

Instructions for use Reflex Shower-toilet chair



Instructions for use

Reflex

5100 5600, 5100 5605

Shower-toilet chair

Basic UDI-DI: 872025610300451005600CA & 872025610301151005605BC



 **lopital®**
Creating balance in healthcare

Important:

Read these instructions carefully before using the Reflex!

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
	Applied parts		Read cleaning and disinfecting protocol
	Direct current 24V DC		Antibacterial
	Class 2 EMC		Temperature
	Date of production		Air pressure
	Maximum load		Humidity level
	Global trade identification number		Serialnumber

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1. Introduction

1.1. Introduction

The Reflex electric height-adjustable 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 Reflex can be used with a commode pan / bucket or in combination with a toilet, can also be used as a toilet seat. The Reflex 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 seat section of the Reflex can be tilted up to 30 degrees backwards. There are no essential performances.



The frame of the Reflex 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 Reflex is 10 years, provided that daily and periodic maintenance is carried out according to the specified maintenance schedule (*See chapter 5. Cleaning and maintenance*).

The Reflex is a medical class 1 product with CE marking. This marking is in accordance with the regulation MDR (EU) 2017/745. The Reflex is tested for electromagnetic radiation according to the 60601-1-2 standard.

The Reflex is available in the following versions:

- 5100 5600 Reflex.
- 5100 5605 Reflex with detachable, swing-out footrests.

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

- Before you start work with the Reflex, check that it has been disconnected from the charger.
- The Reflex will fall into standby mode after a few seconds when the chair is not in use.
- Make sure that the Reflex brake is applied before transferring clients.
- Notify the client before moving the Reflex.
- 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 Reflex upwards or tilting it.
- 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 Reflex.
- Be aware of obstacles when moving upwards and downwards or tilting.
- Only relocate and move the Reflex in the lower position.
- When moving the Reflex, do not adjust upwards or downwards or tilt.
- Always try to move backwards over obstacles (rather than forwards).
- Set the Reflex to the correct height before using with a toilet.
- It is not permitted to charge the Reflex with more than 135 kg / 300 lbs.
- The Reflex is only suitable for moving and caring for one person.
- Only use original parts, supplied by Lopital.
- The use of components (chargers, cables, actuators, batteries, etc.) that have not been supplied by Lopital may result in increased emissions or decreased immunity of the Reflex.
- Use the Reflex in a clean and tidy working environment.
- Only verifiably authorised personnel is allowed to work with the Reflex.
- Charge battery in a well-ventilated, dry space.
- Swimming pool locations are not considered to be 'normal conditions' and will substantially shorten the lifespan of certain components.
- The Reflex cannot be used on a surface with a gradient over 5 degrees laterally.
- The Reflex cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Reflex may only be used indoors.
- Portable and mobile RF communication equipment can affect medical devices.
- Medical electrical devices involve special EMC precautions and must be used as per the EMC information outlined in the instructions for use.
- The chair must not be used adjacent to or stacked on other products. However, should that be necessitated, it must be checked whether the chair functions normally in this configuration too.

Maintenance

- If the charger or 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 Reflex must be inspected and serviced at least once a year.
- Servicing and maintenance of the Reflex may only be carried out by persons authorised by Lopital.
- Constructive components of the Reflex may only be replaced by suitably authorised Lopital personnel.
- If erroneous use, transport, an accident or improper maintenance leads to deformation of the Reflex, 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 Reflex 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 Reflex has been developed and produced for use in professional care environments.



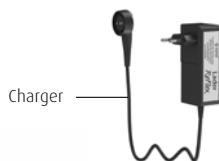
Making changes to the structure can affect the safety of the Reflex. Furthermore, the liability and guarantee conditions of Lopital lapse. As a result, the Reflex no longer meets the Medical Devices Regulation.

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.



Figure 1 Control panel.



