

USER MANUAL

SCALEO
M E D I C A L

Poweo® CITY Standing - Raising aid



CE **MADE IN FRANCE**

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Warning and safety instructions



The Poweo® City standing aid is designed to stand patients with a minimum of autonomy and physical capabilities. In order to avoid any risk of falling and serious injury it is imperative before using to ensure that the patient's condition allows it.



Poweo® City should only be installed, operated and maintained by trained people: please read this manual carefully and the functions should be familiar to you before using the lifter. The Poweo® City must be maintained exclusively by authorized distributors for its maintenance using original spare parts. No modification shall be made without the written consent of SCALEO Medical, who is the manufacturer.



The Poweo® City is designed and manufactured to safely raise patients up to 150 kg / 330 lbs. Beyond this weight, do not use the Poweo® City: please contact SCALEO Medical which will propose you the best patient lifter that satisfies to your transfer needs.



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



The recommended slings are specifically developed by SCALEO Medical for the Poweo® City. It is inadvisable to use slings from manufacturers other than those recommended by SCALEO Medical. If you want to use other manufacturers' slings, require proof of compatibility, and test them before using them with a patient. SCALEO Medical cannot be held responsible for any incident that occurs following the use of non-recommended slings.



The Poweo® City must NEVER be used to transfer, lift or transport people over slopes.



It is not recommended to use Poweo® City on carpets or uneven surfaces and with obstacles that could block the casters: excessive force can cause the unit to become unbalanced when encountering such obstacles and may drop the transferred person.



The maximum load can be lifted while using the engine non-stop for roughly 1 minute. The delay between 2 lifts of maximum capacity should be roughly 10 minutes in order to allow the engine to cool down.



The Poweo® City is not a transport device. It must be used only for short distance transfers and is not intended to replace wheelchairs or other types of transport.



NEVER allow the patient to maneuver the device alone.



NEVER leave the patient unattended while using the Poweo® City.



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, throw away worn slings.

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

The first Poweo® City was released on January 7, 2020.

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 follow the advice and warnings carefully.



This symbol indicates important information regarding the use of the equipment. Failure to follow this information may result in damage or malfunction 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
	Date of manufacturing
	Device reference
	Device serial number
	Temperature range
	Do not burn
	Security pin: do not remove this pin. Periodically inspect this pin.
	Warning: read user manual for instruction
	Indoor use only

Symbol	Meaning
	Read user manual for instruction
	Direct current power source
	Class II electrical protection type
	B type applied parts
	Do not open or disassemble
	Maximum load
	In accordance with European regulations
	Contains potential wastes of electrical or electronic equipment
	Medical Device

General information about Poweo® City

**You have recently purchased a Poweo® City.
We would like to thank you for the trust you have placed in our company.**

The Poweo® City is an innovative standing and transfer aid.
The movement of the lifting arm is unique and ergonomic. This movement provides a progressive rotation of the handlebars throughout the lift.

The Poweo® City is compact, comfortable, easy to maneuver and very stable.

1. Handlebar
2. Remote control
3. Control box with emergency stop button
4. Rear braked casters
5. Legs
6. Raising column
7. Lifting arm with sling rope fastener
8. Mechanical emergency lowering
9. Knee support
10. Knee support adjustment handle
11. Foot rest

Accessories

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

- Quick transfer homecare slings
- Cocoon slings with abdominal belt
- Polyurethane Comfort slings
- Self-tightening slings



Intended use

Poweo® City is an active mobile patient lifter. It is intended to be used on horizontal floors to lift patients without disabilities of the lower limbs that are capable of maintain the upright posture, as well as to transfer them to and from a sitting position.

Poweo® City allows a safe workload of up to 150 kg and it safely and comfortably transfer a dependent person effortlessly, reducing the risk of injury to the caregiver.

Contraindications

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

- When a patient is subject to loss of balance, discomfort,
- For patient whose mental state is impaired (agitated patient),
- In the case of medical contraindication of support following surgery of the shoulder, hip, knee or ankle,
- Severe flexion deformity of the knees 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,
- 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® City 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 components of the Poweo® City, 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® City standing aid is safely delivered with the emergency stop switched in the depressed position. Make sure you have reset the emergency stop before using or recharging the device.

