

Shado®

Shower trolley





Content

CONTENT2
WARNING AND SAFETY INSTRUCTIONS3
SYMBOLS AND PICTOGRAMS5
GENERAL INFORMATION ABOUT THE SHADO®6
ASSEMBLY & COMMISSIONING INSTRUCTIONS11
INSTRUCTIONS FOR USE14
CLEANING AND DISINFECTING26
PERIODIC INSPECTION AND PREVENTIVE MAINTENANCE27
THE SHADO® SHOWER TROLLEY RANGE29
TECHNICAL SPECIFICATIONS31
ELECTROMAGNETIC COMPATIBILITY (E.M.C)36
WARRANTY39
LIABILITY39
END OF LIFE, RECYCLING39
CONTACT INFORMATION

Warning and safety instructions



This user manual contains important safety information concerning the Shado[®] shower trolleys. Carefully read the manual before using the equipment.

This user manual concerns the complete Shado® shower trolley range reference S2700XXX. The last three digits of the reference (XXX) are the variants depending on the model: 160, 180, 200, 240, 350; and features: with electrical actuator (Shado® E), hydraulic jack (Shado® H), with centralized or independent brakes, RGO model, hand remote, sizes of the tray...).



Safety devices must never be taken out or modified. The Shado[®] shower trolley should only be used once those devices are in place and in good working order.



Packaging elements (plastic, polystyrene wrappings etc.) must not be left within reach of children as they can be potentially harmful.



Do not put hands or fingers anywhere close to the structure or the chassis of the Shado[®] while using the height, tilt or backrest adjustment mechanism.



The Shado° shower trolley must be used only by qualified healthcare personal who has followed specific training on the use of the Shado°. This training is provided by SCALEO Medical or one of his certified distributors.



Il existe un risque de blessure pour le personnel soignant en cas de piégeage des doigts au niveau des barrières. Veillez à agripper les barrières au niveau des tubes horizontaux et non verticaux.



The following actions are prohibited as they can cause serious injury to the patient and/or the user:

- Failure to meet the recommendations for installation and use of this manual,
- Failure to meet the recommendations for care and maintenance of this manual,
- Using the Shado® E while the "low battery" alarm is activated,
- Trying to connect the Shado® E to an incompatible electric plug or voltage source,
- Using the Shado® by a patient, a child or anyone else without prior explanation,
- Using the Shado® with a patient weighting more than the maximum load capacity,

- Using the Shado® outdoors,
- Using the Shado® on a slope, with or without a patient on it,
- Moving the Shado® on a non clear surface or carpeted floor,
- Immersion of the shado structure in water,
- Plugging non standard electrical components, modifying the electrical components, using spare parts other than original SCALEO Medical spare parts,
- Cleaning the shower trolley with a hose or with pressurized water,
- Manipulating the shower trolley by the railings, the tray or by any other element that is not made for manipulations,
- Using a torn or damaged mattress,
- Overall failure to follow installation, operation, maintenance, preventive maintenance of the device as described in this manual or under good care practices and hygiene.



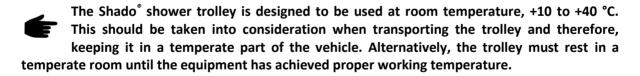
In the case of a mechanical or electrical problem, please contact SCALEO Medical who will either take care of your problem directly or will refer it to the closest authorized dealer. In all cases, you should ask for original spare parts.



The shower trolley must be used solely to transport patients, do not ever use it to transfer objects, or on slopes or a carpeted floor.



When not in use, make sure the brakes are on, and check the immobilization of the Shado°.





The use of the electrical Shado® model requires the abidance to fundamental and logical rules like for instance not to pull the cable to unplug the device.

All technical information, data and instructions for operations contained in this user manual were up to date at the time of print and are compiled on the basis of our experience and knowledge. We reserve the right to incorporate technical modifications within the scope of further development of the product described in this manual.

Symbols and pictograms

Symbols used in this manual:



This symbol is used to point out instructions and information related to safety in the working environment, where injury may occur if the information is disregarded or ignored. Follow these instructions and be careful and attentive at all times.



This symbol indicates important information regarding the use of the equipment. If not taken into consideration, it may lead to damage or functional defects to the equipment.



This symbol indicates important and useful information. If taken into consideration, it will help the operator to work efficiently. It may help simplify routines and to explain complicated facts.

Symbols used in labels:

Symbol	Meaning
	Manufacturer
	Date of manufacturing
REF	Device reference
SN	Device serial number
+5°c	Temperature range
1060 1000 1000	Atmosphere pressure limitation
*	Keep dry
\triangle	Warning
30%	Humidity limitation
IPXX	IPX class

Symbol	Meaning
[]i	Read user manual for instruction
**	Do not store/transport the device in locations with high temperatures or
	Class II electrical protection type
†	B type applied parts
Ī	Fragile
max XXX XXX kg lbs	Maximum safety load
CE	In accordance with all applicable European regulations
X	Contains potential wastes of electrical or electronic equipment
	Recycling
MD	Medical device

General information about the Shado®

You have recently purchased a Shado[®] shower trolley. We would like to thank you for the trust you have placed in our company.

SCALEO Medical offers a complete range of shower trolleys, with six maximum safety loads available: 160 kg, 180 kg, 200 kg, 240 kg, 290 kg and 350 kg.



The model name states the maximum safety load.

The Shado[®] 160, 180 and 200 are available in hydraulic « H » and electric « E » versions. The Shado[®] 240, 290 and 350 are only available with electric actuators. The 200 and 240 models are available in RGO version. The 180 and 200 models are available with a backrest function for a better comfort for the patient, especially for washing hair.

Each model has been developed for specific needs and offers many user friendly options.

