



Instructions for use

## **1002.09C0/D0** **Shoulder support**

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**Subject to technical modification!**

Due to further development of the product, the figures used and technical specifications given in these Instructions for Use may slightly differ from the current state of the product.

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# Contents

<b>1</b>	<b>Introduction .....</b>	<b>5</b>
1.1	How to use these operating instructions.....	5
1.1.1	Abbreviations .....	5
1.1.2	Symbols and formatting .....	5
1.1.3	Definitions .....	6
1.1.3.1	Design of safety notes.....	6
1.1.3.2	Structure of notes .....	6
1.1.3.3	Definition of maximum permitted weight load.....	6
1.2	Symbols used .....	7
1.3	Disposal.....	8
1.3.1	Old products.....	8
1.3.2	Packaging .....	8
1.3.3	Pads and covers .....	8
1.4	Basic requirements.....	9
1.4.1	Use in accordance with the intended purpose.....	9
1.4.2	Applicable standards.....	9
1.4.3	Intended purpose .....	9
1.4.4	Mounting points.....	9
1.4.5	Variants.....	9
1.4.6	Product features.....	10
1.4.6.1	Essential performance.....	10
1.4.6.2	Latex-free materials.....	10
1.4.7	Reportable event.....	10
<b>2</b>	<b>Safety notes.....</b>	<b>11</b>
2.1	General safety notes .....	11
2.2	Safety notes for the product .....	12
2.3	Safety notes regarding the use of accessories.....	13
2.4	Safety notes regarding padding.....	13
<b>3</b>	<b>Operation and use.....</b>	<b>14</b>
3.1	General.....	14
3.2	Mounting the shoulder support to the side rail.....	15
3.3	Attaching the shoulder padding .....	16
3.4	Removing the shoulder support.....	17
<b>4</b>	<b>Cleaning and disinfection .....</b>	<b>18</b>
4.1	General information .....	18
4.1.1	Padding.....	19
4.2	Cleaning agents and disinfectants.....	20
4.2.1	Suitable cleaning agents.....	20
4.2.2	Suitable disinfectants .....	20
4.2.3	Non-usable products / substances.....	20



4.3	Manual preparation.....	21
4.3.1	Pre-cleaning.....	21
4.3.2	Disinfection .....	21
4.3.3	Drying.....	21
4.3.4	Inspections.....	21
4.4	Mechanical preparation .....	22
4.4.1	Basic cleaning and disinfection parameters for chemo-thermal preparation .....	22
<b>5</b>	<b>Maintenance .....</b>	<b>23</b>
5.1	Visual and functional inspections .....	23
5.2	Maintenance .....	24
5.3	Repair .....	24
5.4	Type plate.....	25
<b>6</b>	<b>Technical specifications.....</b>	<b>26</b>
6.1	Ambient conditions .....	26
6.2	Dimensions.....	26
6.3	Weight .....	26
	<b>Index.....</b>	<b>27</b>

# 1 Introduction

## 1.1 How to use these operating instructions

These operating instructions are provided to familiarise you with the features of this product. The operating instructions are divided into separate chapters.

**Please note:**

- Read these operating instructions through carefully and completely before using the product for the first time.
- Always proceed in accordance with the information provided in these operating instructions.
- Store these operating instructions in the vicinity of the product.

### 1.1.1 Abbreviations

EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
SFC	Soft Foam Core (special foam core)
SN	Serial no.

### 1.1.2 Symbols and formatting

Symbol	Meaning
1. 2.	Instructions to follow / list with numbered steps
➤	Result of an action
•	Numbered steps / List entry / precondition
▶▶	Reference to other pages within this document
[...]	Key / Module / Mode
<b>bold</b>	Menu / on-screen button
<i>[italics]</i>	Field to be filled in
1122.33XX	Order number with different variants (XX)




Tab. 1: Symbols and formatting

# 1 Introduction

How to use these operating instructions


## 1.1.3 Definitions

### 1.1.3.1 Design of safety notes

Pictogram	Descriptor	Text
	<b>DANGER!</b>	Identifies an immediate danger to people, which may result in death or serious injuries.
	<b>WARNING!</b>	Identifies a potential danger to people or property, which may result in damage to health or serious property damages.
	<b>CAUTION!</b>	Identifies a potential danger to property, which may result in property damages.

