

# User manual for Tidewave™ Turning Mattress, configurable medical device model TWTURNING

This user manual contains important information about how to safely use the product and must be read before use

### **Article Number:**

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#### 2 Safety information



NOTE: The pump unit shall not be connected to the power outlet before the installation guide is read and understood.

This system is developed and built according to the regulatory safety standards, including:

- EN 60601-1 for basic safety and essential performance as a medical equipment class 1
- EN 60601-1-2 Electromagnetic disturbances, requirements and tests
- EN 60601-1-11 Medical electrical equipment used in the home healthcare environment
- EN 60601-1-6 Medical electrical equipment; usability

Always follow these precautions for your own safety and for product safety:

- Do not let the pump unit be close to water sources or other sources that can inflict water damage
  - Water will damage the electronics and potentially cause fire
- Keep the device away from fire sources such as cigarettes, matches or similar items, as this can cause fire
- Do not store the product under direct sunlight, as sunlight can cause the components to overheat and possibly reduce the products expected lifetime
- Only use suitable cleaning aids, as others may cause added wear to the product, or in a worst-case scenario, cause serious and/or irreversible skin damage to the patient
- Do not expose the product to sharp objects, knives etc, this may damage the product and disrupt its function
- Make sure the product is cleaned and dry before storage, if not, bacteria growth can occur, and the product may be harmful for the next user
- The product can safely be stored in the original packaging
- Make sure this manual is always available for reference
- The product shall only be used with the supplied approved power supply The product is tested for electrical safety with this power supply, and the use of another power supply may cause risk of electric shock or fire
- Portable radio equipment, including antennas, may affect medical devices Do not let any such equipment be closer than 30cm from the Tidewave™ Turning Mattress, cables, or pump unit, as such equipment could cause product malfunctioning, which in a worst-case scenario could lead to patient pressure ulcers

## WARNING

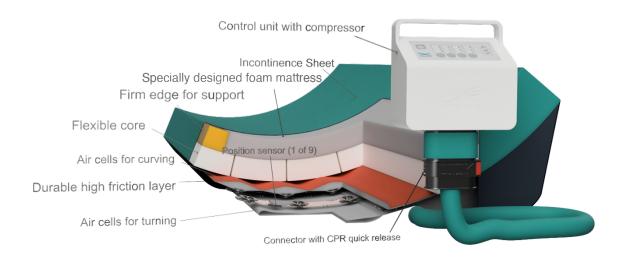
The use of Tidewaye™ Turning Mattress nearby or in conjunction with other electrical equipment should be avoided, such use could cause the product to malfunction. If such use is considered necessary, the product and its auxiliary equipment should be closely monitored to confirm normal operation is maintained. Electrical equipment may be harmful if used in a manner not intended, or if the equipment is damaged. Make sure power is disconnected before any repair or maintenance work is performed to the equipment. Maintenance and repair work should only be performed by certified technicians.

Contact Tidewave Medical AS on email: <a href="mailto:post@tidewave.no">post@tidewave.no</a> for any questions regarding the product.



### 3 Introduction

### 3.1 Product description



Tidewave™ Turning Mattress is designed to give the user continuous movement to prevent and treat pressure ulcers up to and including grade 4. Tidewave™ Turning Mattress consists of a specially developed foam mattress, air cells, and a pump unit with an intuitive control panel. The patient lies centred in the mattress and is slowly turned from side to side at a user adjustable pace and angle of rotation, either continuously or paused at each side. The mattress gives movement to the user in two sequences: First it curves to provide support, then it starts the turning sequence, which is the turning from one side to the other. The system is designed to move so slowly and gently that the user's sleep quality should not be disturbed.

The amount of time the different sequences take is dependent on the user selected pump speed and angle of rotation. From completely flat to curved the time ranges are approximately 40 minutes. For the turning sequence the time ranges are approximately 20-60 minutes.

When the mattress is started, the turning sequence will run continuously until the stop button is pressed.

## 3.2 Application

Tidewave™ Turning Mattress is meant to be used in professional and home health care. Tidewave™ Turning Mattress is intended for patients of all ages to keep them in continuous movement to prevent pressure ulcers up to and including grade 4.

This user manual is intended for health personnel and lay personnel, and in some cases for the patient themself.

### User manual for Tidewave™ Turning Mattress →



#### 3.3 Contraindication

The product shall not be attached to the bed frame in such way that it may conflict with the bed's mechanical movement.

Tidewave™ Turning Mattress shall not be used by patients under 9kg or above 150kg. See technical datasheet for the various intended use weight limits depending on the configurations.

If the patient is mobile and likely to get out of the bed by themselves, even while the mattress is running, the use of this mattress must be risk evaluated by competent care provider before the product can be used.

