

Recommendations by the Quality Task Group (56): Decontamination of Motor Systems

Today, motor systems are a firmly entrenched component of everyday surgical practices. Motor systems are used in the following areas for example:

- Orthopaedic and traumatological surgery (drilling machines, bone cutters, Sabre saws, handpieces, shavers)
- Neurosurgery
- Oral and maxillofacial surgery and dentistry
- Ophthalmology
- Cardiovascular and thoracic surgery

Motor systems are powered either

- electrically (storage battery or mains) or
- by means of compressed air (compressed air lamellar motor, compressed air turbine)

It must be pointed out in principle that this recommendation can only be applied to “new generation” motor systems. It can also be safely applied to older drilling machines subject to certain conditions, but this must definitely be clarified with the manufacturers of the drilling systems. Furthermore, the authors point out that this recommendation is not a substitute for the manufacturer’s instructions but rather should serve as a general recommendation for reprocessors, encouraging them to compile a standard operating procedure on the basis of the manufacturer’s instructions and this recommendation.

The members of the Quality Task Force and experts from manufacturing industry* who participated in the drafting of this recommendation are unanimous that motor systems must be classified as “Critical B” pursuant to the recommendation of the Robert Koch Institute/Federal Institute for Drugs and Medical Devices (RKI/BfArM) because of their complex construction. This means that in principle only automated processes should be used to decontaminate motor systems. Hence all operators who continue to reprocess motor systems manually should contact the manufacturers of such systems and enquire about validated automated cleaning and disinfection processes. Some systems can be upgraded/converted such that automated decontamination is possible.

Reprocessing comprises several steps:

– *Collection of used supplies/reprocessing and transportation*

Before → **COLLECTING** the motor systems after use, the various components of such systems should already be dismantled. In the case of the compressed air tubes and electrical cables, special attention must be paid to ensuring that they are not placed in the same tray as sharp accessories since this could damage the insulation or the outer compressed air sheath. Kinking and winding too tightly must also be avoided.

– *Manual precleaning/precleaning tasks*

In principle, motor systems should first be → **PRECLEANED MANUALLY**. When carrying out precleaning, which should be done immediately after use, i.e. should start in the OT, attention must be paid to ensuring that no protein-fixing disinfectant solutions or, under no circumstances, isotonic saline solutions are used to that effect. Cannulated motor systems should be precleaned with a soft brush before automated reprocessing. A detergent solution is sufficient when carrying out precleaning in the CSSD. Disinfectant solutions should not be used. Motor systems must never be immersed or pretreated in an ultrasonic bath. In some cases, the newer motor systems have also been validated by the manufacturer for automated cleaning and disinfection.

* The Quality Task Force thanks specialists at Aesculap, Synthes, Stryker and Wright Medical for their support.

→ **BEFORE COLLECTING** used motor systems must be dismantled.

→ **FOR MANUAL PRECLEANING** a detergent is sufficient.

Before subjecting the motor systems to automated reprocessing, the manufacturer's instructions must be observed in respect of the following:

- Dismantling of individual components,
- Storage in appropriate trays,
- Sealing of openings,
- Rinsing of lumens,
- Use of alkaline or mildly alkaline or neutral detergents,
- Use of rinse aids,
- Number of times rinsed (ophthalmology).

– *Automated reprocessing/automated cleaning*

→ **AUTOMATED REPROCESSING** of motor systems should preferably be conducted in single-chamber washer-disinfectors. The motors can be damaged if using tunnel washers with major differences in temperature. As a validated process, the Vario-TD programme should be used since this has produced the best cleaning results. The RKI programme is not recommended because of the poorer results achieved with it.

Neutral or mildly alkaline detergents should be used (alkaline reprocessing has, in the meantime, been validated in some cases). Oxidative additives can cause damage.

– *Maintenance, visual inspection, functional testing and drying*

Before functional testing, the respective devices are visually inspected for cleanliness and are lubricated as required. Before doing so, the motor systems must be allowed to cool down. Make sure that the correct lubricant is used for lubrication since incorrect lubricants can cause crust formation or even result in the system becoming jammed. The manufacturer's instructions regarding the type of lubricant and method of application, e.g. how and how much should be used, must be observed.

Any superfluous or dripping oil should be removed, but minute traces of lubricant are not a problem. **Caution!** There are also drilling systems that should not be lubricated; this must absolutely be observed.

