

# toto

- Toto<sup>®</sup> Lateral Turning System, with Toto<sup>®</sup> Touch Control Unit
- Manuel d'utilisation du système de latéralisation Toto®
- Toto® System zur seitlichen Umlagerung
- Gebruikershandleiding van het Toto®
- Guía del usuario del sistema de volteo lateral Toto®
- Sistema per la rotazione laterale Toto®



User guide



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

⚠ This indicates a hazardous situation that could result in damage to property if it is not avoided.

# Toto® Touch 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



Keep dry



Refer to user manual



CE compliant



Type BF applied part



Class II equipment



Caution symbol



Air leak



Air hoses blocked



Service interval



Interface lock



Audio pause



Fragile handle with care



Do not tumble dry



Disposal: Do not dispose of this product as unsorted domestic waste. It must be sent to a separate collection facility for recovery and recycling.



# **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 Macmed Healthcare on 1300 308 184.

#### **Toto Touch Control Unit**

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



# **Toto Lateral Turning System Platform**

- 1x Platform including a fitted cover.
- 1x CPR deflation valve and tubing set.
- 1x Pair of air cells with quick connectors.
- 1x 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.





# Contents

Toto® Touch Lateral Turning System Labelling	2
Kit Contents	3
Product Specifications	5
ntended Use	6
Safety	7
nstructions for Use	8
Toto Touch Control Unit Operating Guide	10
Alarms and Alerts	15
Troubleshooting	16
nspection and Care	18
Cleaning	20
Warranty	22
Technical Specification	23



# **Product Specifications**





**Toto Lateral Turning System - Standard:** a fully customisable control unit and patient turning platform.

# **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)

Product	Depth (flat position - air cells empty) mm (Inches)	Depth (raised position - air cells inflated) mm (Inches)	CPR Deflation Valve
Standard	35 (1.4)	185 (7.3)	Quick Release Pull Tag

# **Toto Touch Control Unit**



Specifications	
Dimensions (width / depth / height) – mm (inches)	240 (9.5) x 100 (4) x 200 (8)
Weight - kg (lbs)	2.2 (4.8)
Rated voltage – EU	220 ~ 240VAC, 50/60Hz, 0.3A
Rated voltage – USA	110 ~ 120VAC, 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 Use

## **Product Description**

Toto is an automated lateral turning system which consists of a Toto Touch control unit and a lightweight, roll-able turning platform with cover.

Designed to assist with patient turning and pressure ulcer prevention plans, the system is designed around inflating alternating air cells within the turning platform positioned underneath the patient's mattress. The patient is then turned laterally via the mattress surface.

The digital control unit provides customised care with a user-determined side selection feature and accurately timed digital inflation and rest durations. Sophisticated blockage and air leak alarms help ensure patient safety, as well as an interface lock to avoid unwanted setting changes.

A convenient therapy pause mode enables patient interaction without having to stop therapy and a service indicator to maintain performance also comes as standard.

The system is compatible with profiling beds and both standard and alternating pressure relieving equipment.

The Toto lateral turning system does not replace pressure relieving and redistribution surfaces and is supplementary to their use.

Bedsides should be used to help prevent patient egress and increase the feeling of security.

#### **Indications**

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

- Those identified as being at moderate to high risk of developing pressure ulcers as defined by Commonly used assessment tools.
- Weighing up to 250kg (551lbs).
- 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 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.

#### Intended Care Setting

The Toto Lateral turning system is intended for use in the following care settings:

- Long-term or extended care, such as nursing homes and care homes.
- Home-care.
- Hospitals.



