









### Instructions for use

## Marina basic & Marina deluxe

Marina basic (excl. mattress) : 6100 2000 & 6100 2050 Marina deluxe (excl. mattress): 6100 2010 & 6100 2060 Shower trolley



Marina basic hydraulic: 6100 2000 Basic UDI-DI: 872025610348661002000PU



Marina basic electric: 6100 2050 Basic UDI-DI: 872025610349361002050P3



Marina deluxe hydraulic: 6100 2010 Basic UDI-DI: 872025610350961002010KT



Marina deluxe electric: 6100 2060 Basic UDI-DI: 872025610351661002060K2

The images above shows the trolleys with mattress. The length of the mattress determines the size of the lying surface. The following mattresses are available:

Article. No.	Gtin	Description	Inside length	Inside width
6720 0010	8720256103523	Mattress 186 cm / 73.2 inch	170 cm / 66.9 inch	70 cm / 27.6 inch
6720 0020	8720256103530	Mattress 206 cm / 81.1 inch	190 cm / 74.8 inch	70 cm / 27.6 inch
6720 0030	8720256103547	Mattress 226 cm / 89 inch	210 cm / 82.7 inch	70 cm / 27.6 inch



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Read these histroctions calefully before using the Marina basic / Marina deluxe:
Date first used
User
Name
Address

#### Manufacturer

Lopital Nederland B.V. Laarakkerweg 9 5061 JR Oisterwijk T +31 (0)13 5239300 www.lopital.com 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						
<u> </u>	Note	<b>(S)</b>	Follow the instructions for use			
===	Direct current 24V DC		Read cleaning and disinfecting protocol			
$\sim$	Date of production		Antibacterial			
MAX LOAD	Maximum load	1	Temperature			
GTIN	Global trade identification number	<b>•••</b>	Air pressure			
SN	Serialnumber	Œ	Humidity level			

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### 1. Introduction

### 1.1. Introduction

The Marina basic / Marina deluxe shower trolley 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 caregiver. The Marina basic / Marina deluxe comprises a mobile base frame and a height-adjustable supporting surface with a soft mattress. The Marina deluxe also has a back adjustment. There are no essential performances.



The frame of the Marina basic / Marina deluxe 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 Marina basic / Marina deluxe is multi-functional in use and corresponds to the use of other devices such as beds, wheelchairs and shower chairs, hoisting equipment and sliders

The expected technical life of the Marina basic / Marina deluxe is 10 years, assuming it is cleaned daily and regularly maintained according to the maintenance schedule supplied (See chapter 5. Cleaning and maintenance).

The Marina basic / Marina deluxe is a class 1 medical device with CE-marking. This marking corresponds with regulation MDR (EU) 2017/745. The Marina basic / Marina deluxe has been tested for electro-magnetic radiation according to the IEC 60601-1-2.

The length of the mattress determines the size of the lying surface. The following mattresses are available:

- 186 cm / 73.2 inch
- 206 cm / 81.1 inch
- 226 cm / 89 inch

### 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 Marina basic / Marina deluxe, check that there has been a fully loaded battery placed in the controlbox (for electric adjustable Marina basic / Marina deluxe).
- The electrically powered Marina switches to standby after a few seconds, when not in use.
- · Make sure that the brakes are applied before transferring clients.
- · Notify the client before moving the Marina basic / Marina deluxe.
- · Be aware of obstacles and persons in the immediately vicinity when moving or adjusting the trolley.
- · Make sure that the client always places his / her arms / legs inside the mattress in order to avoid anything coming jammed.
- · Only relocate and move the Marina basic / Marina deluxe in a physical comfortable position.
- · When moving the Marina basic / Marina deluxe, do not adjust upwards or downwards.
- · Always close the siderails before moving the Marina basic / Marina deluxe with client (manoeuvring, upwards or downwards).
- It is not permitted to load the Marina basic / Marina deluxe with more than 227 kg / 500 lbs.
- The Marina basic / Marina deluxe is only suitable for moving and caring for one person.
- Use only original parts, supplied by Lopital. The use of non-original parts can cause dangers.
- 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 Marina basic / Marina deluxe (for electric adjustable Marina basic / Marina deluxe).
- $\cdot$  Use the Marina basic / Marina deluxe in a clean and tidy working environment.
- $\cdot\,$  Charge battery box 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 Marina basic / Marina deluxe may not be raised by the upper surface.
- The Marina basic / Marina deluxe cannot be used on a surface with a gradient over 5 degrees laterally.

