



INSTRUCTIONS FOR CLEANING AND STERILISING HUMECA MEDICAL EQUIPMENT

FOR BOTH ELECTRIC AND MANUAL DEVICES



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1. Introduction

This brochure is intended as a general manual for cleaning and reusing medical equipment by Humecca instruments. The equipment, operators, cleaning agents and procedures all contribute to the effectiveness of the treatment. The healthcare institution should ensure that the effectively used combination results in a safe medical device.

Equipment with the label “**single use only**” may not be cleaned for reuse. Single-use devices that are delivered unsterile must be sterilised before use. For these devices the appropriate sections from these instructions can be applied unless other specific instructions are provided in the product documentation.

2. Treatment instructions

The adjacent table describes the requisite steps in preparing the medical equipment for reuse or in preparing a new device for first-time use.

3. Cleaning

There are two methods for cleaning electric medical equipment from Humecca Instruments:

1. **manual method**
2. **automated cleaning/washer disinfectant**

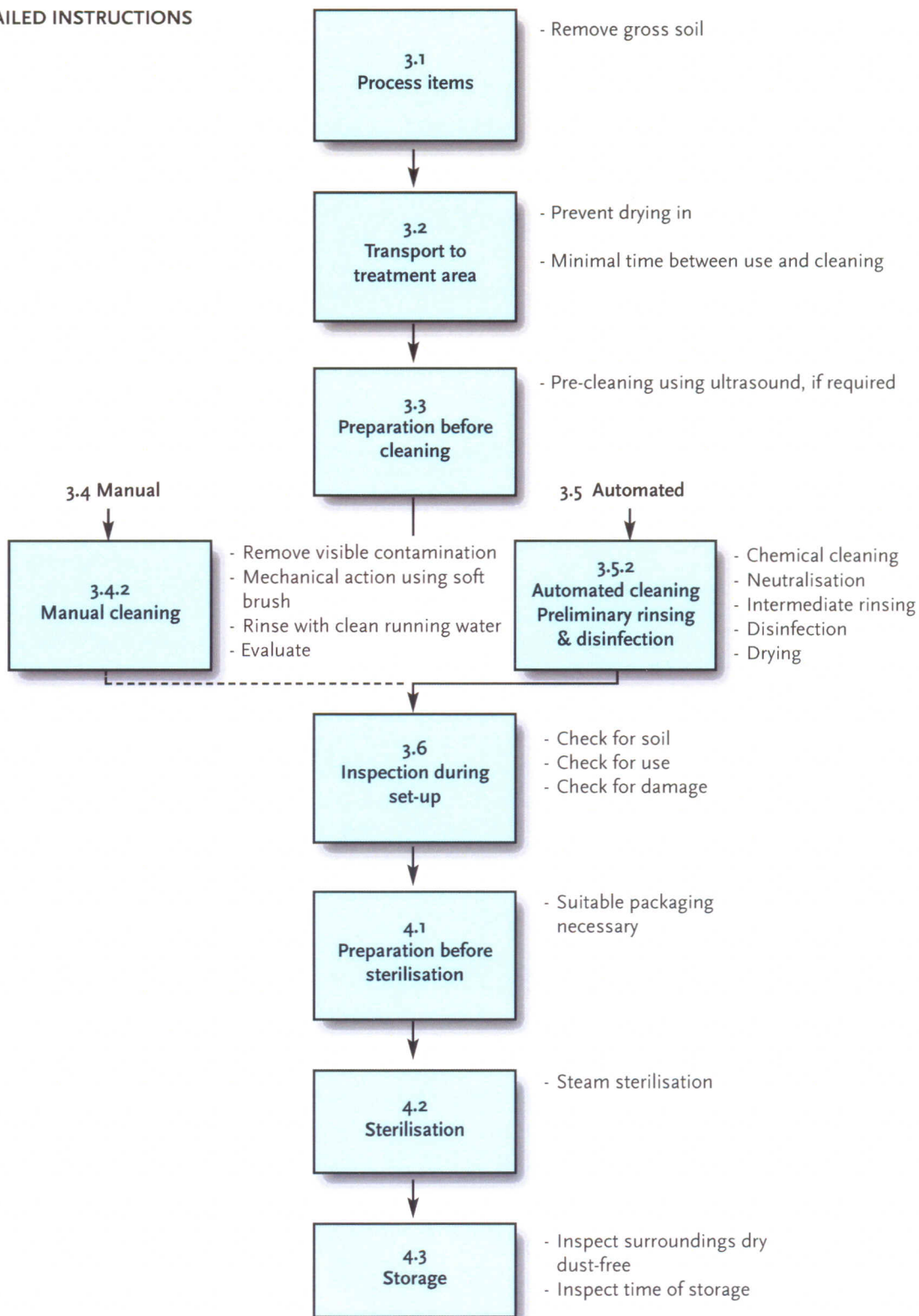
Use the automated method whenever possible. The automated cleaning process is easier to repeat and more reliable. Moreover, staff is less exposed to contaminated equipment and the cleaning agents that are used.