Unpacking the Poweo® City

The packaging of the Poweo® City has been specifically designed for the device to be transported without risk of damage.

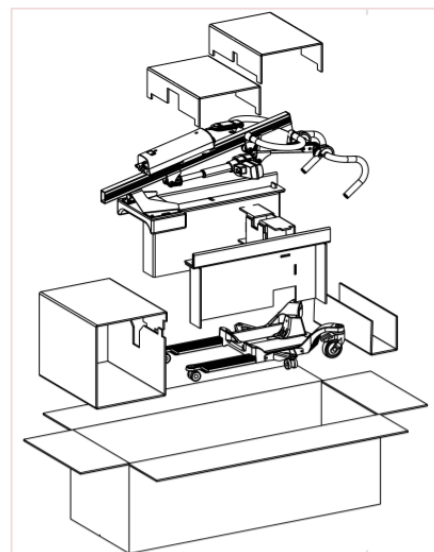
Step 1: Open the box.

Step 2: Remove the top protector.

Step 3: Remove the column and base from the package and place it on a clean, smooth surface.

Step 4: Remove the wedges.

Step 5: Remove the knee support from the package.





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

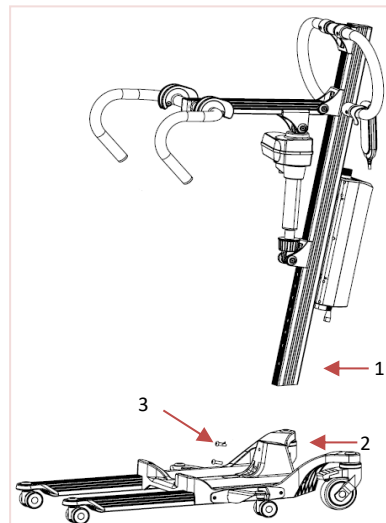
Instructions for assembly

Installing the column on the base

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

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

Step 3: Using the hex wrench, tighten all screws until you have a uniform tightening.

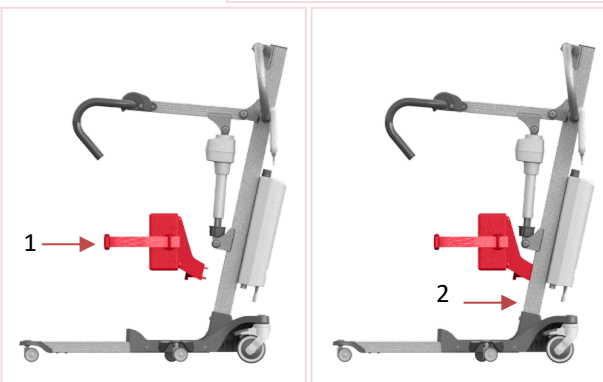


Installation of knee support

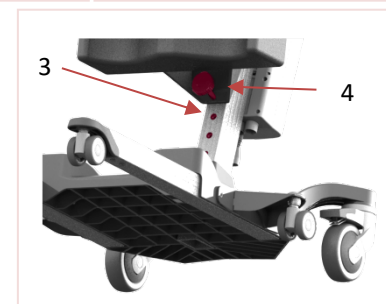
The knee support is delivered in one piece ready to be installed.

To install it, adjust the height of the knee support with the adjustment knob.

Step 1: Position the knee support (1) on the base (2): the notch (3) helps guiding the leg support on its location.



Step 2: Tighten the locking knob (4) to maintain the position of the knee support.



Instructions for use

The Poweo® City control box is equipped with a battery charger that can be used regardless of the voltage and mains 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 power supply cord will be fully compatible.



Before the first use, the battery must be recharged for at least 8 hours. Refer to the "Charging the battery" section for this operation.

Before each use check that the patient lifter and its accessories are correctly installed. Verify it operates properly before using it with a patient.

The few controls below only take a few minutes and allow you to ensure a safe use of your Poweo® City:



- Check the tightness of all the security screws securing the column and the actuator,
- Make sure no part is damaged or show signs of wear,
- Inspect accessible screws and make sure none are loose. Their location is indicated by a label,
- Check the lights on the remote control: battery indicator should be solid green, maintenance indicator should be off,
- Check the features: raise and down the column, caster brakes, emergency stop.



