# Instructions for use

# Reflex

5100 5600, 5100 5605, 5100 5610, 5100 5611, 5100 5612

**Shower-toilet chair**



**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.
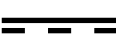Laarakkerweg 9
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| Notes on symbols | |
| --- | --- |
|  | Read the instructions for use before use. |
|  | Direct current 24V DC. |
|  | Note. |
|  | Applied parts. |
|  | Class 2 EMC. |

# Contents

# 1. Introduction

## 1.1. Introduction

The height-adjustable, electric shower and toilet chair Reflex 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 Reflex can also be used as a toilet chair, in combination with a bedpan / bucket.
The Reflex 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 electrically, gradually adjusted in height, in relation to the base frame. The Reflex is thus a multifunctional device. The chair component of the Reflex can be tilted backwards to 30 degrees. These functions are essential performances of the chair.

The average technical life of the Reflex is 10 years, assuming it is cleaned daily and regularly maintained according to the maintenance schedule supplied (*See: Chapter 5 Cleaning and Maintenance).*

*The Reflex is a class 1 product with CE-marking. This marking corresponds with directive 93/42/EC and the revised directive 2007/47/EC for medical devices of 21 March 2010. The Reflex has been tested for electro-magnetic radiation according to the norm 60601-1-2.*

The Reflex is available in the following versions:
· 5100 5600 Reflex
· 5100 5605 Reflex with Flexo leg supports
· 5100 5610 Child Reflex 3-6 years
· 5100 5611 Child Reflex 7-10 years
· 5100 5612 Child Reflex 11-14 years

## 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.
- Make sure that the Reflex brake is applied before transferring clients.
- Notify the client before moving the Reflex.
- When the chair is moving upwards or downwards or tilting do not place feet on the sub-frame; this will prevent any jamming issues.
- 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 appropriate armrest in order to avoid anything becoming jammed.
- 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 / 297.6 lbs.
- The Reflex may not be used to transport loads other than people.
- 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 batteries 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.
- During use of the Reflex, the water temperature may not exceed 43°C / 109.4°F.
- 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.
- 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: service@lopital.nl

⚠ **The Reflex shower-toilet chair must only be operated by persons who have
been sufficiently trained and expert personnel who have experience working
with the target group.**

⚠ **The Reflex must be used in a clinical setting.**

⚠ **Making changes to the construction could affect the safety of the Reflex. This
will also lead to Lopital's liability and warranty conditions being invalidated.
As a result, the Reflex will no longer comply with the guidelines for medical
devices.**

