

Manumed



EN109-1400912-4F
MAY 4, 2022



Instructions for use

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1 Introduction

We are pleased that you have purchased a Manumed treatment couch. This examination and treatment couch is specially designed for the demands of the physical and manual therapist.

The anatomically segmented top part combined with the wide array of section positions enable you to position your patient virtually however you wish.













The section height adjustment is available in two types, an electric height adjustment actuator or the hydraulic pump which is convenient at locations where it is not allowed to use an electric height adjustment or no mains power is not available.

During development and production of this couch a great deal of care was put into the reliability, safety, ease of use and durability.

This instructions for use applies to:

- Manumed Optimal 2- and 3-sections
- Manumed Osteo
- Manumed Comfort
- Manumed Exercise (Bobath)
- Manumed Traction

2 Symbols

Symbol used	Description
	Follow the instructions in the Instructions for Use. It is important that you read, understand and observe the precautionary and operating instructions
	Warning or Caution: Indicates a hazardous situation which, if not avoided, could result in: a. Death or serious injury to the patient (or) b. Minor to moderate injury to the patient (or) c. Damage to the equipment
	Temperature Range. Indicates acceptable temperature range
	Humidity Limits. Indicates acceptable relative humidity
	Atmospheric Pressure. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Waste electrical items that can be recycled. Indicates the electrical and electronic components of the device can be recycled and has to be disposed separately.
	Manufacturer name, address and date of manufacture.
	Model Number
	Reference Number or Part Number
	Serial Number Indicates the serial number so that a specific medical device can be identified.
	Indicates that the item is a medical device.
IP	Ingress Protection Marking, classifies and rates the degree of protection provided against intrusion (body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures.
	Double Insulation



Type B applied part complying with the specified requirements to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.



Alternating current



Product is in conformity with the European Union Medical Device Regulation (EU) 2017/745




Risk of crushing hands

3 Package contents

Manumed couch


1400912 Instructions for Use (PDF on CD-ROM)
1400913 Information booklet

 The use of accessories and cables other than those specified or supplied by the manufacturer of this equipment is not permitted.

Ordering data

For the ordering data of the Manumed, standard accessories and additional accessories we refer to <http://www.enraf-nonius.com>

4 Installation

 DO NOT USE the device in case if you notice any damage from transport!
Please notify your supplier immediately.

- Take the Manumed and any extra parts out of the cardboard packaging and check everything for possible transport damage.
- Read this manual carefully before using the equipment.
- Mains supply connections must comply with the national requirements regarding medical rooms.
- Prior to connection of this apparatus to the mains supply, check that the voltage and frequency stated on the type plate correspond with the available mains supply.
- Avoid exposure to direct sunlight, UV radiation, rain, excessive dust, moisture, mechanical vibrations and shocks.

5 Intended use and intended user

Intended use

The couches are intended **ONLY** to be used to support patients during physical and manual therapy.

Intended user

The Manumed couches are designed to **ONLY** be used by or under the supervision of competent personnel in physiotherapy, rehabilitation, or adjacent areas.

6 Precautionary instructions



It is important to read the following instructions for use carefully before using your Manumed properly and safely.



If the use of this device may have caused or contributed to an undesirable event such as death or serious injury to the user, the manufacturer AND the competent authority of the Member State **MUST** be notified immediately!



The manufacturer cannot be held responsible for the results of using this device for any purposes other than described in these instructions for use.



It is important that you inspect your goods for damage when received. The device must not be used before inspection is complete.



The Manumed is only meant to be used by competent personnel in physiotherapy, rehabilitation or adjacent areas. Avoid any use of the equipment by unauthorized personnel.



At all times keep children away from the equipment when no supervision is at hand!



Use both hands to change the couch settings: one hand for unlocking and the other to adjust the section.



Never adjust a section when it supports the full weight of the patient! Each section of this Manumed is supported by gas springs. As well as easing operation, they offer full support of the sections. However, these gas springs are not strong enough to lift a section while it supports the full weight of the patient.



