	CPR Deflation Valve
Standard	35 (1.4)	Primary: 185 (7.3)	Quick Release Pull Tag
Cradle	50 (2.0)	Primary: 195 (7.7) Cradle: 100 (4)	

Toto® Touch Control Unit

Specifications	
Dimensions (width / depth / height) – mm (inches)	255 (10) x 120 - (5) x 220 (8.5)
Weight - kg (lbs)	2.8 (6)
Rated voltage – UK & EU	220 ~ 240VAC, 50/60Hz, 0.3A
Rated input power (VAC)	20
Protection class	Class 2
Power cord length - meters (Feet)	5 (16.4)
Air output (LPM)	11

Intended Purpose

Frequent repositioning of individuals with impaired mobility and the use of an appropriate support surface are the most significant interventions to prevent pressure damage[1-3]. This is achieved through individual patient assessment and the implementation of manual turning plans.

Toto® Standard & Cradle are automated lateral turning system supporting healthcare professionals in the regular turning of patients, who are at risk of developing pressure ulcers or injuries.

Toto® Cradle has integrated secondary air cell technology designed to prevent any migration users may experience and provides an increased feeling of security.
Extended periods of lying or sitting on a particular part of the body and failure to redistribute the pressure on the body surface can result in sustained deformation of soft tissues and, ultimately, in tissue damage[4]. Repositioning involves changing the position of the lying or seated individual at regular intervals, with the purpose of relieving or redistributing pressure and enhancing comfort.

The frequency of repositioning is determined by considering the individuals level of activity to independently reposition[5]. The 30-degree side lying position is widely accepted as the optimum position for pressure ulcer or injury reduction[6]. Toto® achieves both objectives by allowing for full customisation of turning frequency, with a 30-degree angle of tilt.

The Toto® system comprises a user programmable control unit, and a multiple patient use turning platform, which is positioned underneath the patients' mattress. Toto® is suitable for use with foam mattresses, alternating air mattresses, low-air loss mattresses and mattress overlays that do not exceed 995mm wide and 2100mm long.

The control unit provides customised care with a user-determined side selection feature and accurately timed inflation and rest durations, allowing for patient-prescribed turning intervals. Increased patient safety is achieved, via a sophisticated yet simple to understand system of integrated alarms and a convenient therapy pause mode, enables patient interaction without having to stop therapy.

The turning platform operates via discreet air cells which smoothly, gently and consistently turn the patient laterally via the mattress surface, even when they are asleep. Compatible with profiling beds and both standard and alternating pressure relieving equipment, the platform provides head to toe peak pressure redistribution.

The Toto® system has a maximum user weight of 250kg (551lbs) meaning management of heavier patients becomes easier and less onerous on staff. Toto® can be used in conjunction with support aids and sleep systems, an individual assessment must be carried out to assess for suitability.

Toto® does not replace pressure relieving and redistribution surfaces and is supplementary to their use.

Indications

Toto® is a suitable supplementary device for the prevention of pressure ulcers for patients:

- Identified as being at moderate to high risk of developing pressure damage.
- Weighing up to 250kg (551lbs).
- That are unable to change their position without assistance.
- Requiring regular turning and who are non-compliant with manual turning schedules.

Contraindications

- Do not use without a suitable pressure redistribution surface and package of care.
- Do not use with patients with unstable spinal cord injuries or who are undergoing traction.
- Do not use with patients with equilibrium disturbances.

Advice for laypersons
Toto® default settings are suitable for most users. Any change in skin condition that causes concern, should be reported to a healthcare professional.

Warnings and Precautions

Individual patient assessments should be made prior to use and appropriate pressure redistributing devices put in place. Please note the following:

