INSTRUCTIONS FOR USE

Atle® 180

NJORD MEDTECH

To avoid injury, always read these *Instructions for Use* and accompanied documents before using the product.

 Mandatory to read the *Instructions for Use*

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Foreword

Read this manual carefully!

The information in this manual is crucial for proper use and maintenance of Atle® 180. It will help protect your product as well as ensure that it performs to your satisfaction.

Transferring a person always constitutes a potential risk. This document contains safety related information that must be read and understood to help prevent injuries.

Njord Medtech recommends and warns that to avoid injuries attributed to the use of inadequate parts, only parts designated by Njord Medtech should be used on products and other appliances supplied by Njord Medtech.

Unauthorized modifications of Atle® 180 may affect its operational and functional performance. Njord Medtech will not be held responsible for accidents, incidents or lack of performance that occurs as a result of any unauthorized modification to the product.

If a serious incident occurs during the use of Atle® 180, affecting the user or patient, the user or the patient should report the serious incident to the manufacturer or distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Manufacturer Information

This product is manufactured by:

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Medicinaregatan 8
413 90 Göteborg
Sweden

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🌐 www.njordmedtech.com/

Definitions used in this manual

WARNING:

Means: Failure to understand and follow instructions may result in injury to yourself and others.

NOTE:

Means: Important information regarding correct use of the product. Failure to follow instructions may cause damage to the product.

Keep the manual together with the product so that it can be used as reference or provide access to online documentation at njordmedtech.com. Store the Quick Reference Guide that comes with the product well visible to all staff.

Atle® 180 is a medical device for horizontal patient transfer and used in healthcare in which the transfers are made from one care bed to another examination table or equivalent.

Intended Use

Atle® 180 is a motorized lateral patient transfer aid that is intended to be used in clinical or care environments to transfer patients between horizontal patient platforms, e.g. between a bed and an examination table. The device is intended to be used by healthcare professionals for patients with a maximum weight of 180 kg.

The product is not intended for wet areas and must not be used inside MRI (magnetic resonance) examination rooms, i.e. not in proximity to a magnetic field.

WARNING: The product is not intended to be used inside MRI examination rooms

Atle® 180 should be used in an indoor environment.

There is no need for medical device specific training for professional healthcare users to use Atle® 180.

Operational Life

Atle® 180 has been designed and tested to achieve up to 40 000 cycles. Use of friction-reducing techniques (e.g., additional transfer boards, slide sheets, fully inflated mattresses) may extend product life.

Maintenance according to the specifications in the section “Cleaning and Service” in this manual applies.

WARNING: Using Atle 180 beyond its lifespan may result in injuries.

Important Safety Instructions

The batteries that power Atle® 180 are rechargeable. The batteries are charged via ordinary main plugs. Atle® 180 should not and cannot be used during charging. To avoid a fall accident the caregiver should be attentive to the cord and its placing during charging.

The wheels of Atle® 180 can be rotated 360 degrees to enable a smooth handling of the device. The wheels are for safety reasons possible to lock and should be locked while the device is not intended to be in motion.

Use only accessories intended for Atle® 180.

Atle® 180 should only be used to transfer patients horizontally between the beds. It is not intended to be used for other transfers e.g. move the patient to the side. Atle® 180 is not for moving any other type of object.

NOTE: Atle® 180 should only be used for two horizontal aligned surfaces

Safety Precautions

⚠ Do not position the system so that it is difficult to operate the disconnection device.

⚠ The power cord to the control unit should be positioned to avoid a tripping hazard and/or damage to the cord.

⚠ Manufacturer will prove circuit diagrams, component part list, and product description to assist the service personnel in service repair.

⚠ Uplug the power cord charger from the control panel to disconnect the device from supply mains.

Safety Instructions

WARNING: No modification of this equipment is allowed

WARNING: Do not put fingers, hands or other body parts where space is limited (see Fig 1). This could pinch, cut or seriously harm body parts

1) Between Atle® 180 and bed unit
2) Between the wire and transfer bar
3) On the loops/hooks
4) When changing bobbin
5) At the wire guide

Fig 1

Before use

Before first use, check that all parts are included according to the product description, clean Atle® 180 and test the emergency stop button. Note that the battery must be charged at least 24 hours before first use.

In case of deviation

In need of immediate shutdown during transfer, the emergency stop switch on the product is to be used.

Stop transfer immediately in case of irregular sound from the engine or irregular speed of transfer.

Policy on Number of Staff Members Required for Patient Transfer

Atle® 180 is designed for safe usage with one caregiver. There are circumstances that may dictate the need for a two-person transfer. An example of this is moving the patient from a CT table to a bed. It is the responsibility of the caregiver to determine if a one or two-person transfer is more appropriate.

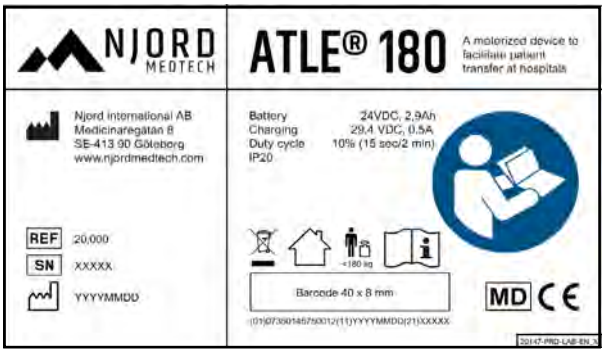
Patient weight

Maximum patient weight for Atle® 180 is 180 kg.

Product label

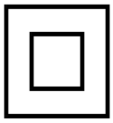
The main product label has a barcode ID, serial number and date of manufacture for the product.

Illustrative example



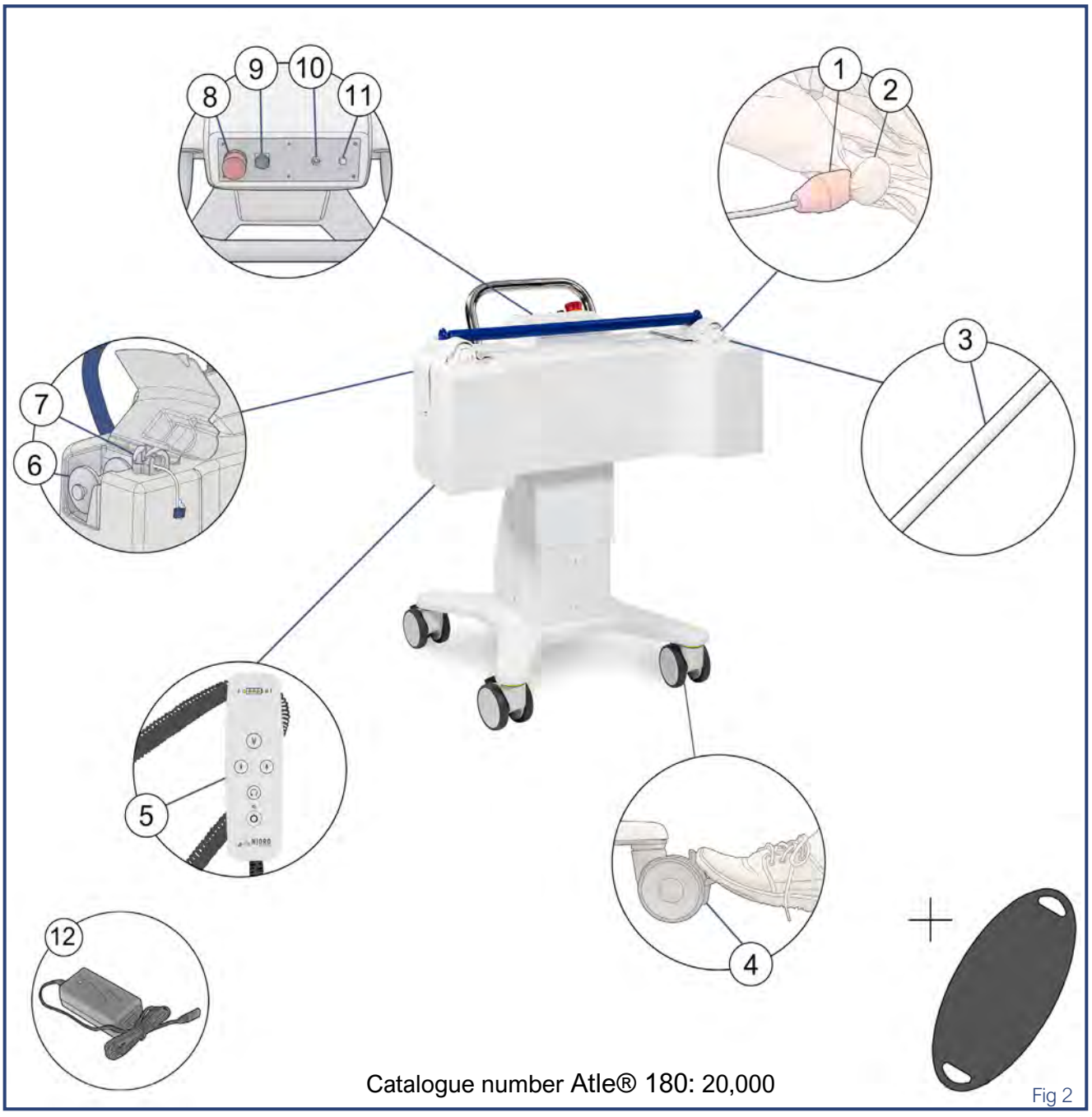
Symbols used

Atle® 180 unit has a traceability product label with the symbols below, the other symbols can be found on Atle® 180 or in the Instructions for Use.