Tab. 2: Design of safety notes

### 1.1.3.2 Structure of notes

Pictogram	Descriptor	Text
	<b>NOTE</b>	Supplementary assistance or further useful information which does not indicate a risk of injury to persons or a risk of property damage are described in the text of the note.

Tab. 3: Structure of notes

### 1.1.3.3 Definition of maximum permitted weight load










The maximum overall load is derived from the proportional patient weight in accordance with inclination.

Depending on the set inclination, the product may be loaded with the following maximum patient weights:






Inclination for TRENDELENBURG position	Up to 15°	Up to 30°	Up to 45°
Maximum patient weight	360 kg	108 kg	67 kg

## 1.2 Symbols used

Symbols are attached to products, type plates and packaging.

Symbols	Labelling
	Labelling of products developed and marketed in accordance with relevant European legal provisions.
	Labelling in accordance with the standard ISO 15223-1. Symbol for "Catalogue number / product number".
	Labelling in accordance with the ISO 15223-1 standard. Symbol for "Serial number".
	Symbol for the labelling of medical devices
	Labelling in accordance with the standard ISO 15223-1. Symbol for "Name and address of the manufacturer". The date of manufacturing can be combined with this symbol.
	Labelling in accordance with the ISO 15223-1 standard. Symbol für "Consult instructions for use".
	Labelling in accordance with the IEC 60601-1 standard. Symbol for "Follow Instructions for use".
	Designation of components that can undergo mechanical chemical-thermal processing.
	Labelling in accordance with the ISO 15223-1 standard. Labelling of packaging materials. Symbol for "Keep dry".

Tab. 4: Symbols

Symbols	Labelling
	Labelling in accordance with the ISO 15223-1 standard. Symbol for "Fragile! Handle with care".
	Labelling in accordance with the ISO 7000 standard. Symbol for "Top".
	Labelling in accordance with the ISO 15223-1 standard. Symbol for "Temperature limit".
	Labelling in accordance with the ISO 15223-1 standard. Symbol for "Atmospheric pressure limitation".
	Labelling in accordance with the ISO 15223-1 standard. Symbol for "Humidity limitation".

Tab. 4: Symbols

## 1.3 Disposal

### 1.3.1 Old products

Getinge will take back used products or those which are no longer in service. For further information, please contact your personal Getinge representative.

Used products or parts thereof may be contaminated. In order to prevent a potential infection, the product must be cleaned and disinfected prior to its return/disposal.

The national regulations and disposal regulations must be observed for all disposal measures.

### 1.3.2 Packaging

The packing materials are made of materials compatible with the environment. The packing material may be disposed of by Getinge on request.

### 1.3.3 Pads and covers

Pads and covers may be disposed of via the household waste.

## 1.4 Basic requirements

### 1.4.1 Use in accordance with the intended purpose

This product is a medical device.

The product is designed solely for the purpose of human medicine.

The patient may only be placed and positioned under medical supervision.

#### Accessories

Accessories or combinations of accessories may only be used as and when indicated in these instructions for use.

Other accessories, combinations of accessories or consumables may only be used if they are designed specifically for the use in question and will not adversely affect either performance features or safety requirements.

### 1.4.2 Applicable standards

The product meets the basic safety and performance requirements in accordance with the local applicable legal specifications for medical devices.

### 1.4.3 Intended purpose

The shoulder support (1002.09X0) is designed to support the patient, especially in the TRENDELENBURG position, immediately prior to, during and after surgical interventions, as well as for examination and treatment. The product may be loaded with a maximum of 20 kg per side.

The product may only be operated by medically trained staff within the OR environment.

Any use other than those described above is deemed not to be in compliance with the intended purpose.

### 1.4.4 Mounting points

The shoulder support may be mounted to all Maquet side rails as well as to all side rails with the following specifications:

- Height: 24.72-28.60 mm
- Width: 9.45-10.20 mm
- Edge shape: Radius of 0.3-1.5 mm or 45° chamfer of 0.3-0.5 mm

### 1.4.5 Variants

The product is available in the following versions:

- 1002.09C0, 190 mm
- 1002.09D0, 250 mm

## **1.4.6 Product features**

### **1.4.6.1 Essential performance**

The product corresponds to IEC 60601-1 and its collateral standards with the following key performance characteristics:

- Ensure positioning quality and comfort using sufficient table top surface and appropriate positioning geometry
- Placement of the patient (or the patient's body parts) without unwanted movement in case of an initial error.

### **1.4.6.2 Latex-free materials**

All used materials (e.g. materials for pads and straps) are latex free.

