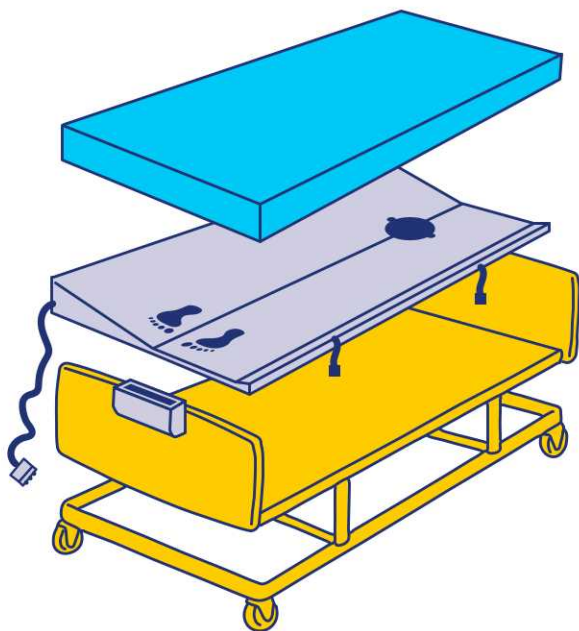




EN



AUTOTURN

Automated lateral turning system 1C - 3C

Patent pending



Contents of the AUTOTURN system

- 1 piece. AUTOTURN 1C Pump System **OR**
- 1 piece. AUTOTURN 3C Pump System
- 1 piece. power cord to the pump system
- 1 piece. AUTOTURN lift mattress
- 1 piece. AUTOTURN Cover
The lift mattress is supplied pre-assembled inside the cover
- 1 piece. user manual.



About using and installing the system

This operator's manual provides some important information about working with the AUTOTURN system.

Please read the instructions before attempting to use this device.

These operating instructions are part of the product and must be kept close to the system so that it can be consulted at any time by personnel and operators.

If the system is transferred to a third party, the instructions must accompany it.

The illustrations in these instructions are intended to provide a clear demonstration of the current situation and are therefore not necessarily to the correct scale, they may vary slightly from the actual design of the device.

All information and advice in this manual has been prepared in accordance with the applicable standards.

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AUTOTURN

system function

Dynamic mode - Automatic

The AUTOTURN system is an automatic side positioning system, for the patient in need of pressure ulcer prevention or treatment.

Positioning is carried out easily and quietly. The system takes approx. 7-14 minutes for a change of position. Due to this very slow and even change of position, the system is perceived as very comfortable by the patient.

The system is based on an air chamber system that lifts the patient lying on it alternately on the right and left sides.

The system thereby places the patient in a 30° side position, alternately right and left side.