### 1.3. Warranty
Lopital products are guaranteed for 2 years with respect to construction and / or
material faults. In the event of varying warranty terms, the exact period will be indicated
on your invoice; this also serves as the warranty itself.
Components that are subject to wear and tear (such as batteries, handcontrols and
cables) will not fall under warranty unless there are clear construction and / or material
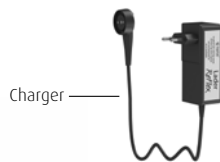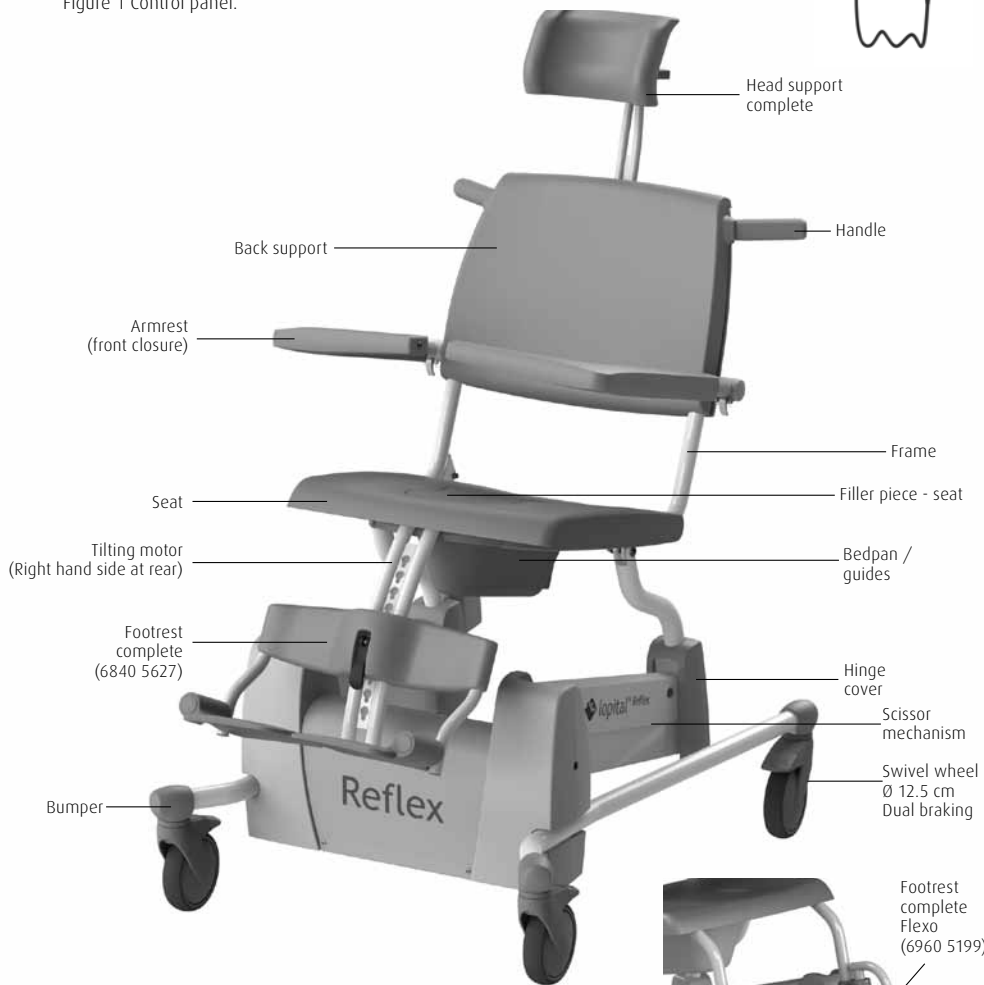faults.

## 2. Use

### 2.1. First use
Before you use the Reflex, you must check to ensure the components on page 32 are
present. These components can be replaced by authorised individuals in the event of
damage. 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.

Figure 1 Control panel.

Charger

Head support complete

Handle

Back support

Armrest (front closure)

Frame

Seat

Filler piece - seat

Tilting motor (Right hand side at rear)

Bedpan / guides

Footrest complete (6840 5627)

Hinge cover

Scissor mechanism

Swivel wheel Ø 12.5 cm Dual braking

Bumper

Footrest complete Flexo (6960 5199)

Reflex with Flexo leg supports complete chair: 5100 5605.

## 2.2. Activating
Before you can use the Reflex, you must activate it by pressing
both up arrows for 2 seconds (*See figure 1*).

## 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 Armrest 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 Armrest 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


Figure 2 Swivel wheel.

- 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).*
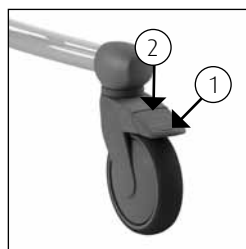
*Option:* Swivel wheel left front *(Article number: 75560025).*

## 3.2. Footrest
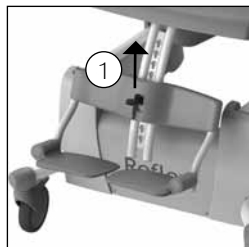

Figure 3 Removing footrest.


Figure 4 Folding up foot plates.


Figure 5 Folding down foot plates.

Footrest 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 foot plate down *(See figure 5).* The same procedure is then carried out with the other leg. Make sure that the footrest is 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 foot plates).

