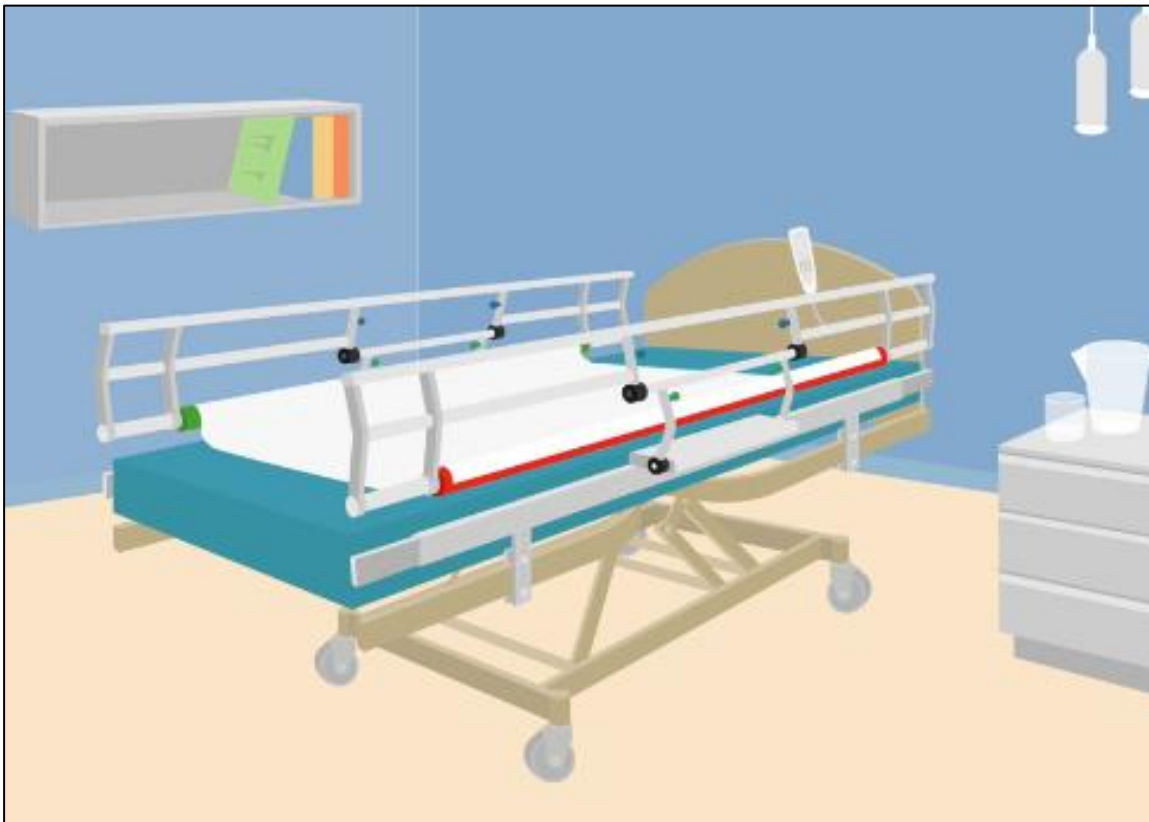


INSTRUCTION MANUAL
&
ASSEMBLY AND MAINTENANCE MANUAL
FOR
TURNAID T4 TURNING SYSTEM



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Certified ISO 13485:2016

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1. Manufacturer

Manufacturer of TurnAid T4 System

TurnAid ApS
Vejlevej 15
DK-7160 Tørring, Denmark

Phone: +45 40 90 50 60
Mail: info@TurnAid.dk
Web: www.TurnAid.dk

2. Application

This instruction manual is intended for the persons using the Turnaid for care, assembly, mounting or maintenance.



ALWAYS READ AND UNDERSTAND THE INSTRUCTION MANUAL BEFORE ASSEMBLY, MOUNTING, MAINTENANCE OR CARE TASKS

Please pay special attention to chapter 4 (Important/Warnings) and to chapter 21 (Risk Assessment and Safety).

TurnAid ApS cannot be held responsible if:

- TurnAid T4 is not used as instructed.
- TurnAid T4 is altered/assembled not in accordance with this Instruction manual.
- Maintenance and storage requirements are not followed.

Should you have any comments or corrections to this instruction manual, the assembly/mounting and maintenance manual, or the TurnAid T4 system itself, please contact us.

Warranty

For TurnAid T4, TurnAid ApS gives a two-year factory guarantee from supply of the system. The warranty is invalidated if the TurnAid is not used, assembled/mounted/dismounted or maintained according to this manual.

The expected useful life of the TurnAid is 10 years.

Only use original spare parts and accessories on the TurnAid.

Description of TurnAid T4 system

The TurnAid T4 consists of:

- 1 set of side rails with integrated electric turning system (right and left side).
- Mounting fitting with electro units: 1 control box, 1 hand control and motor cables.
- 1 Slide sheet
- 1 Turning sheet

Following accessories are available:

- Slide sheet
- Turning sheet
- Foot control
- Transport and mounting trolley
- Siderail bumpers
- Transport bags

TurnAid T4 is an accessory for mounting on care beds. It combines two well-known basic functions – bed rail and electric turning system.

The turning system operates two motors, one on each side of the bed, to drive a turning sheet to move a patient in bed. With a hand control the nursing staff controls the motor rolls.

The turning sheet is attached to each motor roller with Velcro-strips.

A slide sheet is placed on the bed's mattress. To fix this sheet to the mattress you apply 4 elastic bands in the sheet corners and to the movable parts of the lying surface you apply 4 Velcro strips.

TurnAid T4 has three settings:





"bed rail-position"
"working-position"
"folded position"




The TurnAid is adjusted between the settings by unlocking the release handles. Any alteration between settings is only possible with two hands.

Purpose:

- To provide a gentle and dignified handling of a patient.
- To create a care environment with reduced stress and discomfort.
- The bed/side rails ensure safe environment for the patient and the nursing staff.
- To assist the nursing staff with heavy turns and transfers.

Explanation of Pictograms

Pictogram	Denomination	Description
	Warning	This warning sign calls for your special attention.
	CE mark	The mark shows that the product complies with CE requirements. Declaration of Conformity to be found later in the manual
	IMPORTANT	Note especially!
	Level of sealing	Level of sealing IPX0 => No protection against water destroying the device. Not suitable for outdoor use.

Pictogram	Denomination	Description
Type	Type	Describes type of system.
	SPEED-control	Possibility to adjust the speed between 100 – 75 and 50%
• ON	Yellow diode lamp	The ON light diode is yellow when the system is active. If the system is not active, the light diode will be turned off. When the yellow ON lamp is glowing, the operator must <u>immediately operate</u> the TurnAid T4 system.
	Red and green push button (2 nd outermost switches on foot control)	Operating buttons for red and green motor roll, respectively -> tighten turning sheet. Both rolls cannot be operated at the same time. If both buttons are pressed at exactly the same time, you will hear a warning sound, which will stop after 5 seconds. This is the procedure if something goes wrong when operating the rolls and the system has to be reset.
	Red and green push button in continuation of above push-button (inner left and right switches on foot control)	Operating buttons for red and green motor roll, respectively -> loosening of turning sheet. It is possible to operate both buttons at the same time!
• TIME OUT	Yellow diode lamp	The TIME OUT light diode flashes when the system has not been activated for 80 seconds, and the system will give a beep. You can still operate the rolls. When the yellow ON lamp is glowing, the operator must <u>immediately operate</u> the TurnAid T4 system To proceed, the system can be reactivated by 1 push on the ON button. If the system is not reactivated, the lamp will illuminate constantly after 10 seconds, and the system cannot be operated before reactivation. If you do not reactivate the system, the system will turn off completely after 60 seconds.

