

Instructions for use

## **1130.54B0** **Connection bracket**

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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 instructions for use .....	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
1.4	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 .....	9
1.4.6.1	Essential performance .....	9
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
<b>3</b>	<b>Operation and use .....</b>	<b>14</b>
3.1	General .....	14
3.2	Mounting the connection bracket .....	14
3.3	Removing the connection bracket .....	15
3.4	Mounting accessories to the round pipe mount .....	15
3.5	Mounting accessories to the square mounting point .....	16
<b>4</b>	<b>Cleaning and disinfection .....</b>	<b>17</b>
4.1	General information .....	17
4.1.1	No mechanical preparation .....	18
4.2	Cleaning agents and disinfectants .....	19
4.2.1	Suitable cleaning agents .....	19
4.2.2	Suitable disinfectants .....	19
4.2.3	Non-usable products / substances .....	19
4.3	Manual preparation .....	20
4.3.1	Pre-cleaning .....	20
4.3.2	Disinfection .....	20



4.3.3	Drying.....	20
4.3.4	Inspections.....	20
<b>5</b>	<b>Maintenance .....</b>	<b>21</b>
5.1	Visual and functional inspections .....	21
5.2	Maintenance .....	22
5.3	Repair .....	22
5.4	Type plate.....	22
<b>6</b>	<b>Technical specifications.....</b>	<b>23</b>
6.1	Ambient conditions .....	23
6.2	Dimensions.....	23
6.3	Weight .....	23
<b>7</b>	<b>Approved accessories.....</b>	<b>24</b>
7.1	Table structure.....	24
7.2	Accessories .....	24
	<b>Index.....</b>	<b>26</b>

# 1 Introduction

## 1.1 How to use these instructions for use

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

**Please note:**

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

### 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 permitted weight load is calculated using the proportional load of the weight of the patient, plus the additional load posed by side rail accessories, mounted accessories and/or OR personnel.

## 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 of products that have been placed on the market in accordance with the relevant legal requirements of the United Kingdom.
	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".
	Marking according to the standard ISO 15223-1. 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 for "Consult instructions for use".
	Labelling in accordance with the IEC 60601-1 standard. Symbol for "Follow Instructions for use".
	Labelling in accordance with the ISO 15223-1 standard. Labelling of packaging materials. Symbol for "Keep dry".
	Labelling in accordance with the ISO 15223-1 standard. Symbol for "Fragile! Handle with care".

Tab. 4: Symbols

Symbols	Labelling
	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".
	Marking according to the standard ISO 15223-1. Symbol for "Name and address of the importer".

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 avoid potential infection risks, 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.

## 1.4 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 connection bracket (1130.54B0) is designed to be used to mount head positioning accessories immediately prior to, during and after surgical interventions, as well as for examination and treatment.

The maximum load placed on the product may not exceed the appropriate proportional weight of a 454 kg patient.

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

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

### 1.4.4 Mounting points

The connection bracket may be mounted to the following products:

- OR tables, table tops and accessories from Maquet with a small pin mounting point ( $\varnothing$  18 mm)

### 1.4.5 Variants

The product is available in the following versions:

- 1130.54B0  
Connection bracket

### 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 essential performance features:

- Provision of adjustment functions
- Placement of the patient (or the patient's body parts) without unwanted movement in case of an initial error.

## 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!**  
**Risk caused by unauthorised modifications.**

Modifications at the product are not permitted.



**DANGER!**

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

Always observe the instructions for use for the OR table.



**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!**

**When adjusting and moving the OR table, the transporter, the table top or the accessories, as well as when carrying out a table top transfer, collisions may occur between the patient and individual products or parts that are pointing downwards.**

During adjustments, observe the OR table, the transporter, the table top and accessories constantly and avoid collisions. Ensure that tubes, cables and drapes are not trapped.



**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 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!

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

**Products / accessories not attached properly may loosen and cause injuries.**

Ensure that products / accessories are mounted correctly and that the securing elements (handle screws, catches, levers, etc.) are closed and firmly tightened, also ensure that moving parts are correctly secured.

**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!**

**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.

## 2.2 Safety notes for the product

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

The maximum load placed on the product may not exceed the appropriate proportion of a patient weighing 454 kg.

**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 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.

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**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.

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## 2.3

### Safety notes regarding the use of accessories

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**DANGER!****Potentially fatal!****Patient may be endangered as a result of incorrect use.**

Follow the instructions for use for all accessories.

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**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.

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## 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.