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

Footrest on Reflex with Flexo footrest *(Article number chair: 5100 5605).*
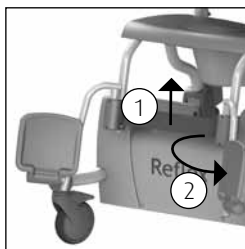
Figure 6 Folding up foot plates.     Figure 7 Turning out footrests.     Figure 8 Folding down foot plates.

- Before the client takes a seat in the Reflex, the foot plates 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 foot rests can be turned out *(See figure 7).* First, the foot rests 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 foot plate 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.**

*Option:* Comfort leg support *(Article number 6960 8026)*
**This option is only possible with the 5100 5605.**
The comfort leg support provides the legs with additional support. The comfort leg support 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, as shown in figures 9, 10, 11 and 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 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.



Setting the angle of the locking pin

Setting the length of the locking pin
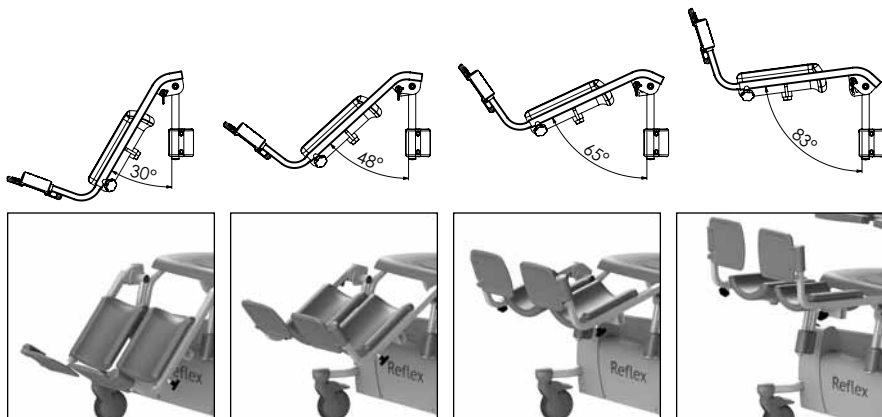
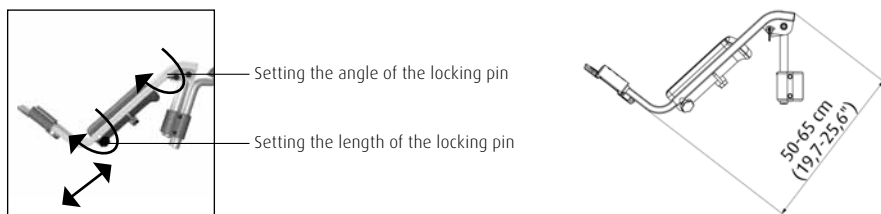Figure 13: Locking pins.

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. Armrest 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:* Armrest with dual locking *(Article number: 6840 5661).*
- The extra lock ensures that the front closure is also locked when turned away *(See figure 16).*

⚠ **When folding the armrest away, avoid the hinging point so as to avoid becoming jammed.**

⚠ **When folding the armrests away, avoid fingers or body parts becoming jammed 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.
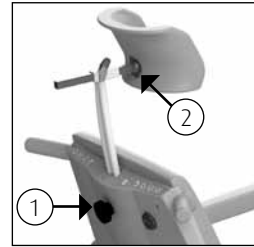
Figure 17 Head support.

⚠ **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 theappropriate armrest.
- During tilting, maintain contact with the person in the chair.

Figuur 20 Tilting backwards.

Figuur 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 lid 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).*
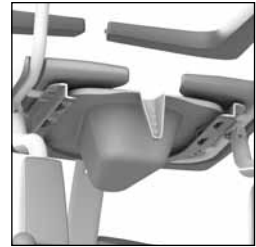


Figure 22 Bedpan.

⚠ **In order to avoid injuries, we advise the carer to remove the lid 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.**



Figure 23 Lopital plastic bedpan.