Requirements to Users of TurnAid T4

Operation demands:

Maximum operation ambient humidity and atmospheric pressure range:

Temperature: minus 5 degrees up to 40 degrees Celsius.

HPA - atmosphere pressure: 800 – 1060

RH - air humidity: 20% - 90% not condensing

Duty cycle from control box → 2min (on)/18min (off)

- Only competent persons should operate the system.
- ONLY competent persons may undertake assembly, mounting, service, and repair of TurnAid T4.
- The user of TurnAid T4, the person using the bed, is hereafter called the **patient**. This person must not operate TurnAid unless a risk assessment has been carried out and it has been defined that the patient is safe to operate the system

2.1 Area of application

TurnAid T4: has a safe patient working load of 40 kg -350 kg

- Minimum: 40 kg
- Maximum: 350 kg

Use TurnAid T4 when the patient is to be transferred/positioned in the bed:

- Between lying on the back, the side, or the stomach.
- Vertically and horizontally in the bed.
- Transfer (as assistance) in and out of bed.

The target group comprises:

- ✓ Persons, in need of assistance with hygiene, getting dressed etc.
- ✓ Persons, lifted in and out of their bed (by means of separate lifting device).
- ✓ Persons mobilised by means of a standing aid.

The typical target group for TurnAid T4 is hence a patient with reduced self-care functions or a palliative patient.

TurnAid T4 is especially suitable for patients at risk of pressure ulcers (decubitus). The construction of the system allows a movement in the sheet which reduces the friction between the patient and the sheet; a friction which often results in tissue damage and causes pressure ulcers.



Keep the hand control(s) out of the patient's reach.



Prior to using TurnAid T4, make sure the system is well-suited for the patient.

3. Accessories

Slide Sheet and Turning Sheet

TurnAid T4 presupposes the use of both a slide sheet and a turning sheet. Extra quantity of these to be ordered separately as the sheet quantity should fit the number of patients and relevant care situations. As a minimum, we recommend that you always have an extra set of slide sheet and turning sheet.


Extra Hand Control

If your supply of TurnAid T4 only comprises 1 hand control, TurnAid T4 can be equipped with an extra hand control. This means if you have two carers, it is possible to have a hand control each side of the bed.


Foot Control


TurnAid T4 to be mounted with one or two foot controls. This will ease the operation of the system, if both hands are required to support the patient. A foot control can be used parallelly with 1-2 handsets. The foot controls are like the handsets secured against incorrect operation – so simultaneous activation of switches will cause nothing to happen.

4. Important warnings


 NEVER use TurnAid T4 otherwise than stated in this instruction manual.

 Any children in the vicinity of the TurnAid T4 must be supervised at all times.

 Always check the TurnAid T4 according to the maintenance instructions in this instruction manual.

 If the TurnAid is not operating correctly stop using the TurnAid T4 and contact the TurnAid dealer.

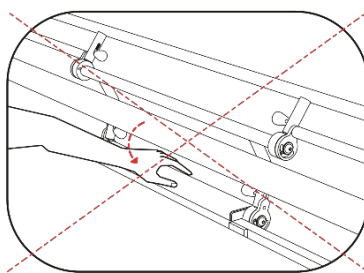
 Never move the bed if the TurnAid T4 is plugged into the mains supply.

 Only competent carers should operate the TurnAid T4.

- ⚠ If the TurnAid T4 is being reused for another patient, be aware that it could be contaminated.
- ⚠ An assessment by a competent professional must be carried out on the patient to ensure the product is suitable.
- ⚠ Do not exceed the duty cycle of the motors.
- ⚠ The TurnAid T4 is intended for interior use only.
- ⚠ A patient showing violent behavior must not use the TurnAid T4.
- ⚠ Ensure mains cable does not get trapped in the TurnAid T4 or the bed.
- ⚠ Avoid spilling liquids or water on the electrical system.
- ⚠ Always fully check electrical system if it gets wet.
- ⚠ Patients must not smoke in a bed fitted with a TurnAid T4.
- ⚠ The TurnAid T4 can be used as a side rail so patients must be assessed for the use of a side rail.
- ⚠ Only competent persons should assemble /disassemble and maintain the TurnAid T4.
- ⚠ NEVER leave TurnAid T4 in "**working-position**" when a patient is in the bed.
- ⚠ ONLY use TurnAid T4 when correctly mounted.
- ⚠ WARNING: No modification of this equipment is allowed
- ⚠ Keep the hand control(s) out of the patient's reach.


- ⚠ When setting the 3 TurnAid T4 positions ALWAYS pay attention to the following:
 - Make sure the patient's fingers, arms, legs, hair and any connected equipment are not caught during setting of the system.
 - Before and after setting ALWAYS check for clearance around the patient.
 - ALWAYS check that the release handles are locked correctly after setting.

- NEVER use force or power when setting the system.
- Do not squeeze own hand/finger between the round metal bars when alternating position of the system.



Do not squeeze your hand/finger between the round metal bars when alternating position of the system.

 Warning: Risk of foot entrapment when used on a low bed.

 Warning: Materials used on the TurnAid could cause allergies.

- NEVER pull the patient over the bed side.
- Having terminated turning or repositioning the patient, ALWAYS check that the patient is positioned safely and correctly.
- Familiarize yourself with the symbols of hand control– see chapter 2 (Explanation of Pictograms).
- Pay attention to the location of the quick guide and use this in case you have doubts during an operation situation.
- Do NEVER exceed the patient's MAX. weight of 350 kg.
- NO extra persons are allowed in or on the bed besides the patient.

4.1 Primary requirements for the bed

For mounting of TurnAid T4, the care bed must comply with the following demands:

- The Bed must be manufactured according to EN 60601-2-52. If the bed fails to comply with the standard, we cannot guarantee that TurnAid T4 complies with safety demands.
- DO NOT EXCEED the bed's max. load and max. user weight when TurnAid T4 is mounted. The TurnAid T4 system has a total weight of 46 kg.

4.2 Compatibility between the bed and the mattress

☞ Observe the following requirements for bed and mattress:

- BED: The TurnAid T4 system is designed for mounting on beds with square side bars on the lying surface between the headboard and footboard.
- Ensure that the gap between the headboard or footboard and the TurnAid T4 meets the requirements for gaps to ensure there are no entrapment risks. Here you must observe a distance of 25 to 60 mm. You can adjust TurnAid T4 length to fit between the headboard and footboard.



- You can mount TurnAid T4 on beds with various widths. The only requirement is that both the slide sheet and the turning sheet must fit the width of the bed.
- MATTRESS: The mattress must fit the bed and comply with the demands of the bed manufacturer.

We recommend that you firmly inflate an alternating pressure mattress before operating the TurnAid T4. A soft mattress will give an uneven support for the patient and thus increase the friction onto the mattress. If you inflate the mattress firmly, friction is reduced and turning will become gentler and more comfortable for the patient. If the mattress is soft, you must ensure that there is no risk of entrapment due to extra compression at the mattress side.

CHANGE OF MATTRESS: When changing the mattress observe that the height for TurnAid T4 *may* have to be altered – see chapter 7.

A too low positioning will make it impossible for the nursing staff to change between **"working-position"** and **"bed rail- position"** as the roll will go against the mattress.

4.3 In general



Observe the following:

- During **assembly/mounting** ensure that no parts, fittings or cables are damaged or squeezed when changing between all the possible positions. This applies for both the bed and TurnAid T4.
- Leave the bed in a position where no one can get injured. If there is a person in the bed, TurnAid T4 must be folded to "**bed rail-position**". In this case, do not forget that the turning sheet must be tightened as much as possible.
- If there is NO person in the bed, you can leave TurnAid T4 in "**folded-position**".
- Do NOT expose the connection cable for TurnAid T4 to unnecessary pulls or sharp bends. In case of a damaged cable, disconnect TurnAid T4 from the power supply and call for a service technician.
- Connect the TurnAid T4 plug to power from electrical outlet.
- When applying other equipment with tubes, wires, or the like please take special care in connection with all moving parts. Cf. chapter 6.14.

