



Creating balance in healthcare



Instructions for use
Mylo Shower-toilet chair



Instructions for use

Mylo

5100 5701

Shower-toilet chair

Basic UDI-DI: 872025610306651005701KD



Important:

Read these instructions carefully before using the Mylo!

Date first used

User

Name

Address

Manufacturer

Lopital Nederland B.V.

Laarakkerweg 9












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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			
	Note		Follow the instructions for use
	Date of production		Read cleaning and disinfecting protocol
	Maximum load		Antibacterial
	Global trade identification number		Temperature
	Serialnumber		Air pressure
			Humidity level

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1. Introduction

1.1. Introduction

The Mylo shower-toilet chair is an aid for the ergonomic care and washing of the client. For both the client and the carer, the comfort is optimal.

The Mylo can be used with a commode pan / bucket or in combination with a toilet, can also be used as a toilet seat.



The frame of the Mylo 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 micro-organisms. 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 Mylo 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 Mylo 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 Mylo brake is applied before transferring clients.
- Make sure that the Mylo seat is always folded down before transferring clients.
- Notify the client before moving the Mylo.
- Make sure that the client always places his / her arms on the armrests provided to prevent possible entrapment.
- Keep the armrests down / closed when moving the Mylo.
- Always try to move backwards over obstacles (rather than forwards).
- It is not permitted to charge the Mylo with more than 150 kg / 330 lbs.

- The Mylo is only suitable for moving and caring for one person.
- Only use original parts, supplied by Lopital.
- Use the Mylo 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 Mylo cannot be used on a surface with a gradient over 5 degrees laterally.
- The Mylo cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Mylo may only be used indoors.

Maintenance

- The Mylo must be inspected and serviced at least once a year.
- In the event of damage to the seat, back or backrest, always replace them for reasons of hygiene.
- Constructive components of the Mylo may only be replaced by suitably authorised Lopital personnel.
- 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 Mylo, 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 Mylo 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 Mylo has been developed and produced for use in a professional healthcare environment.



Making changes to the construction may affect the safety of the Mylo. Furthermore, the liability and guarantee conditions of Lopital lapse. As a result, the Mylo no longer complies with the MDR (EU) 2017/745 regulation for medical devices.

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

In the picture below, the components of the Mylo are named. In the event of damage, these parts can be replaced by authorised persons.





 Laarakerweg 9 5061 JR Oosterwijk The Netherlands T: (+31)13-5239300 CE Weight: - kg / - lbs	GTIN (01) 8720256103---	Item no: -----
	(11) YYMMDD	
	SN (21) -----	
	-- kg / -- LBS Product type	



2.2. Working with the Mylo

Step 1

If necessary, place the seat once again on the chair and / or fold the seat downwards.

Step 2

If necessary, fold the armrests up (*See paragraph 3.3. Armrests*).

Step 3

If necessary, fold the foot plates up and fold the footrest frame up too (*See paragraph 3.2. Footrests*).

Step 4

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

Step 5

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

Step 6

Place both feet on the footrests (*See paragraph 3.2. Footrests*).

Step 7

Close the armrests once the client has taken a seat in the chair (*See paragraph 3.3. Armrests*).

Step 8

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

Step 9

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

3. Operation

3.1. Wheel blocking

- The brake can be applied on the Mylo by pushing the blue lip (1) on the wheel downwards (See figure 1).
- In order to take the Mylo 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).

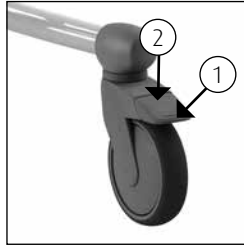


Figure 1 Swivel wheel.



Figure 2 Folding up footrests.

Option: Directional wheel left front

3.2. Footrests

- Before the client takes a seat in the Mylo, the foot plates or footrest frame must be folded upwards. There is now sufficient room to allow the client to easily take a seat (See figures 2 & 3).
- The carer or the client first raises one leg; the carer then folds the foot plate down (See figure 4). The same procedure is then carried out with the other leg.



Figure 3 Folding up footrest frame.

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.



Figure 4 Folding down footrests.



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.



Figure 5 Armrest Mylo.



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 Mylo and / or present a hazard.

3.4. Toilet function

3.4.1. In combination with toilet

- The Mylo can now be moved backwards over the toilet.



Figure 6 Bedpan.



The Mylo does not fit over every toilet.

3.4.2. Use of a bedpan or bucket

- If the Mylo 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 6).
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (See figure 7).
- 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 8) or at the back of the seat (See figure 9).



Figure 7 Lopital plastic bedpan.



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



Figure 8 Stainless steel bedpan, front.



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 9 Stainless steel bedpan, back.

3.5. Foldable and removable seat

If required, you can remove the Mylo seat from the frame. That makes it much easier to clean it and no dirt will remain between the frame and the seat. The seat can be removed from the frame without the need for any tools (See figure 10 & 11).



Figure 10 Folding the seat.



Figure 11 Removing the seat.

4. Cleaning and maintenance

The Mylo 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.

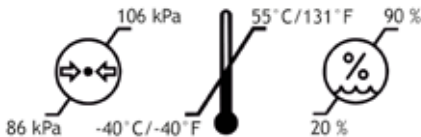
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Mylo may only be carried out by authorised personnel.

