

## Poweo® Activ'

Raising aid



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## Warnings and safety instructions



The Poweo<sup>®</sup> Activ' standing aid is designed to stand up patients with a minimum of autonomy and physical capabilities. Before use, in order to avoid any risk of falling and serious injury, it is imperative to make sure that the patient is capable to use this device.



Poweo<sup>®</sup> Activ' should only be installed, operated and serviced by trained personnel: please read this manual carefully. The functions should be familiar to you before using the lifter.



The Poweo® Activ' must be serviced exclusively by authorized technicians using original spare parts. No modification shall be made without the written consent of SCALEO Medical, who is the manufacturer.



The Poweo® Activ' is designed and manufactured to safely stand up patients of up to 160 kg with the Poweo® Activ' 160 and up to 200 kg with the Poweo® Activ' 200. Beyond this weight, do not use the Poweo® Activ': please consult SCALEO Medical for advice on the best lifter that satisfies your transfer needs.



Poweo® Activ' is not intended for use in balneotherapy, as salty or chlorinated mists may rapidly degrade the device, rendering it inoperative or hazardous.



The slings recommended for the Poweo® patient lifters are the SCALEO Medical slings. They have been specifically developed for the Poweo® Activ. It is your responsibility to ensure that the slings used are compatible with the lifter: the manufacturer of the sling must have carried out tests according to standard EN 10535 (weight resistance, resistance of fasteners, length of loops) ensuring the safety of the assembly and clearly indicating the compatibility of its sling with the lifter in its documentation. If this is not the case, do not use the sling in combination with the lifter: the patient could fall and be seriously injured. SCALEO Medical refuses any liability in the case of an incident while using slings other than those specifically made for their lifters.



Torn, cut, frayed or broken slings can fail, resulting in serious injury to the patient and/or to the user. Only use slings in good condition.



The slings and the lifter have to be used to lift and transfer people. Never use the patient lifters to raise nor to carry objects.



Avoid transferring patients on thick carpeted floors. Ragged surfaces and any obstacles may block the wheels. If the force is too important, the lifter could be destabilized and can tip over, especially if the lifter is being used at its maximum weight capacity.



The Poweo<sup>®</sup> must NEVER be used to transfer, lift or transport people over slopes.



Like all patient lifters, the Poweo<sup>®</sup> is not a transportation device. It must be used only for short distance transfers and it is not intended to replace wheelchairs nor other types of transportation devices.



The maximum load can be lifted for about 1 minute. The delay between two lifts of the maximum load shall be of approximately 10 minutes to let the actuator cool down.

This manual is intended for users of Poweo® Activ' lifters and must not be communicated or made available to any third party without the prior written permission of SCALEO Medical.

The first Poweo® Activ' 160 was commercialized on November 14<sup>th</sup>, 2017, the first Poweo® Activ' 200 on April 22<sup>nd</sup>, 2020 and the first Poweo® Activ' 200 openning legs on November, 2021.

## Symbols and pictograms

### The symbols used in this manual are:



This symbol indicates instructions and safety information, when injuries may occur if warnings are ignored or partially followed. It is important to carefully follow the advice.



This symbol indicates important information regarding the use of the equipment. Failure to follow this information may result in damage of the lift or other equipment.



This symbol indicates important and useful information. This information will help the user and optimize the use of the material. It will simplify routine operations and provide solutions to complex operations.

### Symbols used in labels:

Symbol	Meaning
***	Manufacturer
$\sim$	Date of manufacturing
REF	Device reference
SN	Device serial number
100 100	Temperature range
	Do not burn
SECURITY PIN	Security pin: do not remove this pin. Periodically inspect this pin.
$\triangle$	Warning: read user manual for instruction
	Indoor use only

Symbol	Meaning
[]i	Read user manual for instruction
===	Direct current power source
	Class II electrical protection type
<b>†</b>	B type applied parts
$\otimes$	Do not disassemble
max 160 352 kg lbs	Maximum safety load
CE	In accordance with European regulations
X	Contains potential wastes of electrical or electronic equipment
MD	Medical Device

## General information about Poweo® Activ'

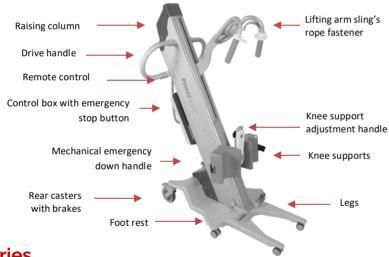
You have recently purchased a Poweo® Activ'.

We would like to thank you for the trust you have placed in our company.

The Poweo® Activ' is an innovative standing and transfer aid. The movement of the lifting arm is unique and ergonomic.

This movement provides progressive rotation of the handlebars throughout the lift.

The Poweo® Activ' is compact, comfortable, easy to maneuver and very stable thanks to its base made of cast aluminum.



### **Accessories**

Poweo® Activ' can be used with the following slings (not included):

- Cocoon sling,
- Self-adjusting sling,
- Comfort sling,

### Intended use

Poweo® Activ are active mobile patient lifters. They are intended to be used on horizontal floors to lift patients without disabilities of the lower limbs that are capable of maintaining the upright posture, and to transfer them to and from a sitting position.

Poweo® Activ' allows a safe weighing capacity of up to 160 kg or 200 kg, depending on the model. The Poweo® Activ' safely and comfortably is intended to transfer a dependent person effortlessly and reducing the risk of injury to the caregiver.

