

**IMPORTANT – KEEP SAFE FOR LATER USE –
READ THROUGH CAREFULLY!**



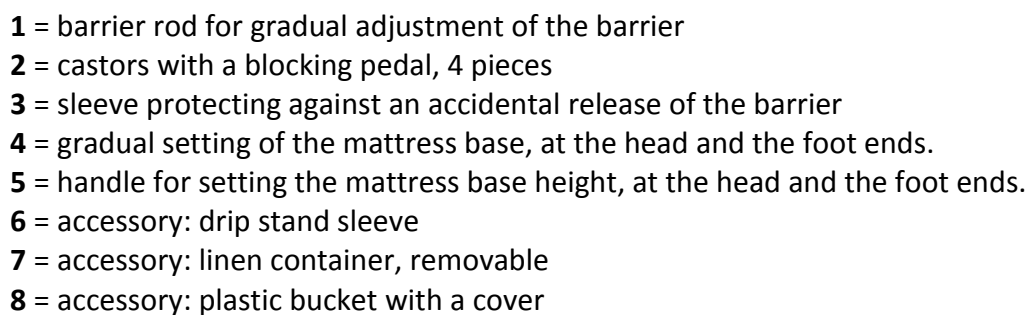
Operating manual

Pediatric bed **JUNIOR**



Date: 2017-01-12

245700_v1



In this manual, the bolded numbers in brackets, () refer to specific components presented in this photo.

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1 INTRODUCTION

Dear Customer,

Stiegmeyer has built this bed to give you the best possible help with the challenges posed by nursing and caregiving. We passionately pursue the goal of developing high-quality durable products. Our beds should make patients and residents feel as safe and comfortable as possible during their stay in bed and also lighten the workload of nursing and care staff. For this reason, the electrical safety and all functions are tested prior to delivery. Each bed leaves our factory in perfect condition.

Correct operation and care are necessary to keep the bed in excellent condition during long-term use. Please therefore read and observe these instructions carefully. It will help you to put the bed into service for the first time and to use it on a daily basis. The instruction manual contains all necessary information to ensure ease of operation and safe handling of this bed, both for you as the operator and for your users. It is a practical reference book and should be kept close to hand at all times.

Even after purchasing a bed, Stiegmeyer is still on hand to help at any time. Our Assist business division can provide you with customised solutions in all matters relating to inspection and maintenance, repair and process optimisation. You can reach our service centre in Germany by phone at +49 (0) 5221 185 - 777. Customers outside Germany can contact our distribution companies in their respective country if they have any questions. Contact details can be found on our website www.stiegmeyer.com.

We wish you and your users every success and satisfaction with the care of your patients and residents.

Stiegmeyer GmbH & Co. KG

Disclaimer

This product is not licensed for use on the North American market. This applies particularly to the United States of America. The distribution and use of the product in these markets, also via third parties, is forbidden by the manufacturer.

2 GENERAL GUIDELINES

Before starting to use this hospital pediatric bed:

- Read carefully the whole operating manual to avoid damages caused by incorrect operation of the pediatric bed.
- Before the first use, clean and disinfect the pediatric bed.
- Our hospital pediatric bed meets all requirements of the Medical Devices Directive 93/42/EEC. According to § 13 of the medical devices act (MPG), it was classified as a class one inactive medical device.
- Before using the pediatric bed, the users are obliged to check if all its functions work correctly and the pediatric bed is in good operating condition. They are also obliged to adhere to guidelines in the operating manual. This also applies to accessories installed on the bed.

This operating manual contains safety guidelines that should be strictly adhered to. All users performing their work using this bed or performing any operations on it must become acquainted with contents of this manual and follow all safety guidelines.

Guidelines for the pediatric bed manager:

- Each technical device can cause hazard when used incorrectly, and therefore you are obliged to train users in correct operation of this hospital pediatric bed.
- The user should also be informed about a place where the operating manual is kept.

2.1 Description of specified groups of people

The following groups of people are mentioned this manual:

Manager

The manager (e.g., clinic, hospital, hospital management) is a natural or a legal person having physical ownership of this hospital pediatric bed. The manager is responsible for safe operation of this medical device.

