

TECHNICAL DOCUMENTATION SERVICING INFORMATION TECH 02.0 – 800.2

QA4™ v2.0 DESIGN MOBILE SURGERY SYSTEM

MPN Name

21300 QA4™ Mobile Surgery System

Serial number 551 to 3450 only - manufactured between 2010 and 2020.

GMDN

33152 Universal operating table, electromechanical

Frequency of service

A QA4™ Mobile Surgery System is to be serviced once annually.

Lifetime

The life expectancy of a QA4™ Mobile Surgery System 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 – once every three years.

Day-to-Day maintenance

Before use, ensure all stretcher functions operate to their full range of movement and that all components disengage, re-engage and lock correctly. Also visually inspect the stretcher for any loose or damaged parts, foreign bodies caught in the castors and hydraulic fluid leakage.

If the stretcher is damaged or faulty it must be taken out of use with immediate effect and the fault reported to Anetic Aid or maintenance department. The stretcher must not be used until the damage or fault has been repaired.

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:

- 992010 QA4 Powered Mobile Surgery System Instructions 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
- Document 94750A - QA4 Surgery Trolley - Powered v2.0 - Parts Identification Drawing will identify any component in need of replacement.

Calibration

A QA4™ Mobile Surgery System variant does not require calibration 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. Ensure all four castors are trailing away from the foot-end.
- 1.2. Apply brakes.
- 1.3. Lift all cotsides into raised position.
- 1.4. Detach the mains lead (if connected).

2. Handset & Actuators

- 2.1. Check the condition of the handset hook.
- 2.2. Check the condition of the handset cable.
- 2.3. Check the performance of each actuator to its full range of movement.
- 2.4. Monitor each button performance & battery level indicator during 2.3 (attaching mains lead if required).
- 2.5. Return the trolley actuators to a mid-traverse, horizontal position, at an appropriate working height.
- 2.6. Attach mains lead and ensure plug is switched to on position.

3. Safety Side Rails

- 3.1. Check condition of side rail mouldings.
- 3.2. Check function & condition of each locating boss (4-piece) / clamp handle (single piece).
- 3.3. Check function & condition of each side rail locating arm (4-piece) / hand grip (single piece).
- 3.4. Check fixings & function of each rotating latch button & latch (4-piece) / hand grip (single piece).
- 3.5. Check function of each side rail rotational movement & locking position integrity.

4. IV Pole

- 4.1. Check fixings & function of IV pole hooks.
- 4.2. Check function of IV pole raise and lower.
- 4.3. Check fixings & function of IV pole clamp casting & clamp handle (if fitted).

5. Backrest:

- 5.1. Check condition of backrest board & moulding.
- 5.2. Check function & condition of emergency backrest release lever.
- 5.3. Check fixings & condition of backrest actuator & actuator hinge.
- 5.4. Check function & condition of gas strut damper.
- 5.5. Check condition of frame cover vac-forming.

6. Head Positioner

- 6.1. Check fixings & function of head positioner gas strut.
- 6.2. Check fixings & function of gas strut activation handle.
- 6.3. Check fixings & condition of head positioner board.
- 6.4. Check fixings & function of release handle & torsion spring.
- 6.5. Check fixings & condition of fixed & pivot brackets.

7. Body Section

- 7.1. Check condition of body section board & moulding.
- 7.2. Check fixings & condition of body section vac-forming.

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8. Leg Section

- 8.1. Check fixings & condition of leg section board.
- 8.2. Remove leg section and check condition of locating pins.
- 8.3. Check fixings & condition of locating blocks & release buttons.
- 8.4. Attach leg section monitoring performance.
- 8.5. Attempt to remove the leg section without activating the release buttons.

9. Lateral Tilt

- 9.1. Check fixings & condition of lateral tilt handle.
- 9.2. Check function of lateral tilt handle to full range of movement.

10. Column & Internal Inspection

- 10.1. Check actuator jack leads are fully connected & secured.
- 10.2. Check internal wiring connections.
- 10.3. Check fixings & condition of lateral tilt rod end bearing.
- 10.4. Check fixings & condition of lateral tilt pivot components.
- 10.5. Check fixings of column plate.
- 10.6. Check condition of column stability.
- 10.7. Visual inspection of internal fixings.
- 10.8. Visual inspection of internal welding.

11. Base vac-forming, Castor & Brakes

- 11.1. Check condition of base vac-forming.
- 11.2. Remove the base vac-forming fixings & lift the base vac-forming.
- 11.3. Check fixings & condition of brake pedals.
- 11.4. Check castor fixings & condition.
- 11.5. Check castor tyre & rotational brake functions.
- 11.6. Check the rigidity of the unison between brake pedals (brake linkage).
- 11.7. Check the fixings & condition of the brake linkage & change levers.
- 11.8. Check control box connections are fully connected & secured.
- 11.9. Check condition of wiring & wiring connections.
- 11.10. Check the age of the battery and replace if ≥ 3 years.
- 11.11. Check handset LED is flashing to indicate charging routine has commenced.

12. 5th Wheel Steer & Base Frame Inspection

- 12.1. Check fixings & condition of 5th wheels.
- 12.2. Check condition of 5th wheel gas spring.
- 12.3. Check fixings & condition of 5th wheel housing components.
- 12.4. Check fixings & condition of 5th wheel steer pedal.
- 12.5. Check function of 5th wheel steer pedal.
- 12.6. Check condition of earth continuity strip
- 12.7. Visual inspection of base frame welding.
- 12.8. Lower base vac-forming and re-attach fixings.

13. Electrical Safety Analysis

- 13.1 Perform electrical safety analysis – Class II Type B fitted with functional earth.

13. Miscellaneous

- 13.1. Check age & condition of mattress.
- 13.2. Evaluate overall condition of trolley.

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End of Document

Date of Change	Issue No.	Brief Description of Change	Signature
8 th May 2024	1	Replaces document reference 95703D	