A maximum patient's weight of 200 kg (250 kg optional) is allowed when the height of the couch is being adjusted.



If the couch is equipped with an electric motor, never let the motor exceed 4 minutes continuous operation. If this should happen, a thermal cut out shuts off the power and protects the motor against overheating. In that case, remove the mains cable and let the motor cool down until it functions again.



The couch is not anti-static.



The Manumed couches are not intended for use in so-called "wet rooms" (hydrotherapy rooms).



Always use the original Enraf-Nonius accessories that are meant for this product.



The couch may not be used in close proximity (i.e. less than 2 meters) to shortwave equipment



Use a clean couch cover / towel / terry cloth / paper cover for every individual. This is required to guarantee a hygienic use.



Do not use cleaning agents that contain alcohol or other aggressive cleaners.



It is **MANDATORY** to have the Manumed checked annually by authorized personnel of Enraf-Nonius or by its authorized distributor.



Never let your full weight rest on the switch bar!



Ensure that you will never rest your feet on the all-around-operation.

Especially when seated next to the couch it can lead to a dangerous situation in which your leg can be jammed between the section and the all-around-operation.



Do not sit on the head and leg section of the couch (danger of tilting at approx. 80 kg).



Head section: is not suited to sit upon and must be used to support the head only.



Arm supports: are not suited to sit upon and must be used to support the arms only.



When adjusting this couch, keep hands away from the couch for at least 20 cm, especially on places that have been marked by the hand crush warning symbol.



The maximum traction force with the Manumed Special Traction (type 004, 916 and 926) is 900 N (90 kg).

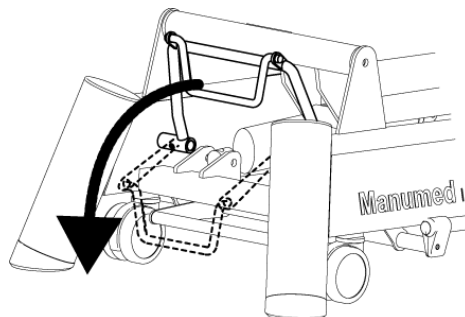
7 Operation

The operation of your Manumed treatment couch is simple and safe. The illustrations show how the various adjustments are done.

MOVING THE COUCH

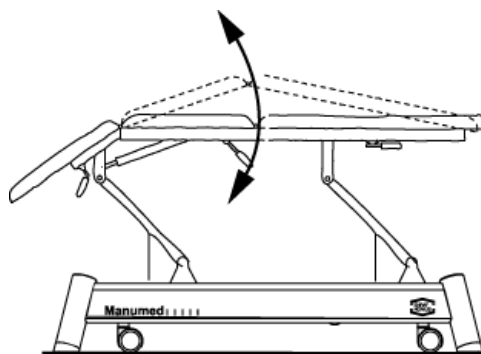
The couch can be moved by using the foot pedal to lower the wheels.

NOTE: Never move the couch with a person or load on it. Move the couch only on a smooth surface. The couch is not designed to move across thresholds.



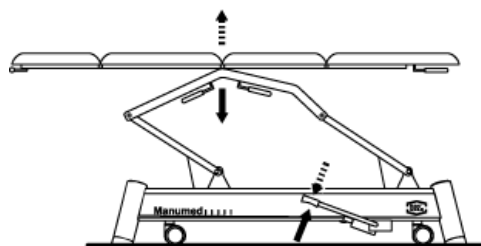
ADJUSTMENT TO THE FLEXION POSITION

Use one hand to unlock the couch section locks while setting the tops into position with the other hand. The flexion setting is made easier by gas springs.



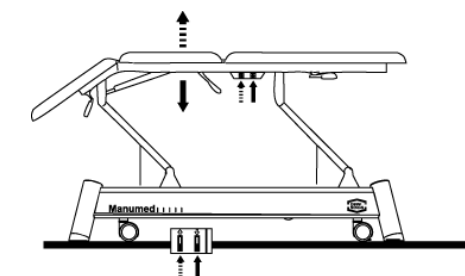
HYDRAULIC HEIGHT ADJUSTMENT

The required height can be reached by pressing and releasing the pedal repeatedly. The couch can be lowered by lifting the pedal with the foot.



