Seba Instructions for Use

ARJOHUNTLEIGH GETINGE GROUP



...with people in mind

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WARNING

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To avoid injury, always read this *Instructions for Use* and accompanied documents before using the product.

Mandatory to read the Instructions for Use.

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EN

Foreword

Thank you for purchasing ArjoHuntleigh equipment.

Please contact us if you have any questions about the operation or maintenance of your ArjoHuntleigh equipment.

Please read and fully understand these *Instructions for Use (IFU)* before using your SebaTM aid.

Information in this *IFU* is necessary to perform the proper operation and maintenance of the equipment. It will help to protect your product and make sure that the equipment performs to your satisfaction. The information in this *IFU* is important for your safety and must be read and understood to help prevent possible injury. Unauthorized modifications on any ArjoHuntleigh equipment can affect safety. ArjoHuntleigh will not be held responsible for any accidents, incidents or lack of performance that occur as a result of any unauthorized modification to its products.

Support

Routine maintenance must be performed on your *Seba* aid every week to maintain safety and reliability of the equipment. See section *"Care and Preventive Maintenance" on page 16.*

If you require further information, please contact ArjoHuntleigh for comprehensive support and maintenance to maximize the long-term safety, reliability and value of the product.

Contact your local ArjoHuntleigh representative for spare parts. The telephone numbers appear on the last page of this *IFU*.

Definitions in this IFU

WARNING

Means: Safety warning. Failure to understand and obey this warning may result in injury to you or to others.

CAUTION

Means: Failure to follow these instructions may cause damage to all or parts of the system or equipment.

NOTE

Means: This is important information for the correct use of this system or equipment.



Means: The name and address of the manufacturer.

Intended Use

This equipment must be used in accordance with these safety instructions. Anyone using this equipment must also have read and understood the instructions in these Instructions for Use (IFU).

EN If there is anything you do not completely understand, ask your ArjoHuntleigh representative.

The ArjoHuntleigh Seba seated-edge-of-bed aid is intended to be used by appropriately trained caregivers in acute and long term care environments to position adult and adolescent patients from a supine to seatededge-of-bed position and back again.

The product should only be used for the purpose specified in these Instructions for Use. Any other use is prohibited.

Patient/resident assessment

ArjoHuntleigh recommends that facilities establish regular assessment routines. Prior to the transfer caregivers should assess each patient/resident according to the following criteria:

- Size
- Mobility Level •
- Medical conditions •
- Ability to understand and respond to • instructions

The Seba aid is intended for patients/ residents:

- Who are able to sit on the edge of the bed
- Who have the ability to lie on their • side
- Whose weight does not exceed 185 kg

If these criteria are not met, an alternative equipment/device shall be used.

Assessment of number of caregivers

Assess how many caregivers are needed based on the patient/resident assessment.

At least two caregivers are needed if the Seba aid is used on:

- an inflated powered mattress
- a mattress in foam material, higher than 18 cm (7 1/8")

Installation requirements

No installation is required.

Expected service life

The expected service life of the Seba aid is 5 years, subject to preventive maintenance being carried out in accordance with the instructions in these Instructions for Use.

Safety Instructions

WARNING

To avoid injury, make sure that the patient is not left unattended at any time.

WARNING

To avoid injury, always follow the allowed combinations listed in this *IFU*. No other combinations are allowed.

WARNING

To avoid injury, always assess the patient prior to use.

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Use on a powered mattress or high foam mattress

WARNING

To avoid injury, pay extra attention to the patient and *Seba* aid when using it on an inflated powered mattress or high foam mattress. Failure to follow these instructions for use, can cause the patient to accidentally fall off the bed.

For best integration with the *Seba* aid, it is recommended to keep the total height of the mattress layers down.

Powered mattress setting

The *Seba* aid can be used on a deflated or inflated powered mattress. Always use the mattress setting mode recommended for ambulatory transfers for the specific mattress used. See respective mattress IFU. It is recommended not to use maximum pressures settings (like AutoFirm and InstaFlate) since this will increase the total height of the mattress.

Usage

When using the *Seba* aid on an inflated powered mattress or high foam mattress (higher than $18 \text{ cm} (7 \text{ } 1/8^{\circ})$):

• Make sure there are at least two caregivers positioned on the transfer side.

