Extension Systems

TESI® ComfoTrac
TESI® ComfoTrac duo

User Manual

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Notations

Times New Roman in type size 11	- Descriptions and explanations;
Arial in type size 10	- keys and buttons of the TESI® benches;
Lucida in type size 10/11	- Text appears on the display of the TESI® benches.

Warnings and safety precautions

Warning!
Warnings which have to be observed by all means!

Caution!
Observe the instructions for use!

Note!
Information that will facilitate your work.

Glossary

Touch Screen	-	Display equipped with a touch panel. The touch panel reacts to the smooth touch of the respective sector.
Button	-	Sector in the Touch Screen which reacts to the smooth touch.
Touch	-	Smooth touch of the Touch Screen.
Stand-by-push-button	-	Switch on the right of the Touch Screen puts the device into the Stand-by-mode. In this mode Stand-by-display lights up.
Lumbar-spine extension	-	Extension of the vertebral column in the lumbar region.
Cervical-spine extension	-	Extension of the vertebral column in the cervical region.
Firmware	-	Software for a microcontroller in Eprom / Flashrom programmed.

Contents

1 Introduction

1.1 Intended use

Device for traction therapy and vibration massage

1.2 Note concerning the operating personnel

The device is to be operated by healthcare professionals only.

1.3 Description of the unit

The **TESI**® benches are medical devices for combined physical therapy. The following options for treatment are offered:

- thermotherapy,
- paravertebral massage,
- vibration,
- static or intermittent extension.

The system permits the optional or combined application of these modes. While the patient feels very comfortable with the treatment, for the therapist it offers high operational comfort for time-saving treatment.

The intermittent **TESI**® bench permits the use of maximal stretching or traction, alternating with periods of complete relaxation. In the treatment of many painful disturbances of the limbs and the spinal column, it is more effective than continuous static extension. Especially designed equipment guarantees best results for the cervical and thoracic extension as well as the extension of the pelvis. Additional possibilities for extension are offered for arm, shoulder as well as pelvis and foot joints.

Therapeutic effects of heat:

- Dilatation of the vascular system; reflectorically also in deep tissue layers. Also suited without any restriction for carriers of implants;
- Increase in elasticity and mobility;
- Pain relief.

Effects of paravertebral massage and vibration:

- Increase in circulation and metabolism;
- Muscle relaxation and increase in elasticity and mobility.

Therapeutic effects of intermittent extension:

- Extension and mobilization of muscular and connective tissue structures;
- Decompression of intervertebral discs and compressed nerves;
- Dissolution of muscular tensions by intermittent traction and detraction.