Functional testing is carried out according to the manufacturer's instructions.

If compressed air is used for drying, it must not be so strong as to press moisture through the gaskets.

– *Pre-sterilisation tasks*

If functional testing has been successfully conducted, the motor system is stored, preferably with accessories, in a system tray and packed. It should not be packed in clear pouches.

– *Sterilisation*

For standard systems → **STERILISATION** with saturated steam under pressure using a fractionated vacuum method is recommended. Steam sterilisation should be conducted at 134 °C using a sterilisation time of at least 5 minutes; attention must be paid to ensuring proper drying.

Condensate formation within the system must be avoided.

– *Operation*

Following sterilisation the motor systems must be allowed to cool down to room temperature. → **COOLING** with sterile fluids must absolutely be avoided since this could lead to irreparable damage.

Functional testing should also be performed before surgery.

Since there is always a risk of failure of such complex systems, a reserve system should be available if surgery cannot be carried out without a motor system.

General remarks

For decontamination of motor systems the manufacturers of such systems should provide the user with validated reprocessing methods according to DIN EN ISO 17664.

→ **FOR AUTOMATED REPROCESSING** the manufacturer's instructions have to be observed.

Use only care products recommended by the manufacturer. Motor systems must be allowed to cool down before maintenance.

If possible, store motor systems in the system tray to prepare for sterilisation.

→ **FOR STERILISATION** Use steam sterilisation with the pulsed vacuum method

→ **COOLING DOWN** with liquids can cause irreparable damage.

Then the user must again validate the process using his own equipment while applying the method validated by the manufacturer. When handing over the systems, the manufacturer should comply with the advisory obligation stipulated by the Medical Devices Operator Ordinance (MPBetreibV) and brief the staff entrusted with reprocessing the motor systems on operation and reprocessing modalities.

The quality of the water used for reprocessing has a major influence on the results obtained as well as on the service life of the washer-disinfector. Hard water can result in deposits in the gears. Demineralised water is recommended. The purchase price for a water treatment system can be easily offset by the savings made from lower expenditure on repairs and for buying new machines.

All manufacturers recommend annual maintenance/servicing. In particular, automated cleaning and the use of mildly alkaline detergents result in machines and attachments running dry over time. If the machines are not lubricated at the time of the annual servicing, this can give rise to poor performance or malfunctioning of the machines. This is true in particular for motor systems that must not be lubricated by the user. Some manufactures extend the warranty when the motor system is serviced after one year.

During the entire decontamination process, including transport, it is important to ensure that in particular electric machines are protected against impact since otherwise the fragile electrical components, e.g. motor magnets, can be damaged.

All manufacturers of motor systems recommend that repairs be conducted only by the original manufacturer. Only this manufacturer has access to the materials and tests methods specified for the design and risk analysis.

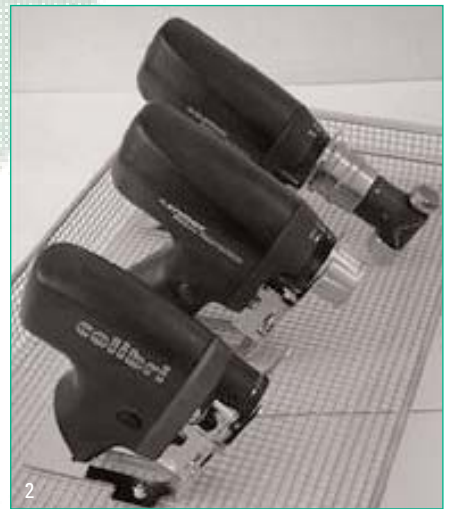
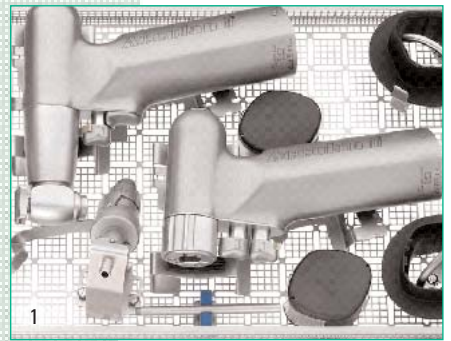


Fig. 3 to 5: Surface discoloration due to unsuitable detergents or water quality

Figs. 1 and 2: Supports for automated reprocessing (Fig. 1: Aesculap factory photo, Fig. 2: Synthes factory photo)