





# Instructions for use

# Nemo

5100 5100

### Shower-toilet chair

Basic UDI-DI: 872025610304251005100DP





# Important:

Read these instructions carefully before using the Nemo!

Date first used	 	 
User	 	 
Name	 	 
Address	 	 

### Manufacturer

Lopital Nederland B.V. Laarakkerweg 9 5061 JR Oisterwijk T +31 (0)13 5239300 www.lopital.nl info@lopital.nl

All of the aids produced by Lopital fulfil the following norms for medical products Class 1 (MDR (EU) 2017/745).

Explanation of symbols in 'instructions for use' and on labels				
<u>(i</u>	Note	(3)	Follow the instructions for use	
$\sim$	Date of production		Read cleaning and disinfecting protocol	
MAX LOAD	Maximum load		Antibacterial	
GTIN	Global trade identification number	1	Temperature	
SN	Serialnumber	<b>***</b>	Air pressure	
		<b>%</b>	Humidity level	

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# 1. Introduction

#### 1.1. Introduction

The Nemo tilting shower-toilet chair is a medical device for caring for and washing clients in an ergonomically responsible manner. For both the client and the carer, the comfort is optimal. The Nemo can be used with a commode pan / bucket or in combination with a toilet, can also be used as a toilet seat. The Nemo consists of a base and a chair section. The seat section has the same comfort as a normal chair and offers the same proper support.



The frame of the Nemo has an antibacterial coating. The coating contains silver ions. Antibacterial coating based on silver ions prevents dangerous micro-organisms such as bacteria, fungi and algae multiply and spread. The effectiveness was confirmed in several tests. Germs were demonstrably reduced in a short time to 99.99%. The coating only affects bacteria that are found on the surface and not on airborne microorganisms. The coating protects users or others from disease-causing bacteria, germs, viruses or other harmful organisms. On a dirty surface, the coating loses its antibacterial properties. So proper cleaning and disinfection is still a must.

The expected technical lifetime of the Nemo is 10 years, provided that daily and periodic maintenance is carried out according to the specified maintenance schedule (See chapter 4. Cleaning and maintenance).

The Nemo is a medical class 1 product with CE marking. This marking is in accordance with the regulation MDR (EU) 2017/745.

# 1.2. Safety



A failure to comply with the following safety points and the further definitions in these instructions for use could lead to hazardous situations. Please read carefully before use.

Use

- Make sure that the Nemo brake is applied before transferring clients.
- · Notify the client before moving the Nemo.
- · Close the armrests with front closure before moving the Nemo upwards or tilting it.
- Beware of obstacles when tilting the seat frame.
- Make sure that the client always places his / her arms on the armrests provided to prevent possible entrapment.

- · Keep the armrests or front closure down / closed when moving the Nemo.
- · Only drive and manoeuver the Nemo in a non-tilted position.
- · When moving the Nemo, do not tilt.
- · Always try to move backwards over obstacles (rather than forwards).
- It is not permitted to charge the Nemo with more than 150 kg / 330 lbs.
- The Nemo is only suitable for moving and caring for one person.
- · Only use original parts, supplied by Lopital.
- The use of components (for instance the gas spring) that have not been supplied by Lopital may result in a dangerous situation.
- Use the Nemo in a clean and tidy working environment.
- Swimming pool locations are not considered to be 'normal conditions' and will substantially shorten the lifespan of certain components.
- The Nemo cannot be used on a surface with a gradient over 5 degrees laterally.
- The Nemo cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- · The Nemo may only be used indoors.

#### Maintenance

- If the gas spring or the cable become damaged, they must be replaced.
- In the event of damage to the seat, back or backrest, always replace them for reasons of hygiene.
- The Nemo must be inspected and serviced at least once a year.
- Servicing and maintenance of the Nemo may only be carried out by persons authorised by Lopital.
- Service and maintenance must not be carried out while a client is sitting on the chair.
- If erroneous use, transport, an accident or improper maintenance leads to deformation of the Nemo, it may no longer be used and you must contact the supplier.

In the event of breakdowns, you must contact Lopital or your local supplier. E-mail: info@lopital.nl



The Nemo shower-toilet chair should only be operated by competent personnel who have experience in working with the user target group and have watched the instruction / training videos on the Lopital website.



The Nemo has been developed and produced for use in professional care environments.



Making changes to the contruction can affect the safety of the Nemo. Furthermore, the liability and guarantee conditions of Lopital lapse. As a result, the Nemo no longer meets the Medical Devices Regulation.