ELECTRIC HEIGHT ADJUSTMENT

By pressing the foot switch continuously, the required height can be reached.



TREATMENT TABLE WITH ELECTRICAL DRAINAGE AND TRENDLENBURG POSITION

This table takes over some tilting tasks from you, even with a patient lying on it, e.g. in situations like:

Drainage up: press 1: table switch ▲.

Drainage down: press 2: table switch ▼.

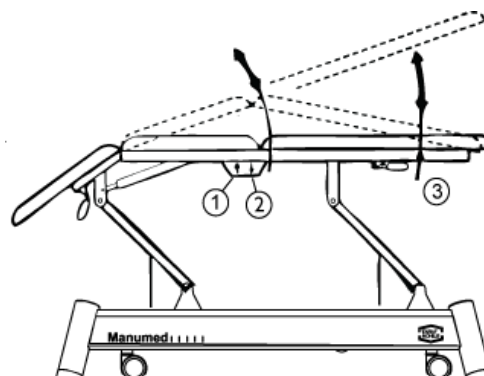
Trendelenburg up:

press 1: table switch ▲, and pull 3: use one hand to unlock the leg section lock, while adjusting the section upward with the other hand.

Trendelenburg down:

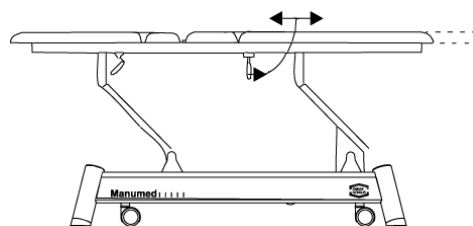
pull 3: use one hand to unlock the leg section lock, while adjusting the section downward with the other hand, and

press 2: table switch ▼



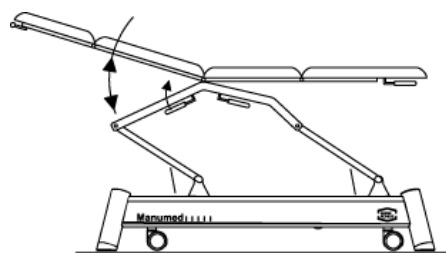
ADJUSTMENT OF ROLLING TOP SECTION (TYPE 916 - 926)

By operating the handle, the rolling top section can be release for traction and locked after traction



ADJUSTING THE BACK SECTION

Pull the handle underneath the back section and adjust the section with the other hand in the desired position.



ADJUSTING THE HEAD AND LEG SECTIONS

Pull the handle underneath one of the leg sections and adjust the leg section with the other hand in the desired position.

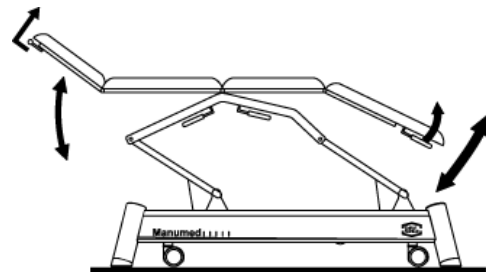
Head section: pull the handle underneath the head section and adjust the head section in the desired position.

Leg section: pull the handle underneath the leg section and adjust the leg section in the desired position.

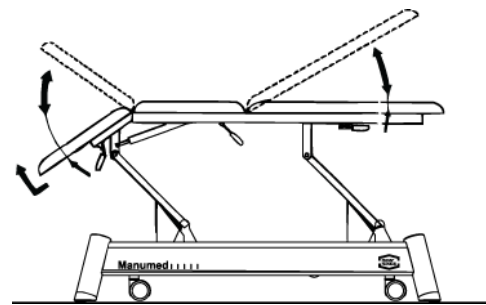
Use one hand to unlock the couch section lock, while adjusting the section with the other hand.

