WARNING
To properly use this medical device, read and comply with the instructions for use and this supplement.

Reprocessing
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Supplement to the instructions for use

WARNING
To properly use this medical device, read and comply with the instructions for use and this supplement.

Instructions for use | Part number | Edition
--- | --- | ---
Babytherm 8004/8010 | 9029458 | 11 – 2010-11 and higher
Babytherm 8004/8010 | 9052336 | 2 – 2010-11 and higher

- Keep this supplement with the instructions for use.

This supplement updates the information of the instructions for use in the following chapters.

Trademarks

<table>
<thead>
<tr>
<th>Trademark</th>
<th>Trademark owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dismozon®</td>
<td>BODE Chemie</td>
</tr>
<tr>
<td>Mikrobac®</td>
<td></td>
</tr>
<tr>
<td>Korsolex®</td>
<td></td>
</tr>
<tr>
<td>Neodisher mediclean®</td>
<td>Dr. Weigert</td>
</tr>
<tr>
<td>acryl-des®</td>
<td></td>
</tr>
<tr>
<td>Mikrozid®</td>
<td>Schülke &amp; Mayr</td>
</tr>
<tr>
<td>Perform®</td>
<td></td>
</tr>
<tr>
<td>Actichlor®</td>
<td>Ecolab</td>
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<tr>
<td>Incidin®</td>
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</tr>
<tr>
<td>Oxyicide®</td>
<td>Ecolab USA</td>
</tr>
<tr>
<td>BruTab 6S®</td>
<td>Brulin</td>
</tr>
<tr>
<td>Dispatch®</td>
<td>Clorox</td>
</tr>
<tr>
<td>Klorsept®</td>
<td>Medentech</td>
</tr>
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<table>
<thead>
<tr>
<th>Trademark</th>
<th>Trademark owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descogen®</td>
<td>Antiseptica</td>
</tr>
<tr>
<td>Oxygenon®</td>
<td></td>
</tr>
<tr>
<td>SteriMax®</td>
<td>Aseptix</td>
</tr>
<tr>
<td>Cleanisept®</td>
<td>Dr. Schumacher</td>
</tr>
<tr>
<td>Rely+On™</td>
<td>DuPont</td>
</tr>
<tr>
<td>Virkon™</td>
<td>DuPont</td>
</tr>
</tbody>
</table>
Reprocessing

Safety information

<table>
<thead>
<tr>
<th>WARNING</th>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk due to inappropriately reprocessed products</strong></td>
<td><strong>Risk due to faulty products</strong></td>
</tr>
</tbody>
</table>
| Reusable products must be reprocessed, otherwise there is an increased risk of infection.  
  – Follow the infection prevention policies and reprocessing regulations of the health-care facility.  
  – Follow the national infection prevention policies and reprocessing regulations.  
  – Use validated procedures for reprocessing.  
  – Reprocess reusable products after every use.  
  – Follow the manufacturer’s instructions for cleaning agents, disinfectants, and reprocessing devices. | Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.  
  – Check the products for signs of wear and replace them if necessary.  
  – Do not use alcohol-based cleaning agents and disinfectants. |

**CAUTION**

Risk due to faulty heating elements

Liquids such as cleaning agents or disinfectants can damage heating elements and cause harm to the patient.

Do not clean the heating elements with a moist cloth or brush.

Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the health-care facility (e.g., concerning the reprocessing cycles).
Classifications for reprocessing

Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-critical</td>
<td>Components that come into contact only with skin that is intact</td>
</tr>
<tr>
<td>Semi-critical</td>
<td>Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin</td>
</tr>
<tr>
<td>Critical</td>
<td>Components that penetrate skin or mucous membranes or come into contact with blood</td>
</tr>
</tbody>
</table>

Classification of device-specific components

The following classification is a recommendation from Dräger.

