Instructions for use gymna. ONE treatment tables

Models T7 & Q8

Manufacturer GymnaUniphy N.V.

Head office Pasweg 6A

B-3740 Bilzen

Telephone +32 (0) 89 510 510 Fax +32 (0) 89 510 511 Email info@gymna-uniphy.com

Website www.gymna.com

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1. SAFETY

1.1 Objective

Your gymna.ONE treatment table is meant for placing persons in various positions exclusively, and may only be used by professional (para)medical personnel. For safe and correct use of the treatment table, it is important that you carefully study these instructions before use.

1.2 Safety instructions

1.2.1 General

- Only qualified personnel trained in therapy application may operate this table.
- Only a mechanic authorised by GymnaUniphy N.V. may open the device or its accessories.
- Observe the instructions and directions in this user manual.
- Place the treatment table on a stable horizontal surface.
- The table is not suitable for patient transport and may not be moved while carrying a patient.
- Do not use the device in a so-called wet room (hydrotherapy).
- Do not allow any fluids to enter the device.
- Clean the device in accordance with the instructions (see chapter 5).
- The maximum load capacity of the table (200 kg) may not be exceeded.
- To prevent toppling, persons exceeding 80 kg in weight must refrain from using the head support.
- Only use original Gymna accessories and parts.
- Always keep this user manual near the device.
- The guideline of the European Committee 93/42/EEG concerning medical equipment, requires medical equipment to be safe. As a result, a technical safety inspection must be conducted annually.

1.2.2 Safety associated with electricity

- Use this device in an area fitted with the facilities as required by legal provisions.
- Check the mains voltage. The mains voltage and frequency of the electricity grid must match the identification plate of the table. If this is not the case: do not connect and contact your Gymna dealer immediately.
- Make sure the power cord is positioned in such a way that it cannot get stuck between the moving parts of the table and ensure that the risk of tripping is minimised.
- Perform damage checks on the power cord regularly; a damaged power cord must be replaced immediately. Consult your Gymna dealer.
- When positioning the device, ensure the plug can be disconnected at all times.

1.2.3 Preventing explosions

- Do not use the device in a room where flammable gasses or vapours are present.
- When the device is not being used, make sure it is turned off.

1.2.4 Electromagnetic compatibility

- Medical electrical equipment requires special precautions for Electromagnetic Compatibility (EMC). Observe the installation instructions.
- Do not use any mobile phones or other radio, short wave or microwave equipment in the vicinity of the device. This type of equipment can cause disturbance.
- Only use accessories provided by GymnaUniphy. Other accessories can cause an increased emission or a decreased immunity.

1.2.5 Electrical controls

- The electrical controls of the treatment table may only be operated by professional (para)medical personnel.
- Do not place your hands or feet near the moving constructions while using the electrical controls. These moving constructions may cause entrapment.
- When they are not being used, deactivate the electrical controls of the treatment table by switching off the key switch and removing the key.
- Do not allow unqualified persons and especially children near the treatment table without supervision.
- Always ensure that only the patient and yourself are near the table during treatment. This is necessary to prevent entrapment.
- Ensure that the patient always keeps his/her arms on the lying surface or on the arm rests.
- Do not place any objects on the stand; they could get entrapped in the mechanism.
- In the lowest position of the table, the arm rests and/or head support may get very close to the floor. Make sure that nobody, including yourself, can get entrapped between the arm rests and/or head support and the floor.
- Always remove the electric plug before cleaning or placing accessories or performing maintenance.

1.2.6 Mechanical controls

While adjusting the various lying surfaces always use two hands: one for operating the lever, the other for supporting the lying surface.

Ensure that the patient always keeps his/her arms on the lying surface or on the arm rests.

1.3 Guidelines

1.3.1 Medical devices

The device meets the essential requirements of the latest 'Medical Devices Directive' of the European Committee (93/42/EEG).