4.4 Inspection upon receipt

Upon receipt of TurnAid T4 check packaging. If the system shows any sign of damage, please do not hesitate to contact TurnAid ApS.

4.5 Inspection prior to daily use

1. From top of mattress to top of bed rail ("**bed rail-position**") there has to be a minimum of 230 mm.
2. The TurnAid T4 length adjustment bar must be placed at the foot end of the bed.
3. From the end of the TurnAid T4 to the headboard or footboard of the bed there have to be min. 25 and 60 mm.



4. The sheet must be mounted so it goes from the top of the mattress to the top of the rolls. Make sure, when operating the rolls that direction and side correspond to the symbols on hand control.
5. Electric parts to be mounted with **red** roll to **red** input and **green** roll to **green** input. Make sure there is nothing underneath, above or close to the system which can restrict its movement, e.g. furniture, window seats, or storage boxes.
6. Avoid that the power cable being damaged in moving parts. Ensure that the bed, upon which TurnAid T4 is mounted, does not have any cables which could be damaged by the TurnAid T4.
7. No cables or other equipment to be squeezed or damaged in any other way when TurnAid T4 is in use.
8. Visually make sure that TurnAid T4 is without damage.
9. The turning sheet is in good condition and goes correctly on the motor rolls.
10. The slide sheet is in good condition and correctly mounted.
11. When connecting the system to the power supply, the function of the hand control(s) system is correct.
12. The quick guide for use of the system is visible close to the bed and is clean and undamaged.

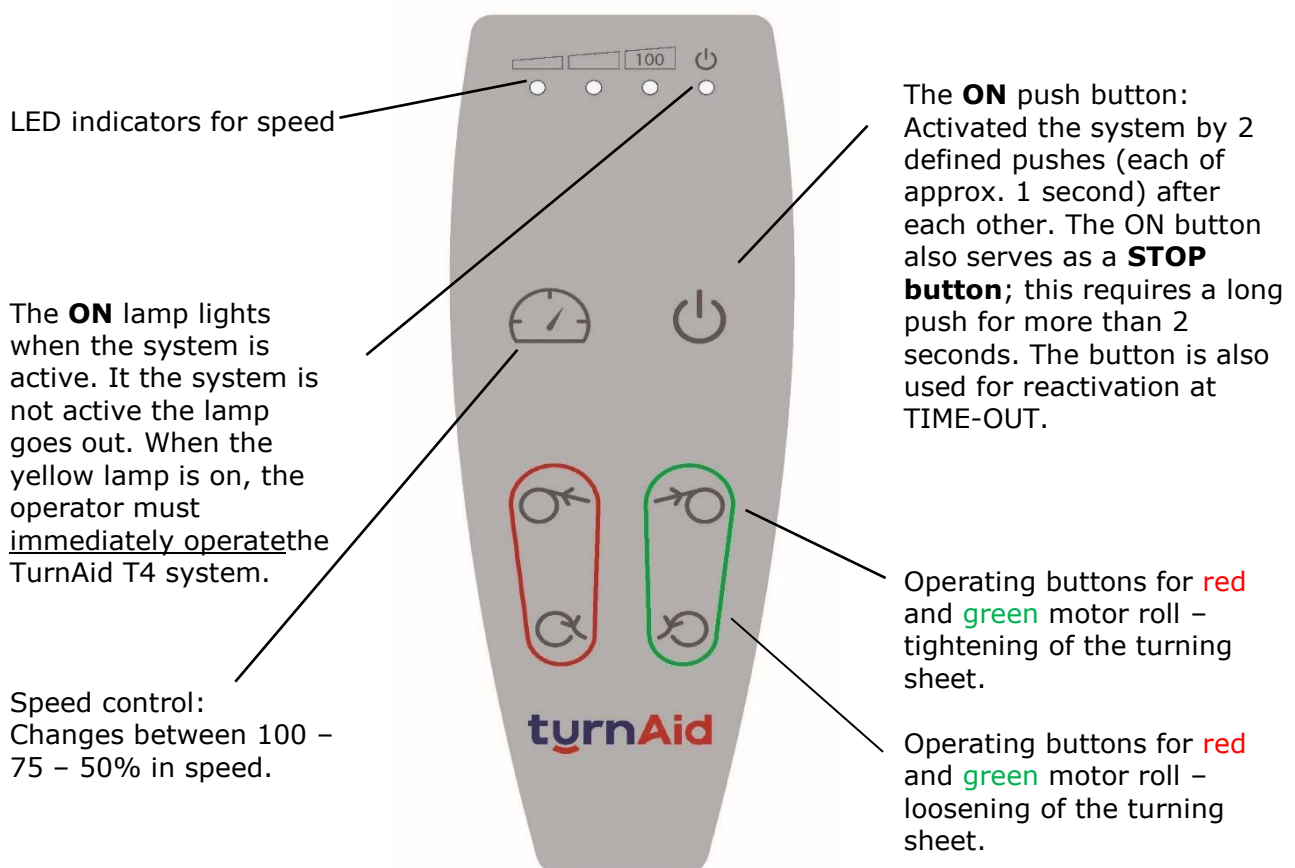
5. Description of functions

TurnAid T4 is designed according to the standard for care beds EN 60601-2-52, and TurnAid T4 complies with all relevant demands for a bed rail.

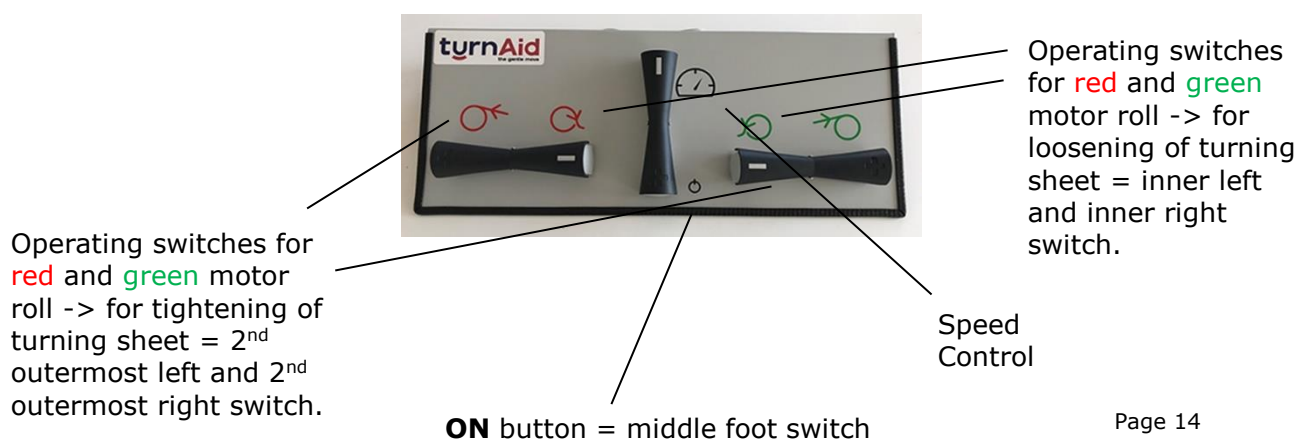
When working with TurnAid T4 and the care bed we recommend that you maintain the bed's height adjustment for the relevant working situations. The bed's height adjustment is not decisive for TurnAid T4's function, but it is important for the carers working position and health.

In general, you operate TurnAid T4 by means of a hand control, however the system can also be operated via foot controls. Especially when turning a person foot control can give carers 2 free hands to guide and support the patient.

