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Creating balance in healthcare

Instructions for use
Lotus Active standup aid

Instructions for use

Lotus

5900 8100

Active standup aid

Basic UDI-DI: 87202561033185900810OP4

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Creating balance in healthcare

Important:
Read these instructions carefully before using the Lotus!

Date first used . . . . . .

User . . . . . .

Name . . . . . .

Address . . . . . .

Manufacturer
Lopital Nederland B.V.
Laarakkerweg 9
5061 JR Oisterwijk
T +31 (0)13 5239300
www.lopital.nl
info@lopital.nl

All of the aids produced by Lopital fulfil the following norms for medical products Class 1 (MDR (EU) 2017/745).

Explanation of symbols in 'instructions for use' and on labels			
	**Note**		**Follow the instructions for use**
	**Date of production**		**Read cleaning and disinfecting protocol**
	**Maximum load**		**Antibacterial**
	**Global trade identification number**		**Temperature**
	**Serialnumber**		**Air pressure**
			**Humidity level**

Contents

1. Introduction

1.1. Introduction

The Lotus is an active standing aid for people who can still stand up independently and have sufficient trunk stability, but cannot walk or walk with difficulty. The carer can move the client safely and efficiently after he/she has taken place on the Lotus. The Lotus is intended for short transfers, for example from the bed to the toilet. The active sitting position of the client reduces the need for strength to get back into a standing position.

The frame of the Lotus 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 Lotus is 10 years, provided that daily and periodic maintenance is carried out according to the specified maintenance schedule (See chapter 4. Cleaning and maintenance).

The Lotus is a medical class 1 product with CE marking. This marking is in accordance with the regulation MDR (EU) 2017/745.

1.2. Safety

A failure to comply with the following safety points and the further definitions in these instructions for use could lead to hazardous situations. Please read carefully before use.

Use

- Make sure you always keep in contact with the client when using the Lotus.
- Make sure that the sitting parts are lowered before the client takes place and you are about to move the Lotus.
- Make sure that the client always holds the handles when you intend to move the Lotus.

- The client must sit on both halves of the seat when sitting on one, this can lead to instability.
- Make sure that the client always keeps his / her feet well-positioned on the foot support plate when using the Lotus.
- Notify the client before moving the Lotus.
- Be aware of obstacles when moving the Lotus.
- It is not permitted to charge the Lotus with more than 200 kg. / 440 lbs.
- The Lotus is only suitable for moving and caring for one person.
- Only use original parts, supplied by Lopital.
- Use the Lotus in a clean and tidy working environment.
- Lotus can be safely used in wet area (for example a bathroom).
- The Lotus is not a shower appliance.
- Swimming pool locations are not considered to be 'normal conditions' and will substantially shorten the lifespan of certain components.
- Only verifiably authorised personnel is allowed to work with the Lotus.
- The Lotus cannot be used on a surface with a gradient over 5 degrees laterally.
- The Lotus cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- The Lotus may only be used indoors.

Maintenance

- The Lotus must be inspected and serviced at least once a year.
- Service and maintenance must not be carried out while a client is sitting on the Lotus active standup aid.
- Constructive components of the Lotus may only be replaced by suitably authorised Lopital personnel.
- If erroneous use, transport, an accident or improper maintenance leads to deformation of the Lotus, 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 Lotus active standup aid 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 Lotus has been developed and produced for use in professional care environments.

Making changes to the contruction may affect the safety of the Lotus. Furthermore, the liability and guarantee conditions of Lopital lapse. As a result, the Lotus no longer complies with the MDR (EU) 2017/745 regulation for medical devices.

