



User manual

Alto

etac[®]
Creating Possibilities

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MD



General

Thank you for choosing an Etac product. In order to avoid damage during assembly, handling and use, it is important to read this manual and save it for future reference. You can also find it at www.etac.com. You can select your language via the “International” and “Local websites” link. Here you will also find other product documentation, such as prescriber information, pre purchase guide, and reconditioning instructions.

In this manual the User is the person with disability for whom the assistive device is intended. The assistant is the person supporting the user.



The images which are referred to on each page are found at the start of the manual (pages 3 to 13). See Figures A to F for the corresponding text.

Device description

Alto (hereafter also referred to as “the device” or “the product”), is an assistant propelled shower commode chair with a battery-powered seat raise-and-tilt.

Intended purpose

Alto is a medical device intended for alleviation of or compensation for a functional impairment due to an injury or disability. The device is designed to be used when performing hygiene tasks in the shower, at a sink, or over the toilet, as well as for transfers to and from the hygiene room.

Intended user group

The user group for the device is based on the individual's functional ability and not on a specific diagnosis, health condition or age. It is intended for individuals with a height of 146 cm or more, or a mass of 40 kg or more.

Secondary users of the device are caregivers providing assistance and clinicians/technicians who set up the device.

Intended environment

The device is intended for indoor use at home environments or institutions and is suitable for use in bathrooms, but not swimming pools or similar corrosive environments.

Intended application

The device is intended for short-term and long-term use and can be applied several times per day.

The device is intended for use with intact skin. The device is intended for refurbishment and reuse.

Expected service life

The expected service life is 8 years. For complete information regarding the service life of the device, see www.etac.com.

Indications

Indication for use is disability, including, but not limited to, an individual with physical disabilities who needs backrest and/or armrests to maintain a sitting position and assistance with transfers to/from the chair.

Contraindications:

There are no known contraindications.

Warnings

Warnings describing a risk element for a specific action or setting of the device can be found in the relevant section.



Ignoring the instructions for use may result in injury.



A defective device must not be used. Risk of injury.



The device must not be modified. Risk of injury.



Check user sensitiveness for pressure ulcer before use.



Body parts may get pinched while applying or removing the pan.



A heated device can cause burns.



The hand control must not be used by persons with cognitive impairment.



Keep children away from the device. Risk of strangulation due to cables.



Keep children away from the device. Risk of squeezing due to moving parts.



Risk of squeezing due to moving parts.



Do not use accessories or parts not described in the instructions for use. Risk of injury.

Declaration of conformity

The device meets the requirements of the Medical Device Regulation (EU) 2017/745.

The device is tested and meets the requirements of the ISO 17966, IEC 60601-1 and IEC 60601-1-2.

Pre-purchase information

Pre-purchase information can be found at www.etac.com.

Instructions for replacement of parts

When installing accessories and spare parts, the assembly instructions must be followed. Assembly instructions can be found at www.etac.com

Contact information

For questions regarding use, maintenance or problems, contact your local dealer.

Adverse event

In case of an adverse event occurred in relation to use of the device, it must be reported to your local dealer and the national competent authority in a timely manner. The local dealer will forward information to the manufacturer.

Customization

is everything that goes beyond the manual's instructions and settings. Device specially adapted by the customer must not retain Etac's CE marking. Etac's warranty expires.

If there is any uncertainty regarding the execution of the customization, consult Etac. Device coupled with another device may not retain either device's CE mark unless combination agreements exist.

Device description

See Figure A

1. Frame lower part.
2. Leg support with foot plate and heel strap.
3. Seat unit.

- en
4. Arm support.
 5. Back support upholstery.
 6. Item no label (serial.no., date of manufacture).
 7. Label electrical information.
 8. Head support.
 9. Hand control.
 10. Charging cable.
 11. Control box, battery.
 12. Actuators.
 13. Adjustment knobs.
 14. Castor.
 15. Locking castor.
 16. Locking, leg support.
 17. Commode pan holders.
 18. Emergency lowering button.
 19. Pressure valve.
 20. Product label.