Reflex with detachable, swing-out footrests, complete chair: 5100 5605



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CE IP--
Weight: -- kg / -- lbs
Type battery: --
Drive operates: --V/
Charge: --V-- mA
Non-Continuous: --

GTIN (01) 6720256103--
SN (11) YYMMDD
SN (21) -- -- -- --
MAG LOAD -- kg / -- LBS
Product type

Item no: -----

Tested to:
UL 60601-1:2005/A2:2010/(R)2012
CAN/CSA-C22.2 No. 60601-1:14
E 114029

MET US

2. Use

2.1. First use

On page 8 you can find the components of the Reflex. These components are the applied parts of the Reflex. These components may come into contact with the user(s) while the Reflex is in use.

2.2. Activating

Before you can use the Reflex, you must activate it by pressing both up arrows for 2 seconds (*See figure 1*). It may occur that the Reflex goes into sleep mode after a period of time. To deactivate the sleep mode, press both up and down buttons for 2 seconds.



Activate the Reflex by pressing both up buttons for 2 seconds.

2.3. Working with the Reflex

Step 1

Disconnect the Reflex from the charger if necessary.

Step 2

Activate the Reflex (*See paragraph 2.2. Activating*).

Step 3

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

Step 4

If necessary, fold the foot plates up or remove the footrests from the Reflex (*See paragraph 3.2. Footrests*).

Step 5

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

Step 6

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

Step 7

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

Step 8

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

Step 9

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

Step 10



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 11

When you wish to tilt the chair or move it upwards / downwards, you must apply the brake (See paragraph 3.5. Moving upwards / downwards and paragraph 3.6. Tilting).

3. Operation

3.1. Wheel blocking

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

Option: Swivel wheel left front.

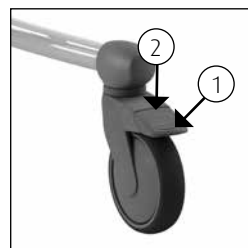


Figure 2 Swivel wheel.

3.2. Footrests

Footrests for Reflex (*Article number chair 5100 5600*).

- The Reflex footrests can easily be removed from the frame by moving the locking lip (1) upwards. The footrest is then moved upwards and removed from the frame. Carry out the same procedure (in reverse order) in order to replace it (*See figure 3*).
- Before the client takes a seat in the Reflex, the foot plates must be folded upwards. There is now sufficient room to allow the client to easily take a seat (*See figure 4*).
- The carer or the client first raises one leg; the carer then folds the footrest down (*See figure 5*). The same procedure is then carried out with the other leg. Make sure that the footrests are set to the right height.
- The footrest height is adjustable in steps over 23 cm / 9 inch (minimum 26.5 cm / 10.4 inch and maximum 50 cm / 19.7 inch, measured from the top of the seat to the upper side of the footrests).



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

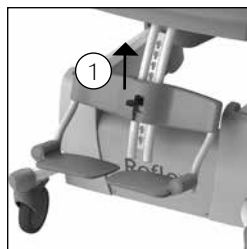


Figure 3 Removing footrests.



Figure 4 Folding up footrests.



Figure 5 Folding down footrests.

Detachable, swing-out footrests on Reflex.
(Article number chair 5100 5605).

- Before the client takes a seat in the Reflex, 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 6). If more room is required, the Flexo footrests can be turned out (See figure 7). 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 then folds the footrest down (See figure 8). 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 6 Folding up footrests.

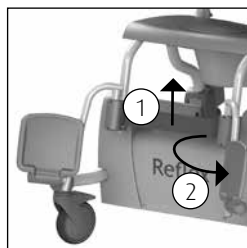


Figure 7 Turning up footrests.



Figure 8 Folding down footrests.



Option: Comfort leg support.

This option is only possible with the 5100 5605.

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 9 to 12). 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 13).



