Service, Maintenance and Repair Manual

CONTENTS

INTRODUCTION

This service and repair manual outlines the steps to carry out a service and the procedures to follow if there is a suspected fault with the Toto system. Malfunction of the control unit may be due to the failure of one of the replaceable electrical components.

If a repair seems unmanageable or the issue falls outside the scope of serviceable repairs, please return the control unit to Frontier Therapeutics Inc.

The electronically controlled control unit provides the air supply to the Toto platform. A digital touch membrane operates the control unit on the front display panel. Features include membrane lockout to prevent accidental changes to the settings, several alarms, LED indicators and an alarm mute completing the operator controls.

On the side of the unit are two air outlets for quick connection to the Toto platform via an air hose assembly.

The mains power supply to the unit can be easily disconnected and is designed to detach if pulled too firmly – protecting the internal wiring from damage.

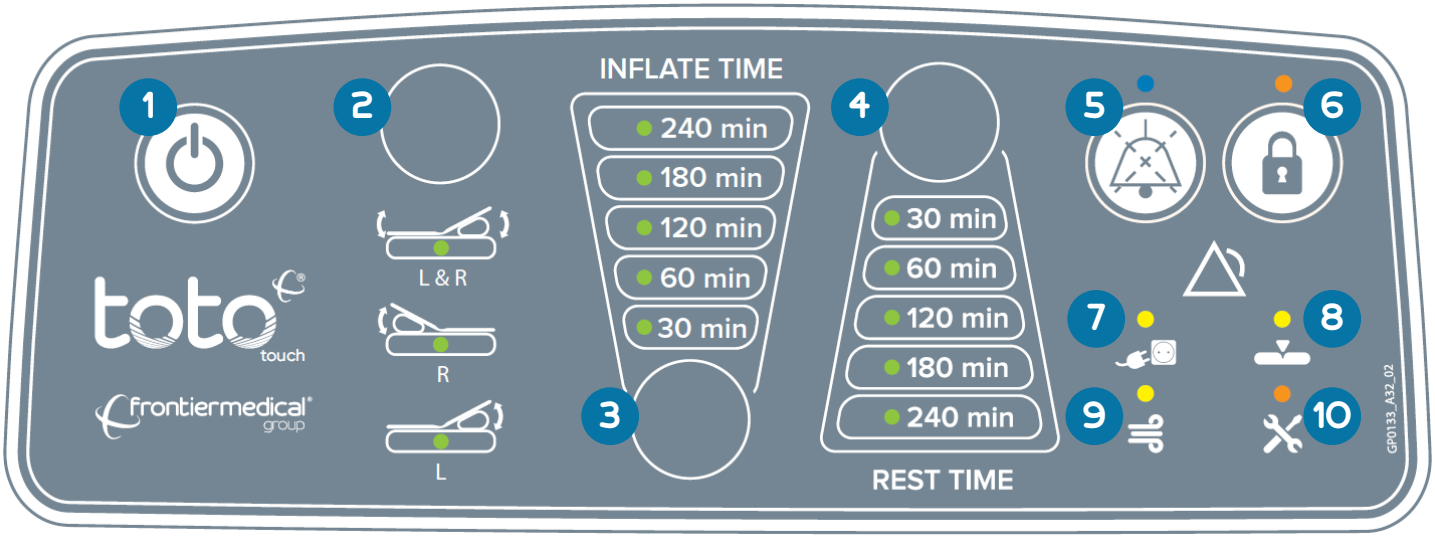
The quality of the control unit underpins the reliability and pressure redistribution capabilities of the system. At the centre of the control unit lies the compressor, which runs at a rapid and continuous rate whenever the unit is operational. The continuous rapid movement places compressor materials under high stress and heat conditions, which can make the unit susceptible to wear and tear over an extended period.

The compressor housing is a sturdy metal cage, secured on all sides by rubber mounts. These mounts serve to insulate the rest of the unit from the vibration of the compressor.

Should the control unit fail to operate, or system pressure fails to reach nominal operating status, please follow the steps to isolate the cause of the problem and make the appropriate repair.

ALARMS AND ALERTS

Toto Touch has several low priority alarms to ensure patient safety and efficacy.



Reference	Alarms and Alerts	Indicated by an Audible Alarm and:
3 4	'Initialisation Failure' Control unit fails to start.	Five 'Inflate time' LEDs and Five 'Rest time' LEDs flashing (when activated).
5	Alarm Mute Button Present alarm has been muted.	A solid blue LED.
6	Lock Signal Control unit is locked.	A solid orange LED.
7	Power loss Power to the control unit has been interrupted.	A solid yellow LED.
8	High-Pressure Alarm Airflow between the control unit and the platform is prevented, i.e. a blocked air hose.	A solid yellow LED.
9	Low-Pressure Alarm The pressure in the system has fallen below the minimum operational requirements, i.e. an air leak.	A solid yellow LED.
10	Service interval Service required; default at one-year use.	A solid orange LED (No audible alarm).

SERVICE PROCEDURE

The following checks should be completed to determine whether or not there is system fault or failure that may require part replacements as part of the routine service procedure. To conduct these checks, you'll require the apparatus specified below:

Tamperproof Label

Air Flow Bungs (Male & Female)

Air Flow Meter

Air Pressure Gauge

1. UNBOXING
   a. Please wear suitable PPE before handling the unit.
   b. Unbox the control unit.
   c. Using appropriate cleaning products, clean down the unit, power lead and work surface.
   d. Place the unit on the clean work surface.

2. FILTER REPLACEMENT
   a. Remove the filter from the back of the unit and clean using cold water.
   b. Dry the filter thoroughly and replace.