Whichever method is applied, staff should always use suitable **personal protective equipment (PPE)**. Always read the Diversey safety and product information carefully for the proper handling and use of the product.

Only specially designed **cleaning agents** (detergents) can be used to clean medical equipment. For manual cleaning, Suma Bac D10 is preferred, an agent with both bactericidal and fungicidal properties.

An alkaline agent (pH 12.5) may be used for automated instrument cleaning. A cleaning agent with protective action (inhibitor) that does not harm the materials should be used.

**FOLLOW THE DETAILED INSTRUCTIONS
STEP BY STEP**



For **automated cleaning** (with washer disinfectant), preference is given to pH-Neutral enzymatic or alkaline agents (with a maximum pH of 12.5). A cleaning agent with protective action (inhibitor) that does not harm the materials should be used. Only use agents that are designed for use in these machines. In any case, follow the indications, instructions and warnings by Diversey. Pay special attention to the concentration used and the total distribution of the cleaning agent. A **recommended dose** is included in the appendix of this brochure. Pay sufficient attention to the **water quality** that is used to dilute cleaning agents and rinse medical equipment. Water hardness, salts, chloride, silicates, iron and mineral residues from hard water can lead to discoloration or harm to the device or hinder effective cleaning and disinfecting. (The chloride content of the water level should not be greater than 120 mg/litre.)

3.1 Place of use

Use absorbent clothes to remove the worst soil.

3.2 Transport to the treatment area

Avoid mechanical damage (for example, do not combine heavy devices with delicate ones).

Watch out for sharp elements to avoid both injury and damage to the medical device.

Bring the medical devices as quickly as possible to the place where they need to be cleaned. (If they need to be moved to the treatment area, they can be covered with a damp cloth so that the soil does not dry up.)

3.3 Preparation before cleaning

Disassemble the device to the extent possible. Consult the Humecca instructions. Most devices for heavy use cannot be disassembled beyond removing attachments. Consult product instructions for the exact procedures.

3.4 Manual cleaning

3.4.1 Pre-cleaning & cleaning

Required equipment:

- Brushes – soft;
- Personal protective equipment (PPE) as recommended by Diversey when using the cleaning agents (minimum of overalls, gloves, face mask and protective eyewear);
- Absorbent cloths.

Procedure:

- Use absorbent cloths moistened with cleaning agent to remove gross soil;
- Make sure that all surfaces are well moistened;
- Prepare a cleaning solution from Suma Bac D10 (see product information for dosage);
- Clean the medical device thoroughly with suitable brushes and pay special attention to rough surfaces and places where the soil is protected against the brushes;
- Activate hinged or moving parts;
- Rinse under clean running water until all traces of the cleaning solution have been removed;
- Make use of ultrasonic cleaning with the agent Suma Med Enzyme, if necessary;
- Pay special attention to hinges, blind holes and connections between interconnecting parts. Activate all jacking devices or clamping devices for blades and knives to remove all residuals from the cleaning solution;
- Check to see whether any soil has remained behind and repeat these steps if necessary;
- Drain on absorbent cloths.

3.5 Automated cleaning with washer disinfector (preferred)

3.5.1 Pre-cleaning

Required equipment:

- Personal protection equipment as recommended by Diversey (minimum of overalls, gloves, face mask and protective eyewear);
- Absorbent cloths.

Procedure:

- Use absorbent cloths moistened with cleaning agent Suma Light D1 to remove the worst soil;
- Make sure that all surfaces are well moistened;
- Rinse with running water;
- Check to see whether any soil has remained behind and repeat these steps if necessary;
- Drain on absorbent cloths.