HAND CONTROL T4



FOOT CONTROL



These instructions presuppose that TurnAid T4 is mounted so right motor roll is **GREEN** – seen from the top of the bed – and left motor roll is **RED** – seen from the top of the bed.

When you fold T4 as shown here in fig. 5.1, the system is in "**bed rail- position**", and having ensured that the turning sheet has been reeled in adequately tightly it is safe to leave the patient without any further precautions.



Fig. 5.1 – "**Bed-rail position**" (during turning)
one side has the roll on top and the other side operate as bed rail


 For alteration of TurnAid T4 to "**working-position**", **release** the two blue handles and fold the top part for the roll with sheet to go at the top. Please note positions of your hands in relation to the release handles. The opposite side remains as bed rail so the patient has a clear view.



Fig. 5.2 – "**Working-position**" (during turning)
the roll in one side is turned from the bottom position to the top position

Now, use TurnAid T4 as help for gentle turning of the patient. If the patient is to be turned by the motor roll, which is against a wall, do not forget to move the bed away from the wall.

The third position for TurnAid T4 is **"folded-position"** (out of bed-position).

If the patient cannot get to the bed side independently, the nursing staff may assist by pulling the person by the sheet. For this, lower TurnAid T4 to **"folded-position"**, fig. 5.3.

- ⚠ When you apply **"folded-position"** to move the patient out to the side of the bed, pay attention that the person is not moved over the edge. Also, note standard rules for any work with sheets and care beds.



Fig. 5.3 – **"Folded-position"** (out of bed position)
for working with the patient at e.g. washing, dressing, undressing etc.

- ⚠ Move the bed away from the wall, if **"folded-position"** is required on both sides of the bed. NEVER leave the patient alone in the bed with **"folded-position"**.

6. Operation

6.1 In general


The next pages will give you various scenarios for operating and transfer situations.

- ☞ In operation, right side is the **green** motor roll (seen from the top of the bed) and left side is the **red** motor roll (seen from the top of the bed)

- ☞ For any transfer, consider if the action in question requires the bed to be moved away from the wall.

- ⚠ During ALL turning and transfers of the patient, ALWAYS note the position of the patient's

limbs. Thereby you avoid any unintentional entrapment of the limbs. Before commencing turning, note that turning of the patient should be made in ONE fluent movement with no interruptions.

 During change of slide or turning sheet or cleaning of the bed, when the patient is in the bed:

- Remove the care-bed from the wall if it was positioned up against a wall.
- Keep the hand control(s) for TurnAid T4 out of reach of the patient.

We have described the following situations with the use of hand control:

- ✓ Turning.
- ✓ Transfer from side to side in the bed
- ✓ Repositioning further up in the bed.
- ✓ Placement of sling.
- ✓ Mobilising out of the bed.
- ✓ Transfer from standing in front of the bed to sitting in the middle of the bed.
- ✓ Turning sheet is incorrectly fitted on the motor rolls.
- ✓ Simultaneous use of the functions for TurnAid T4 and bed.
- ✓ Simultaneous use of 2 hand controls and 2 foot controls.
- ✓ Emergency Stop.
- ✓ Placement of sheet.
 - Placement of slide sheet.
 - Placement of turning sheet.
 - Sheet sizes.
- ✓ Alternating pressure mattresses.
- ✓ Simultaneous use of TurnAid T4 and catheter bags, probes, drains etc.
Please see www.turnaid.dk for further information.

6.2 Turning

You may use TurnAid T4 for turning the patient from the back onto the side (and back) and from the side onto the stomach (and back). Following example illustrates turning from the back to the left side.

- Adjust red motor roll to "**working-position**", cf. fig. 6.2.1 below, i.e. release the two blue handles and fold the top part for the roll with sheet to go to the top.

 Note the position of the nursing staff's hands in relation to the handles. Green motor roll can be set to "**bed rail-position**" or "**working-position**".

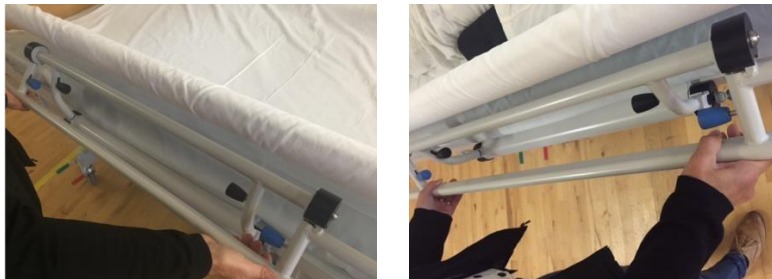


Fig. 6.2.1 – “**Working-position**” during turning



- Power on TurnAid T4 by double-clicking (2 defined pushes) .
- Press  to pull the patient towards you. **Red** motor roll now helps turning the patient from side to side.
- Before the patient starts to turn, bend his/her leg closest to you and at the same time place his/her closest arm on his/her stomach or chest.



Fig. 6.2.2 – Initiating turning

- Continue turning of the patient with the motor roll while you support the person's head and hips until the patient is lying on the side. Then place the patient's lower legs parallel while the upper top leg is slightly bent, cf. fig. 6.2.3. If needed, position a cushion along the patient's straight leg so the top leg may rest on this upon turning.





Fig. 6.2.3 – Adjustment at turning

Apply same turning principle in care and hygiene situations.

6.3 Transfer from side to side in the bed

TurnAid T4 works as an aid if the patient is to be transferred onto the bed side.

Small adjustments of the patient's lying position should be made at **"bed rail-position"** fig. 5.1.

- For easier access to the patient, fold down TurnAid T4 at the side to facilitate access for nursing staff, cf. fig. 6.3.1. In this case, we describe the scenario from the left side of the care bed, and the red motor roll is used.
- Power on TurnAid T4 by double-clicking (2 defined pushes)  .
- Activate the motor on the side to which you want to move the patient.
- Press – and keep pressing – one of the following  to pull the patient towards **red** or **green** side. The motor roll assists in the transfer of the patient in the bed.

☞ NEVER let the patient get into contact with the side rail.

☞ NEVER pull the patient further out than the mattress and lying surface allow.

6.4 Repositioning further up in the bed

When the headrest section of the bed has been raised, the patient will often slide towards the bottom of the bed. To avoid this, elevate the bed's knee break section before the headrest section. Having done so and the patient still slides down in the bed, the turning sheet will typically follow the person's body. To reposition the person in the top end of the bed:

- Place the bed platform in a horizontal level.
- If needed, fold TurnAid T4 to **"bed rail-position"**, cf. fig. 6.4.1 below, to lower the motor rolls (in case they were folded to **"working-position"**).



Fig. 6.4.1 – “Bed rail-position”




- Power on TurnAid T4 by double-clicking (2 defined pushes)  .
- Press  simultaneously to completely loosen the turning sheet. (If required, these two push buttons can be operated simultaneously).
- Place yourself at the top of the bed and alternating press  to pull the patient from side to side while, with a light hand, you guide the turning sheet back towards the top part of the roll motor.
- Repeat the procedure on the opposite side and so on until the sheet has reached its place.



Fig. 6.4.2 – Transfer further up in the bed

6.5 Placement of sling

When using TurnAid T4, it is simple to place a sling for the patient.


- Power on TurnAid T4 by double-clicking (2 defined pushes)  .
- Use the turning function of TurnAid T4 to turn the patient onto the side.



Fig. 6.5.1- Turning onto the side

- Place the sling along the back of the patient. Make sure to center and place the sling correctly according to the instructions from the sling manufacturer.

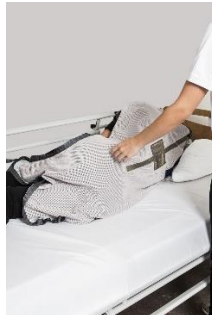


Fig. 6.5.2 – Placement of sling

- Use the turning function of TurnAid T4 to reposition the patient onto the back.