The device does not contain any derivatives of human or animal fibres, medical substances or blood derivatives of human or animal origins.

1.3.2 Disposal of electrical and electronic equipment

The device meets the requirements of the latest directive 2002/96/EG of the

European Parliament and the committee concerning disposal of electrical and electronic equipment (AEEA). The device meets European Directive 2011/65/EC concerning the limitation of use of certain hazardous substances in electrical and electronic equipment of the Council of the European Union and the European Parliament.

1.4 Liability

The manufacturer cannot be held liable for any injuries suffered by the medical professional, the patient or others, or for damage to the equipment used, if for example:

- the diagnosis was wrong;
- the equipment or its accessories were used incorrectly;
- the user manual was interpreted incorrectly or ignored;
- the device was poorly maintained;
- maintenance or repairs were conducted by persons or entities unauthorised by GymnaUniphy.

2. INSTALLATION

2.1 Receipt

- Ensure that your gymna. ONE was transported and/or delivered undamaged.
- Notify your supplier of any damage or defects no later than 3 days after delivery.
- Register the damage by telephone, fax, email or post.
- Do not use a damaged or faulty device.

2.2 Placement and connection

The packaging contains an instruction sheet for transportation and placement: follow it meticulously.

- · Keep the gymna.ONE in its original packaging for as long as possible.
- Use the lifting accessories included in the package.
- To prevent damage, refrain from placing the gymna.ONE on its side.
- Connection: see 1.2.2.

2.3 Displacement

Also refer to the instruction sheet included in the package.

- The gymna.ONE is suitable for moving across even surfaces; refer to chapter 4.1.1.
- The gymna.ONE is not suitable for moving across uneven surfaces (garden paths, etc.).
 In such cases, carry the table or use the transportation packaging and a transportation accessory (pallet truck).
- The gymna.ONE cannot move across doorsteps; it must be lifted over.

2.4 Use in combination with another device

The gymna. ONE treatment table is not suitable for use in combination with another device.

2.5 Functional testing

After delivery a functional test must be performed.

- · Remove all packaging materials.
- Set the key switch to the horizontal position (see 4.2.2.).
- Operate i-Control to adjust the height (see 4.2.3.).
- Check any other motors (4.2.4., 4.2.5., .4.2.6).
- Ensure the remote control for the Thermo cushions works correctly (4.3.2., 4.3.3).

2.6 Transportation and storage

Take the following matters into consideration when transporting or storing the device.

Transport or store the device in its original packaging.

- Maximum transportation or storage period: 15 weeks.
- Temperature: -20 to 60°C.
- Relative humidity grade: 15 85%rH.
- Atmospheric pressure: 500 1060hPa.

2.7 Resale

This medical device must remain traceable and is therefore fitted with a unique identification number. Notify your dealer of the name and address details of the new owner.