# Safety

# **⚠** Warnings and Precautions

Assess each patient before use and put in place appropriate pressure redistributing devices. Please note the following:

- Before use, check the integrity of the platform and air cells for any visible signs of damage. Bursting air cells may result in injury.
- Do not use without a mattress.
- Assess for unusual body shapes and postures.
- Patients who have increased anxiety may not be suitable for automated lateral turning systems.
- Assess other medical devices for suitability.
- Fully deflate the Toto lateral turning system platform before attempting to leave the bed.
- Discontinue or 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 backrest, raise the knee break first.
- Ensure 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.
- Do not strap the mattress to the bed frame as this prevents the system from inflating.
- Secure mattress overlays to the mattress, not the platform.
- The Toto lateral turning system can be used with positioning systems, bed levers and linen cradles if their support frame fits horizontally across the bed. Position under the Toto lateral turning system platform.
- Place evacuation hammocks between the Toto lateral turning system platform and the mattress.
- · Ensure bedsides are fully engaged when the system is active.
- Use bedsides during use. Check for clearance from the top of the mattress to the bottom of the bedside (minimum of 185mm) and assess for risk of entrapment.
- If using footboard protectors, assess for compatibility.
- Do not place the control unit directly underneath the bed frame if placing on the floor so to avoid lowering the bed onto it.
- Do not position the system so that it is difficult to access and operate the CPR deflation valve.
- Use only with the supplied AC power lead and with correct fuse fitted. Should there be a need to replace the fuse, only the correct fuse rating is to be used (3A).
- Potential electromagnetic interference between the control unit and other devices may occur. If interference is suspected, move equipment away from each other and contact the manufacturer.
- Keep away from pets and children.



# Instructions for Use

# 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.
- 3. Ensure the air cells within the platform are secured in position via the popper fastenings by unzipping the cover and visually inspecting.
- 4. If required, re-fit the cover and close the zip ensuring the air cell hoses are fed through the opening at the foot end of the cover.
- The platform cover should be free to move, allowing each side of the platform unrestricted room to inflate.
- 5. Using the quick connectors, connect the air inflation hoses to the air cell hoses 'Red to Red' ensuring the hoses are not twisted or kinked.
- 6. Check the CPR deflation valves are securely in place to ensure no air leaks.
- 7. Replace the mattress on top of the platform.
- NOT strap or fasten the mattress to the bed frame.
- 8. Using the bed hooks, hang the control unit on the bed footboard.
- 9. Using the quick connectors, connect the air inflation hoses to the control unit 'Black to Control Unit' ensuring the hoses are not twisted or kinked.
- 10. Connect the control unit to mains power via the lead supplied.



**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.



**C.** Using the quick connectors, connect the air 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 the bed footboard.



**F.** Using the quick connectors, connect the air inflation hoses to the control unit - 'Black to Control Unit' - ensuring the hoses are not twisted or kinked.





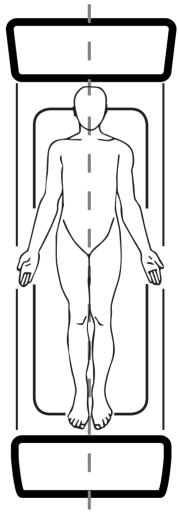
**G.** Connect the control unit to the mains power via the lead supplied.

# **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 bedsides, consider the use of padding, or net infills.

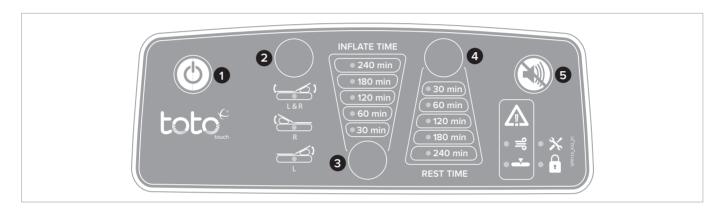




# Instructions for Use

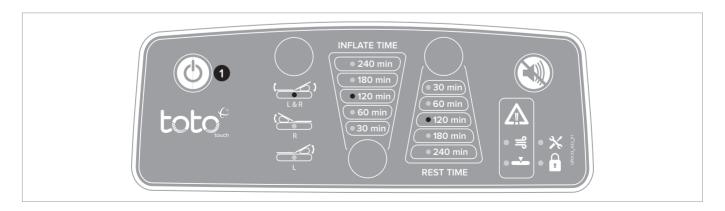
# **Toto Touch Control Unit Operating Guide**

