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QA3™ v2.0 OPHTHALMIC DESIGN PATIENT STRETCHER SYSTEM

MPN	Name
21118	QA3™ Ophthalmic Stretcher

Serial number 28661 onwards only - manufactured from 2024.

Frequency of service

A QA3™ Ophthalmic Stretcher variant is to be serviced once annually.

Lifetime

The life expectancy of a QA3™ Ophthalmic Stretcher variant 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.

No component needs compulsory replacement during the lifetime of the device.

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:

- 992015 – QA3 Powered Function Stretchers 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

Calibration

A QA3™ Ophthalmic Stretcher 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. Press the On / Off button to turn the device on.
1.4. Check the condition of the foot-end membrane.
1.5. Check the condition of the hand control and its cable.
1.6. Check the performance of each powered position to its full range of movement via the hand control and foot-end control.
1.8. Check the condition & function of the IEC mains socket and mains lead.
1.9. Plug the device into mains and check that the device is charging.
1.10. Monitor battery level throughout service.
1.11. Lift both Safety Side Rails into raised position.

2. Safety Side Rails

2.1. Check the condition of Safety Side Rail mouldings.
2.2. Visual inspection of Safety Side Rail boxes condition.
2.3. Check Safety Side Rail boxes fixings (tool tight).
2.4. Check function & condition of Safety Side Rail arms.
2.5. Check function & condition of Safety Side Rail latch.
2.6. Check fixings & condition of Safety Side Rail arm vac-formings.

3. IV Pole

3.1. Check fixings & function of transfusion pole hooks.
3.2. Check function of transfusion pole(s) raise and lower.
3.3. Check fixings & function of transfusion pole casting.

4. Head Positioner

4.1. Check fixings & condition of SRBP boards.
4.2. Check condition & performance of articulation handles.
4.3. Check condition & performance of articulating joints.
4.4. Check fixings of fixed bracket (IF FITTED).
4.5. Check fixings, condition and performance of release lever, torsion spring, fixed bracket and pivot bracket (IF FITTED).
4.6. Check age & condition of head pad.

5. Backrest

5.1. Check condition of backrest board & moulding.
5.2. Check function & condition of backrest lever.
5.3. Check function & condition of gas strut & actuator.
5.4. Check fixings & condition of backrest vac-forming.
5.5. Check fixings & condition of backrest rotating buffers.

6. Body Section

6.1. Check the condition of body section board & moulding.
6.2. Check fixings & condition of body section rotating buffers.
6.3. Check fixings & condition of body section vac-forming.
6.4. Check condition of KneeFlex frame.

7. Tilt actuator, Column & Internal Inspection

7.1. Check fixings & condition of tilt actuator.
7.2. Check condition of column stability.
7.3. Visual inspection of internal fixings.
7.4. Visual inspection of internal welding.

8. Base vac-forming, Castors & Brakes

8.1. Check condition of base vac-forming.
8.2. Remove base vac-forming fixings and lift the cover.
8.2. Checking fixings & condition of brake pedals.
8.3. Check castor fixings & condition.
8.4. Check castor tyre & rotational brake functions.
8.5. Check the rigidity of the unison between brake pedals (brake linkage).
8.6. Check the fixings & condition of the brake linkage & change levers.

9. 5th Wheel Steer

9.1. Check pins, fixings & condition of 5th wheels.
9.2. Check condition & performance of 5th wheel locking strut.
9.3. Check condition and function of 5th wheel steer pedal and return springs.

10. Base Frame Inspection

10.1. Check the condition of the earth continuity strip.
10.2. Visual inspection of base frame welding.
10.3. Lower base cover and re-attach fixings.

11. Electrical Safety Analysis

11.1 Perform electrical safety analysis – Class I.

12. Miscellaneous

12.1. Check the age & condition of the mattress.
12.2. Check the condition of the oxygen delivery bar/drape screen.
12.3. Check the condition & function of the oxygen delivery bar/drape screen clamp.
12.2. Evaluate overall condition of trolley.

End of Document

Date of Change	Issue No.	Brief Description of Change	Signature
23nd May 2024	1	Replaces document reference 992052