

Instructions for use

Elexo

5100 5500

Shower-toilet chair

Basic UDI-DI : 872025610302851005500GT



Important:

Read these instructions carefully before using the Elexo!

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 Elexo 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 Elexo can be used with a commode pan / bucket or in combination with a toilet, can also be used as a toilet seat. The Elexo 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. There are no essential performances.



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

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 working situations. Please read carefully before use.

Use

- Before you start work with the Elexo, check that it has been disconnected from the charger.
- The Elexo will fall into standby mode after a few seconds when the chair is not in use.
- Make sure that the Elexo brake is applied before transferring clients.
- Notify the client before moving the Elexo.
- 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 Elexo upwards.
- Make sure that the client always places his/her arms on the armrests provided to prevent possible entrapment.
- Keep the armrests or front closure down / closed when moving the Elexo.
- Be aware of obstacles when moving upwards and downwards.
- Only relocate and move the Elexo in the lower position.
- When moving the Elexo, do not adjust upwards or downwards.
- Always try to move backwards over obstacles (rather than forwards).
- Set the Elexo to the correct height before using with a toilet.
- It is not permitted to charge the Elexo with more than 180 kg / 400 lbs.
- The Elexo 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 Elexo.
- Use the Elexo in a clean and tidy working environment.
- Only verifiably authorised personnel is allowed to work with the Elexo.
- 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 Elexo cannot be used on a surface with a gradient over 5 degrees laterally.
- The Elexo cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Elexo 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 Elexo must be inspected and serviced at least once a year.
- Servicing and maintenance of the Elexo may only be carried out by persons authorised by Lopital.
- 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 Elexo, 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 Elexo 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 Elexo has been developed and produced for use in a professional healthcare environment.



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

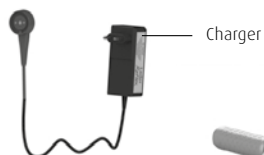
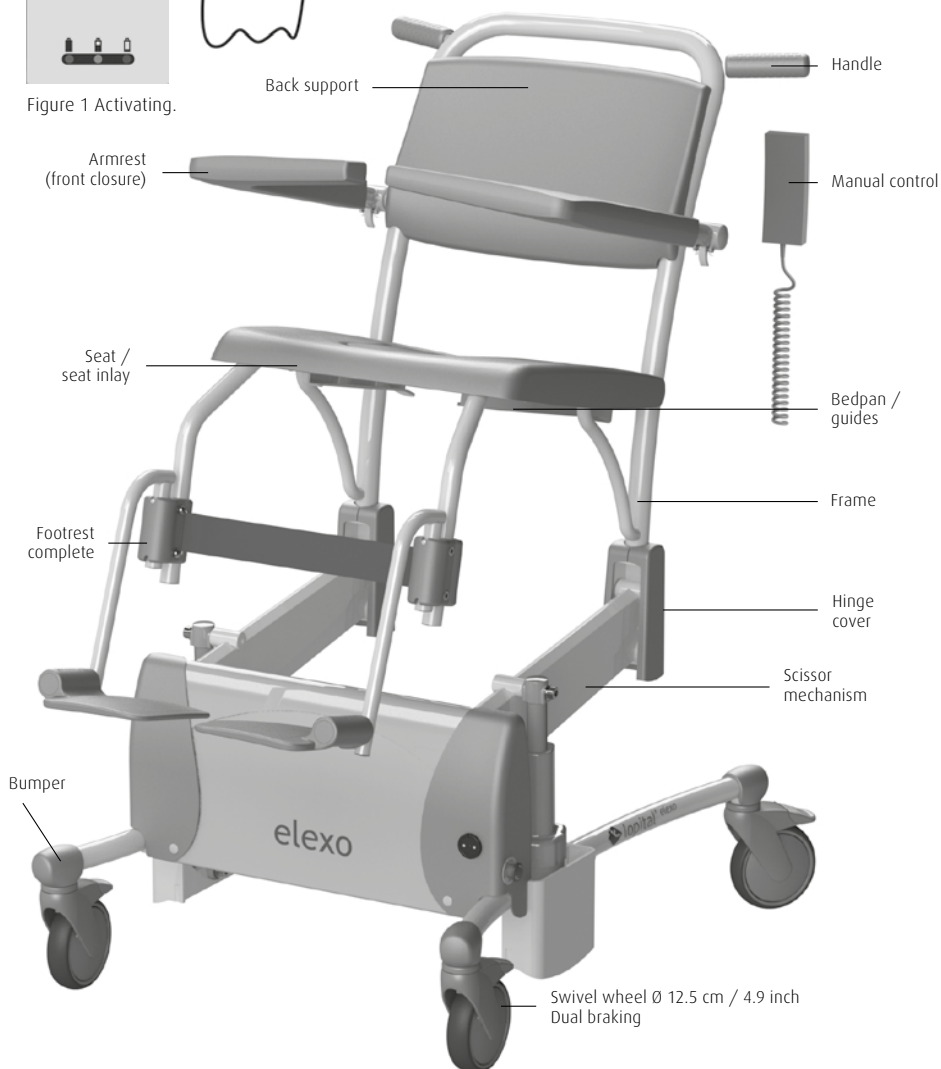