### **Contraindications**

The Poweo® Activ' should NOT be used in the following cases:

- When a patient is subject to loss of balance or discomfort,
- For patients whose mental state is impaired (agitated patients),
- In the case of medical contraindication of support following surgery of the shoulder, hip, knee or ankle,
- Severe flexion deformity of the knee amputation not allowing a standing position, even with support,
- In disabled patients of the lower limbs,
- In patients with curvature of the spine,
- In patients with muscle spasm,
- In patients weighing more than the safe working load of the lifter,
- To transfer patients over a long distance,
- To transfer patients on slopes,
- To replace wheelchairs or other types of transportation.

## Assembly and commissioning instructions

Before putting the Poweo Activ' to use, make sure that the packaging is in perfect condition and that no parts are missing or damaged. If so, immediately take note of the damages with the carrier and contact SCALEO Medical or your distributor.



The elements of the packaging (plastic bags, polystyrene, etc.) should not be left within the reach of children as they constitute a potential danger.



Given the weight of the various elements of the Poweo® Activ', two people are needed to unpack and commission it.



Please read this instruction entirely before beginning, while checking that all the parts are present and in good condition.



SCALEO Medical tests and charges all batteries before packaging. However, the batteries must always be fully charged before first use.



The Poweo<sup>®</sup> Activ' standing aid is safely delivered with the emergency stop button switched on. Make sure you have released it before using or recharging the device.

### Unpacking the Poweo® Activ'

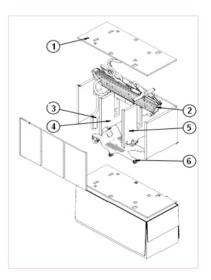
The packaging of the Poweo® Activ' has been specifically designed to transport the device without risk of damage.

Step 1: Open the box.

Step 2: Remove the top protector (1).

Step 3: Remove the column (2) and place it on a clean and smooth surface.

Step 4: Remove the wedges (3), (4) and (5).



Step 5: Remove the base (6) from the package.



Since the settings and carton are specific, it will be useful to keep them for any subsequent shipment of Poweo® Activ' for inspection or maintenance.

### **Instructions for assembly**

### Installing the column on the base



Required equipment: an adjustable torque ratchet with 13 mm socket and a hex wrench.

Step 1: Position the column (1) on the base (2): the notches help guiding the mast on its location.

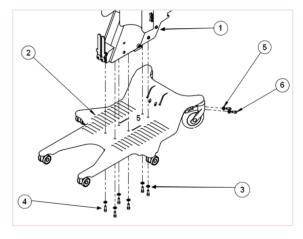
Step 2: Put the washers (3) and screws (4) in place and tighten them manually.

Step 3: Put the washers (5) and screws (6) in place and tighten them manually.

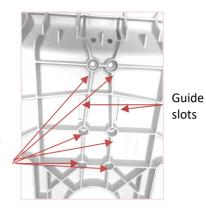
Step 4: Using the hex wrench, tighten all screws until you have an uniform tightening.

The tightening torque to apply is 14.5 Nm.

If possible, follow the procedure below:

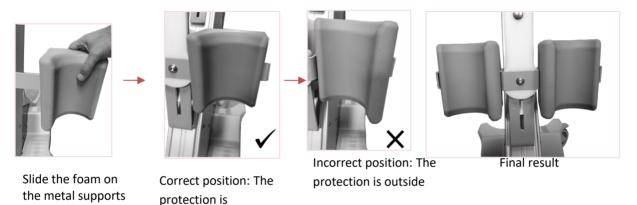


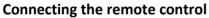
- Place the column on a table at working height,
- Install the base on the column,
- Proceed with the assembly and tightening of the screws.



Place of fixing screws

### Installing the leg support foams







## Instructions for use

The Poweo® Activ' control box is equipped with a battery charger that can be used regardless of the voltage and frequency of the place of use.

The provided power plug must be adapted to the electrical outlet of the country of use: if this information was provided to SCALEO Medical at the time of the order, the supplied AC cord will be fully compatible.



Before the first use the battery must be completely recharged. Refer to the "Charging the Battery" section for this operation.

Before each use, check for correct installation of the lifter and its accessories, and verify proper operation before using with a patient.

The controls below only take a few minutes and will ensure a safety use of your Poweo®:

- Make sure no part is damaged or shows signs of wear.
- Check the tightness of all the security screws securing the column and the actuator. These can be identified by the label here on the right.
- Inspect accessible screws and make sure none are loose.
- Check the lights on the remote control: battery indicator should be solid green; maintenance indicator should be off.
- Check the features: raise and lower the column, caster brakes, emergency stop.



In case of malfunction, or doubt about the proper operation, do not use the Poweo<sup>®</sup> Activ': inform your technical service, your distributor, or contact us at the address on the back of this manual.



Practice by lifting a colleague and by being lifted by others. It is important to experience how the patient will feel while being lifted by putting yourself in his position. Try out and practice using all the relevant slings for the different types of lifts and movements you may encounter. It is also a good idea to inform the patient of the procedure he is about to go through to comfort him.



It is very important to use slings and accessories adapted to the pathology, morphology and weight of the patient and the type of transfer to be performed.



The Poweo® Activ' is designed for use in room temperature, +10 to +40°C. This should be taken into consideration when transporting the lifter; and therefore, keeping it in a temperate part of the vehicle. Alternatively, the Poweo® Activ' must rest in a temperate room until the equipment has achieved proper working temperature.



SCALEO Medical may train the users for the commissioning and use of all the equipment manufactured by SCALEO Medical. If the device has been provided by a distributor, we advise you to contact your distributor for a training course.