The Shado® shower trolley is delivered in a cardboard pallet, including the following:

- 1 shower trolley
- 1 half-circle (standard) or triangular (on demand) headrest, as selected when ordering.
- 1 user manual
- 1 battery and a charger (if ordered an electric model)
- 1 remote control (if ordered)

Identifying the parts of the Shado® shower trolleys

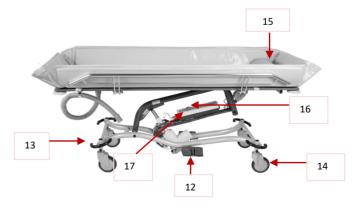
Shado® Hydraulic « H » versions

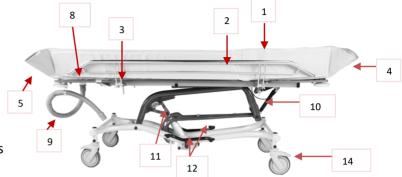
- 1. One PVC mattress
- 2. Two side rails (Stainless steel)
- 3. Four side rails security pin
- 4. One tilting control
- 5. One foot rail (Stainless steel)
- 6. Four head rail mount locking nuts (not pictured)
- 7. Four foot rail mount locking nuts(not pictured)
- 8. One draining plug
- 9. One draining hose
- 10. One trendelenburg position jack (slope gas spring)
- 11. One main raising jack
- 12. Two pedals
- 13. Four pedals for multifunctional wheels (centralized brakes models only)
- 14. Four casters (single or double tire tread depending on the model)
- 15. One headrest grey cushion half moon or (triangular not pictured)

Shado® Electric « E » versions

The Electric models include the same components as the Hydraulic models, plus:

- 16. One emergency stop button
- 17. Control box with battery





Shado® Rgo

- 1. One PVC mattress
- 2. Two high side rails (Stainless steel)
- 3. Four side rails unlocking handle
- 4. One tray tilting control
- 5. One foot rail (Stainless steel)
- 6. Four head rail mount locking nuts (not pictured)
- 7. Four foot rail mount locking nuts(not pictured)
- 8. One draining plug (not pictured)
- 9. One draining hose
- 10. One trendelenburg position actuator (not pictured)
- 11. One main raising actuator
- 12. Two raising pedals
- 13. Four pedals for multifunctional wheels
- 14. Four centralized casters
- 15. One headrest grey cushion half moon
- 16. One battery power pack including emergency stop button





The pictures above are only intended to show and name the main parts. For maintenance purposes, detailed drawings and spare parts list are available on demand or in our website for registered customers.

Accessories and components

The Shado® can be used with the following accessories or components (not included):

Accessories	Reference
COSA shower & disinfection panel	S28001
Trans'Gliss® transfer boards (foldable models)	S8210416, S8210419
Trans'Gliss® transfer boards (non-foldable	S8210420
models)	
Headrest grey cushion triangular	S2752200
Wall charger	S2799003
Removable battery	S2799016

Intended use

The Shado[®] shower trolleys are conceived to perform cleaning routines and care of dependent or bedridden patients. They combine comfort and safety for both, the patient and the caregiver.

- Shado 160 is designed for children and small people, and can be used in small rooms, due to its short tray and mattress.
- The Shado® 180 models are the "standard" range, which are multifunctional and adapt to almost all situations. The Shado® 180 shower trolley is available in three sizes: adult, medium, and child and have many variants and features: stainless steel tray, hand held remote control for the electric models, centralized or independent wheel brakes...
- The Shado® 200 and 240 have a wide tray for the care of patients with particular pathologies.
- The Shado® 290 and 350 are designed for bariatric care and feature a reinforced structure.
- The Shado® RGO provides an optimal distribution of contact pressure. The part of the mattress that supports the lower limbs provides improved comfort. Its unique movement allows all sections to be articulated simultaneously to achieve the best position.

- When shower trollies are used in marine spas, swimming pools or similar environments (aggressive conditions: condensation, salt, chlorine vapors, etc.), meticulous care should be taken at the end of the day, as described on page 25.
- Shower trollies should be stored in a dry environment.

Contraindications

- The Shado® shower trolleys are NOT to be stocked in marine spas, swimming pools or similar environments, since the aggressive conditions of use found in these cases (condensation, salt, chlorine vapors) could deteriorate some of the materials of the device.
- Do not use the Shado® shower trolley on patients which weight exceed the maximum load capacity of the chosen model.
- Do not use the Shado® shower trolley on patients which length exceeds the size of the tray (140 to 210 cm, depending on the model).

Assembly & commissioning instructions

Unpack the parcel with the usual care. Remove the shower trolley from its box after having unlocked the brake pedals.



One N°5 Allen wrench and one 13mm flat wrench are necessary (not provided).

Instructions for assembly

Head rail mounting

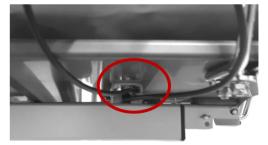
- 1. Unscrew the lock nuts of the bolts.
- 2. Place the head rail in place and install the washers and the bolts on each side of the rail.
- 3. Adjust the head rail and install the locking nuts.
- 4. Using a flat 13 mm wrench, tighten the locking nuts until the head rail is completely blocked.
- 5. For the RGO model, do exactly the same with the front screws.





Please pay attention to the tilting control cable during this assembly: do not pinch it or catch it under the rail.

Final result on a backrest model: take care of the cable installation.



For the RGO model



Install the front mounting nuts

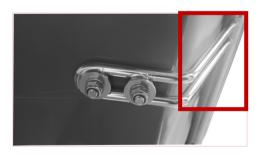




Foot rail mounting

The left side of the foot rail must be installed following the same process as for the head rail:

- 1. Remove the locknuts from the bolts.
- 2. Place the foot rail in place and install the washers, the bolts and the locking nuts of the left side of the foot rail.
- 3. The same procedures applies to the right side, but the drain hose hook must be installed between the foot rail and the washers and licking nuts.