Non-critical
- Control unit
- Device surface:
  - Bed frame, inside and outside
  - Side panels, inside and outside
  - Inner panels, inside and outside
- X-ray tray and X-ray tank
- Bed canopy
- Scale
- Stand, including all attachments
- Hose grommets
- Gel mattress (Babytherm 8010)
- SoftBed foam mattress (Babytherm 8004)

Before reprocessing

Observe before disassembly
1. Switch off the device and all devices connected to it.
2. Disconnect all power plugs.
3. Remove the installed additional devices and accessories.
4. Remove the mattress from the mattress tray. Always store the gel mattress flat.
5. Remove the flexible hose grommets.
- Before disinfecting/cleaning the radiant warmer, allow it to cool down for approx. 30 minutes.
Reprocessing

Validated reprocessing procedures

Overview of the reprocessing procedures of the components

<table>
<thead>
<tr>
<th>Components</th>
<th>Surface disinfection with cleaning</th>
<th>Machine cleaning with thermal disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device surface including components</td>
<td>Yes (see &quot;Surface disinfection with cleaning&quot;, page 6)</td>
<td>No</td>
</tr>
<tr>
<td>Hose grommets</td>
<td>Yes (see &quot;Surface disinfection with cleaning&quot;, page 6)</td>
<td>Yes (see &quot;Machine cleaning with thermal disinfection&quot;, page 7)</td>
</tr>
</tbody>
</table>

Surface disinfection with cleaning

Components:
- Device surface
- All components

<table>
<thead>
<tr>
<th>Surface disinfectant</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Contact time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dismozon plus</td>
<td>BODE Chemie</td>
<td>1.6 %</td>
<td>15 min</td>
</tr>
<tr>
<td>Dismozon pur</td>
<td>BODE Chemie</td>
<td>1.6 %</td>
<td>15 min</td>
</tr>
</tbody>
</table>

Prerequisites:
- The surface disinfectant has been prepared in accordance with the manufacturer's instructions.
- The manufacturer's instructions, e.g., regarding shelf life or application conditions, are observed.
- An uncontaminated, lint-free cloth soaked in surface disinfectant is used for the cleaning surface disinfection.

Cleaning
1. Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant. Dispose of the cloth.
2. Wipe all surfaces. After that, there must no longer be any soiling visible.

Surface disinfection
3. Wipe cleaned surfaces again to visibly wet all surfaces to be disinfected with surface disinfectant.
4. Wait for the surface disinfectant contact time.
5. At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).
6. Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.
7. Wait until the surfaces are dry.
8. Check the surfaces for visible damage and, if necessary, replace the product.

WARNING
Risk due to penetrating liquid
Penetrating liquid may cause the following:
- Damage to the device
- Electric shock
- Device malfunctions
Ensure that no liquid penetrates the device.
Reprocessing

Machine cleaning with thermal disinfection

Use a washer-disinfector that meets the requirements of the standard ISO 15883. Dräger recommends the use of a load carrier for anesthesia accessories and ventilation accessories. Follow the manufacturer’s instructions for the washer-disinfector.

Components:
- Hose grommets

<table>
<thead>
<tr>
<th>Step</th>
<th>Medium</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Temperature</th>
<th>Contact time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary cleaning</td>
<td>Tap water</td>
<td>–</td>
<td>–</td>
<td>Tap water temperature</td>
<td>Min. 2 min</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Neodisher Medi-Zym</td>
<td>Dr. Weigert</td>
<td>In accordance with the manufacturer's instructions</td>
<td>Min. 55 °C (131 °F)</td>
<td>Min. 10 min</td>
</tr>
<tr>
<td>Neutralizing</td>
<td>Neodisher Z</td>
<td>Dr. Weigert</td>
<td>Min. 0.1 % Tap water temperature</td>
<td>Min. 1 min</td>
<td></td>
</tr>
<tr>
<td>Flushing</td>
<td>Demineralized water</td>
<td>–</td>
<td>–</td>
<td>Tap water temperature</td>
<td>Min. 1 min</td>
</tr>
<tr>
<td>Disinfecting</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Min. 93 °C (199.4 °F)</td>
<td>Min. 5 min</td>
</tr>
<tr>
<td>Drying</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Drying time depends on the load</td>
</tr>
</tbody>
</table>

Prerequisites:
- The washer-disinfector has been prepared in accordance with the manufacturer’s instructions.