CE	CE marking indicating conformity with European regulations on medical devices
	Maximum patient weight
	Manufacture
	Date of manufacture
	Waste electrical and Electronic Equipment (WEEE) – do not dispose of this product in general household or commercial waste
MD	Medical Device
	Intended for indoor use only
	Warning; Pinching/Crushing hazard
	Class II equipment, double insulation
SN	Serial number
REF	Catalogue number

!	Error indication
	Battery indication
	Consult instructions for use
	Refer to instruction manual/ booklet
	Charging connector
STOP	Points out the emergency stop button
Hand Control	Hand control connector
Reset	Points out the reset button for the emergency stop
IP 20	Ingress protection code
	Temperature limit
	Humidity limitation

Product description



Catalogue number Atle® 180: 20,000

Fig 2

1) Attachment solution (replaceable)
2) Transfer bar
3) Wire (replaceable)
4) Wheel brake
5) Hand Control with battery indicator
6) Bobbin (replaceable)
7) Wire guide
8) Emergency stop
9) Reset button for emergency stop
10) Charger output
11) Hand Control output
12) Battery charger and power cord

+ sliding boards

To disconnect the device, pull out the charger from the appliance and/or pull out the plug from main socket

General information

Sliding boards are used for supine transfers from one level surface to another. For example, from bed to examination table and back. The smooth, low-friction top surface facilitates easy sliding transfers and makes the sliding board simple to position before a transfer and easy to remove afterward.

Transfer from bed to examination table

The sliding boards are placed under the hips, shoulders and feets. Lift the sheet as close to the patient as possible and guide the sliding boards under the patient, between the bed sheet and the mattress. The sliding boards should be held at the level of the mattress and be pushed horizontally under the patient. For ergonomics and patient comfort the sliding boards do not need to be pushed fully under the patient.

To be able to easily place the sliding board, it should be held as shown in figure 3.
Place your hand in the hole and grasp with a firm grip with the thumb on the top side of the sliding board.

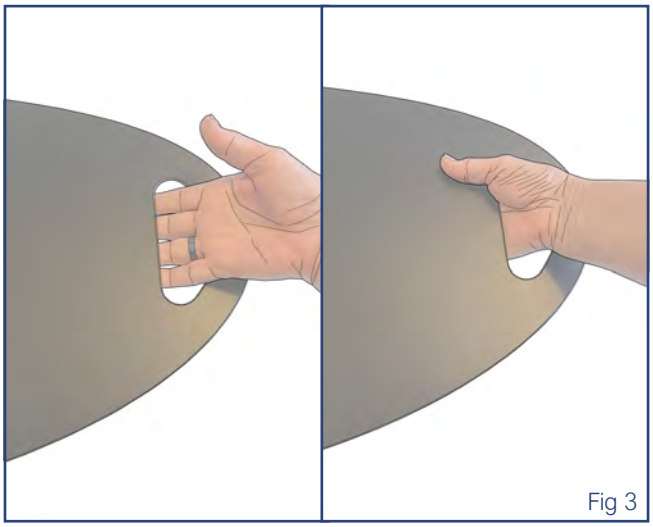


Fig 3

Important information

For the sake of safety, make sure the bed and examination table are stable and locked when conducting the transfer.
Do not leave the patient unattended during a transfer.

Removal of sliding boards

After the patient transfer, remove each sliding board by grasping the handle and pulling it out from under the patient while holding the sheet close to the patient.

Cleaning & hygiene

The surface of the sliding boards must be cleaned after use with each patient. Clean with surfactant (detergent) and disinfectant.

Use of Atle® 180

General horizontal transfer of patient

The transfer technique described below can be used for patients lying in bed to transfer them horizontally between beds, from stretcher to bed and bed to examination table and vice versa.

Before transfer

1) Go to Atle® 180, pull out both wires simultaneously and place them on the empty bedside/examination table unit. Open the loops of the attachment solution.

Ensure the patient is lying on hirs back in a centered position with sheets extending >20 cm from the patient's shoulder and hip.

To facilitate the transfer, sliding boards should be used. Place optional sliding boards under the patient. Good positions are under the feet, the hips and the shoulders.

Fig 4

NOTE: Maximum patient weight at transfer with Atle® 180 is 180 kg

NOTE: Sliding boards should be used for a more secure and comfortable transfer

2) Prepare the transfer by placing the transfer bar on the sheet, at height with the shoulder and hip of the patient. Then fold the remaining sheet over the transfer bar. The transfer bar should be placed close to the patient.

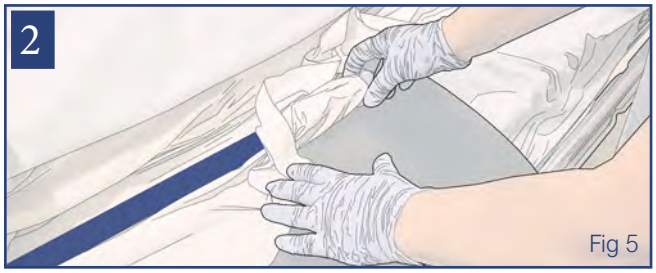


Fig 5

3) Place the bed parallel to and approximately 0.5 meters from the other unit. Atle is placed on the long side of the empty unit.

Fig 6

Attachment solution

4) Attach the loops over the sheet and around the transfer bar. Tighten the loop around the transfer bar so that the loop is fastened tightly. Do the same on the other side (See "attachment solution", page 9).

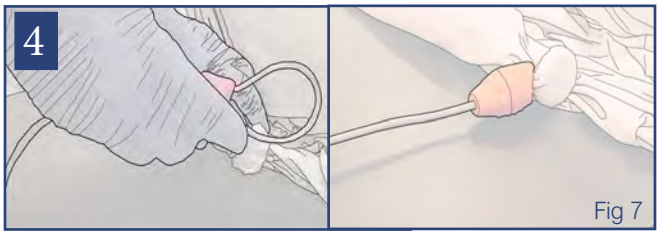


Fig 7

During the transfer

5) Ensure that the bed and examination table are placed at the same height right next to each other. Lock the wheels on the bed. The sliding boards must protrude between the bed and examination table.

Atle® 180 is positioned completely close to the long side of the empty unit. Adjust the height of Atle® 180 so that the position of the wires is just above the mattress; see figure 8. The wires must be positioned in a straight line from Atle® 180´s output towards the transfer bar. Finish positioning Atle® 180 by locking all of the wheels on Atle® 180.

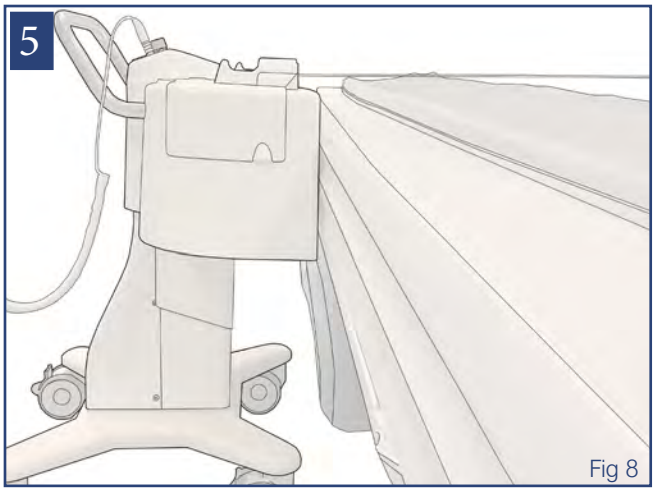


Fig 8

WARNING: Both beds should be positioned right next to each other to avoid the risk of the patient falling between these. For additional safety measures, sliding boards should be used

NOTE: Position Atle® 180 completely close to the bed/table edge with the position of the wires just above the mattress on the examination table/bed, to avoid risk of tipping

6) Initiate motorized transfer via hand control. Press the pull button so that the wires are stretched, then release the button for a second, contact the patient and inform that the transfer starts. Press the pull button again and perform the transfer.