Left side installation of the foot rail



Right side installation of the foot rail

- 4. Using a flat 13 mm wrench, tighten the locking nuts until the rail is completely blocked.
- 5. Install the hose on the support.

Attaching the mattress to the structure for RGO model

Before using the electric backrest function, ensure that the mattress is properly installed and that the cushion is attached to the mattress.



The strap for holding the head part of the mattress is installed under the tray.



Attaching the cushion to the mattress for RGO model

- 1. Slide the strap into the buckle by passing it through the cushion.
- 2. Pass the strap through the buckle to secure the installation.
- 3. By adjusting the loop length, the cushion will be fixed to the correct height.





Commissioning the Shado® shower trolley

Before first using a Shado® trolley electric model, it is highly recommended to perform a full charge of the battery. Please refer to the "Battery management" section of this user manual for instructions.

The Shado® E and RGO models are delivered with the emergency button placed in the "ON" position. Before first use, make sure that the emergency stop button is released to "OFF" position. Refer to the "Security devices" section of this user manual for further instructions.

Instructions for use

Security devices for Shado® E and RGO moldels

Emergency stop

According to European standards all the electric models of the Shado® shower trolleys have a RED emergency stop button which turn off the device when set in the "ON" position.

To activate this function simply press on the red button until it is lowered. To put the functions back on: turn the button clockwise until it is raised again.



Emergency lowering

The emergency lowering function allows the Shado[®] E to be swiftly lowered in case the patient needs to be transferred out of the trolley or if control box is failing.

To activate this function, press strongly on the button marked "Emergency" using a ball-point pen.



Be sure that your hand remains out of the way of the moving mechanical parts during the lowering of the tray. This function requires that the battery has not been removed and that is NOT fully discharged.



Contact SCALEO Medical if one of these elements has a dysfunction or if some of the parts are damaged.

Additional security features of the control box

The Shado® E is equipped with a 24 VDC battery power pack and security devices including:

- Voltage limitation
- Alarm in case the battery is discharged

Battery management

When the battery discharge threshold is reached, the user is alerted by a beep. If the battery does not recharge quickly, the unit turns off and the raising/lowering functions are not active anymore.



A power reserve allows the Shado[®] to be operated if the sound signal rings during the showering of a patient enabling it to finish the transfer.



The AC plug is protected by a plastic cap. The cap must be removed for the charge, and put back in place once the battery is fully charged.

Charging the battery



Use only the supplied cable to charge the shower trolley: charging a battery with an unsuitable cable can cause the cable and/or battery to overheat and damage all components, or cause a fire.

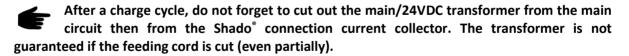


If the emergency stop button is pressed, the battery will not charge.

To charge the battery:

- 1. Connect the AC cable to the AC outlet,
- 2. The green «ON» light turns on,
- 3. The orange «CHARGE» light turns on, only if the battery is connected correctly.

It takes 8 to 10 hours to recharge 100% empty batteries.





The batteries cannot be overcharged. However, to ensure better performance and longevity, it is recommended to let them rest for a few minutes after charging and before use. It is also important to fully charge the battery.



Always unplug the power cord after each charge, without pulling it to avoid damaging the cord.



It is recommended to have 2 batteries to replace the discharged battery with the charged one. Therefore, Shado® will remain functional at all times.

Using the external charger

The external charger allows you to charge one battery while a second battery in being used.

To remove the battery from its compartment (device or wall charger):

- 1. Hold the handle with a hand facing up,
- 2. Close your hand while holding the handle,
- 3. Remove the battery by pulling towards you.

The handle top should be released from the bracket retaining lugs.

For installation, proceed with the reverse operations, taking care to verify that the battery is properly inserted.



The green light is on when the wall charger is plugged in. The orange light is on when the battery is being charged.

Maintenance of the battery

Never recharge batteries in extreme temperatures. If the temperature is too high, the battery charger may stop functioning for security reasons. If this occurs, place the battery and the charger in a cool place, wait a few minutes so the security device let the charge begin, and try again to recharge the battery.



If you plan to not use your Shado® for a long time (≥ 1 month), proceed as follows to keep your batteries in good conditions:

- Fully recharge your battery,
- Push the emergency button to OFF position,
- Remove the battery from its compartment,
- Store your battery charged in a cool, dry, well ventilated area,
- Check periodically (every month) the status of charge of the batteries: even if they are disconnected batteries tend to discharge.



Compliance with these precautions will help you keep your batteries longer and use your equipment in the best conditions. Failure to follow these instructions will void the warranty of batteries that would come to fail due to lack of maintenance.

Brakes and directional lock casters

Depending on the model, some Shado® shower trolleys are equipped with independent brakes while others with centralized brakes.

Centralized brakes

The centralized brakes allow you to control and lock the steering and brake of the wheels in pairs (front and rear).

There are three positions on the brake pedals:

- Press on 1 (YELLOW dot position) to block the direction.
- Press on 2 (RED dot position) to activate the brakes.
- Press on 3, horizontal position (GREEN dot position) to deactivate the brakes and free the casters.
- When the pedal is pressed, it releases the two corresponding casters (front or rear).
- Before locking the wheels in directional lock (YELLOW mark), both wheels must be oriented in the same direction, as shown in the photos below:



Independent brakes

Models including independent brakes enable to activate and deactivate the brakes of each caster independently.

When the brake lever is up, the brake is deactivated and the caster is free. When the brake lever is pressed, the brake is activated and the caster is locked.