#### 3.4 How it works

Tidewave™ Turning Mattress consists of a pump unit with an intuitive control panel, and a foam and air cell combination that makes up the mattress part.

The mattress unique curved shape ensures that the patient lies safely in the centre of the mattress and prevents that the patient falls out of the bed.



Patients with sufficiently moveability could get out of the bed by themselves on the low side of the side the mattress is turned towards, which could result in a fall accident. The siderails should therefore be 22 cm over the top of the lower side when the mattress is turned to the side, to prevent that the patient may get out of the bed by themselves.

If the siderails are less than 22 cm from the top of the lower side of the curve when the mattress is turned to the side, or if no siderails are available, the patient must be under supervision to prevent potential fall incidents.

The air cells are located under the foam mattress and is a dual layer consisting of 12 cells divided in 9 individual inflatable sections with different functionality:

- 1. Curving cells –The top layer of the air cells, curves up the mattress to provide support and pressure relief for the patient. The curving also increases patient safety during turning
- 2. Turning cells The bottom layer of the air cells, does the actual turning of the patient. Left and right sections consisting of 3 individual cells, provides an even and safe turning motion.

After the start button is pressed, the curving cells will start inflating. The curving will take approximately 40 minutes to complete. The curving cells stay inflated during the whole turning program to provide an even and safe lying position. The mattress and patient will turn synchronized from left to right at a continuous slow speed. The patient is turned up to 30 degrees, depending on user settings. If selected, the mattress will pause at the side for a maximum of 30 minutes before resuming to turn towards the opposite side.