Make sure that the patient is following the transfer, especially the feet, shoulders and head. This is done with the help of one hand by adjusting the sheets associated with the transfer.

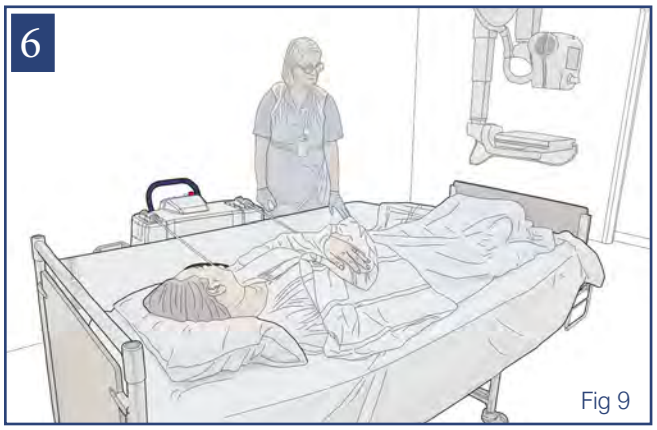


Fig 9

WARNING: Avoid moving your arm / hand between the transfer bar and engine part when the transfer bar approaches engine part at end of the transfer to avoid the squeeze risk

WARNING: To eliminate the squeeze risk, make sure no body parts of the patients is between the bed and the examination table or between bed and Atle® 180

WARNING: To eliminate the squeeze risk, ensure that the patient does not get stuck with body parts in relation to the transfer bar or the wire during the transfer

At the end of the transfer

7) End the transfer when the patient is positioned centered on the new bed unit. Remove the fastener from the sheet and transfer bar by pulling out the wires slightly and widening the loop forward through the wire holder. Remove the transfer bar and the sliding boards.

Fig 10

NOTE: It is possible to move the entire mattress to the examination table with the help of the patient's weight and with sliding boards under the matress

WARNING: The pull should be straight

Transfer at bowl-shaped CT-scanner

When moving from the CT table to another bed it is recommended that two people carry out the transfer with Atle® 180.

One person monitors and conducts the transfer with the hand control in the usual manner while the other person supports the patient on the other side of the examination table during the transfer, over the curved edge of the CT table. The person who supports the patient can choose to lift at the edge of the sheet to create a smooth transfer.

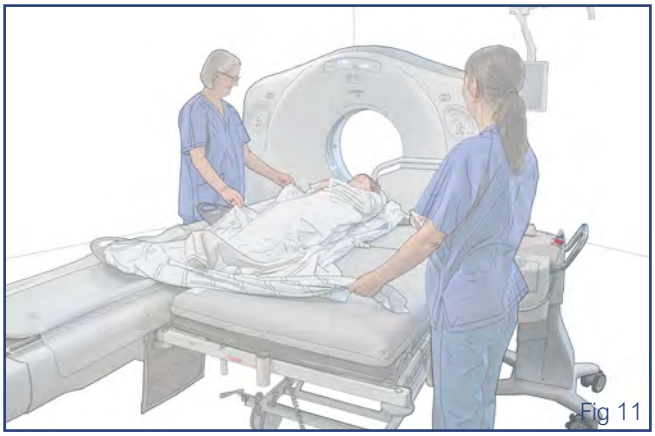


Fig 11

Attachment solution with hooks in a trauma mattress

For all types of traumamattresses with handles along the side, the hook is attached to the loop of the wires and then connected directly to the handles on the mattress.

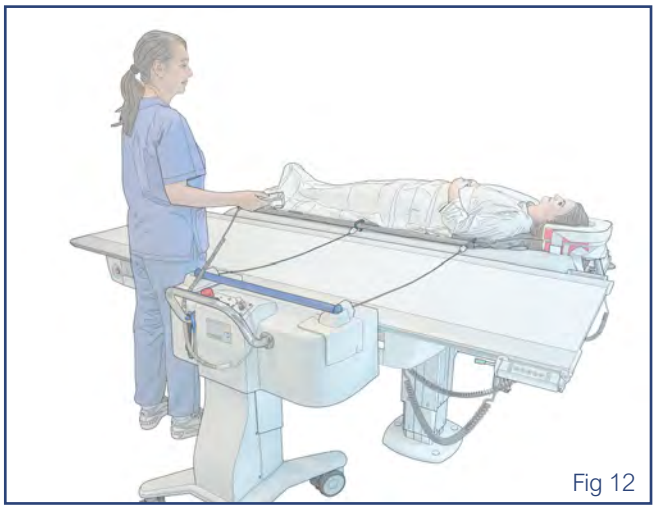


Fig 12

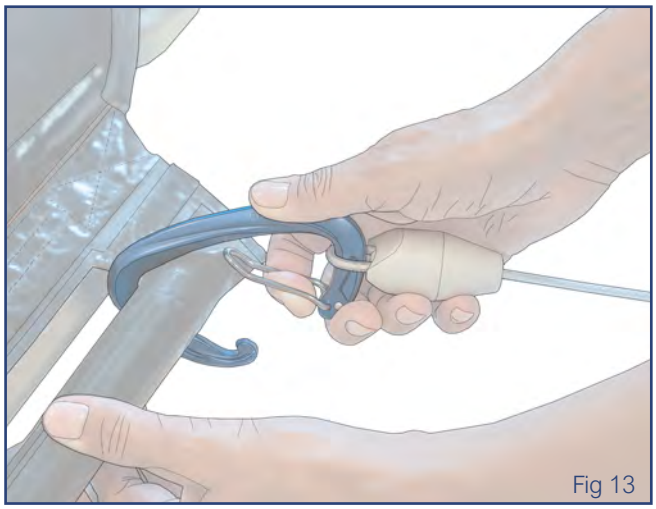


Fig 13

Atle® 180 and beds with plastic bed rails

When moving the patient back to bed from the examination table, it is important that the Atle® 180 is placed correctly against the bed rail. Place the bed against the examination table and lower the bed rail. Make sure that the Atle® 180 stands with both sides ends against the lowered bed rails. Take care that the Atle® 180 does not press against any controls on the bed rail.

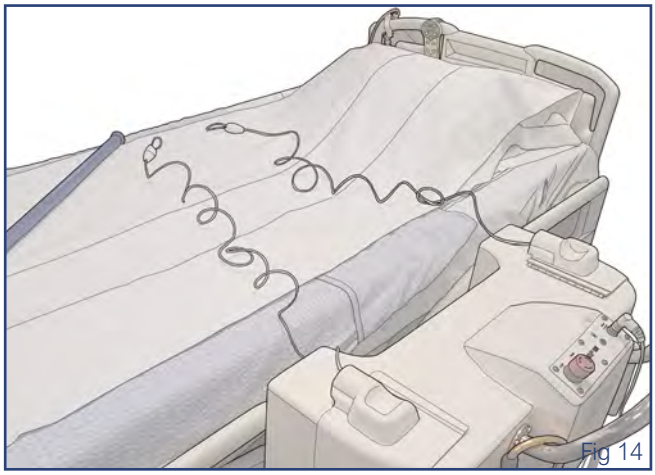


Fig 14

Atle® 180 and anti decubitus mattresses

There is more friction when transferring horizontally with patients lying on anti-decubitus mattresses. This friction can be reduced by using additional sliding boards and appropriately positioning the Atle® 180.

Transfer to the examination table

Position the sliding boards under the patient at the side closest to the examination table, at shoulders, hip and feet; a fourth sliding board can be placed with heavy patients. This fourth sliding board is placed laterally , from hip to shoulder, on the other side of the patient (farthest away from the examination table). The lateral sliding board ensures that the patient does not sink into the mattress and can be transferred more easily.

Transfer back to a bed

Prepare for the patient transfer back to an anti-decubitus mattress by positioning the mattress and Atle® 180 2 cm above the table. Place the Atle® 180 against the bed so that the wires emerge from the Atle® 180 at the same height of the mattress. Insert additional sliding boards under each of the three already placed sliding boards as in figure 16. Then transfer the patient.

