

Recommendation for the Cleaning and Disinfection of the Erigo®

1. General

The Erigo is a noncritical item, described as follows: *“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 in compliance 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 patient 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

- Adjust the height of the Erigo to an ergonomically good position.
- Make sure the Erigo is turned off and the power connector is unplugged.
- Visible dirt and particles should be wiped clean, using a wet cloth or a dry brush before starting the disinfection procedure.

3. Disinfection

- The Erigo can generally be disinfected with the procedure of surface disinfection using wipes and / or sprays.
- The more delicate orthopedic parts must be washed at the end of each workday to ensure proper disinfection. Between patients/therapists these surfaces must however also be disinfected using either wipes or foam spray (see following Recommended Disinfection Procedure 3.1)
- Please ensure that no liquids, including disinfectant comes in contact with electronic interfaces, like the USB connector, the FES socket or the main power socket.
- 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

3.1 Recommended Disinfection Procedures for Erigo Components

The Erigo should be routinely disinfected between all patients and cleaned at regular intervals while in use.

| Components | Disinfection Procedure |
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| <i>After each patient and between therapists</i> | |
| Back cushion Foot padding Foot plates Leg padding Armrests Rollboard FES cables | Wipe ^a |
| Leg cuffs Harness Foot straps | Foam spray ^b or washing machine ^c |
| Monitor / touch screen Remote control | Wipe ^a |
| <i>If needed, e.g. due to pollution with body fluids (e.g. sweat, urine, faeces)</i> | |
| Metal components: - Frame - Foot mechanics - Leg mechanics | Wipe ^a |
| Orthopedic material: - Harness (incl. shoulder belts, chest belt, waist belt, leg loops) - Foot straps | Washing machine ^c |
| - Leg cuffs | Remove pollution fluids and visible dirt from textile parts under running water. Avoid rinsing the metal hinges. Wipe ^a carbon and metal parts. Foam spray ^b textile parts until fully soaked. |

^a Includes mechanical cleaning.

^b Surface needs to be fully wet; dry before reuse.

^c Wash with 60°C; use laundry bag; delicate fabric cycle.

3.2 Recommended Disinfectants

When choosing disinfectants, keep in mind the following: (1) health aspects of the staff/patients, (2) material compatibility, (3) instructions provided by the respective disinfectant / cleaning agent.

Hocoma/DIH recommends the use of disinfectants based on quats (Quaternary Ammonium Compounds), since these provide the best material compatibility, are environmentally friendly and economical.

Please note that some quats are too alkaline for certain materials in our products. Always check the label first: quaternary solutions with a pH >10 are not recommended (or need to be diluted). The use of quats (wipes) containing sodium hydroxide (NaOH) is NOT recommended.

Always make sure to remove any soap residues before disinfection/cleaning and to rinse surfaces with a wet cloth afterwards to prevent build-up of residual cleaning chemicals, especially in case of any visual residuals. Lastly, assure surfaces are dry before use.

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.

Hocoma/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.