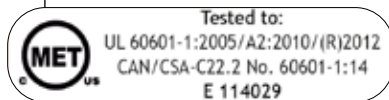
Figure 1 Activating.



 **lopiat**
 Laarlandweg 9
 5061 JR Oisterwijk
 The Netherlands
 T: (+31)13-5239300
 CE IP-
 Weight: -- kg / -- lbs
 Type battery: --
 Drive operates: --V
 Charge: --V-- mA
 Non-Continuous: --

GTIN (01) 8720256103--
 (11) YYMMDD
 SN (21) -- -- -- --
 MAX LOAD -- kg / -- LBS
 Product type

Item no: -----

2. Use

2.1. First use

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

2.2. Activating

The Elexo must be activated before use, which can be done by pressing any button on the hand control for 2 seconds (*See figure 1*).

It may occur that the Elexo goes into sleep mode after a period of time. To deactivate the sleep mode, press any button on the hand control for 2 seconds.



Activate the Elexo by pressing any button for 2 seconds.

2.3. Working with the Elexo

Step 1

Disconnect the Elexo from the charger if necessary.

Step 2

Activate the Elexo (*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 turn the footrests on the Elexo away (*See paragraph 3.2. Footrests*).

Step 5

The Elexo 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 move the chair upwards / downwards, you must apply the brake (*See paragraph 3.4. Moving upwards / downwards*).

3. Operation

3.1. Wheel blocking

- The brake can be applied on the Elexo by pushing the blue lip (1) on the wheel downwards (See figure 2).
- In order to take the Elexo 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).

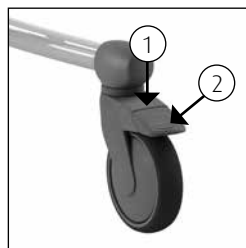


Figure 2 Swivel wheel.

Option: Swivel wheel left front.

3.2. Footrests

- Before the client takes a seat in the Elexo, 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 3). If more room is required, the footrests can be turned out (See figure 4). First, the footrests must be slightly raised (1) and then they can be turned outwards (2).
- The carer or the client first raises one leg; the carer can then fold the footrest down (See figure 5). The same procedure is then carried out with the other leg.



Figure 3 Folding up footrests.

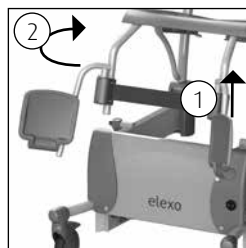


Figure 4 Turning out footrests.



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



Figure 5 Folding down footrests.

Option: Comfort leg supports.

The comfort leg supports provide the legs with additional support. The comfort leg supports can be adjusted in length as well as according to the sitting angle. The angle of the leg supports can be adjusted to 4 positions (See figure 6 to 9). 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 10).



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

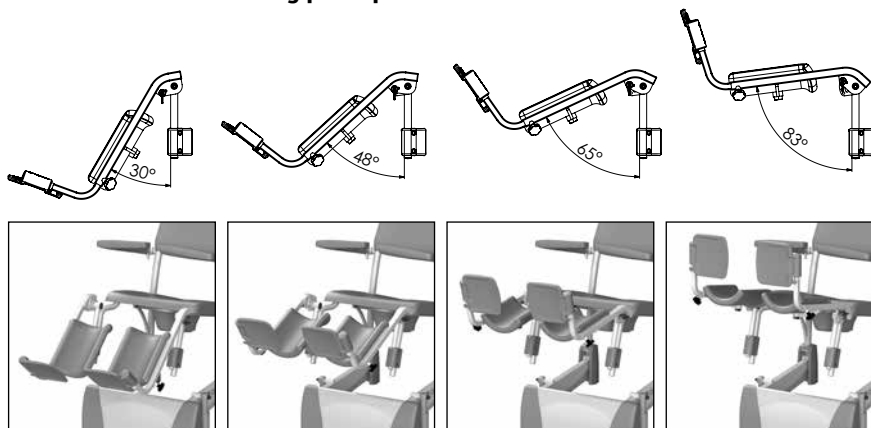


Figure 6 to 9 Adjustable seating angle.