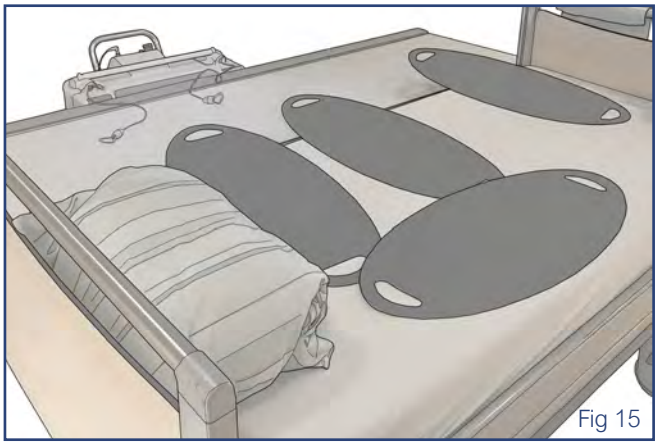


Fig 15

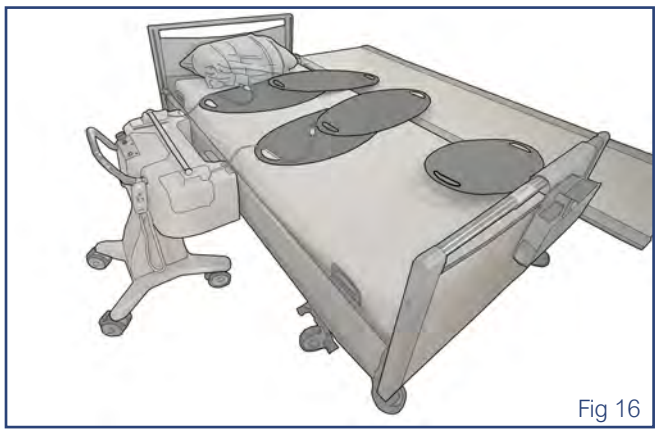


Fig 16

Attachment Solution

Before transfer

1) Prior to patient transfer, Pull out the wires simultaneously and place them on the empty unit, open the loops for preparation of the attachment solution.

Check that the sheet is stretched under the patient and lay the transfer bar on the sheet close to the patient and with the ends of the transfer bar at the level of the shoulders and hips. Fold the
sheet over the transfer bar.

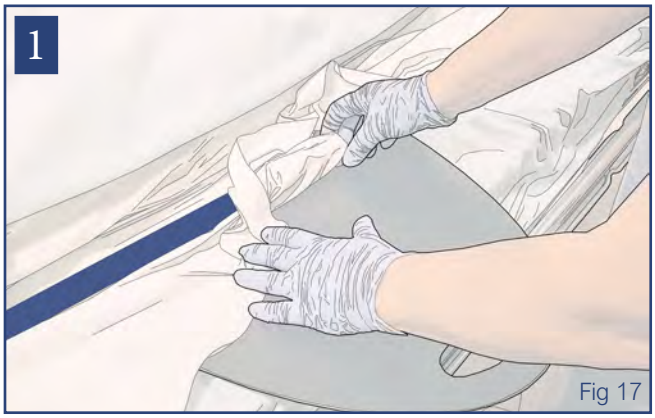


Fig 17

NOTE: Place the transfer bar close to the patient to ensure the optimal position in the middle of the bed/examination table after the transfer

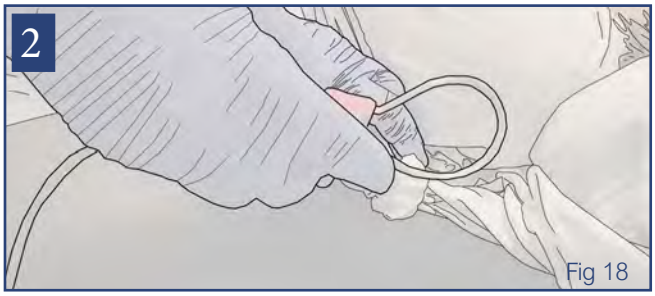


Fig 18

2-3) Attach the loop around one end of the transfer bar. Tighten by advancing the wire holder and then pull the wire. Do the same on the other side.

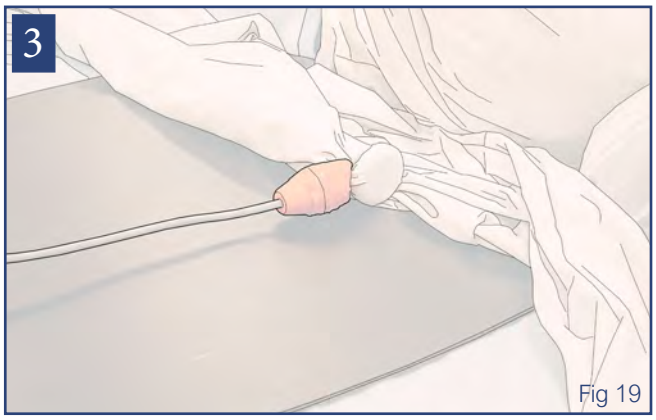


Fig 19

After Transfer

4) When the patient transfer has been completed, release the wires and disconnect it from the transfer bar.

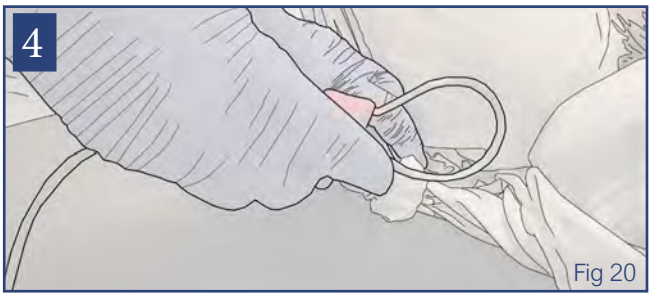


Fig 20

Charging and Hand Control

Charging Batteries

The battery pack is the type of rechargeable Lead. The batteries are charged via the main power outlet. The Atle® 180 uses a 24 Volts that can deliver approx. 50 pulls per charge with a new battery. The battery life is variable (2-3 years) and is influenced by frequency of use and weight of patient.

The battery needs to be charged when it is empty. Only the supplied charger (Mascot 2241P) should be used. For safety reasons, Atle® 180 cannot be used while charging. The charging of Atle® 180 is stopped by unplugging the power cord from the outlet. The hand control indicates that the battery is being charged by traveling lights for charging status.

The battery charges fully in approx. six hours. Note that the battery must be charged for at least 24 hours non-stop before first use. Battery life is not adversely affected by the fact that the battery is charged frequently. Replacement of the battery should be done by trained staff or by the manufacturer service staff.

NOTE: The battery must be charged for at least 24 hours non-stop before first use

WARNING: Replacement of the battery by inadequately trained personnel could result in a hazard

Hand Control

If the light on the right turns red it indicates that something is wrong (error). The LED is permanently lit if there is an internal hardware fault in the control box. On the other hand, if an error is caused by the user, e.g. that you try to run a function when the batteries are charging, the alert LED only lights up while you are trying to activate a function (i.e. when you press a button).

Battery indicator

When the light on the left is red, Atle® 180 must be charged. When one light is green, the battery charge level is less than 33%, when two lights are green, the battery charge level is 33% or better, and when all lights are green, the battery charge level is 66% or better.

Fig 21

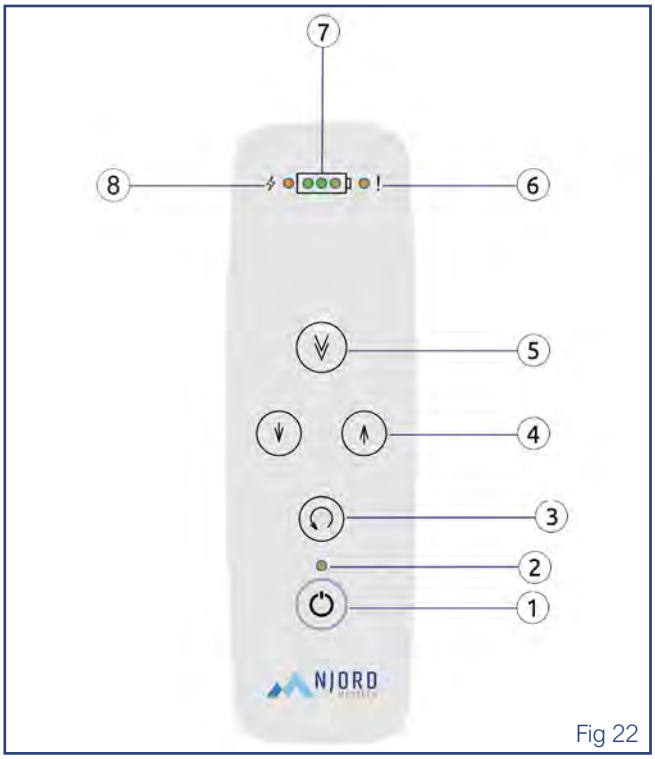


Fig 22

1) On / off button
2) On / off button indicator
3) Reset button for the overcurrent protection
4) Lowering and raising buttons
5) Motorized pull button
6) Error indication
7) Battery level
8) Battery indicator

Only use the supplied hand control.