1.4 Device view TESI® bench

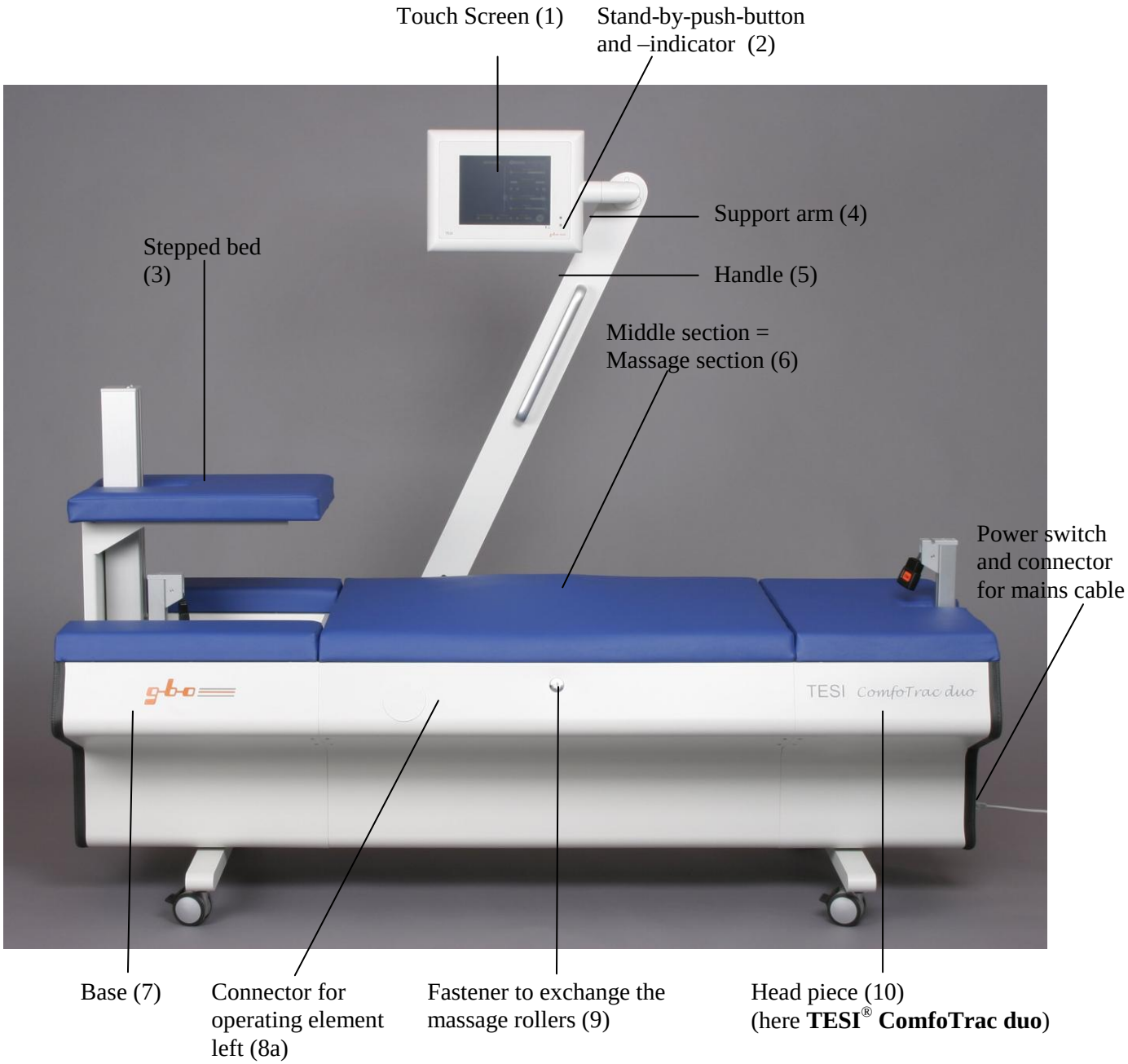


Figure 1: Device view

Cushion, belts and extension unit represent the applied parts of the bench.

1.5 Short instructions

Warning!

Before treatment you should explain the function of the emergency-stop switch to the patient. **The emergency-stop switch should remain in the patient's hand during the whole treatment.**

1. Switch on the bench through the main switch at the front of the head piece (10).
2. The device carries out an automatic check of all functions. The faultless automatic check ends with an acoustic sign (triad-gong).
3. Please note that the extension system can not be used before the heating-up phase which takes 5 minutes. A message on the display informs you about the remaining heating-up time. We recommend to switch on the TESI® device at least 5 minutes before the first treatment session. However, the massage function can be used independently from the extension system.
4. Position the patient with the equipment in accordance to the desired treatment.
5. Set the following:
   a. Temperature,
   b. Roller height.
6. Select the treatment:
   - Extension,
   - Massage,
   - Extension and Massage.
7. Set the treatment time.
8. When massage has been selected, set the parameters:
   a. Roller pressure,
   b. Region of the back,
   c. Speed, the massage starts! The treatment time does not pass yet (please observe Point 9);
   d. if necessary, vibration.
9. When extension has been selected, set the parameters:
   a. Lumbar spine or cervical spine (only for **TESI® ComfoTrac duo**),
   b. Extension height (adjustable only if traction power = 0 N),
   c. Traction power → the traction time is set automatically on continuous traction and extension starts! The treatment time does not pass yet (please observe Point 9);
   d. If necessary, traction time, duration of pause, ripple (course of traction power during the duration of traction), basis (traction power during the duration of pause).
10. Press the **Button (Start)** and the treatment time passes.
11. The treatment time ends with the triad-gong. The traction devices will loosen. The massage rollers will move down and stop. Vibration stops.
12. Remove the straps and belts.
13. After the treatment the patient should remain in an upside position sitting with his legs dangling over the side of the bench for about 3 to 5 minutes and remain quiet and relaxed.
14. If the bench is not used any longer, press the **Stand-by-push-button**.