## 3.5 Technical data

| Power supply: AMF36US24   |   |   |  |                        |  |
|---|---|---|--|------------------------|--|
| Power   | In: 100-230VAC ~ 50/60Hz, out: 24Vdc max 36W  |   |  |                        |  |
| Power consumption   | 24W   |   |  |                        |  |
| during normal conditions  |   |   |  |                        |  |
| Environment:  |   |   |  |                        |  |
| Ambient temperature   | Min +10°C Max +30°C under usage, Min -20°C Max 60°C during storage  |   |  |                        |  |
| Pump unit:  |   | <u> </u>  |  |                        |  |
| Air pressure  | ≤ 200mBarg <sup>1</sup>   |   |  |                        |  |
| 7 iii procedie  |   | rning degree natient v  | veight, and placement o  | on mattress            |  |
|   |   |   | ne pressure surpasses i  |                        |  |
| Noise level   | 19dB according to   |   | , , , , , , , , , , , , , , , , , , ,  |                        |  |
|   |   | g to test method 11-5   | 03/2004 (DE)   |                        |  |
| Weight pump unit  | 5kg   | <u> </u>  | /  |                        |  |
| User settings   |   | turning degree, pause   | e on each side, speed,   | patient care           |  |
| 3   | function, start and   |   | , ,  | •                      |  |
| Turning duration  | Up to 1 hour to ea  | ch side, depending or   | n selected program   |                        |  |
| Air connection  |   | tor, containing 9 tube  |  |                        |  |
| Pump unit dimension   | 25x13x38cm  | , ,   |  |                        |  |
| IP21  |   | tection grade is IP21.  | which means the unit i   | is protected against   |  |
|   |   |   | fingers) and vertical wa   |                        |  |
|   | rain  | · ·   | <b>o</b> ,   | • •                    |  |
|   | I == ==   |   |  |                        |  |
| Mattress variant:   | 70.160.001.EU-  | 80.200.001.EU-S   | 80.200.001.EU-M  | 85.190.001.EU-H        |  |
|   | S   | 85.190.001.EU-S   | 85.190.001.EU-M  | 85.200.001.EU-H        |  |
|   |   | 85.200.001.EU-S   | 85.200.001.EU-M  | 85.210.001.EU-H        |  |
|   |   | 85.210.001.EU-S   | 85.210.001.EU-M  | 90.190.001.EU-H        |  |
|   |   | 90.190.001.EU-S   | 90.190.001.EU-M  | 90.200.001.EU-H        |  |
|   |   | 90.200.001.EU-S   | 90.200.001.EU-M  | 90.210.001.EU-H        |  |
|   |   | 90.210.001.EU-S   | 90.210.001.EU-M  | 90.220.001.EU-H        |  |
| Mattress type   | Continuously and  | 90.220.001.EU-S   | 90.220.001.EU-M  | foam mattress          |  |
|   | Continuously and synchronized turning mattress consisting of foam mattress  |   |  |                        |  |
|   |   |   |  |                        |  |
| Foam type   | Polyurethan HR co   |   |  |                        |  |
| Foam type<br>Air-cells  | Polyurethan HR co   |   |  |                        |  |
| Foam type Air-cells Material air-cells  | Polyurethan HR co<br>9 individual<br>PU coated nylon  | old foam  |  |                        |  |
| Foam type Air-cells Material air-cells Incontinence sheet   | Polyurethan HR co   | old foam  | I  | T                      |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient   | Polyurethan HR co<br>9 individual<br>PU coated nylon<br>PU/Polyethylen (a   | pplied part)  | 55kg - 115kg   | 110kg - 150kg          |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight  | Polyurethan HR construction  9 individual  PU coated nylon  PU/Polyethylen (and 19kg - 40kg   | old foam  | 55kg - 115kg   | 110kg - 150kg          |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load   | Polyurethan HR co<br>9 individual<br>PU coated nylon<br>PU/Polyethylen (a   | pplied part) 40kg – 60kg  | 55kg - 115kg   | 110kg - 150kg          |  |
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| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  | Polyurethan HR construction  9 individual  PU coated nylon  PU/Polyethylen (and 19kg - 40kg)  200kg  13kg   | pplied part) 40kg – 60kg  20kg 19.5kg 19kg  | 55kg - 115kg   | 110kg - 150kg          |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate   | Polyurethan HR construction  9 individual  PU coated nylon  PU/Polyethylen (and 19kg - 40kg)  200kg  13kg   | pplied part) 40kg – 60kg  20kg 19.5kg   | 55kg - 115kg   | 110kg - 150kg          |  |
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| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function Fault state                    | Polyurethan HR construction  9 individual  PU coated nylon  PU/Polyethylen (and 19kg - 40kg)  200kg  13kg   | pplied part)  40kg – 60kg  20kg 19.5kg 19kg ck connector release  | 55kg - 115kg   | 110kg - 150kg          |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function                                | Polyurethan HR of 9 individual PU coated nylon PU/Polyethylen (a 9kg - 40kg 200kg 13kg Yes, same as quid  | pplied part)  40kg – 60kg  20kg 19.5kg 19kg ck connector release s 80x200x15cm  | 55kg - 115kg   | 110kg - 150kg          |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function Fault state                    | Polyurethan HR construction  9 individual  PU coated nylon  PU/Polyethylen (and  9kg - 40kg  200kg  13kg  Yes, same as quice  | pplied part)  40kg – 60kg  20kg 19.5kg 19kg ck connector release s  80x200x15cm 85x190x15cm   | 55kg - 115kg   | 110kg - 150kg          |  |
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| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function Fault state Mattress dimension | Polyurethan HR or 9 individual PU coated nylon PU/Polyethylen (a 9kg - 40kg 200kg 13kg Yes, same as quid Flat foam mattress 70x160x10cm   | pplied part)  40kg – 60kg  20kg 19.5kg 19kg ck connector release s  80x200x15cm 85x190x15cm 85x200x15cm 90x190x15cm 90x210x15cm 90x20x15cm 90x20x15cm   |  |                        |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function Fault state                    | Polyurethan HR of 9 individual PU coated nylon PU/Polyethylen (a 9kg - 40kg 200kg 13kg Yes, same as quid Flat foam mattress 70x160x10cm   | pplied part)  40kg – 60kg  20kg 19.5kg 19kg 2k connector release 85x190x15cm 85x200x15cm 85x210x15cm 90x190x15cm 90x20x15cm 90x20x15cm 90x20x15cm 90x20x15cm  | as applied part type BF  |                        |  |
| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function Fault state Mattress dimension | Polyurethan HR of 9 individual PU coated nylon PU/Polyethylen (a 9kg - 40kg 200kg 13kg Yes, same as quid Flat foam mattress 70x160x10cm   | pplied part)  40kg – 60kg  20kg 19.5kg 19kg 2k connector release 85x190x15cm 85x200x15cm 85x210x15cm 90x190x15cm 90x20x15cm 90x20x15cm 90x20x15cm 90x210x15cm 90x210x15cm 90x210x15cm   | as applied part type BF  | nt                     |  |
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| Foam type Air-cells Material air-cells Incontinence sheet Recommended patient weight Max applied load Mattress weight:  CPR quick deflate function Fault state Mattress dimension | Polyurethan HR of 9 individual PU coated nylon PU/Polyethylen (at 9kg - 40kg) 200kg 13kg Yes, same as quide Flat foam mattress 70x160x10cm The mattress hyging The cover is election. | pplied part)  40kg – 60kg  20kg 19.5kg 19kg 2k connector release 85x200x15cm 85x200x15cm 85x210x15cm 90x190x15cm 90x20x15cm 90x20x15cm 90x20x15cm 90x210x15cm 90x210x15cm 90x210x15cm 90x210x15cm 90x210x15cm 90x210x15cm 90x210x15cm | as applied part type BF  | nt<br>ess is protected |  |



#### 4 Installation

If the product has been stored or transported in temperatures above or below specified operating temperature, give the product 30 minutes to adjust to operational temperatures before further installation. This is to make sure no harm to the product is caused by rapid temperature changes or by operating out of temperature range. This could affect the functions and/or damage the product.