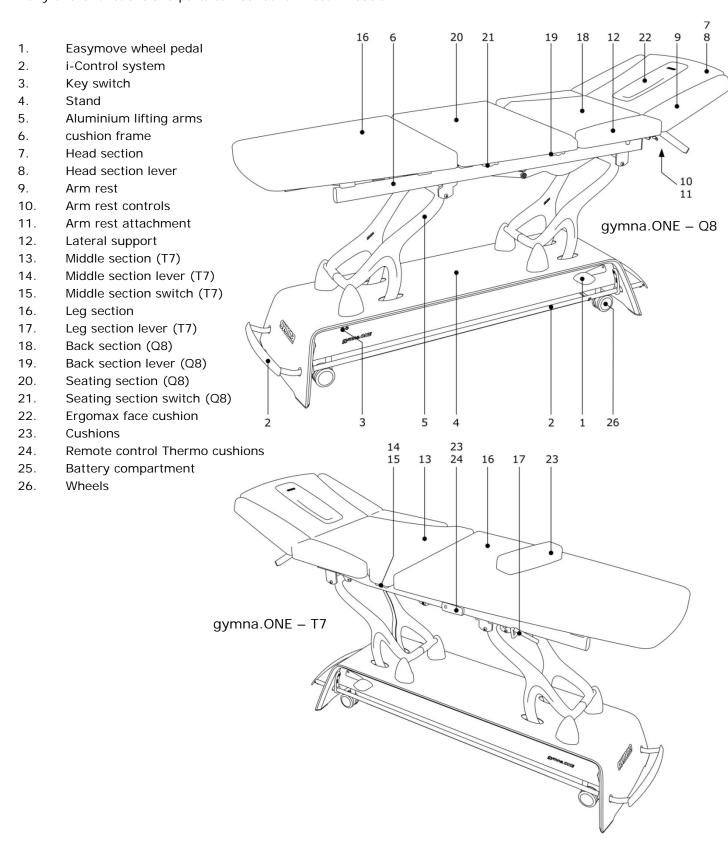
3. DESCRIPTION OF THE TREATMENT TABLE

This user manual describes two gymna. ONE models:

Gymna.ONE – T7, consisting of three parts with arm and lateral support.

Gymna.ONE – Q8, consisting of four parts with arm and lateral support.

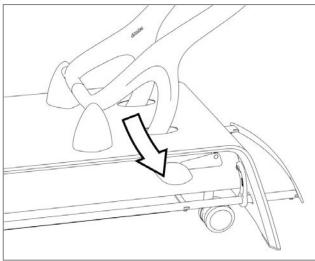
Many of the functions and parts can be found in both models.



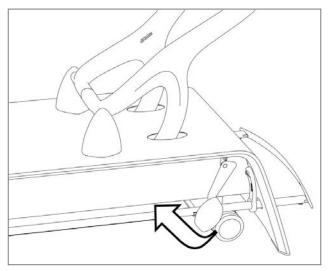
4. OPERATION OF THE TREATMENT TABLE

4.1 Mechanical controls

4.1.1 Displacement



 In one smooth motion, press the pedal (1) of the Easymove wheel system all the way down with your foot. The table is now supported by the wheels and can be moved.

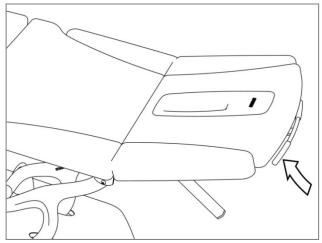


 Pull the pedal back up: the table will slowly lower itself back onto the floor.

Never leave the wheels out during use; pedal (1) must always remain in a horizontal position.

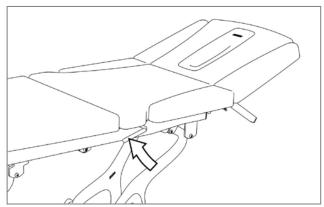
Tip: This operation is easiest when using the foot closest to the pedal while facing the cushions from the side.

4.1.2 Head section



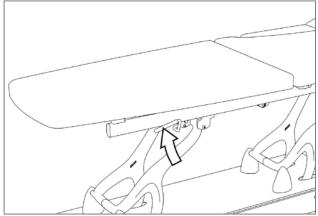
• Pull the lever (8) up for adjusting the head section (7).

4.1.3 Middle section



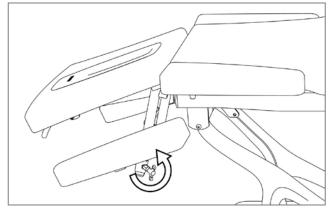
• Pull the lever (14) up for adjusting the middle section (13).

4.1.4 Leg section

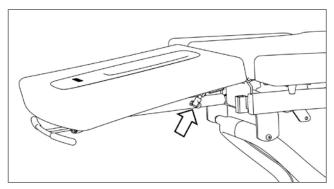


• Pull the lever (17) up for adjusting the leg section (16).

4.1.5 Arm rests



 Adjust the depth of the arm rests (9) by loosening the knobs (10).