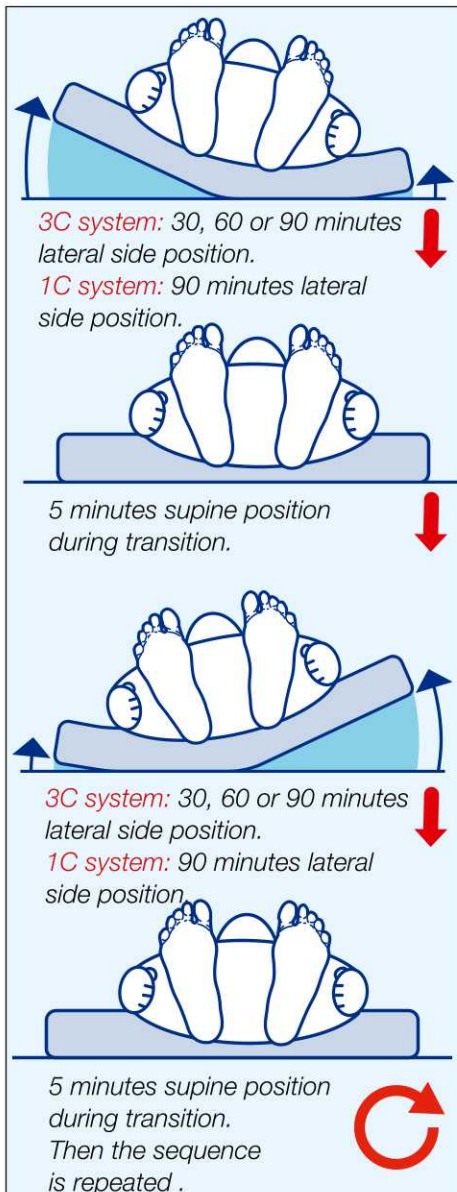
Static mode - Manual adjustment

In Static mode, the system is used as an inclined cushion (without automation), where the slope is manually controlled 0-30°. The slope is determined by how much air is pumped into the system.

Static side position, like a cushion.



The illustration below shows the sequence of the automatic positioning in the AUTOTURN system.



Installation of the AUTOTURN system

Getting the AUTOTURN system on a bed

Remove the mattress from the bed (Figure 1).

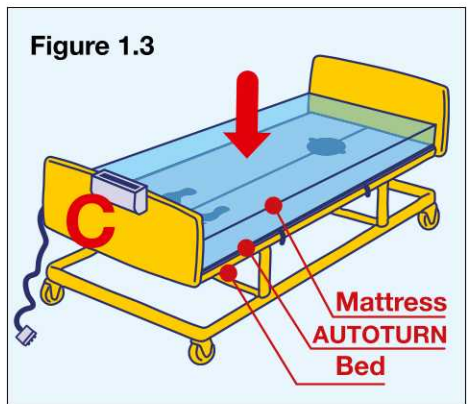
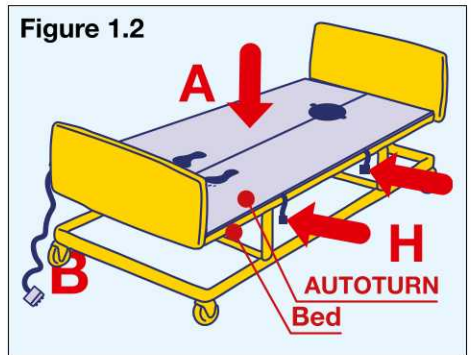
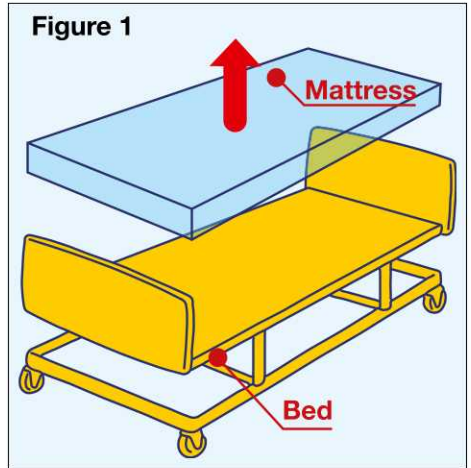
Place the AUTOTURN system (A) on the bed base, orienting the system so that the hose connection (B) is at the foot end of the bed (Figure 1.2).

Attach the AUTOTURN system to the bed base using the straps (H) on the cover (Figure 1.2).

Put the mattress back onto the bed on top of the AUTOTURN system (Figure 1.3).

The AUTOTURN pump (C) is placed on the bed end using the two braces on the back of the pump (Figure 1) (Figure 1.3).

Insert the hose connection (B) into the pump (C) (Figure 2) and (Figure 3) page 7.



Important information! Regarding the hose connection

The orientation of the hose connection (B) determines which side of the mattress is lifted first.

This is important if the system is to be used for static lifting of the patient on one side, such as a sloped cushion. See section "Using the AUTOTURN System for Static Lifting" on page 9.