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

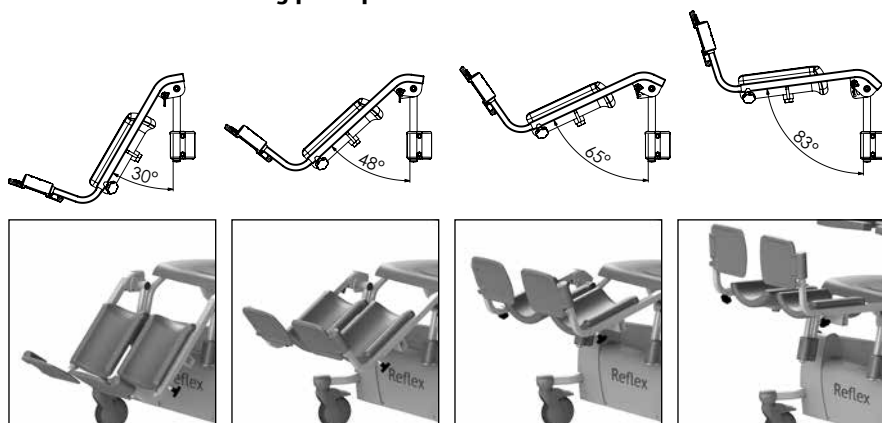


Figure 9 to 12 Adjustable seating angle.

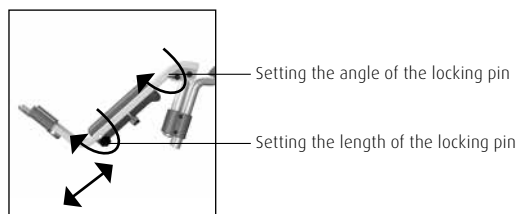


Figure 13 Locking pins.



To adjust the length of the leg support, you have to release the locking pin underneath by loosen it a bit (See figure 13). 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 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 Reflex, 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 14*). The armrest 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.

Option: Armrests with dual locking.

- The extra lock ensures that the front closure is also locked when turned away (*See figure 16*).



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 armrest 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 Reflex and / or present a hazard.

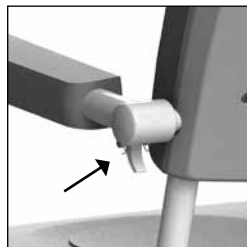


Figure 14 Armrest.

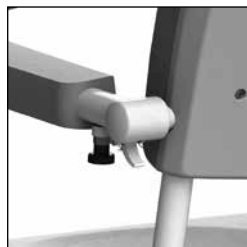


Figure 15 Armrest with dual locking.



Figure 16 Armrest turned out.

3.4. Head / neck support

- The Reflex 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 17).
- 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 Reflex has a curved head / neck support, allowing the head of the client to be supported effectively.

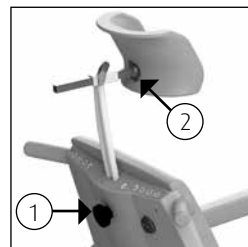


Figure 17 Head support.



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

3.5. 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.
- Move the chair upwards by pressing the button that shows an 'up' arrow. The seat will then move upwards simultaneously (See figure 18).
- You can stop the movement whenever you like by taking your finger off the button.
- During the upward movement, maintain contact with the client.



Figure 18 Moving upwards.

Moving downwards

- Move the chair downwards by pressing the button that shows a 'down' arrow. The seat of the Reflex will move downwards simultaneously (See figure 19).
- You can stop the movement whenever you like by taking your finger off the button.
- During the downward movement, maintain contact with the client.



Figure 19 Moving downwards.



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

3.6. Tilting

- The Reflex is equipped with a backwards tilting function of up to 30 degrees. This function is operated by pushing the button that shows an arrow pointing backwards. The chair will then tilt (See figure 20).
- You must put the Reflex on the brake before using the tilt function.
- When the chair reaches the maximum tilting angle, the movement will automatically stop. The carer can stop the movement at any moment by releasing the button.
- In order to tilt the Reflex forwards again, the button with the arrow pointing forwards must be used (See figure 21).
- Once the chair is back in the horizontal position, the movement will automatically stop.
- During tilting, the front closure must be closed and the client must rest their arms on the appropriate armrest.
- During tilting, maintain contact with the person in the chair.



Figure 20 Tilting backwards.



Figure 21 Tilting forwards.