2 Start of operation

2.1 Transport and assembly

To place the unit, each plane surface is appropriate. Please take notice of having enough space around the device to reach the power switch comfortably and possibly be able to pull off the power cable. Keep a wall distance of at least 20 cm. For fixing the device please use the brakes of the rollers.
The device should neither be placed in front of radiators or radiant heaters nor should it be covered by pillows or blankets while in operation. The device is not made for outdoor operation.

The **TESI®** benches correspond to the regulations, EN 60601. They are devices of protection class I. Within the scope of the Medical Device Directive (MDD) the **TESI®** benches belong to class IIa (please observe also Chapter 7 Warnings and safety precautions).

Please check all components to be in external integrity before use.

Warning!

- The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.
- If the patient and/or the patient cable is directly exposed to a radiator of a medical device for high frequency heat therapy, damage of the device or danger to the patient cannot be excluded. As a rule, a clearance distance of 2 - 3 m is sufficient.
- Do not pierce the heated cover.
- In case of any visible operational disturbances, please contact immediately gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG.

2.2 Connection and switch-on

The **TESI®** bench has been set to be connected to supply voltages of 100 - 240 V. Irrespective of the adjusted mains voltage, the device is appropriate for power frequencies of 50 to 60 Hz.

Connect the device with the mains cable to a socket with protective ground. The protective ground must work correctly.

The **TESI®** bench is switched on by the mains switch at the front of the head piece (10). By this arrangement an erroneous or unintended disconnection of the device during normal operations shall be avoided.

After switching on the **TESI®** bench, an automatic check of all functions will be carried out.

Warning!

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

It is only allowed to connect CompactFlash-cards or chip-cards provided by the manufacturer into the card-slots of the device.

2.2.1 Fuses

1. Unplug the mains plug.
2. The device is protected by 2 fuses on the mains side that are located in a pluggable box at the front of the head piece (10).
3. With a screw driver the box can be pulled out of the receiver by the small slot.
4. Only fuses that correspond to the specifications named in the technical data should be used.

Warning!

Risk of fire if unqualified fuses are used!

2.3 Placing out of operation

In order to disconnect the device just disconnect it from the mains power supply. No other measures are to be taken.

2.4 Waste removal of the device and accessories

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment. The waste removal at the end of the service life will be done by the manufacturer.

2.5 Settings

2.5.1 The menu

You can open the menu by touching the **Button (Menu)**. It provides the following submenus:

- Settings (see Chapter 0);
- Service menu (see Service manual).

The settings are device-specific settings (see Table 1). These settings should be done during assembly by a medical product adviser or a service technician. Once the **TESI®** bench has been switched on and is ready, you can start immediately with the standard settings.

!! Note!

You can only start the menu with the **Button (Menu)**, if no treatment is in progress.

Settings	Setting possibilities	Delivery state
Volume of gong	0 - 3	1
Language	German English Russian Chinese Polish	German
Temperature (°C)	0 - 35	20
Treatment time (min)	0 - 30	10
Volume of audioreplay	0 - 15	0
Automatic stand-by after the end of treatment within a specific time	10 min / 30 min / never	10 min

Table 1: Settings

2.5.2 Modification of the settings

Upon switching on the device, the settings are preset through the **Stand-by-Switch**.