Positioning the components in the load carrier

Procedure:
1. Position the hose grommets in a stable position.
2. Ensure the following:
   - All surfaces and interiors can be completely rinsed.
   - The water can drain off freely.

Performing reprocessing
1. Select a cycle.
2. When the cycle has ended, check the components for visible soiling and repeat the cycle if necessary.
3. Check the components for visible damage and replace if necessary.
Reprocessing

Storage and transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

– Store dry and free of dust
– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

Special reprocessing measures

Gel mattress (Babytherm 8010)

Do not reprocess the gel mattress with disinfectants containing glucoprotamine. Disinfectants containing glucoprotamine can cause the material to liquefy.

SoftBed foam mattress (Babytherm 8004)

Carry out cleaning and surface disinfection as required and when there is a change of patient.

– If it becomes heavily soiled, the cover may be machine-washed at 95 °C. Tumble dry up to 95 °C.
– The mattress core may become soiled in exceptional cases. The mattress core (foam) may then be machine-washed at 30 °C using a mild detergent.

Phototherapy filter glass

The filter glass should only be cleaned and disinfected with products with a pH value between 7 and 9.
Other agents and reprocessing procedures

Disinfectants

Use nationally approved disinfectants suitable for the respective reprocessing procedure and field of application.

Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:

- Bactericidal
- Yeasticidal
- Virucidal or virucidal against enveloped viruses

Follow the manufacturer's instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

<table>
<thead>
<tr>
<th>Class of active ingredient</th>
<th>Surface disinfectant</th>
<th>Manufacturer</th>
<th>Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorine-releasing agents</td>
<td>Clorox Professional Disinfecting Bleach Cleaner</td>
<td>Clorox</td>
<td>EPA¹</td>
</tr>
<tr>
<td>Dispatch Hospital Cleaner Disinfectant Towels with Bleach</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actichlor plus</td>
<td>Ecolab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlor-Clean Tablets</td>
<td>helix Solution</td>
<td></td>
<td>ARTG²</td>
</tr>
<tr>
<td>Oxygen-releasing agents</td>
<td>Descogen Liquid</td>
<td>Antiseptica</td>
<td>CE</td>
</tr>
<tr>
<td>Descogen Liquid r.f.u.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygenon Liquid r.f.u.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dismozon plus</td>
<td>BODE Chemie</td>
<td></td>
<td>CE</td>
</tr>
<tr>
<td>Oxycide</td>
<td>Ecolab USA</td>
<td></td>
<td>EPA</td>
</tr>
<tr>
<td>Perform</td>
<td>Schülke &amp; Mayr</td>
<td></td>
<td>CE</td>
</tr>
<tr>
<td>SteriMax Wipes</td>
<td>Aseptix</td>
<td></td>
<td>CE</td>
</tr>
<tr>
<td>Incidin OxyWipes</td>
<td>Ecolab USA</td>
<td></td>
<td>CE</td>
</tr>
<tr>
<td>Robysta</td>
<td>Kyroin (Japan)</td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>Rely+On Virkon</td>
<td>Du Pont</td>
<td></td>
<td>EPA</td>
</tr>
</tbody>
</table>

¹ EPA
² ARTG
Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Other surface disinfectants are used at one's own risk.
After reprocessing

Assembling and fitting device-specific components

Prerequisites:
- All components have been reprocessed and are dry.

Inserting the mattress
- Place the mattress on the mattress tray.

Inserting the hose grommets
- Insert the flexible hose grommets.

Preparation before next use of device

Checking the operational readiness

Prerequisites:
- The device has been assembled and prepared so that it is ready for operation.
- The therapy accessories have been installed.

Procedure:
1. Check the operational readiness; see instructions for use, chapter “Before each use”.
2. Set the mattress heater to 37 °C on Babytherm 8010.
3. Set the radiant warmer to heating level 3 in man. operating mode.