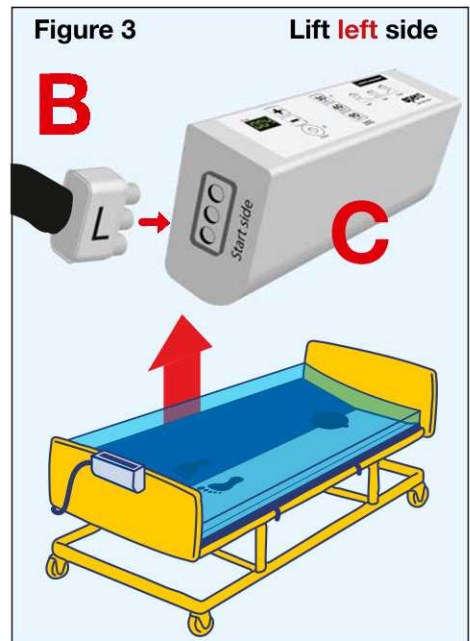
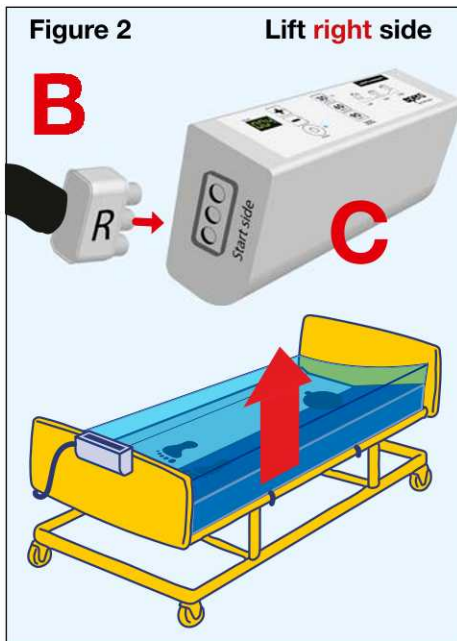
The hose connection (B) is marked with the letters "R" on the right and "L" for the left.

If the lift must start on the right side of the bed, seen from the foot end, the

hose connection with the letter "R" is turned towards the text "Start side" on the pump, as shown in (Figure 2).

If the lift must start on the left side of the bed, seen from the foot end, the hose connection with the letter "L" is turned towards the text "Start side" on the pump, as shown in (Figure 3).

After the first use of the system, the start-up side will be arbitrary, but if it is desired to change the lifting side, the pump is switched off for 3 seconds, after which the system changes the lifting side and continues with the selected turning sequence.



Starting and adjusting the AUTOTURN system

Connect the power cord to the pump (Figure 7)
Connect the power cord to the mains.

Turn on the pump on the "POWER" button (D) (Figure 4).

Set the timer "G" with the "+" and "-" buttons.

The number in the timer "G" indicates how many hours the system should run automatically.

The AUTOTURN system now runs automatically. One side of the mattress is now lifted for 30/60/90 minutes (1C system 90 minutes), then lying flat for 5 minutes