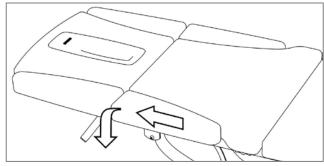
Remove the arm rests by loosening the knobs
 (11) beneath the head section.

With the arm rests removed, the head section can be adjusted almost all the way down.

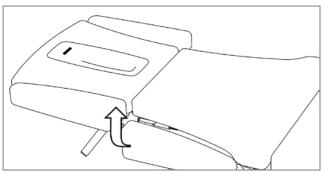
4.1.6 Lateral support

These supporting structures (12) serve to narrow the middle section. The supporting structures are not suitable for carrying a patient.

Lower the lateral support structures before the patient sits down on or leaves the table.



 Lowering: Hold the supporting structures with both hands and push them towards the head section and then down.



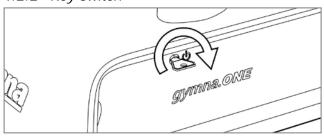
 Folding up: Hold the supporting structures with both hands and push them up and back at the same time. Push on the structure to ensure that it is firmly in place.

4.2 Electrical controls

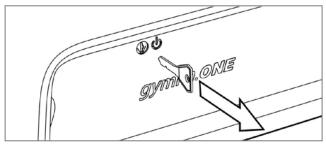
4.2.1 General

- To stop an electrical adjustment; push the switch.
- The operation of the treatment table can be stopped completely by pulling the plug from the socket.

4.2.2 Key switch



The electrical operations of the gymna. ONE only work when the key switch (3) is in the \upDelta position (horizontal key).

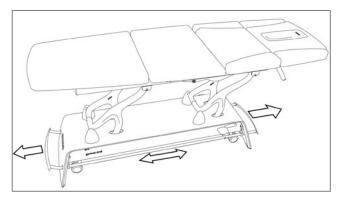


 When they are not being used, deactivate the electrical controls of the treatment table by switching off the key switch and removing the key.

Note: The key switch does not control the cushion heating.

4.2.3 Height adjustment

Height adjustment is operated by moving the i-Control system (2) horizontally with your foot.

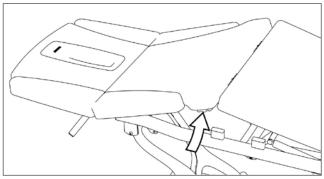


- Movement towards the head section: the table goes down.
- Movement towards the leg section: the table goes up.

i-Control can be used in two different ways.

- Continuous push: the height is being adjusted as long as you push (large or quick adjustment).
- Short push: the height is automatically adjusted by 1-2 cm (simple fine-tuning).

4.2.4 Middle section

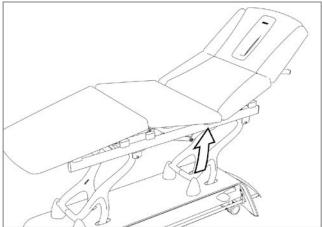


Adjust the middle section (13) by controlling the buttons on the switch (15) beneath the cushion.

• Outward button: middle section goes up.

• Inward button: middle section goes down.

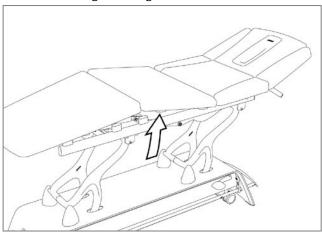
4.2.5 Back section



Adjust the back section (18) by controlling the buttons on the switch (19) beneath the cushion.

Outward button: back section goes up.Inward button: back section goes down.

4.2.6 Seating and leg section



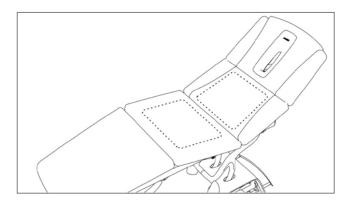
Adjust the seating and leg section (20) by controlling the buttons on the switch (21) beneath the cushion.