## **1.4.7 Reportable event**

Any serious incident involving this product must be reported to MAQUET GmbH and, if necessary, to the local competent authority.

## 2 Safety notes

### 2.1 General safety notes



**DANGER!**

**Potentially fatal!**  
**Danger resulting from improper handling.**

Always observe the instructions for use for the OR table.



**DANGER!**

**Potentially fatal!**  
**Risk caused by unauthorised modifications.**

Modifications at the product are not permitted.



**DANGER!**

**Potentially fatal!**  
**Risk posed to the patient's vital functions due to incorrect positioning.**

Position the patient correctly and keep under permanent observation.



**WARNING!**

**Risk of injury!**  
**Improper patient positioning may cause health damage (e. g. decubitus).**

Position the patient correctly and keep under constant observation.



**WARNING!**

**Risk of injury!**  
**Faulty or defective products may result in injuries.**

- Before use, check the proper working order and fully functional state of the product.
- Stop using faulty or defective products and inform the Getinge representative.



**WARNING!**

**Risk of injury!**  
**If the product is mounted to the OR tables of other manufacturers, there is a risk of tipping or of material breakage if the specifications regarding the side rail interface are not observed.**

Always observe the manufacturer's specifications for the OR table.



**WARNING!**

**Risk of injury!**  
**When transporting, when transferring table tops, when adjusting/moving the OR table or transporter, as well as when positioning a patient, there is a risk of crushing and shearing of the personnel, patient and accessories, especially in the vicinity of the positioning modules.**

Make sure that no one is crushed, sheared or injured in any way, and that accessories do not collide with their surroundings.

**WARNING!****Risk of injury!**

If locking elements (eccentric levers, handle screws, locks etc.) are open, the product/accessory can be moved.

Before opening the locking elements, hold the individual items firmly. After every adjustment procedure, ensure that all locking elements are closed.

**WARNING!****Risk of injury!**

When the O.R. Table, the transporter, the table top, or a piece of accessories are moved or adjusted as well as during the take-over procedure of the table top, collisions with the patient, with the involved products, or downward positioned parts may occur.

During the movement always watch the O.R. Table, the transporter, the table top, and the accessories to avoid collisions. Ensure that no hoses, cables, or blankets are squeezed or sheared by moving parts.

**WARNING!****Risk of injury!**

If the patient is not secured, particularly when adjusting/moving, the patient and/or their extremities may slip in an uncontrolled manner.

Always secure the patient using suitable aids (e.g. straps) and maintain continuous observation.

**WARNING!****Risk of burns!**

The use of high-frequency devices, defibrillators and defibrillator monitors exposes the patient to burn risks due to contact with the metal components in the product or accessories and/or as a result of resting on wet drapes or electrically conductive padding.

Avoid any contact between the patient and metal components; never use damp or wet surgical drapes.

Be absolutely sure to comply with the manufacturers instructions for use!

## 2.2 Safety notes for the product

**WARNING!****Risk of injury due to material failure!**

The product may be loaded with a maximum of 20 kg per side. A table top inclination > 15° increases the load on the shoulder support. The patient must be positioned with additional positioning aids and secured to prevent them from slipping.

**WARNING!****Risk of injury!****Loose or loosened securing elements may cause injuries.**

When mounting, and after every adjustment, tighten all of the locking elements (handle screw, locks, levers, etc.) of the product.

Check the firm seating of the locking elements.

**WARNING!****Risk of injury!**

**Whenever the product is mounted and adjusted, there is a danger of pinching and shearing to the staff, patient and accessories.**

Always ensure that no one can be subjected to pinching or shearing action or injured in any other way and that the accessories do not collide with any nearby objects.

**WARNING!****Risk of OR table tipping!**

**The product influences the centre of gravity of mobile operating tables and mobile/independently manoeuvrable columns of operating table systems.**

When positioning the patient, observe the instructions for use of the operating table used.

## 2.3 Safety notes regarding the use of accessories

**DANGER!****Potentially fatal!**

**Patient may be endangered as a result of incorrect use.**

Follow the instructions for use for all accessories.

**WARNING!****Risk of injury!**

**Accessories that are not approved by Maquet for this product, as well as accessories from other manufacturers, may cause injuries.**

Only use Maquet accessories that have been approved for the product. Accessories made by other manufacturers may only be used after obtaining written permission from Maquet.

