User manual and technical description

MIMI

Infant bed

CE

D9U001310-0101
Version 04
Publication Date: 2019-08

Manufacturer:

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Mimi
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Related links: www.linet.cz

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Dear Customer,
Thank you that you have decided to buy a product of our company and we believe that you will be satisfied with it throughout the whole period of its use. Thanks to careful selection of materials, up-to-date technologies and careful work of our employees our products achieve parameters that guarantee high quality, reliability and permanent utility value.

Table of Contents

1 Introduction

1.1 Manual direction

This manual is not addressed to nursing staff trained in pediatric care only, but to any person entrusted to look after and to take care of infants.

1.2 Application

Mimi is mechanically positionable pediatric bed for hospital and home care. It is intended for safe laying of neonate or small infant in bed. The bed provides safe position and positioning of child and easy transport of child in bed.

The Product is in conformity with safety regulations according to Medical Products Act (MPG) and bears CE label according to EU directions 93/42/EHS for medical products.
The producer proceeds in conformity with certified quality management system according to EN ISO 9001, EN ISO 13485, EN ISO 14001 standards determining stricter conditions for medical equipment manufacturers.

1.3 Mattress

Mimi bed is designed for the following mattress dimensions:

- 65 cm x 35 cm x 3 cm

2 Delivery

The infant bed is delivered completely assembled or the authorized personnel assemble it in site. Check delivery completeness according to delivery list. Any deficiency or defect should be immediately notified to the forwarder and to the supplier and recorded in delivery list.

3 Safety instructions

WARNING!

This is a warning symbol
Prior to using the mattress system the carer should be familiarized themselves with the operation of the bed as detailed in this User Manual. All operations of the mattress system should be done in accordance with this Manual! Any other operation being in discrepancy with the user manual or the purpose of the bed is carried out at the user's risk and the supplier shall not be liable for any possible damage or injury.
It is important to ensure the manual is available to the user throughout service life of the mattress system!

NOTICE!

The basic briefing of mattress handling will be guided by supplier or trained person.

NOTICE!

The supplier cannot be responsible for damages, injuries, accidents or casualties generated by virtue of incautious, neglectful or incorrect handling.

It is important to read this safety instruction prior any use of infant bed and to observe it.

Mimi bed should be left in its lowest position when the patient is unattended in order to reduce risk of injury due to falls!

WARNING!

When routing cables from other equipment in the Mimi bed avoid squeezing those between parts of the Mimi bed!

WARNING!

Mimi bed should not be used with bed hoists and bed lifts!

WARNING!

Infant bed can be used on flat and solid floors only.
Adjusting any position take care there are no persons, body parts or any objects close to moving parts.
Whenever the infant bed is out of use, make sure that the castors are braked.
The infant bed can be used for infants weighting max. up to 15 kg

NOTICE!

As need can be (to change parts), the simple assembly can be done by persons trained by service staff.

4 Technical parameters

Dimensions	ca. l = 92 cm w = 57 cm h = 102 cm
Height adjustment	64 – 94 cm (continuous by gas spring)
Weight	ca.21 kg including infant tub
Trendelenburg / anti–Trendelenburg	ca.14° / 14°
Infant tub	ca. l = 79,5 cm w = 46,5 cm h = 22 -29 cm

5 Environmental conditions

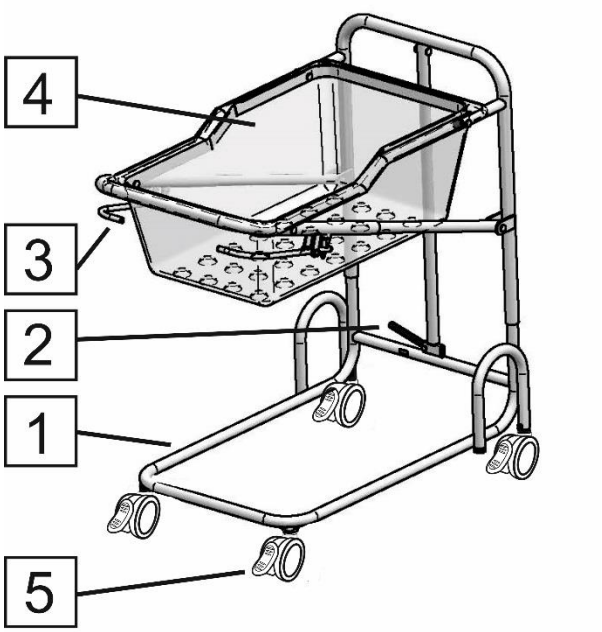
- the ambient temperature ranges from + 10℃ to + 40° C
- the relative humidity ranges from 30% to 75%, Non-Condensing
- the atm. pressure ranges from 795 hPa to 1060 hPa

5.1 Transport and storage conditions:

- Ambient Temperature: -10℃ to +40℃
- Relative Humidity: 10% to 100%

Any use outside these conditions must be discussed with the supplier.