### **Security devices**

### **Emergency stop**

All models of Poweo® Activ' are equipped with an emergency stop button that will power off the lifter when pressed. The emergency stop button is located on the control box (Poweo® Activ' 160 models) or on the top of the battery (Poweo® Activ' 200). Once pressed it must be turned clockwise to release it.





### Mechanical emergency lowering of the Poweo® Activ' 160, with or without display

In case of non-operation of the remote control, a mechanical emergency lowering is still possible. The emergency mechanical descent is activated by pulling the handle at the bottom of the column.



This device disengages the actuator brake. Make sure you have the ability to cushion the descent of the patient because the lowering is fast. 2 people are needed for this operation.





## Electric emergency lowering of the Poweo® Activ' 200 and Poweo® Activ' 160 without display

In case of non-operation of the remote control, the Poweo® Activ' 200 and the Poweo® Activ' 160 without display are equipped with an electric emergency lowering.

For the Poweo® Activ' 160 model, it can be activated using the button located on the control box.

For the Poweo® Activ' 200, using a pen, press the "emergency" yellow button so the lifting arm is lowered.



Be very careful because the lifting arm of the Poweo® Activ' 200 goes down very quickly: your arm or your hand could be injured during the descent. For this function to be operational, it is necessary that the battery is present, and is not completely discharged.

### **Battery management**

The Poweo® Activ 160 is equipped with Linak® electronics, while Poweo® Activ ' 200 is equipped with SCALEO® electronics.

The Poweo® Activ' 200 is equipped with a NiMh battery + SCALEO® charger, which contain electronic protections against short circuits, over voltages and over temperature. If one of these parameters exceeds the specified value, the battery will stop working, preventing the user from overheating and the risk of fire.

The Poweo® Activ' 160 is equipped with a Linak® lead 24 VDC battery + a control box, which also includes all the necessary safety devices. Therefore, the use of SCALEO Medical and / or Linak® batteries and chargers is perfectly safe.

### Charging the battery

Regardless of the model, when the battery needs to be recharged, the lifter will emit a sound signal to warn the user. On the Poweo® Activ' 160 with display and the Poweo® Activ' 200 models, the battery status LED on the remote control will also light up to alert the user.

The Poweo® Activ' 160 equipped with Linak® electronics can be charged directly into the patient lifter or using the optional wall charger. The Poweo® Activ' 200 with SCALEO® electronics is exclusively charged using the external charger which is supplied by default.

Activ' 160 - Linak® w/o display

Scaleomedical.com

Activ' 160 - Linak® with display



Activ' 200 - SCALEO®



- 1: Emergency button
- *5: Emergency lowering button*
- 2: Battery label 6: ON/OFF indicator
- 3: Battery charge LED
- 7: Display
- 4 : Charge status label

To charge the battery of the Poweo® Activ' 160 with Linak® electronics (with or without display):

- 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 properly connected.
- 0

In accordance with current regulations, the Poweo® Activ' does not work while the battery is being charged directly into the patient lifter.



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

To charge the battery of the Poweo® Activ' 200 with SCALEO® electronics:

- 1. Connect the charger to the AC outlet,
- 2. Place the battery in the battery charger,
- 3. Once the battery is detected in the charger, the LED indicator will light up.

The Poweo® Activ' 200 including SCALEO® electronics takes 2:30 to 5 hours to recharge 100% empty batteries. The Poweo® Activ' 160 including Linak® electronics takes 8 - 10 hours to recharge 100% empty batteries.

For intensive daily use, an everyday recharge will be necessary.



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 using. It is also important to fully charge the battery.



Upon request, the charger's power connector can be delivered protected by a plug that ensures additional protection of the charger against splashing water. Remove this plug for charging, and be sure to put it on again after recharge.



To charge the batteries, use only the supplied cable: charging a battery with an unsuitable cable can cause the cable and/or battery to overheat and damage all components.



After each charge, be careful to unplug the power cord without pulling to avoid damaging the cord.



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

### Using the external charger

The external charger allows you to charge one battery while using a second battery in the Poweo® Activ'.

To remove the Linak® battery from its holder (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 operation, making sure the battery is properly inserted.
- The removal of the Poweo® battery does not require any manipulation. Simply pull it towards you. Its shape prevents it from being accidentally connected backwards or improperly, either in the patient lifter or in the external charger.

The LED indicator of the Poweo® Activ' 200 charger displays the status of the recharge. Depending on the color of the LED indicator the user can monitor the different status:

CHARGER LED COLOR	MODE
Yellow - •	The battery is not connected to the charger
Yellow- •	Reset and battery analysis
Orange - •	Fast recharge
Alternately green and yellow - • / •	Compensation charge
Green - •	Slow charge/end of recharge
Alternately green and orange - • / •	Error or battery overheat



The LED indicator of the Linak® external charger for Poweo® Activ' 160 (with or without screen) only indicates an orange color to indicate the battery is been charged. Once charged, the LED indicatore will turn off.

### Maintenance of the battery



Use only the charger provided with the Poweo® patient lifter, do not use another charger. Using an unsuitable charger could provoke the deterioration of the battery or an overheat leading the battery to explode or flame up.



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 allows the charge to begin, and try again recharging the battery.



If you plan not using your lifter 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 charge status 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.



In case of an intensive use failing to meet the service factor of the lifter (1/10), a "battery empty" false alarm may appear on the remote control. In this case do the following:

- Remove the battery from its compartment,
- Wait 10 seconds,
- Put the battery back on its compartment.