1. Touch the **Button (Menu)**.
2. You are in the menu. Touch the **Button** for settings.
3. You are in the submenu settings. The submenu provides the above-mentioned options.
4. Modify the device settings by touching the respective **Button**.
5. To store confirm by touching the Button **(OK)**. If you do not want to store the modifications of the settings touch the Button **(Abortion)**. You return to the menu.
6. Leave the menu by touching the **Button (Return)**. You return to the start display.

3 Description of function

3.1 Acoustic user guidance

The following table shows the acoustic signals and their meaning:

Type of signal	Cause
Beep	• **The interruption switch** has been pressed;
Information sound	• In case the limit of power has been reached or in case of a failure;
Triad-gong	• At the end of the faultless automatic check when switching on the device; • At the end of the treatment time.

Table 2: Acoustic user guidance

3.2 Operating notes

3.2.1 Interruption switch of the patient

Before the start of operation you should explain to the patient how to use the **Interruption switch**. The patient can interrupt the treatment by touching the button at any time. All extension powers will get untied automatically, the patient remains in a comfortable position tied to the equipment. The personnel will be informed by the beep.

Since the extension gets untied automatically, it is not necessary for the personnel to care the patient immediately.

To start the treatment again, touch the **Button (Start)**.

!! Note!

The treatment can be interrupted at any time by touching the **Button (Stop)**.