## 2.4 Safety notes regarding padding

**WARNING!****Health risk!**

For health reasons, the pads must be covered with drapes.

**CAUTION!****Property damage!**

**Pad may be deformed as a result of improper storage!**

Pad should only be stored lying down and at room temperature.

**CAUTION!**

**Improper use can cause property damage!**

Use both hands to remove the padding.

## 3 Operation and use

### 3.1 General



**WARNING!**

**Risk of injury due to overloading!**

**The permitted load of the product depends on the combination of accessories used.**

The product with the lowest permissible load determines the maximum load in the event that it is combined with other accessories.

Refer to the instructions for use of each accessory for the permissible load.

---



**WARNING!**

**Risk of injury!**

**Loose or loosened securing elements may cause injuries.**

When mounting, and after every adjustment, tighten all of the locking elements (handle screw, locks, levers, etc.) of the product.

Check the firm seating of the locking elements.

---



**CAUTION!**

**Property damage!**

During mounting ensure that the clamp is not mounted at the end of a side rail. Place clamp between two side rail screw connections.

---



**NOTE**

The maximum permit weight load cannot be increased by the use of a vacuum mattress.

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**NOTE**

The products are designed to support the patient and, under normal conditions, will not have any immediate contact with the operating area.

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## 3.2 Mounting the shoulder support to the side rail

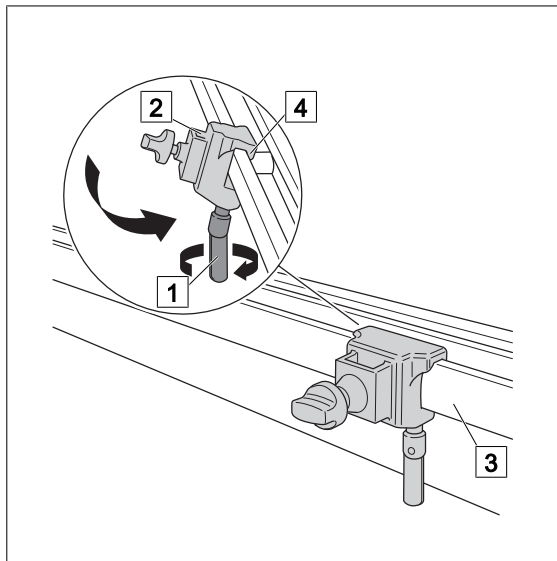


Fig. 1: Putting on the clamp

### Putting on the clamp

1. Open the drop toggle screw [1].
2. Fit the clamp [2] to the side rail [3] in such a way that the two upper hooks [4] of the clamp grip behind the side rail.
3. Move clamp downwards.
  - The clamp is seated fully on the side rail.

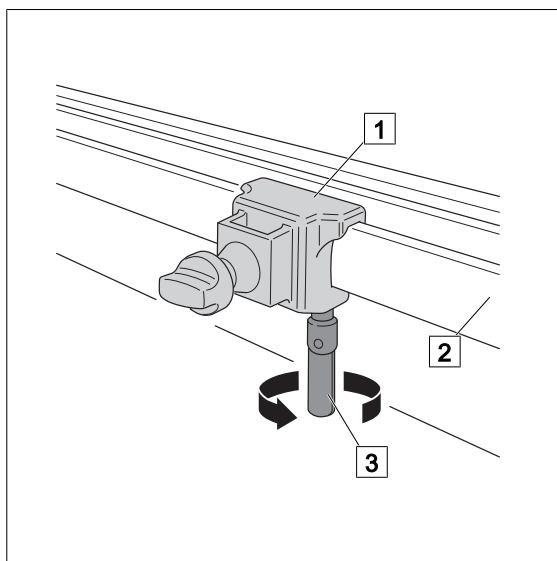


Fig. 2: Fixing the clamp

### Fixing the clamp

1. Push the clamp [1] against the side rail [2].
2. Tighten the drop toggle screw [3] firmly.
  - The clamp is locked.
3. Ensure that the clamp is properly seated.