The handle to unlock the head section is situated underneath the head section itself.

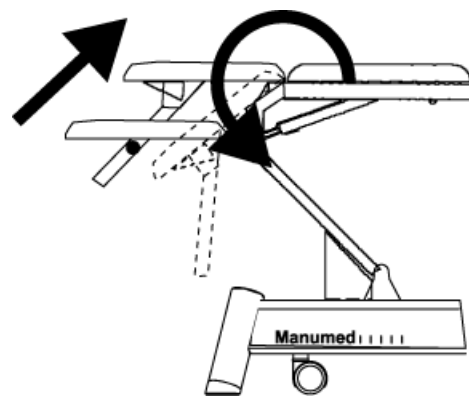
Be sure that the armrests (optional) are slide upwards in case the head section is rotated downwards more than 40 degrees.



Manumed type 400



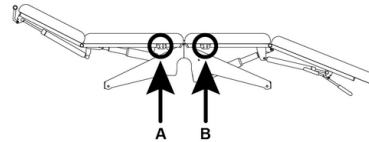
Manumed type 200



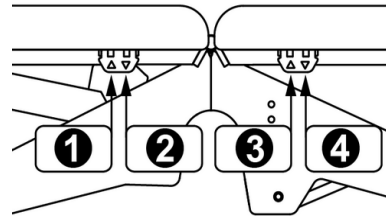
ADJUSTMENT OF THE HORIZONTAL POSITION ON THE MANUMED OSTEO

The Manumed Osteo with electric section adjustment are fitted with programmable operating buttons.

- A. Use the electric operation A and B to adjust the sections up and down independently.
The positions of the back-section and the sitting-section are programmable. Press buttons 3 and 4 (both buttons from B) in order to recall the programmed position
- B. Reprogramming the positions of the back-section and the sitting-section
- Adjust the sections to the desired position.
 - Press keys 1 and 2 simultaneously
 - Confirm the settings by pressing key 3 and 4 within 2 seconds. The new settings are acknowledged with a beep.



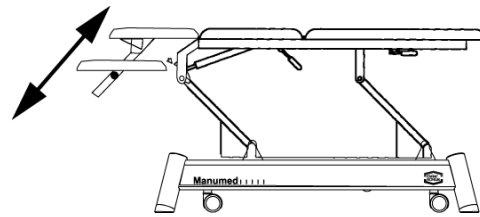
A = electric operation back-section
B = electric operation sitting-section



1 = back-section up
2 = back-section down
3 = sitting-section up
4 = sitting-section down

ADJUSTMENT OF THE ARM COUCH SECTIONS

The arm sections can be adjusted for height by loosening the knob and sliding the arm sections along the runners.

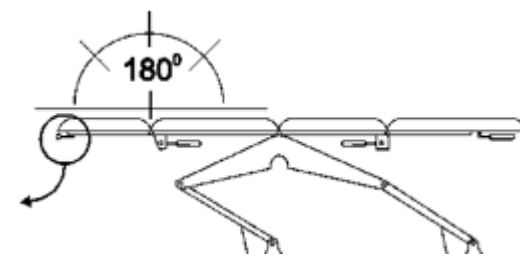


HOW TO REMOVE THE UNLOCK-BUTTON OF THE MANUMED OSTEO

Your Manumed Osteo is provided with the unlock-button on the head-section, it can be removed as follows:


- Adjust the head-section in a horizontal position
- Remove the unlock-button by pulling it out
- The unlock-button can now be removed from the couch

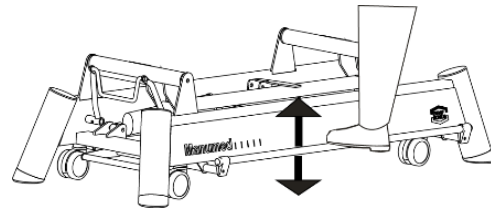
For safety-reasons, the unlock-button can only be removed when the head-section is in horizontal position.