User

Users (e.g., qualified medical professionals, doctors, nurses, other health care providers) are people authorised, due to their education, experience, or received training to operate the Juniorhospital pediatric bed on their own responsibility, or perform any operations on it, or are people to whom the pediatric bed operation was explained. Furthermore, they can recognise any possible hazard and avoid it. These people can also evaluate patient's clinical status.

Patient


In this operating manual, a patient is understood as a child requiring medical care, ill or disabled, and who lies in this hospital pediatric bed.

2.2. Safety guidelines

Description of the safety symbols used


The following safety symbol is used in this operating manual:

Warning against injury to people


	<p>This is a symbol warning against general danger. There is a risk to life and health of people. Possible damage to material or natural environment.</p>
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The safety symbol used cannot replace the guideline content. Therefore, please read the whole guideline and strictly adhere to it!

Safety information for pediatric bed managers

	<ul style="list-style-type: none"> • Before starting use of this hospital pediatric bed, explain its safe operation to each user. Operational guidelines can be found in this operating manual, which must be delivered to you together with the pediatric bed. • Point to every user possible hazards that may occur during incorrect use of this hospital pediatric bed. This applies, in particular, to incorrect use of side guards. • To ensure long and safe use of this medical device without any hazards to patients, users and third parties, you need to perform your duties. • During long use of our pediatric bed, inspect it after specified time (recommended: every six months) for functioning and visible damage (see also: chapter 6.2.2). • Only trained people can be allowed to operate this hospital pediatric bed. • Ensure that also personnel temporarily substituting the regular one were sufficiently trained to correctly operate the bed. • Ensure the personnel follow the safety guidelines.
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Safety guidelines for users

	<ul style="list-style-type: none"> • Receive operating instructions from the bed manager concerning safe operation of the bed. • Before each use of this hospital pediatric bed, ensure it is in a correct, intact condition (see also: chapter 6.2.1). • When any external electrical components are used, ensure their power cords are not entangled with mobile bed parts to prevent their damage. Guarantee safe operation of the pediatric bed and all external components. • Use the JUNIORhospital pediatric bed only when it is in ideal condition. • This bed is not a toy; do not leave children unattended in the same room in which the bed stands, if they are not in it. • When any electrical heating devices are installed, ensure they will not fall into the bed or on it. Otherwise, for example, due to a device overheating, bedlinen may catch fire and cause hazard to a patient.
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- At the moment of its delivery, the JUNIOR hospital pediatric bed is of the latest start-of-the-art.
- The most important aim of safety guidelines is to prevent personal injuries.

2.3. Product description

2.3.1 Intended use

- The Junior hospital pediatric bed is intended for hospitalised patients for diagnosis, monitoring, treatment or alleviation of diseases.
It is a product for general application (product for long-term use), usually intended to be used permanently for more than 30 days. Considering its operational function, it is used in the health care facilities, including in-patient institutions.
- The Junior hospital pediatric bed is intended for children of maximum height 120 cm.
- During use of this pediatric bed, the safe load is 50 kg, where the patient can weight maximum 45 kg. The remaining 5 kg represents the mattress and installed accessories.
- This hospital pediatric bed can be operated solely and only by people trained in this area.

The Junior hospital pediatric bed can be used only when conditions specified in this manual are observed. Any other use is contrary to the intended use.

2.3.2 Specific parameters

- setting a legs down position (anti-Trendelenburg position) by 7°
- setting a head down position (Trendelenburg position) by 7°
- 135 cm x 68 cm mattress base; external dimensions 167 cm x 80 cm
- base height adjustment from 75 cm to 91 cm
- four castors (Ø 10 cm), all can be blocked

2.3.3 Materials used

The JUNIOR hospital pediatric bed was mainly constructed of steel profiles. All surfaces were covered with polyester powder coating.

All surfaces are safe for skin.

2.3.4. Construction

Mattress base

The mattress base horizontal height can be adjusted. A head or legs down position can also be set.


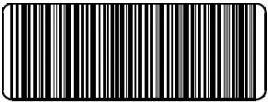



Chassis

The chassis is constructed of welded steel pipes and provided with four castors that can be braked.

Side rails

The JUNIOR hospital pediatric bed is equipped with continuous side rails.