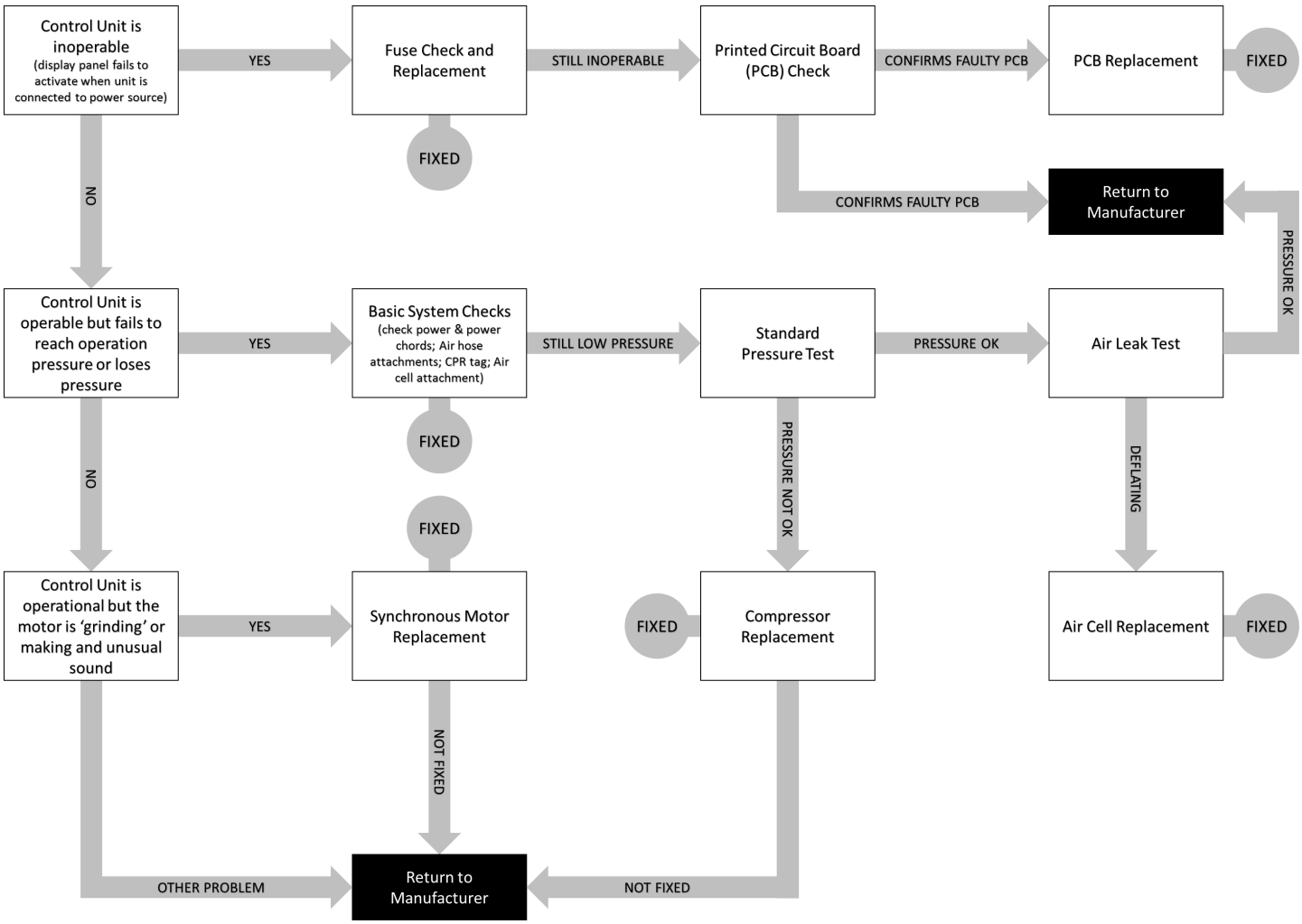
3. FUNCTIONALITY TEST
   a. Connect the control unit to the mains power supply.
   b. Switch the unit on by holding the power button for approximately 5 seconds.
   c. The unit should now be on, and air should be flowing from the female connector.
   d. Connect the flow & pressure test rig to the female connector.
   e. Test the flow; the reading should be between 5LPM & 10LPM.
   f. Now test the pressure, the reading should also be between 110mmHg & 130mmHg.
   g. Test that the LEDs and buttons on the membrane are working correctly by cycling through tilt/rest time settings.
   h. To test the alarm LEDs, carry out the following high and low-pressure tests:
      - Allow the unit pump air from the female connector for approximately 5 minutes until the low-pressure alarm sounds, and the LED illuminates.
      - With the low-pressure alarm still sounding, use the female connector bung to prevent any air from escaping.
      - The low-pressure alarm and LED should now be off and the high-pressure alarm and LED should be active.
      - Use this opportunity to test the mute alarm button and LED, pressing the button should mute any alarm sound and illuminate the blue LED.
      - Switch the unit to pump air out of the male connector and repeat the high and low-pressure tests.
      - To turn the service LED off, simultaneously hold the 'inflate time' and 'rest time' buttons for five seconds.

4. ELECTRICAL SAFETY TESTING
   a. If the unit passes step 3, the unit now requires a safety test per IEC 62353: 2014.
   b. Perform the safety test using a Rigel 288+ tester or similar device (Equipment leakage must produce a value <100µA).
   c. If the unit passes the above test, then the service is complete.
   d. Log the results, date, time and personal details of the engineer.

NOTE - If the unit fails step 3 or 4, follow the problem diagnosis procedure on the next page.

SERVICE PROCEDURE - PROBLEM DIAGNOSIS

If the control unit does not pass the functionality test, use the flow diagram below to diagnose the problem.



5. OPENING THE CONTROL UNIT
   a. Once you've diagnosed the problem, source the appropriate replacement parts (full list on next page).
   b. Remove tamper-proof sticker, unscrew the unit and open it carefully.
   c. After the unit is open check for any visible signs of damage, loose wiring or tubing, dirt and contamination.
   d. Perform repair using appropriate replacement part.
   e. Tighten all internal screws.
   f. Close the unit up and re-place screws
   g. If a repair procedure has taken place, re-conduct section 3 (functionality test) to check for correct function and operation.
   h. If you no longer require to re-open the control unit, put a new tamper-proof sticker over the screws

6. ELECTRICAL SAFETY TESTING (POST REPAIR)
   a. If the unit passes step 3, the unit now requires a safety test per IEC 62353: 2014
   b. Perform the safety test using a Rigel 288+ tester or similar device. (Equipment leakage must produce a value <100µA)
   c. If the unit passes the above test, then the service is complete.
   d. Log the results, date, time and personal details of the engineer

NOTE - If the unit fails step 6, return to the manufacturer.

