Manufacturer: Altomed Limited.

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Device(s):	All Altomed VITAL Instruments

IMPORTANT The instructions provided have been validated by Altomed as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

1. Introduction

Note: Only trained staff should handle these devices

1. These procedures should be followed when cleaning and sterilizing stainless steel and/or titanium reusable instruments. These procedures should be followed in conjunction with any existing Hospital Cleaning and Sterilization procedures. These devices should only be monitored, controlled, handled, cleaned and processed by suitably trained and qualified personnel under an approved quality management system such as ISO 9001 or ISO 13485. Processing systems used must be able to sterilize devices to EN 556. Follow guidelines in HTM2010 and HTM2030. Use HTM2031 if necessary (see Limitations on Processing).

2. WARNINGS:

Note: Ophthalmic medical devices are very delicate and in all instances must be handled with care and treated as fragile

1. Long narrow cannulations and blind holes require particular attention during cleaning.
2. Do not exceed temperatures of 140°C. Initial rinsing/cleaning temperatures should not exceed 35°C as temperatures above this may cause coagulation of proteinaceous substances and should be avoided.
3. The VITAL instruments are very fine and delicate medical devices. These should be handled at all times with the utmost care to prevent handling damage. They should be inspected under a microscope as described in Section 11 prior to sterilization.
4. Follow hospital/facility approved Health & Safety procedures at all times (e.g. C.O.S.H.H. Personal Protective Equipment (P.P.E.) etc). Keep fingers away from sharp tips!
5. Follow hospital/facility and MHRA Guidance to control the processing of the devices.
6. Follow hospital/facility approved procedures or recommendations in *"Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection"* compiled by the Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee) for processing devices that have been exposed to unconventional slow viruses or prion diseases such as Creutzfeldt Jakob Disease (C.J.D), Kuru, Gerstmann-Straussler-Scheinker Syndrome (G.S.S.), Fatal Familial Insomnia (F.F.I.), Scrapie, Bovine Spongiform Encephalopathy (B.S.E.) etc.
7. Carry out procedures in a suitably controlled environment to protect from contamination.
8. Do not process rusty or damaged instruments with good instruments or stainless steel with normal steel or iron instruments.
9. **General note: Do not re-use or reprocess single use devices.**
10. Follow the instructions supplied by the machine and detergent manufacturers. All machines and detergents used should be CE marked.
11. Instruments should not be exposed to Bromine, Iodine, Calcium Chloride, Calcium Hypochlorite, Sodium Hypochlorite or Chlorhexidine. Do not expose Titanium devices Potassium Perchlorate. Any chemicals used should be Tenzide free. Only use CE marked chemicals specifically approved and labelled for use with medical devices.

Single Use Symbol / Do not reuse

CE marked products have this symbol

3. Limitations on reprocessing

1. Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use, processing or handling. Exposure to strong acid or alkaline may reduce the working life of instruments

Processing Instructions

4. Point of use

Note: Take care when securing flush tube to make sure the tips of the device are not rubbed or caught on the inside of the tube

Note: Keep protective cap on at all times except during cleaning, use, or inspections

1. Do not allow contaminants to dry on the device. Altomed recommend the use of a suitable Enzymatic preparation solution such as Ruhof Prepzyme XF to keep any debris moist if required.
2. Remove excess soil by rinsing in purified water as soon as possible after use. Very carefully use a facility approved brush designed for delicate medical devices to remove any pieces of visible debris, open and close jaws as required. Always push the debris away from the lumen then rinse.
3. Connect a VITAL Flush Tube (A7644) to the instrument neck (see fig 1.) ensure the tubing does not touch delicate tips of the device. Slowly and carefully push water through the device until it comes out at the handle then withdraw the water back into the syringe. Use a gentle push pull motion on the syringe to loosen any debris if necessary. Disconnect the Flush Tube from the syringe and expel water from syringe. Rinse Flush Tube and connector in purified water.

Fig 1.

4. Repeat Steps 2 and 3 above until the device is clean.

5. Preparation for cleaning

1. It is recommended to clean the device as soon as is reasonably possible after use as described in Section 4 above. Ensure only trained staff handle and process the device. Care must be taken to prevent any cross contamination. Follow facility approved procedures for transporting contaminated devices. Do not let debris dry on the device.