- · The Marina basic / Marina deluxe cannot be used on a surface with a gradient of over 10 degrees forwards / backwards.
- · The Marina basic / Marina deluxe may only be used indoors.
- · Don't touch the batteryterminals and the client at the same time.
- · Portable and mobile RF communication equipment can affect medical devices. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Marina deluxe / Marina basic electric including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result
- · Medical electrical devices involve special EMC precautions and must be used as per the EMC information outlined in the instructions for use.
- · The emissions characteristics of the Marina basic / Marina deluxe electric make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- The trolley must not be used adjacent to or stacked on other products. However, should that be necessitated, it must be checked whether the trolley functions normally in this configuration too.

#### Maintenance

- · If the charger or cable become damaged, they must be replaced (for electric adjustable Marina basic / Marina deluxe.
- · If the mattress is damaged, replace the mattress for hygiene reasons.
- · It is recommended to replace the mattress after 5 years for hygiene reasons.
- The Marina basic / Marina deluxe must be serviced and inspected at least once a year.
- · No modification of the Marina basic / Marina deluxe is allowed, except length adjustment according to the instructions of Lopital.
- · If the Marina basic / Marina deluxe is adjusted in length, appropriate inspection must be conducted to ensure continued safe use of the shower trolley.
- · Servicing and maintenance of the Marina basic / Marina deluxe may only be carried out by persons with a technical background, who have experience in servicing and maintaining similar products.
- · Constructive components of the Marina basic / Marina deluxe may only be replaced by suitably authorised personnel.

- · The Marina basic / Marina deluxe shall not be serviced or maintained while in use with a client
- · If erroneous use, transport, an accident or improper maintenance leads to deformation of the Marina basic / Marina deluxe, it may no longer be used and you must contact the supplier or manufacturer.

In the event of breakdowns, you must contact Lopital or your local supplier. E-mail: info@lopital.nl



The Marina basic / Marina deluxe may only be operated by persons who have experience working with the target group and have followed the Instruction / trainings video's on the website of Lopital.



The Marina basic / Marina deluxe has been developed and produced for use in a professional care environment.



Making changes to the construction could affect the safety of the Marina basic / Marina deluxe. This will also lead to Lopital's liability and warranty conditions being invalidated. As a result, the Marina basic / Marina deluxe will no longer comply with the regulation MDR (EU) 2017/745 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

The images below shows the components of the Marina basic / Marina deluxe. The detachable parts of the trolley are the mattress and the batterybox.

### Marina basic - hydraulic adjustable (art. no. (excl. mattress): 6100 2000)



### Marina basic – Electric adjustable (art. no. (excl. mattress): 6100 2050)



### Marina deluxe – Hydraulic adjustable (art. no. (excl. mattress): 6100 2010)



### Marina deluxe – Electric adjustable (art. no. (excl. mattress): 6100 2060)







### 3. Operation

### 3.1 Wheel blocking

#### Marina basic

The Marina basic is equipped with 4 swivel wheels.

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

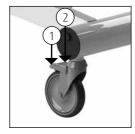


Figure 1 Wheel blocking.

#### Marina deluxe

The Marina deluxe is equipped with a semi-central braking system, so you can brake 2 wheels at the same time. The semi-central control pedal for the brakes is the pedal at the head end and the foot end on both sides of the trolley (See figure 2).

• The brake on the Marina deluxe can be applied by moving the inside of the pedal at the head and foot end downwards, using your foot (1)

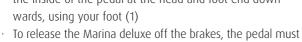




Figure 2 Wheel blocking.

- be moved upwards to a horizontal position with your foot.
  The swivel wheel is disengaged by moving the outside of the pedal at the head and foot end downwards with your foot.
- The swivel wheel is engaged by moving the pedal back into the horizontal position with your foot.

### 3.2. Side rail

- The Marina basic / Marina deluxe is equipped with aluminium side rails that can be collapsed against the edge of the bed-base so that sliding transfers can be carried out.
- The side rail is equipped with safeguards so that the client cannot raise the side rails themselves (*See figure 3*).
- · Before the side rail is collapsed downwards, the safeguard must be unlocked.
- Unlock the safeguard by using one hand to pull the protruding handle and rotating the side rail with your other hand (2) (See figure 3).
- · With folded side rails, the caregiver can lean against the mattress in the middle to better care for the patient.