SPARE PARTS LIST

In order to conduct the service and repair procedures that follow, different kits are available for replacing certain parts. Below is a complete list of the kits available.

To order any of the following, contact Frontier Therapeutics Incorporated, Buffalo, NY 14221 (Tel. +1 800 303 9544).

Stock Code	Description	Kit Contents
010300	Bed Hook Assembly LH/RH Assembly	Screw PB 4 x 12 Screw M3 x 8 P200 Hook Bend Square Premium ϕ6 x 56mm Hook Generic 10 DS Generic 10DS Generic 10DS ϕ10.7 x 14.3 Hook Safety Plate
010301	Male QR Air Hose Connector Assembly	Male QR Connector Body O-ring Quick Release Connector P7
010302	Female QR Air Hose Connector Assembly	Female QR Connector Body Spring Quick Release Connector Connector quick release grey
010303	IEC Mains Connector	Single Item
010304	Air QR Connector Panel	Single Item
010305	Cap Sponge Filter	Single Item
010306	Sponge Filter	Single Item
010307	Rear Case Handle and Fixings	Hand case Screw PB 4 x 12
010308	Rear Case Assembly	Screw Hole Sticker Label Sticker PET Blue Stand Rubber 4244 N.R.H Screw Hole Rubber Stopper Screw PB 4 x 18 Case Rear
010328	110V Motor and Fixings	Motor Synchronous 110V VAM -2.5/3rpm Screw M3 x 16

Stock Code	Description	Kit Contents
010310	Micro Switch Assembly	Micro Switch 1 Micro Switch 2 Screw PA 3 x 30
010311	Diverter Valve Assembly	R-clip 1mm D20mmL ϕ38.8 x 7 Spring R.V Analogue Two Tube Valve Assy Exhaust Valve Screw M2 x 5 P200
010312	3-way Air Hose Assembly	Connector 3-way T-type PA Black Hose Silicon Rubber
010313	Compressor Air Hose Assembly	Connector L-shaped Tube 18mm x 8mm Tube PVC Clear 4.5 x 8 PVC
010327	110V Compressor and Mounting Assembly	CU Compressor Rubber Compressor Mounting
010315	Compressor and Fixings Assembly	Screw PB 4 x 8 Compressor Case Housing Foam EVA black 90 x 10 x 4mm
010323	110V PCB Assembly	PCB Support Fixing CU PCB Assembly Toto 10DS Film Isolating PCB
010324	Front Case and V3 Membrane Assembly	Label Membrane Case Front
010318	Buzzer Assembly	Alarm Buzzer Buzzer Seat
010325	Alarm Speaker	Single Item
010326	Speaker Bracket Assembly	Speaker Frame Screw

CHECKING AND REPLACING THE FUSE

Control unit failures may be a result of a blown fuse. To replace, follow the steps below.

Note: When replacing, only use the same fuse rating (T1AH/250V).

Required Tools:

Flat Head Screwdriver

Required Parts:

1x T1AH/250V Fuse

1. Prepare the Control Unit

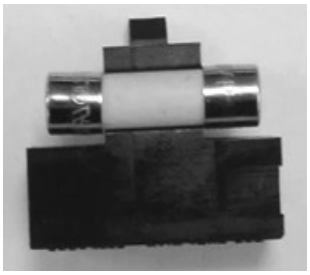
Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Remove the Fuse

Insert the flat headed screwdriver into the fuse holder and lever out of position.

Remove the fuse from the holder and safely discard.



3. Insert New Fuse

Insert a new fuse into the fuse holder and replace.

Ensure the holder is secure.

4. Reconnect and Test

Reconnect the power cord to the control unit and switch on the power supply. If the control unit still fails to operate, the problem may be due to a faulty circuit board. Proceed to the PCB (printed circuit board) check procedure.

If the unit switches on but the fuse “blows” again, repeat the steps to replace the damaged fuse but do not reconnect power as damage may be due to a faulty compressor.

TESTING FOR A FAULTY PCB (PRINTED CIRCUIT BOARD) AND 'PIGGYBACKING' A WORKING SPARE

To determine if the PCB has failed, always test the Control unit using a working spare. When handling the PCB, anti-static gloves (or other anti-static precautions) should be used to protect the PCB from static.

Required Tools:

Phillips Screwdriver

Wire Clippers

Heat Gun

Required Parts:

1x 110V PCB Assembly

REF - 010323

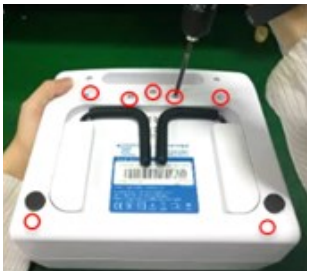
1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Remove the Tamper Proof Label

Using a heat gun (80°C / 176°f), remove and discard the tamper-proof label.



3. Remove Screws

Remove white screw caps.

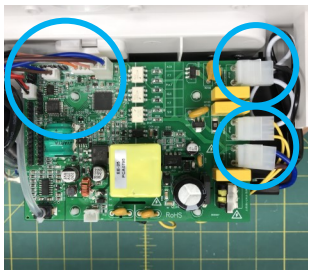
Use a Phillips Head Screwdriver to remove the seven screws that secure the housing.

Place the screws in a safe place (such as small container or jar) to prevent loss.

4. Separate the Housing

Gently loosen the top and bottom housing. Once loose, hold the power socket (IEC connector) to prevent from catching while lifting the top cover and leaning it back on your work surface.

Be careful not to drag the internal wires and tubing during this process.



5. Disconnect the PCB (i)

Disconnect the six electronic leads by cutting the cable ties that secure the leads to the PCB.

Carefully pull away the plastic cases (not the wiring) to disconnect.

6. Disconnect the PCB (ii)

Disconnect the two remaining flat digital leads and one air tube.

Be sure to note the location of all eight connections on the circuit board for easy replacement.

Leave the disconnected PCB in the control unit during testing.