- Unusual body shapes and postures should be assessed prior to use.
- Caution is advised when using with patients with underlying neurological disorders which may lead to increased anxiety.
- Other medical devices should be assessed for suitability.
- Ensure the Toto® platform is fully deflated before attempting to leave the bed.
- Engage therapy pause mode during hygiene procedures and when over-bed tables are being used to avoid the risk of spillages.
- When elevating a profiling bed back rest, raise the knee break first.
- Ensure the surface of the bed frame is clear from debris before placing the Toto® 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® from operating.
- If mattress overlays are being used, these must be securely fastened to the mattress, not the Toto® platform.
- Toto® can be used with positioning systems, bed levers and linen cradles, if their support frame fits horizontally across the bed. These must be positioned under the Toto® platform.
- Evacuation hammocks must be placed between the Toto® platform and the mattress.
- If using foot board protectors, assess for compatibility.
- Do not place the control unit directly underneath the bed frame if placing on the floor to avoid lowering the bed onto the control unit.
- Use only with the supplied AC power lead and with correct fuse fitted. Should there be a need to replace the fuse, ensure only the correct fuse rating is used (3A).
- The use of bed rails should depend on the findings of an individual risk assessment. If the use of bed rails is deemed to be required, assess for the risk of entrapment. Always follow the manufacturer's instructions.
- When Toto is deflated and in the flat position, the distances between the top of the uncompressed mattress and bed rail should be as follows;
  - Top of the bed rail ≥220mm (Diagram 1).
  - Bottom of the bed rail ≤120mm (Diagram 2).
- When inflated, assess the distance between the tilted sides of the mattress and the bed rail. This should be ≤120mm (Diagram 3).
- Assess for risk of entrapment.

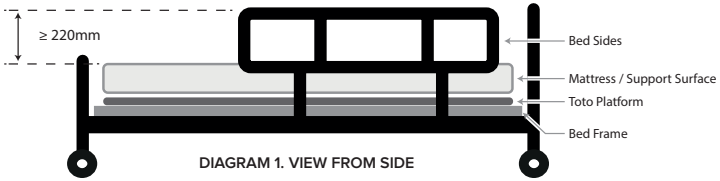


DIAGRAM 1. VIEW FROM SIDE

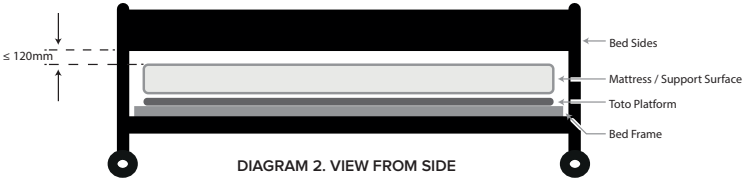


DIAGRAM 2. VIEW FROM SIDE

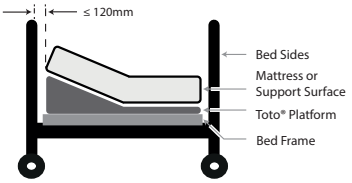


DIAGRAM 3. HEAD SIDE

Patient Target Group

Immobile and less mobile patients who are at risk of developing pressure ulcers or injuries, who require regular turning and those who may be non-compliant with manual turning schedules.

Intended Users

Intended for use in home and professional healthcare facilities by medically trained and untrained users. There are no special skills required to operate or use Toto®. More information can be found online at www.frontier-group.co.uk.

Instructions for Use

Before use, please read the following instructions. Should you have any queries, please contact Frontier Therapeutics Limited on +44 (0) 330 460 6030 or visit our website www.frontier-group.co.uk.

Platform Installation and Operating Guide

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

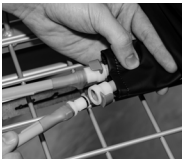
1. Remove all items from packaging and inspect for damage.
2. Remove the mattress and place the rolled platform at the foot end of the bed. Roll out until it is fully extended and positioned centrally to the bed frame (A).
3. Inspect the platform for damage and ensure the air cells are secured in position via the popper fastenings by unzipping the cover and visually inspecting (B).
4. * Ensure that the air hoses are connected by visually inspecting their yellow and blue quick connectors (C).
5. If required, re-fit the cover and close the zip ensuring the CPR air hoses are fed through the opening at the foot end of the cover. Please Note: The platform cover should be free to move, allowing each side of the platform unrestricted room to inflate.
6. Connect the air inflation and air cell hoses using the red quick connectors, ensuring that they are not twisted or kinked (D).
7. Check that the CPR emergency deflation valve is securely closed and there are no air leaks (E).
8. Replace the mattress on top of the platform. DO NOT strap or fasten the mattress to the bed frame.
9. Using the bed hooks, hang the control unit on the bed foot board, ensuring it is securely in place (F).
10. Reattach the CPR air hoses at the foot end of the platform to the control unit using the black quick connectors, ensuring they are not twisted or kinked (G).
11. Connect the control unit to mains power via the lead supplied (H).