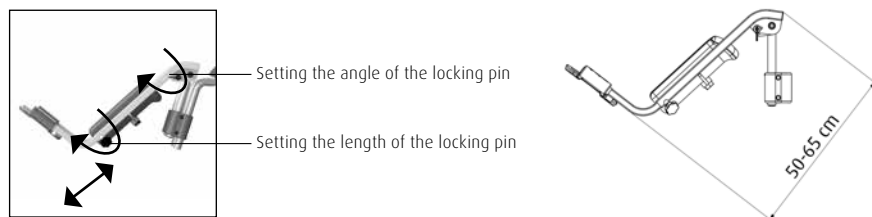


Figure 10 Locking pins.

To adjust the length of the leg support, you have to release the locking pin underneath by loosen it a bit (See figure 10). 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 Elexo, 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 11). 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: Dual locking.

The extra lock ensures that the front closure is also locked when turned away (See figure 13).

Option: Straight armrest.

The independent folding armrests are easy to fold up. Protect the user when moving the armrests upwards and downwards. In the folded up position, they should not fall back down by themselves; in other cases: consult your supplier.



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 Elexo and / or present a hazard.

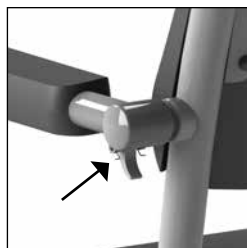


Figure 11 Armrest.



Figure 12 Armrest with dual locking.



Figure 13 Armrest in turned out position.



Figure 14 Straight armrest.

3.4. Moving upwards / downwards

Moving upwards

- If the client is seated in the chair, first apply the brakes to the wheels and then move the chair upwards.
- Move the chair upwards by pressing the button that shows an 'up' arrow. The seat will then move upwards simultaneously (See figure 15).
- 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 15 Moving upwards.



When moving upwards, the position of the chair will tilt from 0° to a maximum of 20° backwards.

Moving downwards

- Move the chair downwards by pressing the button that shows a 'down' arrow. The seat of the Elexo will move downwards simultaneously (See figure 16).
- 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 16 Moving downwards.



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

3.5. Toilet function

3.5.1. In combination with toilet

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



Figure 17 Bedpan.



Figure 18 Lopital plastic bedpan.



Figure 19 Stainless steel bedpan, front.



Figure 20 Stainless steel bedpan, back.



The Elexo does not fit over every toilet.

3.5.2. Use of a bedpan or bucket

- If the Elexo 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 17).
- If you are using the Lopital plastic bedpan, you must slide it as far forwards as possible (See figure 18).
- 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 19) or at the back of the seat (See figure 20).



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.

3.6. Charging battery

- The Elexo is an electrically driven high / low shower-toilet chair and works on a battery.
- The charging point is located on the front of the chair, on the blue cover on the underside of the device (See figure 21).
- If the battery is almost completely empty of charge, the orange light on the manual control will come on; this means that the battery needs to be charged.
- If the LED is on continuous red, the battery must be charged immediately. The chair can then no longer be used.
- Connect the charger to the Elexo (See figure 21).
- Once the charger is connected to the Elexo, the controls will go into 'sleep' setting (all functions are switched off).

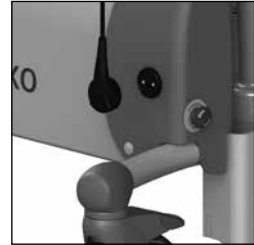


Figure 21 Charging point.



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



Only the original charger for the Elexo 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 Elexo, the controls will go into 'sleep' setting (all functions are switched off).



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

- When the indicator light on the charger goes 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 Elexo from the charger.
- Once activated, the Elexo is now ready for use (See paragraph 2.2. Activating).

LED not on:	Chair is in 'sleep' setting and cannot be used.
Green LED is on:	Chair is ready for use.
Orange LED is on:	Battery needs charging or battery is partially charged.
Orange LED blinks:	Emergency stop has been activated.
Red LED blinks:	Battery must be charged (chair can still be used).
Red LED on:	Battery is completely empty and must be charged immediately.



Figure 22 Battery indication on manual control.



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. Emergency stop

On the left hand side, you will find the emergency stop (See figure 23). Operate this button in an emergency; if the upward or downward movement must be stopped immediately. Once the emergency stop has been pressed, the electronic controls will stop working. Operation may be continued once the situation is stable again. Turn the emergency stop a quarter turn to unlock it again (See figure 24).

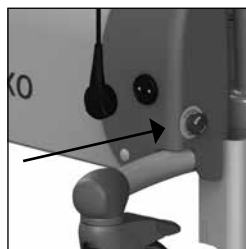


Figure 23 Emergency stop.