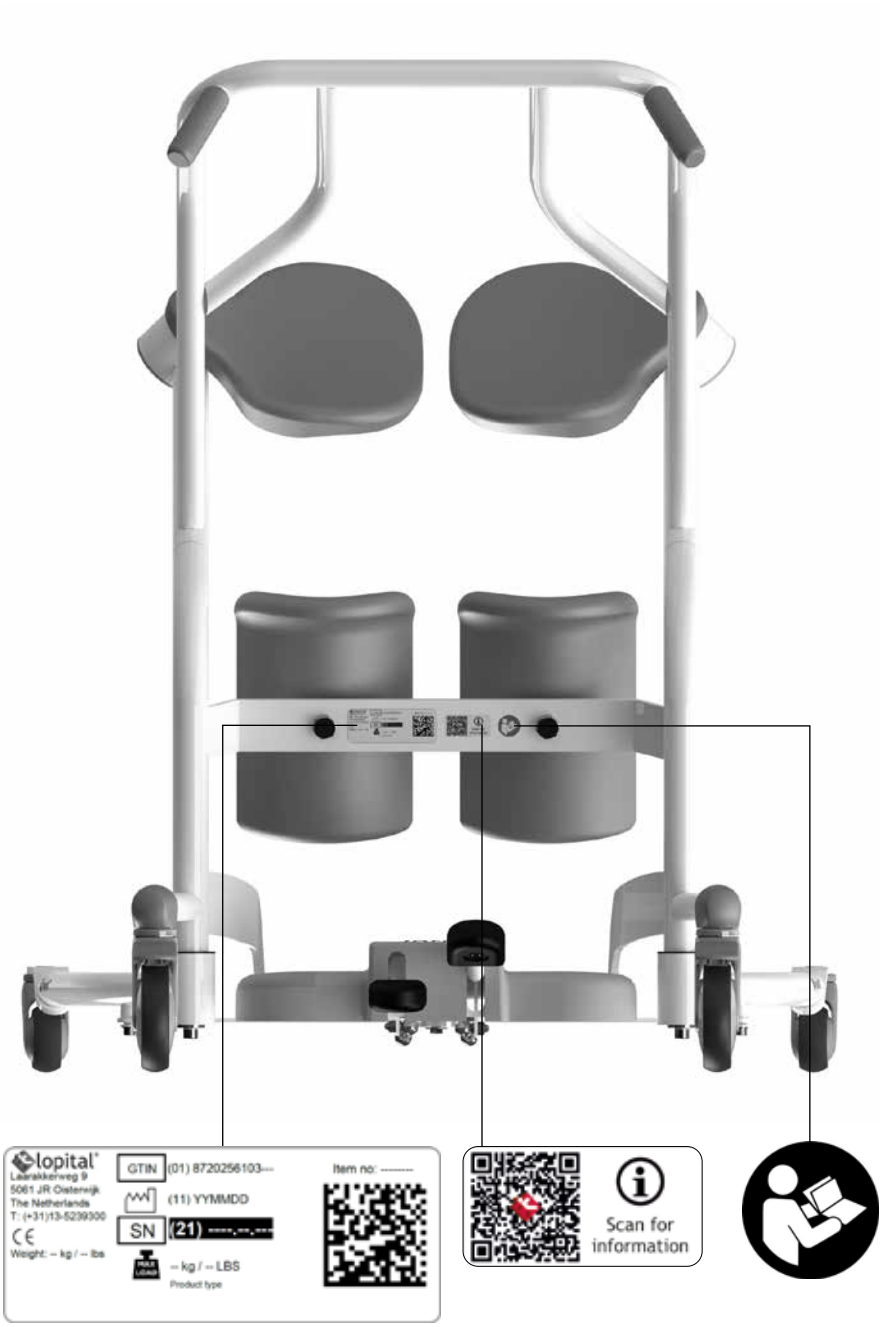
1.3. Warranty

All Lopital products are supplied with a 2-year warranty, on construction and/or material faults, unless otherwise stated. In the event of varying warranty terms, the exact period will be indicated on your invoice; this also serves as the warranty itself. Components and batteries that are subject to wear and tear will not fall under warranty unless there are clear construction and / or material faults.

2. Use

2.1. First use

In the picture below, the components of the Lotus are named. In the event of damage, these parts can be replaced by authorised persons. These components are the applied parts of the Lotus. These components may come into contact with the user(s) while the Lotus is in use.


lopital
Laarakkerweg 9
5061 JR Oisterwijk
The Netherlands
T: (+31)13-5239300
CE
Weight: -- kg / -- lbs
GTIN
(01) 8720256103---
(11) YYMMDD
SN
(21)
-- kg / -- LBS
Product type
Item no: ---------
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2.2. Working with the Lotus

Step 1
Roll the Lotus towards the client and rotate the sitting parts away *(See paragraph 3.3. Rotatable sitting parts).*

Step 2
Spread if necessary the base parts of the Lotus and roll it as close as possible to the client. Have the client put his / her feet on the footrests. Make sure that the shins touch the flexible lower leg supports *(See paragraph 3.2. Base spreading).*

Step 3
The Lotus must be put on the brakes before transferring persons *(See paragraph 3.1. Wheel blocking).*

Step 4
The client can now stand upright. The client can take hold of the vertical hand grips to lever himself / herself into a standing position.

