

# Instructions for use

## Tango XXL

5100 5800

### Shower-toilet chair

Basic UDI-DI :872025610315851005800LY



## Important:

Read these instructions carefully before using the Tango XXL!

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

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# 1. Introductie

## 1.1. Introduction

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



The frame of the Tango XXL 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 average technical life of the Tango XXL 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 XXL 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 XXL brake is applied before transferring clients.
- Notify the client before moving the Tango XXL.
- 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 Tango XXL.
- Always try to move backwards over obstacles (rather than forwards).

- It is not permitted to charge the Tango XXL with more than 360 kg / 800 lbs.
- The Tango XXL is only suitable for moving and caring for one person.
- Only use original parts, supplied by Lopital.
- Use the Tango XXL in a clean and tidy working environment.
- Only verifiably authorised personnel is allowed to work with the Tango XXL.
- Swimming pool locations are not considered to be 'normal conditions' and will substantially shorten the lifespan of certain components.
- The Tango XXL cannot be used on a surface with a gradient over 5 degrees laterally.
- The Tango XXL cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Tango XXL may only be used indoors.

### *Maintenance*

- The Tango XXL 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 XXL 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 XXL, 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](mailto:info@lopital.nl)



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



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







## 2.2. Working with the Tango XXL

### Step 1

If necessary, turn the armrests downwards (See paragraph 3.4. Armrests).

### Step 2

If necessary, turn the footrests away (See paragraph 3.3. Footrests).

### Step 3

The Tango XXL 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 (See paragraph 3.2. Footrests).

### Step 6

Close the armrests 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 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 Tango XXL by pushing the gray lip on the wheel downwards (See figure 1).
- To take the Tango XXL off the brake, the gray lip on the wheel must be pushed upwards again.

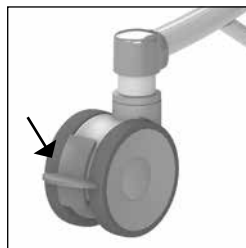


Figure 1 Swivel wheel.

### 3.2. Directional wheel

- The standard Tango XXL comes with a swivel wheel that is fitted to the left front side of the device (*See figure 2*). The direction of the wheel can be blocked by pushing the green lip on the wheel downwards. This makes it easier to push the device over long distances as the chair is less inclined to move sideways.
- In order to remove the blocking, the green lip on the wheel must be pushed upwards again.

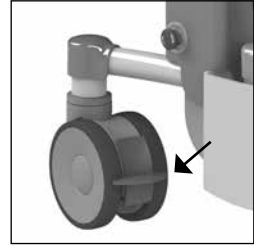


Figure 2 Directional wheel.

### 3.3. Footrests

- Before the client takes a seat in the Tango XXL, the footrests must be raised slightly and turned outwards. There is now sufficient room in front of the chair and the client can easily take a seat.
- Once the person has taken a seat, the carer or client raises one leg, the carer then turns the footrest forwards until it falls into the lock. The client can then rest their foot on the support.
- The same procedure is then carried out with the other leg.
- The footrests of the Tango XXL 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.



Figure 3 Footrest.



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

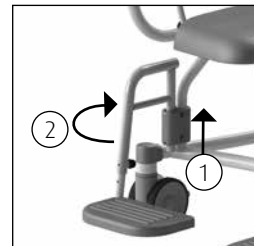


Figure 4 Turning out footrest.

### 3.4. Armrests

- The independent, turning armrests are easy to use.
- The safety catch is pulled outwards to unlock the armrest (1) (See figure 5).
- The armrest can now easily be turned to the back (2) (See figures 5 & 6).
- 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.

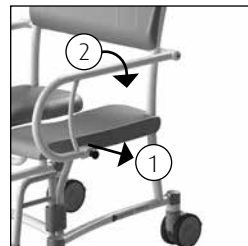


Figure 5 Armrest.



**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 Tango XXL and / or present a hazard.**



Figure 6 Armrest turned out.

### 3.5. Toilet function

#### 3.5.1. In combination with toilet

- The Tango XXL can be moved over the toilet.



**The Tango XXL does not fit over every toilet.**

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

- If the Tango XXL 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 7).
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (See figure 8).
- 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 9) or at the back of the seat (See figure 10).



Figure 7 Bedpan.

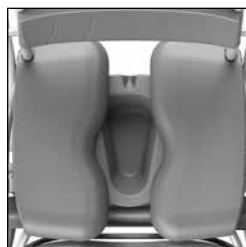


Figure 8 Lopital plastic bedpan.



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



**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.**

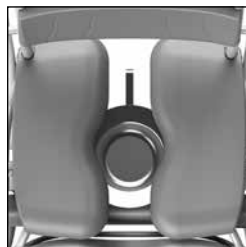


Figure 9 Stainless steel bedpan, front.

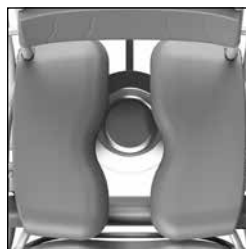


Figure 10 Stainless steel bedpan, back.

### 3.6. Removable seat

If required, the seat of the Tango XXL 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 11*). To put the seat back, press the seat back onto the frame. Ensure that the seat fits well around the frame.



Figure 11 Removable seat.

## 4. Cleaning and maintenance

The Tango XXL 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.

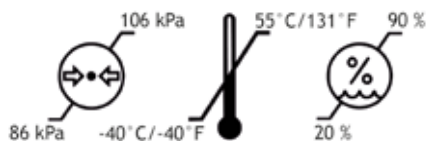
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Tango XXL may only be carried out by authorised personnel.