This operation allows the electronics to reset and cancels the "false" alarm.

### The controls

All models of Poweo® Activ' are offered with a remote control allowing to activate the lifting and lowering functions of the lifter.

The Poweo® Activ' 200 and the Poweo® Activ' 160 with display control box are equipped with two controls: a remote control and a fixed control panel. The user can activate the functions of the lifter (up, down...) from both controls indistinctly.

### Remote controls

Additionally to the lifting and lowering buttons, the remote controls of the Poweo® Activ' 200 and the Poweo® Activ' 160 with display control box have a LED indicator that shows the status of the battery. There are three states: green, red, flashing red. The red LED indicator means that the battery needs to be recharged, while the green light indicates an optimal charge.



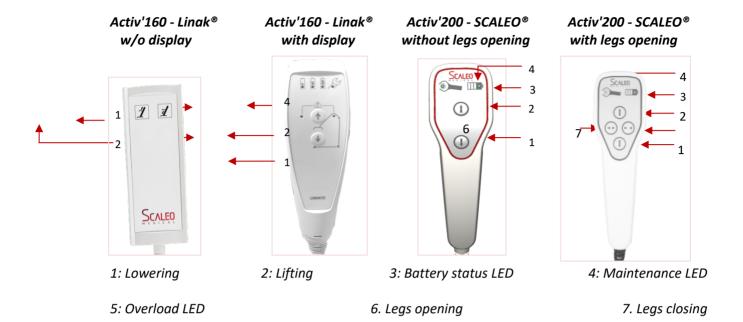
When the LED indicator turns RED, there is still enough power to perform at least one patient descent.

These hand controls provide further benefits in use:

- Compact, light and ergonomic,
- Anti-slip coating on the back to prevent dropping,
- Bio compatible materials,
- Exchangeable cable for long lasting usage,

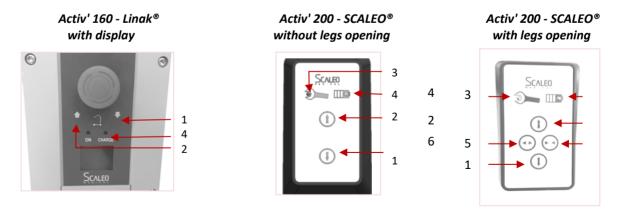
They also provides essential information about battery status, overload occurrence and service:

- Overload indicator: if the lifter is overloaded, it cannot be operated.
- Battery status: 3 levels.
- Maintenance status: when the lifter is used for over 12 months, or when 8000 lifting cycles have been performed.
- The periodical inspection time is set before shipment and requires specific tools and software to modify it.
- The Poweo® Activ' 160 without display emits a sound signal to indicate the battery must be recharged.



### **Control panels**

The control panel of the Poweo® Activ' 160 with display control box is located in the control box; it is located at the top of the mast of the Poweo® Activ' 200. The control panel enable to lift and lower the lifter, as the remote control, and allows the patient lifter to be used if the remote control is lost or damaged.



1: Lowering 2: Lifting 3: Maintenance LED

4: Battery charge LED 5: Legs opening 6: Legs closing



The Poweo® Activ' 160 without display control box does not have a control panel.

The Poweo® Activ' 160 with display control box also includes additional features:

• LCD display with real time information about the current function and the battery status.

• The control box records and displays the most important information for a better management of the lifter.

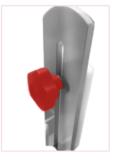
• Data can be displayed by pressing briefly the button 1:



### **Knee supports**

Adjust the height of the knee support with the adjustment knob:

- 1. Loosen the knee support lock knob by turning it counter-clockwise,
- 2. Manually adjust the height,
- 3. Tighten the locking knob clock-wise to maintain the position of the knee support.



The top of the knee support should be a few centimeters away from the top of the knees.



If it is impossible to position the legs perpendicular to the footrests, care should be taken not to pull on the knees too much during lifting to avoid injuring the patient's patella.



### **Casters brakes**

The braking and unlocking of the casters are performed with the foot:







Braked caster

### Standing and transferring with the Poweo® Activ'



The Poweo® Activ' is a device to stand up patients with their active participation. Therefore, in order to avoid any accident, it is imperative:

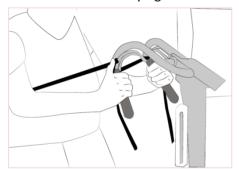
- To make sure beforehand that the patient is able to stand up while holding the handlebars, see the list of contraindications above,
- To never allow the patient to maneuver the device alone,
- To never leave the patient unattended while using Poweo® Activ',
- To ensure that the patient keeps his / her hands on the handlebars when using the Poweo® Activ'.

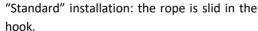


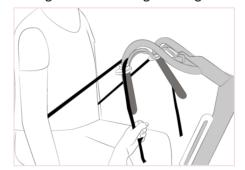
When the handlebars are down, do not bend it by pushing it against the mast and do not pull it upwards so as not to disengage it from the mast. In the event of disconnection, contact your distributor.

1. Position the Poweo® Activ' facing the patient, so that the patient rests his feet on the footrest and holds the handlebars.

- 2. Lock the wheels of the Poweo® Activ' to maintain its position and to avoid any movement while standing up the patient.
- 3. Place the sling on the lower back of the patient by ensuring that the bottom edge of the sling is at the base of the spine, and pass the belt under the arms of the patient.
- 4. Fasten the buckle and tighten the belt to secure the sling installation.
- Low the handlebars.
- 6. Secure the sling cords tightly and symmetrically, by positioning them in the notch on the handlebars.
- 7. The ropes should preferably be placed from the inside to the outside of the harness latch notch. It must be firmly tightened and locked according to the following drawings:







Pull down the rope to secure the installation.



