

Manufacturer: Altomed Limited.



Altomed Ltd. 2 Witney Way, Boldon, Tyne/Wear. NE35 9PE. Tel: 0191 519 0111 Fax: 0191 519 0283

Device(s): All Altomed VITAL Instruments

IMPORTANT

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. P.P.E. etc)
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
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. Remove excess soil by rinsing in purified water after use. Very carefully connect a VITAL Flush Tube (A7664) to the VITAL instrument (see fig 1.) ensure the instrument tips do not touch the inside of the tube. Flush with purified water using a syringe or Quickrinse Machine **Fig 1.**
2. Care must be taken to ensure fingers are kept away from any sharp surfaces and that any delicate tips are cleaned with the utmost care. VITAL instruments are very fragile and should only be handled by trained staff with extreme care.
3. 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*
4. Pack device in a suitable container e.g. Microwash Tray, to prevent damage to devices during transportation. Care must be taken to prevent unwanted contamination.
5. Follow hospital/facility approved procedures for transporting contaminated devices.



5. Preparation for cleaning

1. It is recommended to clean devices as soon as is reasonably possible after use. Flush the VITAL instruments using a Quickrinse Machine or syringe see Fig 1.
2. Ensure staff who will be processing the devices are trained in handling the devices

6. Cleaning 1: Equipment and Chemicals

1. Equipment: Ultrasonic Cleaner and/or Washer /Disinfector as applicable, CE marked and approved by the hospital/facility with a validated cycle.
2. Detergent: CE marked pH neutral Endozymatic detergent, *Altomed recommend Ruhof Endozyme AW Triple Plus.* Any chemicals used should be CE marked and be specifically 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. Ensure the Ultrasonic Machine is clean empty and dry prior to use.
2. Fill fluid reservoir with purified water/detergent 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.*
3. Degass the solution by following the machine manufacturer's instructions for use.
4. Flush cannulated devices with the detergent to ensure lumens are clean and free flowing.
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. Carefully place items into the solution. Ensure they are fully immersed and that any air contained in the device is displaced. Replace lid and leave for a minimum of 5 minutes or as specified in HTM2030. *(Altomed have validated a 2 minute exposure cycle using Ruhof Endozyme Triple Plus however it is recommended to follow HTM guidance.)*
7. Switch off the cleaner, remove the instruments and drain them. Rinse thoroughly in sterile purified water to remove any residues; flush lumens thoroughly see Fig 1.
8. Carefully hand dry using absorbent, non-shedding cloth, industrial hot air dryer or drying cabinet. If necessary use medical grade compressed air to dry any cannulated devices.



<p>8. Cleaning 3: Washer / Disinfector</p>	<ol style="list-style-type: none"> Place instruments into a suitable container (e.g. Microwash Tray) to protect devices from handling damage that can occur during processing. Load instruments so that as much contaminated surface area is exposed as possible, e.g. open jaws, hinges 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. Where available use machine attachments to flush the lumen inside cannulated devices. If not available flush lumens with the detergent prior to processing to remove organic matter (see Fig 1.) then rinse in purified water to remove any residues. Run a hospital/facility approved and validated cycle. The initial rinse should be 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 (HC(91)33 / BS2745) <i>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;</i> Please note however it is recommended to follow HTM Guidance where applicable. 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 Quickrinse Machine or syringe. If necessary repeat cycle or carry out manual cleaning.
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<p>9. Cleaning 4: Manual</p> <p> Note: <i>Carry out any manual cleaning gently. Be careful not to damage delicate tips.</i></p> <p> Note: <i>Take care when drying so tips do not become damaged</i></p>	<ol style="list-style-type: none"> 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. <i>Altomed recommend an Endozyme detergent e.g. Ruhof Endozyme Triple Plus</i> 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 lumened surfaces with the detergent as necessary. 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 hard 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. Transfer the item to second sink. Rinse device thoroughly with sterile distilled water, ensure device is fully immersed and any residues are removed. Flush cannulated devices with sterile purified water, see Fig 1. Remove from the rinse water and drain. Carefully hand dry using an absorbent, non-shedding cloth, an industrial hot air dryer or drying cabinet. If necessary use medical grade compressed air to dry any cannulated devices.
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<p>10. Special note:</p>	<ol style="list-style-type: none"> Any reusable brushes used should be cleaned after use and disinfected, ideally in a washer disinfector. Reusable brushes should be stored dry.
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<p>11. Inspection/ maintenance</p> <p> Symbols denoting instructions</p> <p></p>	<ol style="list-style-type: none"> Visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of any debris such as organic matter and any chemical residues. 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.
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<p>11. Inspection / maintenance - continued</p> <p> Note: <i>Check all devices against either a master sample or the drawings shown in the Altomed Catalogue. Contact Altomed if in any doubt</i></p>	<ol style="list-style-type: none"> 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, <i>Altomed recommend Ruhof Surgi-Stain</i>. 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, <i>Altomed recommend the Ruhof Premix-Slip lubricant</i>
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<p>12. Packaging</p> <p> Lot Number Symbol</p> <p> Use By Symbol</p>	<ol style="list-style-type: none"> 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. Ensure packing is large enough to prevent pressure on the seals. <i>Altomed recommend products to BS 868</i>. Ensure traceability with LOT number and shelf life with use by date. Pack devices so jaws, lock boxes, ratchets etc are open and exposed to sterilization process.
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<p>13. Sterilization:</p> <p> Ethylene Oxide</p> <p> Moist Heat</p> <p> Radiation</p> <p>Common Sterile Symbols</p>	<ol style="list-style-type: none"> 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 Ensure all devices are suitably packed in a protective barrier (e.g. pouch, wrap) to maintain sterility after removal from the sterilizer. <i>Altomed recommend using materials to EN868</i>. <i>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 3 minute holding time</i>. These conditions may vary, see also Table 5 in HTM2010 for suitable variations if required.
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<p>14. Storage</p> <p> Protect device from rain and direct sunlight</p>	<ol style="list-style-type: none"> 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. 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 in wet or damaged packing. NEVER STORE INSTRUMENTS WHEN WET.
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<p>15. Damaged devices</p>	<ol style="list-style-type: none"> 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.
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