HEIGHT ADJUSTMENT WITH THE CIRCULAR SWITCH BAR.

By pressing the circular switch bar - which is located underneath the framework - up or down with your foot, the required height of the couch can be set.

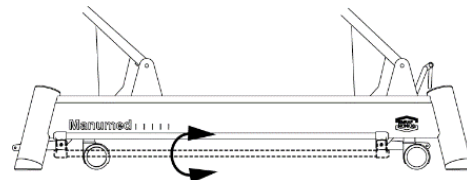
 Never let your full weight rest on the switch bar!



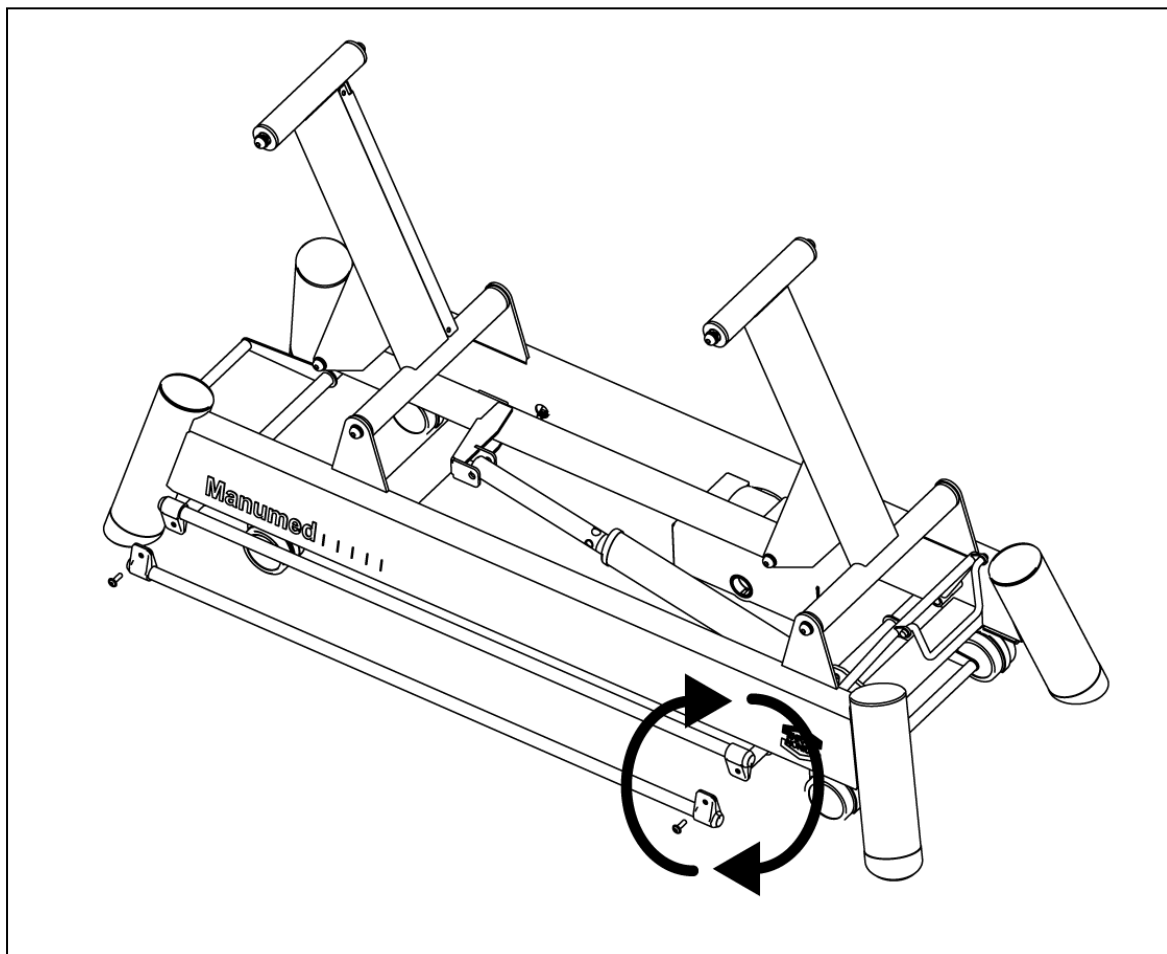
CHANGING THE HEIGHT OF THE CIRCULAR SWITCH BAR.