- Never let go of the patient when the patient is positioned on the *Seba* aid.
- Be prepared to stop any unwanted sliding of the patient during placement, raising and lowering.
- Be careful not to position the patient too close to the edge of the mattress.
- To raise the patient in bed: One caregiver raises the patient, while the other caregiver supports the patient's legs.



• To lower the patient in bed: One caregiver lowers the patient's upper body, while the other caregiver helps lifting the patient's legs. When lowered, make sure the patient is NOT too close to the edge of the bed.



Preparations

Actions Before First Use (7 steps)

- Visually check the package for damage. If the product looks damaged due to freight, make a complaint to the transport agency.
- 2. The packaging should be recycled according to local regulations.
- Check that all parts of the product are supplied. Compare with section "*Parts Designation*" on page 8. If any part is missing or damaged - do NOT use the product.
- 4. Read this IFU.
- 5. Install the hook according to section *"Hook Installation" on page 7.*
- 6. Disinfect the product according to section "*Cleaning and Disinfection Instructions*" on page 14.
- 7. Choose a designated area, where the *IFU* and Quick Guide should be kept and is easily accessible at all times.

Actions Before Every Use (3 steps)

- 1. Visually inspect the *Seba* aid. If any part is missing or damaged do NOT use the product.
- 2. Assess the patient. See section *"Intended Use" on page 4.*
- Assess if one or two caregivers are needed. See section "Assessment of number of caregivers" on page 4.

In between Use (2 steps)

- 1. To store the Seba aid:
 - use the hook to hang the *Seba* aid by the positioning grip "*Parts Designation*" on page 8, or
 - stand the Seba aid on the floor.
- 2. Disinfect the product according to section "*Cleaning and Disinfection Instructions*" on page 14.

General information

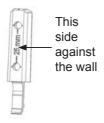
The Quick Guide is equipped with a Quick Response (QR) code. Scan it to get to the *Seba* aid web page.



Hook Installation

Fig. 1

Fig. 2



The hook kit includes:

- 2 brackets
- 2 hooks

Not included:

• Flat head screws (4 mm)

Before installing the hook, make sure the wall properties and the surface are suitable to hold the weight of the *Seba* aid.

Attach the hook kit (4 steps)

- Place the bracket at a height of 140 cm (4 feet 7 inches) or higher, measured from the lower screw hole. (See Fig. 1)
- 2. Mount the bracket so that the arrows are visible and pointing up. (See Fig. 2)
- 3. Slide the hook over the bracket until it snaps into place. (See Fig. 3)
- 4. The hook it is now installed

Detach the hook from the bracket (2 steps)

- 1. Push in the tip of the bracket towards the wall. (See Fig. 4)
- 2. While pushing, pull the hook up.

Arrows up

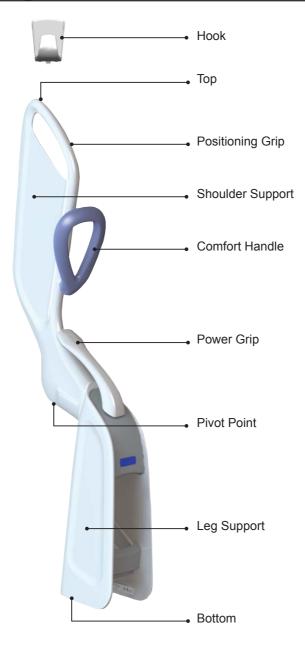
Fig. 3



Fig. 4



Parts Designation



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Product Description/Functions

Directions

• The *Seba* aid can be used on both the left and right side of the bed.

Positioning grip

- The positioning grip can help maximise patient stability. (See Fig. 5)
- Reduces the primary load for the caregiver during raising and lowering in bed.

Shoulder support

- Thin profile for easy positioning.
- Supports the patient.

Comfort handle

This comfort handle is for patient use when using the *Seba* aid and can: (See Fig. 6)

- give the patient reassurance.
- promote patient participation.
- rotate for use on both sides of the bed.

Power Grip

Used to raise the patient from bed for optimal force assistance. (See Fig. 7)

- Provides ergonomic efficiency.
- Rotates for use on both sides of the bed.