# 3

## Operation and use

### Attaching the shoulder padding

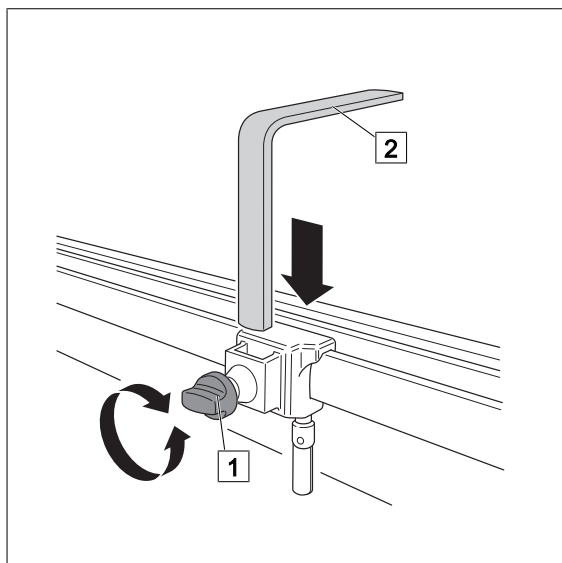


Fig. 3: Mounting the square bar

#### Mounting the square bar

1. Unscrew the handle screw [1].
2. Insert the square bar [2] into the clamp.
3. Tighten the handle screw.
  - The square bar is attached to the clamp.
4. Ensure that the clamp is properly seated.

## 3.3

### Attaching the shoulder padding

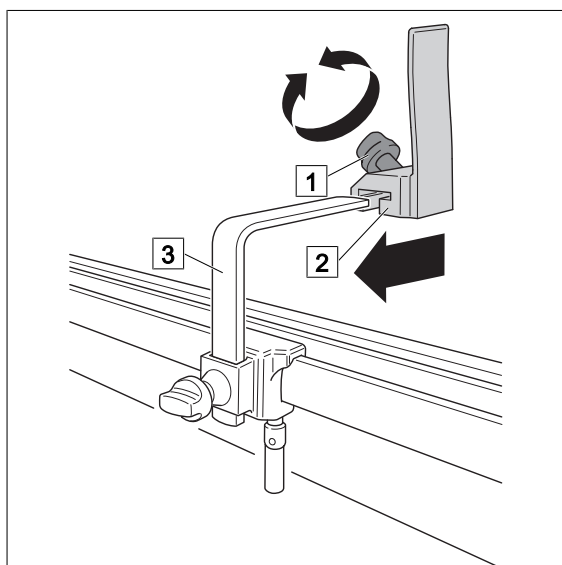


Fig. 4: Mounting the pad holder

#### Mounting the pad holder

1. Unscrew the handle screw [1].
2. Push the clamp [2] of the pad holder onto the square bar [3].
3. Tighten the handle screw.
  - The pad holder is attached to the square bar.
4. Ensure that the pad holder is properly seated.