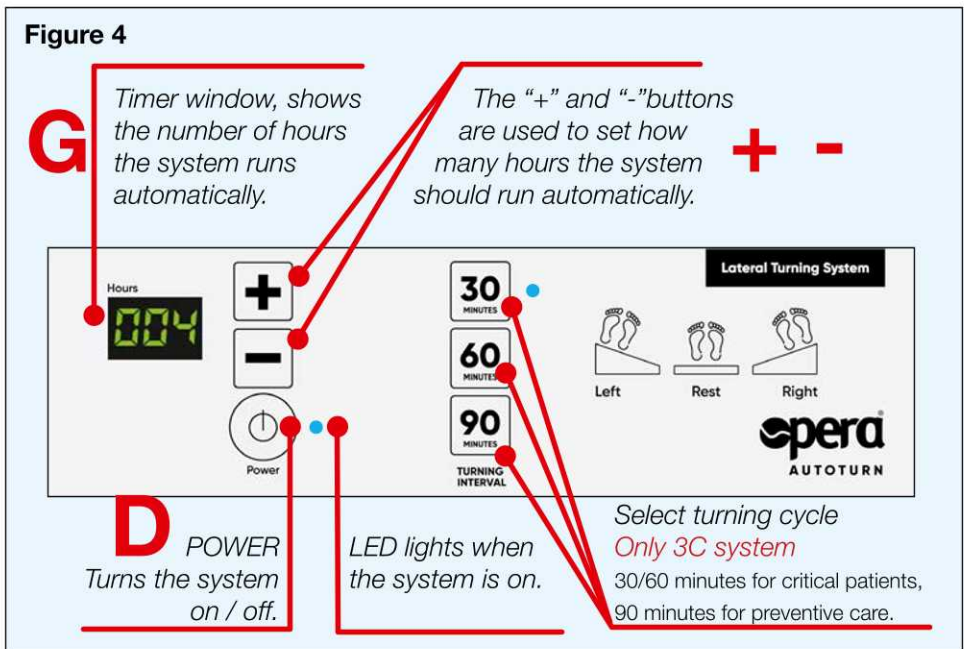
during transition, then the other side is lifted for 30/60/90 minutes (1C system 90 minutes), then lying flat for 5 minutes during transition.

This sequence is repeated for the number of hours set in the timer "G", then returned to lying flat. See illustration on page 5.

IMPORTANT. When not in use after automatic operation, the system is turned off by the POWER button (D), and then by the mains socket.

Disconnect hose connection (B) from the pump (C).
DO NOT install the cover (E) on hose connection (B).

Figure 4



Using the AUTOTURN system for static lifting

If the AUTOTURN system is to be used for a static lift as an inclined cushion, the hose connection is reversed according to the side that is to be lifted.

See section “Important! About the hose connection” page 7.

The pump is started and pumped until the desired lift height is reached.

Then disconnect the hose connection (B) from the pump (C) (Figure 5).

The hose connection (B) is now closed with the cover (E) (Figure 6).

When the cover (E) is mounted on the hose connection (B), the pump (C) is turned off by the “POWER” button (D).

The AUTOTURN system will now remain in this position until the cover (E) is removed again and the air is thereby eliminated from the system.

Make sure the air chambers are completely emptied before re-attaching the hose connection (B) to the pump (C).

Figure 5

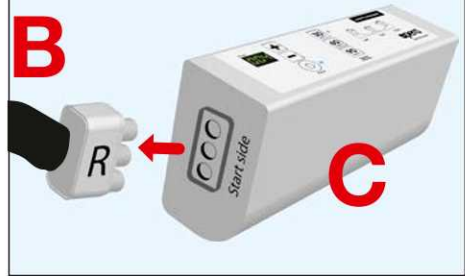


Figure 6

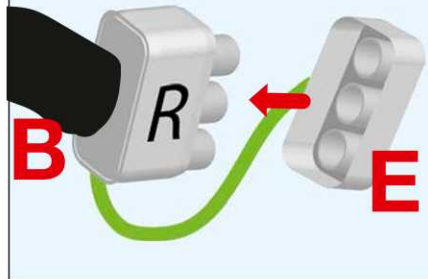
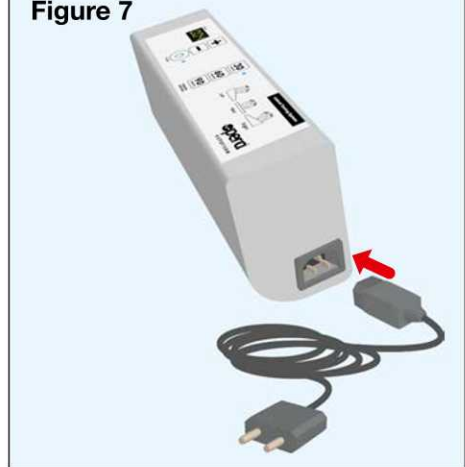


Figure 7



Indications and contraindications

Indications / Purpose

Pressure ulcer prevention and treatment.