6 Description



1. Undercarriage
2. Control pedal for height adjustment
3. Tilting
4. Infant tub
5. 4 braked castors

Picture No.1 — *Description of Mimi bed*

6.1 Function

According to the modification the following positions of infant bed can be set by tub or height adjustments:

1. Height (due to gas spring)
2. Trendelenburg / Anti-Trendelenburg (due to mechanical spring)

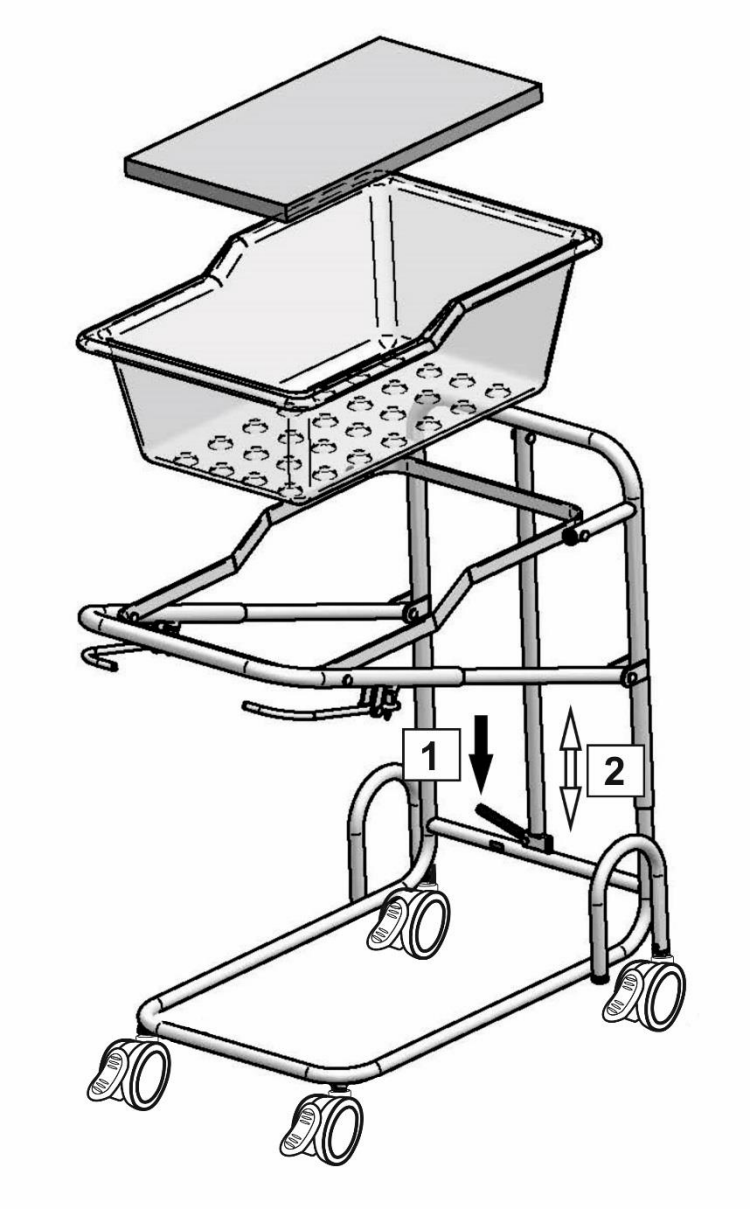
Adjustments are done mechanically – by control levers

Functions check

Prior any use of a new infant bed check bed functions, i.e. check if all positions can be reached (positions adjustment according to the model), and if the movement is smooth.

