

Instructions for use
Flexo Shower-toilet chair



Instructions for use

Flexo

5100 5199

Shower-toilet chair

Basic UDI-DI: 872025610303551005199GC



Important:

Read these instructions carefully before using the Flexo!

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			
	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

Contents

1.	Introduction.....	5
1.1.	Introduction.....	5
1.2.	Safety.....	5
1.3.	Warranty.....	7
2.	Use.....	8
2.1.	First use.....	8
2.2.	Working with the Flexo.....	9
3.	Operation.....	10
3.1.	Wheel blocking.....	10
3.2.	Footrests.....	10
3.3.	Armrests with front closure.....	12
3.4.	Moving upwards / downwards.....	13
3.5.	Toilet function.....	13
3.5.1.	In combination with toilet.....	13
3.5.2.	Use of a bedpan or bucket.....	14
4.	Cleaning and maintenance.....	15
5.	Environmental conditions.....	16
6.	Removal of parts.....	17
7.	Technical specifications.....	17
7.1.	Structure.....	17
7.2.	Drive.....	17
7.3.	Dimensions.....	17

1. Introduction

1.1. Introduction

The height-adjustable shower-toilet chair Flexo is a medical device for caring for and washing clients in an ergonomically responsible manner. Comfort is the primary consideration for both the client and the carer.

The Flexo can also be used as a toilet chair, in combination with a bedpan / bucket or a toilet. The Flexo comprises a base frame and chair component. The chair component provides the same comfort as a regular chair and offers the same degree of support. The chair component can be hydraulically adjusted in height, in relation to the base frame. The Flexo is thus a multifunctional device.



The frame of the Flexo 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 Flexo 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 Flexo 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 the Flexo brake is applied before transferring clients.
- Notify the client before moving the Flexo.
- To avoid entrapment, do not place your feet on the lower frame when raising, lowering or tilting the seat.

- Close the armrests with front closure before moving the Flexo upwards.
- 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 Flexo.
- Be aware of obstacles when moving upwards / downwards.
- Only relocate and move the Flexo in the lower position.
- When moving the Flexo, do not adjust upwards / downwards.
- Always try to move backwards over obstacles (rather than forwards).
- Set the Flexo to the correct height before using with a toilet.
- It is not permitted to load the Flexo with more than 150 kg / 330 lbs.
- The Flexo is only suitable for moving and caring for one person.
- Only use original parts, supplied by Lopital.
- Use the Flexo in a clean and tidy working environment.
- Only verifiably authorised personnel is allowed to work with the Flexo.
- Swimming pool locations are not considered to be 'normal conditions' and will substantially shorten the lifespan of certain components.
- The Flexo cannot be used on a surface with a gradient over 5 degrees laterally.
- The Flexo cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Flexo may only be used indoors.

Maintenance

- The Flexo 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 Flexo 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 Flexo, 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 Flexo 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 Flexo has been developed and produced for use in professional care environments.



Making changes to the construction may affect the safety of the Flexo. Furthermore, the liability and guarantee conditions of Lopital lapse. As a result, the Flexo 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

On page 7 you can find the components of the Flexo. In the event of damage, these parts can be replaced by authorised persons.



2.2. Working with the Flexo

Step 1

Fold the armrests up or turn the front closure downwards (*See paragraph 3.3. Armrests with front closure*).

Step 2

If necessary, fold the footrests up or turn the footrests away (*See paragraph 3.2. Footrests*).

Step 3

The Flexo 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-support (*See paragraph 3.2. Footrests*).

Step 6

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

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*). **Always move the chair in the low position.**

Step 9

When you wish to move the chair upwards / downwards, you must apply the brake (*See paragraph 3.4. Moving upwards / downwards*).

3. Operation

3.1. Wheel blocking

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

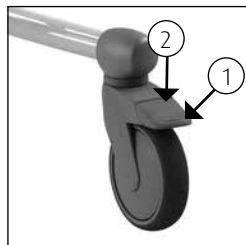


Figure 1 Swivel wheel.

Option: Steering wheel left front.

3.2. Footrests

- Before the client takes a seat in the Flexo, 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.

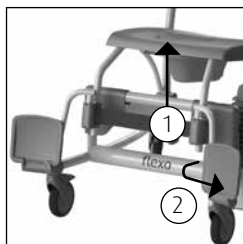


Figure 3 Turning out footrests.



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 support can be adjusted to 4 positions (See figure 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.