** Only applicable for Toto® Cradle.*

A. Remove the mattress and place the rolled platform at the foot end of the bed. Roll out until it is fully extended and positioned centrally to the bed frame.

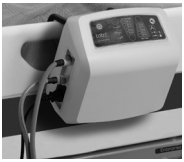
B. Inspect the platform for damage and ensure the air cells are secured in position via the popper fastenings by unzipping the cover and visually inspecting.

C. Ensure that the air hoses are connected by visually inspecting their yellow and blue quick connectors.



D. Connect the air inflation and air cell hoses using the red quick connectors, ensuring that they are not twisted or kinked.

E. Check that the CPR emergency deflation valve is securely closed and there are no air leaks.



F. Using the bed hooks, hang the control unit on the bed foot board, ensuring it is securely in place.

G. Reattach the CPR air hoses at the foot end of the platform to the control unit using the black quick connectors, ensuring they are not twisted or kinked.

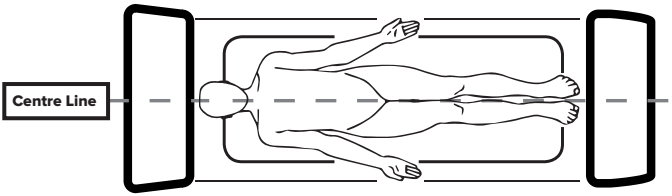
H. Connect the control unit to the mains power via the lead supplied.

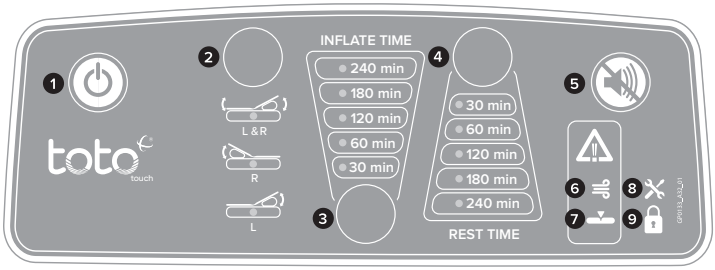
Patient Positioning

Position supine patients along the centre line of the mattress by aligning the patient's nose with the centre of the headboard. Ensure the head and shoulders are supported preventing neck rolling and pivoting at the hips.

Toto® is indicated for side lying if patients can self-support, and they are in the middle of the bed.

When using bedside, consider the use of padding, bumpers, or net infills.





Toto® Touch Control Unit Operating Guide

1. Start, stop and pause the control unit.
2. Air cell side selection - Left only, Right only or Both.
3. Air cell inflation time - Length of time the air cell remains inflated; minimum 30 minutes, maximum 240 minutes.
4. Air cell rest time - Length of time the air cells remain deflated and the platform is flat; minimum 30 minutes, maximum 240 minutes.
5. Alarm mute and interface lock mode activation.

Turning the Toto® Touch Control Unit On

- Press and hold the start/stop button ❶ for three seconds.
- A single beep confirms activation along with default lit LEDs.
- Note the system default settings below; these can be changed as appropriate.
    - o Air cell side selection - both sides.
    - o Air cell inflation time - 120 minutes.
    - o Air cell rest time - 120 minutes.
- The pump automatically inflates the left side of the platform; this can be changed as appropriate.

Air Cell Inflation Selection

- Press the side selection button ❷ to scroll through the three available options:
    - o Left and right air cell (Default).
    - o Right air cell only.
    - o Left air cell only.
- Side selection refers to the patient's side, as standing at the foot end of the bed.
- A single beep confirms activation along with a lit LED.

Changing the Air Cell Inflation Time

- Press the inflate time button ❸ to scroll through the five available options:
    - o 30 minutes.
    - o 60 minutes.
    - o 120 minutes (Default).
    - o 180 minutes.
    - o 240 minutes.
- A single beep confirms activation along with a lit LED.

Changing the Air Cell Rest Time

- Press the rest time button ❹ to scroll through the five available options:
    - o 30 minutes.
    - o 60 minutes.
    - o 120 minutes (Default).
    - o 180 minutes.
    - o 240 minutes.
- A single beep confirms activation along with a lit LED.

Once settings have been selected, lock the interface by pressing the interface lock button ❺confirmed by the padlock LED ❾ turning on and a double beep (see Interface Lock).