2.3.5 Descriptions of symbols on the product

Symbol	Meaning
	The label caution warning!
	Code label 075.
<div style="border: 1px solid black; padding: 5px; width: fit-content;">To prevent the suffocation risk, Keep plastic packaging in a place out of the reach of infants and children</div>	Packaging label /junior plus
	Mattress height label
	Safe load
	Company logo label

3 PUTTING INTO USE

Each JUNIOR hospital pediatric bed was inspected at the production plant for safety and functionality, and left it in a perfect condition.

The pediatric bed manager is obliged to verify, at appropriate intervals (recommended: every 6 months), by visual and functional inspection that the bed is in good operating condition (see also: chapter 6.2.2).

- Before putting into use, remove all transport protection and film used to pack the bed.
- Remove the protective film from the mattress!
- Before the first use, clean and disinfect the pediatric bed.

Before each use, the user is obliged to ensure that:

- All functions for position and height adjustment work correctly.
- Bed castors are blocked (see also: chapter 4.1).

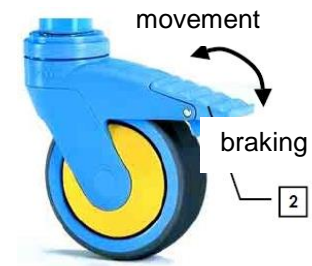
Only then you can start to use our hospital pediatric bed.

4. OPERATION

4.1. Castors

The pediatric bed is provided with four braked castors and can be moved easily. This pediatric bed is not intended for long transport outside a room, along corridors and through threshold, with a child in it.

All four castors are equipped with a pedal (2), to brake them.



Movement: With your foot, lift the pedal towards the castor.

Braking: With your foot, push the pedal down.



When the bed with a child inside is left unattended, brake all four castors.

4.2 Setting height/lowering of a mattress base

The mattress base height of our hospital pediatric bed can be changed in a range from 75 cm to 92 cm, at three positions.

By changing the height on one end of the mattress base, Trendelenburg or anti-Trendelenburg position can be set.



- When a child is left in the bed unattended, then the base must be set in the lowest position, and the safety side rails must be fully raised.
- There is a risk of trapping! Ensure that during adjustments of the mattress base height or position patient's limbs do not reach beyond the base or under it.
- When side rails are used, safety guidelines provided in chapter 4.3.1 must be observed!

Lifting

- With one hand, grab a handle (5) at the base and lift it slightly.
- With the other hand pull a release pin (4) for changing the height.
- The release pin will "catch" automatically at the next step.
- Repeat the above actions on the other side of the bed.




Lowering

- With one hand, grab a handle (5) at the base and lift it slightly.
- With the other hand pull a release pin (4) for changing the height.
- Then lower the mattress base slowly. **Be careful not to drop the base!** The release pin will "catch" automatically at the next step.
- Repeat the above actions on the other side of the bed.

4.3 Side rails

4.3.1 Special safety guidelines for use of side rails

The side rails perfectly secure the patient against undesired falling out from our hospital pediatric bed.


	<p>For the rails to fulfil their intended security function, when the patient is left in bed unattended, the following safety guidelines must be observed:</p> <ul style="list-style-type: none"> • Always pull the safety side rails to their maximum protective height. • Set the mattress base at its lowest position. • Use only and solely rails that are in a good operating condition, undamaged and "catching" strongly! • Use only appropriate, fitting and not too soft mattresses, up to 9 cm thick. • Ensure children in the bed do not wear anti-slip socks with a rubber sole, so-called "ABS socks". Very lively children wearing such socks can climb side rails and fall out of the bed. <p>When these safety guidelines are not observed, there is a risk of a child being trapped by or climbing up the rails.</p>
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To ensure child's safety, the side rails can be set up, one by one, from their lowest position up to the maximum protective position.