Buttons

Pulling button

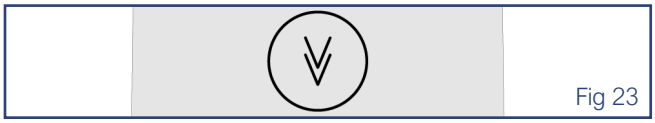


Fig 23

The button with double arrows is used to pull the patient towards Atle® 180. The transfer continues as long as the button is pressed or until it reaches its limit.

Raising / lowering buttons

Fig 24

The up and down arrows are used to raise and lower the motor housing. The motor housing will be be raised or lowered as long as the button is pressed or until it reaches its limit.

Reset button

Fig 25

An overcurrent protection is triggered when Atle® 180 is exposed to too high a load. To reset the overcurrent protection, the user is required to press the reset button. The user can then press the pull button again.

On/off button

Fig 26

When the green light is on, the device is on and ready to use.

NOTE: Only the supplied charger and hand control should be used

WARNING: Periodic checking or replacement of the charger is neccessary

Brakes and Emergency Stop

Brakes

Foot operated brakes are fitted on all the four wheels.
To lock the wheels, press down the back of the pad.
To release the brakes, push the lower part of the pad up.

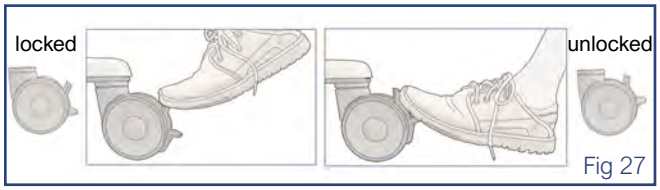


Fig 27

WARNING: Without the wheels locked, Atle® 180 is a risk of tipping

NOTE: When transferering heavier patients, it is important to lock the wheels, especially the wheels in the front

Emergency stop

The user can shut off the power at any time by pressing the red emergency button on the control panel. Reset the emergency stop function by turning the emergency stop button and then pressing the reset button next to the red emergency stop button. While finding the battery level again the error indication on the hand control will light red and there might be some sounds but Atle® 180 can be used as normal.

First-time users should practice the emergency stop manoeuvre before operating.

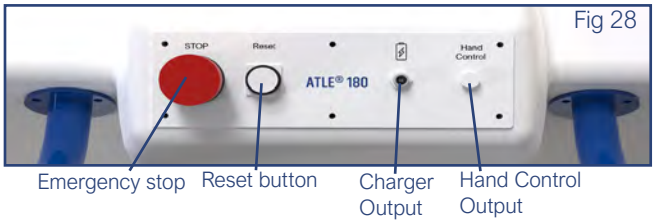


Fig 28

NOTE: If something is placed on Atle, the emergency stop can be activated

After Use

When the expiration date of the device is reached, the product must be recycled according to set standards for each country and hospital.

Cleaning of Atle® 180

Surfaces that the caregiver touches must be cleaned manually after each transfer. Clean the surfaces on Atle® 180 regularly using abundantly disinfection directly on the product or with a cloth. The cleaning liquid should contain both detergent/surfactant and disinfection. Process the surface repeatedly for 60 sec and then leave the surface to air dry. The surface should not have any dirt visible.

Pay attention to parts that are most likely to be touched:

- The hand control
- The control panel
- The handle
- Attachment solution
- The wires

Replacement of the wire

The wire and the bobbin should be replaced with a new one in case of suspicion or risk of contamination, visible damage to the surface layer on the wire or discoloured wire.

WARNING: if the bobbin are not changed when there is a suspicion of contamination there is a risk of spreading an infection

The bobbin is replaced as follows.

1) Open the cover to the bobbin by inserting a finger into the opening on the side of the cover

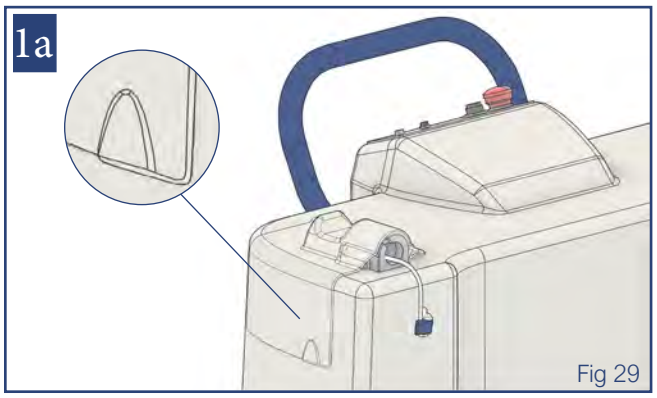


Fig 29

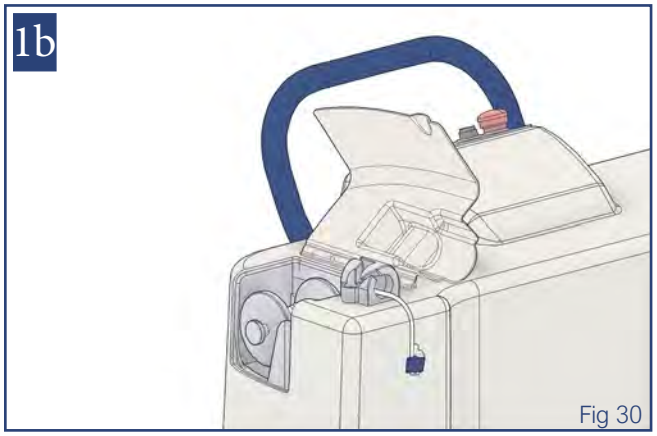


Fig 30

2) Take out the wire from the wire guide by pulling the wire to the side and through the opening.

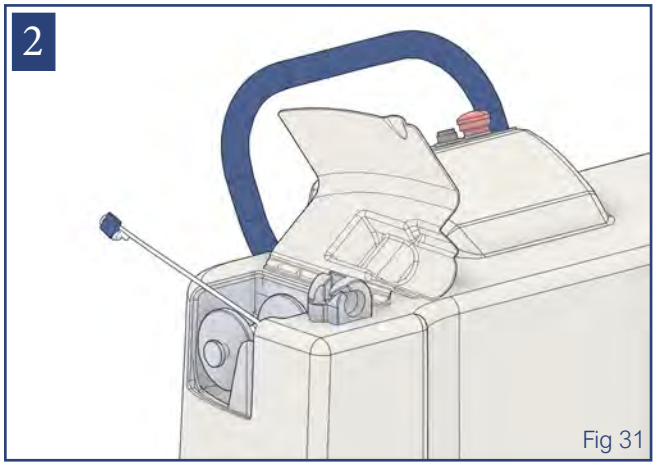
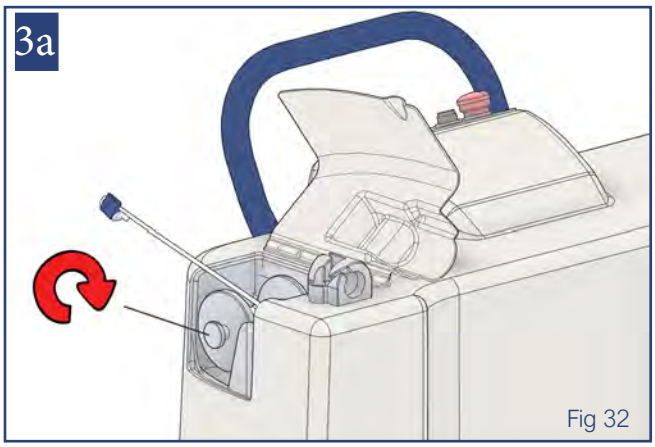
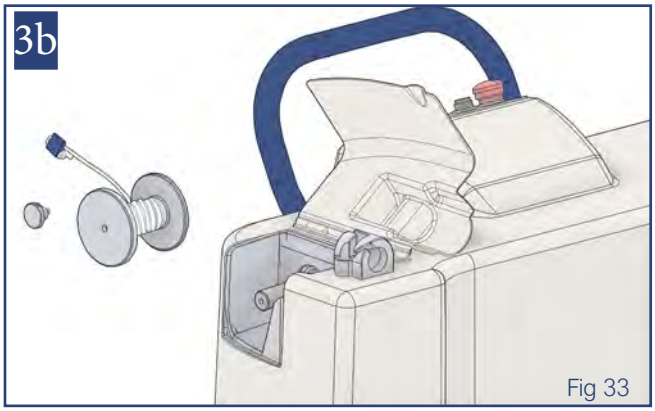