Therapy Pause Mode

The therapy pause mode temporarily deactivates all control unit functions, returning the platform to a flat position.

- Press the start/stop button ❶ a single beep confirms activation.
- The currently selected side selection, inflate and rest time LEDs flash when active.
- For safety, the alarm activates after 10 minutes. To continue in this mode for another 10 minutes, press the Alarm Pause button ❺, repeat this process until Therapy Pause Mode is no longer required.
- To deactivate, press the start/stop button ❶. A single beep confirms deactivation and the control unit returns to the previously selected settings.

Interface Lock
The interface lock prevents any unwanted changes to the control unit settings.

- Press and hold the alarm mute button 5 for four seconds.
- Confirmed by the padlock LED 9 and a double beep.
- When the interface is locked, only the alarm mute button is operational.
- To deactivate, press and hold the alarm mute button 5 for four seconds.
- Deactivation is confirmed by the padlock LED 9 turning off, and a double beep.

Alarm Mute Control Button

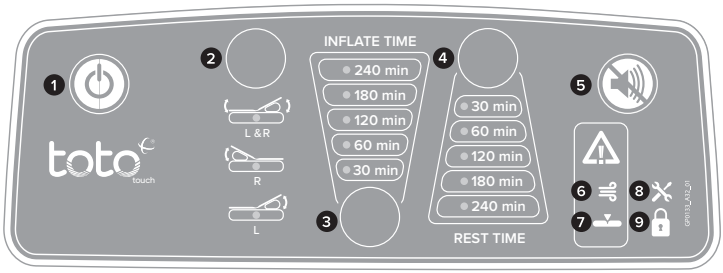
When activated, the alarm can be paused for up to 10 minutes while troubleshooting, after which time, the alarm recommences if the problem remains.

- To mute the alarm, press the alarm mute button 5.

If a new alarm condition occurs when paused, the initial alarm terminates and a new alarm will activate.

Alarms and Alerts

The Toto® Touch control unit has three integrated alarms and one information alert to ensure patient safety and efficacy.



Alarms and Alerts	Alarm Condition	Indicated by an audible alarm and:
Air Leak Alarm - The pressure in the system has fallen below the minimum operational requirements, i.e. an air leak.	Low priority	Air Leak LED permanently lit yellow (when activated) (6).
Blockage Alarm - Airflow between the control unit and the platform is prevented, i.e. a blocked air hose.	Low priority	Blockage LED permanently lit yellow (when activated) (7).
Service Interval - Service required; default at one-year use.	n/a	Service LED permanently lit amber (8) (NO AUDIBLE alarm).
Power Loss Alarm Power to the control unit has been interrupted.	Low priority	Audible alarm, no LED lit.
Initialisation Failure Control unit fails to start	n/a	All 'Inflate time LEDs' and 'Rest time LEDs' flashing (when activated).

The sound pressure level of the alarm audio or the reminder audio signal ranges from 55dB-85dB.

The alarm frequency is 2000HZ.

While troubleshooting, the alarm can be muted for up to 10 minutes. If the fault is not corrected during this time, the alarm re-activates.

If a new alarm condition occurs within 10 minutes, mute will cease, and the new condition will generate an alarm.

Please Note:

- The corresponding alarm indication LED remains lit when the alarm is muted.
- If the alarm condition is corrected while muted, the LED and mute will automatically terminate.
- The alarm audio signal comes from a speaker, and the reminder audio signal comes from a buzzer.
- Alarm activation may take up to two minutes from when the alarm state occurs.