Symbols

See figure B

Symbols on the product and in this manual:

1. Warning, precaution or limitation.
2. Useful advise and tips.
3. Material for recycling.
4. The part/function is unlocked and can be moved/adjusted.
5. The part/function is locked and can not be moved/adjusted.
6. Maximum user weight (see technical data).
7. Click on the icon or scan the QR code for video.
8. Follow instructions for use.
9. Manual cleaning (see service and maintenance).
10. Machine washing (see service and maintenance).
11. Do not stand on the foot plates. Risk of injury if the device tips over.
12. Do not sit on the front edge of the seat. Risk of injury if the device tips over.
13. Total weight of the device including maximal user weight
14. Risk of squeezing.
15. This side up
16. Temperature limit
17. Humidity limit
18. Atmospheric pressure limit
19. Forest Stewardship Council

Labels

See figure C

Label description:

1. Unique Device Identification.
2. Product name.
3. Product description.
4. Item no.
5. Serial no.
6. CE-mark.
7. MD-mark.
8. Manufacturer.
9. *Bar code acc. to GS1-128 GTIN-14 and serial no.*
10. Type of protection.
11. Interval of use.
12. Input power.
13. Input voltage.
14. Recycle electronic equipment.
15. Class II equipment.
16. Type BF applied part (applies to the entire product).

*The device's date of manufacture can be read from the barcode on the device. The number 11 is shown below the barcode in brackets. The number combination after these brackets is the date of manufacture.

Technical data

See Figure D

Electronic data

Operating voltage	25,7 V
Battery type	Li-Ion BA22
Typical operation time	70 cycles per charge
Input voltage	100 – 240 V ~ , 50/60 Hz
Protection level against ingress of water into the electrical parts	IP46, protected against water jets
Volume level actuators	Max 50 dB
Battery, capacity	1500 recharges from 0-100%
Battery, charging time	Appr. 10h from 0-100%

Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The user of the system must ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
Conducted emissions CISPR 11	Group 1 Class B	The device must emit electromagnetic energy in order to perform its internal function. Nearby electronic equipment may be affected.
Radiated emissions CISPR 11	Group 1 Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Flicker emissions IEC 61000-3-3	Complies	

Immunity test	Compliance/ IEC 60601 test level
ESD Immunity IEC 61000-4-2	± (2, 4, 6 ,8) kV ± (2, 4, 8 ,15) kV
Radiated RF Immunity IEC 61000-4-3	10V/m
Wireless Proximity Test	-
EFT Immunity IEC 61000-4-4	± 2 kV (100kHz)
Surge Immunity IEC 61000-4-5	± 0.5, ±1, ±2 kV ± 0.5, ±1 kV ± 0.5, ±1, ±2 kV ± 0.5, ±1 kV ± 2 kV
Conducted RF Immunity IEC 61000-4-6	3Vrms (6Vrms inside ISM / ASR bands)
Magnetic Fields Immunity IEC 61000-4-8	30A/m
Supply Dips Immunity IEC 61000-4-11	>95% dip in UT for 0.5 cycle >95% dip in UT for 1 cycle 30% dip in UT for 25/30 cycles
Supply Interruptions Immunity	IEC 61000-4-11



Use of accessories, components or cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified. Otherwise, degradation of the performance of this equipment could result.

Handling

See Figure E

Installation upon delivery

Fully charge the battery before first use (see section "Charging").

Hand control

Press and hold the "Stand by" button for three seconds to activate or deactivate the hand control. The hand control is activated for 10 min. from the last button press.

Stop button, movement in progress is immediately cancelled and the hand control is switched off.

Green light=The hand control is activated

0-20% battery capacity

20-40% battery capacity

40-100% battery capacity

Green light = Mains cable is connected and the product is charging. The product cannot be used when the mains cable is connected. If the "Stand By" button is pressed during charging, the LED will flash and a signal will sound.

Press the button "up" to elevate the seat.

Press the button "down" to lower the seat.

Press the button "backward tilt" to tilt the seat backwards.

Press the button "forward tilt" to tilt the seat forwards.

The hand control is best placed on the upper part of the chassis ("the push handle"), when not in use.



Ensure that the user has the arms on the arm supports and feet on the foot supports.
Risk of squeezing due to moving parts.

Remaining battery capacity during use:

1. **11+10+9** shines with a steady light from 100%* down to 40%. Then **11** goes out.
2. **10+9** lights up steadily down to 20%*. Then **10** goes out.
3. **9** shines with a steady light down to 11%* when it changes to a flashing light down to 0%.

*% of total battery capacity

The battery life depends on the frequency of charging. The capacity is 1500 recharges from 0-100%.

Forward tilted seat can be elevated to maximum 650 mm. If the seat is elevated higher than 650 mm it cannot be tilted forwards.

Emergency lowering:

If for some reason lowering or tilting the seat with the hand control is not possible, the emergency lowering button can be used. Press and hold the button to lower the seat to the lowest position and tilt the seat up. A signal sounds while the button is pressed.



The duty cycle printed on the actuator system label must always be followed. If exceeded, there is a risk that the actuator system is damaged. The duty cycle is max. 10%, max. 2 min. in use followed by 18 min. not in use.