7 Positions adjustment

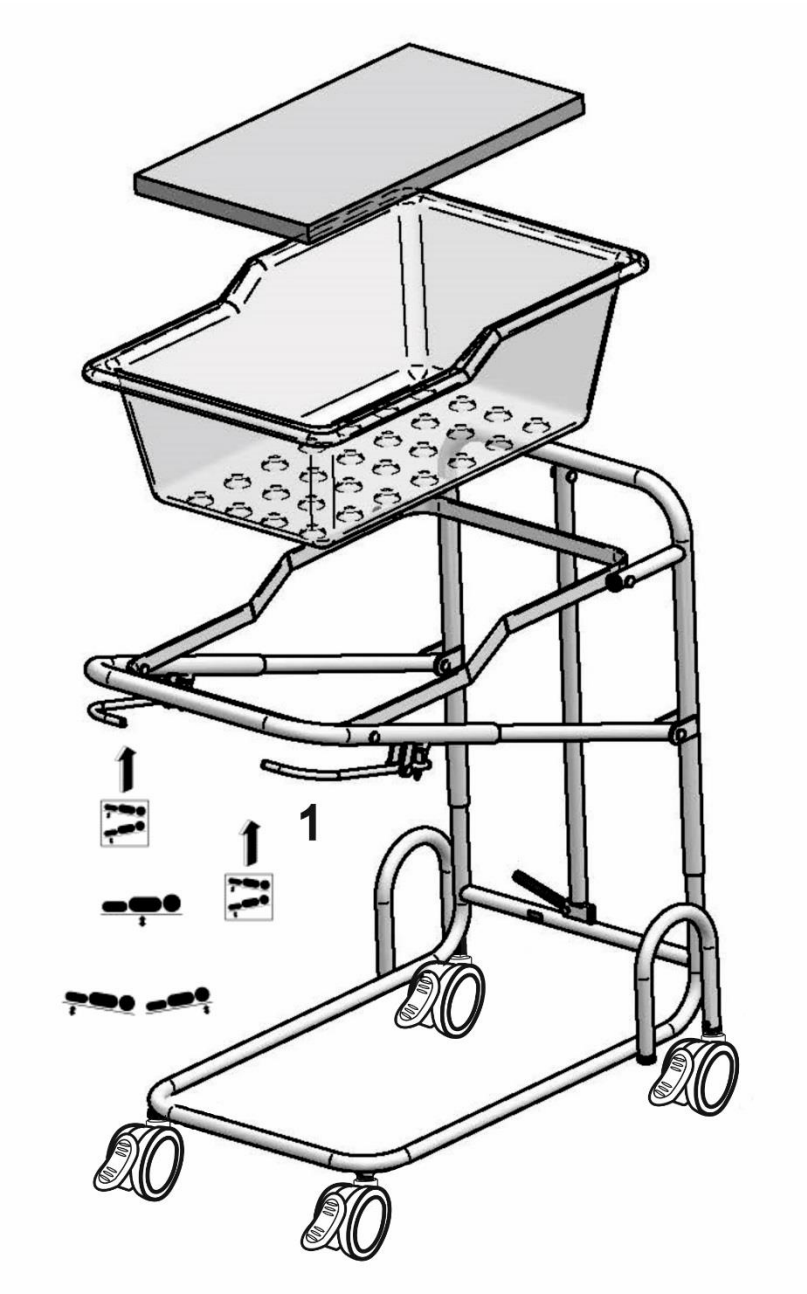
7.1 Height adjustment



Picture No.2 — *Height adjustment by Mimi*

Tread on pedal (1) and pull the metal frame vertically (arrow 2) and set the required height of basket.