System Error Trouble Shooting Guide		
Problem	**Cause**	**Initial Checks / Trouble Shooting**
No LEDs lit; no audible alarm heard.	• Control unit may not be attached to a power source. • The fuse may need replacing.	1. Check that the mains power outlet is live and active. 2. Check the control unit is switched on. 3. If following points 1 and 2 does not resolve the problem, switch off and unplug the control unit: - Check the mains plug fuse (3A). - Check the control unit fuse (1A). 4. Restart the control unit. **If the problem persists, contact Frontier Therapeutics Limited Tel: +44 (0) 330 460 6030 for assistance.**
Air-leak alarm LED (6) lit permanently yellow with an audible alarm.	• Pressure has fallen below the minimum operational requirements.	1. Press the alarm pause button. 2. Check the Cardiopulmonary Resuscitation valve is closed and correct. 3. Check all air cells and hoses for any air leakage. 4. Resolve and wait for the alarm to reset. **If the problem persists, contact Frontier Therapeutics Limited Tel: +44 (0) 330 460 6030 for assistance.**
Blockage alarm LED (7) lit permanently yellow with an audible alarm.	• Airflow obstruction between the control unit and the platform.	1. Press the alarm pause button. 2. Check for twists or kinks in the air hoses between the platform and control unit. 3. Resolve and wait for the alarm to reset. **If the problem persists, contact Frontier Therapeutics Limited Tel: +44 (0) 330 460 6030 for assistance.**
Service LED (8) permanently lit amber.	• Service required.	**Please contact Frontier Therapeutics Customer Services for support Tel: +44 (0) 330 460 6030** **The Control Unit continues to function even though the service LED remains lit.**
Interface panel is lit but unresponsive.	• Interface panel is locked.	1. Check that screen lock LED is lit amber (9). 2. Press and hold the alarm mute button for four seconds to deactivate. **If the problem persists, contact Frontier Therapeutics Limited Tel: +44 (0) 330 460 6030 for assistance.**
An audible alarm is sounding; no LEDs lit.	• Loose or absent power lead. • Mains power accidentally turned off. • Mains power failure.	1. Reconnect mains power lead to the control unit. 2. Check the mains power wall switch is turned on. 3. Attempt to restart the control unit. **If the problem persists, contact Frontier Therapeutics Limited Tel. +44 (0) 330 460 6030 for assistance.**

Do not open the control unit. Opening the unit could cause personal injury or equipment damage.
NB. The Toto® Touch control unit completes self diagnostic evaluation on start up.

Cardiopulmonary Resuscitation Emergency Deflation System

The Toto® system features a quick release Cardiopulmonary Resuscitation deflation valve which allows for rapid deflation for emergency procedures.

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

To re-inflate the system, replace the Cardiopulmonary Resuscitation tag ensuring both sealing connectors are firmly attached and restart the Toto® Touch control unit

Cardiopulmonary Resuscitation Deflation Valve Closed.

Cardiopulmonary Resuscitation Deflation Valve Open.

Inspection and Care

The Toto® lateral turning system cover, platform assembly, air cells, Cardiopulmonary Resuscitation deflation valve and tubing set and control unit each have a unique GS1 compliant barcode which should be retained and used in the event of a warranty claim. NEVER remove these labels.

Cover

Regularly inspect the outer and inner surfaces of the cover for signs of damage.

Report damaged covers to the ward or department manager or appropriate healthcare professional.

Withdraw damaged covers from service and replace.
Check zip fasteners for function and integrity.

Platform
Regularly inspect the interior and exterior of the platform, ensuring that the poppers and air cells are intact.
Ensure the platform has not drifted out of position and the air hoses are not blocked, kinked or twisted.

Fitting and Replacing Damaged Air Cells

In the event of an air cell puncture or leak, either or both air cells can be replaced. Please contact Frontier Therapeutics Customer Services for replacement parts Tel: +44 (0) 330 460 6030.

1. Switch off the control unit and disconnect from mains power.
2. Disconnect the CPR air hoses from the foot end of the platform using the red quick connectors.
3. Unzip and pull back the cover revealing the platform.
4. Determine the faulty air cell and remove by unfastening the popper fastenings.
5. * Disconnect the air hoses at the head end of the platform using the yellow and blue quick connectors.
6. Unthread the CPR air hoses and red quick connectors from their securing loops at the foot end of the platform.
7. * Unthread the air hoses with the yellow and blue quick connectors at the head end of the platform from their respective securing loops.
8. Inspect the platform for other signs of damage, including the potential source of the damage.
9. Fit the new air cell ensuring it is in-line with the correct section, and in the correct orientation with the red CPR air hose quick connectors at the foot end of the platform. Secure in place with the popper fastenings.
10. Thread the CPR air hose and red quick connector through its securing loop at the foot end of the platform.
11. * Thread the air hose connections through their respective securing loops at the head end of the platform and reconnect using the yellow and blue quick connectors.
12. Re-fit the cover and close the zip ensuring the hose with the red quick connectors that attach to the CPR air hoses are fed through the opening at the foot end of the cover.
13. Re-attach the CPR air hoses at the foot end of the platform using the red quick connectors, ensuring they are not twisted or kinked.