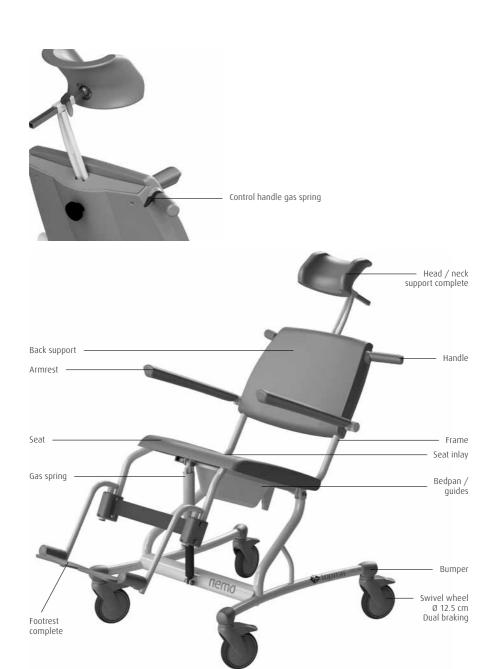
### 1.3. Warranty

All Lopital products are supplied with a 2-year warranty, on construction and / or material faults, unless otherwise stated. In the event of varying warranty terms, the exact period will be indicated on your invoice; this also serves as the warranty itself. Components and batteries that are subject to wear and tear will not fall under warranty unless there are clear construction and / or material faults.

# 2. Use

### 2.1. First use

On page 8 you can find the components of the Nemo. In the event of damage, these parts can be replaced by authorised persons.





### 2.2. Working with the Nemo

### Step 1

Make sure that the Nemo is placed in the sitting position and fold the armrests upwards (See paragraph 3.3. Armrests).

### Step 2

If necessary, fold the foot plates up or turn out the foot plates of the Nemo (See paragraph 3.2. Footrests).

### Step 3

The Nemo must be put on the brakes before transferring persons (See paragraph 3.1. Wheel blocking).

### Step 4

The client can take a seat in the chair. Support the client if necessary.

### Step 5

Place both feet on the footrests and calves against the calf-supports. (See paragraph 3.2. Footrests).

### Step 6

Fold the armrests downwards after the client has sat down in the chair (See paragraph 3.3. Armrests).

## Step 7

Notify the client about the processes you will be carrying out.

### Step 8

Take the chair off the brake when you wish to move it (See paragraph 3.1. Wheel blocking).

### Step 9

When you wish to tilt the chair, you must apply the brake (See paragraph 3.5. Tilting).

# 3. Operation

# 3.1. Wheel blocking

- The brake can be applied on the Nemo by pushing the blue lip (1) on the wheel downwards (See figure 1).
- In order to take the Nemo off the brake, the same lip on the wheel must be moved upwards by tapping the upper side of the lip (2) (See figure 1).



Figure 1 Swivel wheel.

Option: Swivel wheel left front.

#### 3.2. Footrests

- Before the client takes a seat in the Nemo, the footrests must be folded upwards. This will ensure there is sufficient space for the person to easily take a seat in the chair (See figure 2). If more room is required, the footrests can be turned out (See figure 3). First, the footrests must be slightly raised (1) and then they can be turned outwards (2).
- The carer or the client first raises one leg; the carer can then fold the footrest down (See figure 4). The same procedure is then carried out with the other leg.



# Always replace this component on the chair when you have finished using it. This will avoid the component being lost.



Figure 2 Folding up footrests.



Figure 3 Turning out footrests.



Figure 4 Folding down footrests

### Option: Comfort leg supports

The comfort leg supports provide the legs with additional support. The comfort leg supports can be adjusted in length as well as according to the sitting angle. The angle of the leg supports can be adjusted to 4 positions (*See figures 5 to 8*). To change the seating angle, you have to release the locking pin. When you have determined the correct position, lock the sitting angle of the comfort once again (*See figure 9*).



Make sure that the locking pin slips in well into one of the 4 holes.

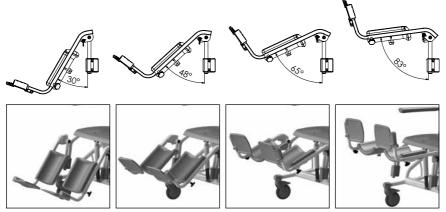


Figure 5 to 8 Adjustable seating angle.



Figure 9 Locking pins.

To adjust the length of the leg supports, you have to release the locking pin underneath by loosen it a bit (See figure 9). Choose the right length for the leg support and tighten the locking pin again.