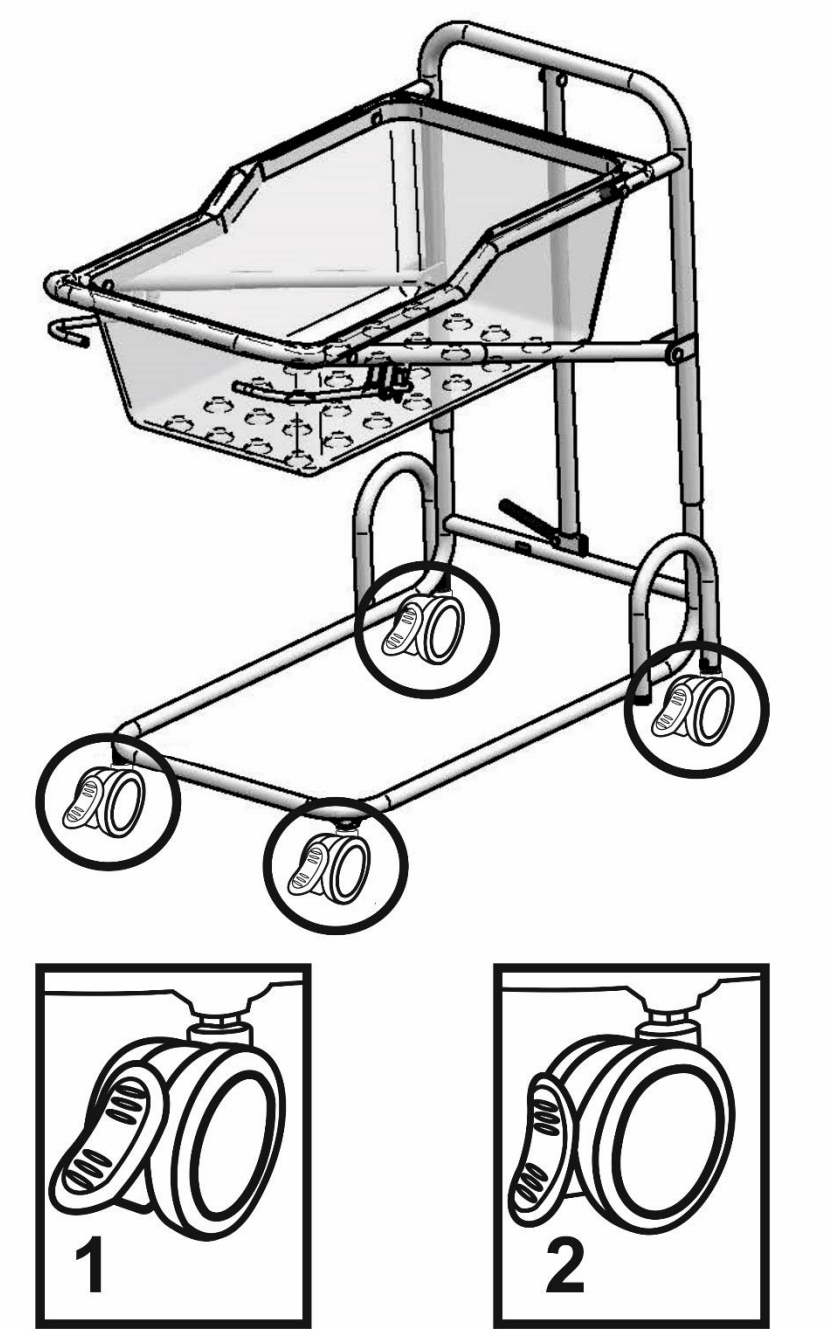
7.2 Trendelenburg / anti-Trendelenburg tilting



Picture No.3 — *TR/ATR. Tilting adjustment*

1. Head rest down
   - Drag safety lock (1) towards the handle in arrow direction, release the handle lock, pull up and set the required position.
2. Leg rest down
   - Release handles safety lock, push down and set the required position.

7.3 Castors braking



Picture No.4 — *Castors braking*

- released – see detail 1
- braked – see detail 2

8 Assembly

As need can be (to change parts), the simple assembly can be done by persons trained by service staff.

9 Cleaning instructions

Prior first use clean the infant bed by dry cloth.

9.1 Germicide / sterilization

Prior to any use the infant bed the germicide should be done. First disconnect the bed from electric power. The bed can be completely cleaned and germicide done by usual detergents and germicides in concentrations stipulated for medical care (0,5% PERSTERIL, 1% CHLORAMIN etc).
For germicide use following recommended agents or equivalents:
Terralin, Perform and Sargotan Med (Schülke &Mayr GmbH, Norderstedt).
For use of such germicides strictly observe instructions given by the producer! Especially care of dosage. For cleaning do not use abrasives or solvent agents, otherwise the tub surface can be damaged or corroded.

10 Troubleshooting

Fault	Probable cause	Action
The position setting cannot be mechanically changed	Mechanics are blocked	Check moving parts and remove cloth pieces or other object or materials in conformity with the manual for use
The position adjustment cannot be done or some position cannot be locked	Mechanics defect, moving parts can be bent	The defect parts should be changed by authorized persons. Do not use the bed till servicing!

11 Storage

For infant bed storage obey following:
The infant bed should be always covered in a manner eliminating damage or enamel scratches.

12 Maintenance

The bed maintenance should be done at least once in 24 months. If any arising fault is found and cannot be eliminated, set the bed out of use. The maintenance check should follow next steps:

12.1 Completeness

According to the Delivery list visually check if any part is missing and therefore reordered or replaced.

12.2 Wear

The infant bed has to be regularly checked if there are no abrasions, scratches or other damages. Their cause should be identified, faults eliminated and faulty parts exchanged. The position adjustment and locking have to be always smooth.

12.3 Functionality

Check if all position adjustments can be done up to extreme positions.

12.4 Castors

Check castor functions and remove dust, threads, hairs or other winded up materials.