#### 4.1 Mattress

Place the mattress on the bedframe with the foam side facing up. The connector air hose shall face the foot end and be threaded through the bedframe if suitable. Make sure the air hose is free to move and not pinched. Make sure the connector with the CPR push button is easily accessible for all personnel.

### 4.2 Pump unit

Flip out the pump unit hooks and hang it on the foot end of the bed. Do not cover the pump unit, this could cause overheating and damage to the unit.

#### 4.3 Quick connector

Connect the mattress to the pump unit by pressing the connectors together. There will be a click sound when the CPR push button is locked in.

## 4.4 Power supply

For the power supply, plug the DC power plug into the socket on the underside of the pump unit. Make sure it is plugged all the way in.

Then connect the AC (mains) power plug to the wall socket.



NOTE: Power socket must be easily accessible, as disconnecting from the power socket will separate the pump from the power source.









#### 4.5 CPR/Quick connector verification



Verify that the CPR mode is working by pushing the red CPR button and disconnect the connector. The red Service Light shall be indicated on the control panel and the pump shall stop. Reconnect the connector and verify the red service light goes off

## 4.6 Ready for use



The pump unit takes up to 30 seconds from the time it is plugged into the wall, until the system is ready for use. The lights on the control panel will go on when it is ready to start. The lights will automatically be switched off after 10 seconds of inactivity while not running. To switch the lights back on, press one of the settings buttons.

Take some time to familiarise yourself with the mattress safety functions and maintenance instructions in the next chapters, and eventually operating instructions, found in chapter 7 and chapter 8.

## User manual for Tidewave™ Turning Mattress →



## 5 Disconnecting

Disconnection is performed in the opposite sequence of steps as the connection

- 1: Unplug the AC (mains) power plug from the wall socket and disconnect the DC connector from the underside of the pump unit.
- 2: Disconnect the air hose by pressing the red CPR push button on the connector.



- 3: Lift the pump unit off the foot end of the bed and fold in the hooks.
- 4: Store the product in a dry and room temperature environment, keeping out of direct sunlight. The mattress should lie flat with the underside down during storage.



## 6 Cleaning and maintenance

### 6.1 Cleaning

Regular cleaning and disinfecting must be performed according to these instructions. Deviation from these instructions may void the manufacturer's warranty. Avoid cleaning internal components such as the foam, tubes, or air cells, doing so might deteriorate function. It is recommended to clean the cover of the mattress and the pump unit surfaces weekly or when the mattress is assigned to another patient, to prevent spreading of bacteria and viruses. Washing instructions for special cases are for whenever there is a suspicion of contagion, infection, or difficult stains.

### 6.2 Standard cleaning and disinfection procedure

#### Mattress:

 Apply disinfectant liquid (alcohol <95% or chlorine <5%) to the hygiene cover and wipe off with a damp cloth (hot water) within 2 minutes of application. Longer exposure to these chemicals will increase the wear of the hygiene cover and could leave traces which may irritate the patient skin.

#### Pump unit:

• Wipe down with a damp cloth. If there is a suspicion of bacteria or virus, or especially difficult stains, disinfectant liquid (alcohol < 95%) can be used.

### 6.3 Cleaning procedure for special cases



- 1. Disconnect the AC (mains) power plug.
- 2. Disconnect the pump unit from the mattress by pressing the red CPR push button.
- 3. Open the top zipper to extract the top section of the hygiene cover. Place the rest of the mattress in a suitable clean and dry location.
- 4. The hygiene cover can be washed on normal wash up to 70°C, and can be dried in a tumble drier up to 60°C. Do not bleach, iron nor dry-clean the hygiene cover.
- 5. After wash, inspect the hygiene cover for microscopical damages or holes by holding the cover up to a light source. If any holes or damages is found, replace the hygiene cover as it could become a potential source of infection of biohazardous organisms which in worst case could cause death.



The cover is washable up to 70°C



Do not bleach



The cover can be tumble



Do not iron



Do not dry clean

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dried up to 60°C



## 7 Safety Functions

## 7.1 CPR - Cardiopulmonary resuscitation

In case of an emergency where there is a need to quickly return the mattress to flat position, press the red CPR button on the quick connector. This will disconnect the air hose and release the air rapidly. The pump unit service indicator will show a red light, and the pump will stop. The quick connector must be correctly reconnected before the system can be started again.