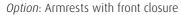
Make sure that both the sitting angle and the length of the leg supports are locked properly as soon as they have to support a load.



Always place these parts on the seat as soon as you finish using them. This prevents you from looking for the parts.

#### 3.3. Armrests

- The independent folding armrests are easy to fold up.
- Protect the user when moving the armrests upwards and downwards
- In the folded up position, they should not fall back down by themselves; in other cases: consult your supplier.



- · When the client has taken a seat on the Nemo, the armrests with front closure can be folded down: these are then turned in front of the client
- The armrests with front closure are secured in a horizontal position.
- The armrests can be unlocked by pressing the security catch at the hinging point on the frame (See figure 11). The armrests can then be turned up for the client and folded up.
- · Always protect the client when folding the armrests up or down
- The armrests can also be used as a support when taking a seat or standing up.

Be aware that the armrests are not locked in all positions.



 The extra lock ensures that the front closure is also locked. when turned away (See figure 13).



When folding the armrests away, avoid the hinging point to prevent possible entrapment.



When folding the armrests away, avoid fingers or body parts becoming entrapped between the armrest and the back support.



The armrests or front closure must not be used as a lever arm (e.g. when moving the chair over an obstacle) or as a push / pull bar. You must not sit on it either. This could damage the Nemo and / or present a hazard.



Figure 10 Armrest.



Figure 11 Armrests with front closure



Figure 12 Armrest with dual locking.



Figure 13 Armrest turned out.

# 3.4. Head / neck support

- The Nemo has a head / neck support that can be adjusted in terms of both height and depth.
- In order to set its height, the rotating button (1) on the back of the chair must be undone. Once you have reached the required height, do the button up again (See figure 14).
- To set the depth of the head / neck support, the handle (2) is unlocked. Once you have reached the required height, do the handle up again. The depth setting has a range of 7 cm.
- The Nemo has a curved head / neck support, allowing the head of the client to be supported effectively.

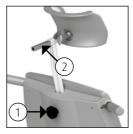


Figure 14 Head / neck support.



# Always replace this component on the chair when you have finished using it. This will avoid the component being lost.

# 3.5. Tilting

- In order to tilt the Nemo in an ergonomic and responsible manner, the operator should be standing diagonally behind the Nemo. Grasp the hand grip using your right hand (1). Using the left hand, hold the frame of the head support firmly (2) (See figure 15). The chair frame can be tilted by squeezing the operating handle.
- · The Nemo is equipped with a tilting function up to a maximum of 30 degrees backwards. This function can be operated by pressing the control handle. The seat element will then tilt (See figure 16).
- To operate the tilt function you must put the Nemo on the brake.
- The caregiver can stop the tilting at any time by releasing the handle.
- To tilt the Nemo forwards the control handle can be used again (See figure 16).
- During the tilting the arm supports must be folded downwards and the arms of the client must rest on the arm supports.
- In addition, during the tilting the client must have placed his / her feet on the foot support.
- · Maintain contact with the client during the tilting.



Figure 15 Tilting frame.



Figure 16 Control handle.



Before tilting the chair, check to ensure there are no persons or objects in the vicinity of the chair.

#### 3.6. Toilet function

3.6.1. In combination with toilet

- · Remove the lid on the seat before the person sits down in the chair
- The Nemo can now be moved backwards over the toilet



Figure 17 Bedpan.



### The Nemo does not fit over every toilet.

3.6.2. Use of a bedpan or bucket

- If the Nemo is being used as a toilet chair, the special guides under the seat can be used to accommodate a stainless steel / plastic bedpan or bucket.
- The bedpan or bucket is slid in from the back of the chair (See figure 17).
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (See figure 18).
- · If you are using a stainless steel bedpan or bucket, the bedpan can be placed in 2 positions under the seat. At the front of the seat (See figure 19) or at the back of the seat (See figure 20).



Figure 18 Lopital plastic bedpan.



Figure 19 Stainless steel bedpan, front.



In order to avoid injuries, we advise the carer to remove the inlay from the seat and insert the bucket or bedpan before the client takes a seat on the chair.



The Lopital plastic bedpan, stainless steel bedpan and bucket must be cleaned and disinfected after use, for example in a bedpan washing unit.



If the Lopital plastic bedpan, stainless steel bedpan or bucket has been used, it must be removed from the chair before the chair is moved or adjusted in height.



Figure 20 Stainless steel bedpan, back.