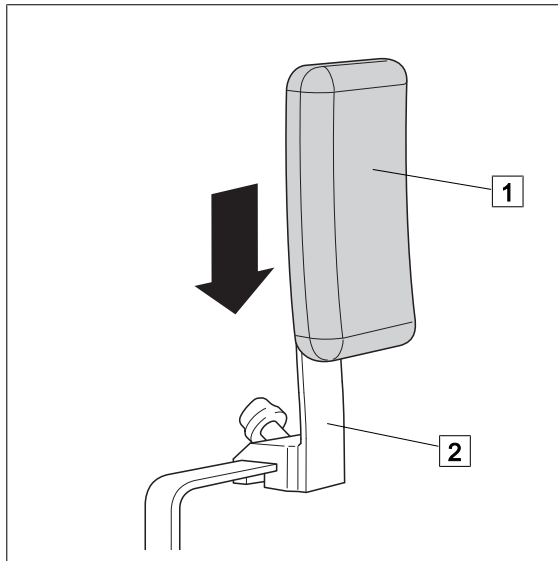


Fig. 5: Attaching the padding

#### Attaching the pad

1. Push the pad [1] onto the pad holder [2].
2. Ensure that the pad is properly seated.

### 3.4 Removing the shoulder support

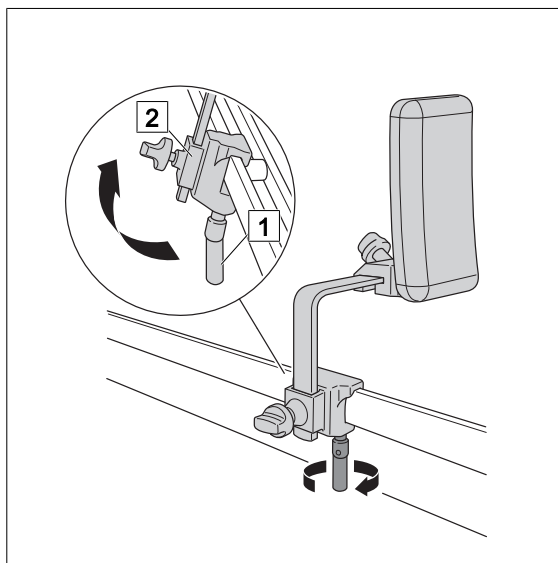


Fig. 6: Removing the shoulder support

#### Removing the clamp

1. Open the drop toggle screw [1].
2. Swing the clamp [2] up and remove.

## 4 Cleaning and disinfection

The product must be cleaned and disinfected after each use. The product can be wiped down to disinfect it.

The product can be classified as a non-critical medical device without increased reprocessing requirements.

### 4.1 General information



#### **DANGER!**

##### **Risk due to mishandling of cleaning agents and disinfectants!**

- The entire cleaning process may only be completed by qualified technicians.
- For information on concentration, temperature and contact and drying times, refer to the instructions of the detergent and disinfectant manufacturer.
- Observe current national and international regulations for hygiene in the medical field.
- Observe the cleaning and hygiene regulations of the hospital.



#### **DANGER!**

##### **Risk of infection!**

**Residues on the product (e.g. blood, secretions etc.) can prevent proper disinfection.**

- Remove coarse impurities from the product immediately with suitable non-fixing agents.
- Adjust the cleaning agent to the disinfectant (using a combination agent if necessary) in order to avoid interactions.



#### **DANGER!**

##### **Risk of infection!**

**Product may be contaminated.**

- Always wear gloves when cleaning / disinfecting.
- If necessary, take further protective measures.



#### **DANGER!**

##### **Risk of explosion!**

**Agents containing alcohol can form explosive vapour mixtures and ignite where high-frequency equipment is being used. The cleaning and disinfecting agents must be dried before use.**

Ensure that there are no alcoholic residues on the product during high frequency use.



**WARNING!**

**Risk of injury!**

If unsuitable cleaning agents and disinfectants are used, the antistatic property and electrical conductivity of the product may be lost, which are required to prevent electrostatic charges as required by the standard.

Only use detergents and disinfectants of the specified active ingredient groups.

---



**CAUTION!**

**Improper cleaning and disinfection can cause property damage!**

- Observe the manufacturer's instructions for concentrations of cleaning agents and disinfectants
  - Perform visual and functional inspections after each cleaning and disinfection process.
- 

**4.1.1 Padding**



**CAUTION!**

**Improper cleaning and disinfection can cause property damage!**

**Moisture can penetrate into damaged padding. Hygienic requirements will no longer be fulfilled.**

Replace damaged padding immediately.

---



**NOTE**

Remove pads which are removable from the product before cleaning and disinfection, then only replace them once they have dried.

---

## 4.2 Cleaning agents and disinfectants

### 4.2.1 Suitable cleaning agents

The cleaning agents must be compatible with the disinfectants used. The use of fixing agents in the cleaning process such as alcohols or aldehydes should be avoided.

Cleaners with the following properties may be used:

- Slightly alkaline
- Surfactants and phosphates as active cleaning components

### 4.2.2 Suitable disinfectants

Use only surface disinfectants with the following active ingredient bases for manual disinfection:

Ingredient group	Active ingredients
Aldehydes	2-ethyl-1-hexanal, formaldehyde, glutardialdehyde, glyoxal, o-phthaldialdehyde, succinaldehyde
Guanidine derivatives	Alkyl-biguanide, chlorhexidine-digluconate, cocospropylene-diamine guanidinium diacetate, oligomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-diimino imido-carbonyl imino-hexamethylene, polyhexanide)
Quaternary ammonium compounds	Alkyl-didecyl-polyoxethyl ammonium propionate, alkyl-dimethyl-alkylbenzyl ammonium chloride, alkyl-dimethyl-ethyl ammonium chloride, alkyl-dimethyl-ethylbenzyl ammonium chloride, benzalkonium propionate, benzalkonium chloride (alkyl-dimethyl-benzyl ammonium chloride, coco-dimethyl-benzyl ammonium chloride, lauryl-dimethyl-benzyl ammonium chloride, myristyl-dimethyl-benzyl ammonium chloride), benzethonium chloride, benzyl-dihydroxyethyl-coco-alkyl ammonium chloride, dialkyl-dimethyl ammonium chloride (didecyl-dimethyl ammonium chloride), didecylmethyl-oxyethyl ammonium propionate, mecetronium-ethyl sulfate, methyl-benzethonium chloride, n-octyl-dimethyl-benzyl ammonium chloride