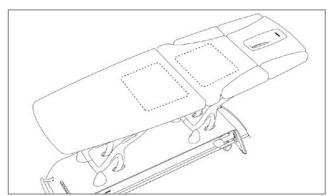
- Outward button: seating and leg section goes up.
- Inward button: seating and leg section goes down.

4.3 Thermo cushions

4.3.1 General

Your gymna.ONE treatment table is fitted with heated Thermo cushions. This system increases the patients' comfort level and helps them relax and give in to the therapy. It has proven especially useful during passive treatments and also provides you with a comfortable working environment.

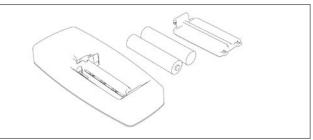




The pleasant warmth radiates from two flexible mats inside the cushions, placed at the lower back and seating area.

4.3.2 First use

The cushion heating is controlled with a magnet attached remote control (24). The remote control is specifically programmed for your gymna.ONE. The remote control only works on one table.



Place the two AAA batteries in the battery compartment, as depicted (25).

- The remote control is now ready for use.
- The remote control range is around 5 meters.

4.3.3 Use of the remote control

By pressing the depicted button repeatedly, the low, mid and high temperature settings are activated.

1 light on: low setting, around 34°C
 2 lights on: mid setting, around 36°C
 3 lights on: high setting, around 38°C

All lights off: heating off

4.3.4 Time switch

The Gymna Thermo cushion system is fitted with a time switch. It automatically deactivates the system 30 minutes after it was last used. This prevents the heating system from wasting electricity.

4.3.5 Safety

- Always use the low setting first when activating the heating system.
- Only switch to the mid or high setting after deliberation with the patient.
- Do not use the heating system if the cushions are severely damaged (tears, perforations, etc.). Have the cushions replaced if this is the case.
- In some cases readings of an EMG feedback device may be scrambled by the heating system of the table. The best solution in such cases is to temporarily unplug the table from the socket.

4.3.6 Error reports on the remote control

- Slow or no response:
 - You are outside of the range of the receiver inside the gymna. ONE table; move closer to the table.
- 3 lights are alternating:
 - o The batteries need to be replaced.
- 3 lights light up briefly:
 - o The remote control needs to be (re)programmed for the gymna.ONE table, see chapter 4.3.7.
- 3rd light goes on:
 - There is an error in the system. Unplug the table from the socket. Check all the plugs and connections.

Contact your Gymna dealer if the problems persist.

4.3.7 Programming the remote control

The remote control is programmed specifically for your table at delivery. Still, it may require reprogramming (e.g. when replaced). Proceed as follows:

- Make sure the remote control is fitted with two (charged) AAA batteries.
- Operate the i-Control and set the table to the upper most position.
- Maintain the i-Control in the upper position for at least 5 seconds.
- Release the i-Control and then press the button on the remote control.
- Do not release the button until the three lights briefly light up.
- Release the button: the remote control is now (re)programmed for your table and ready for use.

5. CLEANING

Always unplug the table before cleaning.

5.1 Cushions

The cushions of the gymna. ONE are made of two layers of foam, covered with sustainable vinyl artificial leather. Special precautions must be observed for cleaning and disinfecting.

- Use lukewarm water and a microfibre cloth for cleaning.
- Add a PH neutral soap solution in the case of persistent stains.
- Remove the soap residue with a damp cloth.
- NEVER use detergents, solvents (alcohol), aggressive soaps, bleaching agents or abrasives.
- Blood stains must be removed with cold water immediately.
- Massage oil must be removed with a PH neutral soap solution immediately.
- Do not use any substances containing oil or grease for maintenance.

5.2 Ergomax face cushion

The removable Ergomax face cushion is made of soft integral PUR foam and has a closed external layer. This makes Ergomax waterproof and easy to clean at the tap. The cleaning instructions are the same as for the cushions.