Charging

- The device must reach room temperature before charging.
- Charging must only be done in a dry environment and the electrical connections of the device must be dry before power is connected.
- Make sure that the mains voltage to be connected to the product or the system is the one stated on the label.
- Connect the mains cable to the mains socket.
- Fully charge the battery before first use, appr. 10 hours.
- Charge the product when needed, see the lights on the hand control for remaining battery capacity.

When charging the battery:

- 1-5 1. **9** lights up with flashing light up to 20% *.
2. **9** lights up with steady light +**10** lights up with flashing light up to 40%*.
3. **9+10** lights up with steady light +**11** lights up with flashing light up to 100% and then assumes steady light.

*% of total battery capacity.

- 6 All lights go out when the mains cable is removed from the mains socket.

7 Environmental conditions

- 8 Operating:

- 9 Temperature 5 °C to 40 °C

- 10 Relative humidity 20% to 80% - non-condensing

- 11 Atmospheric pressure 700 to 1060 hPa (rated to be operated at an altitude ≤ 3000 m).

Transfer



Make sure the castors are locked when the user sits down or gets up from the chair. **20**



Facing the castors outward increases the stability. **21**



Do not stand on the foot plates. Risk of injury if the device tips over.



Do not sit on the front edge of the seat. Risk of injury if the device tips over.

Moving the device:

Move the chair backwards over a threshold. We recommend using a threshold ramp. **18**



When the seat height is set low, the leg supports may catch on the castors affecting the ability to manoeuvre the chair. To resolve this, raise the seat height.

Transferring:

Assess the risks and take notes. You as a carer are responsible for the safety of the user. Aids should be used if the transfer is deemed as risky, e.g. a suitable floor or ceiling lift. Visit www.etac.com.

It is important to ensure that the castors are locked and facing outward before carrying out transfer.

Raise and swivel the leg supports and arm supports to the side for the user to sit down in or get up out of the chair. Carry out the transfer. **19-24**

Stationary position:

Always lock as many castors as possible when the chair is used in a stationary position.



The leg supports can touch the floor when the seat is tilted forward and set to a low height. We recommend removing the leg supports before tilting the seat forward.

Settings

See Figure F

Settings

Arm supports:

The height of the arm supports and/or width between the arm supports can be adjusted. Loosen the screws, twist the support to the desired position and retighten the screws. Then loosen and refit the arm support plate in the correct position. **1-5**

Leg supports:

Various height adjustment options are available by moving the locking pin. The leg supports have 6 different height settings. **6**

Head support:

The head support is adjustable in height, depth and angle and is laterally settable (see illustrations **E5**).

Safety



Do not block the mains socket while charging, so that the mains cable can be unplugged without difficulties.
The surface temperature of the actuators can reach 46°C during use.

The battery has a safety valve which will open in the event of a battery failure. If the valve opens, the battery is unusable and needs to be replaced.

Service and maintenance

Maintenance, inspection and cleaning must be done regularly. Check for malfunctions, mechanical damage, wear and tear and cracks. Worn-out parts must be replaced.

When reconditioning, the reconditioning instruction must be followed. When replacing parts, original parts from Etac must be used.

When installing spare parts, the assembly instructions must be followed. Reconditioning instruction, assembly instructions and spare parts list can be found at www.etac.com.



Do not repair the device yourself. Risk of injury. Repairs must be carried out by a professional.

Lithium ion battery

Rechargeable batteries are consumable components that become less efficient as they age. Lower capacity may lead to fewer hours of use between charges.

Recharge batteries every 12 months at a minimum.

Cleaning and disinfection

Cleaning must be carried out regularly. The product may need to be cleaned between users to avoid infection.

- Clean the product with standard non-abrasive cleaners (pH between 5-9). Rinse and dry.
- Disinfect the product with 70% disinfectant solution. Allow to air dry.

Cleaning in a clinical environment:

Clean the product and its accessories in a washing machine or tunnel (unless otherwise stated).

Cleaning by washing machine or tunnel must be done in accordance with EN/ISO 60601-2-52:

- 2 min wash with 70 °C water at a pH-value 5-8, 0,5 % cleaning and disinfectant solution.
- 20 s rinse with 85 °C water at a pH-value 5-8, and 0,2 % clear rinsing solution.
- 10 min cooling at 20° C ambient temperature.

Solutions for cleaning, disinfectant and rinsing must not:

- Contain caustic solutions
- Change the surface structure or adhesive properties of the plastic
- Break down grease

The limit values according to EN/ISO 60601-2-52 must not be exceeded.