In case of malfunction, or doubt about the proper operation, do not use the Poweo® City: inform your technical service, your distributor, or contact us at the address indicated 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 of the patient, his morphology, his weight and the type of transfer.



The Poweo® City is designed for use in temperature range between +5 and +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® City must rest in a temperate room until the equipment has achieved proper working temperature.



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

Security devices

Emergency stop

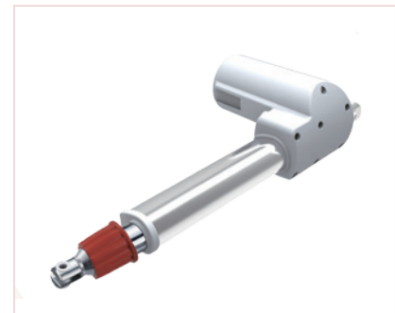
The Poweo® City is equipped with an emergency stop button cutting the power when pressed. This button can be found at the top of the control box.



According to the norms, once pressed, the button must be turned clockwise in order to power on the patient lifter.

Mechanical emergency lowering

In case of non-operation of the remote control, a mechanical emergency lowering is still possible by maneuvering the red ring located at the top of the actuator.





Contact SCALEO Medical if the reasons for the dysfunction are unknown, or if any part is damaged. Do NOT use the lifter until the problem is solved.

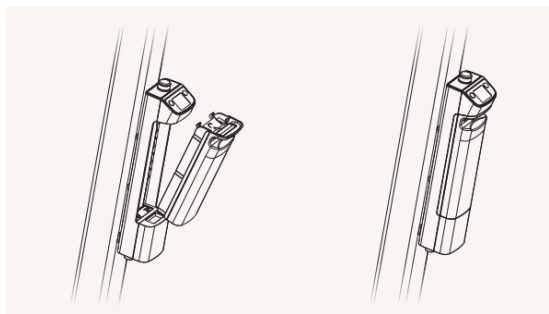
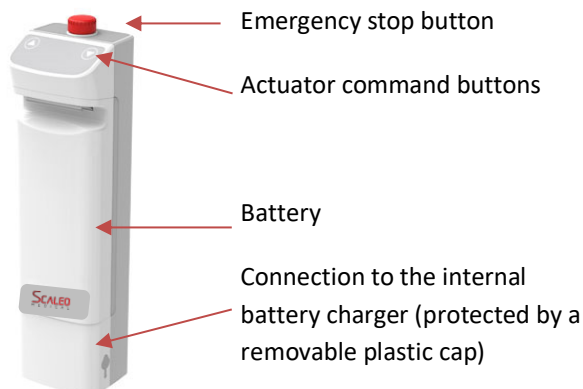


Be very careful because the lifting arm goes down very quickly: your arm or your hand could be injured during the lowering process. For this function to be operational, it is necessary that the battery is present, and is not completely discharged.

Battery management

The control box of the Poweo® City is equipped with a lead acid battery and an emergency stop, compliant to European standards.

How to remove or put the battery back in place:



Charging the battery

The bar graph on the remote control allows to check the status of the battery.

			
Red + buzzer: the battery is discharged, stop using the Poweo® and recharge. the	Green, one bar: the battery is almost discharged, finish the current transfer and recharge the battery.	Green, two bars: the Poweo® can be used without any problem.	Green, three bars: the battery is fully charged, the autonomy is optimal.

When the bar graph goes RED: connect the charger to the Poweo® City and to an AC power source.

In order to connect the charger to the patient lifter, you will need to remove the plastic cap protecting the charger of water projections.

The GREEN light on the charger indicates that the charger is properly functioning.

The light turns to ORANGE during the charge.

The light turns again to GREEN when the charge is complete.

An 8 hours charge allows to fully recharge an empty battery pack.

If the lifter is used regularly, the battery should be recharged every evening.



According to the relevant norms, the patient lifter will not operate while the battery is charging.



If the emergency stop button is pressed while charging the battery will not be charged.

Once the battery is fully charged, the lifter will be able to perform at least 30 transfers with 50 cm amplitude for a 75 kg load.