3.2.2 Touch Screen

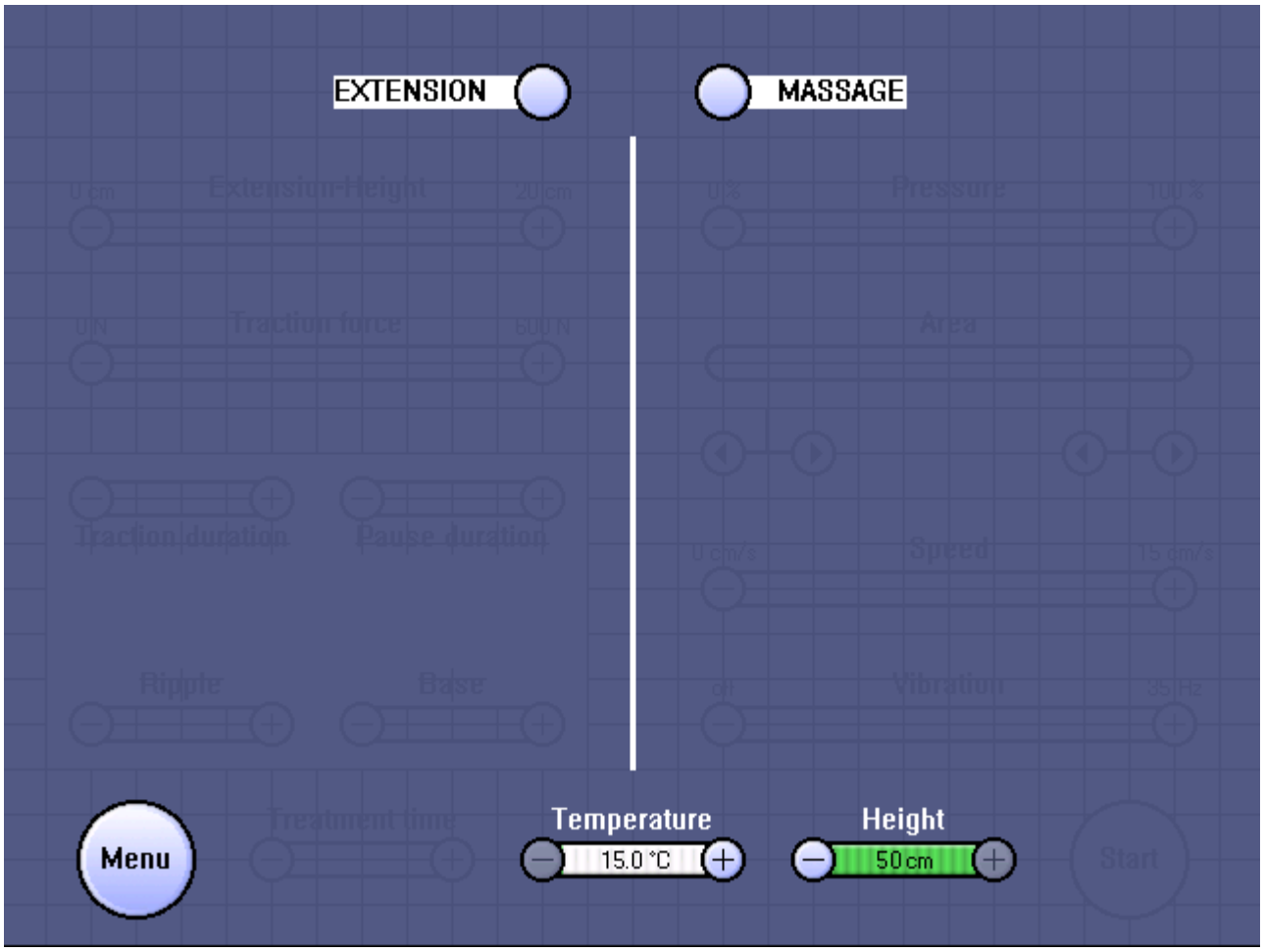


Figure 2: Basic display of the Touch Screen

The display shows in case of **Extension**:	The display shows in case of **Massage**:
• the remaining treatment time • the temperature • the rise of step • the extension height • the traction power • the traction time • the pause time • Ripple (form of the traction power during the traction time) • Basis (percentage of the traction power given during the pause time) • Switchboard for Start/Stop • Switchboard for menu.	• the remaining treatment time • the temperature • the rise of step • the roller pressure • the speed • the vibration • the region of the back of the massage • Switchboard for Start/Stop • Switchboard for menu.

3.3 Settings / Functions

Settings / Functions	Setting possibilities/ Confirmation by	Range of values
Treatment time	Therapist	0 – 30 Min.
Temperature	Therapist	20 – 35 °C
Rise of step	Therapist	0 – 50 cm
Traction power lumbar spine (cervical spine)	Therapist	0 – 600 N (160 N)
Traction time	Therapist	1 – 30 s, endless
Pause time	Therapist	0 – 30 s
Ripple (Form of the traction power during the traction time)	Therapist	0 – 90 %
Basis (percentage of the traction power given during the pause time)	Therapist	10 – 90 %
Massage device speed	Therapist	0 – 15 cm/s
Massage device roller pressure	Therapist	0 – 100 %
Massage device vibration	Therapist	15 – 35 Hz
Massage device region of the back	Therapist	analog
Interruption switch/Button (Stop)	Patient / Therapist	

Table 3: Settings

!! Note!

- The traction power is limited to 160 N in case of cervical spine extension and to 600 N in case of lumbar spine extension.
- For the traction time, continuous traction is offered automatically. When the traction time is changed for the first time, the pause time will be set automatically to 1 s.
- It is possible to set all parameters before and during the treatment.
- It is possible to switch on and off extension and massage by touching the respective **Buttons**. When a form of treatment is active it is shown by a rose dot in the respective **Button**.
- It is possible to stop the treatment at any time by touching the **Button (Stop)**.

4 Therapy

4.1 Thermotherapy

For thermotherapy the cover of the middle section of the **TESI®** bench can be heated for the patient. When required the thermotherapy can be combined with all other therapies.

By touching the **Button (+)** or **Button (-)** on the Touch Screen the temperature of the cover of the middle section of the **TESI®** bench can be increased up to a maximum heating capacity of 35 °C or be reduced.

4.2 Massage

Through casters which pass the vertebral column with adjustable pressure it is possible to apply a paravertebral roller massage with in depth muscular effect. The height of the massage rollers is adjustable. If required the massage can be supported by an additional and separately connectable vibration.