Before starting washing:

- The product must be fixed and placed upright with locked wheels. In order to maintain the flexibility of the cables, it is important that the cable is positioned in such a way that the weight of the cable does not load the spiraliser during the

washing process.

- The cables must be connected during cleaning to prevent water ingress.
- To ensure that the pre-lubricated inner tube remains lubricated, the actuator may only be washed when the piston rod is fully retracted.

The constituent materials are resistant to common disinfectants.

The following surface treatment methods have been used to protect against corrosion:

Painted surfaces = Powder coated polyester.

Unpainted steel surfaces = Fe/Zn-Ni

5-year guarantee against material and manufacturing defects. For terms and conditions, see www.etac.com.

Transport, storage and disposal

Storage

Temperature -10°C to +50°C

20-80% relative humidity, non-condensing atmospheric pressure, 700 to 1060 hPa (rated to be stored at an altitude ≤ 3000 m).

Do not exceed the storage temperature as it will shorten the product life and performance.

Recharging during storage: First recharge of the battery must be no later than 12 months after production date stated on the label.

Hereafter the battery must be recharged at least every 12 months.

If the battery is completely discharged, then recharge the battery before storage.

Do not store the battery near combustible material.

If the device has been stored for a long time (more than four months), its function must be checked by an expert before use.

Transport

Temperature -10°C to +50°

20-80% relative humidity, non-condensing atmospheric pressure, 700 to 1060 hPa (rated to be stored at an altitude ≤ 3000 m).

If the actuator is assembled in the application and is exposed to push or pull during transportation, the actuator can be damaged.

Do not drop an actuator or otherwise damage the housing during disassembly or transportation.

The lithium ion batteries must be packed and transported in accordance with applicable regulations. Always ask your local transportation provider how to handle the transportation of lithium ion batteries.

Disposal

Batteries:

Hand in batteries for recycling in accordance with local regulations.

Actuator and control box:

Hand in electronics for recycling.

Troubleshooting guide

Problem	Possible cause	Action
LED-light F9 flashes.	The battery is almost discharged.	Charge the battery.
Raising, lowering or tilting does not work.	The hand control has been deactivated.	Switch the hand control back on by pressing and holding the "Stand by" button for 3 seconds.
	The mains cable is plugged in for charging.	Unplug the mains cable and switch the hand control back on by pressing the 'Stand by' button for 3 seconds.
	Cables are incorrectly connected.	Have the product serviced
	The battery is discharged.	Charge the battery.
The battery is not charging.	Battery failure.	Have the product serviced
The seat tilts sideways.	Actuators at different heights.	Perform a reset by pressing the "down" and "up" buttons simultaneously for 5 seconds. The frequency of the signal will increase after 5 sec., then hold the "down" button until the seat is in the lowest position. When the button "down" is released the signal will stop.
The hand control does not start. There is a beeping sound when the "Stand by" button is pressed.	The battery has been stored at a temperature outside the specified storage temperature.	Plug the mains cable into the mains socket. Unplug the mains cable and turn on the hand control by pressing the "Stand by" button for 3 seconds.

Accessories

See Figure G

- | | | |
|---|---|--|
| 1. Leg and calf support, elevating | 15. Comfort seat | 29. Head support and bracket |
| 2. Foot plate, leg and calf support | 16. Soft Comfort seat | 30. Heel straps |
| 3. Angle adj. foot support | 17. Soft Comfort seat - narrow opening | 31. Hemiplegic arm support |
| 4. Amputee leg support | 18. Soft cushion - standard opening | 32. Arm support lock |
| 5. Commode pan | 19. Soft cushion - oval opening | 33. Short leg support |
| 6. Pan-holder attachments | 20. Seat cover | 34. Angled leg support |
| 7. Attachments for low pan-holder mounting | 21. Soft back pad | 35. Wipeable back support |
| 8. Commode pan holders | 22. Comfort padding | 36. Head support upright |
| 9. Bucket holders | 23. Arm support cushion, pair | 37. Seat closed at the back |
| 10. Pan | 24. Trunk support | 38. Pan holder |
| 11. Lid with handle | 25. Chest and hip positioning belts* | 39. Bucket with handle and lid |
| 12. Splash guard | 26. Chest belt | 40. Cover leg- and calf support |
| 13. Soft Comfort seat, 2 cm high, open at back | 27. Hip belt | 41. Castor direction lock |
| 14. Soft Comfort seat, 4 cm high, open at back | 28. Crossbar 605 mm | |

*With wipeable back only as hip belt