**NOTE:** The foam mattress is soft. Use a CPR board placed between the patient and the mattress before performing CPR.



#### 7.2 Back section

The system can operate with the back section raised up to 30 degrees.



If the back section is raised too high, the turning motion will temporarily stop and the "back section over 30 degrees" indicator will show a red light. The turning will resume as soon as the back section is lowered to 30 degrees or below.

The turning program must be stopped or put in static mode before the back section is raised to a sitting position for medication, care etc. This is to avoid risk of harm to the patient or damage to the mattress.

#### 7.3 Alarm sound

In the case of a malfunction, detection of an error or power loss preventing the mattress to be working as normal, the mattress will function as an ordinary foam mattress. There is therefore no immediate or reasonably delayed risk of a harm, hence no audible alarm as this could give misleading information to users and healthcare providers.

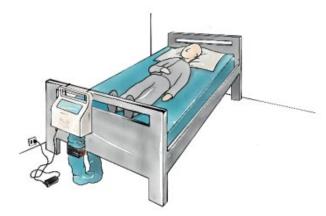


### 8 Start up

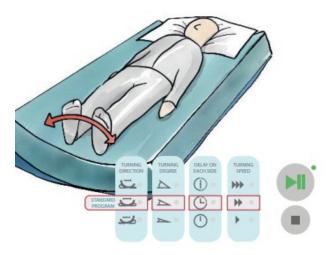
All factory settings are set at standard setting. Begin with low or medium turning degrees to allow the patient to get used to the turning function. This is sufficient for most patients. In case of other preferences, the different settings can be changed, refer to chapter 9.4 under settings. User settings only need to be configured once, as the pump unit remembers the settings configuration until it is manually changed.

- 1. Before starting the mattress, the patient should be positioned in supine (face up, centred in bed).
- 2. Use positioning cushions, if needed. Ensure that heels are properly offloaded.
- To start the turning program, press start.
   The mattress will begin curving. This process will take approximately 40 minutes, and then the continuous turning starts.
- 4. For patient care mode (static), press the start button once more while the program is running. This activates a 30-minute stop.
- To stop the turning program, press the stop button
   The air cells will deflate, and the mattress will return to a flat state in a few minutes.
- If you intend not to use the product for a while, it is recommended to unplug the AC (mains) power plug to minimize power consumption.

If the turning program is quickly restarted after a stop, there might still be some air left in the cells. In that case, the pump will initiate active deflation for up to 10 minutes before the program automatically resumes normal operation and starts the turning program. This is to make sure the turning cycles operates as intended.









#### 8.1 In and out of bed

The turning program must be stopped before the user enters or gets out of the bed. This is to avoid risk of harm to the user and or the mattress.

#### 8.2 Care function

The mattress can temporarily be paused for situations such as care or medical assistance. The regular duration of the care function is 30 minutes.



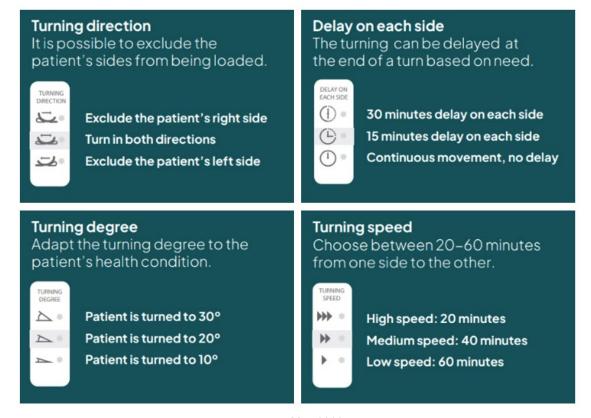
To use the care function, press the start button while the turning program is running. The green light will start blinking and the mattress will deflate to a flat position. After 30 minutes, the turning program will automatically resume or can be resumed earlier by pressing the start button again.

#### 8.3 Postponed startup

By pressing the start button twice, the mattress will wait 30 minutes before the curving and turning program begins. This is useful for home healthcare as it enables the patient to start the mattress themselves and have enough time to get in bed. Postponed startup is also useful for patient who are sensitive to sound and movements, needing time to fall into sleep before the pump begins.