Pivot Point

- · Eases and controls the lifting and manoeuvring.
- It aligns with the patient's hip for optimised efficiency.

Leg support

• Keeps lower body free of stress and strain.

How to carry the Seba aid

Carry the *Seba* aid by holding it under the pivot point. (See Fig. 8)



Fig. 5



Fig. 7



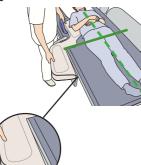




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Raise Patient in Bed

Fig. 9



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Fig. 11



(20 steps)

Preparations

- 1. If any other equipment will be used, place it nearby.
- 2. Apply the brakes on the bed.
- 3. Adjust the bed to an ergonomic height for the caregiver.
- 4. Fold down the side rail (if any) on the transfer side.
- 5. Make sure the patient is positioned centrally in bed or towards the opposite side of the transfer side. ((See Fig. 9)

If not, use local technique to reposition.

Placement

- 6. Place the *Seba* aid underneath the patient's shoulder.
- 7. Align the pivot point with the patient's hip joint.(See Fig. 9)
- 8. Make sure the leg support is placed just outside and parallel to the bed. ((See Fig. 9)

Roll patient onto the Seba aid

- 9. Help the patient to bend their legs.
- Roll the patient onto the *Seba* aid and ask the patient to reach for the comfort handle. (See Fig. 10)
- Help the patient to place their legs on the leg support and make sure they are outside of the bed. (See Fig. 11)
- 12. Ask the patient to hold on to the comfort handle. (See Fig. 11)

Continue with the steps on the next page

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Fig. 13







Fig. 15



Raise the patient using the power grip

- 13. Fold the power grip up and out to a vertical position. (See Fig. 12)
- 14. Take a firm hold of the positioning grip with one hand and the power grip with the other.
- 15. Turn towards the foot end of the bed.
- 16. Raise the *Seba* aid and the patient by pushing the power grip and pulling the positioning grip at the same time. (See Fig. 13)

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CAUTION

Do NOT apply force to the comfort handle during raising. The comfort handle is intended for the patient.

Alternative methods

Bed back raise (See Fig. 14)

- Raise the head end of the bed while keeping one hand on the patient's shoulder.
- Hip Swing (See Fig. 15)
 - Grab the positioning grip with one hand and put the other hand on the patient's hip. Swing the patient up to a sitting position.

Stabilizing

- 17. Support the patient, now sitting on the edge of the bed.
- 18. Adjust the bed height for the patient.
- 19. Carefully, remove the Seba aid.

Disinfect

20. Disinfect the *Seba* aid according to section *"Cleaning and Disinfection Instructions" on page 14.*

Lower Patient in Bed

Fig. 16









(16 steps)

Preparations

- 1. Place the Seba aid close by.
- 2. Apply the brakes on the bed.
- 3. Adjust the bed height for the patient.
- 4. Fold down the side rail (if any) on the transfer side.
- 5. Sit the patient down on the bed, make sure that at least half of the patient's thighs are on the bed.

Placement

- 6. Place the *Seba* aid next to the patient towards the head end of the bed.
- 7. Make sure the Seba aid is (See Fig. 16)
 - on top of the mattress,
 - close to the patient and
 - with the back of the leg support close to the bed side. (See Fig. 17)
- 8. Ask the patient to hold on to the comfort handle.
- 9. Help the patient get positioned. Make sure to:
 - lean the patient forward towards the comfort handle and
 - place the shoulder on the shoulder support. (See Fig. 18)
- 10. Adjust the bed to an ergonomic height for the caregiver.

Continue with the steps on the next page





Fig. 21



Lower the patient using the shoulder grip

11. Lower the patient gently on the bed as follows:

- take a firm hold of the positioning grip with one hand,
- place the other hand on the patient's shoulder and
- pay attention to the patient's legs during the movement so that they don't get stuck or scratched against the bed. (See Fig. 19)

EN

Alternative method

Bed back lowering (See Fig. 20)

• Lower the back rest of the bed from its most upright position while keeping one hand on the patient's shoulder.