Raising and lowering side rails

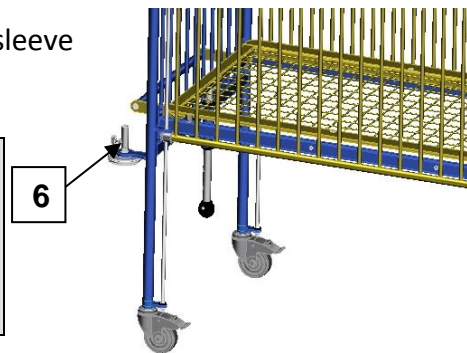
- Bed castors should be blocked.
- By turning a sleeve (3) following arrows in the above figure, a possibility to set the rail at different heights is unblocked.
- With both hands, grab two outermost rail bars (1)
- Pull them towards you as indicated in the figure, to unblock the locks
- Then lower or raise the rail to the desired height, releasing the outermost rail bars (1)
- When the rail is set at the required height, secure it against accidental lowering by blocking the rail bar with the sleeve (3).
- Turn the sleeve (3) all the way in the direction opposite to the one indicated by arrows in the figure.
- The second rail is adjusted in the same way.

	<p>When changing the rail height you must hold the rail strongly with both hands! Otherwise, the rail will drop down. There is a risk of injury!</p> <p>The possibility of unintended lowering of the rail must be prevented as specified in the operating manual!</p>
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4.4 Drip stand sleeve (accessory)

Each buffer rollers can be provided with a drip stand sleeve (6), installed at the production plant or added later.

	<p>For safety reasons, only and solely a drip stand from the STIEGELMEYER company can be used in these sleeves.</p>
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5 CLEANING AND DISINFECTION

The JUNIOR pediatric bed is not intended for mechanical cleaning.

For disinfection, cleaning and disinfecting agents generally used in most of hospitals can be used, including hot and cold water, mild detergents, alkali, alcohol. The bed should be cleaned with a wet cloth.


These agents cannot contain any components modifying the surface structure of plastics.

	<ul style="list-style-type: none"> • Regular cleaning and disinfection is a precondition for ensuring child's hygienic safety. • The chemical disinfecting agents of alkalinity exceeding pH ranging from 6 to 8 should not be used. • Never use corrosive or erosive agents. • Do not use agents that may scratch the bed surface. • Powder coatings are not resistant to disinfection with UV rays - the coating may be discoloured. • Ensure that no liquid deposits are left on metal components of the bed after cleaning/disinfection is finished (avoid drops formed at edges). Otherwise, corrosion may occur in such locations in the future.
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	<p>When these guidelines are not adhered to, significant damage to the device, resulting in its incorrect work, cannot be excluded!</p>
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5.1 Manual cleaning

- Most agents typically used in the hospital and care sector can be used for disinfection by wiping with a cloth, including: cold and hot water, detergents, alkali, and alcohols.
- These agents cannot contain substances modifying the surface structure or adhesiveness of plastic materials.

	<ul style="list-style-type: none"> • Do not use any cleaning agents that are scouring, contain abrasive substances or rough sponges. They can damage the lacquered coating. • Do not use any organic solvents, such as chlorinated/aromatic hydrocarbons and ketones, or cleaning agents containing acids.
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6. MAINTAINING IN OPERATING CONDITION


6.1 Maintenance

These hospital pediatric beds are constructed and manufactured in a way ensuring their safe operation for a long time.

As in case of any other technical device, it is necessary to perform maintenance of the pediatric bed mechanical parts at regular intervals. This will prolong the pediatric bed life.


Maintenance cycle: Before putting any new patient into our bed, inspect all mechanical components. After one year, at the latest, a comprehensive visual and operational inspection of the pediatric bed, together with its maintenance is recommended.

A checklist with items to be verified during maintenance, visual and operational inspection is provided on successive pages.

	<ul style="list-style-type: none"> • When the bed is operated incorrectly, as well as after its long use, damages, defects and other issues resulting from wear cannot be excluded. These defects can be hazardous, if not detected and removed on time. • When any damage or incorrect functioning of our hospital pediatric bed is suspected, immediately withdraw the bed from use, until defective parts are repaired or replaced!
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6.1.1 Checklist of items inspected during maintenance

Action	Means
Check if all screw connections and/or front metal supports are fastened tight, and when necessary, tighten and/or replace them with new ones.	relevant tools
If necessary, clean and slightly spray pivot bearings and friction bearings.	spray for Teflon or oil spray not containing any resins or acids (e.g. Weicon Bio-Fluid)
Coat any area with chipped coating	Acrylic coating of relevant colour (anti-corrosion protection).