Check whether the danger has passed or the problem has been resolved before resetting the emergency stop.



The orange LED on the hand control will flash when the emergency stop has been activated.



Figure 24 Emergency stop.

4.2. Sleep setting

After around an hour, the chair will fall into a 'sleep' setting and the battery indication LEDs on the manual control 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 button.

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

- Remove the plug from the manual control (1) (*See figure 25*).
- Press the emergency lowering button (2) (*See figure 25*).

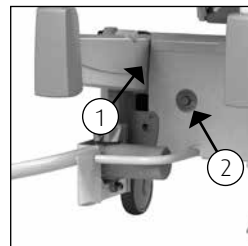


Figure 25 Emergency lowering button.

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

4.4. On / Off switch

On the right hand side of the cover cap, there is the on / off switch (*See figure 26*). If the chair is out of use for an extended period, you are advised to turn it off. This will prevent any unauthorised use of the chair.

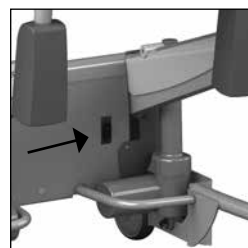



Figure 26 On / off switch.

5. Cleaning and maintenance

The Elexo 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.

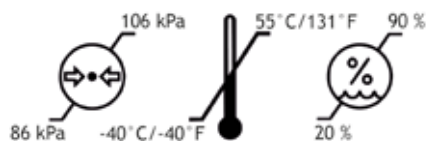
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Elexo may only be carried out by authorised personnel.

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 Elexo are present, including the footrests, the seat filler piece and the manual control.
Weekly	<ul style="list-style-type: none">• Check wheels for hairs, dust and soap residues and remove if necessary.• Check that the chair is still working correctly.• 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.

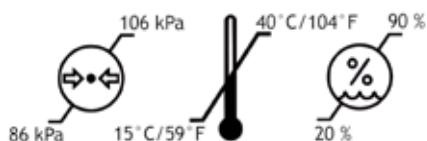
6. Environmental conditions

Conditions during storage and transport



During transport, the seat must be switched off (*See paragraph 4.4. On / Off switch*).

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 Elexo shower-toilet chair belongs to category 'BF'.



The Elexo shower-toilet chair is a class 2 EMC product.

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

8.1. Structure

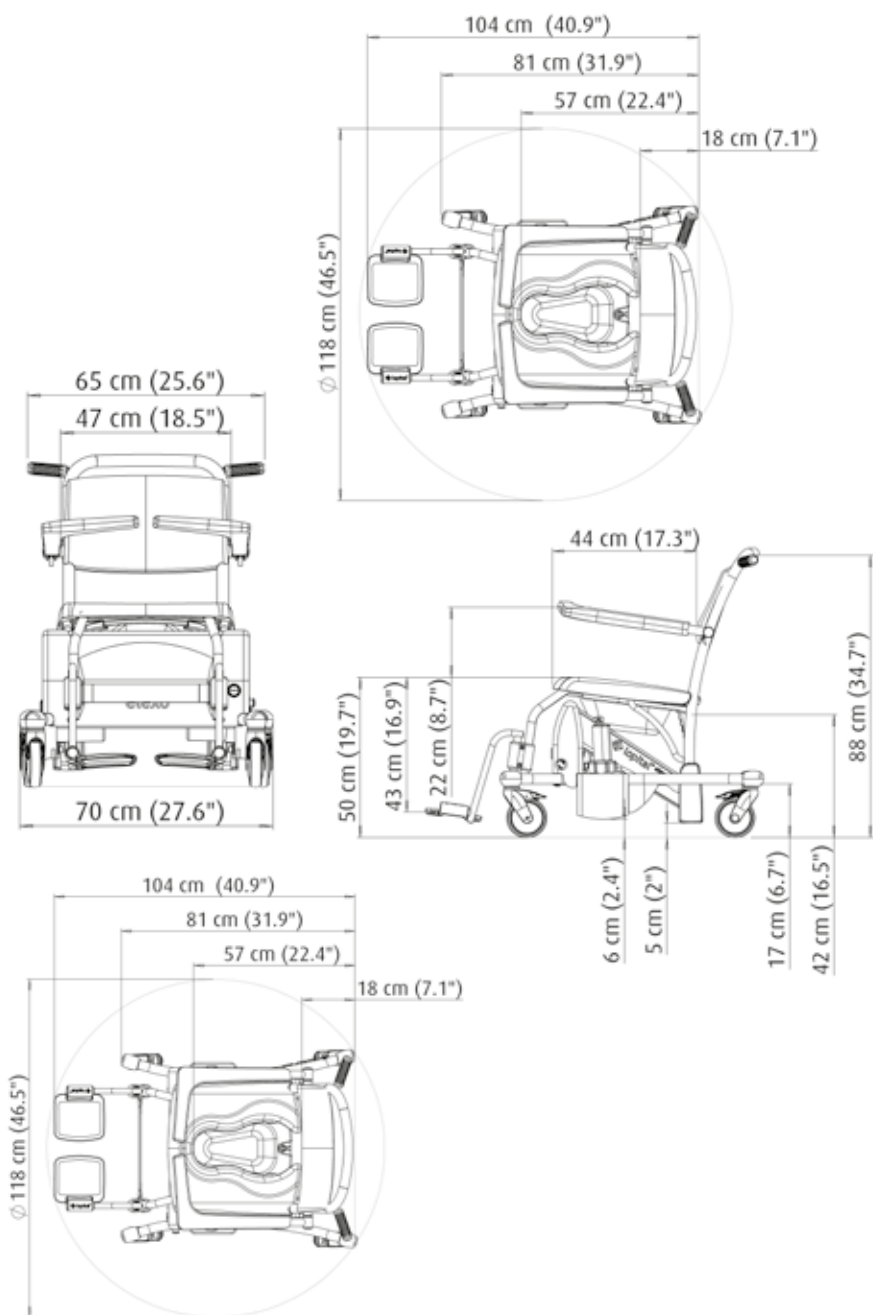
Frame:	Stainless steel and steel tubes and plates that are equipped with a two-layer powder coating
Hinge points:	Stainless steel, cover caps made of plastic V0
Wheels:	Plastic, Ø 12.5 cm / 4.9 inch, double blocking facility
Body support:	PUR (polyurethane).
Weight:	47 kg / 103.6 lbs
Maximum permitted load:	180 kg / 400 lbs
Weight comfort leg support:	3.6 kg / 8 lbs per unit