- · Turn the side rail upwards again to close the side rail (see figure 4). The side rail locks automatically.
- The side rail can be placed in 2 positions, wide and narrow. When you fold the side rail upwards, the side rail is first locked in the wide position (see figure 5). By pulling the handle of the lock (see figure 4) you can move the side rail further back to its narrow position.



Figure 3 Side rail.

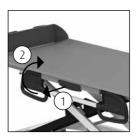


Figure 4 Side rail down.



Figure 5 Side rail wide.

### 3.3. Moving upwards/downwards

### Hydraulically adjustable versions

### Moving upwards

- · If the client is lying on the shower trolley, first put the brake on the wheels and then move the trolley upwards.
- · The trolley is moved upwards by pressing the long part of the foot pedal slowly and evenly (See figure 6).
- · During use of the pedal, the carer will stand by the long edge of the Marina so that the carer cannot twist their upper body away from their feet.
- · During the upward movement, maintain contact with the client.

### Moving downwards

- · The trolley is lowered by pressing the short part of the foot pedal (See figure 7).
- · The trolley lowers under the influence of gravity. The lowering speed can be steadied by keeping the pedal gently depressed.



Figure 6 Moving upwards.

Figure 7 Moving downwards.





### **Electrically adjustable versions**

#### Moving upwards

- · If the client is lying on the shower trolley, first put the brake on the wheels and then move the trolley upwards (1) (See figure 8).
- · Move the trolley upwards by pressing the button that shows an 'up' arrow. The trolley will then immediately move upwards (See figure 8).
- · You can stop the movement whenever you like by taking your finger off the button.
- · During the upward movement, maintain contact with the client
- · If the remote control is not being used, it can be hung on the side rail or on the push-bar.
- · Ensure that the curly cable on the operating device does not get jammed.

### Moving downwards

- · Move the trolley downwards by pressing the button that shows a 'down' arrow. the trolley will immediately move downwards (2) (See figure 8).
- · You can stop the movement whenever you like by taking your finger off the button
- · During the downward movement, maintain contact with the client

When the hand control is lost or defect, the shower trolley can be adjusted in height by pressing the buttons on the control box (see figure 9).

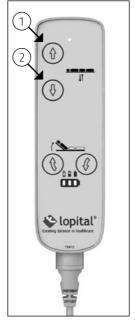


Figure 8 Hand control.



Figure 9 Control box.



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

### 3.4. Backrest adjustment

The Marina deluxe is equipped with a back adjustment. The back adjustment is available with an electrical or mechanical drive

# Mechanical back adjustment (hydraulic adjustable Marina deluxe)

The back can be moved upwards by means of the handle on the side of the trolley (see figure 10). Release the handle when the back is in the correct position. To move the back down, the hendle must be pressed again.

# Electric back adjustment (electrical adjustable Marina deluxe)

The stepless electric back adjustment is operated by pressing the buttons on the hand control (see figure 11). Release the button when the backrest is in the correct position.



Figure 10 Back adjustment mechanical.





Figure 11 Back adjustment elektrical.

### 3.5. Tilting (Anti-trendelenburgstand)

- In order to remove water from the mattress during or after showering, the bed base on the Marina basic / Marina deluxe can be tilted.
- Turn the lever on the upper frame, under the head end, outwards in order to position the bed base in the drainage position.
- · This control can be found on both sides of the trolley.
- Turn the lever inwards before restoring the bed base to its horizontal position.



Figure 12 Anti-trendelenburg.

### 3.6. Waterdrainage

Water is drained away from the Marina basic / Marina deluxe via a drainage hose. To do this, remove the hose from the recess (1) and route it to the lowest possible drainage point. Always click the hose into the recess of the lying plate during transport, in connection with leaking and dripping.



Figure 13 Waterdrainage.

### 3.7. Changing battery

(Only electrical adjustable Marina basic / Marina deluxe). The Marina basic / Marina deluxe is an electrically adjustable high-low trolley and works on a battery. The battery is located at the head-end of the trolley. (See figure 14).

