

# TECHNICAL DOCUMENTATION SERVICING INFORMATION TECH 04.0 – 800.4

## AT4™ ELECTRONIC TOURNIQUET

### MPN Name

40080 AT4™ Electronic Tourniquet

Serial number 800-4001 onwards only - manufactured from 2013.

### Frequency of service

An AT4™ Electronic Tourniquet is to be serviced once annually.

### Lifetime

The life expectancy of an AT4™ Electronic Tourniquet is 10 years from date of introduction to clinical use, dependent on the level of care and maintenance. The performance of this device may reduce once the life expectancy has been reached and exceeded.

The battery requires replacement during the lifetime of the device:

Sonnenschein battery is to be replaced every two years.

NX battery is to be replaced every six years.

NOTE: NX battery fitted from serial number 806-4000 onwards.

### Day-to-Day maintenance

Before use, ensure all device functions operate correctly. Also visually inspect the device for any loose or damaged parts. If the devices performance changes from that specified or required the device should be taken out of service immediately.

Ensure that O-rings on cuffs and associated hoses are in good condition before use.

It is recommended that when not in use the device is connected to the mains electrical supply to recharge the battery. The battery will not be damaged by leaving it connected to the mains when fully charged.

### Regulations

The following regulations will be adhered to as part of the servicing activities:

- Health and Safety at Work Regulations 1999 (management regulations)
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

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### **Guidance documents**

The following guidance documents will be referenced as part of the servicing activities:

- 992043 AT4 Electronic Tourniquet Instruction for Use.
- Medicines & Healthcare products Regulatory Agency: Managing Medical Devices Guidance for health and social care organisations.
- BS EN 62353 2014 - Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment.
- 94740B-01 or 94740B-02 AT4 Parts Identification Drawing.

### **Calibration**

An AT4™ Electronic Tourniquet variant does not require calibration to an accredited national standard.

The manometer and electrical safety analyser used shall be calibrated to an accredited national standard.

### **Qualification of personnel**

In line with the MHRA document, Managing Medical Devices, servicing should only be conducted by suitably trained personnel following manufacturer's guidelines.

### **Documented procedures**

Following documented procedures as part of servicing activities is recommended.

### **Records**

Records of servicing activities will be maintained to provide evidence of conformity and of effectiveness.

Records will remain legible, readily identifiable and retrievable. Changes to records shall remain identifiable.

Records will be maintained for at least the lifetime of the device.

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#### SERVICE SCHEDULE

##### 1. Initial set-up & inspections

- 1.1. Switch the unit on.
- 1.2. Check version of software installed (currently 4.2), update to latest version if required.
- 1.3. If maintenance LED is lit (or lights during any stage of this schedule) – investigate the cause before proceeding.
- 1.4. Take the unit into calibration mode to “001” – “CAL” to check current battery voltage.
- 1.5. Record current battery voltage on 95710B – Maintenance Entry Sheet – Calibration / PAT Record and abort calibration mode.
- 1.6. If required, replace battery as detailed under Lifetime on page 1 – recording new battery voltage, post fitting, on 95710B – Maintenance Entry Sheet – Calibration / PAT Record.
- 1.7. Monitor battery level LED during remainder of schedule.
- 1.8. Check the condition of the cuff supply hosing connectors (male & female).
- 1.9. Check the condition of the cuff supply hosing connectors O-ring washers (male).
- 1.10. Check the condition of the panel mounted cuff supply hose & storage connectors and that they are secure.
- 1.11. Detach mains lead (if connected).
- 1.12. Switch the unit on.
- 1.13. Dial 100mmHg on both channels and press both inflate buttons.
- 1.14. Allow unit to exhaust, auto deflate and allow the pump to stop running – ensuring the pump is not audibly loud.
- 1.15. Press the elapsed time selection button repeatedly and scroll through the elapsed time selections a full cycle.
- 1.16. Check pressure select knob caps are in place and pressure select knob is secure to spindle.
- 1.17. If maintenance LED is lit (or lights during any stage of this schedule) – investigate the cause before proceeding.
- 1.18. Switch the unit off.

##### 2. Mains

- 2.1. Check the condition of the mains lead.
- 2.2. Connect the mains lead to the unit & a wall socket.
- 2.3. Check the mains lead IEC socket (unit mounted) is secure.
- 2.4. Switch the wall socket to the on position.
- 2.5. Check that the battery LED is lit (800 & 801 units = solid amber / 802 to 806 units = solid green / flashing amber).
- 2.6. Switch the unit on.
- 2.7. Check that the battery LED is (800 & 801 units = solid amber / 802 to 806 units = solid green / flashing amber).
- 2.8. Switch the wall socket to the off position and disconnect the mains lead from the unit.