Maintenance of the battery



It is not possible to overcharge the battery. However, to ensure optimal performance through-out its lifetime, we recommend giving the battery a rest for a couple of minutes after charging so it can cool down before being used. It is also important to fully charge a battery that will not be used for a long time period (≥ 1 month).



Never use another charger or cable than the one provided with the Poweo® City. Using electrical equipment not adapted to the charger could lead the battery to explode or to emit explosive gases.



Never charge the battery in extreme temperatures conditions or in a very wet environment.



If you plan to not use 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,
- Store your charged battery in a cool, dry, well-ventilated room,
- Check periodically (every month) the status of charge of the batteries: even if they are disconnected, batteries tend to discharge.

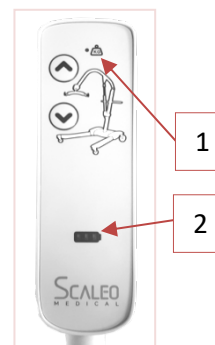
Respecting these simple precautions will allow your batteries to remain in good condition and last longer.

The remote control

The remote control includes two buttons: lifting and lowering of the lifting arm.

The two additional indicators:

1. Warn the user if the patient lifter is overloaded: the indicator is GREEN if the load is correct and switches to RED in case of overload.
2. Display the charge status of the battery: the bar graph changes color



according to the state of charge: green if the charge is good, orange, then red when the battery is to be recharged.

Knees supports

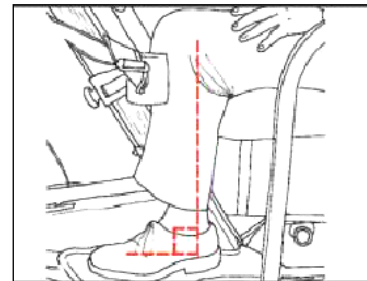
The height of the knee support is adjusted using the adjustment knob.

Please refer to the Installation of knee support section here above for detailed instructions on how to adjust the height.

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



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



Casters brakes

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



Braked caster



Free caster

Standing and transferring with the Poweo® City



For an ergonomic transfer, it is recommended to maintain a 90° angle for the back, the knees, and the ankles.



If the patient to be transferred is on a wheelchair, do not forget to block the brakes of the chair before any transfer procedure.

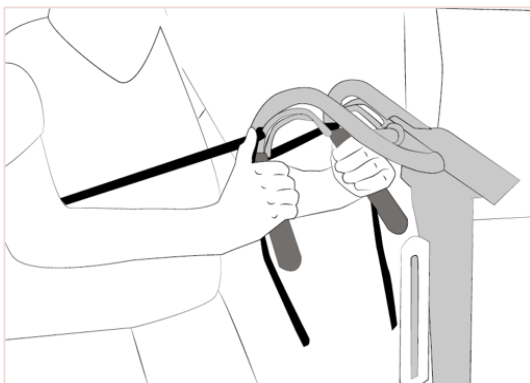


Should the patient have its gravity center offset due to a very large size or morphology, it is highly recommended to compensate this offset by shortening one of the sling cords and by avoiding raising the patient in a full upright position.

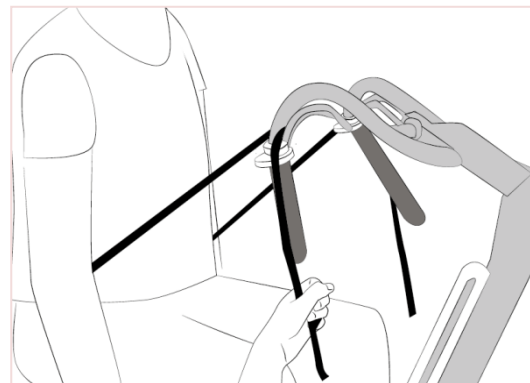


Quick transfer is intended only for patients with minimal muscular tone on lower limbs. When transferring, it is important that the patient's shins are in contact with the lifter.