Existing pressure ulcers.

Risk of pressure ulcer.

The AUTOTURN system can be used in beds with or without adjustable surfaces.

When using the AUTOTURN system in beds with adjustable surfaces, be sure to follow guidelines to avoid shear.

The AUTOTURN system is suitable for the prevention of pressure ulcers including all levels of skin damage risk.

The product can be used with all grades of pressure ulcer.

However, it is important that the person responsible for treatment is consulted and their recommendation/s followed.

The system is designed for patients with a body weight of up to 225 kg.

The AUTOTURN system is suitable and recommended:

- For immobile people with moderate to high risk of pressure ulcers, according to the Braden scale
- For persons whose disability or sickness means they must spend long periods lying down
- For people who cannot change their position when lying down
- For people who have suffered from one stroke with partial paralysis
- For people with spinal cord injury, who want to change their position when lying down, using their arms.



Contraindications / Risks of use / The product cannot be used

The AUTOTURN system cannot be used in patients with:

- Mobile patients who turn themselves in bed.
- Unstable fractures
- Severe burn injuries.
- Equilibrium Disorders
- Underlying neurological diseases that lead to anxiety behaviour in patients.

Allowed uses / locations

The AUTOTURN system can be used in all beds with removable mattress.

The AUTOTURN system can be used for the same patient for an extended period of time.

The AUTOTURN system is an aid for the prevention of pressure injuries and an auxiliary therapy for the treatment of pressure injuries.

Even with the use of the AUTOTURN system, the skin should be examined regularly by caregivers and / or qualified medical personnel with knowledge of pressure injuries

Note! Claims of any kind for damages resulting from improper or inappropriate use are excluded.

It is the operator who is solely responsible for all damages in the event of incorrect or inappropriate use.

Safety



This section provides an overview of the important safety aspects, for optimum protection of patients and caregivers, as well as safe and trouble-free use of the system.

If the AUTOTURN System is used in a bed with bed rails, the bed rail must be 220 mm higher than the mattress when lying flat.

The AUTOTURN system is an aid for pressure injury prevention and auxiliary therapy for the treatment of pressure injuries.

Even with the use of the AUTOTURN system, the skin should be examined regularly by caregivers and / or qualified medical personnel with knowledge of pressure injuries.

Note! The operator alone is responsible for all damages in the event of incorrect or inappropriate use.

Warning Notice

If the pump is to be disconnected from the mains during operation or if there is a power failure, an acoustic warning signal will sound for approx. 5 minutes. The warning signal can be closed by pressing the "POWER" key (D) (Figure 4) page 8. Then restart the system.

The location of the pump and the location of the mains cable must

be chosen so that unintentional disconnection from the supply network is excluded. The power cord must be routed in such a way that it cannot be pinched or crushed. It must also be guided in such a way that it does not pose a risk of stumbling.

CPR function

If a medical emergency should occur, rapid deflation may be necessary.

To do this, pull the red strip marked CPR to open for venting the hose connections to the mattress. See illustration below.

By disconnecting this connection, the air chambers will be quickly emptied and the bed will return to a horizontal position.

This process can be further accelerated by pressing the mattress.

Make sure the air chambers are completely emptied before re-attaching the CPR connection again.

Then restart the system.



Warranty and liability provisions

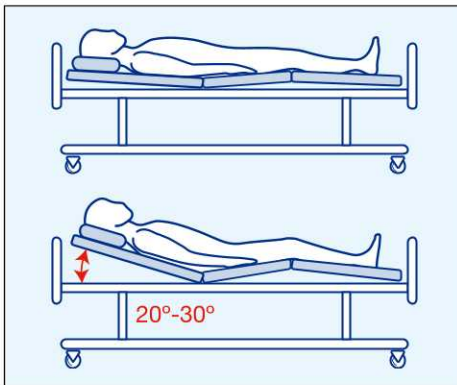
Elevation of the care bed

The system supports the elevated position of the healthcare bed in the head and foot parts. However, attention must be paid here to the correct position and pose of the patient in care. This will depend on body shape and clinical picture. In case of doubts or questions, please ask the treating doctor or the specialist care provider.