3.5.2 Cleaning

Required equipment:

- Washing machine or disinfection device (see remark below);
- Cleaning and rinsing agent as required for the washer disinfectors.

Procedure:

- Place the medical devices in the washer disinfector:
 - Avoid contact between devices (due to movement during washing, damage may be caused and the washing process may be obstructed). Use the specially designed sterilisation basket;
 - Place the medical devices so that the cannulas do not lie horizontally and are aimed downwards (so they empty out);
- Start the cleaning and disinfecting programme on the washer (see remark below);
- Empty the washing machine at the end of the disinfectant programme. Visually check each device to make sure that there is no residual soil and that everything is dry. Repeat the cleaning process if soil remains. Remaining moisture can be removed with medical compressed air.

Remark: Cleaning and washer disinfectors must meet the requirements of NEN 15883.

There are two types of washing programmes:

1. Enzymatic washing programme

This washing programme must include the following steps:

- Pre-washing preferably with softened or demineralised water (2-4 minutes at approximately 18 °C).
- The detergent may be omitted.
- Wash with an enzymatic detergent (Suma Med Enzyme) for at least 6 minutes at a temperature between 37 °C and 48 °C. See table for dosage.
- Wash for at least 2 minutes.
- Disinfection phase at 93 °C and time according to the guidelines. Dose Suma Med Rinse Plus. (Use RO or demineralised water)
- See table below for dosage.
- Dry for 15 minutes at 110 °C.

2. Alkaline washing programme

This washing programme must include the following steps:

- Pre-washing preferably with softened or demineralised water (2-4 minutes at approximately 18 °C).
- The detergent may be omitted.
- Wash with an enzymatic detergent (Suma Med Enzyme) for at least 6 minutes at a temperature between 37 °C and 48 °C.
- Wash with alkaline detergent (Suma Med Alu Free) for at least 6 minutes at a temperature between 55 °C and 60 °C. See table below for dosage.
- Neutralisation (if use is made of alkaline agents) recommendation in dosing Suma Neutral. See table for dosage.
- Intermediate rinsing of at least 2 minutes. Softened or demineralised water.
- Disinfection phase at 93 °C and time according to the guidelines. Dose Suma Med Rinse Plus. See table below for dosage. (use RO or demineralised water)
- Dry for 15 minutes at 110 °C

Automated cleaning and disinfection using Suma Med Enzyme

Washing programme for Humeca	Pre-rinse CW	1st cleaning	Dosage	Rinsing	Thermal disinfection	Dosage	Drying
Water	< 25 °C	Demineralised / softened ½ - ½		Demineralised/ softened and WW ½ - ½	Demineralised		
Products and dose adjustments		Suma Med Enzyme dose	2 to 6 ml/l		Heat to 90 °C and Suma Med Rinse Plus dose	0.2 to 0.4 ml/l	110 °C
		Wash > 37 and < 48 °C		Cold	93 °C		
	2 min.	Cleaning time 6 min.		3 min.	5 min.		15 min.

Automated cleaning and disinfection using alkaline cleaner Suma Med Alu Free

Washing programme for Humeca	Pre-rinse CW	Cleaning	Dosage	Rinsing	Intermediate rinsing	Thermal disinfection	Dosage	Drying
Water		Demineralised / softened ½ - ½		WW	Demineralised /softened and WW ½ - ½	Demineralised		
Products and dose adjustments		Suma Med Alu Free dose at 40 °C	1.5 to 4 m/l	Neutral dose 0.2 to 2 ml/l		Heat to 90 °C and Suma Med Rinse Plus dose	0.2 to 0.4 ml/l	110 °C
		Wash > 55 °C and < 60 °C		Cold	Cold	93 °C		
	2 min.	Cleaning time 6 min.		2 min.	2 min.	5 min.		15 min.

* With use of Ultrasonic Suma Med Enzyme 3 ml/l at 37 °C

Product information and safety sheets can be downloaded via www.Diversey.nl

3.6 Inspection

All medical devices must be inspected before preparation for sterilisation.

Visual inspection without magnifying glass under good lighting conditions will generally suffice. All parts of the devices must be checked for visible soil, damage and/or corrosion. Special attention should be paid to:

- Places where soil “continues to stick”, such as interconnecting surfaces, hinges, shafts, etc.
- Recesses (holes, etc.);
- Elements where soil can be pressed against the device;
- Check for damage to the extent that the device no longer works or blemishes are formed that can damage tissue or surgical gloves.