1. Place the sling on the lower back of the patient, making sure the bottom edge of the sling is at the base of the spine. Pass the belt under the arms of the patient.
2. Secure the belt with the buckle and tighten the belt to secure the installation of the sling.
3. Lower the handlebar to a minimum height while keeping it raised. Brake the lifter to avoid any unwanted movements.
4. Position the lifter facing the patient, open the legs of the lifter if needed. The feet of the patient should rest on the base of the lifter.
5. Lower the handle, then pass the sling under the arms of the patient.
6. Secure the sling cords tightly and symmetrically, by positioning them in the notch on the handlebar. 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:



“Standard” installation: the rope is slid in the hook.



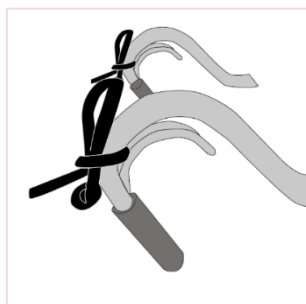
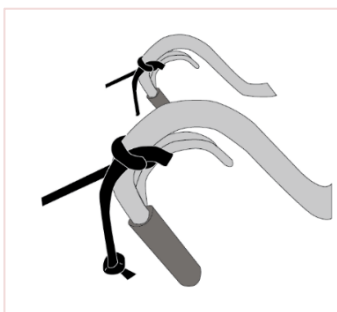
Pull down the rope to secure the installation.



The cords must be tightened firmly before lifting. They will slide and lock under the effect of the weight during lifting. If the cords are not tight enough, lifting could be asymmetrical and less comfortable.



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



***Optional installation:
Tie the rope around the
handlebars.***

7. Using the remote control, gently lift the patient and tighten the cords until his buttocks are off the chair.

8. Unlock the brakes of the lifter and transfer the patient.



Ensure that the patient holds the handlebar with his hands during the transfer, or at least that his hands are out of reach of any moving part of the lifter.



Avoid raising the patient to a full standing position; this position is less comfortable than the sitting position in the transfer operation.



It is possible that the handlebars shown above are not identical to the product received. However, the instructions to follow are the same.

Choosing the sling

The recommended slings for the Poweo® City 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.

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



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

Cleaning and disinfecting

The following program for cleaning and disinfection has been established in compliance with the “Guide to good practices for 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 the items when relevant

General guidelines

- Respect the general hygiene precautions (gloves, goggles, protective clothes, and mask)
- Disinfect your hands after removing your protection gloves
- Respect the expiry dates of products used
- Respect the dilutions
- Never mix different cleaning or disinfection products
- In case of eye contact, 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 it from the AC source.

Recommended procedures for cleaning and disinfecting

- The device should be thoroughly cleaned and / or 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: Facilitates the cleaning procedure, lower the level of contamination, protects the staff and the environment.
 2. **Clean:** eliminate dirt.
 3. **Disinfect:** destroy or inactivate micro-organisms.
 4. **Dry:** protect equipment from contamination once disinfected.
 5. **Store:** keep 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 control 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

		Ref : FOR_06_32 Version : A	Form attached to: PRO_06_01	Written by : CASTINEIRA Gilbert	Date : 29/04/2020
		PERIODIC INSPECTION OF THE POWEO® CITY			
Periodic inspection:		Preventive maintenance:			
CLIENT		Client N° SAGE :			
Name :		City:			
Model : City ☐		Serial N°:			
2- Checkpoints					
PI	PM	Completed actions	OK	Observations	
☐	☐	Cleaning/ Disinfection	☐		
Base:					
☐	☐	Base geometry and flatness	☐		
	☐	Cleaning and lubrication of wheels	☐		
☐	☐	General conditions of the footrest	☐		
☐	☐	Conditions of the column guide notches	☐		
Column :					
☐	☐	Joint wear control	☐		
	☐	Internal assembly screw	☐		
	☐	Hoisting actuator	☐		

☐	☐	Fixation of the control box	☐	
	☐	Remote control connection	☐	
☐	☐	Fixation of the emergency stop	☐	
	☐	Mechanical emergency lowering	☐	
Components and accessory check :				
☐	☐	Handlebar	☐	
☐	☐	Sling rope fastener attachments	☐	
☐	☐	Foams and knee support belt	☐	
☐	☐	Battery charging cord	☐	
☐	☐	Remote-control	☐	
☐	☐	Battery(ies)	☐	
☐	☐	Slings Quantity presented :	☐	
Functional check :				
☐	☐	Rolling	☐	
☐	☐	Test : up / down with no load	☐	
☐	☐	Test: up/ down loaded	☐	
☐	☐	Emergency lowering (electric, mechanical)	☐	
☐	☐	Emergency stop	☐	
Labeling :				
☐	☐	Control label	☐	
	☐	Manufacturer or distributor logo	☐	
		Number of performed actions	Date :	
Name of technician :			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.