6. Cleaning 1: Equipment and Chemicals

1. Equipment: Ultrasonic Cleaner and Washer /Disinfector as applicable, CE marked and approved by the hospital/facility with validated cycles.
2. Detergent: CE marked pH neutral Endozymatic detergent, *Altomed recommend Ruhof Endozyme AW Triple Plus.* Any chemicals used should be CE marked and be specially designed and labelled for use with medical devices.

7. Cleaning 2: Ultrasonic Cleaner

Note: It is not recommended to use old or contaminated solutions in the Ultrasonic Cleaner

Note: Take care when drying so tips do not become damaged

1. Follow guidelines and procedures in HTM2030 and Ultrasonic Bath Manufactures Instructions.
2. Ensure the Ultrasonic Machine is clean empty and dry prior to use.
3. Fill fluid reservoir with detergent solution to ensure complete immersion of device. Follow the Chemical and Ultrasonic Cleaner Manufacturer's instructions for use. *Altomed recommend using an endozymatic detergent such as Ruhof Endozyme Triple Plus.* Degass the solution and bring to the correct operating temperature following machine manufacturer's instructions for use.
4. Pre-clean devices as described in Section 4 Steps 2, 3, 4 as necessary using detergent solution.
5. Protect the devices by packing them in Microwash Trays, finger matting or securing blocks to prevent them touching other devices or the sides and bottom of the Ultrasonic bath.
6. Switch off the Ultrasonic bath and carefully place items into the solution. Ensure they are fully immersed and that any air contained in the device is displaced. Replace lid, switch on and leave immersed for as long as specified in the Chemical and Ultrasonic Manufacturer Instructions.
7. Switch off machine, remove and drain instruments. Rinse device including the lumen thoroughly in clean hot water (60°C or hotter) before drying and prior to processing in a washer/disinfector.
8. Dry using hospital approved absorbent non-shedding cloths, hot air dryer or drying cabinet. Wear suitable PPE when handling hot devices. If device is not visually clean, repeat procedure.

8. Cleaning 3: Washer / Disinfector

1. Clean devices first as described in Sections 6 and 7 above and ensure they are visually clean. Place instruments into a suitable container (e.g. Microwash Tray) to protect from handling and processing damage.
2. Follow HTM 2030 and Washer/Disinfector Manufacturers instructions for use.
3. Load instruments so that as much contaminated surface area is exposed as possible, e.g. when device allows, open jaws, hinges etc and place any devices with holes, lumen or concave surfaces so that they can drain freely. Load the machine so that the load configuration does not impede the cleaning process. Keep heavy objects at the bottom of trays, do not overload baskets and do not let instruments touch each other.
4. Run a hospital/facility approved and validated cycle. The initial rinse should be at or below 35°C followed by a hot water disinfection rinse where the surface of the device should reach 71°C for a minimum of 3 minutes, 80°C for 1 minute or 90°C for 1 second see HTM 2030) *Altomed have validated a cycle with the following parameters: 5 minute pre-wash at 20°C followed by an Endozyme wash at 50°C for 5 minutes, a 1 minute rinse at 60°C for 5 minutes, a 1 minute rinse at 60°C and a thermal disinfection cycle* of 90°C for 6 minutes. HTM2030 and MHRA Guidance should be followed where applicable.
5. When unloading check devices, including cannulations and holes etc. for complete removal of visible soil. Ensure instruments are dry. If necessary test lumen flow rates using a syringe. If necessary carry out manual cleaning Section 9 and repeat Sections 6,7 and 8.

9. Cleaning 4: Manual

Note: Carry out any manual cleaning gently. Be careful not to damage delicate tips.

Note: Take care when drying so tips do not become damaged

1. Use a double sink system dedicated only for cleaning instruments - DO NOT use a hand wash basin. Ensure the water temperature is warm but does not exceed 35°C. Use a hospital/facility approved detergent diluted as necessary to the manufacturers guidelines in the first sink. Detergent used should be CE marked and designed specially for medical devices. *Altomed recommend an Endozyme detergent e.g. Ruhof Endozyme Triple Plus*
2. Fill the second sink with purified water or ensure a water jet gun is available at the sink. Carefully immerse instrument in the solution and displace any trapped air. Ensure solution reaches all areas of the device, flush any lumens as shown in Section 4 with the detergent.
3. Keeping the device fully immersed in the solution, brush, wipe, agitate, irrigate, jet wash or hand spray the item to dislodge any visible dirt. Do not use steel wool, abrasive powders or wire bristled brushes. Pay particular attention to joints, lock serrations, or any area where debris may collect. Remove from the solution and drain over the detergent filled sink.
4. Transfer the item to second sink. Rinse device thoroughly with the purified water, ensure device is fully immersed and any residues are removed. Flush device with purified water as in Section 4. Remove from the rinse water and drain.
5. Dry using hospital approved absorbent non-shedding cloths, hot air dryer or drying cabinet. Wear suitable PPE when handling hot devices. If device is not visually clean, repeat procedure

10. Special note:

1. Any reusable brushes used should be cleaned after use and disinfected, ideally in a washer disinfector. Reusable brushes should be stored dry.