** Only applicable for Toto® Cradle.*

Nature and Frequency of Preventative Maintenance

Inspection and Care of the Toto® Touch Control Unit

The Toto® Touch control unit is designed to be reliable and long lasting, with few parts requiring maintenance.

A routine service is required when the service light illuminates. Please refer to the Toto® Service, Maintenance and Repair Manual for further information. Supporting videos are also available.

Clean air filters at least every 12 months by removing and running under clean water and allowing to dry. Inspections should be undertaken to note any visible signs of damage.

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

Although there are no requirements for Portable Appliance Testing, guideline recommendations indicate that extension leads and portable electrical equipment should be re-tested every six months. Please refer to local guidance.

An electrical safety test in accordance with BS EN 62353:2014 Medical Electrical Equipment - Recurrent Test and Test After Repair of Medical Electrical Equipment, should be carried out after maintenance, inspection, servicing and repair, and before the control unit is sent out to, or returned to a user.

Cleaning and Disinfection

All components of the system can be cleaned with detergent and water to remove any visible contamination and chemically disinfected with chlorine. The following represents guidance on the correct cleaning and decontamination process but does not replace local policy and guidelines.

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

Light and Heavy Soiling
Decontaminate with a 0.1% (1,000ppm) - 1% (10,000ppm) Chlorine solution.

Rinse with clean water and wipe down with a single-use, non-abrasive cloth and thoroughly dry.

Do not apply a 1% chlorine-based solution for more than two minutes, doing so may cause long term damage.
Prolonged use of alcohol-based cleaning agents may reduce the life of the product.
If used, thoroughly rinse with clean water and allow to dry before use.

Machine Washing Instructions

Cleaning and disinfection may be achieved by laundering at temperatures not exceeding 65ºC for ten minutes or 73ºC for three minutes.

Drying
To avoid shrinkage, line dry in a clean indoor environment. Thoroughly dry before re-fitting to the Toto® platform.
Do not mangle or iron.

Platform, Cabling, Control Unit and Air Hoses
Before cleaning, disconnect from the mains power supply.
The platform, cabling, control unit and air hoses can be wiped clean with alcohol wipes and a chlorine derivative. Take care when wiping the control unit not to allow liquids to enter through any openings.

End of Life Disposal

Cared for correctly the Toto® system is long lasting and durable. The control unit has a life expectancy of up to 5 years.

To minimise hazards to health and the environment, and to ensure the device is recycled, dispose of at a separate collection facility for electrical and electronic equipment in accordance with the Waste Electrical and Electronic Equipment Directive, and as denoted by the wheelie bin symbol marked on the product.

At the end of its life, clean and disinfect the platform according to the instructions and dispose of with non-hazardous clinical waste.

Storage
When not in use, the Toto® lateral turning system should be stored in a secure location away from the public using the transport bag supplied.

- Do not drag.
- Never store other items on top of the Toto® platform.
- Do not store next to radiators or other heating devices.
- Do not store in damp conditions.

Warranty

The Toto® system warranty is valid for two years from the time of shipping. In the event of a defect or fault, please contact Frontier Therapeutics Customer Services on Tel: +44 (0) 330 460 6030 or email: info@ frontier-group.co.uk immediately.

Frontier Therapeutics Limited guarantees the equipment is free from defects in material and workmanship, under regular use and service.

During the warranty period, any product that has become defective due to faulty workmanship or material will be replaced as deemed appropriate by Frontier Therapeutics Limited, 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 Limited spares or replacement parts are used.

Frontier Therapeutics Limited will not accept responsibility for damage caused by misuse, negligence, accidental damage nor non-observance of the instruction set out in this document.

This warranty does not affect your statutory rights.

Fire Testing
The Toto® platform meets the requirements of BS 7175:1989 Section 2 Methods of test for the ignitability of bedcovers and pillows by smouldering and flaming ignition sources.

BS EN 597-1:2015. Furniture. Assessment of the ignitability of mattresses and upholstered bed frames. Ignition source smouldering cigarette. BS EN 597-2:2015. Furniture. Assessment of the ignitability of mattresses and upholstered bed frames. Ignition source: match flame equivalent.