Step 5
Turn the sitting parts away. Now the client can take place on the Lotus.

Step 6
Disengage the breaks if you wish to move the Lotus *(See paragraph 3.1. Wheel brakes).*

Step 7
If wanted, you can move the base spreader to the narrower position by pushing the other pedal. Roll the client towards the (wheel)chair, toilet or bed *(See paragraph 3.2. Base spreading).*

Step 8
Spread if necessary the base parts of the Lotus and roll it as far as possible to the (wheel) chair, toilet or bed.

Step 9
The Lotus must be put on the brakes before transferring persons *(See paragraph 3.1. Wheel blocking).*

Step 10
Have the client stand upright. The client can take hold of the vertical handgrips to pull himself / herself into a standing position.

Step 11
Turn the sitting parts away again. Now the client can take place on the (wheel)chair, toilet or bed.

Step 12
Have the client take his / her feet from the footplate. Disengage the break for moving the Lotus.

3. Operation

3.1. Wheel blocking

The Lotus has 2 braked wheels on the side of the caretaker. The 2 smaller swivel wheels are unrestrained.

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

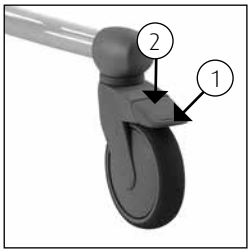


Figure 1 Swivel wheel.

3.2. Base spreading

The Lotus can be used as a standup aid with shower-toilet chairs, shower stretchers, beds, toilets, chairs and wheelchairs. The Lotus is equipped with a mechanical base spreader. By using the base spreader, the Lotus can be rolled close to the person with the disability. In the narrower position, the Lotus can be manoeuvred easily in small rooms. By kicking one of the pedals, the base parts will move inwards or outwards (depending on the pedal chosen).


Figure 2 Base spreader.

3.3. Rotatable sitting parts

The Lotus is equipped with 2 comfortable sitting parts that can be rotated away. Rotate both parts away before rolling the Lotus towards the client *(See figure 3)*. Have the client stand on the Lotus. Ensure that he / she positions his / her legs in the centre of the footplate and that the shins rest against the lower leg support. Now the client can pull himself / herself up. Now, rotate the sitting parts back, thus enabling the client to sit down *(See figure 4)*.


Figure 3 Sitting parts rotated away.

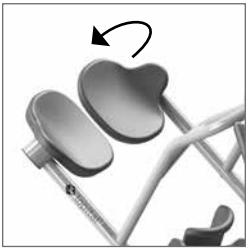


Figure 4 Sitting parts.

4. Cleaning and maintenance

The Lotus 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.

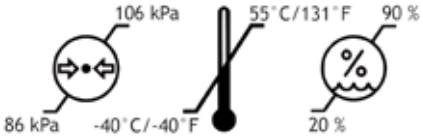
Check the wheels regularly for hairs, dust and soap residues and remove when necessary. Maintenance and repairs to the Lotus may only be carried out by authorised personnel.

Maintenance schedule	
After every use	• Clean the Lotus with water and regular household cleaning products. • PUR foam components must be cleaned and disinfected.
Weekly	• Check wheels for hairs, dust and soap residues and remove if necessary. • Check that the standup aid is still working correctly.
Annually	• According to the regulation MDR (EU) 2017/745 medical devices, the Lotus must be maintained according to the manufacturer's guidelines.

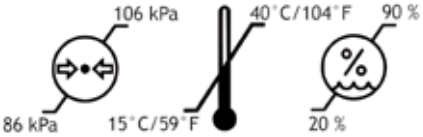
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website www.lopital.com/downloads.

5. Environmental conditions

Conditions during storage and transport



Conditions during use



6. Removal of parts

All parts that are replaced or removed can be sent back to Lopital BV. You may also offer the parts to the engineer for destruction. We will ensure that all parts are processed in an environmentally-friendly manner.