The circular switch bar can be mounted at 2 different heights. In case you want to change the heights of the bars than dismantle both bars (with the 6 mm hexagonal screws). Now mount the left bar upside down at the right side and the right-side bar upside down at the left side.

See below for a graphic reproduction.



Changing the height of the circular switch bar:



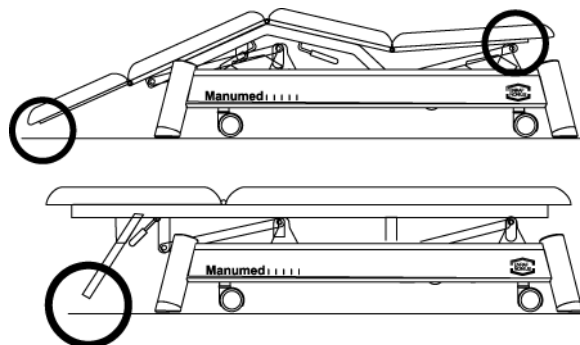
8 Safety instructions

HEIGHT ADJUSTMENT (GENERAL)


Ensure that neither the patient nor the operator can get any part of the body or clothes near or in between the moving parts of the mechanism when the couch is being raised or lowered.

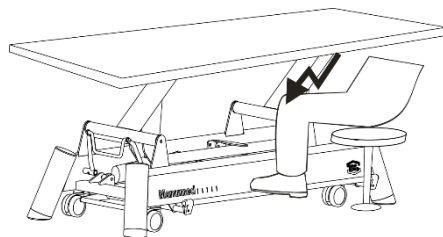
Be particularly careful for those situations indicated below (the couch is set in flexion position combined with the lowest possible position):

- Underneath the head section, between the head section and floor.
- Underneath the leg section, between the leg section and framework.
- Under the couch adjustment bars (therapist's feet). These situations occur only when the couch is adjusted to the lowest possible position.



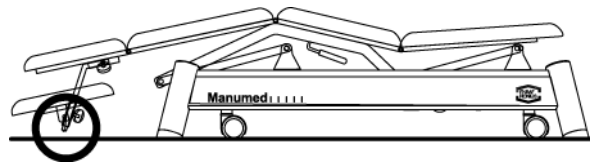
HEIGHT ADJUSTMENT

-  Ensure that you will never rest your feet on the all-around-operation. Especially when seated next to the couch it can lead to a dangerous situation in which your leg can be jammed between the section and the all-around-operation.




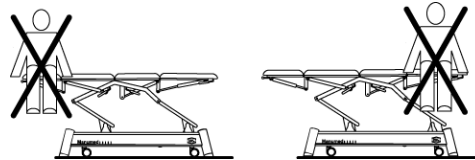
HEIGHT ADJUSTMENT (HEAD SECTION WITH ARM SUPPORTS)

If the couch is equipped with a head section with arm supports, it is not possible to completely lower the back section (flexion position).




DANGER OF TILTING

 Do not sit on the head and leg section of the couch (danger of tilting at approx. 80 kg).




Load

 *Head section:* is not suited to sit upon and must be used to support the head only.
Arm supports: are not suited to sit upon and must be used to support the arms only.

Risk of crushing hands

On this couch a warning sticker is placed.

 When adjusting this couch, keep hands away from the couch for at least 20 cm, especially on places that have been marked by the hand crush warning symbol.




Fix rolling top section

Fix all rolling top sections of the Manumed Special Traction (type 004, 916 and 926) when the couch is not actually used for traction treatment (for example in case a client is entering or getting off the couch)

Traction only in horizontal position

Traction should only be realised with all top sections of the Manumed Special Traction (type 004, 916 and 926) in horizontal position.