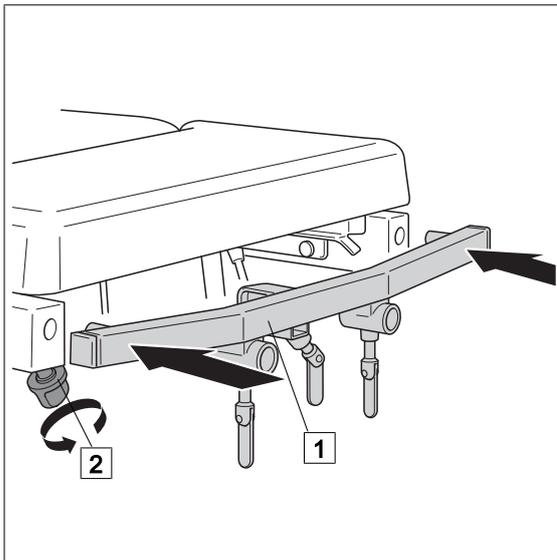


**WARNING!**

**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.

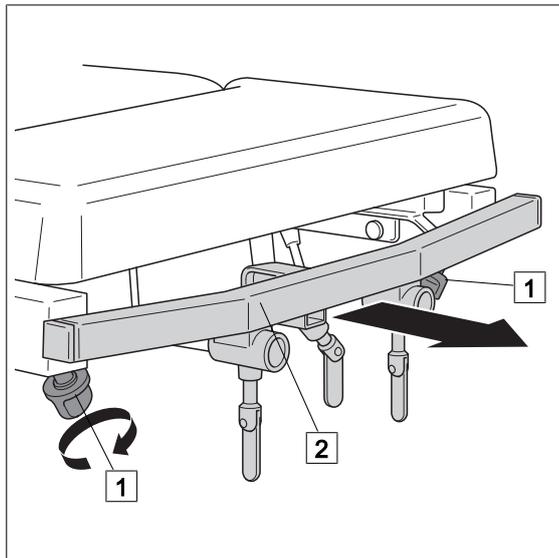
### 3.2 Mounting the connection bracket



1. Slide the connection bracket **1** into the mounting point on the OR table.
2. Tighten both handle screws **2** on the operating table.
3. Check the proper seating of the connection bracket.

Fig. 1: Mounting the connection bracket

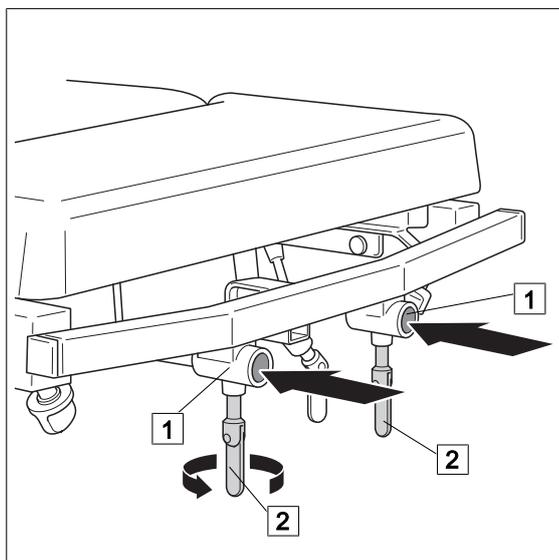
### 3.3 Removing the connection bracket



1. Open both handle screws [1] on the operating table.
2. Remove connecting bracket [2].

Fig. 2: Removing the connection bracket

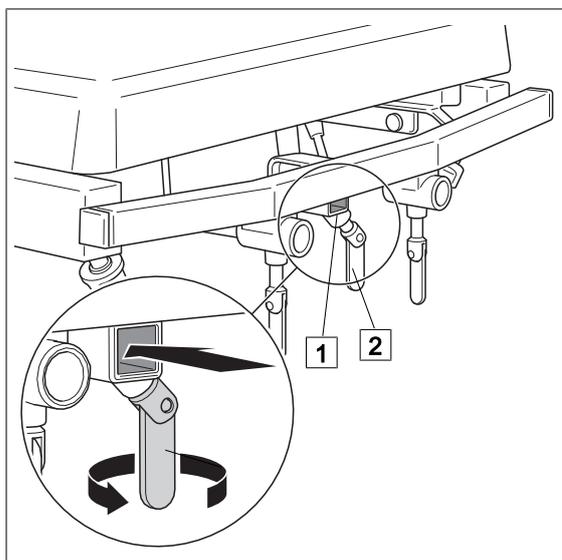
### 3.4 Mounting accessories to the round pipe mount



1. Slide the accessory into the round mounting point [1] of the connection bracket.
2. Tighten both drop toggle screws [2] firmly.  
➤ The accessory is locked.
3. Ensure that the accessory is firmly positioned.

Fig. 3: Mounting accessories to the round pipe mount

### 3.5 Mounting accessories to the square mounting point



1. Slide the accessory into the square mounting point **1** of the connection bracket.
2. Tighten the drop toggle screw **2** firmly.
  - The accessory is locked.
3. Ensure that the accessory is firmly positioned.

Fig. 4: Mounting accessories to the square mounting point

## 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****No mechanical preparation**

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

Do not use any mechanical cleaning or disinfection processes.