11. Inspection/ maintenance

Symbols denoting instructions

1. Visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of any debris such as organic matter and any chemical residues.
2. If devices are not visibly clean, reprocess using manual cleaning or automated cleaning if necessary. If unsure about cannulated device flush with sterile purified water and check the flow rate.

11. Inspection / maintenance - continued

Note: Check all devices against either a master sample or the drawings shown in the Altomed Catalogue. Contact Altomed if in any doubt

3. Inspect device under a microscope as follows; contact Altomed if in any doubt to suitability:
   Alignment - All jaws, teeth, arms etc. correctly aligned and interlocking where appropriate.
   Finish - Device should be clean with no staining, debris or residues. Any markings should be clear and easily visible. Staining may be removed by using a specially designed cleaning agent, *Altomed recommend Ruhof Surgi-Stain.* Follow the chemical manufacturers instructions for use to clean the device if necessary.
   Structure - No scratches, nicks, bends, distortions, cracks, flaking, pitting or other signs of physical or handling damage.
   Movement - Smooth without grating, scratching, jerking or excessive play unless designed to be otherwise.
   Locking Mechanisms - Should open and closed easily, check also for any cracks in box locks and hinges
   Tips - Check the integrity of any delicate parts, e.g. probes, scissor tips etc.
   Assemblies - All interlocking and detachable parts should fit easily and correctly without the need to apply any excessive force
   Cutting edges - Should give a clean cut along the length of the blade. Test by cutting damp tissue paper: ensure cut is clean, along full length of blade and does not pull at tissue fibres.
   Lubrication - When necessary instruments should be lubricated on all moving parts after cleaning. Follow the Lubricant Manufacturers instructions. Any lubricants used must be specifically designed, CE marked and labelled for use with medical devices, *Altomed recommend the Ruhof Premix-Slip lubricant*

12. Packaging

LOT Lot Number Symbol

Use By Symbol

1. Use hospital/facility approved and validated protocols and packing material, e.g. pouches or wraps. Protect devices from handling damage (e.g. Microwash Tray) during processing.
2. Ensure packing is large enough to prevent pressure on the seals. *Altomed recommend products to BS 868.* Ensure traceability with LOT number and shelf life with use by date.
3. Pack devices so jaws, lock boxes, ratchets etc are open and exposed to sterilization process.

13. Sterilization:

STERILE EO Ethylene Oxide

STERILE Moist Heat

STERILE R Radiation

Common Sterile Symbols

1. Use a hospital/facility approved and validated protocol and sterilize to EN556. Ensure all equipment and systems are controlled, maintained and calibrated e.g. HTM2010 HTM2030
2. Ensure all devices are suitably packed in a protective barrier (e.g. pouch, wrap) to maintain sterility after removal from the sterilizer. *Altomed recommend using materials to EN868.*
3. *The preferred sterilization cycle and one that has been validated by Altomed is a standard Autoclave cycle operating between 134°C and 137°C with a minimum 3 minute holding time.* These conditions may vary, see also Table 5 in HTM 2010 for suitable variations if required.

14. Storage

Protect device from rain and direct sunlight

1. Stores should ensure optimum quality conditions are maintained. Devices should be kept away from floors, walls, and ceilings. Store in a clean, dry well ventilated environment.
2. Sterile devices should be clearly identified with use by dates and be segregated from non-sterile devices where appropriate. Keep products out of direct sunlight at normal room temperature and humidity. Ensure all devices are dry before storage. Reject any devices devices in wet or damaged packing. **NEVER STORE INSTRUMENTS WHEN WET.**

15. Damaged devices

1. If a devices fail inspection protocols it should be rejected. If in any doubt as to the integrity of a device after processing , send to the Altomed Repairs Department for evaluation, include a signed Decontamination Certificate. If the device is beyond repair then it should be decontaminated and wrapped to protect handlers from sharp edges. It should then be disposed of by following hospital/facility approved procedures.