Maintenance schedule	
After every use	<ul style="list-style-type: none"> • Clean chair with water and regular household cleaning products. • PUR foam components must be cleaned and disinfected. • Check to ensure all parts of the Mylo are present.
Weekly	<ul style="list-style-type: none"> • Check wheels for hairs, dust and soap residues and remove if necessary. • Check that the chair is still working correctly.
Annually	<ul style="list-style-type: none"> • According to the regulation MDR (EU) 2017/745 medical devices, a chair must be maintained according to the manufacturer's guidelines.

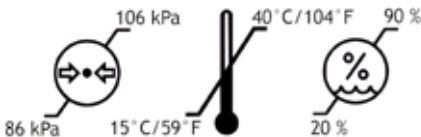
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website www.lopital.com/downloads.

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.

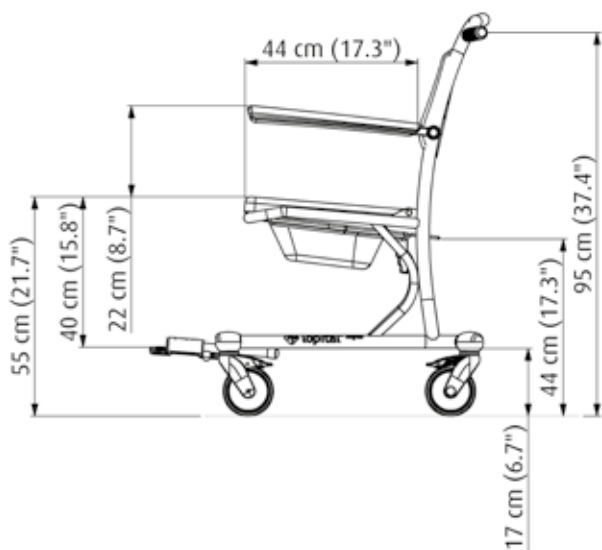
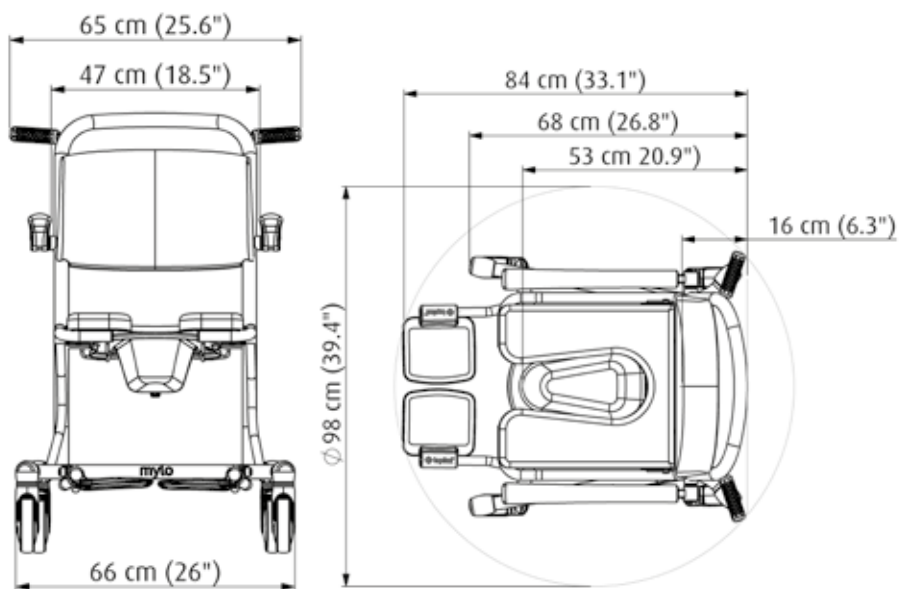
7. Technical specifications

7.1. Structure

Frame:	Stainless steel and steel tubes and plates that are equipped with a 2-layer powder coating
Hinge points:	Stainless steel, cover caps made of plastic V0
Wheels:	Plastic, Ø 12.5 cm / 4.9 inch, double blocking facility
Body support:	PUR (polyurethane).
Weight:	19 kg / 41.9 lbs
Maximum permitted load:	150 kg / 330 lbs

7.2. Dimensions

Surface area:	66 cm / 26 inch wide, 84 cm / 33.1 inch deep
Seat height:	55 cm / 21.7 inch



Manufacturer's Declaration of Conformity
CE marking in accordance with the Medical Device Regulation

Brand name:	Lopital
Medical device:	Mylo
Device description:	Mobile shower-/toilet chair
Models:	51005701
Classification:	Class I
Basic UDI-DI:	872025610306651005701KD
Conforms to regulation:	Medical Device Regulation (EU) 2017/745
Standards applied:	<i>NEN-EN-ISO 14971:2019 Medical devices-Application of risk management to medical devices</i> <i>NEN-EN 12182:2012 Assistive product for persons with disability-General requirements and test methods</i> <i>ISO 17966:2016 Assistive products for personal hygiene that support users-Requirements and test methods</i> <i>EN ISO 62366 : 2007 Medical devices - Application of usability engineering to medical devices</i> <i>UNI-CEI-EN-ISO 13485:2016 Medical devices-Quality management systems-Requirements for regulatory purposes</i> <i>NEN-EN-ISO 9001:2015 Quality management systems - Requirements</i> <i>NEN-EN-ISO 14001:2015 Environmental management systems - Requirements with guidance for use</i>
Certificate/report no.:	Certificate: Reports:



Authorised signatory, Cees van Dam, director:

Signature:



Date:

2021-05-03

Place:

Oisterwijk