TESTING FOR A FAULTY PCB AND 'PIGGYBACKING' A WORKING SPARE CONTINUED

Required Tools:

Phillips Screwdriver

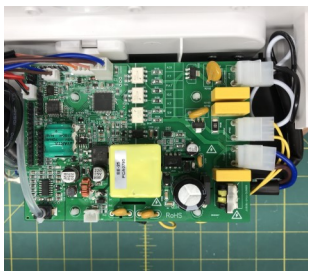
Wire Clippers

Heat Gun

Required Parts:

1x 110V PCB Assembly

REF - 010323



7. Piggybacking the Spare PCB

Take the spare PCB and connect all eight leads into the corresponding connectors

Six electronic leads; two digital; one air pipe.

8. Test

Reconnect mains power, switch on the control unit and check the display panel.

If the unit now operates, the internal PCB has failed and needs replacing. Proceed to the printed circuit board replacement procedure for the next steps.

NOTE: If the control unit still does not operate, return to Frontier Therapeutics Inc. for further repair or replacement.

REPLACING A FAULTY PCB

When handling the PCB, anti-static gloves (or other anti-static precautions) should be used to protect the PCB from static.

Required Tools:

Phillips Screwdriver

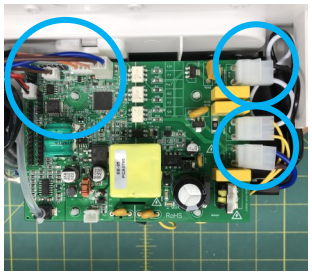
Needle Nose Pliers

Required Parts:

1x 110V PCB Assembly

REF - 010323

1x Tamper proof label



1. Prepare the Control Unit

Disconnect the eight leads from the new PCB; Six electronic leads; two digital; one air pipe and place in a safe environment.

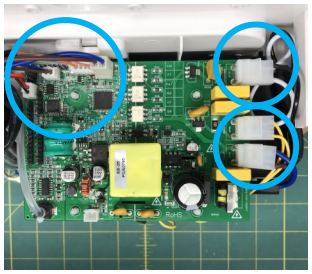
2. Remove PCB

Using needle-nosed pliers, unclip the faulty PCB from the control unit. Note the orientation of the PCB before removing it from the unit.

Dispose of the faulty PCB in an environmentally safe manner.

3. Insert new PCB

Align the replacements PCB against the four holes and carefully reconnect the clips by pressing firmly into place.



4. Connecting the new PCB

Connect all eight leads to the PCB; Six electronic leads; two digital; one air pipe.

Before closing the housing, make sure all power leads and pipes are free from the side edges. Ensure the regulator tubing does not kink.

5. Reassemble

Align the top and bottom housing before slowly pushing closed. Ensure that the top case is correctly aligned.

Holding the top and bottom housing firmly together, turn the control unit upside down, with the back facing upwards.

Use a Phillips Head Screwdriver replace the seven screws and tighten to secure the housing together, replace the two white caps.

6. Test

Connect the control unit to mains power and switch on to confirm the operation.

Apply new 'U' shaped Tamper proof label covering all screws at the top of the unit.

STANDARD PRESSURE TEST - TESTING AIRFLOW AND CHECKING FOR A FAULTY COMPRESSOR

The control unit compressor is designed for longevity and covered by a two-year warranty from Frontier Therapeutics Inc. From time to time compressor failure can occur. The Standard Pressure Test should be carried out to check the compressor is working at full operational capacity and that sufficient airflow is being generated to maintain maximum performance.

Required Tools:

Phillips Screwdriver

Sphygmomanometer

Air Flow Meter

Required Parts:

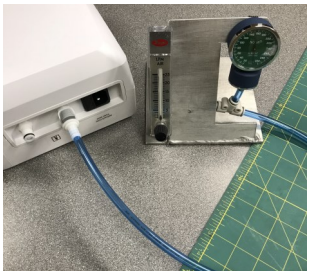
1. Equipment Set-up

Connect one air pipe to the rear of the Sphygmomanometer and another to the base of the Airflow meter. These two air hoses are then connected by a 'Y' piece to form a single air pipe outlet.

Check all pipe attachments are secure before commencing the test.

Initially set the equipment to free-flow mode, i.e. no resistance or backpressure against the full flow of air from the compressor.

Ensure the airflow valve at the front of the airflow meter is fully open by turning the valve anti-clockwise.



2. Switch Test

After the 2 minutes the "warm-up" period has elapsed, connect the fitting of the pressure test equipment to the female connector on the side of the control unit.

Ensure the equipment is set to 'free flow mode' The valve at the front of the airflow meter should be fully open. If not, turn anti-clockwise to open the valve to the maximum. With the system in free-flow mode, the ball inside the airflow meter should rise to a minimum of 11 litres per minute (LPM).

Close the airflow meter valve (maximum resistance). The ball bearing inside the Airflow meter should drop to 0, and the Sphygmomanometer pressure reading should rise to a minimum of 140 mmHg.

3. Results

If airflow measurements fail to meet the specified minimum levels during any stage of the pressure test, the compressor is not operating at full capacity, and replacement is required.

Proceed to Compressor replacement procedure.

If all pressure and airflow measurements met the expected levels, the problem might be due to a leaking Air Cell or another defect with the Control unit.

Directly connecting the compressor to the pressure testing equipment (Sphygmomanometer and Air Flow Meter) confirms the system pressure readings at maximum and minimum airflow (in free-flow mode or with different degrees of backpressure applied). If the pressure test fails and pressure readings do not achieve the required performance, replace the compressor and repeat the test.

It is advised to allow the control unit to "warm-up" before undertaking the Standard Pressure Test, to ensure the diaphragm inside the compressor has loosened and is operating at maximum capacity. After opening the unit, reconnect power and allow the system to run for a minimum of thirty minutes before commencing this test.

REPLACING A FAULTY COMPRESSOR

Having established a fault with the compressor by following and completing the standard pressure test procedure detailed previously (steps 1 through 6), replace the faulty compressor with a new compressor.