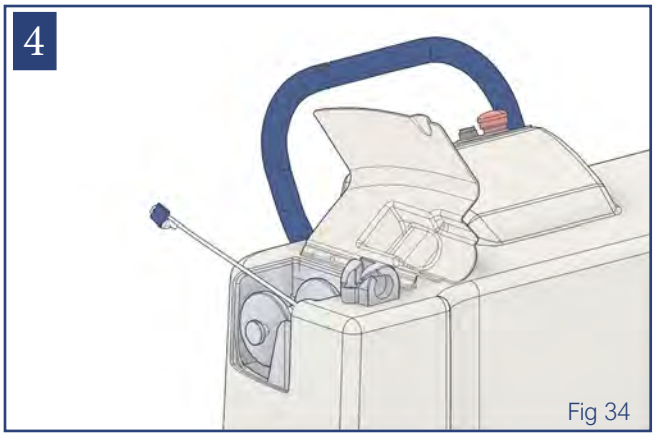
Fig 31

3) Remove the bobbin by unscrewing the screw and pull out the bobbin.

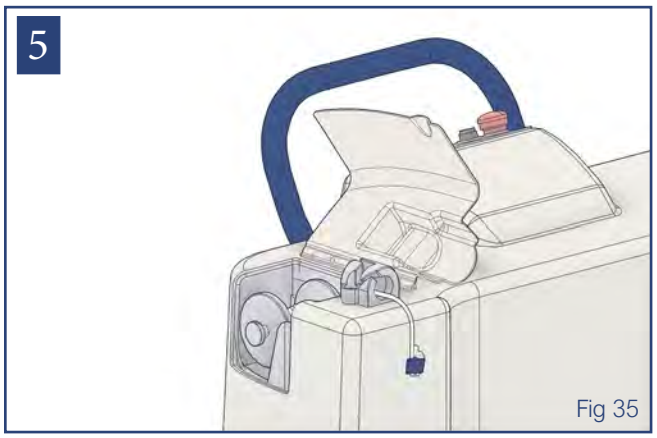




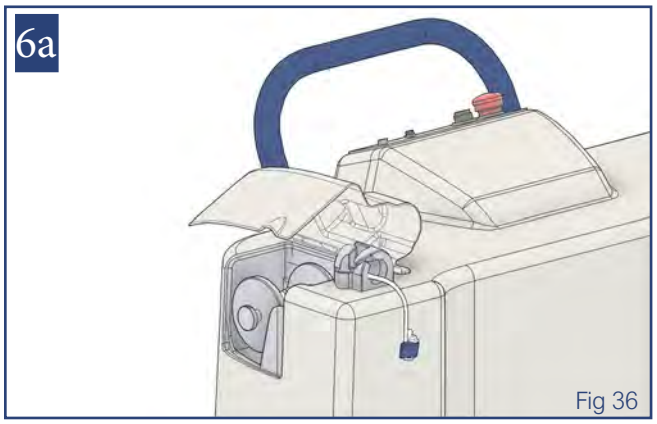
4) Take a new bobbin and attach it by pushing it onto the pin. Finish by tightening the screw.

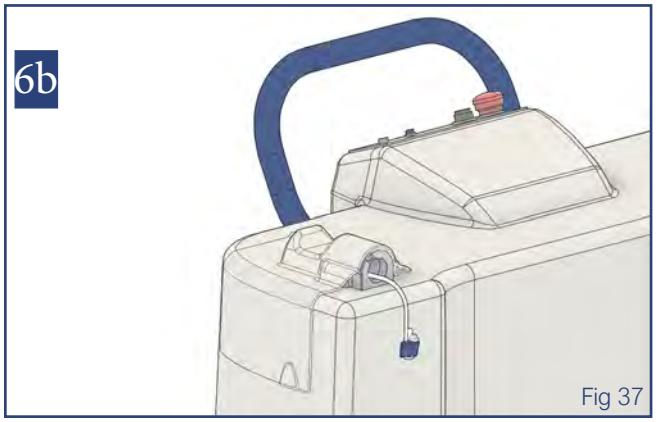


5) Put the wire back into the wire guide.



6) Close the cover





NOTE: Incorrectly placed bobbins may fall off the pin and the patient transfer cannot be performed

WARNING: To avoid squeeze risk, do not use Atle® 180 when changing bobbins

Maintenance

Replacement of components must be done by medically trained engineers or by the manufacturer service staff.

More severe contamination may require the external parts to be unscrewed, and the internal components to be cleaned by medically trained engineers.

Preventive and check-up service is recommended once per year. The hospital's technician or the manufacturer's service technician performs this procedure. Key areas are engine maintenance, pull test and condition of the wire. After the service has been performed, a functional test is done without a patient.

Atle® 180 is subject to wear and tear, and the following actions must be performed when specified to ensure that the product remains within its orginal manufacturing specification.

NOTE: Do not use Atle® 180 while serviced or maintained

Points to be inspected by user/service technician	Frequency		
	Initially ↓	Before every use ↓	Annually ↓
1) Ensure that the battery charge indicator is within the normal range		X	
2) Check that Atle® 180 is charging when a battery charger is connected to Atle® 180; the charging status LEDs on the hand control will wander. If the battery is not taking charge or the battery has a short operation time, replacement of the battery is needed, see points for service technician		X	
3) Press the emergency stop button to make sure that all electrical power is cut off. No action should occur when activating the buttons on the hand control	X		X
4) Check all the functions on the hand control. Ensure that the hand control cover is intact	X		X
5) Check that Atle® 180 can be switched on and off with the power on / off button on the hand control		X	
6) Check that Atle® 180 pulls when you press the hand control pull button and that it stops when you release the button. The wires should moves towards Atle® 180 when it pulls		X	
7) Check that Atle® 180 can be raised and lowered by pressing the hand control up and down button	X		X
8) Check the reset button on the control panel by pressing the appropriate button; you can transfer with Atle® 180 by pressing the pull button	X		X
9) Check all the functions on the control panel	X		X

Note: The list continues on the other page

Points to be inspected by user/service technician	Frequency		
	Annually		
	Before every use		
	Initially ↓	↓	↓
10) Press the reset button for the emergency stop button to see that all electrical power is on again	X		X
11) Verify the proper functioning of the four wheels, check the brakes and that they spin well	X		X
12) Check front and rear wheels regularly for hair and debris; clean when necessary			X
13) Check that the wires can be pulled out of Atle® 180 by hand without significant resistance	X		X
14) Check that the wires are completely loose and can be pulled out	X		X
15) Check that the wires are not damaged and open the covers over the bobbins and check that the bobbins are not damaged, if damage see “Replacement of the wire”	X		X
16) Check the home position sensors, by pulling the transfer bar all the way into Atle® 180 and Atle® 180 stops pulling automatically (the sensors do not work if engine noise is heard when the transfer bar is in the home position)	X		X

Points to be inspected by service technician	Frequency		
	Annually		
	Before every use		
	Initially ↓	↓	↓
1) Check all bolts, nuts and locknuts to ensure they are tight			X
2) If the product does not work as intended, immediately contact Njord Medtech for support			X
3) Connect a dynamometer on the opposite side of the bed to Atle® 180 (note, wire >1 m in length), connect the transfer bar / hooks to the dynamometer and press the pull on the hand control. Read that Atle® 180 gives 900-1250N before the overcurrent protection is triggered			X
4) Check that Atle® 180 is charging when a battery charger is connected to Atle® 180; the charging status LEDs on the hand control will wander. If the battery is not taking charge or the battery has a short operating time, replace the battery*			X

* The battery (power pack RPP10) can be ordered from Njord Medtech or designated distributor