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

3.7. Toilet function

3.7.1. In combination with toilet

- The Reflex can also be moved over the toilet.
- Remove the inlay on 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 Reflex to the appropriate height.
- Move the Reflex, if necessary, upwards or downwards to achieve the right position.
- The Reflex can now be moved backwards over the toilet.
- Lower the Reflex, if necessary, to achieve the right position.



The Reflex does not fit over every toilet.

3.7.2. Use of a bedpan or bucket

- If the Reflex 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 22).
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (See figure 23).
- 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 24) of aan de achterkant van de zitting (See figure 25).

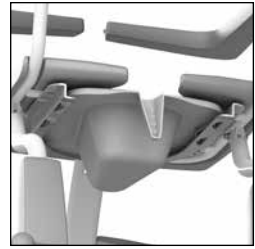


Figure 22 Bedpan.



Figure 23 Lopital plastic bedpan.



Figure 24 Stainless steel bedpan, front.



Figure 25 Stainless steel bedpan, back.



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.

3.8. Charging battery

- The Reflex is an electrically driven high / low shower-toilet chair and works on a battery.
- The charging point is located on the back of the chair (1) (See figure 26).
- If the battery is almost empty, the LED (2) next to the battery symbol on the control panel will blink red to indicate that the battery must be charged (See figure 26).
- Connect the charger to the Reflex (See figure 26).
- Open the metal flap (1) and connect the charger to the Reflex (See figure 26).
- Once the charger is connected to the Reflex, the controls will go into 'sleep' setting (all functions are switched off).

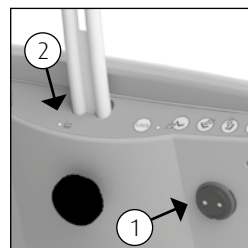


Figure 26 Charging point.



Make sure you push the plug into the correct position in the charging point.



Only the original charger for the Reflex may be used. If you use another charger, Lopital cannot be held liable for any consequences, such as damage to the electronics.



Once the charger is connected to the Reflex, the controls will go into 'sleep' setting (all functions are switched off).



The charger that must be used for the Reflex is the 'Mascot 2241'.

- When the indicator LED on the charger turns green, the battery is charged. The charger can remain connected even when the battery is completely charged. Leaving it connected will not cause any damage.
- Disconnect the Reflex from the charger.
- Once activated, the Reflex is now ready for use (See paragraph 2.2. Activating).



Figure 27 Battery indication on control panel.

LEDs not on:	Chair is in 'sleep' setting and cannot be used.
Green LED is on:	Chair is ready for use
Red LED blinks:	Battery must be charged (chair can still be used).
Red LED on:	Battery is completely empty and must be charged immediately



Charge battery in a well-ventilated, dry space.



After using the chair, connect it to the charger to maintain the battery. Charge the chair at least once a week!

For instruction videos go to www.lopital.com or www.youtube.com/user/LopitalNL

4. Safety functions

4.1. Lock button

The Reflex is fitted with a lock button (1) (See figure 28). Operate the lock button if the Reflex is not to be used for an extended period. This will prevent any unauthorised use of the chair.

When you press the lock button, the red LED (2) next to the lock button will come on to indicate that the chair is not working.

In order to use the chair again, you must reset it, by keeping both upwards buttons pressed in for 4 seconds.

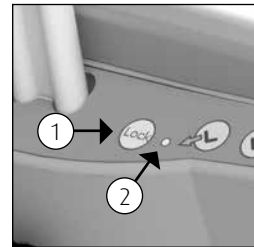


Figure 28 Lock button.

4.2. Sleep setting

After around an hour, the chair will fall into a 'sleep' setting and the battery indication LEDs on the handcontrol will go out. In order to use the chair again, it must be activated (See paragraph 2.2. Activating).

4.3. Emergency lowering

If the controls stop working and the chair is in a raised position, it can be lowered using the emergency lowering handle.

Check first to make sure the chair is not in sleep setting!

- Place the emergency lowering handle at the appropriate place (1) (See figure 29).
- Turn the handle clockwise (2) (See figure 29).