The harness latch notch can vary depending of the type of device Ropes should be tightened firmly before lifting the patient. They will slip slightly and will lock under the effect of weight when lifting. If the ropes are not tight enough before lifting, this may result in uneven and less comfortable lifting for the patient.



If the patient is heavy, it is recommended to attach the strings to the outside of the handlebars and to increase their amplitude. This will avoid pinching.

8. Using the remote control, gently lift the patient until his buttocks lift off the chair.



The patient must hold the handlebars with his hands.



If possible, avoid transferring the person in the upright position: this position is less comfortable than sitting while transferring.

9. Unlock the wheels of Poweo® Activ' and bring the patient to his new support (chair, couch,...).

### Choosing the sling

Recommended slings for the Poweo® Activ' are the slings mentioned in the "Accessories" section of this manual, which are manufactured by SCALEO Medical.



Reminder: It is essential to use the appropriate type of sling to the pathology, weight and size of the patient. It is also important to choose the appropriate sling depending on the type of transfer and the environment.

	Patien	t weight	Waist size
Size	kg	lbs.	cm
XS	20-30	44-66	50-65
S	30-50	66-110	60-90
М	50-90	110-198	75-110
L	90-160	198-352	100-150
XL	160-200	352-440	120-180



The slings intended for the institutions are provided with a label enabling the periodic checks required by the EN 10535 standard to be recorded.

## **Cleaning and disinfecting**

The following program for cleaning and disinfection has been established in compliance with the "Guide for good practices for the disinfection of medical devices" edited by the French council of public Health.

**Device classification:** *Not critical* **Infectious hazard:** *low risk* 

Level of treatment required: Low-level disinfection

This procedure is relevant to any medical device of the described category: Apply each quideline

when necessary

### General guidelines

- Always respect the general hygiene precautions (gloves, goggles, protective clothes and mask).
- Disinfect your hands after removing your protection gloves.
- Respect the expiration dates of the cleaning products.
- Respect the dilutions.
- Never mix different cleaning or disinfection products.
- In case of contact with eyes, rinse thoroughly with water, call a doctor in case of persistent pain.
- Never perform a cleaning or disinfection operation when the device is powered: disconnect the device from the AC outlet.

### Recommended procedures for cleaning and disinfecting

- The device should be thoroughly cleaned and disinfected at least once a month.
- The device should be systematically and thoroughly cleaned and disinfected between 2 patients.
- 1. **Prepare the equipment for disinfection:** Purpose: Makes it easier to clean, lowers the level of contamination, protects the staff and the environment.
- 2. Clean: eliminates dirt.
- 3. **Disinfect:** destroys or inactivates micro-organisms.

- 4. **Dry:** protects equipment from contamination once disinfected.
- 5. **Store:** keeps the disinfected devices clean.

### Products that should be avoided for cleaning and disinfecting:

- Peracetic acid at concentrations> 10%,
- Organic solvents like halogenated hydrocarbons / aromatic or acetone,
- Products with a pH> 8 and <5,
- Products containing corrosive or caustic substances.

## Periodic inspection and preventive maintenance

The aim of a periodic control visit is to verify the safety and the maintenance issues on the equipment. This control, as well as the preventive maintenance must be performed regularly every year for the patient lifter and twice a year for the slings – according to annex B of the EN ISO 10535 standard and the recommendations from health authorities.

### Periodic inspection / Preventive maintenance checklist

5	· · <b>· · · ·</b>	\I FO	Ref: FOR_00 Version		Form attache PRO_06_01	ed to:		<b>Vritten by :</b> CASTINEIRA Gilbert	Date: 22/04/2020
MEDICAL			PERIODIC INSPECTION OF THE POWEO® Activ'						
Perio	dic ins	pection:	Preventive maintenance:						
	CLIE	NT	Client N° SAGE :						
Name	:					(	City/D	pt:	
Mode	1:								
	160 🗆					:	Serial	N°:	
Activ'	200 🗆	1							
2	2- Che	ckpoints							
PI	PM	Complete	ed actio	ns			ОК	Observations	
PI 🗆	PM	Complete Cleaning,					ОК	Observations	
		-	/ Disinfe					Observations	
		Cleaning,	/ Disinfe r:		Red			Observations	
Main	tenan	Cleaning, ce indicato Oran	/ Disinfe r: ge	ction	Red ce counter			Observations	
Main	tenan	Cleaning, ce indicato Oran	/ Disinfe r: ge the ma	ction				Observations	
Main	tenan	Cleaning, ce indicato Oran Resetting	/ Disinfe r: ge the ma	ction				Observations	
Main	tenan	Cleaning, ce indicato Oran Resetting	/ Disinfe r: ge ; the ma	ction	ce counter			Observations	
Main  Base	itenan	Cleaning, ce indicato Oran Resetting Saving da	/ Disinfer: r: ge the ma	ction  intenance	ce counter			Observations	
Main  Base	tenan	Cleaning, ce indicato Oran Resetting Saving da	/ Disinfer: r: ge the maita metry ar and lubr	ction  intenance  and flatne	ce counter ss of wheels			Observations	

Colur	nn :		
		Joint wear control	
		Control of the guide rollers	
		Internal assembly screw/ trolley (200)	
		Hoisting actuator (160)	
		Sealing tape	
		Fixation of the control box	
		Remote control connection	
		Fixation of the emergency stop	
		Fixation of the control panel	
		Mechanical emergency lowering	
Com	ponen	ts and accessory check :	
		Handlebar	
		Directional handles	
		Foams and knee support belt	
		Battery charging cord (160)	
		Battery charger (200)	
		Remote-control	
		Battery(ies)	
		Slings Quantity presented :	
Func	tional	check:	
		Rolling	
		Test : up / down with no load	
		Test: up/ down loaded	
		Emergency lowering (electric, mechanical)	
		Emergency stop	
Label	ling :		
		Control label	
		Manufacturer or distributor logo	
		Number of performed actions	Date :
Nam	e of te	chnician :	Signature :



If the periodical inspection reveals problems relating to the patient or caregiver security, 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.