Technical specifications

Technical specifications of the Poweo® City

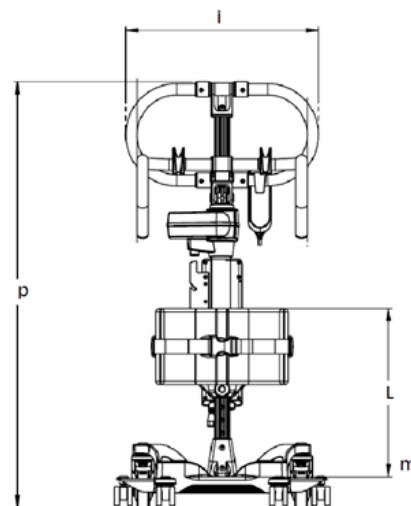
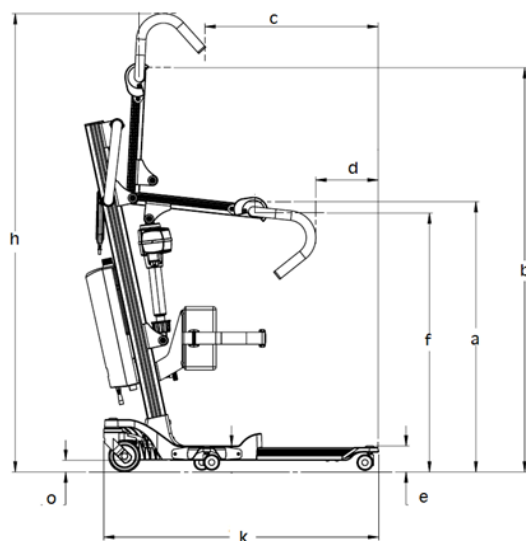
All Poweo® lifters are built in France in our workshop under the ISO 13485 quality system.
The Poweo® City in its standard version is equipped with aluminum feet, mast and arm, allowing for an extremely light device.

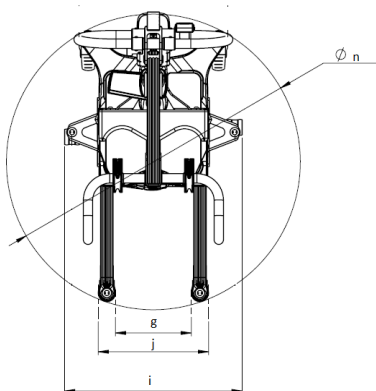


The lifespan of the Poweo® City is 10 years, provided that the recommended periodic inspections and preventive maintenance are correctly carried out.



All the values indicated on our documentation were recorded on a reference product. Series values may vary slightly depending on assembly and industrial processes tolerances.





Description	Key	Value in mm
Maximum reach at 600 mm	a	854
Maximum reach from base	b	1278
Minimum distance between the wall and the CSP @ maximum height	c	546
Minimum distance between the wall and the CSP @ minimum height	d	196
Height of the legs	e	82,4
CSP minimal height	f	818
Internal width	g	244
Maximum height	h	1449
Minimum height	p	1117
External width	i	570
Width of the legs	J	354
Length of the legs	k	866
Adjustment range of the support under patellar	L	137
Minimum height of support under patellar	M	337
Turning diameter	N	944
Ground clearance	O	37
Hoisting range	120	
Total weight, battery included	27 kg	

Lifting speed (no load)	10,3 mm/sec
Lifting speed (max/ 2 load)	7,8 mm/sec
Lifting speed (full load)	5,4 mm/sec