Roll the patient off the Seba aid

- 12. Lift the patient's legs onto the bed.
- 13. Make sure to align the bent legs in a centre line along the patient's upper body. (See Fig. 21)
- 14. Use the *Seba* aid to roll the patient onto their back. (See Fig. 22)
- 15. Remove the Seba aid.

Disinfect

16. Disinfect the *Seba* aid according to section "*Cleaning and Disinfection Instructions*" on page 14.

Cleaning and Disinfection Instructions

If you have any questions regarding disinfecting the equipment, or wish to order disinfectant, contact ArjoHuntleigh Customer Service.

The following procedure should be carried out after every use.

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To avoid eye and skin damage, always use protective glasses and protective gloves.

If contact occurs, rinse with plenty of water. If eyes or skin become irritated, consult a physician. Always read the Instructions for Use and Material Safety Data Sheet of the disinfectant.

WARNING

To prevent cross-contamination, always follow the disinfection instructions in this Instruction for Use.

Allowed Disinfectants

- 70% alcohol,
- Chlorine solution of 1000 ppm
- Arjo Clean
- Arjo Disinfectant Cleanser IV
- Arjo All Purpose Disinfectant
- · Arjo CenKleen IV
- Arjo Plus V

Accessories for Disinfecting

- · Protective gloves
- · Protective glasses
- Spray bottle/shower handle with water
- Spray bottle/shower handle with disinfectant
- Cloths
- Soft bristle brush



Fig. 24



Fig. 25



Fig. 26



Fig. 27



Always follow these steps for Cleaning and Disinfection

The Seba aid (12 steps)

- 1. Put on protective gloves and glasses.
- 2. Make sure the disinfectant is mixed according to the instructions on the disinfectant bottle label.
- 3. Remove visible residue.
- Rinse the *Seba* aid with lukewarm water 20-35 °C (68-95 °F).
- 5. Spray detergent on the Seba aid. (See Fig. 23)
- 6. Use a soft bristle brush soaked in disinfectant Scrub the: (See Fig. 24)
 - support areas in contact with patient,
 - positioning and power grip and
 - comfort handle.
- 7. Soak a cloth in disinfectant and wipe all areas of the *Seba* aid. (See Fig. 25)
- 8. Allow a disinfection time according to the instructions on the disinfectant bottle label.
- Rinse the *Seba* aid thoroughly with lukewarm water 20- 35 °C (68-95 °F) until all the disinfectant has been removed. (See Fig. 26)
- 10. Wet a new cloth with water and wipe off all traces of disinfectant left in hidden areas.
- If the disinfectant is tough to remove, spray water on the affected area and wipe it off with a disposable towel. Repeat until all of the disinfectant has been removed.
- 12. Let all parts dry.

The hook (4 steps)

- 1. Wipe down the hook with a wet cloth. (See Fig. 27)
- Soak a cloth in disinfectant and wipe down the hook.
- 3. Wet a new cloth with water and wipe off all traces of disinfectant left on the hook.
- 4. Let it dry.

Care and Preventive Maintenance

SCHEDULE Caregiver Obligations Action/Check	After Every USE	Every WEEK
Clean/Disinfect	Х	
Visually check all parts		Х
Visually check mechanical attachments		Х

Caregiver Obligations

Caregiver obligations shall be carried out by personnel with sufficient *Seba* aid knowledge following the instructions in this *IFU*.

After every use

EN

The Seba aid has to be cleaned and disinfected immediately after every use, see section "Cleaning and Disinfection Instructions" on page 14.

Every week

Visually check all parts.

- Check where contact is made by either patient or the caregiver.
- Make sure no cracks or sharp edges have developed that could cause the patient or caregiver injury or that has become unhygienic causing cross-contamination.
- If any part is damaged, contact qualified personnel.

Check mechanical attachments.

• Check the attachment of the comfort handle and the power grip.

Troubleshooting

If something is wrong with the Seba aid, contact qualified personnel.

Approvals and List of Standards

CERTIFICATE	STANDARDS	EN
EN12182:2012	Technical aids for disabled persons. General requirements and test methods.	
Bio Compatibility	Passed the tests as defined in EN ISO 10993-1:2009.	
CE	Declaration of Conformity CE marking in accordance with the Medical Devices Directive 93/42/EEC. The equipment has been tested and fulfils all essential requirements.	