⚠ **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 batteries

- The Reflex is an electrically driven high / low shower-toilet chair and works on batteries.
- The charging point is located on the back of the chair (1) *(See figure 26).*
- If the batteries are almost completely empty, the LED (2) next to the battery symbol on the control panel will blink red to indicate that the batteries 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).*



Figure 24 Stainless steel bedpan, front.



Figure 25 Stainless steel bedpan, back.

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

⚠ **Make sure that 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.**



Figure 26 Charging point.

⚠ **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 light on the charger goes green, the batteries are charged.
  The charger can remain connected even when the batteries are 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)*.

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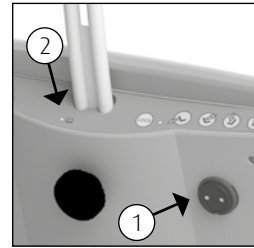                     must be charged immediately



Figure 27 Battery indication on
control panel.

⚠ **Charge batteries in a well-ventilated, dry space.**

⚠ **After using the chair, connect it to the charger to maintain the batteries.
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. You do this by keeping both upwards buttons pressed in for 4 seconds.
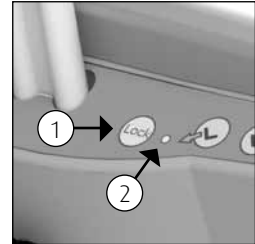


Figure 28 Lock button.

## 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)*.



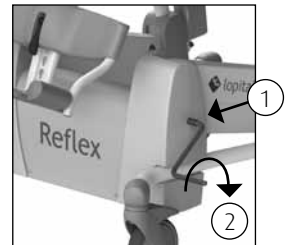Figure 29
Emergency lowering handle.

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: service@lopital.nl

# 5. Cleaning and maintenance

The Reflex must be cleaned after every use, with water and regular household cleaning agents. Remove excess soap residues. PUR integrated foam components with IMC coating should be rubbed clean and disinfected. Do not use any abrasive or other aggressive cleaning products (e.g. chlorine bleach). Practical experience has shown that regular household cleaning agents with limited alcohol content (max. 5%) are most suitable for this purpose. The product Neoquat combi® is recommended for disinfection purposes (on the basis of long-term testing). If necessary, the PUR components can be cleaned with a solution of 70% ethanol or propanol.

You must ensure that both the disinfecting and cleaning processes involve the components being rubbed and not just submerged. 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 decontaminated.

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** | · Clean chair with water and regular household cleaning products. |
| **Daily** | · PUR foam components must be cleaned and disinfected.<br>· Check to ensure all parts of the Reflex are present, including the footrests, head support and filler piece for the seat. |
| **Weekly** | · Clean frame.<br>· Check wheels for hairs, dust and soap residues and remove if necessary.<br>· Check that the chair is still working correctly.<br>· Charge the battery at least once a week. |
| **Annually**<br> | · According to the guidelines for medical devices, a chair must be maintained in line with the manufacturer's instructions. 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.<br><br>For more information about the maintenance contract, please contact Lopital (service@lopital.nl) or speak to your supplier. |

# 6. Storage and transport

During transport and storage, the ambient conditions must remain moderate. In other words, the temperature should remain between -40 and +55 degrees Celsius (-40 to 130 degrees Fahrenheit) and humidity levels should be kept as low as possible. Vibration during transport must be kept to a minimum in order to avoid damaging the hinged mechanisms on the chair. The chair must be switched off during transport *(See paragraph 4.1. Lock button).*

# 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 / 298 lbs |
| Weight comfort leg support: | 3.6 kg / 7.9 lbs per unit |

### 8.2. Drive

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

62 cm (24,4")

47 cm (18,5")

70 cm (27,6")

106 cm (40,9")

91 cm (35,8")

68 cm (26,8")

30 cm (11,4")

50 cm (19,7")

50 cm (19,7")

50 cm (19,7")

21 cm (8,3")

44 cm (17,3")

96 cm (37,8")

43 cm (16,9")

10 cm (3,9")

17 cm (6,7")

8 cm (3,2")

100 cm (39,4")

