

# Instructions for use Tango XL Shower-toilet chair



# Instructions for use



Shower-toilet chair Basic UDI-DI : 872025610314151005705F7





#### Important:

Read these instructions carefully before using the Tango XL!

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#### 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					
Â	Note	8	Follow the instructions for use		
$\sim$	Date of production	**	Read cleaning and disinfecting protocol		
MAX LOAD	Maximum load	$\otimes$	Antibacterial		
GTIN	Global trade identification number	X	Temperature		
SN	Serialnumber	<b>*</b>	Air pressure		
		) (%)	Humidity level		

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	Introduction

# 1. Introduction

#### 1.1. Introduction

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

The Tango XL can also be used as a toilet chair, in combination with a bedpan / bucket. The Tango XL is a shower-toilet chair with independent, folding armrests, polyurethane two-piece removable seat, rails for a bedpan and rotating and foldable footrests.



The frame of the Tango XL 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 average technical life-cycle of the Tango XL is 10 years, assuming it is cleaned daily and regularly maintained according to the maintenance schedule supplied *(See chapter 4. Cleaning and maintenance)*.

The Tango XL 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 Tango XL brake is applied before transferring clients.
- Notify the client before moving the Tango XL.
- Make sure that the client always places his / her arms on the armrests provided to prevent possible entrapment.
- $\cdot$  Keep the armrests down / closed when moving the Tango XL.
- Always try to move backwards over obstacles.

- It is not permitted to charge the Tango XL with more than 250 kg / 550 lbs.
- The Tango XL is only suitable for moving and caring for one person.
- Only use original parts, supplied by Lopital.
- Use the Tango XL in a clean and tidy working environment.
- The Tango XL may only be operated by an authorised person.
- Swimming pool locations are not considered to be 'normal conditions' and will substantially shorten the lifespan of certain components.
- The Tango XL cannot be used on a surface with a gradient over 5 degrees laterally.
- The Tango XL cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Tango XL may only be used indoors.

#### Maintenance

- The Tango XL 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 Tango XL 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 Tango XL, 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

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The Tango XL 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 Tango XL has been developed and produced for use in a professional healthcare environment.

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Making changes to the contruction may affect the safety of the Tango XL. Furthermore, the liability and guarantee conditions of Lopital lapse. As a result, the Tango XL 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 Tango XL are named. In the event of damage, these parts can be replaced by authorised persons.





#### 2.2. Working with the Tango XL

Step 1

If necessary, fold the armrests up (See paragraph 3.4. Armrests).

Step 2

Turn the footrests out of position (See paragraph 3.3. Footrests).

*Step 3* The Tango XL 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* Turn the footrests back in position and both feet on the footrests *(See paragraph 3.3. Footrests)*.

#### Step 6

Fold the armrests again once the client has taken a seat in the chair (*See paragraph 3.4. Armrests*).

*Step 7* Notify the client about the processes you will be carrying out.

Step 8

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

# 3. Operation

### 3.1. Wheel blocking

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

#### 3.2. Directional / braked wheel

The Tango XL has a standard design with a directional / braked caster. This makes pushing along greater distances easier because the seat will drift less sideways. The directional / braked caster is fastened in front.

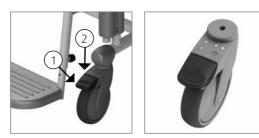


Figure 2 Directional / braked wheel.

To block the wheel direction, push down the black lip. N.B. Make sure the black lip moves 1 stand downwards (1) *(See figure 2)* to lock the direction. When the black lip moves 2 stands downwards, the wheel will be blocked. In order to lock the direction again, the same lip on the wheel must be moved upwards by tapping on the upper side of the black lip (2) *(See figure 2)*.

#### 3.3. Footrests

Before client positions him or herself on the Tango XL, the footrests must be lifted slightly and turned outwards. This provides enough room in front of the seat, so that the client can sit down easily.







Figure 4 Footrests.

When the client is seated, the carer or the client must first lift one leg, then the carer turns the footrest forwards until it falls in the lock. The client rests his / her foot on the footrest. Then repeat the procedure for the other leg. The footrests of the Tango XL are adjustable in length. To do this, pull off the tube adjuster and select the desired position. Then push the tube adjuster back onto the frame.