13 Environmental Protection

The company LINET, spol. s r.o. is aware of the necessity to protect the environment for future generations and therefore devotes great attention to the development, innovation – planning, production and use of such technology and materials that are environmentally friendly.

This product is constructed from materials that are environmentally friendly! The product does not contain dangerous substances based on cadmium, mercury, and asbestos, PCB or CFC! The operational noise-level of the product meets the requirements for the protection of public health against undesirable noise and vibration in protected indoor building premises. Wooden parts used in the product are not made from exotic wood such as mahogany, jacaranda, ebony, teak, grenadil or santo, and do not come from the Amazonian rainforests or other virgin forests.

All waste packaging left over from when the product is made operational is marked in accordance with the legal regulations on packaging. Sort the waste packaging, which is left over once the product is made operational by following the graphic symbols and deliver it to a person authorized to further utilize it.

The product contains recyclable steel, plastic and electronic components – to optimize recycling once the operation of the product ends, separate the individual parts so that the raw materials from which the product is made can be put to further use (see CHART).



The product may contain lead accumulators (AKB) marked with this graphic symbol:
Once the service life of these accumulators ends, deliver them to a person authorized for recollection (you will not have to pay a recollection charge!).

The product is not designed for removal as part of communal waste!

13.1 Information for the users of electric and electronic equipment (see CHART)

This symbol on the product or accompanying documentation means that the electric or electronic components used (waste from electric and electronic equipment = OEEZ/WEEE) may not be disposed of (destroyed) together with communal waste. In order to correctly eliminate the entire product, deliver OEEZ/WEEE to the workplaces of firms specialised in this task, where they will be accepted free of charge

By removing this product appropriately you will help preserve valuable natural resources and help prevent potential negative effects on the environment and human health, which could result from the incorrect destruction of waste. You can request further details from authorized environmental protection authorities, or the closest collection point for separated waste collection

Fines may be imposed under national regulations if an incorrect procedure for waste removal is used.

Information for users about the removal of electric and electronic equipment in other countries outside the European Union:

The symbol shown above is valid only in the countries of the European Union. You can apply to your authorities or the equipment seller for detailed information about the correct way of removing separated OEEZ/WEEE (electric and electronic equipment) and lead accumulators.

Protect your health and the environment. Thank you

14 EC Declaration of Conformity

EC DECLARATION OF CONFORMITY	Number:	PSEN0025
	Version:	03

1. Product - instrument Type / Model:

Electrically operated hospital bed – ***Mimi / 131***

2. Name and address of the manufacturer:

Commercial name	**LINET spol. s r.o.**
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
Reg. No.	00507814
Telephone	+420 312 576 111
Fax	+420 312 522 668

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of declaration:

Product:	**Mimi**
Description and function designation:	Mechanically operated infant crib intended for neonatal and/or postneonatal departments (standard care, acute care and long term care). This EC conformity declaration also covers all applicable accessories approved by manufacturer.
Classification of the product as the medical device:	**Class I** non sterile, without measuring function, according to annex IX of Government Order No.54/2015 Coll. (MDD 93/42/EEC) – rule 1

5. The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Act No. 268/2014 Coll., on Medical Devices (Directive 93/42/EEC)
- Act No. 350/2011 Coll., on chemical substances and mixtures (Regulation (EC) No 1907/2006)
- Government Order No.54/2015 Coll., with is specifies technical requirements for medical devices (Directive 93/42/EEC)
- Applicable requirements of Government Order No.176/2008 Coll., on machinery devices (Directive 2006/42/EC)

6. References to the relevant harmonized standards used or references to the other technical specifications in relation to which conformity is declared:

EN ISO 14971:2012, EN ISO 10993-5:2009, EN ISO 10993-10:2013

Place and date of declaration issue: Slaný, 20.07.2018

Signed for and on behalf of **LINET spol. s r.o.**

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Ing. Tomáš Kolář, Managing Director

Z S01P10_6, Verze 03

CE

15 Appendix I - Record of service checks and routine maintenance

PURPOSE AND DESCRIPTION OF WORK	DATE	TECHNICIAN

16 Appendix II – Mattress System Handover Protocol

Order No.:

Purchaser:

Model No.:

Supplier:

Handover date:

Serial No.:

I confirm that the training of attending staff on the use of the mattress system has been completed.
Warranty period:

.....	.....	.....
Date	Stamp and signature of Supplier	Stamp and signature of Purchaser

This handover protocol confirms the start of the warranty period.

Always quote order number or products in any communication with the supplier.