The massage is independent of the thermotherapy and extension treatment and it can be combined with these if required.

1. By touching the **Buttons (+,-)** set:
   - Temperature (if thermotherapy is required),
   - Rise of step.
2. Touch the **Button** of massage. The roller pressure will be set on 50%.
3. By touching the **Buttons (+,-)** set the treatment time.
4. By touching the **Buttons (+,-)** set the roller pressure.
5. By touching the **Buttons (<,>)** set the region of the back.
6. By touching the **Buttons (+,-)** set the speed, the massage starts! The treatment time does not pass yet (see Point 8).
7. If required, set the vibration by touching the **Buttons (+,-)**.
8. Touch the **Start-Button**. The treatment time passes.
9. At the end of the treatment time the triad-gong sounds. The extension traction (if extension has also been selected) will get untied. The massage rollers go down and stop. Vibration stops.
10. Remove the straps and belts.
11. After the treatment the patient should remain in an upside position sitting with his legs dangling over the side of the bench for about 3 to 5 minutes and remain quiet and relaxed.

12. If the bench is not used any longer, press the **Stand-by-push-button**.

!! Note!

- The treatment can be stopped at any time by touching the **Button (Stop)**.
- The treatment can be stopped at any time by pressing the **Interruption switch**.
- 10 minutes after the end of the treatment the device will automatically activate the stand-by-mode, which means that the stepped bed will move down.This setting can be modified *(see chapter 2.3.2).*

4.3 Extension

Warning!

Before treatment you should explain the function of the emergency-stop switch to the patient. **The emergency-stop switch should remain in the patient's hand during the whole treatment.**

Note!

Your TESI® device uses high precision amplifiers for the measurement of the traction force. These amplifiers require a heating-up phase to reach the best possible performance.
The extension system can not be used before the heating-up phase is elapsed. A message will be shown that informs you about the remaining heating-up time.

However, the massage function can be used independently from the extension system.

We recommend switching on the TESI® device at least five minutes before the first treatment session.

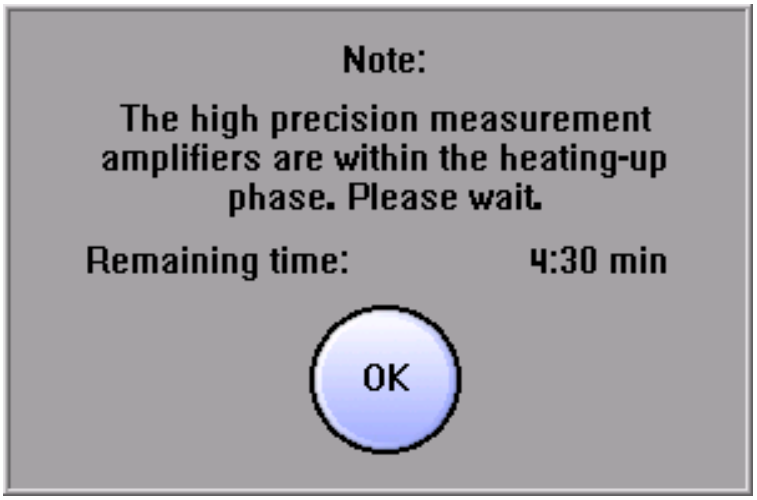


Figure 3: **Message during heating-up phase**

1. By touching the **Buttons (+,-)** set:
   - Temperature (if thermotherapy is required)
   - Rise of step.
2. Touch the **Button** of extension.
3. Set the treatment time by touching the **Buttons (+,-)**.
4. Select lumbar spine extension or cervical spine extension by touching the respective **Button** (only in case of ComfoTrac duo).
5. Apply the equipment to the patient, see also Chapter 4.3.2.
6. Set the extension height by touching the **Buttons (+,-)**.
7. Set the traction power by touching the **Buttons (+,-)** → the traction time will be set automatically on continuous traction, and the extension starts! The treatment time will not pass yet (see Point 11).
8. If required set the traction time and pause time by touching the **Buttons (+,-)**.
9. If required set the form of the Ripple by touching the **Buttons (+,-)**. That is the form of the traction power during the traction time.