- · There is a battery indication on the hand control (see figure 15).
- · Charge the battery on the chargerstation (see figure 16).
- · In order to remove the battery, use one hand to unlock the catch (1) on the battery, then slide the battery to the right (2) (see figure 14).
- · To install the fully charged battery, it must first be positioned next to the electronic housing and then clicked into the holder.
- · You can better insert and remove the battery when the back adjustment is in the highest position (Only Marina deluxe).

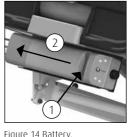


Figure 14 Battery.

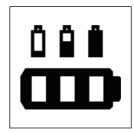


Figure 15 Battery indication hand control.



Make sure that the Marina basic / Marina deluxe is always ready for use by having a fully charged reserve battery on standby. If this is not the case, lift the client from the stretcher with a patient hoist or manually with at least 2 persons.



When the battery box is fully charged, it will be able to perform the high / low movement in combination with the back adjustment approximately 45 times.



Figure 16 Chargestation.



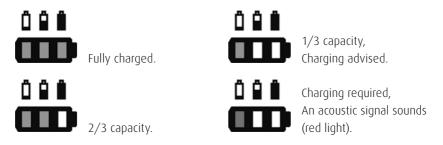
After 4/5 years it is recommended to replace the battery box.



Only use batteries that are supplied with the Marina basic / Marina deluxe. The batterybox that is used for the Marina basic/Marina deluxe is the 'Ti-motion BAT-4259-002' 2.9 Ah, 24 V.



Figure 17 chargestation with battery.



### 3.8. Charging battery

(Only electrical adjustable Marina basic / Marina deluxe). .

- · Place the battery to be charged on the battery chargestation (see figure 17).
- · A green light indicates that the battery charger is switched.
- · The charged battery can remain on the battery charger without being damaged.
- · In order to remove the battery, use one hand to unlock the catch on the battery and the other to support the battery itself.



Charge batteries that are not used, once every six months to avoid damage.



Charging the batteries before they are completely empty will extend their lifespan.



The expected battery lifespan depends on following the manufacturer's charging instructions.



The charger that is used for the Marina basic / Marina deluxe is the 'Ti-motion TRC2'.



Charge batteries in a well-ventilated, dry space.

### 4. Safety functions

### 4.1. Emergency stop

(Only electric adjustable Marina basic / Marina deluxe).

On the side of the head-end, there is an emergency stop. Operate this button in an emergency, if the upward or downward movement must be stopped immediately. Once the emergency stop is pressed, the electronic controls will stop working. The emergency stop interrupts all power.

Operation may be continued once the situation is stable again. Turn the emergency stop a quarter turn to unlock it again (See figure 18).



First check to ensure the hazard has been removed or the problem has been resolved, before resetting the emergency stop button.



Figure 18 Emergency stop.



If the button is activated, no leds will light up on the hand control.

### 4.2. Emergency lowering button

(Only electric adjustable Marina basic / Marina deluxe). If the handcontrol stop working and the trolley is in a raised position, it can be lowered using the emergency lowering button. This button is located on the controlbox (See figure 19).



Figure 19 Emergency lowering Button

First check to ensure that the emergency button has not been pressed!

· Press the emergency lowering button (See figure 19).

The shower trolley will now return to the lowest position (make sure no persons or objects are under the stretcher). Take the client from the trolley and make sure the device is not used until it has been repaired. Place the trolley in a safe place and indicate that it is out of order.

### 5. Cleaning and maintenance

The Marina basic / Marina deluxe must be cleaned after every use, with water and regular household cleaning agents. Do not use any abrasive or other aggressive cleaning products. If necessary, the mattress can be disinfected with a solution of 70% ethanol or propanol.

For the best and most efficient cleaning of the mattress and the bed base, the mattress can be lifted up and removed. Dry the plate on which the mattress lies.

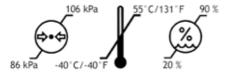
Check the wheels regularly for hairs and dust and remove when necessary. Maintenance and repairs to the Marina basic / Marina deluxe may only be carried out by authorised personnel.