5.2.1 Disinfecting

Important: Clean before disinfecting.

Oil and grease residue must be removed from the surface with PH neutral soap before disinfecting. Only then may the surface be disinfected.

The cushions and Ergomax can be disinfected with a large number of disinfectants: McDonald's SK, McDonald's HA, MC Playlandreiniger taski force Spray Z22, Sprint Performer, McDonald's UR conc, Sprint Multiuso, Suma Quicksan D4.3, Sprint Spitfire Spray, 303 Fabric Cleaner, Micro Clean, Helipur, Meliseptol, Meliseptol Rapid, Melisep SF, Quatohex, Cosimed Desinfectionsmittel, Esemfix, Mikrozid AF, Incidur Spray, Incidur N, Incidin perfect Konzentrat, Incidin Plus, Incidin Extra N, Incidin Extra, Incidin liquid Pray, Sagrotan Hygienespray, Mikrobac forte, Desomed Rapid Universal.

5.3 Metal frames

The metal parts of the frame are powder coated and should be cleaned with a soft dry microfibre cloth. For persisting stains a slightly damp cloth may be used. Use clean water or glass cleaner.

5.4 Lifting arms

The lifting arms of the gymna. ONE are cast in aluminium and provided with a special coating. If necessary, only clean with a clean soft and dry microfibre cloth.

5.5 Stand

The stand is largely made of pressed and glued beech veneer, which is finished with an impenetrable film layer (white or black) on both sides. The sides of the stand are treated to repel fluids.

The stand is easy to clean and does not require any special maintenance.

- Clean the surface regularly with a clean soft and dry microfibre cloth.
- For persisting stains a slightly damp cloth may be used.
- Use clean water or glass cleaner.
- Remove any spilled fluids immediately.
- Do not use any abrasive substances, wax or other furniture polishing agents.
- Do not use any detergents containing strong acids such as decalcifiers.

6. SERVICE, FAULTS

6.1 Service

Only a technician authorised by GymnaUniphy N.V. is allowed to open and/or disassemble the device for repairs. None of the parts inside the device may be replaced by the user.

Your local GymnaUniphy dealer will provide service and warranty. The terms of delivery of your local GymnaUniphy dealer apply.

If your technical staff is qualified by GymnaUniphy to perform repairs, your dealer can provide charts, parts lists, drawings, spare parts and other information per request.

6.2 Faults

The following actions may be performed by the user in the case of faults.

Important: Always unplug the table before trying to solve any faults.

- i-Control is not working
 - o Check the position of the key switch.
 - Perform a damage inspection of the power cord.
 - o Check whether the device has enough space to move forwards/backwards.
- Electrically adjustable cushion is not working
 - o Check the position of the key switch.
 - o Perform a damage inspection of the power cord.
 - o Check all the power connections beneath the cushions.
- · Thermo cushions are not working
 - o Check whether the remote control is working correctly (see 4.3.6).
 - o Check all the power connections beneath the cushions.
- Cushions cannot be adjusted
 - o If the table is not being used for an extended period of time, the supporting gas struts can 'stick'.
 - Use one hand to completely pull up the relevant lever, wait a few seconds and then use the other hand to pull up the lying surface.

6.2.1 Persisting problems

In the case of persisting problems, you should always contact the dealer.

State the identification and version numbers of the table, to be found on the identification plate.

The identification plate is located on the inside of the frame, beneath the foot.

7. WARRANTY

7.1 General

GymnaUniphy and the local GymnaUniphy dealer only assume responsibility for the proper functioning provided that:

- any repairs, modifications, expansions or calibrations are performed by authorised personnel;
- the electrical installation of the room involved meets the relevant legal provisions;
- the device was only used by authorised personnel, observing the instructions of this user manual;
- the device was used for the purpose of its design;
- the device is serviced regularly and in accordance with the instructions;
- the technical lifespan of the device and its accessories has not been exceeded;
- the legal provisions concerning use of the device have been observed at all times.

