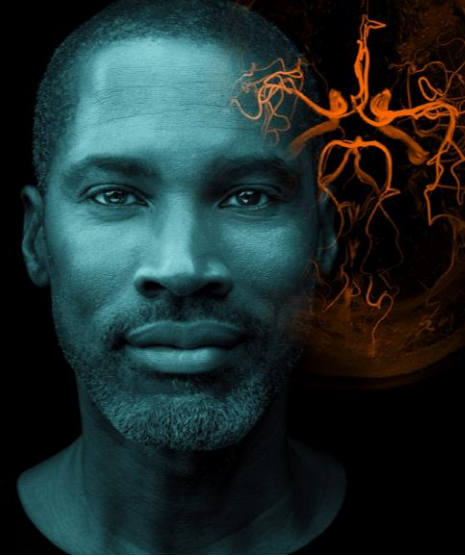
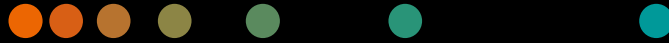


Cleaning and Disinfection Guide

XP-WH Mammomat Systems



Introduction

This document provides detailed information about cleaning and disinfecting your Mammomat System, system components and accessories.

Scope of the Instructions for Use

This Instruction for Use document applies to the following Mammomat systems:

- ◆ Mammomat Fusion
- ◆ Mammomat Inspiration
- ◆ Mammomat Revelation

Applicability

This document is valid only in conjunction with the Instructions for Use of the corresponding Mammomat Systems

Cleaning

Before cleaning and disinfecting, the device has to be switched off.

However, when cleaning the parts which come into contact with the patients during exam, it is not necessary to turn off the system.

These parts are:

1. Compression plates
2. Biopsy Unit
3. Object Table
4. Patient handles and
5. Face Shield

All parts of the unit which come into contact with the patient must be cleaned prior to examination. The plastic trays can be removed from the holder to simplify cleaning.

NOTE:

The compression plate can become contaminated or opaque. Therefore, the patient's breast to be examined must be free of cosmetics (e.g. perfume).

CAUTION

Using incorrect cleaning agents can accelerate the aging process of the plastics or leave traces behind.

Equipment damage due to unsuitable cleaning agents!

- ◆ Observe the specifications by the manufacturer of the cleaning/ disinfecting agent.

CAUTION

Use of unsuitable cleaning agents.

Damage of equipment due to penetration of cleaning agent into the equipment or injury due to ignition!

- ◆ Wipe off the system with a damp, non-fluffing, non-woven cloth or cotton cloth (100 %).
- ◆ Moisten the cloth only with water or a lukewarm, diluted, aqueous solution using a household cleanser without abrasives.
- ◆ Use biocompatible and non-inflammable cleaning and disinfection agents (see list of recommended agents).

NOTE:

- ◆ Cleaning agents must not penetrate into the equipment. Equipment damage due to incorrect cleaning!
- ◆ Never wipe the surface of the Moodlight Plexiglas cover (option) with a dry cloth. Improper cleaning procedures can damage the surface of the Moodlight Plexiglas.
- ◆ Wipe off the system with a damp, lint-free, non-woven cloth or sponge.
- ◆ Moisten the cloth only with water or lukewarm, diluted, aqueous solution using a household cleanser without abrasives.
- ◆ For thorough cleaning, always a non-abrasive cleaning agent, such as antistatic plastic cleaner and care product.

Disinfection

As a general rule, no disinfectants sprays must be used, since the spray mist may penetrate into the equipment which means the safety of the equipment can no longer be assured (damage to electronic components, formation of flammable air solvent vapor mixtures).

NOTE:

- ◆ Anesthetics and skin disinfectants used during biopsies can damage or discolor the plastic parts of the compression plates.
- ◆ Equipment damage due to anesthetics or disinfectants!
- ◆ If such substances get onto the compression plates, wipe these off immediately with a moist cloth.

Comply with the entries in the following table when disinfecting and sterilizing mammography accessories:

| | Disinfection | | Sterilization |
|--|---------------|---|--|
| Compression troughs | not permitted | alcohol-based products petroleum-based products products containing hydrogen peroxide | - |
| | permitted | disinfectants with quaternary ammonium compounds such as "acryl-des" (by Schülke) | |
| | we recommend | disinfectants without alcohol and hydrogen peroxide for all compression troughs disinfectants with quaternary ammonium compounds | |
| | Disinfection | | Sterilization |
| Compression holder | not permitted | chlorine-containing products organic acids containing products | - |
| | permitted | disinfectants with quaternary ammonium compounds | |
| | we recommend | disinfectants with quaternary ammonium compounds | |
| Standard needle holder Special needle holder for dedicated biopsy systems | not permitted | alcohol-based products products containing hydrogen peroxide | steam sterilization at least 100 cycles (134 °C and 3 bar) |
| Stainless steel bushing (Turon) | - | | as with surgical instruments, for example an autoclave procedure |
| Magnification table, covers such as the detector cover | | no restrictions on disinfectants | - |
| | we recommend | 30% H ₂ O ₂ (hydrogen peroxide) disinfectants with alcohol disinfectants with quaternary ammonium compounds | |

NOTE:

Please note that disinfectants based on substituted phenols and chlorine-splitting compounds have a slightly corrosive effect and therefore are not recommended generally.

Reference:

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