Other specifications

Regulations	Class I medical device according to the European Medical device regulation 2017/745
Compliance with standards	Compliant with the standards EN ISO 10535, EN 60601-1, EN 60601-1-2
Service factor	1/10
Maximum lifting capacity	150 kg / 330 lbs.
Materials	Aluminum
Actuator voltage	24VDC
Front casters	2 casters Ø 50 mm
Rear casters	2 casters Ø 100 mm with brake ; 2 casters Ø 50 mm
Conditions of use	Indoor use only
IP class	IPX4
Storage/use temperature range	+5°C / +40°C
Noise level	L wa = 52 dBa

Technical specifications of parts and accessories

Technical specifications of the battery

Technology	Lead
Enclosure	ABS UL94V0
Tension	24V
Capacity	3 Ah
IP Class	IP54

Compliance to standards	EN 60601-1 :2005 +C1:2006 +C2:2007
Temperature range of operation	5°C to 40°C
Condition of use	For indoor use only

Technical specifications of the charger

Permissible AC tensions	100~240V AC
Permissible AC frequencies	50/60Hz, 1A
Maximum charge current	28V DC, 1.5A
Compliance to standards	EN 60601-1 :2005 +C1:2006 +C2:2007, RoHS
Temperature range of operation	0°C to 40°C
Condition of use	For indoor use only

Electromagnetic compatibility

- The Poweo® City requires special care regarding the Electromagnetic compatibility (EMC). 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® City.
- The use of accessories, transducers, and cables other than those specified, except for the transducers and cables sold by the manufacturer as replacement parts for internal use, can result in an increase or a decrease of the resistance of the device.
- The Poweo® City must not be used next to or stacked with any other devices. If it is not possible to do otherwise, the Poweo® City must be monitored to verify the normality of its function in which it's being used.
- With regard to the standard NF EN 60601-1-2: 2007, the essential performance of the Poweo® City is not to 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 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 premises.	
Harmonic Emissions IEC 61000-3-2	Not applicable		
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 to the maximum transmission power of the communication device.			
Maximum rated output power of the transmitter W	Separation distance depending on the frequency of the transmitter		
	m		
	from 150 kHz to 80 MHz	80MHz to 800MHz	de 800MHz to 2,5GHz
		d= 0,35VP	d= 0,7VP
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 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.				
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 Poweo®, 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	3 V/m	d= 0,35VP 80MHz to 800MHz d= 0,7VP from 800MHz to 2,5GHz 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	

	level between 9V/m and 28V/m		equipment marked with the following symbol: 
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 tip over if they are not used correctly. Not conforming to the following safety measures could lead to serious 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 if it is charging.
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 demand original authorized spare parts.
4. The proper use of this device, just like the use of any electrical and mechanical device requires the abidance to certain fundamental and common rules, such as not pulling the electrical power cables in order to unplug the device 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. For cleaning the equipment and the accessories, use standard and approved products.
7. Recharge the battery every evening.
8. Incorrect use:
 - Using the lifter while the battery alarm is on,
 - Using functions without having read this manual,
 - Using the patient lifter with a heavier weight than the maximum safety load,
 - Use of the lifter or its accessories by children,
 - 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 onto incorrect voltage. This may cause the charger or the battery destruction and/or malfunctions of the battery charging function,
 - Plugging in electrical components other than those intended by the manufacturer,
 - Cleaning the lifter with excessive water, or with a pressurized hose,
 - Guiding the lifter by using non intended parts,
 - Using damaged, torn, or worn slings.



Injury or damage to the equipment may occur if the Poweo® 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 carried out,**
- **The maximum load capacity is exceeded,**
- **Repairs or electrical modifications are made by non-qualified personnel.**

Warranty & Liability

Warranty

The Poweo® City standing aid and all their parts have a four (4) year warranty, except for the battery and the slings 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 modifications to the device will render the warranty void.
- Any technical intervention made by 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 a non-authorized distributor,
- Incorrect use of the equipment, negligence, accident, human error, or maintenance and cleaning with non-adapted products,
- If REGULAR PREVENTIVE AND ANNUAL MAINTENANCE ARE 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® City 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 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: 3664844POWWRTBX

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

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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 you of the importance of paying attention to safety measures and the necessity of regular maintenance.

This is a matter of responsibility for your establishment and safety 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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M E D I C A L