Onderhoudsschema	
After every use	<ul> <li>Clean the Marina basic / Marina deluxe with water and regular household cleaning products.</li> <li>Clean and disinfect mattress.</li> <li>Check to ensure all parts of the Marina basic / Marina deluxe are present.</li> </ul>
Weekly	<ul> <li>Check wheels for hairs, dust and soap residues and remove if necessary.</li> <li>Check that the trolley is still working correctly.</li> <li>Charge the battery at least once a week.</li> </ul>
Annually  lopital*  year  year  Service & Onderhoud	According to the regulation MDR (EU) 2017/745 medical devices, a trolley must be maintained in line with the manufacturer's instructions. Those instruction's can be found in the maintenance protocol, see website Lopital (www.lopital.com).  This process will preferably be carried out by Lopital or another authorised body. Lopital offers the option of having the trolley thoroughly inspected and serviced once a year via Periodic Preventative Maintenance.
Tel: +31 (0)13 523 9300 www.lopital.nl	For more information about the maintenance contract, please contact Lopital (info@lopital.nl) or speak to your supplier.

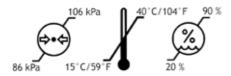
For a detailed explanation regarding cleaning and disinfecting, see the document 'Cleaning and Disinfection Protocol' on our website www.lopital.com/downloads/.

### 6. Environmental conditions

Conditions during storage and transport



Conditions during use



## 7. Removal of parts

All parts that are replaced or removed can be sent back to Lopital or your supplier. 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 Marina basic / Marina deluxe is splash-proof; this means that the Marina can be used under the shower. This is given with instruction IPX4. The electronic components used in the Marina basic / Marina deluxe electrical are IPX6.

#### 8.1. Structure

Frame. Aluminum tubes and plates with an antibacterial coating

Covers. ABS met PMMA coating

Mattressfilm. PVC

Plastic parts (except covers): Fiberglass filled PA

Fasteners: Steel and stainless steel 6100 2000 : 76 kg / 168 lbs Weight:

> 6100 2010 : 80 kg / 176 lbs 6100 2050 : 76 kg / 168 lbs 6100 2060 : 80 kg / 176 lbs

Maximum load-227 kg / 500 lbs

8.2. Drive

High/low drive: Hydraulic of electric, push-only

Flektric.

Controlbox: 24VDC, max. 250W

Batterybox: 24V, 2.9Ah

Battery charger: 100-240V AC, 50-60 Hz, max. 1 A, Charge station Mode of operation: non-continuous (10% 2min ON, 18 min OFF)

8.3. Dimensions

External dimensions (lxwxh): 186x81x64-114 cm / 73.2x31.9x25.2-44.9 inch

206x81x64-114 cm / 81.1x31.9x25.2-44.9 inch 226x81x64-114 cm / 89x31.9x25.2-44.9 inch

Net lying space (lxw): 170x70 cm / 66.9x27.6 inch

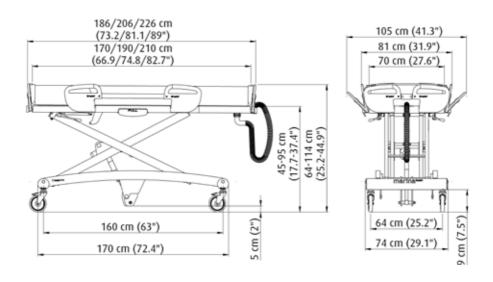
> 190x70 cm / 74.8x27.6 inch 210x70 cm / 82.7x27.6 inch

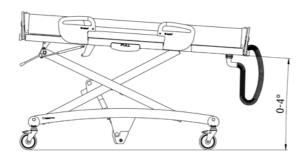
Mattress edge height: ca. 20 cm / 7.9 inch Bed base height: minimum 45 cm / 17.7 inch, maximum 95 cm / 23.2 inch

Water drainage hose: internal Ø4 cm / 1.6 inch

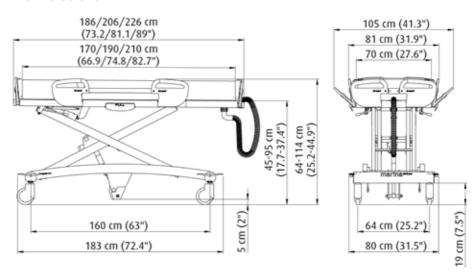
Wheel base: 160 cm / 63 inch Track width: 64 cm / 25.2 inch Undercarriage height: 19 cm / 7.5 inch

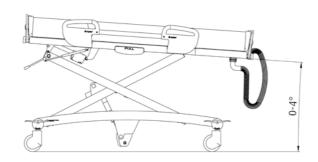
### Marina basic

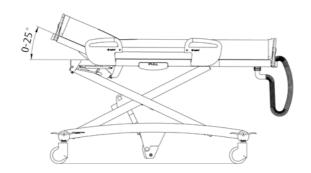




### Marina deluxe







### 8.4. Length adjustment

The Marina basic / Marina deluxe is equipped with a length adjustment. For example, the shower trolley can easily be extended or shortened

If you want to adjust the length of your Marina basic / Marina deluxe, we recommend that you have this done by your supolier.