Reflex Shower-toilet chair | **Instructions for use** | 47
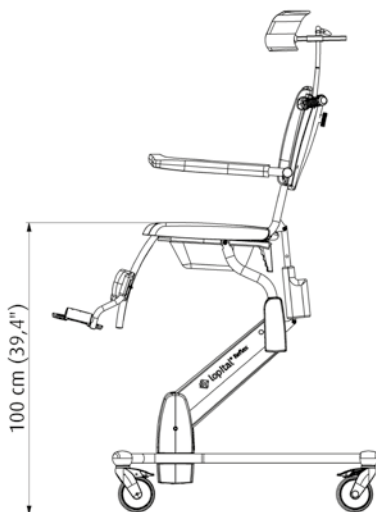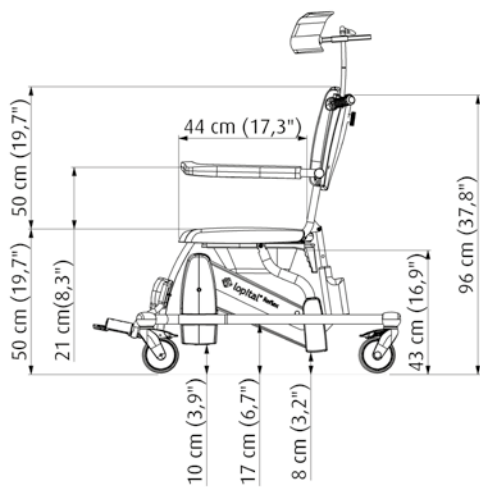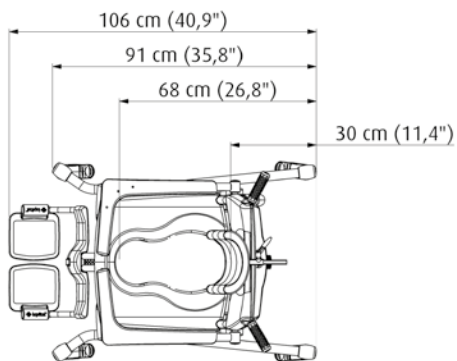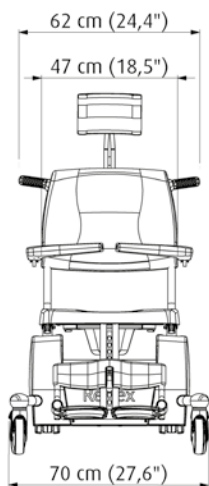
# 9. Electromagnetic compatibility

| 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<br><br>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<br><br>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<br><br>IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/<br>Flicker emissions<br><br>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)<br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±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<br><br>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<br><br>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<br><br>IEC 61000-4-11 | <5% Un<br>(>95% drop in Un) for 0,5 cycle<br><br>40% Un<br>(60% drop in Un) for 5 cycles<br><br>70% Un<br>(30% drop in Un) for 25 cycles<br><br><5% Un<br>(>95% drop in Un) for 5 seconds | <5% Un<br>(>95% drop in Un) for 0.5 cycle<br><br>40% Un<br>(60% drop in Un) for 5 cycles<br><br>70% Un<br>(30% drop in Un) for 25 cycles<br><br><5% Un<br>(>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<br><br>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 |
| RF Common mode/ Conducted Susceptibility IEC 61000-4-6<br><br>Radiated RF Electromagnetic Field IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz<br><br>3 V/m 80 MHz to 2,5 GHz | 3 V<br><br>3 V/m | 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<br><br>$d = 1,2 \sqrt{P}$<br><br>$d = 1,2 \sqrt{P}$    80 MHz to 800 MHz<br><br>$d = 2,4 \sqrt{P}$    800 MHz to 2,5 GHz<br><br>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).<br><br>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]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| 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.<br>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

| 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 | Separation distance according to frequency of transmitter | | |
| W | m | | |
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |
| | $d = 1{,}2\ \sqrt{P}$ | $d = 1{,}2\ \sqrt{P}$ | $d = 2{,}4\ \sqrt{P}$ |
| 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.

# Notes