Fig. 6.5.3 – Returning to the back

- Pull straps free from the opposite side.
- Place all straps so they are ready for attachment to the lift.
- Fold TurnAid T4 to "**folded-position**" (fig. 5.3)
- Now, you can lift the patient.

6.6 Mobilising out of the bed

TurnAid T4 may be used as an aid when you mobilise the patient out of bed; below this is shown in combination with a person turn table.



- Power on TurnAid T4 by double-clicking (2 defined pushes)  .
- Apply TurnAid T4's turning function as described above to situate the turn table under the patient.



Fig. 6.6.1 – Situation of person turning device

Possibly fold TurnAid T4 to "**bed rail-position**" to lower the motor rolls if they were previously been folded to "**working-position**".

- Press  to loosen the turning sheet. (These two push buttons can be operated simultaneously, if required)
- Raise the backrest to allow the patient sit up.

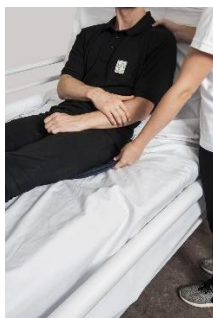


Fig. 6.6.2 – The patient gets into sitting position

- Lower the bed so the patient has good foot support when he/she is moved towards the bed edge.

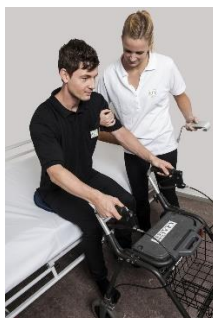




Fig. 6.6.3 – The patient sits on the edge of the bed

- Rotate the turn table so he/she gets the feet over the side of the bed. (When the patient has found his/her balance, you may elevate the head end of the bed, and the patient can use this for support).
- Lower the bed's back part when the patient can balance or has alternative support.
- Press  to move the patient further out to the bed edge.
- Lower the bed until patient's feet have contact with the floor.
- Press  to move the patient closer to the bed side while the bed is lowered again. This will assist the patient to gain a standing position.

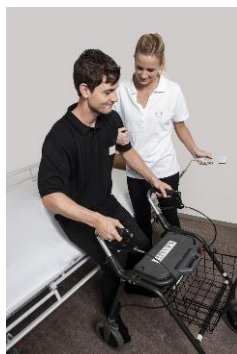


Fig. 6.6.3 – The patient gains a standing position

You may also use the above technique if the patient is to be pulled to the bed side. This could be in connection with personal care. REMEMBER: Lower TurnAid T4 to **"folded-position"** (out of bed position), cf. fig. 5.3.

6.7 Transfer from standing in front of the bed to sitting in the middle of the bed

Provided the patient still has a degree of independent standing function, the turning sheet of TurnAid T4 can assist the patient to get back into the bed.




- Fold TurnAid T4 to **"folded-position"** and tighten the sheet's center mark (center stitch on fabric) towards the motor roll in front of you.
- Adjust the height of the bed to suit the patient, who with his/her ability to stand can seat himself/herself on the bed.
- Lower the bed height. Tighten the sheet with the TurnAid T4 motor roll behind the patient. Gently pull the patient into a sitting position in the middle of the bed.

6.8 Turning sheet in incorrectly fitted on the motor rolls

In some cases, the turning sheet can be obliquely rolled onto the motor rolls. In principle, this does no harm and you can still use TurnAid T4. However, prolonged oblique operation will give creases in the turning sheet under the patient with potential consequences such as decubitus.

If the turning sheet goes less than 80 mm obliquely on one of the motor rolls, the nursing staff can straighten the turning sheet.

If the turning sheet goes more than 80 mm obliquely on one of the motor rolls, do the following:

- Power on TurnAid T4 by double-clicking (2 defined pushes)  .
- Loosen the turning sheet to make it go straight again. Press .
- Tighten the sheet again by pressing  while you straighten/guide the sheet into correct position with you hand.

For a more detailed description, see cf. instructions under 6.12.2 – Positioning of turning sheet.

6.9 Simultaneous use of functions for TurnAid T4 and the care bed.

TurnAid T4 does not affect the functions of the bed. ONLY REMEMBER to loosen the turning sheet before elevating the bed's back, thigh, or foot part.

Normally, you make the bed flat before the use of TurnAid T4. In some situations, it may be an advantage to raise the bed's backrest or footrest section before turning. If the patient is wide across the hips and at the same time narrow across the shoulders, a slight raise of the bed's backrest or footrest section during turning will provide a better positioning of the patient.

Prior to raising the bed's headrest or footrest, TurnAid T4 must be adjusted to "**working-position**".



6.10 Simultaneous use of 2 hand controls/1 hand control

As standard, TurnAid T4 will be supplied with one handset. It is possible to add another handset or foot controls. It is possible to use up to 2 handsets and 2 foot controls simultaneously.

With several operating units, you cannot activate several functions on each single control at the same time. Excepted from this is loosening of the turning sheet, i.e. simultaneous use of



With 2 hand controls, 2 persons can carry out transfer/turning without having to pass the hand control from one person to the other. Each person can have one hand control on his/her side of the bed.

6.11 Speed Control

The TurnAid handset and foot control both have a new function. Pressing the button **Speed Control** it is now possible to change between 3 different speeds: 100% - 75% - 50%. This means that if a patient feels insecure, the turning procedure can be carried out more slowly.

6.12 Placement of sheet



*A slide sheet is placed directly on the bed's mattress. On top of this, the turning sheet is placed and attached to the 2 motor rolls - respectively the **green** and the **red**, NEVER place anything between the slide sheet and the turning sheet. This will impact on the sliding effect. For placement of both sheet types, always make sure that the bed is in a flat position!*

The below instructions for placement of slide and turning sheet, respectively, are without the patient in the bed. However, both the slide and the turning sheet can be changed with the patient in the bed.

6.12.1 Placement of slide sheet

- Place the slide sheet on top of the mattress with right side turning upwards. To make sure of this, check the edge stitching.
- Fit each of the 4 elastic bands of the slide sheet around each corner of the mattress.
- Attach the 4 Velcro tapes (located onto the bottom side of the slide sheet). Each tape is attached around the bed's adjustable surface parts which follow the lying surface up and down when elevated.





 If the straps are wrongly attached to the bed's outer frame or the motor rolls, the straps and possibly the system together with the bed will be damaged, when the bed's surfaces are raised.




Fig. 6.12.1.1 – Placement of slide sheet

 The slide sheet for TurnAid T4 creates the sliding effect between the slide sheet and the turning sheet. For this reason, the slide sheet cannot be compared with the slide sheet traditionally used for the manual handling of persons without the use of a turning device.

 When placing the slide sheet on an alternating pressure mattress, the mattress should be fully inflated. This should be done before any placement of the sheet takes place, and you should make sure that the straps are not tightened too much as this may decrease the functionality of the mattress.

 The slide sheet is a wearing part. In case there is any damage to the sheet, make sure to replace it.

6.12.2 Placement of Turning Sheet

- Power on TurnAid T4 by double clicking (2 defines pushed)  .
- Fold both sides of the system to "**working-position**" so both motor rolls will turn upwards.

- Turn each motor roll so the Velcro tape appears on the top side of the roll.
- Place the turning sheet in the middle of the bed with the Velcro tapes on each side of the sheet along the rolls. REMEMBER to place the sheet with its bottom side downwards so its Velcro tapes also turn downwards.
- Starting with the upper sheet corner, attach the Velcro tape to the roll in one sliding movement while your hand straightens the sheet all the way down to the bottom end. The sheet must turn across the top side of the roller, to ensure a correct direction of the sheet when you operate the rolls. A wrong placement may cause the patient's arms, fingers or others to be trapped between the sheet and the roll. The control only provides a low power to the motors in the tightening direction and they will stop in case there is any overload in this direction.