# 4. Cleaning and maintenance

The Nemo must be cleaned after every use, with water and regular household cleaning agents. PUR integrated foam components with IMC coating should be rubbed clean and disinfected. Do not use any abrasive or other aggressive cleaning products. If necessary, the PUR components can be disinfected with a solution of 70% ethanol or propanol.

The time the products must be left on the components has a significant impact upon the lifespan of the PUR components. As a result of the material properties of PUR, contact with sharp objects must be avoided. This could lead to damage or tears in the material. Finally, we would like to point out that non-critical parts of the PUR components must also be cleaned and disinfected.

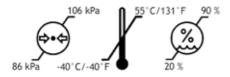
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Nemo may only be carried out by authorised personnel.

Maintenance schedule				
After every use	<ul> <li>Clean chair with water and regular household cleaning products.</li> <li>PUR foam components must be cleaned and disinfected.</li> <li>Check to ensure all parts of the Nemo are present, including the footrests, head support and inlay for the seat.</li> </ul>			
Weekly	<ul> <li>Check wheels for hairs, dust and soap residues and remove if necessary.</li> <li>Check that the chair is still working correctly.</li> </ul>			
Annually	According to the regulation MDR (EU) 2017/745 medical devices, a chair must be maintained according to the manufacturer's guidelines.			

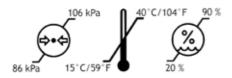
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website www.lopital.com/downloads.

# 5. Environmental conditions

Conditions during storage and transport



Conditions during use



# 6. Removal of parts

All parts that are replaced or removed can be sent back to Lopital BV. You may also offer the parts to the engineer for destruction. We will ensure that all parts are processed in an environmentally-friendly manner.

# 7. Technical specifications

#### 7.1. Structure

Frame: Stainless steel, steel tubes and plates equipped with

a two-layer powder coating

Hinge points: Stainless steel

Wheels: Plastic, Ø 12.5 cm / 4.9 inch, double blocking facility

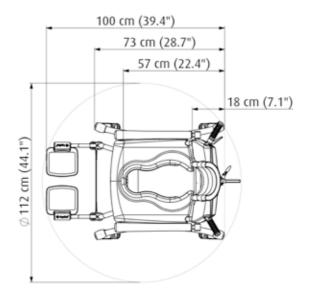
Body support : PUR (polyurethane).
Weight: 24 kg / 52.9 lbs
Maximum permitted load: 150 kg / 330 lbs
Weight comfort leg support: 3.6 kg / 8 lbs per unit

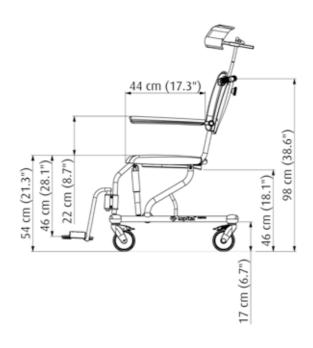
### 7.2. Dimensions

Surface area: Head support adjustment: Tilt adjustment:

66 cm / 26 inch wide, 100 cm / 39.4 inch deep depth 7 cm / 2.8 inch & height 12 cm / 4.7 inch 30 degrees backwards











### Lopital Nederland B.V.

Laarakkerweg 9 | 5061 JR | Oisterwijk | The Netherlands Tel (0031) 013 5239300 | E-mail Info@lopital.nl Website www.lopital.com

# Manufacturer's Declaration of Conformity

C ∈ marking in accordance with the Medical Device Regulation

Brand name: Lopital

Medical device: Nemo

Device description: Mobile shower-/toilet chair with inclination

Models: 51005100

Classification: Class I

Basic UDI-DI: 872025610304251005100DP

Conforms to regulation: Medical Device Regulation (EU) 2017/745

Standards applied: NEN-EN-ISO 14971:2019 | Medical devices-Application of risk management to medical devices

NEN-EN 12182:2012 | Assistive product for persons with disability-General requirements and test

ISO 17966:2016 | Assistive products for personal hygiene that support users - Requirements and test

IEC 62366:2007 | Medical devices - Application of usability engineering to medical devices

UNI-CEI-EN-ISO 13485:2016 | Medical devices-Quality management systems-Requirements for regulatory

NEN-EN-ISO 9001:2015 | Quality management systems - Requirements

NEN-EN-ISO 14001:2015 | Environmental management systems - Requirements with guidance for use

Certificate/report no.: Certificate:

Reports:

Authorised signatory, Cees van Dam, director:

Signature:

Date:

Place:

2021-05-03

**Oisterwijk** 







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