##### 3. Display, LED's & Speaker

- 3.1. Check the on/off LED is lit solid green.
- 3.2. Check that all displays are displaying the relevant figures.
- 3.3. Check that all displays are backlit (800 & 801 only).
- 3.4. Press the IVRA button.
- 3.5. Check the IVRA LED is lit solid amber.
- 3.6. Press either channels inflate button (with selected pressure set at 000mmHg).
- 3.7. Check the IVRA LED flashes red and an audible beep can be heard.
- 3.8. Press the IVRA button.

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### 4. Calibration & Performance

- 4.1. Records the results of the following on 95710B – Maintenance Entry Sheet – Calibration / PAT Record.
- 4.2. Monitor performance of panel mounted female connectors, control knobs, LEDs, displays, buttons and pneumatics throughout 5.
- 4.3. Connect manometer, test hose & test cuff to blue channel.
- 4.4. Dial selected pressure on blue channel to 100mmHg.
- 4.5. Press inflate button on blue channel.
- 4.6. Compare applied pressure display to manometer reading (+/- 6% tolerance).
- 4.7. Dial selected pressure to 200, 300, 400, 500mmHg comparing applied pressure display to manometer at each stage.
- 4.8. Press deflate button on blue channel twice – slow then fast deflate.
- 4.9. Repeat on red channel from 4.3.
- 4.10. Re-calibrate if required.

### 5. Low Pressure / Pressure Drop Alarms & Maintenance LED

- 5.1. Partially open manometer relief valve on manometer test hose (1/8 approx).
- 5.2. Press inflate button on red channel.
- 5.3. Await low pressure alarm to trigger and close relief valve.
- 5.4. Allow applied pressure to be achieved 94% of selected (applied pressure display will stop flashing).
- 5.5. Press the alarm mute button and allow applied pressure to be achieved.
- 5.6. Disconnect test hosing from panel mounted cuff supply hose female connector.  
Note: Pressure drop alarm should sound immediately.
- 5.7. Allow unit to auto deflate and press alarm mute button.
- 5.8. Press deflate button then alarm mute button.
- 5.9. Repeat on blue channel.
- 5.10. Dial selected pressure on both channels to 000mmHg.

### 6. IVRA Performance

- 6.1. Connect cuff supply hose to both channels.
- 6.2. Connect test cuff to both channels.
- 6.3. Press IVRA button – ensuring IVRA LED is solid amber.
- 6.4. Dial selected pressure to 300mmHg on blue channel.
- 6.5. Press inflate button on blue channel – ensuring IVRA LED turns solid green.
- 6.6. Press deflate button on blue channel – IVRA LED should flash red and an audible beep sound.
- 6.7. Press inflate button on red channel – IVRA LED should flash red and an audible beep sound.
- 6.8. Dial selected pressure on red channel to 300mmHg.
- 6.9. Press inflate button on red channel.
- 6.10. Press deflate button on red channel – IVRA LED should flash red and an audible beep sound.
- 6.11. Press deflate button on blue channel.  
Note: AT4e will slow deflate only to 25mmHg.
- 6.12. Press deflate button on red channel – ensuring IVRA LED turns solid amber.  
Note: AT4e will slow deflate only to 25mmHg.
- 6.13. Press IVRA button.

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**7. Portable Appliance Electrical Safety Tests**

7.1. Perform electrical safety analysis – Class I with protective earth.

**8. Miscellaneous**

- 8.1. Check the fixings & condition of the fascia & transitional moulding (including handle).
- 8.2. Check the fixings & condition of the cuff hooks.
- 8.3. check the fixings & condition of the storage locating mushrooms.
- 8.4. Check the condition of the storage facility(s).
- 8.5. Check the fixings & condition of the base frame.
- 8.6. Check the condition & function of the castors.
- 8.7. Check that all labels are present and in good condition.
- 8.8. If available, check the internal pressure of The Rhys-Davies Exsanguinator does not exceed 60mmHg corresponding to a maximum external circumference of 47cm.
- 8.9. If available, check the condition of the surface of The Rhys-Davies Exsanguinator for degradation.

End of Document

Date of Change	Issue No.	Brief Description of Change	Signature
23 <sup>nd</sup> May 2024	1	Replaces document reference 95703H	