Fig. 6.12.2.1 – Attachment of turning sheet to motor roll





- Tighten in approx. $\frac{3}{4}$ of the sheet on the motor roll by pressing  or  on the hand control.
- Attach the turning sheet to the Velcro tape on the opposite motor roll.
- Tighten the turning sheet on the motor roll by pressing  or  until it is straight on the mattress with its dark stitching in the middle of the mattress.



Fig. 6.12.2 – Reeling in of turning sheet

RECOMMENDATION: If possible, keep the sheet's dark stitching in the middle of the mattress. This ensures the same amount of sheet on both sides.



Attention: If the turning sheet is worn or damaged it should be replaced.

6.12.3 Sheet sizes

Both the slide sheet and the turning sheet are available in sizes suitable for standard beds. They are also available in larger widths, allowing TurnAid T4 to be fitted to wide beds.

For Mattress Width 80-90 cm (Standard)

Slide sheet width 95 (standard) Turning sheet width 350 cm (standard)

For Mattress Width 95-110 cm

Slide sheet width 115 cm Turning sheet width 400 cm

6.13 Alternating pressure mattresses

If you use an alternating pressure mattress for the patient, it can be an advantage to set the mattress to firm before you commence turning with the turning sheet. This will reduce the friction and increase the comfort for the patient.



After use, only loosen the turning sheet a little.



NEVER mount the slide sheet too tightly so it pulls the mattress down.

6.14 Simultaneous use of TurnAid T4 and catheter bags, probes, drains, and similar

You may use TurnAid T4 for a patient who also uses a catheter bag, probes, drains, infusion or similar. Cables and tubes etc. for the above systems risk being squeezed or damaged by the system if they are not positioned correctly through the system sides.

Consequently:



Always position tubes and cables through the opening between each system side and the head or footboard.

NEVER hang containers for infusion, nutrition or drain fluids directly on any parts of the system.

NEVER position tubes and cables through any openings in the system sides.

7. Unpacking and preparation

A complete TurnAid T4 system consists of 2 system sides (bed rail sides) with motor rolls and electronic parts. The motor rolls for the bed side rails are color coded, where **GREEN** is right side, seen from the top of the care bed, and **RED** is the left side, seen from the top of the care bed.

Always make sure the system is complete. A parts list and an assembly/mounting guide will accompany your product.

The standard version includes all parts to fit the bed/mattress, and for TurnAid T4 to function as intended.

We recommend that you use a transport/mounting trolley when transporting the system. If the system has to go upstairs, all lifts, where possible, should be made by 2 persons.

8. Assembly prior to use

Prior to use please check that the bed is suited for TurnAid T4. Installation of TurnAid T4 must be carried out by a competent person.

8.1 Requirements for the bed

The bed must comply with the standard EN 60601-2-52.


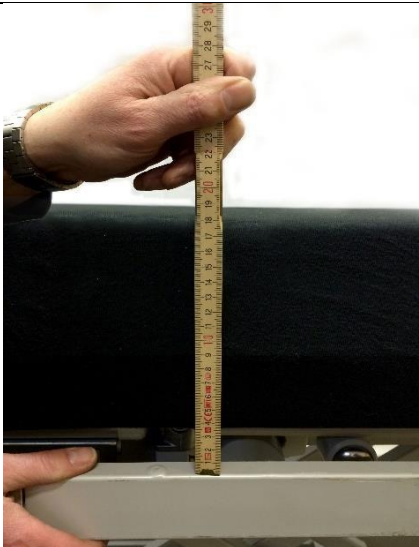

Demands of the bed manufacturer:

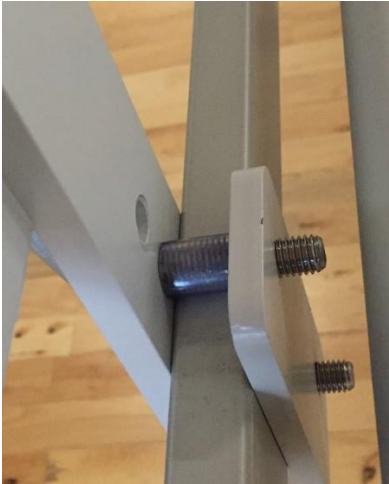


NEVER exceed the bed manufacturer's guidance for max. user load and max. user weight when TurnAid T4 has been mounted.



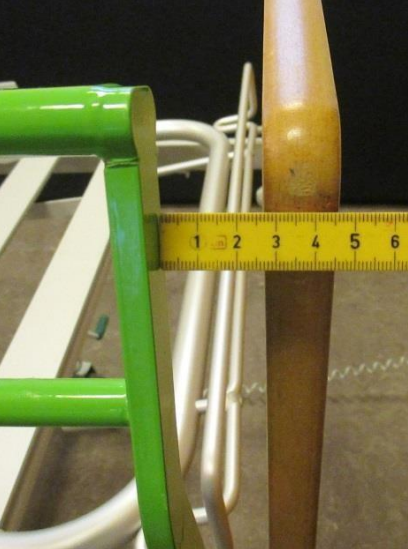



Weight TurnAid T4: 46 kg.






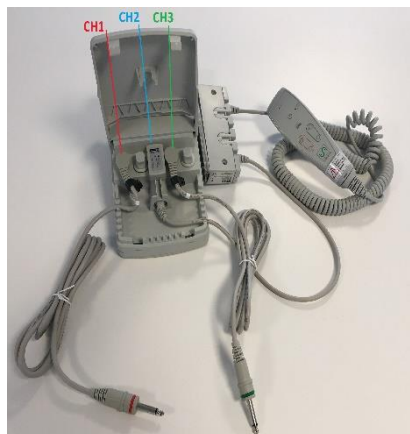
Calculation of user weight: With a bed of SWL (safe working load) of 350kg, the maximum patient weight will reduce due to the weight of the TurnAid device. Please refer to the bed instruction manual for information on the weight capacity.

8.2 Assembly

		
<p>Tools necessary for assembly:</p> <ul style="list-style-type: none"> • 8 mm Allen HEX wrench • 4 mm Allen HEX wrench • 3 mm Allen HEX wrench • Folding ruler or measuring tape 	<p>Measure the height from the bed's side-frame bar to the top of the mattress.</p>	<p>Take off the mattress and existing bed rails to make room for TurnAid T4.</p>

		
<p>Place the fitting in the correct height in relation to the distance you measured between frame and mattress. Screw in the bolt with the plastic hose in the top. Cf. this picture for correct height.</p>	<p>Place the 2 combined bed rails with motor roll from TurnAid T4 on the bed sides. The bar marked with green goes to the right side of the care bed (seen from the head end) and the bar marked with red goes to the left side of the care bed (seen from the head end).</p>	<p>Situate both bed rails with the square bar at the bottom right to the headboard at the top of the bed allowing between 25 mm and 60 mm between bed rail and headboard.</p>

		
<p>Tighten both bolts on both sides.</p> <p>Warning: If fitted to a low bed, ensure the TurnAid T4 does not hit the floor.</p>	<p>Loosen the shoulder bolt in the bottom part with a 3 mm Allen key.</p>	<p>Pull out the extension allowing for a 25-60 mm gap between the footboard and TurnAid T4. Retighten the shoulder bolt. Repeat on the opposite side.</p>
		
<p>Loosen the shoulder bolt to adjust the lower bar. Pull this out towards the footboard and tighten the bolt again. Repeat on the opposite side.</p>	<p>Height adjustment is correct when the bar is just above the mattress top side and there is a minimum gap of 22 cm from mattress surface to the top of the bed rail.</p> <p>Do not forget to retighten the bolts.</p>	<p>The control box and hand control are pre-assembled and it should not be disassembled. Only pull out the plugs for the motor rolls if you have to transport the system</p>