Raising and lowering the stretcher

Electric models

The stretcher can be raised by keeping the raising pedal pressed, which is the left one. The actuator will automatically stop when it reaches the highest position.

The stretcher can be lowered by keeping the lowering pedal pressed which is the right one.

The actuator will automatically stop when it reaches the lowest position.



In order to stop the raising or lowering process, stop pressing the pedal.

Up and down directions of the movements are figured by red arrows on the pedals

Hydraulic model

The stretcher can be raised by pressing several times on the raising side of the pedal, which is the longest side.

The stretcher can be lowered by keeping the lowering pedal pressed, which is the shortest side

Lowering side = short side



Raising side = long side

Slope command

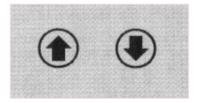
The stretcher can be tilted around the middle axis.

The Shado® enables an important positive slope so as to drain the water during showering.

The slope command is located behind the head rail.

Electric model

The command is bidirectional and assisted by an actuator. The positive slope is for evacuating water. Simply press the buttons to obtain the desired slope.



Hydraulic models

To activate the slope on hydraulic models, please follow the following instructions:

- 1. Hold the head rail with both hands,
- 2. Press the BLACK command lever,
- 3. Manually adjust the slope of the trolley while pressing the BLACK lever,
- 4. Set free the lever in order to keep the chosen position.



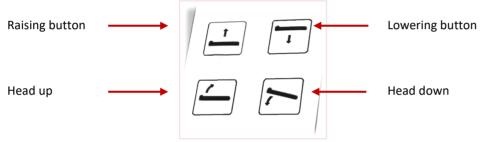
Hand remote control

The hand remote control is available in option for electric models.

The wired remote control allows users to control the configuration of the Shado[®] Electric models using the hands, in particular the raising, lowering and the slope functions.

The remote control of Shado® is IP65, perfectly sealed against spray water.



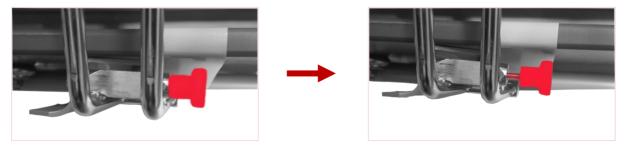


Opening and closing the rails

The complete Shado® range enables the opening and closing of the side rails.

Opening the rails

Pull at the same time the left and right handles according to the picture below. During this operation, the side rail must "go down/fall" freely onto your forearms. Then fold it back under the stretcher.



Closing the rails

Lift the rail up again until the limit stop by gripping it at the top. Locking of the rails is automatic. A "click" sound must be heard.



Each time you use the trolley, please check that the locks are fulfilling their function: the patient may fall off the trolley if the rail opens unexpectedly.







ATTENTION: the rail is not properly locked.

The rail is properly locked: the trolley is safe.



NEVER move the trolley by the removable rails (side or head). The rail attachment could be deteriorated, causing the rail to fail.

Backrest

Some models of the Shado®180, Shado®200 and Shado®240 are equipped with a movable backrest. This function allows raising the head of the patient up to 45°.

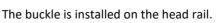
The command of this feature is located behind the head rail.



Before using the backrest function, please make sure that the mattress is properly installed:



The retaining strap of the head part of the mattress is installed under the tray.





Using the backrest function is easy: pressing the BLUE lever will unlock the gas spring and allows the back rest to be moved.

To raise the head of the patient while the tray is on a horizontal position, simply press the BLUE lever. Once the desired position is reached, release the BLUE lever to lock and set up the position.

Pressing the lever again will unlock the gas spring. The weight of the head of the patient will enable the head section to go back to the initial horizontal position.



If needed, use your free hand to help the head section to go back to the desired position, while maintaining the lever pressed.

Sitting position for RGO model

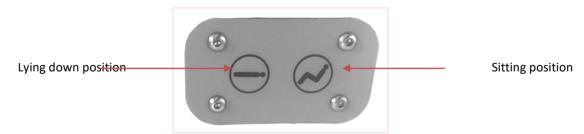
The ergonomic design of the Shado® RGO allows a comfortable sitting or lying down position for the patient.

The tray features 4 sections: backrest, seat, legs and thighs.



When the sitting position is activated, the "seat" section slips under the back section to avoid any risk of slipping and to ensure a perfectly ergonomic position.

The sitting / lying down position control is located behind the head rail, at the right side.



Using this function is extremely simple: a continuous push on the buttons allows activating an electric actuator and thus, passing from a sitting position to a lying down position and reversely.



Transfers must be made in the lying down position and on the central section of the trolley in such a way that the weight of the patient is spread according to his weight.

Transferring with the Shado® shower trolley



Transfers must be made in the lying down position and on the central section of the trolley in such a way that the weight of the patient is spread according to his weight. It is absolutely forbidden to sit the patient at the extremities of the trolley; this could damage the equipment and cause a fall.



The use of technical aids such as sliding sheets or transfer boards is highly recommended. even essential to avoid the risk of musculoskeletal disorders of caregivers.



Make sure that you have enough room to manipulate the shower trolley: 80 cm wide for 160 and 180 models, 90cm, for 200 and 240 models, 110 cm for 290 and 350 models.



Always make sure you have properly raised the rails during transport.



Always keep body parts away from the mobile structure during the positioning of the stretcher.



Always make sure that the 4 wheels are in contact with the ground before positioning or withdrawing a patient on the trolley.

Transfer from the bed to the shower trolley

- 1. Activate the brakes of the bed and raise it until reaching a comfortable height.
- 2. Set the trolley next to the patient's bed, either on the right hand side or on the left hand side, with the drain hole towards the feet of the patient.
- 3. Fold back the removable side rail on the bed side.
- 4. Position the Shado next to the bed.
- 5. Adjust the height and tilting of the stretcher.
- 6. Lower the mattress edge of the Shado on the bed.