Compliance

The Toto System conforms to MDD 93/42/EEC and MDR 2017/745 and the following standards: BS EN ISO 9001:2015 Quality Management Systems. BS EN 13485:2016 Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes. BS EN 14971:2019 Medical Devices. Application of Risk Management to Medical Devices. BS EN ISO 15223-1:2021 Medical Devices. Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied. General Requirements. BS EN ISO 10993-5:2009 Biological Evaluation of Medical Devices. Tests for In Vitro Cytotoxicity. BS EN 10993-10:2013 Biological Evaluation of Medical Devices. Tests for Irritation and Skin Sensitization.

The control unit is tested to EU Directive 2014/30/EU and BS EN 62353:2014 Medical Electrical Equipment – Recurrent Test and Test After Repair of Medical Electrical Equipment.

Manufactured to comply with EN 60601-1 (Safety) and EN 60601-1-2 (EMC);

IEC/EN 60601-1; IEC /EN 60601-1-11; IEC/EN 60601-1-8.

Restriction of the use of certain hazardous substances (RoHS) Directive. 2011/65/EU.

Toto DOES NOT incorporate as an integral part. A substance, which used separately may be considered to be a medicinal product as defined by European Communities medicinal products Directive (Directive 2001/83/ EC, as amended) and Human Medicines Regulation 2012 (SI 2012/1916).

Toto DOES NOT incorporate as an integral part any substance or human blood derivative as defined in point 10 of article 1 European Communities medicinal products Directive (Directive 2001/83/EC, as amended), nor is it manufactured utilising tissues of animal origin as defined by the same directive.

No modification of this equipment is allowed.

Toto® Touch complies with the following EU Directives and Harmonised Standards:

Directive	Harmonised Standard	Referenced EMC Emission Standards
MDR 2017/745	EN 60601-1:2006/A1:2013 (Electrical Safety) EN 60601-1-2:2007/ AC:2010 (EMC)	EN 55011:2009/A1:2010 Class B (RF) EN 61000-3-2:2014 (Harmonics) EN 61000-3-3-2013 (Flicker)
Restriction of the use of certain hazardous substances (RoHS) Directive. 2011/65/EU	EN 50581:2012	N/A

Complaints and Adverse Events Reporting

Any healthcare professional (e.g., customer or user of this system of products) who has any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and performance should notify the distributor or Frontier Therapeutics Limited.

If any Frontier Therapeutics Limited product ever malfunctions and is suspected to have caused or contributed to the death or severe injury of a patient, Frontier Therapeutics, your physician, distributor and your local competent authority should be notified immediately. When filing a complaint, provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether or not a written report from the distributor is requested.

Further Information

If further information is needed or required, contact Frontier Therapeutics Limited on Tel: +44 (0) 330 460 6030 or visit our website www.frontier-group.co.uk.

Technical Specification

Toto® Touch Technical Specifications	
Power input - UK & EU	AC 220-240VAC 50Hz, 0.2A
Fuse rating	T1AL250V
Compressor	SAA-1
Air distributor	Timing motor working as a rotary valve
Control system	Digital control system
Power consumption	14 Watt (typical) / 20 Watt (maximum)
Cycle control	Distributor valve supplying air to the inflatable cells
Cycle time	Adjustable 30 > 240 minutes
Pressure setting	140mmHg to 160mmHg
Piping output	2
Platform and Air Cell Material	Nylon and thermoplastic polyurethane (TPU)
Max. load on platform	250Kg
PU Cover Material	Polyurethane transfer coating on weft knitted polyester fabric
Operating environment	Temperature range: 10°C to 40°C Relative humidity range: 30% to 70% Atmospheric pressure range: 70kPa to 106kPa
Storage/Transportation	Temperature range: -10°C to 60°C Relative humidity range: 10% to 70% Atmospheric pressure range: 70kPa to 106kPa
Classification IEC60601-1	Class II equipment - Type B applied part - IP21

References

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3. Rae KE, Isbel S, Upton D. Support surfaces for the treatment and prevention of pressure ulcers: a systematic literature review. J Wound Care 2018;27:467–74.
4. Defloor T, De Bacquer D, Grypdonck MHF. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. Int J Nurs Stud, 2005; 42(1):37-46
5. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (ed). EPUAP/NPIAP/PPPIA: 2019. Guideline 5.2 Repositioning Frequency
6. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (ed). EPUAP/NPIAP/PPPIA: 2019. Guideline 5.8 Repositioning Individuals in Bed

easyCare systems

toto cradle

Special Products and Service

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