SCALEO Medical should be informed of the result of inspections performed on its devices.

### Poweo® Service tool

SCALEO Medical has equipped the Poweo® Activ' 200 with an embedded software to manage the maintenances and inspections of the Poweo® patient lifters.

The electronic board has the following main functions:

### Control of the lifter

- 1 jack driving capability.
- Electrical emergency lowering.
- Main actuator software safety :
  - The lifter stops if over loaded (max value + 10kg),
- Battery management.
- Alarms. The user will be warned by a visual alarm on the remote control if the periodical inspection date is within two months or has expired.
- Defect detection:
  - Main fuse out of order,
  - o Real time clock out of order or incorrect,
  - Main actuator 97% worn.

### **Record capabilities**

- Date of first use: first power ON of the lifter. This date is used to calculate the date of first periodical inspection.
- History of :
  - Transfers per weight range: [10-30kg][30kg-60kg] [60kg-110kg] [110kg 170kg-]
     [170kg-SWL],
  - Actuator,
  - Alarms.
  - o Emergency lowering device use,

- Main actuator use,
- o Changes of the period of periodical inspection,
- o Changes of the safe working load (SWL) value,
- o Main actuator replacements,
- Battery recharges,
- o Battery alarms.

### Lifter parameters memorization

- Maximum safety load of the lifter.
- Frequency of periodic inspection, consumption of the actuators.

Most of the functions can be controlled by the technician, using a user-friendly software: the Poweo® Service tool.

	Version	: Distributors
Features	PC software	Card interface
Main fuse test		Х
Real time clock repair	X <sup>(1)</sup>	X
Main actuator control	X <sup>(1)</sup>	X
Periodical inspection period setting	Х	X <sup>(2)</sup>
Setting the date of periodical inspection at current date	Х	X
Disable the periodical inspection alarm	X	X
Real time setting of the lifter	Х	
Control of the lifter without the remote control	X	
Reading all the parameters of a Poweo® lifter	Х	
Data saving	Х	
Writing lifter parameters in a text file	Х	
Writing lifter history in a text file	Х	

- (1) Performed by reading lifter parameters.
- (2) Limited to 6 or 12 months.

## **Technical specifications**

### Technical specifications of the Poweo® Activ'

All Poweo® lifters are built in France in our workshop under the ISO 13485 quality system. The Poweo® Activ' in its standard version is equipped with an aluminum base, feet, mast and arm, resulting in an extremely light device.

- The lifespan of the Poweo® Activ' standing aid is 10 years or 30,000 cycles, provided that the recommended periodic inspections and preventive maintenance are properly made.
- All the measurements refer to a reference device. Measurements on serial products may slightly differ due to tolerances on the assembly and manufacturing processes.
- Optional accessories (slings) are delivered with their own user manuals including complete technical specifications.

Description	Poweo® Activ' 160   Poweo® Activ' 200		
Description	Value in mm		
Maximum reach at 600 mm	57		
Maximum reach from base	-	147	
Minimum distance between the wall and the CSP @ maximum height	-	783	
Minimum distance between the wall and the CSP @ minimum height	253		
Height of the legs	75		
Height under the handlebar	1570		
CSP minimal height	910		
Hoisting range	8	345	
Maximum internal width	1118		
Internal width at the maximum reach	1329		
Minimum internal width	143		
Maximum internal width	-	253	

External width	591
Width of the legs	348
Length of the legs	313

Adjustment range of the support under patellar	7	8	
Minimum height of support under patellar	316		
Turning diameter	11	36	
Maximum lifting capacity	160 kg	200 kg	
Total weight, battery included	43,5 kg	45 kg	
Lifting speed (max/ 2 load)	15 mm/sec	30 mm/sec	

Description	Poweo® Activ' 200 With legs opening	
SWL (Max Safe working load) (kg)	200	
Lifter weight (incl Battery) (kg)	60	
Max lifting height (mm)	1465	
Min lifting height (mm)	913	
Min storage height (mm)	1329	
External width legs closed (mm)	582	
External width legs fully open (mm)	974	
Internal width legs closed (mm)	467	
Internal width legs fully open (mm)	859	
Leg clearance (floor to top of legs) (mm)	697	
Chassis clearance (floor to top of legs) (mm)	107	
Lifter total length (mm)	1209	
Turning radius (mm)	635	

### Other specifications:

Regulations	Class I Medical Device according to the European Medical device regulation 2017/745
Compliance with standards	EN ISO 10535, EN 60601-1, EN 60601-1-2
Service factor	1/10
Materials	Aluminum, steel
Actuator voltage	24V
Front casters	4 casters Ø 50 mm or 75 mm
Rear casters	2 casters Ø 125 mm with brakes or 100 mm
Conditions of use	Indoor use only
IP class	IPX4
Storage/use temperature range	+5°C / +40°C
Noise level	L wa = 52 dB