Do not bend over the mattress against the bed side, as it could be damaged.

- 7. Activate the brakes of the shower trolley.
- 8. Roll over the patient on the Shado[®].
- 9. Adjust the tray by using the pedal.

- 10. Release the brake of the wheels and pull the trolley a step further from the bed.
- 11. Raise and secure the side rail back up.
- 12. Set the head cushion under the nape of the patient.

Transfers using a Trans'Gliss



Two caregivers are required, one on each side of the bed.

- 1. Activate the brakes of the bed and raise it until reaching a comfortable height.
- 2. Set the trolley next to the patient's bed, either on the right hand side or on the left hand side, with the drain hole towards the feet of the patient.
- 3. Fold back the removable side rail on the bed side.
- 4. Position the Trans'Gliss® under the patient.
- 5. Position the Shado next to the bed.
- 6. Adjust the height and tilting of the stretcher until it is a little bit lower than the bed.
- 7. Activate the brakes of the Shado[®].
- 8. Lower the mattress edge of the Shado® on the bed
- 9. Fold down the side rail of the opposite side of the transfer.
- 10. The caregivers use the Trans'Gliss to transfer the patient to the bed.



Please refer to the Trans'Gliss user manual.

- 11. Set the head cushion under the nape of the patient.
- 12. Raise back the side rail opposite to the transfer side.
- 13. Release the brakes.
- 14. Move the Shado® to the side and pull up and lock the side rails on the transfer side.
- 15. Remove the Trans'Gliss® from the patient.
- 16. Adjust the height to a comfortable position.

Transfer to the shower room

1. Position the stretcher to the most convenient height to operate the Shado® comfortably.



- 2. If you are using a shower trolley with centralized brakes, select the guiding type for the wheels:
 - Use the free wheels for difficult operations
 - Use the unidirectional wheels for simple movements.



Activating the unidirectional wheels on the opposite side to the user is enough for simple movements.

3. Tilt the stretcher to improve the comfort of the patient.

Showering

- 1. Activate the brakes of the wheels.
- 2. Position the draining hose above a draining outlet.
- 3. Adjust the slope of the stretcher to obtain efficient draining.

When the shower is over:

- 1. Dry the patient.
- 2. Put back the draining hose on its holder.
- 3. Unlock the brakes of the wheels.
- 4. Bring the patient back to his room.
- 5. Perform an "after use" servicing routine before using the Shado with another patient. Refer to the "Cleaning and disinfecting" section of this manual.



The draining hose on its holder



Cleaning and disinfecting

If you are using an electrical model:



- make sure to unplug the trolley before going through any kind of maintenance, cleaning, or transport.
- press the emergency stop button to avoid any unwanted movement of the device during cleaning process.

Daily maintenance

Maintenance after each use and between patients

The Shado® must be cleaned and disinfected, like any device having direct contact with the patient skin. Depending on the frequency of use, and imperatively once a day, a complete cleaning/disinfection/ drying operation must be performed on the whole unit in order to maintain safety and perfect operation.

For cleaning, use standard products approved by sanitary authorities. It should be made with liquid soap or nonabrasive and chlorine free cleaning products.

Cleaning the mattress and cushion

The mattress and the cushion should be cleaned in the same way, without the use of solvent products, and rinsed extensively. The material used for the manufacturing of the mattress resists to most disinfection products if used at recommended dosages (70° alcohol at 1/1 dosage).

Using chlorinated products at certain dosages (7/10) may alter the color of the mattress. Adjust the slope of the stretcher to obtain efficient draining and avoid any stagnation under the mattress.

Cleaning the tray



Cleaning the structure of the Shado[®] and the bottom surface of the mattress should always be done with the mattress off.

- 1. Unscrew the draining hose and the inferior part of the hole which is under the stretcher,
- 2. Unhook the mattress slings from under the stretcher and remove the mattress,
- 3. Clean the structure using disinfectant cleaning wipes.



The medical device is classified as non-critical and the structure of the Shado cannot be immersed. The lower structure should only be cleaned by wiping with disinfectant cleaning solution.

Periodic inspection and preventive maintenance

Annual periodical inspection

The aim of a periodic control visit is to control the safety and the maintenance issues on the equipment. This control must be performed regularly every year and the preventive maintenance must be performed every 3 years — according to annex B of the EN ISO 10535 standard and the recommendations from health authorities.

Periodic control/ Preventive maintenance checklist

SCALEO		Written by : FENNICHE Yannis	Date : 26/09/2023
M E D I C A L	PERIODIC INSPEC	TION FOR SHADO	

Perio	dic co	ontrol:	Preventive maintenance :						
		CLIENT	N° Client SAGE :						
Name	:		Town/Country:						
Mode	l (artic	le number) :	Seria	l numi	ber:				
PC	РМ	Actions to be done		ОК	Comments				
		Cleaning / Disinfection							
		Inspection of corrosion and paint							
		Inspection of welds							
Bas	e :								
П	П	Geometry and flatness of the base		П					
		Control of axis and brake pedals							
		Cleaning of front and rear wheels							
Stru	cture								
		Control of the wear level of the joints							
	П	Fixture of the main actuator							
		Fixture of the tilting stretcher jack							
		Presence of all pins in the different articulation	on						
		axes							
Trai	l:								
		General check							
		Check fixture							
Rail	s:								
		Check: locking and unlocking of the lateral r	ails						
		Check : Head and foot rails							
		Check : Rails locking screw							
Actu	ators	and controls :							
		Battery holder (version E)							
		Electronic box (version E)							
		Charger (version E)							
		Pedal : High / Low							
		Tilting stretcher jack control							
		Battery (version E)							
Matt	ress	and headrest :							
		Straps							
	П	Sealing		П					
		Drain hose							
Fun		I tests :							
		Rolling		П					
	П	Test : Up / Down with no load							
H		Test: Up / Down with maximum load							
H	H	Tray tilting system							
	П	Tray tilting system Emergency stop (version E)							
-	H	Emergency lowering (version E)	П						
Labeling:									
Lab		Label of product							
		Control sticker							
		User manual							
		Number of completed actions							
Name	Name of technician : Date & Signature :								

If the periodical inspection reveals problems relating to the security of the patient or the caregiver, the technician in charge of the inspection must immediately inform the user, and add a comment in the inspection report. The equipment should not be used until the problem is corrected.