## 8.4 **Settings**

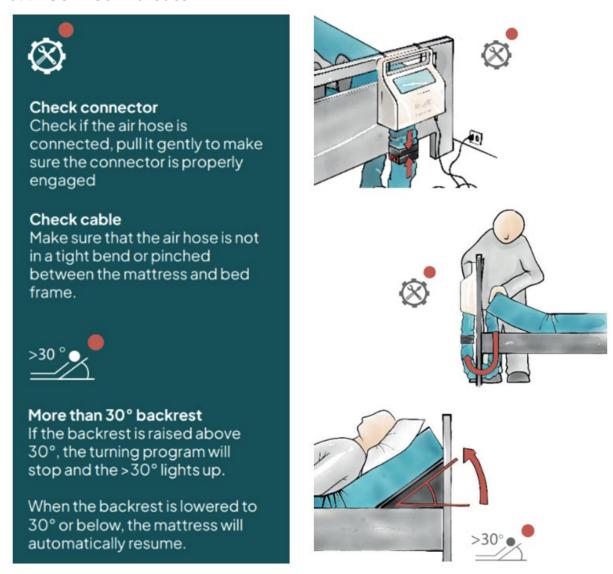
To choose a setting, press the round button accompanying the individual setting, one to three times. The active setting lights up on the panel.





#### System fault state 9

#### 9.1 Service indicator



If none of the above seem to be the problem, check out the troubleshooting guide chapter 9.2.



## 9.2 Trouble shooting guide

| TROUBLESHOOTING GUIDE               |   |  |  |  |
|-------------------------------------|---|--|--|--|
| TROODELONGO TINO GO                 |   |  |  |  |
| Error                               | Cause   | Solution   |  |  |
| No lights on control panel          | The lights will automatically turn off due to inactivity when pump is not running | Press a settings button  |  |  |
| The system will not start           | AC (mains) power is not connected   | Connect AC (mains) power plug to wall socket, refer to chapter 4 Installation  |  |  |
|                                     | There is no power in the outlet   | Use another outlet   |  |  |
|                                     | Power cord is damaged   | Contact a certified Tidewave™ service technician   |  |  |
|                                     | DC power plug is not connected  | Make sure the DC power plug on the bottom side of the pump unit is properly connected  |  |  |
|                                     | Service indicator shows a red light   | Check if the air hose is connected and properly engaged  |  |  |
|                                     | Back section high indicator shows a red light                                     | Lower the back section to 30 degrees or below  |  |  |
|                                     | Back section high indicator<br>shows a red light even if the<br>mattress is flat  | Open the bottom zipper on the mattress, to access the air cells and check if they are oriented the right way up, as illustrated in chapter 6.3 If in doubt, contact a qualified Tidewave™ service technician |  |  |
| Service indicator shows a red light | Air hose is disconnected  | Connect the air hose as demonstrated in chapter 4.3 and wait one minute and try to start   |  |  |
|                                     | System needs rebooting  | Disconnect the AC (mains) power plug from<br>the wall socket, wait 10 seconds before<br>plugging it back in  |  |  |
|                                     | Air hose is pinched   | Make sure the air hose is free to move and not pinched, refer to chapter 4.1 Mattress  |  |  |
|                                     |   | Reset the service indicator red light by pressing and holding the stop button for at least 10 seconds or until the service light turns off   |  |  |
|                                     | Other   | If the service light is still showing a red light:<br>Contact a qualified Tidewave™ service<br>technician  |  |  |
| Patient is not turned properly      | System is not plugged in  | Make sure the AC (mains) and DC power cords are connected and start the system Refer to chapter 8 Start up   |  |  |
|                                     | Patient is not centred longitudinally in the bed                                  | Reposition the patient until centred in bed  |  |  |
|                                     | Patient has spasm   | Turning might be difficult to observe if the patient has spasm, wait until the spasm ceases and observe for 10 minutes to confirm the system is operative  |  |  |
|                                     | Back section elevated over 30 degrees   | Lower the back section to 30 degrees or below, refer to chapter 7.2 Back section   |  |  |
|                                     | Pump unit defect  | Contact a qualified Tidewave™ service technician   |  |  |



| TROUBLESHOOTING GUIDE                     |   |  |  |  |
|---|---|--|--|--|
| Error                                     | Cause   | Solution   |  |  |
| Mattress is not inflated                  | Pump unit is not powered  | Connect the power, refer to chapter 4.4 Power supply   |  |  |
|   | Quick connector is not connected  | Connect the quick connector, make sure the lock is properly engaged, refer to chapter 4.3 Quick connector  |  |  |
|   | Air hose or connector is damaged  | Contact a qualified Tidewave™ service technician   |  |  |
|   | Pump unit defect  | Contact a qualified Tidewave™ service technician   |  |  |
|   | Back section elevated over 30 degrees   | Lower the back section to 30 degrees or below, refer to chapter 7.2 Back section   |  |  |
| Nearby electrical equipment is interfered | Electromagnetic interference caused by unintended radiation form the device     | Determine if the interference is caused by the Tidewave™ Turning Mattress by powering off the pump unit If the interference disappears when the pump |  |  |
|   | These electromagnetic radiation waves are transferred through air and can cause | unit is off, try the following steps if possible: Move the affected equipment further away from the mattress   |  |  |
|   | nearby equipment to malfunction   | Increase the distance between the equipment Connect the equipment or the Tidewave™ pump unit to another wall socket, powered by a different circuit  |  |  |
|   |   | If interference is still present, contact a qualified Tidewave™ service technician   |  |  |