		
<p>Loosen the 2 screws on the bracket so it goes over the frame at the head end of the bed.</p>	<p>Mount the control box with the bracket on the traversing bar at the head end of the bed so the cable fittings face downwards. Tighten the 2 upper screws to secure the fitting.</p>	<p>Check the cables for motor rolls are mounted. Red side into CH1 and green side into CH3.</p>
		
<p>Mount the jack plug for the motor roll in the end of each roll. Make sure the cable from CH1 is the red side and cable from CH3 is the green side.</p>	<p>Position the cables to the control box so they do not get crushed or trapped. Check this with the bed in its lowest position.</p>	<p>Mount the signal cable from the foot control and motor cable. The motor cable goes into CH2, and the signal cable for the foot control goes into free plug on the junction box under the control box.</p>

		
	<p>Let the cables of the motor roll hang in a loop from under the roll on the exterior side of the square bar to under the bed. Check: motor cables are not too tight with the motor rolls in top position. Ensure there is no risk of cable entrapment e.g. by a brake pedal, when the bed has been completely lowered.</p>	<p>Adjust the length with the roll folded to "working-position" (rolls in top position). By this the jack plugs will not be damaged during use.</p>
		
<p>Test all functions of TurnAid T4 and the bed. Make sure that nothing is trapped and no electric cords are pulled.</p>	<p>Attach the quick guide to the footboard of the bed.</p>	<p>Fix the slide sheet to the mattress (cf. chapter 6.13.1). Start by positioning the elastic cord around the individual corners on the mattress.</p>

		
<p>Slightly elevate the lying surfaces of the bed and with the Velcro straps attach the slide sheet to the parts of the lying surface. Make sure not to fasten the straps to the bed itself - only to the movable parts of the lying surface.</p>	<p>Fix the turning sheet (cf. chapter 6.13.2.). Fold the motor roll upwards. Place the sheet on the bed with the Velcro side facing down. Start at the top end of the bed and attach the sheet to the roll in one long sliding movement.</p>	<p>Tighten the sheet on the roll and attach the sheet in the same way on the opposite roll.</p>
		
<p>Straighten any creases by tightening the sheet forwards and backwards between the rolls. If needed guide the sheet by hand.</p>	<p>Loosen the sheet allowing the center mark of the sheet to be in the middle of the mattress.</p>	<p>Congratulations! You have now completed the correct installation and ensured a safe use of TurnAid T4</p>

Electric Components

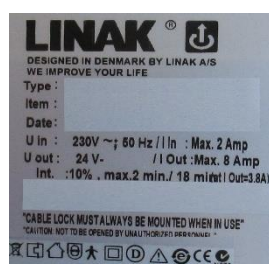
(Electric components have been assembled prior to delivery to you; you only have to plug in the plugs for the motors.)

Pos. No.	Description
1	Control Linak for TurnAid T4
2	Cable-distribution box for open-bus cables for TurnAid T4
3	Junction box, type Linak MJB-UBL, open-bus cables
4	Hand control, type HB34, for TurnAid T4, standard
5	Gear motor for roll, incl. gear (2 pcs. mounted inside the rolls)
6	Cable for motor, type LA23, L=115 mm
7	Cable between control and distribution box for TurnAid T4
8	Cable between two distribution boxes for TurnAid T4, L=600 mm
9	Power cable for control box
10	Motor cable for motor in roll for TurnAid T4, L=1200 mm (Fitted to the rolls)
11	TurnAid T4 bed rail with roll right side (GREEN)
12	TurnAid T4 bed rail with roll left side (RED)
13	 Class II equipment

9. Electric connection

Connect TurnAid T4 to the power supply, 100-240 V, 50/60 Hz AC. Electrical connection preferably is made through grounded socket outlet.

Marking of control box:



If you detect damage to the electric parts, pull out the plug and call a service technician.

10. Disassembly of TurnAid T4 and transport instructions

In case you want to dismount TurnAid T4 from the bed, follow below instructions.

- Pull out the main cable from the socket plug.
- Pull the 2 cables from the motor rolls out of the control box, plug no. 1 and 3.
- Clip off the strips attaching the cables to the bed.

- Dismount the 2 system sides. If you can remove the parts without any cables getting stuck, it is not necessary to pull the cables out of the distribution box. (Otherwise, the locking cam on the distribution box must be taken off before plugs can be pulled out).
- Dismount fittings for electric parts. Place these parts in the bag for electric parts.
- If required, remount the original bed rails on the bed. Follow the instructions from the bed supplier.
- TurnAid T4 has now been dismantled.
- Special packaging for storage of the system sides and the electronic units is not necessary.

11. Maintenance and storage

In daily use you must each day check the following points. Prior to any maintenance make sure that TurnAid T4 has been disconnected from the power supply

Daily


1. Visually check that TurnAid T4 is without damages and oblique fittings.
2. Ensure turning sheet is in good order and runs correctly on the motor rolls.
3. Slide sheet is in good order and is correctly mounted.
4. When you plug in the system to the main supply, check that the function of the hand control is correct.
5. Quick guide for use of the system is visibly close to the bed, clean, and without any damages.

12. Cleaning

TurnAid recommends regular cleaning of the system

TurnAid T4 has two cleaning aspects: The system itself, the slide-, and turning-sheets.

 TurnAid could be contaminated so wear protective clothing

Before cleaning: Make sure the plug for TurnAid T4 has been pulled out of the socket in the wall! Do not spill liquid on the electrical system			
Part	Description	Cleaning Instruction	Treatment
TurnAid T4 system	TurnAid T4 has the level of sealing IPX0, and is thus not flush tight.	<p>Using a twisted cloth, wash in a solution of e.g. Virkon (or similar) and water with a twisted cloth.</p> <p> NEVER USE acids, bases, or solvents during cleaning.</p> <p>Having completed cleaning, disinfect the system with 70% hospitals spirit.</p> <p>TurnAid T4 cannot be autoclaved.</p> <p>Upon washing and drying, lubricate moving parts with Triflow or similar Teflon based lubrications.</p>	Upon completing the cleaning, check that the system is completely dry.
Slide sheet	Slide sheet in 100% polyamide. Supplied only in white.	Washed at 95°C.	÷ machine drying ÷ ironing
Turning sheet	Turning sheet in 100% cotton. Turning sheet in 50% cotton / 50% Poly	<p>Washed at 80°C.</p> <p>Washed at 95°C.</p>	÷ machine drying + ironing at ••

After cleaning, always check the functionality of the TurnAid T4.

13. Storage

Storage demands:

Maximum storage ambient humidity and atmospheric pressure range:

Temperature: minus 5 degrees up to 40 degrees Celsius.

HPA - atmosphere pressure: 800 – 1060

RH - air humidity: 20% - 90% not condensing.

Work cycle from control box → 2min (on)/18min (off)




14. Maintenance to be undertaken by the owner

Check frequently that all parts move easily and freely and that no cables are damaged. If necessary, tighten bolts. We recommend that you lubricate all the locking parts and the shaft for the roll with a Teflon based spray oil once year, or if you hear any noise or it seems the system is not turning correctly.

15. Inspection - in general

What	How	When	Possible Storage
The entire system	Inspection of the entire system.	Annually	
All system parts	Check all system parts for wear, damage, and correct function.	Currently, however, at least once a year with a thorough inspection.	Dry.
Locking parts	We recommend you to lubricate locking parts with Teflon based spray oil.	Once a year; or if they emit any noises or are very tight.	
End of motor roll	We recommend lubricating all ends of the motor rolls with Teflon based spray oil.	Once a year; or if it emits any noises or runs very tight.	
Cables and wires	Check that cables are not damaged or at risk of being damaged	Day-to-day. If you detect damages to cables, order new ones for re- placement or call a service technician.	Dry.
Motor	Safety test of the motor's performance and mechanical condition.	At least once a year.	
Bolts, screws, nuts, and the like	Check that all bolts, screws, nuts, and the like have been tightened. Retighten if necessary.	Day-to-day.	
Hand control(s), Foot control(s)	Check all operating units for wear, damages, and correct function.	Day-to-day; however at least once a year, where a thorough inspection is made.	Dry.
Slide and turning sheet	Check sheets for wear, tear, and correct function.	Day-to-day; especially after each single washing.	