Maintenance schedule	
<b>After every use</b>	<ul style="list-style-type: none"> <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 XXL are present, including the footrests.</li> </ul>
<b>Weekly</b>	<ul style="list-style-type: none"> <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>
<b>Annually</b>	<ul style="list-style-type: none"> <li>• According to the regulation MDR (EU) 2017/745 medical devices, a chair must be maintained according to the manufacturer's guidelines.</li> </ul>

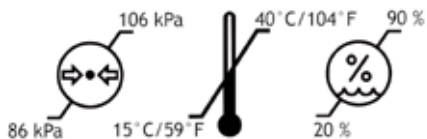
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website [www.lopital.com/downloads](http://www.lopital.com/downloads).

## 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.

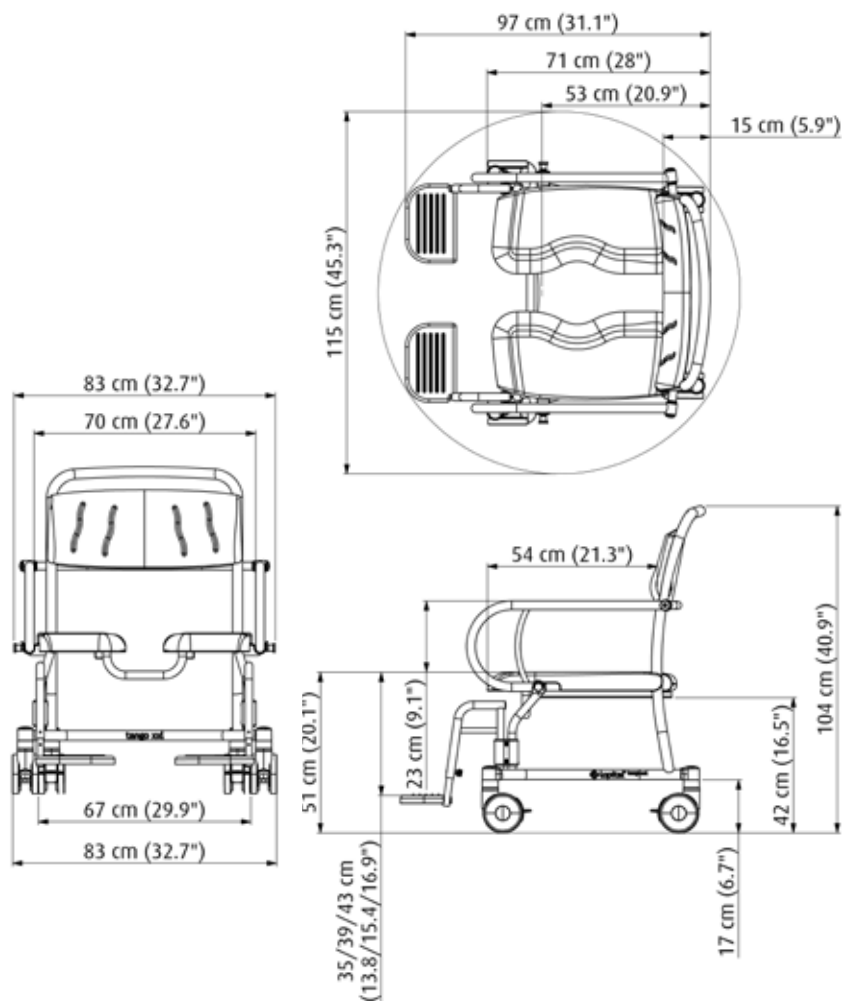
## 7. Technical specifications

### 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 / 4.7 inch, double blocking facility
Body support :	PUR (polyurethane).
Weight:	31 kg / 68.3 lbs
Maximum permitted load :	360 kg / 800 lbs

### 7.2. Dimensions

Surface area:	83 cm wide / 32.7 inch, 97 cm / 31.3 inch deep
Seat height:	51 cm / 20.1 inch





## Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

<b>Brand name:</b>	Lopital	
<b>Medical device:</b>	Tango XXL	
<b>Device description:</b>	Mobile shower-/toilet chair	
<b>Models:</b>	51005800	
<b>Classification:</b>	Class I	
<b>Basic UDI-DI:</b>	872025610315851005800LY	
<b>Conforms to regulation:</b>	Medical Device Regulation (EU) 2017/745	
<b>Standards applied:</b>	<p>NEN-EN-ISO 14971:2019   <i>Medical devices-Application of risk management to medical devices</i></p> <p>NEN-EN 12182:2012   <i>Assistive product for persons with disability-General requirements and test methods</i></p> <p>ISO 17966:2016   <i>Assistive products for personal hygiene that support users-Requirements and test methods</i></p> <p>IEC 62366: 2007   <i>Medical devices: Application of usability engineering to medical devices</i></p> <p>UNI-CEI-EN-ISO 13485:2016   <i>Medical devices-Quality management systems-Requirements for regulatory purposes</i></p> <p>NEN-EN-ISO 9001:2015   <i>Quality management systems - Requirements</i></p> <p>NEN-EN-ISO 14001:2015   <i>Environmental management systems - Requirements with guidance for use</i></p>	
<b>Certificate/report no.:</b>	Certificate:	
	Reports:	

**Authorised signatory, Cees van Dam, director:**

**Signature:**



**Date:**

2021-05-03

**Place:**

Oisterwijk



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