### Technical specifications of parts and the accessories

### Technical specification of the Linak® battery of the Poweo® Activ' 160 :

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 Linak® charger (embedded in the control box) :

Input AC voltage range	100~240V AC
Input AC frequency range	50/60Hz, 1A
Maximum charging current	400 mA

Compliance to standards	EN 60601-1 :2005 +C1:2006 +C2:2007
Storage/use temperature range	0°C / +40°C
Conditions of use	Indoor use only

### Technical specification of the SCALEO battery of the Poweo® Activ' 200 (S16 30 200):

Technology	NiMh
Plastic case	ABS PC UL94V0
Voltage	24V
Capacity	3 Ah
IP class	IPX4
Compliance with standards	EN 60601-1, UL94V0 case
Temperature range of use	+10°C / +40°C
Condition of use	Indoor use only
Security devices	<ul> <li>Protection against explosion risks: the case is vented for removal of exhaust gas</li> <li>Built-in electronic protection against surges on intensity, short-circuit</li> <li>Built-in electronic protection against overheating during charging</li> </ul>

### Technical specifications of the battery charger of the Poweo® Activ' 200 (S17 50 001):

The provided charger is able to work with any AC power value: voltage from 100V to 240V, frequency 50Hz or 60Hz. The only adaptation needed is the AC cord.

Input AC voltage	100-240VAC
Input AC frequency	50-60Hz
Output DC voltage and current	N.A. depends on the charge cycle (1)
Charging capacity	NiMh batteries, 10 to 20 cells
Maximum output current	0.9A
Compliance with standards	EN ISO 60601-1, EN ISO 60601-1-2, UL94V0 case
Temperature range of use	-10°C / +40°C
Condition of use	Indoor use only

Security devices	<ul> <li>Operating voltage LED</li> <li>Modulation of the charging current according to the state of charge of the battery</li> <li>Automatic load stop with visual alarm in case of overheating of the battery during charging</li> </ul>
Usage	As a « table » charger or attached to the wall (pins and screws provided)

The charge of NiMh batteries is a smart charge: a complete charge consists in a fast charging period, then a slow charging period, then a compensation charge.

## **Electromagnetic compatibility**

- The Poweo® Activ' requires special care regarding the electromagnetic compatibility (E.M.C.).
   It must be installed and commissioned by the EMC information provided in this user manual.
- The RF communication devices and portable phones may affect the Poweo® Activ'.
- 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 patient lifter Poweo® Activ' is not used next to other devices or stacked with them, if it is not possible to do otherwise, the Poweo® Activ' have to 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 Poweo® Activ' is to never perform unwanted movements.

# Directives and manufacturer's declaration - Electromagnetic emissions The Poweo® is designed to be used in the electromagnetic environment specified below. The user of the Poweo® must make sure it is used in such an environment. Emission test Conformity Electromagnetic environment - Guidelines RF Emissions Group 1 The Poweo® uses RF energy only for its internal functions. Therefore, its RF

Ellission test	Comorning	Electromagnetic environment - duidennes
RF Emissions CISPR 11	Group 1	The Poweo® 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 Poweo® is suitable for use in all premises, including domestic premises and those directly connected to the public power network supplying domestic
Harmonic Emissions IEC 61000-3-2	Not applicable	premises.
Voltage fluctuations / Flicker IEC 61000-3-3	Not applicable	

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

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

Maximum rated output	Separation distance depending on the frequency of the transmitter m			
power of the transmitter				
W	from 150 kHz to 80 MHz	80MHz to 800MHz	de 800MHz to 2,5GHz	
		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	
Dir	ectives and manufacturer's declaration -	electromagnetic immunity		

The Poweo® is designed to be used in the electromagnetic environment specified below. The user must make sure 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 Poweo® requires continued operation during network outages of power, it is recommended to feed the Poweo® 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 Poweo® is designed to be used in the electromagnetic environment specified below. The user of the Poweo® must make sure it is used in such an environment.

			Portable and mobile RF communications should not be used closer to any part of the Poweo®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter.  Recommended separation distance:
Conducted RF	3 Vrmsf	Non	The solution and a separation and a sepa
disturbances IEC 61000-4-6	150 kHz to 80 MHz	applicable	Non applicable
Radiated RF	3V/m 80MHz to	3 V/m	
disturbances	2.7GHz with		d= 0,35√P 80MHz to 800MHz
IEC 61000-4-3	discreet		d= 0,7VP from 800MHz to 2,5GHz
	frequencies 385, 450, 710, 745, 780,		
	810, 870, 930,		Where P is the maximum power output of the transmitter in watts (W),
	1720, 5240, 5500,		according to the transmitter manufacturer and d is the separation distance
	5785, 1845,		in meters (m). The field strengths from fixed RF transmitters, as determined
	1970, 2450 with		by an electromagnetic investigation (a) should be below the level of
	level between		

9V/m and	compliance in each frequency range. (b) Interference may occur in the
28V/m	vicinity of the equipment marked with the following symbol: $^{(\!(ullet)\!)}$

NOTE 1: At 80 MHz and 800 MHz 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 Poweo® is used exceeds the applicable RF compliance level above, the Poweo® 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 Poweo®.

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

## Complementary safety advice



The patient lifters can fall down if it is not used correctly. Not conforming to the following safety measures could lead to serious bodily harm to the patient or the caregiver. So please read the following instructions carefully.