	Side rail locking mechanism, verify if operates correctly.
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6.2. Review

The pediatric bed manager is obliged to inspect the used pediatric bed regularly, to guarantee its safe condition.

Test cycle:

We recommend an annual inspection as a standard.

	<p>When the bed is damaged, it should be immediately withdrawn from use, until defective parts are repaired or replaced!</p> <p>Afterwards, the bed should be reinspected in accordance with the report, to confirm the damage or the defect is remedied and the bed can be used again.</p>
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6.2.1 Checklist of items inspected by a user

Inspection		OK	Not OK	defect description
Visual inspection				
Chassis	damages , deformations			
Mattress base	damages			
Side rails	damages			
Optional: acrylic glass inserts	damages			
Operational inspection				
Base height adjustment	setting, whether it holds fast			
Castors	braking, movement			
Side rails	if they "catch" with sufficient strength, and can be unlocked			
Optional: acrylic glass inserts	fast locking			
Signature of inspecting person:		Inspection results:		Date:

6.2.2 Inspection form for hospital pediatric beds

Customer/health care institution/office				
Address:				
The following was performed: <input type="checkbox"/> reinspection <input type="checkbox"/> inspection before putting into use				
<input type="checkbox"/> <input type="checkbox"/> inspection post-repair/ after restoring to the operating condition				
Device type: <input checked="" type="checkbox"/> hospital pediatric bed				
Bed type: Junior Plus		Asset reg. number:		
Location		Serial number:		
Manufacturer: Stieglmeier		Usable parts: none		
Devices used for the inspection (type/asset reg. number):		1.		
Classification according to the medical devices act (MPG): Class I		2.		
I. Visual inspection		OK	Not OK	defect description
Labels and plaques specifying the type	if present, legible			
Bed frame	damages, deformations			
Castors	damages			
Mattress base	damages			
Joints	if not damaged			
Rails, acrylic glass inserts (optional)	damages			
Connecting items	if well fixed, if complete			
Parts subject to quick wear, such as points of theoretical joint	damages			
II. Operational inspection		OK	Not OK	defect description
Joints and pivots	correct cooperation in movement			
Base height adjustment	setting, whether it holds fast			
Castors	braking, movement			
Side rails, optional: acrylic glass inserts	fast locking, if they "catch" sufficiently strong, correct cooperation in movement			
Inspection results:				
All values are within the acceptable range: <input type="checkbox"/> yes <input type="checkbox"/> no			Next inspection date:	
The bed passed the inspection: <input type="checkbox"/> yes <input type="checkbox"/> no				
If the bed did not pass the inspection:				
<input type="checkbox"/> damaged, the bed cannot be used! => to be restored to the operating condition				
<input type="checkbox"/> damaged, the bed cannot be used! => the bed has to be scrapped				
<input type="checkbox"/> the bed does not meet the safety requirements				
Labelled with a validity mark: <input type="checkbox"/> yes <input type="checkbox"/> no				
The following documents are attached to this inspection report:				
Notes:				
Inspection date:		Inspector:		Signature:

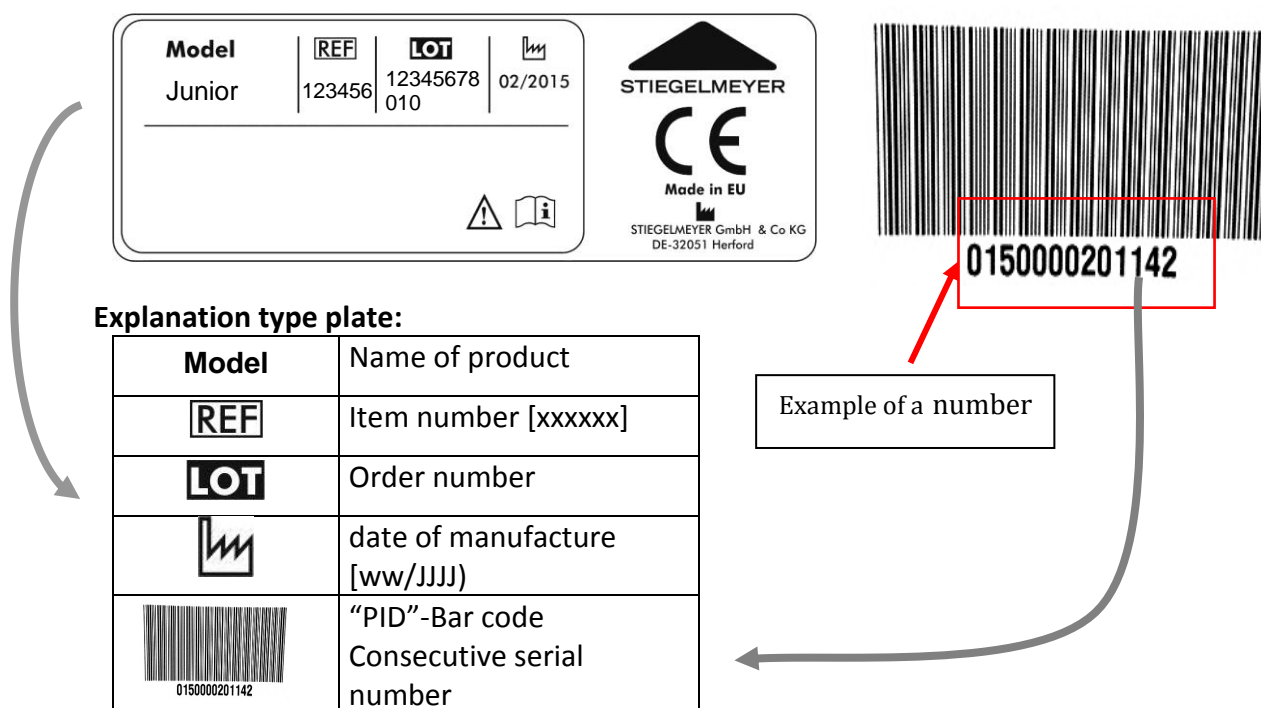
6.3 Spare parts

In order to maintain operational safety and the right to claim under warranty, only original Stieglmeyer replacement parts may be used!

For quick and easy ordering of replacement parts we require the following information from you:

- Customer number

and the following details, which you will find on the type plate and on a separate bar code located on the cross tubing at the head end of the bed.




The diagram illustrates the location of the type plate and barcode on the bed. The type plate contains the following information:

Model	REF	LOT	⚡
Junior	123456	12345678 010	02/2015

Below the table are icons for a warning triangle and a book, and the Stieglmeyer logo with 'CE' and 'Made in EU' markings. The barcode is located on the cross tubing at the head end of the bed, with the number 0150000201142 highlighted in a red box. An arrow points from this box to a box labeled 'Example of a number'.

Explanation type plate:

Model	Name of product
REF	Item number [xxxxxx]
LOT	Order number
⚡	date of manufacture [ww/JJJJ]
 0150000201142	"PID"-Bar code Consecutive serial number

To maintain the bed in a safe operational condition and the guarantee right, only original spare parts from Stieglmeyer should be used!

6.4 Manufacturer's address

To order replacement parts in Germany and for any customer service requirements or other questions, please contact our service department:

Stieglmeyer GmbH & Co. KG

Ackerstrasse 42, 32051 Herford

Phone: +49 (0) 52 21 185-777

Fax: +49 (0) 5221 / 185-219

Email: servicezentrum@stieglmeyer.de

Internet: www.stieglmeyer.com

Customers outside Germany can contact our sales distributors in their respective country if they have any questions. Contact details can be found on our website.

7 ACCESSORIES

Various items from a wide range of accessories can be selected for our hospital pediatric bed. Correct and safe operation of the bed can only be guaranteed when the original Stiegemeyer accessories are used. We can provide a list of accessories available for a given model after receiving information about the pediatric bed type.

Some options are presented below:

Mattress, with breathable textile	Article number: 172155
Linen container	Article number: 913966
Bucket with a cover	Article number: 905467
Drip stand	Article number: 701899
Drip stand holder	Article number: 905469

8 TECHNICAL PARAMETERS

8.1 Dimensions and weight

Dimensions:		Weight:	
Mattress base:	135 cm x 68 cm	Bed weight	ca. 70 kg
External dimensions:	167 cm x 80 cm	(without accessories):	depending
Height:	170 cm		on accessories
Base height adjustment	75 cm x 91 cm	Safe load	50 kg
		during use:	
Side rails height:	105 cm–155.5 cm		
	set gradually		
Castor diameter:	Ø10 cm		

8.2 Requirements for environmental conditions

The following environmental conditions must be ensured:
During use and storage:

	Minimum	Maximum
Temperature:	+ 5 ° C	+ 50 ° C
Relative air humidity:	20 %	90 % (without condensation)

8.3 Applicable standards





- Classification: Class I non-invasive, inactive medical device according to rule 1, in accordance with Annex IX, Directive 93/42/EEC.