Tab. 5: Active ingredients of disinfectants

### 4.2.3 Non-usable products / substances

The following products/substances must not be used for cleaning and disinfection:

- Alcohol-based agents (e.g. hand and skin disinfectants)
- Halogenides (e. g. fluorides, chlorides, bromides, iodides)
- Dehalogenating compounds (e. g. fluorine, chlorine, bromine, iodine)
- Products that scratch the surface (e.g. scouring agents, wire brushes, steel wool, cleaning sponges containing iron)
- Standard commercial solvents (e. g. benzene, thinner)
- Water containing particles of iron
- Products containing acid (e.g. hydrochloric acid)
- Saline solutions

## 4.3 Manual preparation



**CAUTION!**

**Improper cleaning can cause property damage!**

Cleaning agents may not be sprayed directly into joints and cracks, and do not use pressure / steam cleaners!



**CAUTION!**

**Improper preparation can cause property damage!**

Use soft, lint-free cloths to prepare the product.

---

### 4.3.1 Pre-cleaning

In case of heavy soiling it is recommended to pre-clean the product with non-fixing agents.

**The following actions are to be carried out as required:**

1. Remove dirt with a slightly alkaline cleaner and a soft, lint-free cloth.
2. Thoroughly clean the product with a soft, lint-free cloth moistened with pure water.

### 4.3.2 Disinfection

1. Select a suitable disinfectant according to the specifications.
2. Use the concentration specified by the disinfectant manufacturer for proper disinfection.
3. Thoroughly wipe the product with a soft, lint-free cloth moistened with disinfectant solution.
4. Make sure that the product is free of impurities.

### 4.3.3 Drying

Wipe-down disinfection does not require any drying, as excess disinfectant evaporates.

1. Observe the drying time specified by the disinfectant manufacturer.
2. Ensure that only dry padding is attached to the product.

### 4.3.4 Inspections

1. Carry out visual and functional inspections.

## 4.4 Mechanical preparation

**DANGER!**

**Risk of injury due to hot surfaces!**

**The product becomes hot during the preparation process and may cause burns.**

Allow the product to cool off following mechanical preparation.

**CAUTION!**

**Material damage due to friction and crevice corrosion!**

**During machine preparation, lubricants are washed out of the joints and moving parts.**

- Lubricate joints and moving parts with appropriate lubricants after preparation.
- Use paraffin oil based lubricants if possible with accessories.
- A lubrication plan can be requested from the responsible Getinge office.

**NOTE**

Only chemo-thermal preparation of products that are approved for this purpose and have the following labelling:

**NOTE**

Mechanical preparation of the product will accelerate the natural ageing process of the materials, and may result in the following material changes:

- Discolouration of components
- Bending of components made of laminated paper

Slight sagging and discolouration of components does not affect proper use.

### 4.4.1 Basic cleaning and disinfection parameters for chemo-thermal preparation

The following parameters must be observed during cleaning:

- Rinsing temperature 50 °C to 60 °C (duration: 255 to 380 seconds)
- Post-rinsing temperature 85 °C to 90 °C (duration: 20 seconds)
- Drying temperature 60 °C (duration: 290 seconds)
- Rinse pressure maximum 1.5 bar (on rinse goods)

The following or comparable cleaners can be used:

- neodisher Dekonta AF, Dr. Weigert
- neodisher BU, Dr. Weigert

## 5 Maintenance

### 5.1 Visual and functional inspections

To ensure correct operation, it is necessary to have visual and functional inspections performed by a trained person prior to each use.

Documentation of the results of the visual and functional inspections is recommended and should include the date and signature of the person who performed the inspections. The following table may be used as a template.