Required Tools:

Phillips Screwdriver

Wire Clippers

Needle Nosed Pliers

Heat Gun

Required Parts:

1x 110V Compressor

REF - 010327

1x Tamper Proof Label

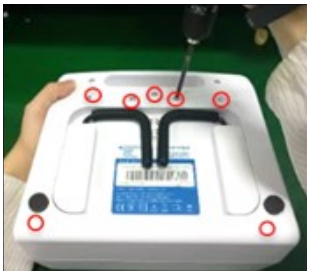
1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Remove the Tamper Proof Label

Using a heat gun (80°C / 176°f), remove and discard the tamper-proof label.



3. Remove Screws

Remove white screw caps.

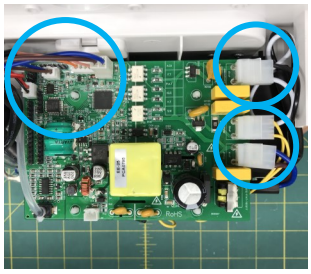
Use a Phillips Head Screwdriver to remove the seven screws that secure the housing.

Place the screws in a safe place (such as small container or jar) to prevent loss.

4. Separate the Housing

Gently loosen the top and bottom housing. Once loose, hold the power socket (IEC connector) to prevent from catching while lifting the top cover and leaning it back on your work surface.

Be careful not to drag the internal wires and tubing during this process.



5. Disconnect the PCB (i)

Disconnect the six electronic leads by cutting the cable ties that secure the leads to the PCB.

Carefully pull away the plastic cases (not the wiring) to disconnect.

Disconnect the two remaining flat digital leads and one air tube.

6. Disconnect the Compressor

Secured the compressor by three screws located on either side of the unit. Using a Philips head screwdriver, unscrew, remove and store in a safe place.

Locate and unscrew the two screws securing the synchronised motor, remove and store in a safe place.

Gently lift the compressor and PCB assembly out of the casing, ensuring the power lead does not get caught in the process.

REPLACING A FAULTY COMPRESSOR CONTINUED

Required Tools:

Phillips Screwdriver

Wire Clippers

Needle Nosed Pliers

Heat Gun

Required Parts:

1x 110V Compressor

REF - 010327

1x Tamper Proof Label

7. Removing From the Cage

Remove the compressor from the cage by disconnecting the rubber mounts.

Dispose of the faulty compressor in an environmentally safe manner.

8. Preparing the New Compressor

Unpack the replacement compressor.

Carefully thread the power lead through the base of the cage before sliding the new compressor into position (with power lead closest to the PCB, and air pipe connector positioned towards the base).

9. Secure

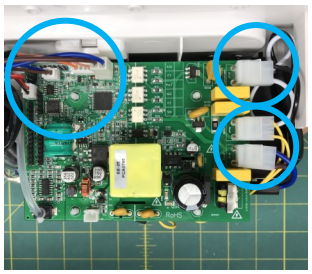
Secure the compressor to the metal cage by connecting the new rubber mounts.

Visually check that each mount is secure – gently move the compressor to ensure all mounts are connected, and the compressor is suspended correctly.

10. Insert New Compressor

Gently insert the compressor and PCB assembly into the casing and secure back in place with the six Philips head screws.

Reattach the air pipe to the compressor, using gentle pressure to ensure a firm fit and secure with a new cable tie.



11. Reconnect PCB

Connect all eight leads to the PCB; Six electronic leads; two digital; one air pipe.

Before closing the housing, make sure all power leads and pipes are free from the side edges. Ensure the regulator tubing does not kink.

12. Reassemble & Test

Align the top and bottom housing before slowly pushing closed. Ensure the top case correctly aligned.

Holding the top and bottom housing firmly together, turn the control unit upside down, with the back facing upwards.

Use a Phillips Head Screwdriver replace the seven screws and tighten to secure the housing together, replace the two white caps.

Connect the control unit to mains power and switch on to confirm the operation.

Apply new 'U' shaped Tamper proof label covering all screws at the top of the unit.

SYNCHRONOUS MOTOR REPLACEMENT

The synchronous motor runs the valve that operates the timing mechanism for the alternation cycle. If the valve becomes worn or damaged, it will no longer rotate smoothly, and its function reduces. If this happens, a distinct grinding noise can be heard.

Required Tools:

Phillips Ccrewdriver

Wire Clippers

Flat Head Screwdriver

Heat Gun

Required Parts:

1x 110V Motor & Fixings

REF - 010328

1x Tamper Proof Label

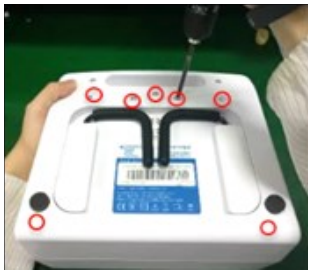
1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Remove the Tamper Proof Label

Using a heat gun (80±5°C), remove and discard the tamper-proof label.



3. Remove Screws

Remove white screw caps.

Use a Phillips Head Screwdriver to remove the seven screws that secure the housing.

Place the screws in a safe place (such as small container or jar) to prevent loss.

4. Separate the Housing

Gently loosen the top and bottom housing. Once loose, hold the power socket (IEC connector) to prevent from catching while lifting the top cover and leaning it back on your work surface.

Be careful not to drag the internal wires and tubing during this process.

5. Disconnect the Power Lead

Trace the power lead running from underneath the synchronous motor to its connection on the PCB.

Disconnect this lead from the PCB by carefully pulling the plastic casing (not the wiring) and gently remove the lead.

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6. Disconnect the Exhaust Silencer

Using a Philips head screwdriver, remove the two screws holding the exhaust silencer to the three-way outlet valve.

SYNCHRONOUS MOTOR REPLACEMENT CONTINUED

Required Tools:

Phillips screwdriver

Wire clippers

Flat Head screwdriver

Heat gun

Required Parts:

1x 110V Motor & Fixings

REF - 010328

1x Tamper proof label

7. Removing the 3-way Valve (i)

Using a thumb and forefinger, push down firmly on the plastic valve casing to release tension while removing the split pin – a deal of downward pressure is required.

While maintaining downward pressure, take a small screwdriver or another implement to gently lift the split pin from the top of the motor shaft. Place the pin in a safe place.

8. Removing the 3-way valve (ii)

The valve is made of two plastic circular casings and should remain attached during removal.