With the head end of the bed elevated, it is important to make sure that the patient is prevented from falling forward.

Depending on the body shape, a head cushion should only be used appropriately.

The maximum elevation of the head end of the bed should 20°-30°, but if necessary the head of bed can be higher for short/long periods for situation when eating and drinking.



When used correctly, Opera® gives a 24-month guarantee from the invoice date.

During this period, defective parts will be repaired or replaced free of charge due to manufacturing defects.

Opera® assumes no liability for damages due to:

1. Not follow the operating instructions
2. Non-compliant use with the instructions
3. Unauthorised changes
4. Technical changes
5. Use of unauthorised spare parts.

The warranty is based on legal provisions and directives.

If the system is intervened without the prior approval of Opera®, the warranty lapses.

If the warranty is claimed and if, after verification, it should prove that these are based on signs of wear and tear or other types of damage not covered by the warranty, Opera® is entitled to transfer the expenses incurred (test, transportation costs, and the like) to the client.

Cleaning and disinfection

Cleaning the AUTOTURN system

AUTOTURN Cover

(the blue outer cover)

The internal lifting mattress must be removed from the AUTOTURN Cover before washing the cover. see page 15.

AUTOTURN Cover can be washed in washing machine v. 90° C. and tumble drier on low setting.



AUTOTURN Cover can be cleaned in autoclave v. Max. 121° C.

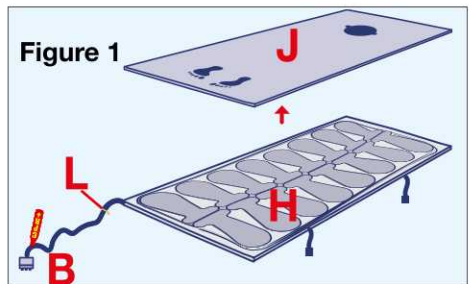
If the AUTOTURN system has been contaminated by body fluids, it can be cleaned.

The AUTOTURN inner mattress can be cleaned with warm water and soap. Disinfection can be done with a 1% chlorine based appropriate solution.

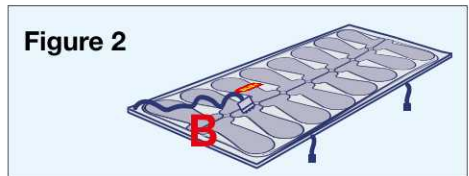
The AUTOTURN Control Box can be sprayed with a suitable disinfectant or with alcohol / propyl alcohol on a damp cloth for wiping.

Note! Do not use caustic or abrasive cleaners or sharp objects to clean the AUTOTURN system.

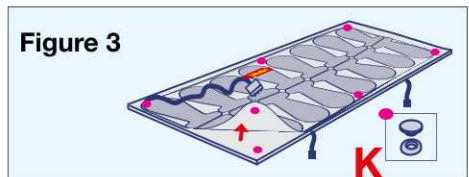
If the AUTOTURN system needs to be cleaned you can take out the inner mattress (H) figure 1, open the zipper in the cover (J) figure 1 and remove the upper part.



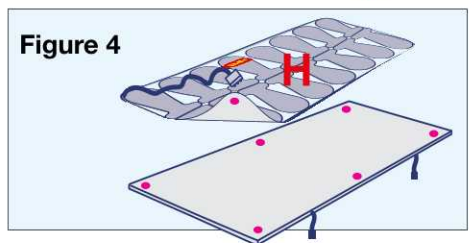
Open the zipper (L) figure 1 and pull the connection tubes (B) Figure 1-2) through the opening into the lower part of the cover.