Troubleshooting

Type of error	Possible cause	Action
Hand control does not respond	- The emergency stop button is activated - The plug to the hand control is unplugged - Battery needs to be changed	- Deactivate the emergency stop by clicking on the “reset” button on the control panel - Summon technical trained personnel or Service technician
The wires cannot be pulled out	- The wire is stuck or tangled on the bobbin	- Open the cover to the bobbin and release the tangled wire either by removing/untangling the wire from the bobbin one turn at a time or by taking out the bobbins and pulling the wire out completely
Every time the wires are pulled in or out, they are at different lengths	- The wires are wound differently on the bobbins	- Open the cover to the bobbin and release the wire one turn on the bobbin on the side where the wire pulls short
The transfer bar cannot be attached	- The attachment solution has been put on incorrectly - The sheet is two fold or too thick - The attachment solution is worn out	- Adjust according to instructions under “Sheet attachment solution”
The torque/engine does not start via the hand control	- The battery is discharged - The main power switch is rejected - The emergency stop has been activated - Overload: the patient is too heavy	- Charge Atle® 180 - Turn on the main power switch - Deactivate the emergency stop by press the “reset” button on the control panel - Atle® 180 is intended for patients that weigh a maximum of 180 kg
The torque/engine stops	- The patient weighs more than 180 kg - The mattress texture gives a very high friction - The mattress structure and material allows the patient to create too much friction	- Perform manual transfer - The stop measure stops the machine over 1200N
The error indication on the hand control glows red and Atle® 180 makes a sound	- The emergency stop button has been released after activation	- After the emergency stop has been restored, Atle® 180 needs a few minutes to find the battery status and while doing this, the error indication will light up and Atle® 180 will make light noises, but it is possible to use Atle as usual

Troubleshooting

Type of error	Possible cause	Action
Error indication on the hand control glows red (indicates charging, charging level and error indication)	- Problem with power supply or motor. - Charge the battery (connect the charger to the device and the wall socket. check that the charging indicator lights up on the hand control, it is a wandering light	- Reset the device with the “reset” button on the control box - Reset the emergency stop with the reset button on the control panel
Sound from the control box - error indication	- Emergency stop button has been activated - The overcurrent protection can be triggered due to the wire getting stuck or tangled or too high a load for the pull - The height adjustment can be stuck in the bed so the overcurrent protection is triggered	- Deactivate the emergency stop by turn the emergency stop button and than press the “reset” button

Atle® Labels

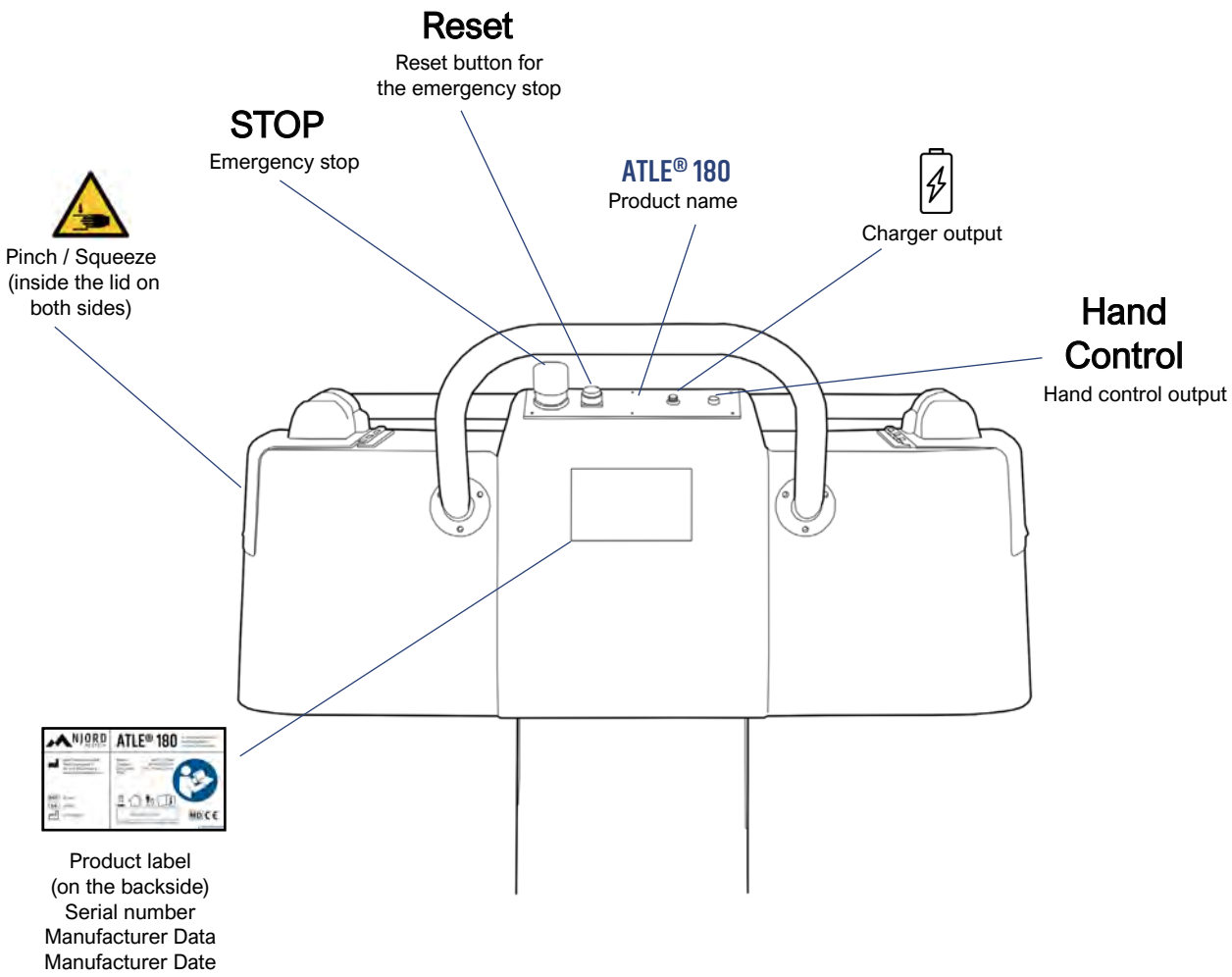


Fig 38

Product data

Life expectancy is 40,000 transfers with Atle® 180

Product information	Atle® 180
The total weight of the product	50 kg
Maximum patient weight to transfer	180 kg
Time required for transfer	15 seconds
Maximum temperature	43°C
Electrical	
Battery type	Lead, ventilated housing
Battery charger	24 VDC charger
Battery capacity	24V, 2.9Ah
Power source	Mascot 24V Lead Acid battery charger Type 2241P
Protection class	Class II, double insulated
Duty cycle	10 % 15 sec continuous pull with 2 min rest time
Atle® 180 meets the requirements of the EMC-directive (2014/30/EU) Atle® 180 meets the requirements according to standards: IEC 60601 regarding safety and essential requirements for medical electrical equipment.	
Mechanical	
Sound	< 59 dbA
Speed when transfer	7 cm/second
Protection rating (against moisture)	Atle® 180 system: IP20
Environmental conditions	
Ground Requirements	Maximum Slope: 1° Surface condition: Flat hard surface
Ambient temperature range	Operation: 5° to 40°C (+41 to +141 F) Storage: Indoor environment, not wet space
Relative humidity range	Operation: 15 to 93%, non-condensing Storage: <93%, non-condensing
Atmospheric pressure range	Operation: 795 hPa to 1060 hPa (2000 m max) Storage: 500 hPa to 1060 hPa

Technical specification

Safe Disposal and END of LIFE	
Battery	All batteries in the product must be recycled separately. Batteries are to be disposed in accordance with national or local regulations. Sealed lead-acid, rechargeable, recyclable.
Package	Wood and corrugated cardboard, recyclable.
Electrical and electronic components	Systems having electrical & electronic components or an electrical cord should be disassembled & recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.


Intended for indoor use


Class II, double insulated

WARNING: To avoid electric shock, make sure that the equipment is connected to:
- Continuously powered supply mains with protective earth
- A mains disconnection device

To disconnect the device, pull out the charger from the appliance and/or pull out the plug from main socket