8.4. Disposal information



- For all components subject to disposal, the owner is obliged to ensure they are not infectious/contaminated.
- When the bed is scrapped, used plastic and metal parts must be disposed of separately, according to the requirements.
- In case of any questions, please contact your local authorities, disposal companies or our customer services department, at the address specified on page 15.

9. DECLARATION OF CONFORMITY

	EC Declaration of Conformity	 STIEGELMEYER										
<p>We,</p> <p>Stieglmeyer GmbH & CO. KG Ackerstrasse 42, 32051 Herford, Germany</p> <p>hereby declare under sole responsibility as the manufacturer that the product model named below:</p> <p style="text-align: center;">Hospital cot Junior</p> <p>in the version submitted complies with the regulations of the EC Directive 93/42/EEC Annex VII for Medical Devices, last amended by Directive 2007/47/EC dated 5 September 2007.</p> <p>It is categorised as a Class I active medical device.</p> <p>The relevant technical documentation is kept by the manufacturer's safety representative.</p> <p>To evaluate the conformity to the Directives, all applicable parts of the following standards were referred to:</p> <table border="0" style="width: 100%;"> <tr> <td colspan="2">Harmonised standards:</td> </tr> <tr> <td>EN 716-1:2008+A1:2013</td> <td>Furniture and travel cots: Safety requirements</td> </tr> <tr> <td>EN 716-2:2008+A1:2013</td> <td>Furniture and travel cots: Test methods</td> </tr> <tr> <td>EN ISO14971: 2012</td> <td>Risk management for medical devices</td> </tr> <tr> <td>EN ISO 10993-1:2009+AC:2010</td> <td>Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management</td> </tr> </table> <p>Herford, 2017-01-10</p> <div style="display: flex; justify-content: space-around; margin-top: 50px;"> <div style="text-align: center;">  <p>Georgios Kampisiulis Kemmler (Management)</p> </div> <div style="text-align: center;">  <p>Hans-Peter Löw (Management)</p> </div> </div>			Harmonised standards:		EN 716-1:2008+A1:2013	Furniture and travel cots: Safety requirements	EN 716-2:2008+A1:2013	Furniture and travel cots: Test methods	EN ISO14971: 2012	Risk management for medical devices	EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management
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EN 716-2:2008+A1:2013	Furniture and travel cots: Test methods											
EN ISO14971: 2012	Risk management for medical devices											
EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management											

IMPORTANT! - KEEP FOR FURTHER USE - READ CAREFULLY**Warnings:**

- a) Be aware of risks posed by open flame and other strong sources of heat, including electrical or gas radiators placed near the bed.
- b) Do not use the bed if any of its components is damaged, torn or missing; use only components approved by the manufacturer.
- c) Do not leave anything in bed and do not place the bed near any other equipment that can be used as a support for foot or cause a risk of child's suffocation or hanging, such as cables, curtain or blind cords.
- d) Do not use more than one mattress in the bed.
- e) To prevent a risk of child's suffocation, before the first use remove plastic packaging from the product. Destroy the packaging or keep out of the reach of children and infants.

Note:

- f) It is recommended to brake at least two castors during use.
- g) It is recommended for the mattress height not to exceed the safe height indicated with a label on the leg.
- h) The lowest position of the bed base is the safest when the child begins to sit up or stand up without assistance.
- i) When a child is left in the bed unattended, always check if the side rail is blocked in its highest position.
- j) The label indicates the maximum mattress thickness of 9 cm.
- k) The mattress length and width should ensure the gap between the mattress and the bed sides and ends does not exceed 3 cm.
- l) To prevent any injury to a child caused by falling, the bed should not be used when the child can climb up and leave the bed.

Distributor

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