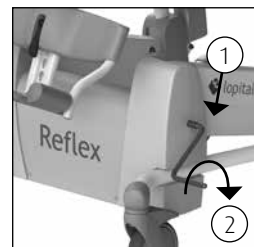


Figure 29 Emergency lowering handle.

The chair will now return to the lowest position (make sure no persons or objects are under the chair).

Take the client from the chair and make sure the device is not used until it has been repaired. Place the chair in a safe place and indicate that it is out of order.

Contact the technical service or Lopital's service department.


E-mail: info@lopital.nl

5. Cleaning and maintenance

The Reflex 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.

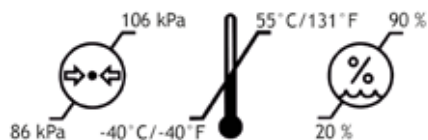
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Reflex may only be carried out by authorised personnel.

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 Reflex are present, including the footrests, head / neck support, seat inlay and handcontrol.
Weekly	<ul style="list-style-type: none"> • Check wheels for hairs, dust and soap residues and remove if necessary. • Check if the chair is still working correctly. • Charge the battery at least once a week.
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.

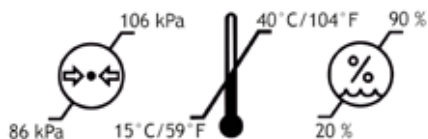
6. Environmental conditions

Conditions during storage and transport



During transport, the seat must be switched off (*See section 4.1. lock button*).

Conditions during use



7. 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.

If you take care of disposal of the product yourself, you must take account of the fact that batteries and chargers must be disposed of as small chemical waste.

8. Technical specifications



The Reflex Shower-toilet chair belongs to category 'BF'.



The Reflex Shower-toilet chair is a class 2 EMC product.

The Reflex is splash proof; this means that the Reflex can be used under the shower. This is given with instruction IPX4.

8.1. Structure

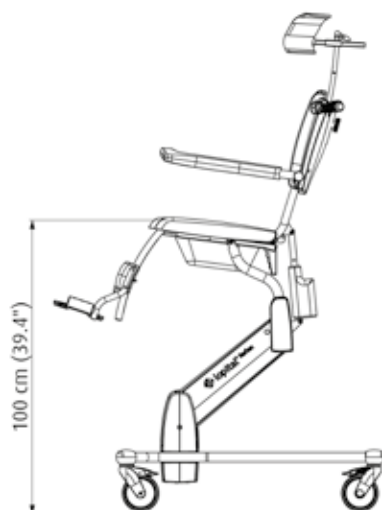
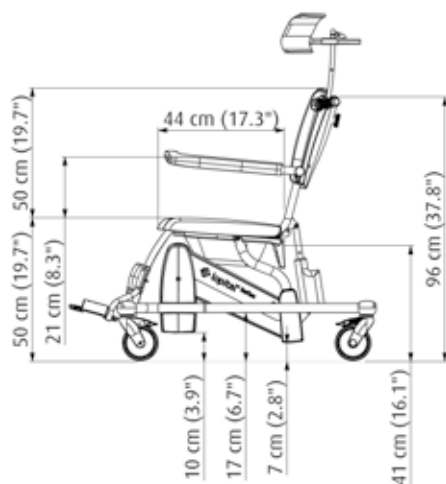
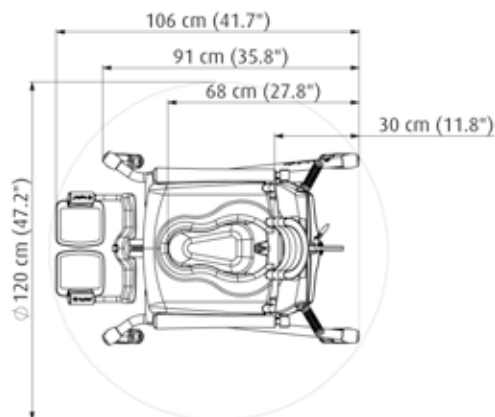
Frame:	Stainless steel and steel tubes and plates that are equipped with a 2-layer powder coating
Hinge points:	Stainless steel, cover caps made of plastic V0
Wheels:	Plastic, Ø 12.5 cm / 4.9 inch, double blocking facility
Body support :	PUR (polyurethane).
Weight:	53 kg / 117 lbs
Maximum permitted load:	135 kg / 300 lbs
Weight comfort leg support:	3.6 kg / 8 lbs per unit

8.2. Drive

Drive:	Actuator 24V Stainless steel spindles for high / low movement 24V actuator for tilt adjustments
Battery:	Battery capacity 7Ah
Charger:	110-240V AC, 50-60Hz, max. 0,35A, cable length 1.5 m.