#### Repairs, service, and maintenance 10



Repair and service shall only be conducted by technicians approved and trained by Tidewave Medical AS and only with original Tidewave™ Turning Mattress spare parts. If this is not followed, manufacturer warranty may be voided. Incorrect service or repairs can cause product malfunctioning, risk of electric shock, fire, serious injuries, or death.

Service is recommended, at a minimum, every 24 months. Service personnel have access to a service instruction manual with more in-depth information regarding service and repairs.

#### 10.1 Maintenance

Inspect the incontinence cover, air hose, connector, pump unit, power cord, power supply etc visually for wear and tear. In case of damage to components such as power cord, power supply, pump unit or mattress, or in case of a fault state that cannot be addressed by the trouble shooting guide in chapter 9.2, contact a qualified Tidewave™ technician. In both cases the product shall be disconnected and not used until the product is repaired.

### 10.2 Product life expectancy

Expected product life is 10 years with normal use and replacement of wearing parts. Wearing parts such as hygienic cover, foam mattress and power supply has a life expectancy of 5 years. Normal use is defined as standard settings and a maximum of 12 running hours per day (24hrs). Settings other than standard, for example; high pump speed, high turning angle, no pause, will increase the product wear. More than 12 hours running time per day will also increase the product wear. During these conditions, shorter product life is to be expected.

## 10.3 Storage

The mattress and pump unit are to be stored in a dry environment, kept out of direct sunlight, in temperatures between -20°C to +60°C and humidity between 5% to 95%.

## 10.4 Transport

- During transport, the product must be handled with care Avoid heavy objects on top of the product, this may damage or deteriorate the product causing it to not work correctly or to not work at all
- Do not expose the product to direct sunlight over long periods of time, as this may damage the components or shorten the product's life expectancy
- Do not use a sharp object to open the transport packaging, this might damage the product causing it to malfunction and misbehave or to not work at all
- Avoid exposing the product to moisture during transport as this may damage the components resulting in shorter life expectancy or cause the device to not work at all
- Avoid temperatures under -20°C or over 60°C as this may shorten the product life expectancy or damage the components causing them to malfunction or not work at all

#### 10.5 Other considerations

- Original power supply is type AMF36US24 The product shall only be used with this power supply, as other power supplies are not tested and might cause hazardous situations such as fire
- Wall socket used for the power supply shall be easy accessible, enabling disconnection for separating the pump unit from the power mains



- In case of emergency where the air must be deflated as guick as possible, push the CPR push button on the quick connector, and the air will be released The pump unit will automatically detect the disconnection and stop
- Avoid the use of sharp objects around the product, as this can cause damage to the air cells and interfere with the product's functionality
- The mattress can be used with a fitted or stretch cotton sheet or equivalent
- Use pillows or a similar item to further increase pressure distribution around the heels of the patient
- If service indicator is showing a red light, or there are some other issues with the product, follow the trouble shooting guide steps in chapter 9.2
- The mattress and pump unit can be delivered to qualified Tidewave™ service personnel for recycling after end of product life Tidewave™ service personnel will then handle recycling according to local government instructions and biological evaluation of the product
- The product is tested and approved according to 60601-1-2 electromagnetic disturbances, but nearby equipment may interfere or be interfered with by the product In the case of interference, follow the trouble shooting guide in chapter 9.2
- During use, recommended room temperature is between +10°C to +30°C, atmospheric pressure between 700 hPa to 1060 hPa, and humidity between 5% and 95% for longest possible product life expectancy



## 10.6 Accessories and spare parts

Available spare parts and accessories for the product 90.200.001.EU are:

|   | Description                               | Article number / Part number |
|---|---|------------------------------|
|   | Pump unit                                 | TW-AP / TW-DEV0006           |
|   | Transportation box for the Pump Unit      | TW-DEV0007                   |
| 7 | Air-cells: 90x200 / 80x200 / 85x200       | TW-ASSY0018                  |
|   | Air-cells: 70x160                         | TW-ASSY0002                  |
|   | Hygienic top cover: 70x160                | TW-M0004                     |
|   | Hygienic top cover: 80x200                | TW-M0079                     |
|   | Hygienic top cover: 85x190                | TW-M0100                     |
|   | Hygienic top cover: 85x200                | TW-M0080                     |
|   | Hygienic top cover: 85x210                | TW-M0101                     |
|   | Hygienic top cover: 90x190                | TW-M0102                     |
|   | Hygienic top cover: 90x200                | TW-M0003                     |
|   | Hygienic top cover: 90x210                | TW-M0103                     |
|   | Hygienic top cover: 90x220                | TW-M0104                     |
|   | Soft foam 70x160                          | TW-M0002                     |
|   | Soft foam 80x200                          | TW-M0077                     |
|   | Soft foam 85x190                          | TW-M0085                     |
|   | Soft foam 85x200                          | TW-M0081                     |
|   | Soft foam 85x210                          | TW-M0088                     |
|   | Soft foam 90x190                          | TW-M0091                     |
|   | Soft foam 90x200                          | TW-M0056                     |
|   | Soft foam 90x210                          | TW-M0094                     |
|   | Soft foam 90x220                          | TW-M0097                     |
|   | Medium foam 80x200                        | TW-M0078                     |
|   | Medium foam 85x190                        | TW-M0086                     |
|   | Medium foam 85x200                        | TW-M0082                     |
|   | Medium foam 85x210                        | TW-M0089                     |
|   | Medium foam 90x190                        | TW-M0092                     |
|   | Medium foam 90x200                        | TW-M0057                     |
|   | Medium foam 90x210                        | TW-M0095                     |
|   | Medium foam 90x220                        | TW-M0098                     |
|   | Hard foam 85x190                          | TW-M0087                     |
|   | Hard foam 85x200                          | TW-M0083                     |
|   | Hard foam 85x210                          | TW-M0090                     |
|   | Hard foam 90x190                          | TW-M0093                     |
|   | Hard foam 90x200                          | TW-M0058                     |
|   | Hard foam 90x210                          | TW-M0096                     |
|   | Hard foam 90x220                          | TW-M0099                     |
|   | Transportation cover 80x200/85x200/90x200 | TW-M0067                     |
|   | Transportation cover 70x160               | TW-M0072                     |
|   | 24V Power Supply                          | AMF36US24 / TW-E0046         |

Contact your local Tidewave™ Turning Mattress distributor for more information about accessories and spare parts.



#### Warnings and symbols 11

| À      | Warning – Follow instructions indicated in this user manual                                 |
|--------|---|
|        | Class II electrical device – Double insulated   |
|        | Electrical device is recycled according to local regulations                                |
| 0      | Do not use damaged electrical outlets or plugs, due to risk of electric shock or fire       |
| 200    | Make sure your hands are dry before working with electrical components                      |
|        | Keep the product away from water/splash, due to risk of electric shock or fire              |
| 8      | Only approved Tidewave™ service personnel may disassemble, repair, or assemble this product |
|        | DC Power  |
| $\sim$ | AC Power  |



| []i               | Read the user manual   |
|-------------------|--|
|                   | Read the user manual before the product is used  |
|                   | Only for indoor use  |
| +60°C             | Storage and transport in temperatures between -20°C to +60°C   |
| 95%               | Storage and transport in humidity between 5% to 95%  |
| 1060hPa<br>700hPa | Storage and transportation in atmospheric pressure between 700hPa and 1060hPa  |
| <u></u>           | Minimum and Maximum patient weight to ensure the product's intended use  For mattress size 70x160, the minimum and maximum patient weight is 9 - 40 kg, and for mattress size 90x200, the minimum and maximum patient weight is 40 - 150 kg. |
| =                 | Maximum applied load on the mattress is 200kg. Applied load above 200kg may damage the mattress.   |
| <b>†</b>          | The mattress hygiene cover is an applied part type BF The mattress hygiene cover is electrically insulated from the rest of the equipment  |



| CE  | This product is CE marked and declared in accordance with the European regulations 2017/745 MDR, as a class 1 medical device   |
|-----|--|
| REF | Article number / catalogue number  |
| LOT | The production identification number   |
| SN  | The product serial number  |
| UDI | Unique Device Identification, consisting of Device Identification, Product Identification and manufacturing date  Used for post market surveillance and reporting for the EUDAMED database |
| MD  | This equipment is a Medical Device   |
| cc  | Production information such as country and date with the following format: YYYY-MM-DD (year, month, and day)   |
|     | Importer outside of the EU   |
|     | Distributor  |



| 12 | Notes |
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#### **Contact information** 13

### 13.1 Manufacturer information



Tidewave Medical AS Hillevågsveien 101 4016 Stavanger Email: post@tidewave.no www.tidewave.no

Organization number: 918 491 775

## 13.2 Distributor and service personnel



Bano Life AS, Tlf: +47 64 91 80 60 Email: post@banolife.no www.banolife.no

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