One copy of this form should be handed to the customer, one copy held by SCALEO Medical and by the authorized distributor.

The Shado® shower trolley range

The Shado shower trolley range is composed of the following models:

Electric models

Independent brakes - Electric jack for adjustable height and Hydraulic jack for Proclive/Declive

```
S 27 00 040
               Shado® 160 PVC tray Child XS
S 27 00 034
               Shado® 180 PVC tray Child S
S 27 00 038
               Shado<sup>®</sup> 180 PVC tray Medium
S 27 00 125
               Shado® 180 PVC tray Medium with backrest
S 27 00 032
               Shado® 180 PVC tray Adult
S 27 00 053
               Shado® 180 PVC tray Adult with remote control
S 27 00 105
               Shado® 180 PVC tray Adult with backrest
S 27 00 042
               Shado<sup>®</sup> 200 PVC tray
S 27 00 106
               Shado<sup>®</sup> 200 PVC tray with backrest
S 27 00 044
               Shado<sup>®</sup> 240 PVC trav
S 27 00 107
               Shado® 240 PVC tray and backrest
S 27 00 045
               Shado<sup>®</sup> 200 PVC long tray
S 27 00 047
               Shado<sup>®</sup> 240 PVC long tray
```

Brakes controlled by pair - Electric jacks for adjustable height and gas spring proclive/declive

```
S 27 00 068 Shado<sup>®</sup> 180 PVC tray Child S with backrest S 27 00 070 Shado<sup>®</sup> 180 PVC tray Adult S 27 00 127 Shado<sup>®</sup> 180 PVC tray Adult with backrest
```

Brakes controlled by pair - Electric jacks for adjustable height and for proclive/declive

```
S 27 00 020
              Shado® 160 PVC tray Child XS
S 27 00 060
              Shado® 160 PVC tray Child XS with remote control
S 27 00 014
              Shado<sup>®</sup> 180 PVC tray Child S
S 27 00 061
              Shado® 180 PVC tray Child S with remote control
S 27 00 018
              Shado<sup>®</sup> 180 PVC tray Medium
S 27 00 126
              Shado® 180 PVC tray Medium with backrest
S 27 00 012
              Shado® 180 PVC tray Adult
S 27 00 111
              Shado® 180 PVC tray Adult with backrest
S 27 00 022
              Shado<sup>®</sup> 200 PVC tray
S 27 00 112
              Shado<sup>®</sup> 200 PVC tray with backrest
              Shado® 200 PVC tray – Rgo model
S 27 00 121
S 27 00 024
              Shado<sup>®</sup> 240 PVC tray
S 27 00 113
              Shado<sup>®</sup> 240 PVC tray with backrest
              Shado® 240 PVC tray Adult – RGO model
S 27 00 122
S 27 00 028
              Shado® 200 PVC long tray
S 27 00 029
              Shado<sup>®</sup> 240 PVC long tray
S 27 00 091
              Shado<sup>®</sup> 290 PVC tray – high speed
S 27 00 026
              Shado® 350 PVC trav
```

Hydraulic models

Independent brakes - Hydraulic jacks for adjustable height and for Proclive/Declive

```
S 27 00 039 Shado<sup>®</sup> 160 PVC tray Child XS S 27 00 033 Shado<sup>®</sup> 180 PVC tray Child S
```

S 27 00 037	Shado® 180 PVC tray Medium
S 27 00 123	Shado® 180 PVC tray Medium with backrest
S 27 00 031	Shado® 180 PVC tray Adult
S 27 00 103	Shado® 180 PVC tray Adult with backrest
S 27 00 041	Shado [®] 200 PVC tray
S 27 00 104	Shado [®] 200 PVC tray with backrest
S 27 00 043	Shado [®] 200 PVC long tray

Brakes controlled by pair - Hydraulic jacks for height and for Proclive/Declive

S 27 00 019	Shado [®] 160 PVC tray Child XS
S 27 00 013	Shado [®] 180 PVC tray Child S
S 27 00 017	Shado [®] 180 PVC tray Medium
S 27 00 124	Shado® 180 PVC tray Medium with backrest
S 27 00 011	Shado [®] 180 PVC tray Adult
S 27 00 101	Shado [®] 180 PVC tray Adult with backrest
S 27 00 021	Shado [®] 200 PVC tray
S 27 00 102	Shado [®] 200 PVC tray with backrest
S 27 00 025	Shado [®] 200 PVC long tray

Technical specifications

Technical specifications of the Shado®

All Shado® shower trolleys are manufactured and tested in our workshops in France, under ISO 13485 certified quality management system.

The side, head and foot rails of Shado® shower carts are made of corrosion-resistant stainless steel. The structure of Shado® shower carts is made of cataphoresis-treated steel.

The mattress cover and cushions are resistant to ignition by a burning cigarette. (Complies with EN 1021-1 standard). The padding inside is flame-resistant for 60 seconds (UL94-2015 HF-1 compliant).