Figure 20 Disassembly of lying plate and mattress.

Each length has his own mattress:

• Mattress 186 cm, article number: 6720 0010 • Mattress 206 cm, article number: 6720 0020 · Mattress 226 cm, article number: 6720 0030

To adjust the length of the shower trolley, the mattress must be removed. Then dismantle the lying plate (see figure 20). The length adjustment is now visible. Loosen the bolts of the length adjustment (1) (see figure 21). Slide the adjustable frame out or in of the base frame and fix it at the desired. length (2). Then mount the lying plate and place the correct mattress on the lying plates.

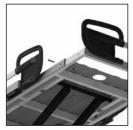


Figure 21 Length adjustment.

### 8.5. Replacement of parts

The following components can be replaced by service personnel in event of damages.

- Mattress
- Drainage hose
- Lying plates

If other parts needs to be replaced, this must be done by authorised personnel. Contact your dealer or contact Lopital.

#### Mattress

- 1. 1.To remove the mattress you have to loosen the push buttons.
- 2. You can lift the mattress. Please note, it can occur that the mattress is clamped to the drainage point. Lift the mattress at this point carefully.
- 3. Place the new mattress and fasten the push buttons.

### Drainage hose

- 1. Unscrew the drainage hose.
- 2. Place the new drainage hose.

### Lying plates

- 1. To replace the lying plates, you have to detach the mattress and the drainagehose.
- 2. Unscrew the 4 screws from the lyingplates
- 3. Remove the lying plates.
- 4. Place the new lying plates on the frame and fix it with the 4 screws
- 5. Mount the drainage hose.
- 6. Place the mattrass on the lying plates.



Figure 22 Replacement Mattress.



Figure 23 Replacement Drainage hose.



Figure 24 Lying plates.

# 9. Checklist for technical problems

Problem	Cause	Solution	
Marina basic / Marina deluxe is difficult to move.	Dirt and soap between wheels.	Clean wheels.	
directive in over	Defect wheel or defect bra- king system.	Contact Lopital or your supplier.	
	Emergency button is used.	Turn emergency button 90 degrees to the right.	
	Battery empty.	Charge battery.	
Marina basic / Marina deluxe does not move upwards	Plugs removed.	Check plugs (To side of control box).	
or downwards.	Manual control is not working.	Check plug.	
	Motor, pump or control box defect.	Contact Lopital or your supplier.	
	Charger is not plugged in.	Connect charger.	
The light on the charger is not on.	Charger is not working.	Contact Lopital or your supplier.	
Marina basic /	Emergency button is used.	Turn the emergency button 90 degrees to the right.	
stops.	Technical issue.	Contact Lopital or your supplier.	

For all other issues please contact Lopital or your supplier.:

Telephone: +31 (0)13 5239300 E-mail: info@lopital.nl

### 10. Relation with other supports

#### Slide sheets

A slide sheet is the ideal device for transferring from bed to trolley and vice versa. The physical burden and time required when using a slide sheet is minimal. A slide sheet is suitable for most bed and chair transfers from and to the Marina basic / Marina deluxe.

### Hoist / ceiling hoists

The Marina basic / Marina deluxe has been designed for use with a hoist. The shower trolley has an undercarriage height of 16 cm / 6.3 inch from a bed height of 45 -95 cm / 17.7-37.4 inch.

#### Wheelchair

In lower settings of 45-55 cm / 17.7-21.7 inch, clients can be transferred from shower trolley to wheelchair and vice versa. An ideal device to be used during this operation is the small slide sheet (and possibly a sliding board).

#### Red

The Marina basic / Marina deluxe is primarily used to wash clients while lying down. Less able persons can be moved, using a slide sheet, from any (high or low) bed to the Marina in a lying position. The Marina basic / Marina deluxe must be brought to the same height as the bed to carry out this process.