Dimensions

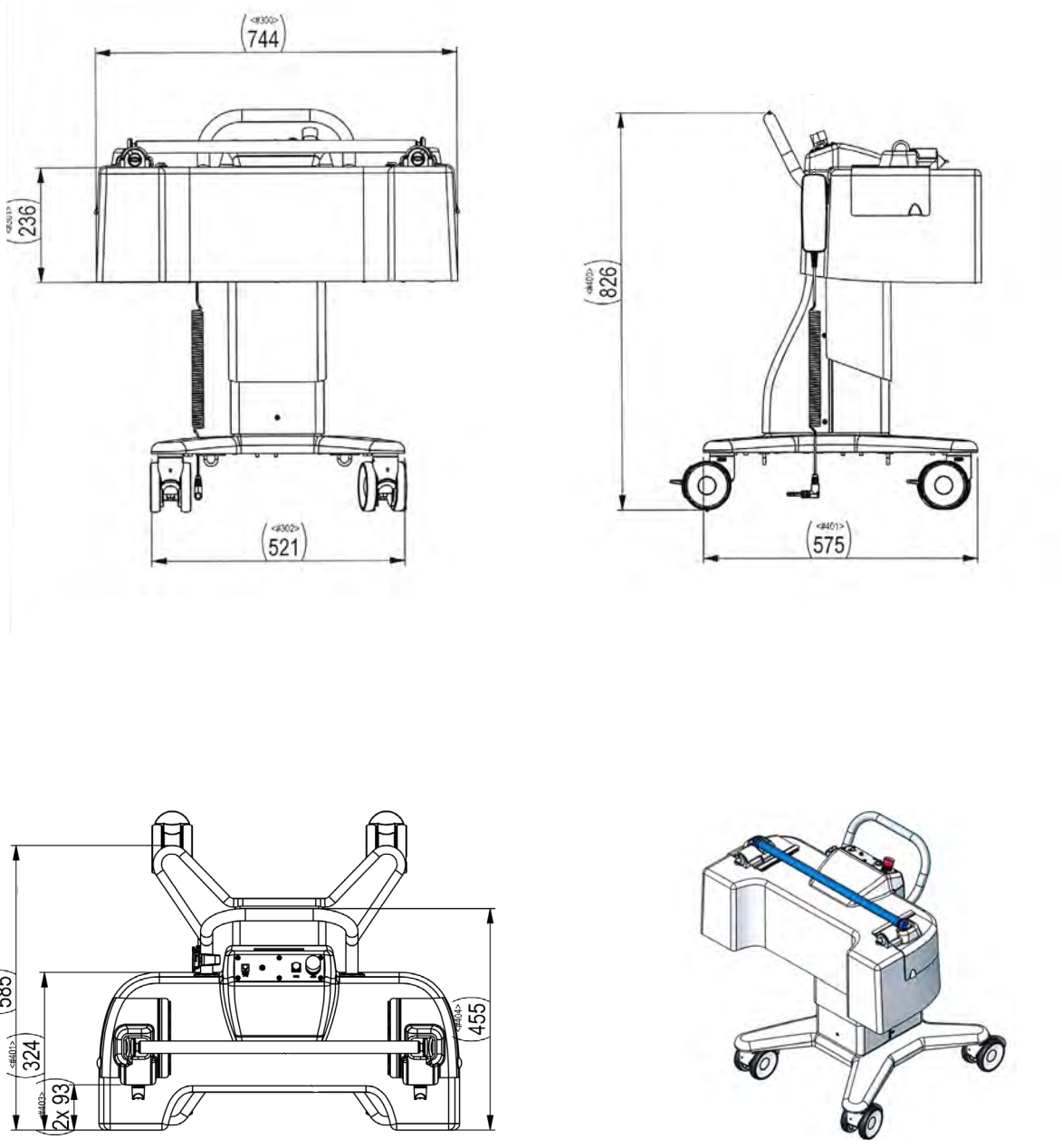


Fig 39

Electromagnetic Compatibility

Electromagnetic Compliance

Atle® 180 has been tested for compliance with current regulatory standards regarding its capacity to block EMI (electromagnetic interference) from external sources.

Nonetheless, some procedures can help reduce electromagnetic interferences:

- Ensure that other devices in patient-monitoring and /or life-support areas comply to accepted emissions standards.
- Maximize the distance between electro-medical devices. High-powered devices may produce EMI that can affect Atle® 180.

For more information on how to manage the unit's RF electromagnetic environment, please consult the AMI TIR 18-2010 - Guidace on Electromagnetic Compatibility of Medical Devices for Clinical / Biomedical Engineers.

NOTE: The emission characteristics of Atle® 180 make it suitable for use in hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) Atle® 180 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting Atle® 180

WARNING: Use of accessories, cables and spare parts other than those specified or provided by Njord Medtech could result in increased electromagnetic emissions or decreased electromagnetic immunity of Atle® 180 and result in improper operation

WARNING: To operate properly, Atle® 180 should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used

WARNING: Portable RF communications equipment should be no closer than 30 cm (12 inches) to any part of Atle® 180 to help prevent electromagnetic interference. Otherwise, it result in degradation of the performance of Atle® 180

WARNING: Significant risks of reciprocal interference may be posed by the presence of the system during specific investigations or treatments. Potential electromagnetic or other interference between the system and other devices may occur. If interference is suspected, move equipment from sensitive devices or contact the manufacturer

Electromagnetic Emissions

Guidance and Manufacturer´s Declaration - Electromagnetic Emissions - For all Equipment and Systems			
Atle® 180 is intended for use in electromagnetic environment specified below. The customer or the user of Atle® 180 should assure that it is used in such an environment.			
Emissions test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Conducted continuous emission EN 55011/ CISPR 11	Group 1/ Class A 0,15 - 30 MHz	Group 1/ Class A 0,15 - 30 MHz	Atle® 180 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The EUT has no applicable port.
Radiated emission of EM fields EN 55011/ CISPR 11	Group 1/Class A 30 - 1000 MHz	Group 1/Class A 30 - 1000 MHz	Atle® 180 is suitable to use in professional healthcare facility environment.
Limits for harmonic current emissions EN IEC/IEC 61000-3-2	Class A	Class A	The product has a rated active power P < 75 W at rated load condition. The product is deemed to comply with the standard without testing.
Voltage fluctuations and flicker EN IEC/IEC 61000-3-3 / EN IEC/IEC 61000-3-11	Class A	Class A	This product has a maximum power consumption of less than 75 W. It is therefore not likely to produce voltage fluctuations or flicker above the limits of the standard.

Electromagnetic Compatibility

Electromagnetic Immunity

Guidance and Manufacturer´s Declaration - Electromagnetic Immunity - For all Equipment and Systems			
Atle® 180 is intended for use in electromagnetic environment specified below. The customer or the user of Atle® 180 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance**	**Electromagnetic environment guidance**
ESD EN/IEC 61000-4-2	C: ± 8 kV A: ±2, ±4, ±8, ±15 kV	C: ± 8 kV A: ±2, ±4, ±8, ±15 kV	The floor should be made of wood, concrete or tiles. The EUT is not intended to be patient coupled.
RF EM fields EN IEC/IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz + table 9	10 V/m 80 MHz to 2.7 GHz + table 9	N/A
Prox. fields from wireless communication equipment EN IEC/EIC 61000-4-3	9 - 28 V/m 80 MHz to 6 GHz + table 9	9 -28 V/m 80 MHz to 6 GHz + table 9	N/A
Electrical fast transient/burst EN IEC/IEC 61000-4-4	± 2 kV AC mains 100 kHz frequency	± 2 kV AC mains 100 kHz frequency	Mains voltage should be at a normal level for a hospital environment and (1), (2).
Surge EN IEC/ IEC 61000-4-5	± 0.5 kV ± 1 kV	± 0.5 kV ± 1 kV	(2), (3)
Conducted disturbances, induced by RF field EN IEC/IEC 6100-4-6	3 V outside ISM bands between 0.15 -80 MHz 6 V inside ISM and amateur radio bands between 0.15 -80 MHz	3 V outside ISM bands between 0.15 -80 MHz 6 V inside ISM and amateur radio bands between 0.15 -80 MHz	The EUT is not intended to be patient coupled and (2)

Electromagnetic Immunity

Guidance and Manufacturer´s Declaration - Electromagnetic Immunity - For all Equipment and Systems			
Atle® 180 is intended for use in electromagnetic environment specified below. The customer or the user of Atle® 180 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Power frequency magnetic fields EN/IEC 61000-4-8	30 A/m 50/60 Hz 230 V, 50 Hz 100 V, 60 Hz	30 A/m 50/60 Hz 230 V, 50 Hz 100 V, 60 Hz	The magnetic fields around power supply linear should be on normal levels for typical commercial environment or hospital environment.
Voltage dips and interruption EN/IEC 61000-4-11	0% Ut for 0,5 cycle 70% Ut 25/30 cycles Single phase at 0°	0% Ut for 0,5 cycle 70% Ut 25/30 cycles Single phase at 0°	N/A
Proximity to magnetic fields Table 11 EN IEC/IEC 61000-4-39	30 kHz, 134,2 kHz, 13,56 MHz	30 kHz, 134,2 kHz, 13,56 MHz	N/A
Supplementary information: 1) The signal cable is less than 3 m 2) The DC cable is less than 3 m 3) The signal cable is not intended to be connected to outdoor cables			

Njord Medtech® is set on a mission to solve unmet needs in radiology and patient handling for sustainable healthcare. The company has been incubated within the Sahlgrenska University Hospital since 2017 and incorporated in 2019.

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NJORD MEDTECH