Technical Specifications

General	
Maximum patient weight	185 kg (408 lbs)
Weight of the Seba aid	4.5 kg (9.9 lbs)
Material	PP (polypropylene), ABS plastic (Acrylonitrile Butadiene Styrene), Aluminium Zinc aluminium alloy

Operating conditions	
Ambient temperature	+5°C to 40°C (41°F to 104°F)
Relative humidity	Not applicable
Atmospheric pressure	Not applicable

Transport and Storage	
Ambient temperature	-20°C to 70°C (-4°F to158°F)
Relative humidity	Not applicable
Atmospheric pressure	Not applicable

Recycling	
Package	Corrugated card board and PE foam recyclable.
The product	Metal and plastic parts shall be separated and recycled according to local regulations.

Allowed Combinations		
Hook	• Hook kit: 8664999	
Medical Beds	 Enterprise 5000 Model: 5000X,5001X, E5000X Enterprise 8000 Model: 8000X, 8001X, 8002X, 8003X, E8000X Enterprise 9000 Model: 9000X, E9000X Minuet 2 Model: 160, 161 Citadel Bed Frame System 	

EN

Allowed Comb	inations	
Medical Beds	 The Seba aid is compatible with a broad range of beds in acute care and long term care settings. The Seba aid is compatible with beds that fulfil the following requests: with a mattress platform where the mattress platform is able to be raised minimum 45 cm (17 3/4") above the floor where the width of bed and mattress are minimum 80 cm (31 1/2") where the combined width from the outer surface of the bed to the edge of the mattress does not exceed 8,5 cm (3 3/8") where elevations (if any) for keeping the mattress in place does not hinder or obstruct the Seba aid movement. 	
Mattresses	 Evolve Pentaflex Range:150SLXXX/XX, 250SLXXX/XXX, 120PMXXX/XXX, 252PMXXX/XXX, POXXX/XXX Nimbus 3 Nimbus 4 Nimbus Professional Autologic 110, 175, 200: PXA001XXX, PXB005XXX, PXB001XXX Alpha Response Alpha Active 3 Alpha Active 4 Alpha Trancell Delux: TRA04, ATD002DAR, ATD001DAR First Step Select: First Step Classic, First Step AirRail First Step All-in-one TheraKair Visio Citadel Patient Therapy System The Seba aid is compatible with mattresses: made of foam material with a maximum height of 21 cm (8 1/4") that are powered replacement mattress systems, with a maximum inflated height of 22 cm (8 5/8") that are powered overlay mattress systems, with a maximum inflated overlay height or 12.5 cm (4 7/8"), combined with a foam base with a maximum height of 18 cm (7 1/8")	
No other combinations are allowed		

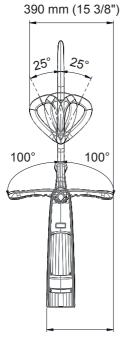
Dimensions

Measurements in mm, and inches (")

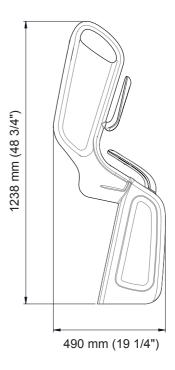
Front View

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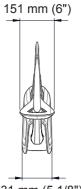
Side View







Top View





Labels on the Seba aid

On the label you will find the following information:

Symbol explanation	
SEBXX-XXXX	Model number
REF	Reference number
SN	Serial number
CE	CE marking in accordance with The Medical Devices Directive 93/42/EEC.
	Manufacturer name and address

~~~	Date of manufacture	
Ĩ	Read the <i>IFU</i> before use	EN
	Maximum patient weight	

# **Spare Part**



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### **GETINGE GROUP**

Getinge Group is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, Getinge and Maquet. Getinge provides solutions for infection control within healthcare and contamination prevention within life sciences. Maquet specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

### ARJOHUNTLEIGH GETINGE GROUP

ArjoHuntleigh focuses on patient handling and hygiene, disinfection, DVT prevention, medical beds, therapeutic surfaces and diagnostics.



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