Loosen the 6 kamsnaps (K) Figure 3.



The inner mattress (H) Figure 4, can now be removed. The cleaned mattress is mounted as shown in reverse order.



Notification of accidental events

Malfunctions or malfunctions in the appliance that have caused personal injury must be notified immediately to the competent authority and the company Opera®.

Note! The competent authority may require that the operator be notified of the incident by an expert at his own expense and submit the assessment in writing. The expert shall be selected in agreement with the competent authority.

The technical safety assessment includes the following elements:

- What the event can be attributed to
- Whether the product was in good condition
- If there is any further danger after repair of malfunction
- Whether new knowledge has been obtained, which require others or further precautions.

Technical data

Dimensions (L x B x H)

Cover: 200 x 85 x 15 cm
Lifting mattress: 200 x 85 cm
Pump: 8 x 27 x 13,5 cm

Veight

Pump: 1.5 Kg
Mattress with cover: 4 Kg

Lifting angle

Dynamic (automatic): 30°
Static (manual): 0° - 30°

Electrical data

Mains voltage:240V
Frequency: 50Hz / 60Hz
Power consumption:Max. 12 W
Classification: Klasse II
Fuse: T500mA L250V

Storage

-10° to 50° Celcius.
Relative humidity 0% to 95% without condensation.

Conditions of use

Designed for continuous operation.
Application temperature:
0 ° to 40 ° Celcius.
Relative humidity 20% to 95% without condensation.

Standards

See approvals on page 16.

Approvals, standards and regulations

Cover upper part

Medical BI ELASTIC PES PU

Antibacterial and Antifungal:
ISO 22196:2011 - **PASS**

Flammability BS 7175 ignition source 5
Pre-treatment: None
Method of Test: BS 7175: 1989 (2013)
Section 3 - **PASS**

Flammability BS 7177: 2008 + A1:
2011 Low Hazard
Method of Test: BS EN 597-1: 1995 &
BS EN 597-2: 1995 - **PASS**

EN 1021-1-2: - **PASS**

Cover bottom part TPU

Fire retardant black
600D TPU coating dacron fabric.

Antibacterial and Antifungal:
ISO 22196:2011 - **PASS**

Flammability BS 7175 ignition source 5
Pre-treatment: None
Method of Test: BS 7175: 1989 (2013)
Section 3 - **PASS**

Flammability BS 7177: 2008 + A1:
2011 Low Hazard
Method of Test: BS EN 597-1: 1995 &
BS EN 597-2: 1995 - **PASS**

EN 1021-1-2: - **PASS**

Pump

Tested and approved in accordance to:
IEC 60601-1: 2006 +A1: 2013:
General Requirements for Basic Safety
and Essential Performance.

Tested and approved in accordance to:
EN60601-1-2: 2007
General Requirements for Basic
Safety and Essential Performance,
Collateral Standard: Electromagnetic
Compatibility.

Tested and approved in accordance to:
IEC 60601-1-11: 2015 (2. Edition) for
use in conjunction with IEC 60601-
1:2012 (3. Edition) + A1: 2012
General Requirements for Basic Safety
and Essential Performance,
Collateral Standard: Requirements
for medical electrical equipment and
medical electrical systems used in the
home healthcare environment.

Changing the filter in the pump










1. On the back of the pump there is a cover
2. Open the cover
3. On the inside of the cover is the filter, replace the filter and mount in reverse order.