If the top casing comes free during this process (7), place in a safe place until time to replace the valve, when it can be reattached.

9. Removing the 3-way valve (iii)

Gently lift the plastic valve up and over the shaft, sliding the 'L' shaped metal bracket through the black plastic handle at the side of the valve, to reveal the spring and synchronous motor beneath.

10. Removing the Motor (i)

Remove the spring and the two screws that hold the motor in place, and place in a safe place.

11. Removing the Motor (ii)

Lift the motor off its mounts and remove, ensuring the power lead does not get caught in the process.

Dispose of the faulty motor in an environmentally safe manner.

12. Installing a New Motor

Unpack the replacement motor.

Carefully thread the power lead under the base of the compressor cage before repositioning the new motor on its mounts, ensuring screw holes are correctly aligned.

Secure in place using the two Philip head screws. Be careful not to overtighten.

SYNCHRONOUS MOTOR REPLACEMENT CONTINUED

Required Tools:

Phillips Screwdriver

Wire Clippers

Flat Head Screwdriver

Heat Gun

Required Parts:

1x 110V Motor & Fixings

REF - 010328

1x Tamper Proof Label

13. Installing a New Motor (ii)

Reposition the spring over the shaft, larger coils at the base finer coils on top.

14. Refitting the 3-way valve (i)

If the top plastic casing of the valve is loose, reposition and hold firmly in place before replacing the valve over the shaft.

Firmly push down on the valve while replacing the split pin through the top of the shaft. A significant amount of pressure is required to counteract the force of the spring. Replace the silencer.

15. Refitting the 3-way valve (ii)

Using a Philips screwdriver refit the two screws holding the exhaust silencer to the three-way outlet valve.

16. Connecting the New Motor

Reconnect the motor power lead to the circuit board and attach a new cable tie to secure all power leads as before.

17. Reassemble & Test

Align the top and bottom housing before slowly pushing closed. Ensure the top case correctly aligned.

Holding the top and bottom housing firmly together, turn the control unit upside down, with the back facing upwards.

Use a Phillips Head Screwdriver replace the seven screws and tighten to secure the housing together, replace the two white caps.

Connect the control unit to mains power and switch on to confirm the operation.

Apply new ‘U’ shaped Tamper proof label covering all screws at the top of the unit.

QUICK RELEASE CONNECTOR REPLACEMENT

Both the male and female quick release connectors on the side of the control unit can be removed and replaced. For significant damage, the connector plate can also be removed and replaced.

Required Tools:

14mm Spanner

Required Parts:

1x Male Connector

REF - 3200010

1x Female Connector

REF - 3200011

1x Connector Plate

REF - 010304

1x Tamper Proof Label

1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Replace the Quick Connectors

Carefully remove the male/ female screw-in quick connector from the left-hand side panel of the control unit using a 14mm spanner.

Fit the new male/female connector to the control unit. Do not over tighten.

BED HOOK REPLACEMENT

The bed hooks on the rear of the Control Unit can be replaced if they become damaged or worn.

Required Tools:

Phillips Screwdriver

Heat Gun

Required Parts:

1x Bed Hook LH/RH kit

REF— 010300

1x Tamper Proof Label

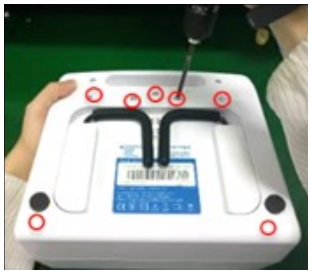
1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Remove the Tamper Proof Label

Using a heat gun (80±5°C), remove and discard the tamper-proof label.



3. Remove Screws

Remove white screw caps.

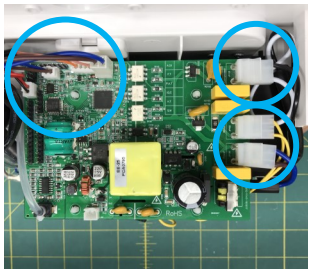
Use a Phillips Head Screwdriver to remove the seven screws that secure the housing.

Place the screws in a safe place (such as small container or jar) to prevent loss.

4. Separate the Housing

Gently loosen the top and bottom housing. Once loose, hold the power socket (IEC connector) to prevent from catching while lifting the top cover and leaning it back on your work surface.

Be careful not to drag the internal wires and tubing during this process.



5. Disconnect the PCB (i)

Disconnect the six electronic leads by cutting the cable ties that secure the leads to the PCB.

Carefully pull away the plastic cases (not the wiring) to disconnect.

Disconnect the two remaining flat digital leads and one air tube.

6. Removing the PCB, Compressor and Other Components

Using a Philips head screwdriver unscrew the 3 screws each side securing the compressor, unscrew the two screws securing the synchronised motor.

Gently lift the compressor and PCBA along with the synchronised motor assembly out of the casing, to reveal the eight screws securing the bed hooks.

Place the screws in a safe place (such as small container or jar) to prevent loss.

BED HOOK REPLACEMENT CONTINUED

Required Tools:

Phillips Screwdriver

Heat Gun

Required Parts:

1x Bed Hook LH/RH kit

REF— 010300

1x Tamper Proof Label

7. Replacing the Bed Hooks

Using a Phillips Head screwdriver unscrew the eight screws securing the fixing hooks to the rear housing.

Place the screws in a safe place (such as small container or jar) to prevent loss. Remove the fixing hook assembly from the rear casing.

Unpack and fit the replacement hook kit. Checking for the smooth movement of the hooks.

10. Reassemble & Test

Align the top and bottom housing before slowly pushing closed. Ensure the top case correctly aligned.

Holding the top and bottom housing firmly together, turn the control unit upside down, with the back facing upwards.

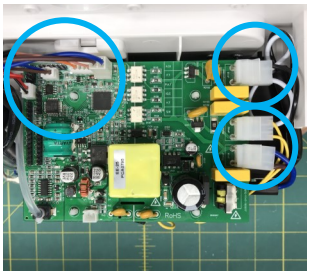
Use a Phillips Head Screwdriver replace the seven screws and tighten to secure the housing together, replace the two white caps.

Connect the control unit to mains power and switch on to confirm the operation.

Apply new 'U' shaped Tamper proof label covering all screws at the top of the unit.