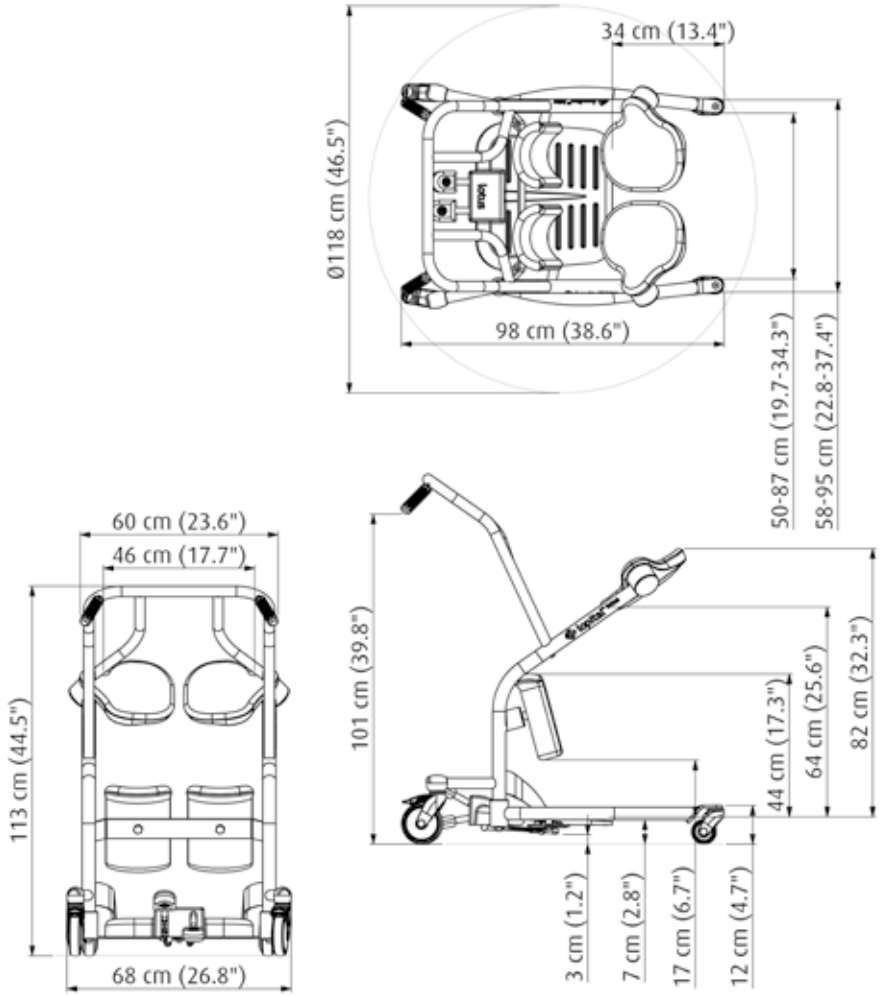
7. Technical specifications

7.1. Structure

Frame:	Stainless steel and steel tubes and plates that are equipped with a two-layer powder coating
Foot plates:	Plastic V0
Weight:	35 kg / 77.2 lbs
Maximum permitted load:	200 kg / 440 lbs

7.2. Dimensions

Surface area:	Wide:	68 cm / 26.8 inch narrow position
		95 cm / 37.4 inch with base spread out
	Deep:	98 cm / 38.6 inch


34 cm (13.4")
Ø118 cm (46.5")
98 cm (38.6")
50-87 cm (19.7-34.3")
58-95 cm (22.8-37.4")
60 cm (23.6")
46 cm (17.7")
113 cm (44.5")
68 cm (26.8")
101 cm (39.8")
44 cm (17.3")
64 cm (25.6")
82 cm (32.3")
3 cm (1.2")
7 cm (2.8")
17 cm (6.7")
12 cm (4.7")

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Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

Brand name:	Lopital
Medical device:	Lotus
Device description:	Standing aid
Models:	59008100
Classification:	Class I
Basic UDI-DI:	8720256103318590081OOP4
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 10535:2007 | *Hoists for the transfer of disabled persons – Requirements and test methods* IEC 62366: 2007 | *Medical devices - Application of usability engineering to medical devices* UNI-CEI-EN-ISO 13485:2016 | *Medical devices-Quality management systems-Requirements for regulatory purposes* NEN-EN-ISO 9001:2015 | *Quality management systems – Requirements* NEN-EN-ISO 14001:2015 | *Environmental management systems – Requirements with guidance for use*
Certificate/report no.:	Certificate: Reports:

Authorised signatory, Cees van Dam, director:

Signature:	**Date:**	**Place:**
	2021-05-03	*Oisterwijk*

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