7.2 Warranty period

The warranty period for the device expires 3 years after the purchase date. The date on the purchase invoice is binding. This warranty covers all material and production defects exclusively. Consumables are not covered by the warranty period. The warranty period for the artificial leather upholstery expires after one year.

7.3 Exceptions

The warranty does not apply to repairs or defects caused:

- by incorrect use of the device;
- by incorrect interpretation or failure to follow the instructions in this manual in detail;
- by neglect or misuse;
- after maintenance or repairs conducted by persons or entities that are not authorised by GymnaUniphy.

8. TECHNICAL LIFESPAN

The expected lifespan of the device is 10 years counting from the production date. Please refer to the identification plate. If possible, GymnaUniphy will try to provide service, parts and accessories for 10 years after the production date.

8.1 End of lifespan

Do not treat this device as domestic waste, recycle it using your local public collection system or return it to your dealer.

If you wish to destroy the gymna. ONE yourself, or wish to take responsibility for this, please observe the information below concerning the materials used.

- The frames are composed of steel with a galvanised, powder lacquer or chrome finish.
- The lifting arms of the gymna. ONE are composed of aluminium and can be recycled.
- The cushions consist of chipboard, PE foam and vinyl upholstery. The foam and upholstery can be treated as 'small chemical waste'.
- The Ergomax face cushion is made of PUR foam: 'small chemical waste'.
- Engines and gas struts can be treated as "white and brown goods".
- The packaging and user manual can be recycled.
- The batteries of the remote control must be recycled; bring them to a collection point.

IMPORTANT

In any case: observe your national and local regulations.



9. TECHNICAL INFORMATION

9.1 Dimensions and weight

Max. lifting capacity : 200 kg

9.2 Electric data

Mains voltage : 100-240 V~, 50/60 Hz

Maximum consumption:3.0 AInsulation class:IIClassification:I

"Applied parts" : Type BF

9.3 Operating conditions

Period of use : max. 10% (max. 2 min./18 min.)

Max. operating temp. : 10 to 35°C

Max. humidity : 30 - 75%rH

Atmospheric pressure : 700 - 1065 hPa

Moisture resistance : IP21 (drop resistant)

9.4 Cushion heating

LOW temperature : $\pm 34 \,^{\circ}\text{C}$ MID temperature : $\pm 36 \,^{\circ}\text{C}$ HIGH temperature : $\pm 38 \,^{\circ}\text{C}$

Heating mats : 2 pieces, 30 x 40 cm each

Time switch : 30 minutes max.

Maximum consumption : 180W

Batteries remote control : 2x AAA (1.5 V Alkaline, or 1.25 V chargeable NiCd/NiMH/Li-FeS2)

9.5 Conformity

- The treatment table meets the IEC/EN 60601-1, IEC/EN 60601-1-2 standards.
- The device meets the essential requirements of the 'Medical Devices Directive' of the European Committee (93/42/EEG).
- The treatment table and GymnaUniphy N.V. meet de European Directive 2002/96/EC concerning disposal of electrical and electronic equipment (AEEA) of the Council of the European Union and the European Parliament.
- The treatment table and GymnaUniphy N.V. meet the European Directive 2011/65/EC concerning the limitation of use of certain hazardous substances in electrical and electronic equipment of the Council of the European Union and the European Parliament.
- The treatment table meets the safety and efficiency requirements of the Canadian medical Device Regulations SOR/98-282.

9.6 **Symbols**

The product meets the essential requirements of the relevant directives of the European community.

Maximum lifting capacity

Insulation class II

Manufacturing date (followed by year-month)



Manufacturer



Alternating current



Electrical protection type BF



Do not treat product as domestic waste





Attention: consult the instructions included

OPTIONAL ACCESSORIES 10.

10.1 Traction support

To be placed in the apertures between the hinges of the lying surfaces.