16. Trouble Shooting

Problem	Remedy
No light in the ON diode	No current - connect the power.
System not operating	No current - connect the power.
System not operating	Check if there is a power failure.
System not operating	<p>Press the  button twice.</p> <p>Press   simultaneously until the beeping stops (approx. 5 seconds), then try again.</p> <p>All plugs connected properly? Locking cams placed correctly?</p> <p>If you have just assembled and mounted the system, check that all plugs are placed correctly. Cf. view in chapter 8.</p>
Motor cannot work with full load	Motor damaged - contact TurnAid.
Green or red motor roll will not operate	Check that all plugs have been correctly placed in the control unit - cf. chapter 8.
Green or red motor roll can only rotate one way	Check that all plugs have been correctly placed in the control unit - cf. chapter 8.
Turning sheet is positioned in the wrong direction on the motor roll	Dismount the turning sheet from the motor rolls. Turn it and position it again according to instructions in chapter 6.13.2.
Turning sheet has/makes creases /folds during reeling	Dismount the turning sheet from the motor rolls. Straighten possible creases/folds and position it again according to the instructions in chapter 6.13.2
Slide sheet has/makes creases/folds	Dismount the slide sheet from the bed's movable lying surfaces. Straighten the creases/folds and mount it again. Cf. chapter 6.13.1.
Turning sheets does not operate smoothly over the slide sheet	Check that turning and slide sheet have been mounted correctly. Cf. chapter 6.13.1 and 6.1.2.

Problem	Remedy
	Check that turning and slide sheet have no defects. If necessary, replace a damaged sheet.

17. Technical Specifications

Total weight of system:	46 kg
Length of the system:	190 cm
Height of the system	57 cm
Width of the system	10 cm.
Max work load (SWL = SafeWorkLoad)	350 kg
Noise level:	<70 dB(A)
Motor system: Duty cycle of motor system Protection level Electric connection	50%-75%-100% IPXO Input: 100-240V, 50/60Hz A: 0,5 Input power (VA) 24V
Control box, with integrated adapter: Brand Type Item U in I in Int. Protection level	Linak CO6+09421X09200 CO615291-00 100-230 V -, 50/60Hz Max 2 A 10%, max 2 min./18.min IPX6

18. Disposal

TurnAid T4 is manufactured by an environmentally conscious supplier according to the requirements of the WEEE-directive 2012/19/EU concerning disposal of electric and electronic waste. The product may contain parts hazardous to the environment if it is disposed of in refuse/recycling sites which do not comply with the regulations. To encourage that the material in TurnAid T4 is recycled as much as possible, we have marked the two system sides and the electro part with following symbol:

Upon termination of the use of TurnAid T4 we recommend following disposal (through your local recycling station):

- All electronic parts to be dismantled and disposed of as electronic components.
- Metal parts which cannot be reused to be disposed of as scrap.
- Sheet parts which cannot be reused locally to be combusted or otherwise reused.

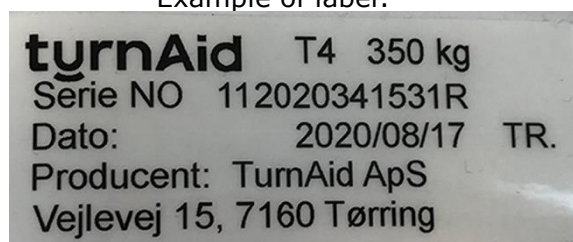
Disposal of waste must follow the rules and regulations of each country in respect of waste handling. In case of questions, do not hesitate to contact TurnAid ApS.

19. Marking

On the top inside of each system side you find a label, containing information about:

Type	Serial number
Production date	Producer

Example of label:



20. Risk Assessment and Safety



20.1 Risk Assessment


Upon delivery, TurnAid T4 is equipped with safety functions according to the Medical Device Directive applying for the area to which the system is supplied. In case of resale of the system either domestically or across borders please be advised that you as the responsible owner/user of the system are also responsible for the equipment being equipped and mounted/assembled according to the rules for your working place.

TurnAid T4 is designed so there is NO imminent danger of wrong operation with harmful consequences for the patient or the nursing staff.


TurnAid T4 should only be used, maintained, assembled/dismounted competent persons.

- In no way try to circumvent the built-in safety functions of the system.
- ALWAYS read and understand the instruction manual prior to taking the system into use.
- If the system is used other than intended, please contact TurnAid ApS.
- TurnAid T4 CANNOT operate unless it has been connected to the power supply and it has been powered on.
- TurnAid T4 has no electric back up function so unintended use of the system cannot happen if it has been disconnected from the power supply.

- When TurnAid T4 is connected to the power supply, it is secured against unintended movement, as the TurnAid T4 will only start by double clicking (2 long pushes) . Unauthorised persons such as visitors or the patient cannot start the system. Should the patient accidentally be lying on a hand control, the person cannot activate TurnAid T4. Lying on a hand control gives one long push and this is insufficient to start the system! Electrical functions were secured against unintended operation as defined double clicking on the ON button is ALWAYS needed to activate the system. Furthermore, the system has a built-in timer which will turn off the system after 90 seconds.
- If foot controls are installed on the Turn Aid T4, these will be placed under the bed out of reach of unauthorised persons.
- The ON button works as safety stop if there should be a malfunction of the buttons of hand control, or if someone accidentally presses a foot control switch whilst the system is connected to the power supply (so the motor rolls will be activated), the activated function can always be stopped if you push one of these buttons for more than 2 seconds. Then the motor rolls cannot be operated until you start again as usually with 2 pushes of .

 TurnAid T4 is an auxiliary for the transfer of a patient. Observance of safety regulations in connection with the use of the system rests with the buyer.

20.2 Safety


 NEVER use TurnAid T4 otherwise than stated in this instruction manual.


 NEVER leave TurnAid T4 in **"working-position"** when a patient is in the bed.


 ONLY use TurnAid T4 when correctly mounted.

 Keep the hand control out of the patient's reach.

 Warning: Risk of foot entrapment when used on a low bed.

 Warning: Materials used on the TurnAid could cause allergies.

 ALWAYS disconnect the system from the power supply if you have to clean, service, repair or dismount the system. No parts must be serviced with patient in the system.

 Frequently check that the system's electric wires are intact and ok. All electric parts have been shielded and double-isolated. Movable parts have been secured with a spring device to eliminate the danger of clipping/squeezing.

 When setting the 3 TurnAid T4 positions ALWAYS pay attention and care to:

- Make sure the patient's fingers, arms, legs, hair and any connected equipment are not caught during the setting of the system.
- Before and after setting ALWAYS check for clearance around the patient.
- ALWAYS check that the release handles are locked correctly after setting.

- NEVER use force or power when setting the system.
- Do not squeeze your hand/finger between the round metal bars when alternating position of the system.

IMPORTANT RESERVATION IN RELATION TO:

SGS Report No. LR/2017/10015, EN 60601-2-52

Clause: 201.9.1.101 PROTECTION AGAINST PATIENT entrapment in non-moving parts.

In violation of the rules and guidelines as described in this Instruction Manual for the TurnAid T4 Turning system, and the TurnAid T4 is malfunctioned and left in "Working Position" with the rolls at the top, TurnAid T4 does not comply with Clause 201.9.1.101.