Function checks should be performed where possible:

- A check should be made to see whether interconnecting devices have been properly assembled;
- Medical devices with moving parts should be activated to check whether they still work properly (a lubricant for medical applications can be used that is suitable for steam sterilisation if required and only according to the instructions for use).

4. Sterilisation

Steam sterilisation is recommended. This is suitable to sterilise Humecca medical instruments. The design and performance of the autoclave, however, may affect the efficiency of the process. Healthcare institutions should validate their procedure using the materials and the operators who usually handle the instruments.

4.1 Preparation before sterilisation

Use special containers from Humecca where applicable.

4.2 Sterilisation process

Steam sterilisation (moist heat) in an autoclave using a pre-vacuum (forced air) is recommended. Autoclaves must satisfy the requirements of and must be validated in accordance with ISO 13683.

Humecca instruments has validated autoclave cycles for the sterilisation of complete medical devices.

The following process parameters are validated by Humecca instruments and recommended for sterilisation.

Method:	steam sterilisation in accordance with ANSI/AAMI/ISO 11134.
Cycle:	saturated steam with vacuum / fractional forced air.
Exposure time ¹ :	4 minutes. <i>The exposure time can be extended to 18 minutes in order to comply with the recommendations from WHO, RKI, etc. Humecca medical instruments can withstand such sterilisation cycles.</i>
Temperature:	134 °C - 137 °C (273 °F - 279 °F).
Pressure:	2 bar (30 PSI) or 3 bar (45 PSI).
Drying time ² :	Varies depending on the load, packaging method and materials. A drying time of 8 minutes is required for the electric devices for heavy use of Humecca instruments.

¹ Exposure time: period in which the load and the complete chamber are kept at the sterilisation temperature.

² Drying time: the period in which steam is removed from the chamber and the chamber pressure is reduced to let the condensate of the load evaporate, either through sustained drainage or through the injection and extraction of hot air or other gases.

REMARK: final responsibility for the validation of sterilisation techniques and equipment lies with the healthcare institution.

To guarantee optimal treatment, all cycles and methods must be validated for different sterilisation chambers, packaging methods and/or all sorts of configurations for the load.

5. Storage for use

Storage life is dependent on the sterile barrier that is applied as well as storage, environmental and handling conditions. Each healthcare institution should determine a maximum storage life for use for sterilised medical equipment.

6. References

ISO 11134: Sterilisation of healthcare products – Requirements for validation and routine inspection – Industrial steam sterilisation

ISO 13683: Sterilisation of healthcare products – Requirements for validation and routine inspection of steam sterilisation in healthcare institutions.

APPENDIX 1

CLEANING AGENTS USED IN THE VALIDATION OF THE TREATMENT INSTRUCTIONS.

A **cleaning agent** (detergent) specially developed to clean medical devices must be used.

- For manual cleaning, a combined cleaning and disinfection agent with both bactericidal and fungicidal properties is preferred.
- For automated cleaning (with washer disinfectant), an enzymatic or alkaline agent (with a maximum pH of 12.5) with inhibitor is preferred. However, only use agents that are recommended for these machines.
- In all cases, observe the indications, instructions and warnings of the supplier of the cleaning agent.

Remarks:

- The above table shows the cleaning agents that Humeca has used in validating the handling instructions in this document.
- Personal protection equipment must be provided for the operators in accordance with the instructions of the supplier and the safety information sheets.
- The suitability of alternative agents must be monitored based on information from the supplier and/or physical tests.

Agents used in the validation of manual and automated (with washer disinfectant) cleaning.

Supplier	Product	Packaging	Use for
Diversey	Diversey Suma Med Enzyme	2 x 5 litres	Suitable for manual/ultrasonic and automated washing
Diversey	Diversey Suma Med Alu Free	10 litres	Automated cleaning (alkaline cleaner with protector)
Diversey	Diversey Suma Med Neutral	2 x 5 litres	Neutralisation of alkaline residues
Diversey	Diversey Suma Med Rinse Plus	2 x 5 litres	Rinsing agent (can also be used for soaking)
Diversey	Diversey Suma Light D1.2	6 x 1 litres	Hand detergent
Diversey	Diversey Suma Bac D10	6 x 2 litres	Combined cleaning and disinfectant agent for manual cleaning