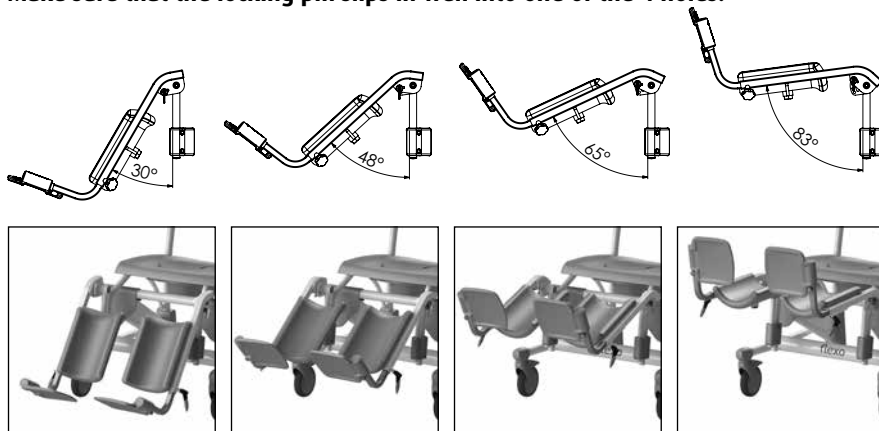


Figure 5 to 8 Adjustable seating angle.

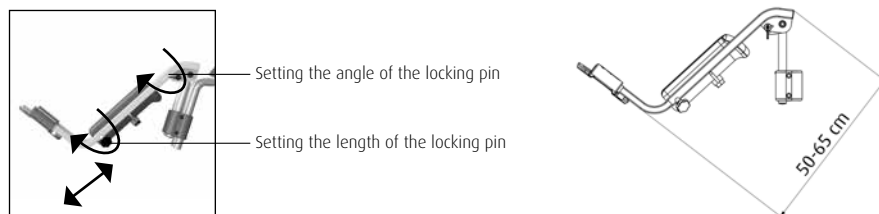


Figure 9 Locking pins.

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 with front closure

- If the client has taken a seat on the Flexo, the armrests with front closure can be folded down; these are then turned for the person concerned.
- 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 10). The armrests can then be turned up for the client and folded up.
- Always protect the client when folding the armrests up / 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.

Option: Armrests with dual locking.

- The extra lock ensures that the front closure is also locked when turned away (See figure 12).

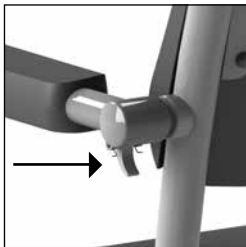


Figure 10 Armrest.



Figure 11 Armrest with dual locking.



Figure 12 Armrest turned out.

Option: Straight armrest.

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 13 Straight armrest.



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 Flexo and / or present a hazard.

3.4. Moving upwards / downwards

Moving upwards

- If the client is seated in the chair, first apply the brakes to the wheels and then move the chair upwards.
- The chair will move upwards if you depress the long part of the foot pedal gently and evenly (See figure 14).
- During use of the pedal, the carer will stand by the long edge of the Flexo so that the carer cannot twist their upper body away from their feet.
- During the upward movement, maintain contact with the client.

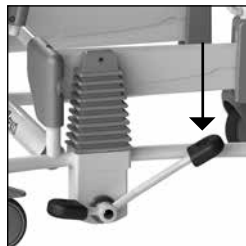


Figure 14 Moving upwards.



When moving upwards, the position of the chair will tilt from 3° to a maximum of 20° backwards.

Moving downwards

- The chair component is moved downwards by depressing the short part of the foot pedal (See figure 15).
- The chair component lowers under the influence of gravity. The lowering speed can be modified by keeping the pedal gently depressed.
- During the downward movement, maintain contact with the client.

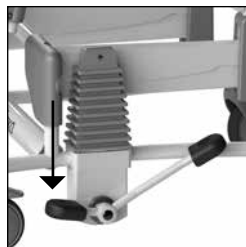


Figure 15 Moving downwards.



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

3.5. Toilet function

3.5.1. In combination with toilet

- The Flexo can also be moved over the toilet.
- Remove the seat inlay from the seat before the person sits down in the chair.
- Once the person has taken a seat and the armrests are closed, the carer must move the Flexo to the appropriate height.
- Move the Flexo, if necessary, upwards or downwards to achieve the right position.

- The Flexo can now be moved backwards over the toilet.
- Lower the Flexo, if necessary, to achieve the right position.



The Flexo does not fit over every toilet.

3.5.2. Use of a bedpan or bucket

- If the Flexo 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 16).
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (See figure 17).
- 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 18) or at the back of the seat (See figure 19).



Figure 16 Bedpan.



Figure 17 Lopital plastic bedpan.



In order to avoid injuries, we advise the carer to remove the seat 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 18 Stainless steel bedpan, front.