---

## 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.

### 4.3.4 Inspections

1. Carry out visual and functional inspections.

## 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	(Space for other tests)	<input type="checkbox"/>	<ol style="list-style-type: none"> <li></li> </ol>	<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

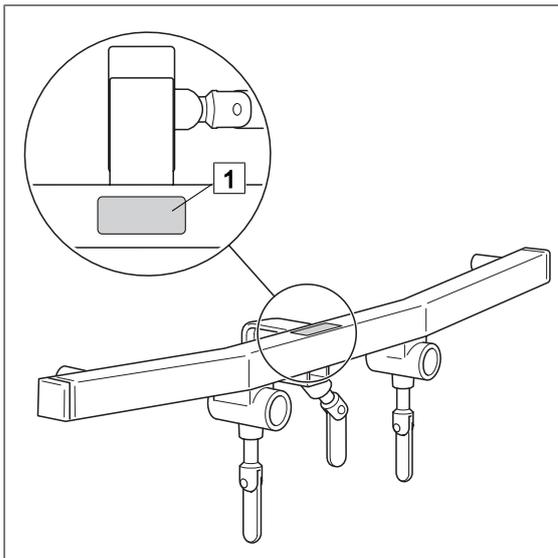
A damaged product may not be used and you may not repair it yourself. Please have the following information at hand for your Getinge representative:

- 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. 5: 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	530 mm
Width	150 mm
Width (across side rails)	140 mm

### 6.3 Weight

Net weight	1.7 kg
------------	--------

## 7 Approved 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 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.

Only accessories listed in this chapter may be mounted to this product.

### 7.1 Table structure

The accessories list for the permitted accessories is structured. This means that the inset accessories are mounted to the above accessories that are less inset.

**Example:**

1130.81A0	Head rest adapter
	1130.54B0 Connection bracket +
	1130.64C0 Head rest

The head rest adapter (1130.81A0) is mounted on the table top. This head rest adapter may have the connection bracket (1130.54B0) or head rest (1130.64C0) attached to it. Other optional accessories may be attached to an accessory, if the accessory has a "+" in the table. For information about the accessories please refer to the relevant instructions for use.

### 7.2 Accessories

1002.06A0	Haslinger head rest
1002.07A0	Head rest adapter
	1002.15A0 Head support for shoulder operations
	1002.6200 Head rest, flat
	1002.71A0 Horseshoe head rest
	1002.72A0 Horseshoe head rest
	1002.73A0 Head rest
	1003.4700 Head support plate
	1005.3600 Special clamps for skull clamp
	1005.3500 Skull clamp +
1002.65A0	Connection fixture
	1002.15A0 Head support for shoulder operations

Tab. 7: Accessories

	1002.6200	Head rest, flat
	1002.71A0	Horseshoe head rest
	1002.72A0	Horseshoe head rest
	1002.73A0	Head rest
	1003.4700	Head support plate
1005.2900	Standard holder	
	1005.3400	Connection clamp for skull clamp
	1005.3500	Skull clamp +
	1005.3600	Special clamps for skull clamp
	1005.3500	Skull clamp +
1005.50A0	Standard holder	
	1005.51A0	Connector
	1005.52C0	Skull clamp
	1005.56A0	Horseshoe head rest
1005.5800	Support arm	
	1002.5800	Connector
	1002.15A0	Head support for shoulder operations
	1002.6200	Head rest, flat
	1002.71A0	Horseshoe head rest
	1002.72A0	Horseshoe head rest
	1002.73A0	Head rest
	1003.4700	Head support plate
1007.16A0/B0	Head rest adapter	
	1002.15A0	Head support for shoulder operations
	1002.6200	Head rest, flat
	1002.71A0	Horseshoe head rest
	1002.72A0	Horseshoe head rest
	1002.73A0	Head rest
	1003.4700	Head support plate

Tab. 7: Accessories



<b>A</b>	
Abbreviations	5
Accessories	9
Air humidity	23
Ambient conditions	23
Applicable standards	9
Atmospheric pressure	23
<b>C</b>	
Cleaning	17
Cleaning agents	19
<b>D</b>	
Definition	
Caution	6
Danger	6
Environment	6
Note	6
Warning	6
Descriptor	6
Dimensions	23
Disinfectant	19
Disinfection	17
Disposal	
Cleaning and disinfection	8
Packing	8
<b>E</b>	
Extension plate	
Mounting	14
Removing	15
<b>I</b>	
Inspection	22
Intended purpose	9
<b>M</b>	
Maintenance	22
<b>P</b>	
Packing	8
Pictogram	6
Preparation	18
<b>R</b>	
Repair	22
<b>S</b>	
Standards	9
Symbols	7
<b>T</b>	
Temperature	23
<b>V</b>	
Variants	9
Visual and functional inspections	21, 22
<b>W</b>	
Weight	23

**Notes**

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