# 11. Electromagnetic compatibility

Professional healthcare environment

IEC 61000-3-3

Pioressional neamine	ie environniem				
	Guidance and Man	ufacturer's declaration-electromagnetic emissions			
		or use in the electromagnetic environment specified below. The customer or the sure that it is used in the following environment:			
Emissions Test Compliance Electromagnetic Environment - guidance					
RF emissions CISPR11	Group 1	The Marina basic / Marina deluxe 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 A	The Marina basic / Marina deluxe is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.			
Harmonic emissions	Not applicable.				
Voltage Fluctuations/ Flicker emissions	Not applicable.				

#### Guidance and Manufacturer's declaration-electromagnetic immunity The Marina basic / Marina deluxe is intended for use in the electromagnetic environment specified below. The customer or the user of the Marina basic / Marina deluxe 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)	±8 kV contact	±8 kV contact	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, the
	±15 kV air	±15 kV air	relative humidity should be at least 30%.
IEC 61000-4-2			
Electrical fast transient/	±1 kV for input/	±1 kV for input/	
burst	output lines	output lines	
IEC 61000-4-4			
Surge	Not applicable.	Not applicable.	
IEC 61000-4-5			
Voltage dips, short interruptions, and voltage variations on power supply input lines	Not applicable.	Not applicable.	
IEC 61000-4-11			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

#### Guidance and Manufacturer's declaration-electromagnetic immunity

The Marina basic / Marina deluxe is intended for use in the electromagnetic environment specified below. The customer or the user of the Marina basic / Marina deluxe 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	3 Vrms 6 V in ISM bands 150 kHz to 80 MHz	3 V 6 V in ISM bands	
Radiated RF Electromag- netic Field IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	
Procimity fields from RF wireless communication systems IEC 61000-4-3	Refer to table below	Refer to table below	

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0,3	28
710			Pulse modulation b)			9
745	704 - 787	LTE Band 13, 17	217 Hz	0,2	0,3	
780		13, 17				
810		GSM				
870		800/900, TETRA 800, iDEN 820, COMA 850, LTE Band 5	Pulse modulation b)			
930	800 - 960		2	0,3	28	
1720		GSM 1800; CDMA 1900; 1 990 GSM 1900; Pulse modulation <sup>b)</sup>				
1845	1 700 - 1 990		Pulse modulation b)			
1970		DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz	2	0,3	28
2450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
5240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.



### Lopital Nederland B.V.

Laarakkerweg 9 | 5061 JR | Oisterwijk | The Netherlands Tel (0031) 013 5239300 | E-mail <u>Info@lopital.nl</u> Website www.lopital.com

### Manufacturer's Declaration of Conformity

C ← marking in accordance with the Medical Device Regulation

Brand name: Lopital

Medical device: Marina basic / Marina deluxe

**Device description:** Mobile shower trolley with hydraulically powered high/low adjustment

Models: 61002000 & 61002010

Classification: Class I

Basic UDI-DI: 872025610348661002000PU & 872025610350961002010KT

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 62366: 2007+A1:2014 | 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



### Lopital Nederland B.V.

Laarakkerweg 9 | 5061 JR | Oisterwijk | The Netherlands Tel (0031) 013 5239300 | E-mail Info@lopital.nl

Website www.lopital.com

### Manufacturer's Declaration of Conformity

C ∈ marking in accordance with the Medical Device Regulation

Brand name: Lopital

Medical device: Marina basic / Marina deluxe

Device description: Mobile shower trolley with electrically powered high/low adjustment

Models: 61002050 & 61002060

Classification: Class I

Basic UDI-DI: 872025610349361002050P3 & 872025610351661002060K2

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 60601-1-2:2014 | 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+A1:2013 | 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

AAM/IEC 60601-1:2015 + AMD 1:2012 / CAN/CSA-C22.2 No. 60601-1:14 | Medical electrical equipment -

part 1: General requirements for basic safety and essential performance

CSA CAN/CSA-C22.2 NO.60601-1-6:11 AMD 1/IEC 60601-1-6 | Medical electrical equipment – General

requirements for basic safety and essential performance – Collateral standard: Usability

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:

2021-08-25

Oisterwijk

Document no: PTF2050-00 08-2021