Figure 19 Stainless steel bedpan, back.

4. Cleaning and maintenance

The Flexo 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.

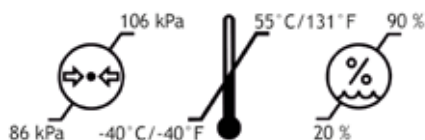
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Flexo may only be carried out by authorised personnel.

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 Flexo are present, including the footrests and removable parts of the seat.
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. This process will preferably be carried out by Lopital or another authorised body. Lopital offers the option of having the chair thoroughly inspected and serviced once a year via Periodic Preventative Maintenance. <p>For more information about the maintenance contract, please contact Lopital (info@lopital.nl) or speak to your supplier.</p>

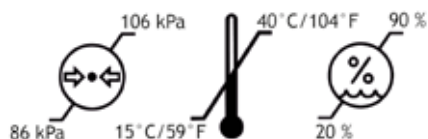
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website www.lopital.com/downloads.

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

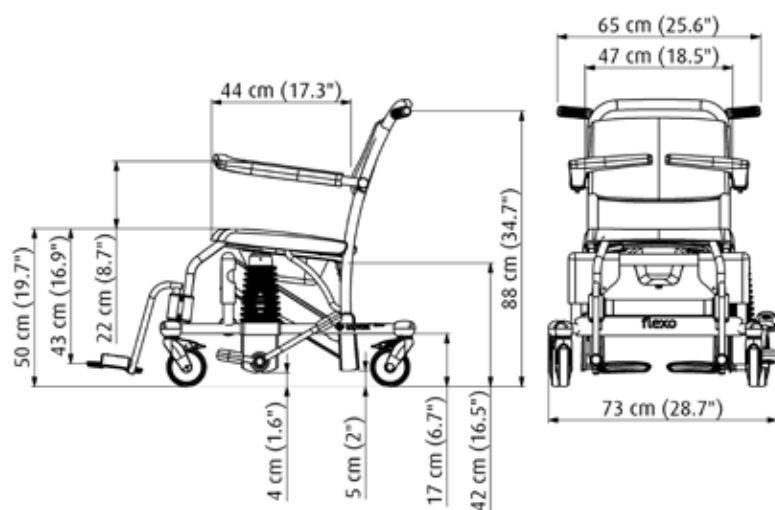
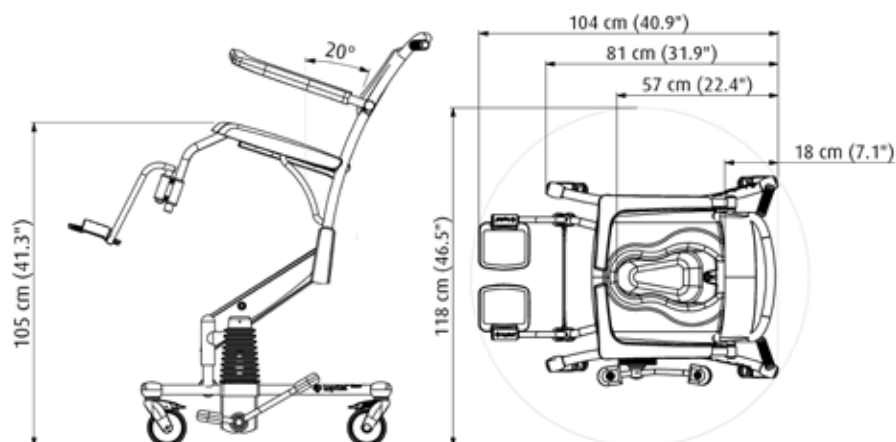
Frame:	Stainless steel and steel tubes and plates that are equipped with a two-layer powder coating
Hinge points :	Stainless steel, cover caps made of plastic V0
Wheels:	Plastic, Ø 12.5 cm / 4.9 inch dual blocking facility
Body support :	PUR (polyurethane).
Weight:	38 kg / 84 lbs
Maximum permitted load :	150 kg / 330 lbs
Weight comfort leg support:	3.6 kg / 8 lbs per unit

7.2. Drive

Integrated hydraulic pump

7.3. Dimensions

Surface area:	73 cm / 28.7 inch wide, 104 cm / 40.9 inch deep
Seat height:	Adjustable: minimum 50 cm / 19.7 inch, maximum 105 cm / 41.3 inch



Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

Brand name: Lopital

Medical device: Flexo

Device description: Mobile shower-/toilet chair with hydraulically adjustable height

Models: 51005199

Classification: Class I

Basic UDI-DI: 872025610303551005199GC

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 methods*

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

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 purposes*

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:

2021-05-03

Place:

Oisterwijk