**Suggestion:**

No.	Inspection	Defects are present		No defects
1	Has the product not been cleaned and disinfected in accordance with hygiene regulations?	<input type="checkbox"/>	<ol style="list-style-type: none"> <li>Do not continue to use the product.</li> <li>Clean and disinfect the product in accordance with hygiene regulations.</li> </ol>	<input type="checkbox"/>
<b>Comment:</b>				
2	Are there damages to mechanical parts?	<input type="checkbox"/>	<ol style="list-style-type: none"> <li>Do not continue to use the product.</li> <li>Notify Getinge authorised service.</li> </ol>	<input type="checkbox"/>
<b>Comment:</b>				
3	Is it not possible to complete all adjustments on the product?	<input type="checkbox"/>	<ol style="list-style-type: none"> <li>Do not continue to use the product.</li> <li>Notify Getinge authorised service.</li> </ol>	<input type="checkbox"/>
<b>Comment:</b>				
4	Are there cracks/damages to the product?	<input type="checkbox"/>	<ol style="list-style-type: none"> <li>Do not continue to use the product.</li> </ol>	<input type="checkbox"/>
<b>Comment:</b>				
5	Are there fissures in the padding?	<input type="checkbox"/>	<ol style="list-style-type: none"> <li>Do not use the padding any longer.</li> </ol>	<input type="checkbox"/>
<b>Comment:</b>				

Tab. 6: Visual and functional inspections

No.	Inspection	Defects are present		No defects
6	(Space for other tests)	<input type="checkbox"/>	1.	<input type="checkbox"/>
<b>Comment:</b>				

Tab. 6: Visual and functional inspections

## 5.2 Maintenance

This product is maintenance-free.

Wear caused by use and age may influence the safety-relevant functions of the product. Check the state of the product prior to each use.

If defects are discovered, do not continue to use the product. Inform the relevant Getinge representative for repairs.

## 5.3 Repair

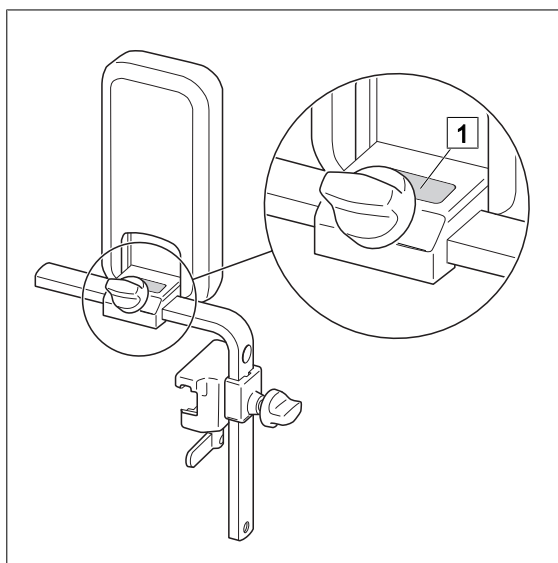
A damaged product may not be used and you may not repair it yourself. Please have the following information at hand for your Getinge representative:

- Description of the defect
- Product number (see type plate)
- If available: Serial number (see type plate)
- Construction year (see type plate)

Hotline for Germany: +49 (0) 180 32 12 144

Hotlines for other countries can be found at [www.getinge.com](http://www.getinge.com).

## 5.4 Type plate



Position of the type plate **1** on the product.

Fig. 7: Type plate position

## 6 Technical specifications

**NOTE**

For dimensions, adjustment ranges and weight specifications, there is a tolerance of  $\pm 5\%$ , if no other tolerance is specified.

### 6.1 Ambient conditions

Temperature: Shipping / storage	-20 °C to + +50 °C
Temperature: Operation	+10 °C to +40 °C
Relative humidity: Shipping / storage	10 % to 95 %
Relative humidity: Operation	30 % to 75 % (non-condensing)
Atmospheric pressure: Shipping / storage	500 hPa to 1060 hPa
Atmospheric pressure: Operation	700 hPa to 1060 hPa

### 6.2 Dimensions

Length	240 mm
Width	240 mm
Height	70 mm

### 6.3 Weight

Net weight	4.2 kg
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**A**

Abbreviations	5
Accessories	9
Air humidity	26
Ambient conditions	26
Applicable standards	9
Atmospheric pressure	26

**C**

Cleaning	18
Cleaning agents	20
CLEANMAQUET	7

**D**

Definition	
Caution	6
Danger	6
Environment	6
Note	6
Warning	6
Descriptor	6
Dimensions	26
Disinfectant	20
Disinfection	18
Disposal	
Cleaning and disinfection	8
Packing	8
Pad	8

**L**

Latex-free	10
------------	----

**P**

Packing	8
Pictogram	6

**R**

Repair	24
--------	----

**S**

Standards	9
Symbols	7

**T**

Temperature	26
-------------	----


**V**

Visual and functional inspections	23
-----------------------------------	----

**W**

Weights	26
---------	----

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