- 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

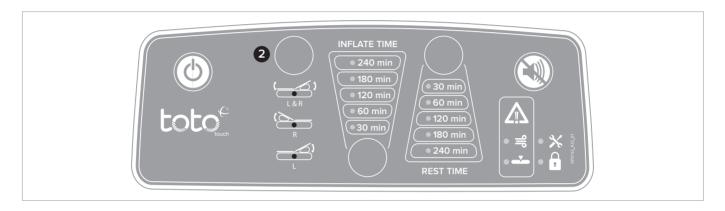
- Press and hold the start/stop button (1) for three seconds.
- A single beep confirms activation along with default lit LEDs.
- Note the system default settings below; please change as appropriate.
  - o Air cell side selection both sides.
  - o Air cell inflation time 120 minutes.
  - o Air cell rest time 120 minutes.
- The pump automatically inflates the left side of the platform; please change as appropriate.





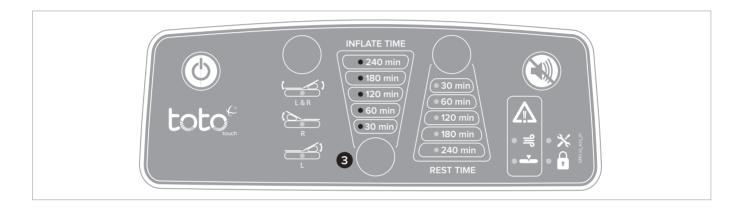
# **Air Cell Inflation Selection**

- Press the side selection button (2) 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.



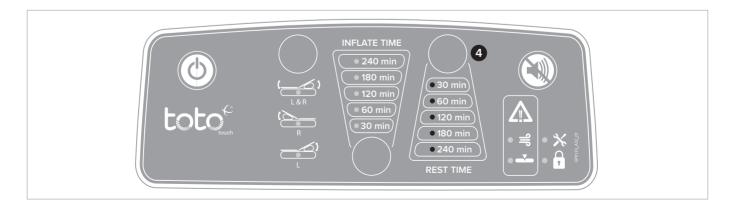
# Changing the Air Cell Inflation Time

- Press the inflate time button (3) 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 the lit option LED's.



# Changing the Air Cell Rest Time

- Press the rest time button (4) 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 the lit option LED's.

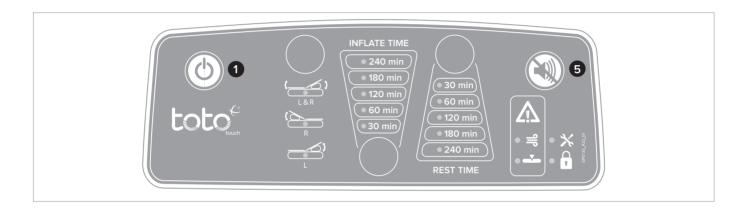




# **Therapy Pause Mode**

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

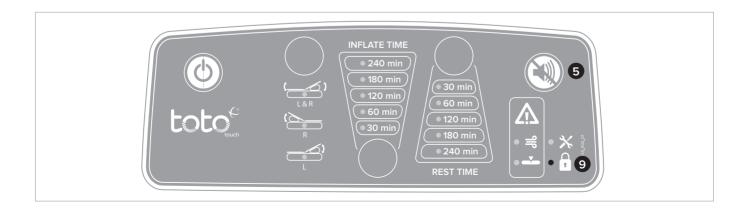
- Press the start/stop button (1) a single beep confirms activation.
- The currently selected side selection, inflate and rest time LEDs flash when active.
- For safety, the alarm activates after 10 minutes. To continue in this mode for another 10 minutes, press the Alarm Pause button (5), repeat this process until Therapy Pause Mode is no longer required.
- To deactivate, press the start/stop button (1). 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.