TRACTION AT 900 N MAXIMUM


 The maximum traction force with the Manumed Special Traction (type 004, 916 and 926) is 900 N (90 kg).

9 Cleaning, maintenance and troubleshooting

!!! IMPORTANT !!!

It is very important for the life of the upholstery that it is properly cleaned. Skin oils, perspiration, make-up products, hairspray, etc. and overly aggressive detergents and disinfectants can have a very detrimental effect on the lifespan of the upholstery.

Cleaning

 Do not use agents that contain alcohol or other aggressive cleaners.

- The couch must be cleaned before it is first used and before it is disinfected.
- Clean the couch with a damp cloth.
- Use a mild detergent to clean the surface.
- Remove soap residue with a damp cloth and clean water.

Disinfection

- Clean the couch as described above before proceeding to disinfect the couch.
- Follow the disinfectant's instructions for use.
- Never use a mixture of disinfectants or a disinfectant and soap mixture.
- Preferably use a cloth to apply the agent to the imitation leather.
- Avoid water accumulation in the hinge points of the metal frame. (In the worst case, exposing the hinges to water in the long-term can result in rust formation)
- The disinfectants listed on the information sheet, are tested and safe for use on the imitation leather of the treatment table.

For the most current version of the list see www.enraf-nonius.com/downloads.


Remark:

Since we have no control over the production and raw materials used for the disinfectants, we are unable to give a general guarantee that these agents will not damage the upholstery.

Troubleshooting

If you encounter any problem with the Manumed, stop using the couch and contact your supplier.

Maintenance

 It is mandatory to have the couch checked annually by authorized personnel of Enraf-Nonius or by its authorized distributor.

- Check the operation of every section adjustment regularly (at least once every month). For correct operation keep the bars of the mechanism clean and free of grease.
- Check at least once every 6 months the functioning of the height adjustment if this has not been used for a long time.
- Disconnect the mains cable from the electricity supply if the couch is not being used for a long period.

Expected service life

Provided the annual maintenance is carried out by a qualified Enraf-Nonius service technician or by an official distributor as described in the service manual, and the maintenance technician is of the opinion that the couch is suitable for use according to the specifications, the Manumed will remain suitable for its intended use.

End of life

The Manumed contains materials which can be recycled and/or are noxious for the environment.



Please ensure that you are well informed of the local rules and regulations regarding the removal of equipment and accessories.

10 Specifications

Technical data

Mains voltage:	100-240V ~
Frequency:	50/60 Hz
Duration of continuous operation	short-time operation, 4 minutes maximum.
IP classification	IPX0 (treatment couch)

Type		Hydraulic high-low	Electric high-low	Fixed height	separate arm sections	separate leg sections	flexion position	table top size (cm)	height adjustment (cm)	lifting capacity	Max current consumption
212	Optimal 3-section	x						204 x 67/57/80	47 - 97	200 kg	
222	Optimal 3-section		x					204 x 67/57/80	47 - 100	200 kg	2.0 A
213	Optimal 3-section	x					x	204 x 67/57/80	47 - 97	200 kg	
243	Optimal 3-section		x				x	204 x 67/57/80	47 - 100	200 kg	2.0 A
214	Optimal 3-section	x			x			204 x 67/57/80	47 - 97	200 kg	
224	Optimal 3-section		x		x			204 x 67/57/80	47 - 100	200 kg	2.0 A
215	Optimal 3-section	x			x		x	204 x 67/57/80	47 - 97	200 kg	
245	Optimal 3-section		x		x		x	204 x 67/57/80	47 - 100	200 kg	2.0 A
311	Optimal 2-section	x						201 x 67/57/80	47 - 97	200 kg	
312	Optimal 2-section	x						201x67	45 - 95	200 kg	
321	Optimal 2-section		x					201 x 67/57/80	47 - 100	200 kg	2.0 A
322	Optimal 2-section		x					201x67	45 - 98	200 kg	2.0 A
313	Optimal 2-section	x			x			201 x 67/57/80	47 - 97	200 kg	
323	Optimal 2-section		x		x			201 x 67/57/80	47 - 100	200 kg	2.0 A