The expected lifetime of the Shado® shower trolley is ten (10) years, except for the battery which lifetime depends on its use, as well as some of the parts of the equipment such as caster wheels cushion and mattress. They may be required to be replaced during the lifetime of the equipment. SCALEO Medical engages to have on stock all spare parts for a period of 10 years.

	Electric Shado® E and RGO	Hydraulic Shado®				
Maximum load capacity	160 180, 200, 240, 290, 350kg 160, 180 kg or 200kg					
Tilting degree of tray - (depends on the height of the tray)	+12° / - 2° RGO model : +7.5° / -2°, ± 1°					
Ground clearance	55 mm					
Wheels/casters	Four 3 positions casters, op	erated by pairs or				
	Four independent 2 pos	sitions casters				
	arnothing 150 mm single tire tread, except S					
	arnothing 150 mm double tire tread for the S	hado [®] 290 and 350 models				
Power pack/ charger	Voltage 24 VDC 2.9Ah	N.A.				
Standard charger	Voltage 240V 50/60 Hz (1) Charging voltage 27,6VDC \pm 2% Charging current Max. 400mA Charging time 8 hours maxi	N.A.				
Number of cycles; Up and down with full battery	≈ 40 cycles	N.A.				
IP protection	IPX4 Remote control (in option) : IP65	IPX5				
Sound power level (dB)	44,1 ± 0,2	N.A.				
Fire resistance	Mattress and cushion: EN 1021- 1:2014 & UL94-2015 Tray: UL 94 Actuator plastic case UL94V0 Electric box UL94V1	Mattress and cushion : EN 1021-1:2014 & UL94-2015 Tray : UL 94				
Total weight	82 kg to 163 kg depending on the model and options	Approx. 83 kg depending on the model and options				
Tray	Gray in PVC, Thickness = 15 mm					

Specifications of the actuators

						200	240				
		160	180	180	180	&	&				
		XS Enfant M Adult RGO RGO Long tray		290	350						
Electrical actuator	Main		10 000 N						12 000 N		
24VDC (Newtons)	Minor	900 N I 1900 N I				2 500 N	25	00 N			

Dimensions

		160 XS	180 Enfant	180 M	180 Adult	200	240	Long tray		290	350
Maximun	n load (kg)	160	180	180	180	200	240	200	240	290	350
Tray len	gth (cm)	140	161	176		186 210 180		.86			
Overall le	ength (cm)	161	181	196	206 230 2		206 230		2	06	
Tray wi	Tray width (cm)		60			71			71 89		89
Overall w	vidth (cm)		77	•		88			106		
Tray in high	Tray height		98					97			
position (cm)	Side rails height		113					112			
Tray in low	Tray height		52 65		52				65		
position (cm)	Side rails height				6	68			:	80	



Note: The dimensions of the models manufactured in series are indicative and can slightly vary due to the variations on the assembly process.

RGO models dimensions

		200 RGO 240 RGO		
Tray I	ength	1860 mm		
Overal	length	2050 mm		
Tray	width	710 mm		
Overal	l width	908 mm		
-	Tray height	1074 mm		
Tray in high position	Siderails height	1226 mm		
Turnin lanna attion	Tray height	589 mm		
Tray in low position	Siderails height	741	. mm	

Other specifications

Environmental tolerance for use			
Input AC voltage range From 100 to 240 V AC ± 10%			
Humidity limitation 30 to 90% humidity			
Temperature limits From + 5 ° C to + 40 ° C			
Atmospheric pressure Between 200 and 1060 hPa			
Environmental tolerance for storage			
Humidity limitation 30 to 90% humidity			
Temperature limits From - 10 ° C to + 40 ° C			
Atmospheric pressure Between 200 and 1060 hPa			
Environmental tolerance for transport			
Humidity limitation	30 to 90% humidity		
Temperature limits From - 30 ° C to + 60 ° C			

Compliance with norms and regulations

- All the Shado® shower trolleys models are medical devices Class I, in compliance with the European regulation 2017/745 to medical devices.
- All the Shado® shower trolleys meet the requirements of European standard EN 10535 relating to hoists for disabled persons
- Safety of electro medical devices:
 - All the Shado® shower trolleys electric models meet the requirements of European standard EN 60601.
 - Electrical Protection Class 2.

Technical specifications of the accessories and components

Technical specification of the battery:

Technology	Lead
Material of the case	ABS UL94V0
Nominal voltage	24V
Capacity	2.9Ah
IP Class	IPX5
Storage/use temperature range	+5°C / +40°C
Conditions of use	Indoor use only

Technical specification of the wall charger:

Input AC voltage range	100~240V AC
Input AC frequency range	50/60Hz
Maximum charging current	650 mA
Compliance to standards	EN 60601-1 :2005 +C1:2006 +C2:2007 , RoHS

Charging time	4h 30
Conditions of use	Indoor use only

Electromagnetic compatibility (E.M.C)

- The Shado® shower trolleys require special care regarding the E.M.C. They must be installed and commissioned considering the EMC information provided in this user manual.
- The RF communication devices and portable phones may affect the Shado shower trolleys.
- The use of accessories, transducers and cables other than those specified, except transducers and cables sold by the manufacturer as replacement parts for internal components, can result in increased emissions or decreased immunity of the device.
- It is appropriate that the Shado[®] shower trolleys are not used next to other devices or stacked with them, if it is not possible to do otherwise, the Shado[®] must be monitored to verify normal operation in the configuration in which it is used.
- In terms of the standard NF EN 60601-1-2: 2007, essential performance of the Shado[®] is to never perform unwanted movements.