8. Replacing the PCB, Compressor and other components

Gently lift the compressor and PCBA along with the synchronised motor assembly back into the casing and secure in place.



9. Reconnect PCB

Connect all eight leads to the PCB; Six electronic leads; two digital; one air pipe.

Before closing the housing, make sure all power leads and pipes are free from the side edges. Ensure the regulator tubing does not kink.

AIR CELL REPLACEMENT

In the event of puncture or damage, one or both of the platforms air cells can be replaced.

Required Tools:

Required Parts:

1x Air Cell Left

REF — 4200010

1x Air Cell Right

REF — 4200011

1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Prepare the Platform & Remove the Air Cell(s)

Unzip and pull back the cover revealing the platform.

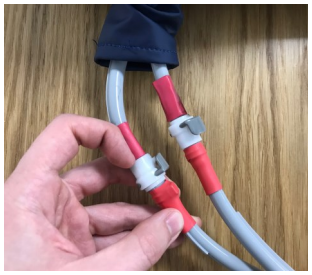
Identify the faulty Air Cell(s) and remove by pulling the poppers to release.

Inspect the platform for any visible signs of damage, including what could have caused the Air Cell(s) to have become damaged.

3. Fitting New Air Cell(s)

Fit the new Air Cell(s) ensuring the poppers are attached in the correct location.

Feed the Air Cell hoses through loops at the bottom of the platform base.



4. Recommence Therapy

Ensure that the air cell hoses can are fed through the sheath at the bottom of the cover.

Reattach the air hoses using the quick connectors – Red to Red, ensuring they are not twisted or kinked.

Re-connect the Toto Control unit to mains power and recommence therapy.

CPR DEFLATION VALVE REPLACEMENT

In the event of damage, the CPR deflation valve can be replaced.

Required Tools:

Required Parts:

1x CPR Hose Assembly

REF— 010106

1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Prepare the Air Hoses

Disconnect the Air Hoses from the platform and Control Unit by pressing the release button on the quick connectors and pulling apart.

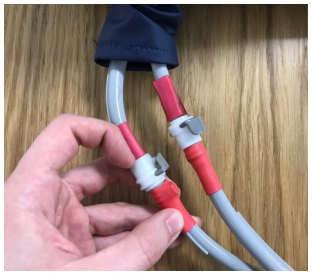
Locate the CPR valve and remove the grey Air Hoses by pulling away from the CPR valve body, do this on both sides.

Make a note of the type of connectors on each side. Once removed, dispose of the CPR valve in an environmentally safe manner.

3. Fitting a New CPR Valve

Position the new CPR valve and push the grey air hoses into position.

A correctly assembled Air Hose will have a male and female connector along each side.



4. Recommence Therapy

Ensure that the air cell hoses can are fed through the sheath at the bottom of the cover.

Reattach the air hoses using the quick connectors – Red to Red, ensuring they are not twisted or kinked.

Re-connect the Toto Control unit to mains power and recommence therapy.

PLATFORM COVER REPLACEMENT

Both the male and female quick release connectors on the side of the control unit can be removed and replaced. For significant damage, the connector plate can also be removed and replaced.

Required Tools:

Required Parts:

Standard Platform Cover

REF - 4200001

1. Prepare the Control Unit

Switch off the power supply to the control unit, disconnect the air hoses and remove the power cord from the electrical socket in the side of the unit.

Using a soft cloth to protect the unit from damage, place the control unit on a level work surface with the back facing upwards.

2. Prepare the Platform

Disconnect the Air Hoses from the platform by pressing the release button on the quick connectors and pulling apart.

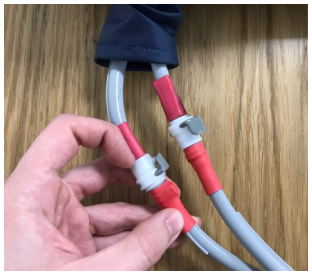
Unzip and remove the cover.

Inspect the platform for any visible signs of damage.

3. Fitting a New Cover

Install replacement cover by opening it and laying it out flat.

The platform base can then be placed into it, ensure to attach the platform base to the four popper fixings located in each corner of the cover.



4. Recommence Therapy

Reattach the air hoses using the quick connectors – Red to Red, ensuring they are not twisted or kinked.

Re-connect the Toto Control unit to mains power and recommence therapy.