AUTOTURN product range

Product name	Size in cm	Max weight in Kg	Product no.	Application
AUTOTURN 1C incl cover w/ TPU lower part	85 x 200	225	MAM055	System containing AUTOTURN lifting mattress, 1 AUTOTURN cover w/ TPU lower part, and 1 x 1C pump
AUTOTURN 3C incl cover w/ TPU lower part	85 x 200	225	MAM055-30	System containing AUTOTURN lifting mattress, 1 AUTOTURN cover w/ TPU lower part, and 1 x 3C pump
AUTOTURN 3C Bariatric incl cover w/ TPU lower part	110 x 210	400	MAM055-40	System containing AUTOTURN lifting mattress, 1 AUTOTURN cover w/ TPU lower part, and 1 x 3C pump
Autoturn Standard Mattress Full mattress - No pump	85 x 200	225	MAM056	Mattress containing AUTOTURN lifting mattress, 1 AUTOTURN cover w/ TPU lower part,
Autoturn Bariatric Mattress Full mattress - No pump	110 x 210	400	MAM066	Bariatric mattress containing AUTOTURN lifting mattress, 1 AUTOTURN cover w/ TPU lower part,
AUTOTURN Replacement Cover	85 x 200	N/A	PRMTP093	Replacement cover for the AUTOTURN lifting mattress
AUTOTURN Bariatric Replacement Cover	110 x 210	N/A	PRMTP094	Replacement cover for the AUTOTURN Bariatric lifting mattress
AUTOTURN Pump 1C	27 x 13 x 10	N/A	MAM057	1 cycle Pump for the AUTOTURN system
AUTOTURN Pump 3C	27 x 13 x 10	N/A	MAM058	3 cycle Pump for the AUTOTURN system
AUTOTURN Pump filter X10	2.6 x 3.7 x 0.3	N/A	PRMTP095	Filter for the Autoturn pump

Explanation of symbols on the packaging

Explanation of symbols on the packaging				
	Read the user guide		Expiration date	 Conformité Européenne
	Production number		Single-patient device	 Material in the packaging
	Manufacturer		Date of manufacture	 Product number



Declaration of Conformity (CE)

The company Levabo ApS, Sverigesvej 20A, 8660 Skanderborg, declares that the products are designed and manufactured in accordance with the technical documentation and legal requirements.

Product

AUTOTURN is an active medical product in accordance with:

EU Regulatory MDR (EU) 2017/745, Medical Devices - Class 1.

Production

EN ISO 9001: 2015 QMC
EN ISO 13 485: 2016 MD-QMC

Maintenance

Autoturn Mattress

The mattress should be cleaned regularly, see cleaning page 14

Autoturn Pump

The Autoturn control box can be cleaned with a suitable disinfectant or with alcohol/propyl alcohol on a damp cloth to wipe dry.

The filter in the pump should be changed once a year, see page 17

Troubleshooting

The pump does not start

Check that the cord is properly plugged into the pump and the power outlet and the power outlet is turned on

Mattress does not lift but the pump is running

Check that the hose coupling is properly connected to the pump
Check that the CPR vent is properly closed

Pump does not pump as expected

Switch off the pump, unplug it, wait 10 minutes.

Plug the pump into the power socket and switch on the pump.

FAQ

Which bed do I need to install the Autoturn system?

The Autoturn system can be integrated into a standard bed with a removable mattress.

How do I clean the Autoturn system?

The Autoturn cover (the blue cover) is washable and can be washed in the washing machine at 90° C. and tumble dry on a low setting.

Note: The inner lifting mattress is not machine washable. The inner lifting mattress can be washed with warm water and soap.

Disinfection can be performed with an appropriate 1% chlorine based solution on a damp cloth for wiping.

What are the dimensions of Autoturn?

(L x W x H)

Cover: 200 x 85 x 15 cm

Lifting mattress: 200 x 85cm

Pump: 8 x 27 x 13.5 cm

How much does Autoturn weigh?

Pump: 1.5 kg

Mattress with cover: 4 kg

What is the maximum user weight for Autoturn?

The system is designed for users with a body weight of up to 225 kg.

Tips

Change lifting side

If the pump lifts in the opposite side of what you want, switch off the pump, wait a few seconds, switch the pump on again and it will lift in the opposite side.

Bed Bath

When washing bedridden patients, Autoturn can be a great help to get the patient in 90° side position for washing and personal hygiene.



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