Directives and manufacturer's declaration - Electromagnetic emissions

The Shado® is designed to be used in the electromagnetic environment specified below. The user of the Shado® must make sure to use it in such environment.

Emission test	Conformity	Electromagnetic environment - Guidelines
RF Emissions CISPR 11	Group 1	The Shado® uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic devices.
RF Emissions CISPR 11	Class B	The Shado ® is suitable for use in all premises, including domestic premises and those directly connected to the public power network supplying domestic
Harmonic Emissions EN 61000-3-2:2015	Not applicable	premises.
Voltage fluctuations / Flicker EN 61000-3: 2013	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the Shado®

The Shado® is designed to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Shado® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Shado®, as recommended below, according the maximum transmission power of the communication device.

Maximum rated output	Separation of	distance depending on t	he frequency of the transmitter	
power of the transmitter		m		
W	from 150 kHz to 80	80MHz to 800MHz	de 800MHz to 2,5GHz	

	MHz		
	Non applicable	d= 0,35√P	d= 0,7√P
0,01	Non applicable	0,04	0,07
0,1	Non applicable	0,11	0,22
1	Non applicable	0,35	0,7
10	Non applicable	1,1	2,2
100	Non applicable	3,5	7

Directives and manufacturer's declaration - electromagnetic immunity

The Shado® is designed to be used in the electromagnetic environment specified below. The user should ensure it is used in such an environment.

INMMUNITY test	Test level - IEC 60601	Level of compliance	Electromagnetic environment guidelines
Electrostatic discharges (E.S.D.) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor materials should be wood, concrete or ceramic tile. If floors are covered with synthetic material, should the relative humidity be at least 30%.
Transitional burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Transitional surge IEC 61000-4-5	± 1 kV between phases ± 2 kV line to ground	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on the input lines Power IEC 61000-4-11	<5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) 5 s	Not applicable	Not applicable
Magnetic field @ 50/60 Hz IEC 61000-4-8	30 A/m	30 A/m	Quality of power supply network should be of a typical commercial or hospital environment. If the user of Shado® requires continued operation during network outages of power, it is recommended to feed the Shado® from an uninterruptible power supply or battery.

NOTE U_T is the AC mains voltage prior to application of the test level.

Directives and manufacturer's declaration - electromagnetic immunity

The Shado® is designed to be used in the electromagnetic environment specified below. The user of the Shado® must ensure it is used in such an environment.

Conducted RF disturbances IEC 61000-4- 6	3 Vrmsf 150 kHz to 80 MHz	Non applicable	Portable and mobile RF communications should not be used closer to any part of the Shado®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter. Recommended separation distance Non applicable
Radiated RF disturbances IEC 61000-4- 3	3V/m 80MHz to 2.7GHz with discreet frequencies 385, 450, 710, 745, 780, 810, 870, 930, 1720, 5240, 5500, 5785, 1845, 1970, 2450 with level between 9V/m and 28V/m	3 V/m	d= 0,35VP 80MHz to 1GHz d= 0,7VP de 800MHz to 2,7GHz Where P is the maximum power output of the transmitter in watts (W), according to the transmitter manufacturer and d is the separation distance in meters (m). The field strengths from fixed RF transmitters, as determined by an electromagnetic investigation (a) should be below the level of compliance in each frequency range. (b) Interference may occur in the vicinity of the equipment marked with the following symbol:

NOTE 1: At 80 MHz and 1 GHz frequency range applicable is the highest.

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 mobile radios, amateur radio, broadcasting AM and FM and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters should be considered an electromagnetic site investigation. If the field intensity measured at the location where the Shado® is used exceeds the applicable RF compliance level above, the Shado® should be observed to verify that operation is normal. If abnormal performance is observed, additional measures may be needed, such as redirect or reposition the Shado®.

b: In the frequency range 150 kHz to 80 MHz, it is appropriate that the field strengths are less than 3 V / m.

Warranty

The Shado® shower trolley have a two (2) years warranty, except for the battery and the accessories that are guaranteed one (1) year.

- Any intervention on the device contrary to this manual will entirely void the warranty.
- Any abnormal use or non-compliant usage will entirely void the warranty.
- Any modifications to the device will entirely void the warranty.
- Any technical intervention made by non-qualified personnel or a non-authorized distributor will entirely void the warranty.

Liability

SCALEO Medical assumes no liability for any injury or harm and consequences thereof directly or indirectly caused to operators, patients, or any third party in the following cases:

- Non-compliance with the instructions or recommendations supplied within this User Manual,
- Using un-adapted spare parts and accessories,
- Assembling, adjusting and repairing carried out by non-qualified personnel,
- Abnormal use of the equipment, negligence, accident, human error, or maintenance and cleaning with non-adapted products
- Non-compliance to servicing and annual preventive maintenance requirements according to EN 10535 B annex requirements, the requirements from local health authorities and the advices and instructions presented in this manual.

End of life, recycling

SCALEO Medical shower trolleys and accessories are at least 90 % recyclable.

The end of life disposal of the device must be done respecting the recycling circuit and local relevant regulation. This particularly concerns the electrical and electronic equipment (WEEE) and the lead battery (B/A).

For waste management that respects the environment, please kindly contact the sales manager in your area.

Contact information

The information and advice provided in this user manual are also intended to inform you of the importance of paying attention to safety measures and the necessity of regular maintenance.

Any serious incident related to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

This is a matter of <u>responsibility</u> for your establishment, and a question of <u>safety</u> for your patients and staff.

Please do not hesitate to contact us if you require electrical diagrams, lists of components, descriptions and/or any information that could be useful for your qualified technicians.



ZAC Parc 2000, 107 rue Joe Dassin 34080 Montpellier - France +33 (0) 4 67 72 94 86 info@scaleomedical.com www.scaleomedical.com