- 1. Before executing any maintenance, cleaning, or transport procedure, be sure to unplug the lifter.
- 2. If the lifter breaks down or malfunctions, do not try to repair it yourself. You should seek the help of a qualified technician, an authorized distributor, or the customer service department of SCALEO Medical.
- 3. Always request original authorized spare parts.
- 4. The proper use of this device requires the abidance to certain fundamental and common rules, such as not pulling the electrical power cables in order to unplug the AC cord after the battery has been recharged.
- 5. Apply the brakes when the patient lifter needs to be still. Check that it is properly immobilized.
- 6. Use standard and approved products to clean the equipment and the accessories.
- 7. Recharge the battery every evening, when used on a daily basis.
- 8. incorrect use:
- Using the lifter while battery alarm is on,
- Using functions without having read this user manual,
- Use of the lifter or its accessories by children,
- Using the patient lifter with a higher than the maximum safety load,
- Outdoor use,
- Use, with or without a patient, on a slope,
- Moving the patient lifter over non cleared floors, or thick carpets,
- Plugging the charger of the lifter onto incorrect voltage,
- Plugging in electrical components other than originally intended,
- Cleaning the lifter with excessive water, or with a pressurized hose,
- Guiding the lifter by using the handlebar or other non-intended parts,
- Using damaged, torn, or worn slings.



Injury or damage to the equipment may occur if the Poweo<sup>®</sup> is not properly used, more precisely if:

- The protective covers of the chassis are taken off by non-qualified personnel,
- A regular maintenance is not set up,
- Maximum load capacity is exceeded,
- Repairs or electrical modifications are made by non-qualified personnel.

## Warranty & Liability

### Warranty

The Poweo<sup>®</sup> Activ' patient lifters have a four (4) year warranty, except for the battery, the slings, the control box and the hand control that are guaranteed one (1) year.

- Any intervention on the machine contrary to this manual will entirely void the warranty.
- Any incorrect use or non-compliant usage will result in the cancellation of the warranty.
- Any modification to the device will render the warranty void.
- Any technical intervention made by a non-qualified personnel or a non-authorized distributor will render the warranty void.

Batteries not serviced in compliance with the servicing process of this manual will not be taken under 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 of the instructions and recommendations supplied within the present user manual,
- Using un-adapted spare parts,
- Assembling, adjusting and repairing carried out by non-qualified personnel or non-authorized distributors,
- Incorrect use of the equipment, negligence, accident, human error, or maintenance and cleaning with non-adapted products,
- When the REGULAR PREVENTIVE AND ANNUAL MAINTENANCE IS NOT CARRIED OUT in accordance with the annex B of the EN ISO 10535 standard, and the advices and instructions presented in this manual.

## End of life, recycling

The lifespan of the Poweo® Activ is 10 years if the standing aid is used according to the manufacturer requirements.

SCALEO Medical lifters 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.

## **EU Declaration of Conformity**



## EU Declaration of Conformity Déclaration UE de conformité

Manufacturer / Fabricant

SCALEO Medical 107 rue Dassin, Parc 2000, 34080 Montpellier France

(SRN): FR-MF-000002929

We hereby declare under our sole responsibility that the following products

Déclarons sous notre entière responsabilité que les produits suivants :

POWEO Activ' and POWEO City active lifters in annex 1, POWEO Activ' et POWEO City transfert actifs en annexe 1, IUD-ID de base: 3664844POW/RTBX

Class I, rule 13 according to appendix VIII of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

Classe I, règle 13 suivant l'annexe VIII du RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL,

Are compliant with the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and amendments concerning medical devices and the French Public Health code by compliance to the Harmonized European standards EN 10535: 2007, and EN 14971:2012, EN 60601-1:2006 + AC:2010+A1:2013, EN 60601-1-2:2001 + A1:2006 and compliant with the DIRECTIVE 2011/65/UE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Sont conformes au RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL, relatif aux dispositifs médicaux et à ses amendements, et au Code de la Santé Publique par conformité aux normes harmonisées européennes EN 10535 : 2007, EN 60601-1 : 2006+AC:2010+A1:2013, EN 60601-1-2:2001 + A1:2006 et conforme à la directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques.

Montpellier, February 20th, 2023 Montpellier, le 20 Février 2023

> Michel MALGOUYRES Président

DOQA326 -EU Declaration of conformity POWEO Active lifters - 20230220



### EU Declaration of Conformity Déclaration UE de conformité

### ANNEX 1

Reference	Description	Class	UDI-DI
S 14 001	Poweo® City - SWL 150 kg – TMotion Control Box with non-removable battery	Class I	3664844002803
S 14 002	Poweo® City - SWL 150 kg – LINAK Jack and Control Box with removable battery	Class I	3664844002797
S 14 012	Poweo® City low base - SWL 150 kg – LINAK Jack and Control Box remov. battery	Class I	3664844002780
S 18 001	Poweo® Activ' 160 fixed legs – SWL 160 kg – LINAK Control Box with screen	Class I	3664844002766
S 18 002	Poweo® Activ' 160 fixed legs – SWL 160 kg – LINAK Control Box without screen	Class I	3664844002773
S 18 003	Poweo® Activ' 200 fixed legs – SWL 200 kg – SCALEO electronic, NiMh battery	Class I	3664844002759
S 18 004	Poweo® Activ' 200 legs opening – SWL 200 kg – SCALEO electronic, NiMh battery	Class I	3664844002742

## **Contact information**

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

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

If any serious incident that has occurred to the device, please contact the manufacturer and the competent authority of your country in which the user and/or patient is established.

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.



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