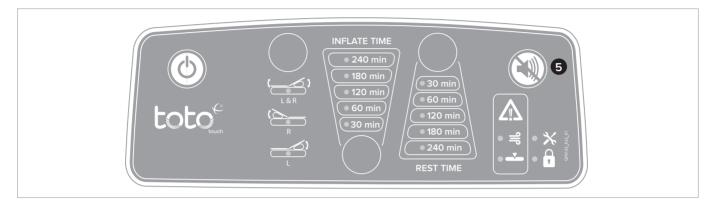


#### **Alarm Mute Control Button**

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 the new alarm activates.



# **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 may range 55dB-85dB.

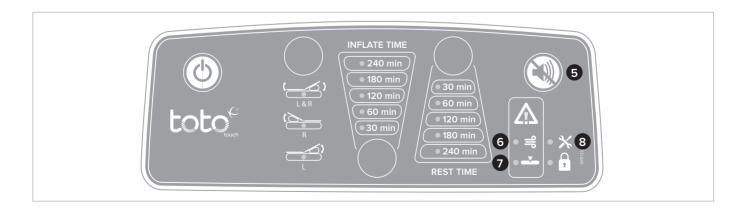
The alarm frequency is 150HZ to 1000HZ.

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

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

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.





System Error Trouble Shooting Guide			
Problem	Cause	Initial Checks / Trouble Shooting	
No LEDs lit; no audible alarm heard.	<ul> <li>Control unit may not be attached to a power source.</li> <li>The fuse may need replacing.</li> </ul>	<ol> <li>Check that the mains power outlet is live and active.</li> <li>Check the control unit is switched on.</li> <li>If following points 1 and 2 does not resolve the problem, switch off and unplug the control unit:         <ul> <li>Check the mains plug fuse (3A).</li> <li>Check the control unit fuse (1A).</li> </ul> </li> <li>Restart the control unit.</li> <li>If the problem persists, Please contact Macmed Healthcare for support on 1300 308 184.</li> </ol>	
Air-leak alarm LED (6) lit permanently yellow with an audible alarm.	Pressure has fallen below the minimum operational requirements.	<ol> <li>Press the alarm pause button.</li> <li>Check the CPR valve is closed and correct.</li> <li>Check all air cells and hoses for any air leakage.</li> <li>Resolve and wait for the alarm to reset.</li> <li>If the problem persists, Please contact Macmed Healthcare for support on 1300 308 184.</li> </ol>	
Blockage alarm LED (7) lit permanently yellow with an audible alarm.	Airflow obstruction between the control unit and the platform.	<ol> <li>Press the alarm pause button.</li> <li>Check for twists or kinks in the air hoses between the platform and control unit.</li> <li>Resolve and wait for the alarm to reset. If the problem persists, Please contact Macmed Healthcare for support on 1300 308 184.</li> </ol>	
Service LED (8) permanently lit amber.	Service required.	Please contact Macmed Healthcare for support on 1300 308 184  The Control Unit continues to function even though the service LED remains lit.	
Interface panel is lit but unresponsive.	Interface panel is locked.	<ol> <li>Check that screen lock LED is lit amber (9).</li> <li>Press and hold the alarm mute button for four seconds to deactivate.</li> <li>f the problem persists, Please contact Macmed Healthcare for support on 1300 308 184.</li> </ol>	
An audible alarm is sounding; no LEDs lit.	<ul> <li>Loose or absent power lead.</li> <li>Accidental mains power is turned off.</li> <li>Mains power failure.</li> </ul>	<ol> <li>Reconnect mains power lead to the control unit.</li> <li>Check the mains power wall switch is turned on.</li> <li>Attempt to restart the control unit.</li> <li>If the problem persists, Please contact Macmed Healthcare for support on 1300 308 184.</li> </ol>	

riangle Do not open the control unit. Opening the unit could cause personal injury or equipment damage.





# **CPR Emergency Deflation System**

The Toto lateral turning system features a quick release CPR 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 CPR tag ensuring both sealing connectors are firmly attached and restart the Toto Touch control unit.



CPR Deflation Valve Closed



CPR Deflation Valve Open



# Care

#### Inspection and Care

The Toto lateral turning system cover, platform, air cells and control unit has 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 torn 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 / Replacing Damaged Air Cells

In the event of an air cell puncture or leak, it is possible to replace either or both air cells. Please contact Macmed Healthcare for replacement parts on 1300 308 184.