TROUBLESHOOTING GUIDE

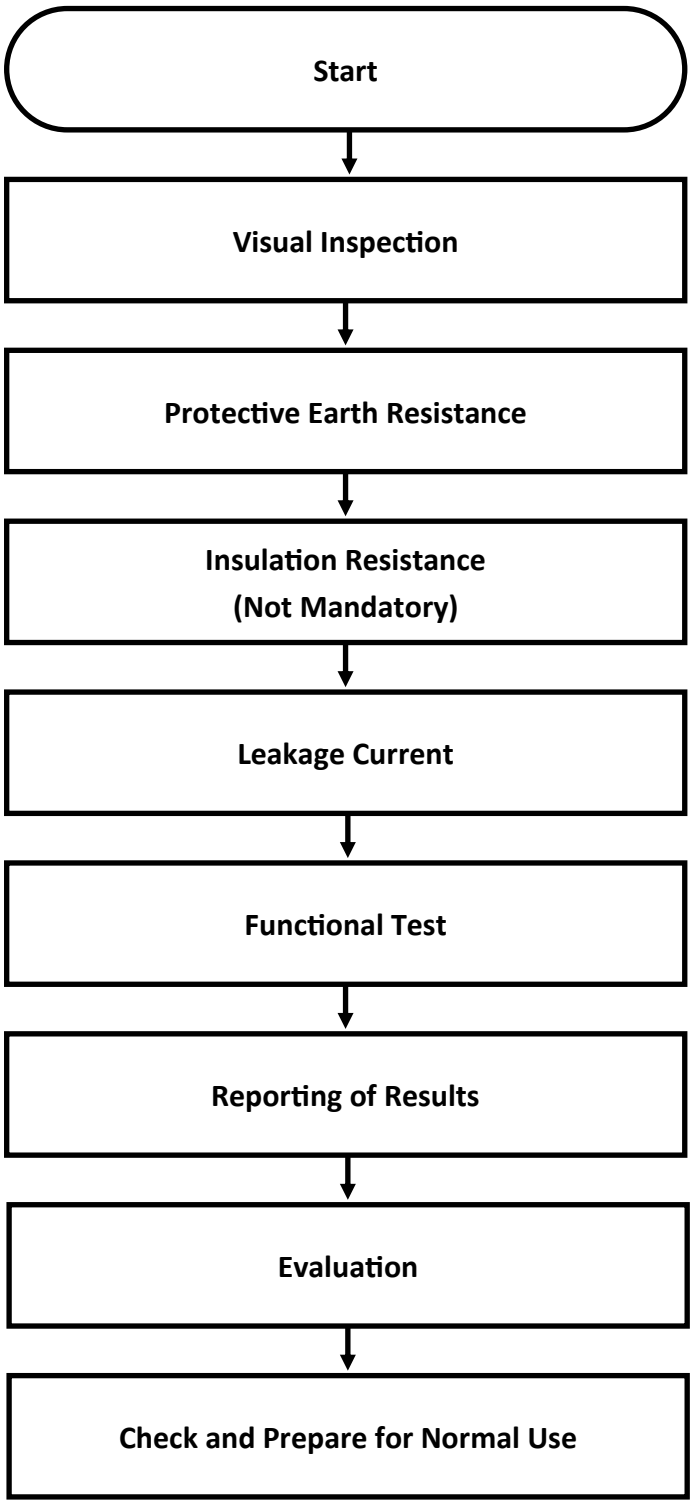
Problem	Cause	Initial Checks / Trouble Shooting
No LEDs lit; no alarm.	Control unit may not be attached to a power source. The fuse may need replacing.	Ensure that the control unit is powered by a live and active mains power outlet. Check the control unit is switched on. If following points 1 and 2 does not resolve the problem, switch off and unplug the control unit: - Check the mains plug fuse (3A). - Check the control unit fuse (1A). Restart the control unit.
Low-pressure alarm LED permanently lit yellow; an audible alarm present.	Pressure has fallen below the minimum operational requirements.	Press the mute alarm button. Check the CPR valve is closed correctly, ensuring all sealing connectors are correct. Check each air cell is securely attached to the connecting air cell hose. Check all air cells and hoses for any air leakage.
High-Pressure Alarm LED permanently lit yellow; an audible alarm present.	Airflow between the control unit and the platform has become obstructed.	Press the mute alarm button. Check for twists or kinks in the air hoses between the platform and control unit. Resolve and wait for the alarm to reset.
Service LED permanently lit amber.	Service required.	Indicates the need for routine maintenance. N.B. The Control unit will function while the service LED is lit. To turn the service LED off, simultaneously hold the 'inflate time' and 'rest time' buttons for five seconds.
Interface panel is lit but unresponsive.	Interface panel is locked.	Check that screen lock LED is lit amber. Press and hold the alarm mute button for four seconds.
Audible alarm; no LEDs lit.	Accidental removal of power lead. Accidental mains wall power is turned off. Mains power failure.	Reconnect mains power lead to the control unit. Check the mains power wall switch is turned on. Attempt to restart the control unit.

If the problem persists, contact Frontier Therapeutics Inc. Tel. +1 800 303 9544 for assistance. Do not open the Control unit. Opening the unit could cause personal injury or equipment damage.

ELECTRICAL SAFETY TEST AND TEST AFTER REPAIR

BS EN 62353:2014—Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment.

These tests should be completed before the Control Unit is sent out to or returned to the user.



GENERAL SAFETY PRECAUTIONS

Do not use this equipment in the presence of flammable anaesthetics. The air intakes for the control units are at the sides of the unit. Mount the control unit on the footboard of a bed frame to minimise the risk of accidental damage. Should the bed not have a suitable footboard, place on a solid surface such as a table, or on the floor.

PROTECTION AGAINST HAZARDS

Avoid spilling liquids on any part of the control unit.
If spills do occur:

Disconnect the unit from the mains wall socket.
Follow recommended cleaning guideline for light and heavily soiling.

Liquids remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing hazards to patient and staff.

Ensure that there are no liquids in, or near the electrical IEC, power switch and plug before reconnecting the power supply.
Check the operation of controls and other components.
Perform applicable checkout procedures.

DISPOSAL

At the end of life, dispose of waste according to the European Union Waste Electrical and Electronic Equipment (WEEE) Directive and in compliance with relevant local regulations.

POWER CORD

Never operate the system with a worn or damaged power cord. Should the power cord be found to be worn or damaged, replace immediately.

INTERFERENCE

Although this equipment conforms to the intent of the Directive IEC 60601-1-2 regarding Electromagnetic Compatibility, all electrical equipment may produce interference. If interference is suspected, move equipment from sensitive devices or contact the Manufacturer.

(IEC 60601-1-2. Medical Electrical Equipment – Part 1: General Requirements for Safety, Amendment No. 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests).

CLEANING GUIDELINES

Follow the manufacturer's instructions as detailed in the user guide. Failure to do so may result in cross-contamination or equipment damage.
Clean and decontaminate all aspects of the product after use and between patient episodes.
Always disconnect the control unit from mains power before cleaning. Do not spray disinfectant directly on to the unit or immerse the unit in any liquids.
Do not use high-temperature autoclave steam cleaning devices or phenolic based cleaning products. Use of either of these could result in damage to equipment.

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) IEC 62353:2014 (Electrical Safety)	EN 55011:2009/A1:2010 Class B (RF) EN 61000-3-2:2014 (Harmonics) EN 61000-3-3-2013 (Flicker)
The 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 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: 10ºC to 40ºC / 50ºf to 104ºf
	Relative humidity range: 30% to 70%
	Atmospheric pressure range: 700hPa to 1060hPa
Storage/Transportation	Temperature range: -10ºC to 60ºC / 50ºf to 140ºf
	Relative humidity range: 10% to 70%
	Atmospheric pressure range: 700hPa to 1060hPa
Classification IEC60601-1	Class II equipment
	Type BF applied part
	IP21

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