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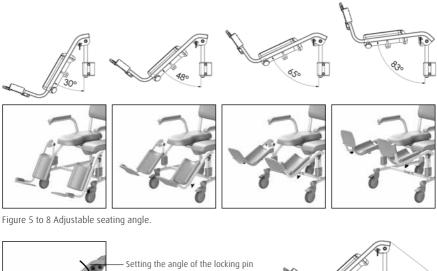
#### Always put this component back on the chair when you have finished using it. This will prevent the component from being lost.

#### 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 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 support once again *(See figure 9).* 



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



— Setting the length of the locking pin



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 support are $\Delta$ 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.

#### 3.4. 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 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 Tango XL and / or present a hazard.

#### 3.5. Toilet function

- 3.5.1. In combination with toilet
- The Tango XL can be moved backwards over the toilet.



#### The Tango XL does not fit over every toilet.

#### 3.5.2. Use of a bedpan or bucket

- If the Tango XL 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 12).*
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (*See figure 13*).
- 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 14*) or at the back of the seat (*See figure 15*).



Figure 10 Armrest.



Figure 11 Armrest folded away.



Figure 12 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.



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 13 Lopital plastic bedpan.



Figure 14 Stainless steel bedpan, front.



Figure 15 Stainless steel bedpan, back.

Figure 16 Seat.

#### 3.6. Removable seat

If required, the seat of the Tango XL can be taken off the frame. By doing so, the seat can be cleaned even better. The seat can be taken off the frame without using tools. Pull the seat upwards in the front (See figure 16). To put the seat back, press the seat back onto the frame. Ensure that the seat fits well around the frame.

# 4. Cleaning and maintenance

The Tango XL 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.

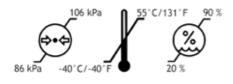
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Tango XL may only be carried out by authorised personnel.

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 Tango XL are present, including the footrests.</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	<ul> <li>According to the regulation MDR (EU) 2017/745 medical devices, a chair must be maintained according to the manufacturer's guidelines.</li> </ul>			

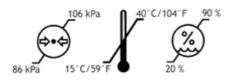
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website www.lopital.com/downloads.

# 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

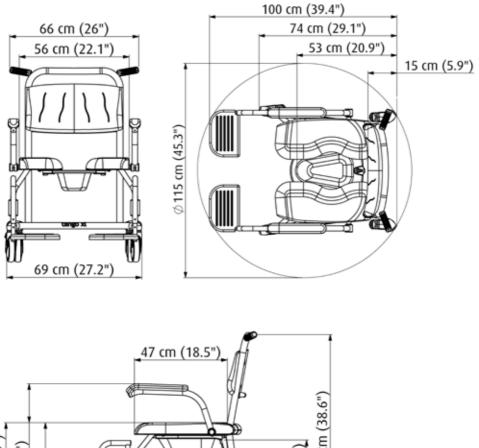
#### 7.1. Structure

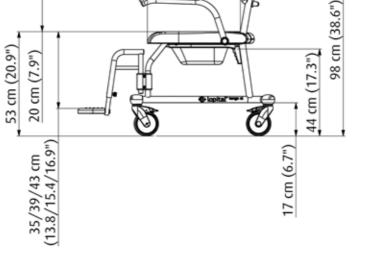
Frame:

Hinge points: Wheels: Body support: Weight: Maximum permitted load: Weight comfort leg support: Stainless steel and steel tubes and plates that are equipped with a two-layer powder coating Stainless steel, cover caps made of plastic V0 Plastic, Ø 12.5 cm / 4.9 inch, double blocking facility PUR (polyurethane). 24 kg / 52.9 lbs 250 kg / 550 lbs 3.6 kg / 8 lbs per unit

#### 7.2. Dimensions

Surface area: Seat height: 69 cm / 27 inch wide, 100 cm / 39.4 inch deep 53 cm / 20.9 inch







#### Lopital Nederland B.V.

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#### Manufacturer's Declaration of Conformity $C \in$ marking in accordance with the Medical Device Regulation

Brand name:	Lopital		
Medical device:	Tango XL		
Device description:	Mobile shower-/toilet chair		
Models:	51005705		
Classification:	Class I		
Basic UDI-DI:	872025610314151005705F7		
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		
	EN ISO 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:	Place:
	5	2021-05-03	Oisterwijk







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