Type		Hydraulic high - low	Electric high - low	Fixed height	separate arm sections	separate leg sections	flexion position	table top size (cm)	height adjustment (cm)	lifting capacity	Max current consumption
446	Osteo 4-section 3 motors		x				x	214 x 67	51 - 103	200 kg	2.0 A
448	Osteo 6-section 3 motors		x		x		x	214 x 67	51 - 103	200 kg	2.0 A
449	Osteo 7-section 3 motors		x		x	x	x	214 x 67	51 - 103	200 kg	2.0 A
612	Comfort 3-section	x						200 x 67	46- 96	200 kg	
622	Comfort 3-section		x					200 x 67	46 - 99	200 kg	2.0 A
632	Comfort 3-section		x					200 x 67	46 - 99	200 kg	2.0 A
613	Comfort 3-section	x				x		200 x 67	46 - 96	200 kg	
623	Comfort 3-section		x			x		200 x 67	46 - 99	200 kg	2.0 A
511	Exercise 2-section	x						203 x 120	44 - 94	200 kg	
521	Exercise 2-section		x					203 x 120	44 - 97	250 kg	2.0 A
510	Exercise 1-section	x						100/120 x 200	44 - 94	200 kg	
520	Exercise 1-section		x					100/120 x 200	44 - 97	250 kg	2.0 A
004	Traction fixed height			x				195 x 67	83	135 kg	
916	Traction 4-section	x						203 x 67	45 - 95	200 kg	
926	Traction 4-section		x					203 x 67	45 - 95	200 kg	2.0 A
Technical modifications reserved!											

Safety and performance standards

This equipment complies with all requirements of the Medical Device Regulation (EU) 2017/745.

Medical device classification I

Safety class according to IEC 60601-1 II, double insulated
Type B Applied part

Environmental conditions

Environmental conditions for transport and storage

Environmental temperature	-10° to +50° C
Relative humidity	20 to 90 %
Atmospheric pressure	800 to 1060 hPa

Environmental conditions normal use

Environmental temperature	-10° to 40° C
Relative humidity	30 to 70 %
Atmospheric pressure	700 to 1060 hPa

11 Contact

For assistance, please visit our website www.enraf-nonius.com

The latest version (in electronic or printed format) of this Instructions for Use can be obtained free of charge from our website www.enraf-nonius.com or by contacting distributor or by calling the telephone number: +31-(0)10-2030600. The Instructions for Use will be sent (free of charge) to you within 7 (seven) calendar days.

12 Product liability

A law on Product Liability has become effective in many countries. This Product Liability law implies, amongst other things, that once a period of 10 years has elapsed after a product has been brought into circulation, the manufacturer can no longer be held responsible for possible shortcomings of the product.

To the maximum extent permitted by applicable law, in no event will Enraf-Nonius or its suppliers or resellers be liable for any indirect, special, incidental or consequential damages arising from the use of or inability to use the product, including, without limitation, damages for loss of goodwill, work and productivity, computer failure or malfunction, or any and all other commercial damages or losses, even if advised of the possibility thereof, and regardless of the legal or equitable theory (contract, tort or otherwise) upon which the claim is based. In any case, Enraf-Nonius entire liability under any provision of this agreement shall not exceed in the aggregate the sum of the fees paid for this product and fees for support of the product received by Enraf-Nonius under a separate support agreement (if any), with the exception of death or personal injury caused by the negligence of Enraf-Nonius to the extent applicable law prohibits the limitation of damages in such cases.

The opposing party (product's user or its representative) shall disclaim Enraf-Nonius from all claims arising from third parties, whatever nature or whatever relationship to the opposing party.

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Vareseweg 127 | 3047 AT | Rotterdam | The Netherlands
Tel: +31 (0)10-20 30 600 | info@enraf-nonus.nl



PARTNER FOR LIFE

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