8.3. Dimensions

Surface area:	70 cm / 27.6 inch wide, 106 cm / 40.9 inch deep
Seat height:	Adjustable: minimum 50 cm / 19.7 inch, maximum 100 cm / 39.4 inch
Footrest adjustment:	23 cm / 9.1 inch
Head support adjustment:	Depth 7 cm / 2.8 inch & height 12 cm / 4.7 inch
Gradual tilt adjustment:	30° backwards



Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

Brand name:	Lopital		
Medical device:	Reflex		
Device description:	Mobile shower-/toilet chair with electrically adjustable height and inclination		
Models:	51005600 & 51005605		
Classification:	Class I		
Basic UDI-DI:	872025610300451005600CA & 872025610301151005605BC		
Conforms to regulation:	Medical Device Regulation (EU) 2017/745		
Standards applied:	<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 60529:2019 <i>Degrees of protection provided by enclosures (IP Code)</i></p> <p>IEC 60601-1:2005 + A1:2012 <i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</i></p> <p>IEC 60601-1-2:2007 <i>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests</i></p> <p>IEC 60601-1-6:2010 <i>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability</i></p> <p>IEC 62366-1:2007 <i>Medical devices - Part 1: Application of usability engineering to medical devices</i></p> <p>CAN/CSA-C22.2 No. 60601-1:14 <i>Medical electrical equipment - part 1: General requirements for basic safety and essential performance</i></p> <p>ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012 <i>General requirements for basic safety and essential performance</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>		
Certificate/report no.:	Certificate: NL-36634 Reports: 2174112.50 (A,B,C,D), 2174112.0501-EMC		

Authorised signatory, Cees van Dam, director:

Signature:



Date:

2021-05-03


Place:

Oisterwijk

9. Elektromagnetische compatibiliteit

Guidance and Manufacturer's declaration-electromagnetic emissions		
The Reflex is intended for use in the electromagnetic environment specified below. The customer or the user of Reflex should assure that it is used in the following environment:		
Emissions Test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR11	Group 1	The Reflex uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The Reflex is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration-electromagnetic immunity			
The Reflex is intended for use in the electromagnetic environment specified below. The customer or the user of the Reflex should assure that it is used in the following environment:			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% Un (>95% drop in Un) for 0,5 cycle 40% Un (60% drop in Un) for 5 cycles 70% Un (30% drop in Un) for 25 cycles <5% Un (>95% drop in Un) for 5 seconds	<5% Un (>95% drop in Un) for 0.5 cycle 40% Un (60% drop in Un) for 5 cycles 70% Un (30% drop in Un) for 25 cycles <5% Un (>95% drop in Un) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. Reflex is equipped with a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE Un is the a.c. mains voltage prior to application of the test level			

Guidance and Manufacturer's declaration-electromagnetic immunity			
The Reflex is intended for use in the electromagnetic environment specified below. The customer or the user of the Reflex should assure that it is used in the following environment:			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - guidance
<p>RF Common mode/ Conducted Susceptibility IEC 61000-4-6</p> <p>Radiated RF Electromag- netic Field IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Reflex, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,4 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Reflex is used exceeds the applicable RF compliance level above, the Reflex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Reflex.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distance between portable and mobile RF communications equipment and the Reflex			
The Reflex is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Reflex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Reflex as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,4 \sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,38	0,38	0,76
1	1,2	1,2	2,4
10	3,8	3,8	7,6
100	12	12	24
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



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