- 1. Switch off the control unit and disconnect from mains power.
- 2. Disconnect the air hoses from the platform using the guick connectors.
- 3. Unzip and pull back the cover revealing the platform.
- 4. Determine the faulty air cell and remove by unfastening the popper fastening.
- 5. Inspect the platform for other signs of damage, including the potential source of the damage.
- 6. Fit the new air cell ensuring it is in-line with the correct section and secure in place with the popper fastening.
- 7. Replace the cover ensuring correct orientation and feed air cell hoses through apertures at the bottom.
- 8. Reattach the hoses using the quick connectors 'Red to Red' ensuring they are not twisted or kinked.



# **Disposal**

To minimise hazards to health and the environment, and to ensure the device is recycled, dispose at a separate collection facility for electronic waste equipment and as denoted by the wheelie bin symbol marked on the product.

# **Storage Guidance**

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.

# 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.

Clean air filters at least every 12 months, and inspections should be undertaken to note any visible signs of damage.

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

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



# Cleaning

All components of the system can be both mechanically 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 product is suitable for re-use.

# **Light Soiling**

Clean with detergent and water to remove any visible signs of dirt and contamination and decontaminate with a 0.1% chlorine-based solution (1,000ppm).

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

Prolonged used 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.

# **Heavy Soiling**

In cases of gross contamination, clean with detergent and water to remove visible signs of dirt and contamination and then decontaminate with a 1% chlorine-based solution (10,000ppm).

Do not apply a 1% chlorine-based solution for more than two minutes, doing so may damage the cover long term.

Thoroughly rinse with clean water and wipe down with a single use, non-abrasive cloth and thoroughly dry before reuse or storage.

### **Machine Washing Instructions**

Cleaning and disinfection may be achieved by laundering at temperatures not exceeding  $65^{\circ}$ C for 10 minutes or  $73^{\circ}$ C 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 apertures.



# **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 cover located on the back panel of the control unit (x1).
- 5. Remove and clean the filter with clean water and allow to dry thoroughly.
- 6. Replace the cleaned filter and refit the air filter cover on the control unit.
- 7. The control unit is now ready for use.











# Warranty

The Toto lateral turning system warranty is valid for two years from the time of shipping. In the event of a defect or fault, please contact Macmed Healthcare on 1300 308 184 or email: admin@macmedhealthcare.com immediately.

Macmed Healthcare 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 Macmed Healthcare 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-Macmed Healthcare spares or replacement parts are used.

Macmed Healthcare 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 lateral turning system 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.

# Standards and Regulation

This Active Class I Device complies with the requirements of the MDD 93/42/EEC (as amended by Directive 2007/47/EC).

The control unit is tested to EU Directive 2014/30/EU.

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.

#### Other Standards

BS EN ISO 9001:2015 Quality Management Systems

ISO 13485:2016 Medical Devices - Quality Management Systems

No modification of this equipment is allowed.



# **Technical Specification**

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

Directive	Harmonised Standard	Referenced EMC Emission Standards
Medical Devices Directive (MDD) 93/42/EEC, as amended by 2007/47/ EC	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

Toto Touch Technical Specifications		
Power input - Europe	AC 220-240VAC 50Hz, 0.2A	
Power input - USA	AC 100-120VAC 60Hz, 0.3A	
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)	
Operation mode	Non-continuous	
Cycle control	Distributor valve supplying air to the inflatable cells	
Cycle time	Adjustable 30 > 240 minutes	
Pressure setting	120mmHg ± 10mmHg	
Piping output	2	
Max. load on platform	250Kg	
Operating environment	Temperature range: 10°C to 40°C Relative humidity range: 30% to 70% Atmospheric pressure range: 700hPa to 1060hPa	
Storage/Transportation	Temperature range: -10°C to 60°C Relative humidity range: 10% to 70% Atmospheric pressure range: 700hPa to 1060hPa	
Classification IEC60601-1	Class II equipment Type B applied part IP21	

