



RB015-8004 / Version: 2.0 / Status: Approved
Last release: 5/6/2020 by JdB

Form: MFL-00f007 / 20190225/V5.0

Recommendation for the Cleaning and Disinfection of the RYSEN™

Update April 2020

1. General

According to the Guideline for sterilization and disinfection in Healthcare facilities, Motek/DIH products are noncritical item. *"Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical."*¹

The following processes are recommended, but should be adapted to comply with the local or national guidelines which may apply within the Healthcare Facility or the country of use:

- Pre-Cleaning / Cleaning (if necessary)
- Disinfection

Patients may be at high risk for infections. We therefore recommend that you take additional cleaning and disinfection measures as well as protection measures for patients and therapists. While we recommend the following, we advise that you first and foremost follow the guidelines already in place at your facility, or consult with an internal disinfectant expert for further advice.

2. Pre-Cleaning / Cleaning

- Make sure the device is switched off
- Visible dirt and particles should be wiped clean, using a wet cloth or a dry brush before starting the disinfection procedure.

3. Disinfection

- The device can generally be disinfected with the procedure of surface disinfection using wipes and / or sprays.
- The more delicate orthopedic parts such as harnesses, leg straps and leg loops must be washed. For proper disinfection (see below).
- Please ensure that no liquids, including disinfectant come in contact with electronic interfaces.
- The use of disinfection showers is not permitted due to the electric connections and the unsealed moveable parts.
- Ensure that surfaces to be disinfected are covered well with disinfectant

¹ Rutala WA et al., 2008



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3.1 Recommended disinfection procedure for device components

Component	Disinfection procedure
After each patient	
Orthopedic material:	
- Leg straps or loops (when they are in direct contact with skin)	Wipe ¹
At the end of each working day	
Surfaces:	
- Remote control	Wipe ¹
If needed, e.g. Contaminate by bodily fluids	
Surfaces:	
- Console	Wipe ¹
Orthopedic material:	
- Harness	Washing machine ²
- Leg straps	
- Leg loops	

¹ Includes mechanical cleaning (brushing).

² Wash at 60°C with a laundry bag on a delicate fabric cycle. Check the label of the harness for the washing instructions.



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3.2 Recommended disinfectants

When choosing disinfectants, health aspects of the staff, patients and material compatibility need to be in focus. Motek recommends using disinfectants based on quats (quarternary ammonium cations) as they provide the best material compatibility, are environmentally friendly and economical. Please make sure to remove any soap residue before disinfection with quats.

Examples of recommended products are:

- InnoCID RFD-i 44 RAPID FOAM (PRISMAN Pharma International AG)
- Descosept Special (Dr. Schumacher)
- MikroZid sensitive liquid (Schülke)
- Cleanisept (Dr. Schumacher)
- Mikrobac basic (Bode)

Examples of recommended products for US customers are:

- QUAT-STAT SC (Betco)
- First Defense™ 40-90 (Foster)
- IAQ 2500 (Fiberlock)

These recommendations are not exhaustive as there may be local processes or substances that already comply with cleaning and disinfecting requirements.

Note: Alcohol-based disinfectants may be used, but they might lead to changes in the material composition in the medium to long term.

Disclaimer:

The responsible organization (operator of the medical devices) has the obligation to fulfill all applicable general, local or national hygiene instructions to protect patients, employees and third-party personnel from any kind of possible infections. Motek/DIH cannot be held responsible for infectious diseases caught while using their products.

(These recommendations are not exhaustive. There may be local processes/substances that already comply with cleaning and disinfecting requirements)

- Please note that alcohol-based disinfectants can be used, but may lead to changes in material composition over medium to long-term application.
- In case of any uncertainties, please always consult an internal disinfectant expert.