8.2. Drive

Drive:	Actuator 24V DC Push Only 8000N
Battery:	Battery capacity 7Ah
Charger:	110-240AC, 50/60Hz, max. 0,35A, cable length 2.8 m

8.3. Dimensions

Surface area:	70 cm / 27,6 inch wide, 104 cm / 41 inch deep
Seat height:	Adjustable: minimum 50 cm / 19.7 inch, maximum 105 cm / 41.3 inch



Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

Brand name: Lopital

Medical device: Exlexo

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

Models: 51005500

Classification: Class I

Basic UDI-DI: 872025610302851005500GT

Conforms to regulation: Medical Device Regulation (EU) 2017/745

Standards applied:

NEN-EN-ISO 14971:2019 | *Medical devices-Application of risk management to medical devices*

NEN-EN 12182:2012 | *Assistive product for persons with disability-General requirements and test methods*

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

IEC 60529:2019 | *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005 + A1:2012 | *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007 | *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 60601-1-6:2010 | *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

IEC 62366:2007 | *Medical devices - Application of usability engineering to medical devices*

CAN/CSA-C22.2 No. 60601-1:14 | *Medical electrical equipment - part 1: General requirements for basic safety and essential performance*

ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012 | *General requirements for basic safety and essential performance*

UNI-CEI-EN-ISO 13485:2016 | *Medical devices-Quality management systems-Requirements for regulatory purposes*

NEN-EN-ISO 9001:2015 | *Quality management systems - Requirements*

NEN-EN-ISO 14001:2015 | *Environmental management systems - Requirements with guidance for use*

Certificate/report no.:

Certificate: NL-36630

Reports: 2176154.50 (A,B,C,D), 2176154.0502-EMC



Authorised signatory, Cees van Dam, director:

Signature:

Date:

2021-05-03


Place:

Oisterwijk

9. Electromagnetic compatibility

Guidance and Manufacturer's declaration-electromagnetic emissions		
The Elexo is intended for use in the electromagnetic environment specified below. The customer or the user of Elexo should assure that it is used in the following environment:		
Emissions Test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR11	Group 1	The Elexo 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 Elexo 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 Elexo is intended for use in the electromagnetic environment specified below. The customer or the user of the Elexo 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. Elexo 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 Elexo is intended for use in the electromagnetic environment specified below. The customer or the user of the Elexo 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 Radiated RF Electromag- netic Field IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Elexo, 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 Elexo is used exceeds the applicable RF compliance level above, the Elexo should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Elexo.</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 Elexo			
The Elexo is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Elexo can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Elexo 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	d =1,2 √P	d =1,2 √P	d =2,4 √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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