10. If required set the basic value by touching the **Buttons (+,-)**. That is the percentage of the traction power given during the pause time.
11. Touch the **Button (Start)**. The treatment time passes.
12. At the end of the treatment time the triad-gong sounds. The extension traction gets untied. If massage has also been selected: the massage rollers go down and stop. Vibration stops.
13. Remove the straps and belts.
14. After the treatment the patient should remain in an upside position sitting with his legs dangling over the side of the bench for about 3 to 5 minutes and remain quiet and relaxed.
15. If the bench is not used any longer, press the **Stand-by-push-button**.

!! Note!

- The cervical spine extension is only possible with the TESI® ComfoTrac duo bench.
- Please note that the extension rope can only be moved when the extension treatment is activated.
- The traction power is limited to 160 N in case of cervical spine extension and to 600 N in case of lumbar spine extension.
- For the traction time, continuous traction is offered automatically. When the traction time is changed for the first time, the pause time will be set automatically to 1 s.
- The treatment can be stopped at any time by touching the **Button (Stop)**.
- The treatment can be stopped at any time by pressing the **Interruption switch**.
- 10 minutes after the end of the treatment the device will automatically activate the stand-by-mode, which means that the stepped bed will move down.This setting can be modified *(see chapter 2.3.2).*

4.3.1 The use of the cervical cushion during the extension

When the cervical padding is used during the extension please check the diffraction angle because it changes the position a lot during the treatment. In most cases the cervical cushion is not used, except in cases of excessive contortion of the superior dorsal region.

4.3.2 How to set up the equipment for cervical spine extension

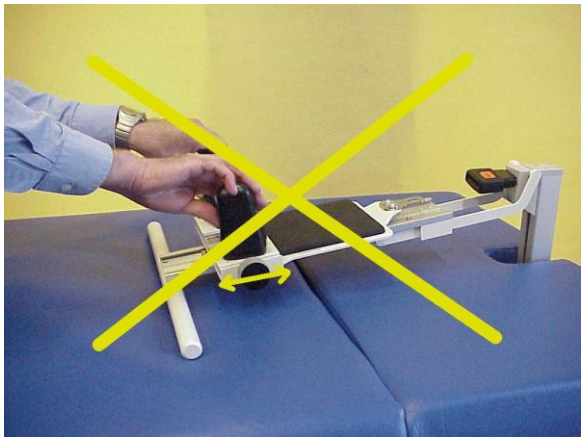
!! Note!

- The cervical spine extension can only be carried out with the **TESI® ComfoTrac duo** bench.
- The cervical cushion will not normally be required for cervical spine extension. Please refer also to Chapter 4.3.1.

1. Move the cervical spine extension bar from its home position as far upwards as possible so that the cervical spine extension unit can be fully and easily suspended (approx. 10 cm should be sufficient).
2. Position the patient on the bench.

3. Set the basic position of the cervical spine extension unit when the patient's head is resting on the cover of the extension unit and is held firmly by the extension clamps. The spacing of the clamps can be adjusted. Be sure that:

the horizontal basic position is set by moving the unit as shown in this illustration and that in doing so the extension carriage is positioned at or close to the bottom end of its range of movement.



the basic position is **not** set by moving the extension carriage on the unit.

4. Now fasten the cervical spine extension rope to the belt fastener on the tongue of the belt of the extension carriage.
5. Continue with the other settings as described in Chapter 4.3.
6. Start the extension exercise.

4.3.3 How to set up the equipment for lumbar spine extension

Adjusting the thorax belt

The thorax belt is required for the counterextension exercise and for all extensions of the lower extremities. It should be installed on the unit before the patient lies down on the bench. We recommend that you release the straps of the thorax belt fixed at the head end of the unit and leave them to hang loosely. This will permit the belt to be adjusted for each patient's needs.

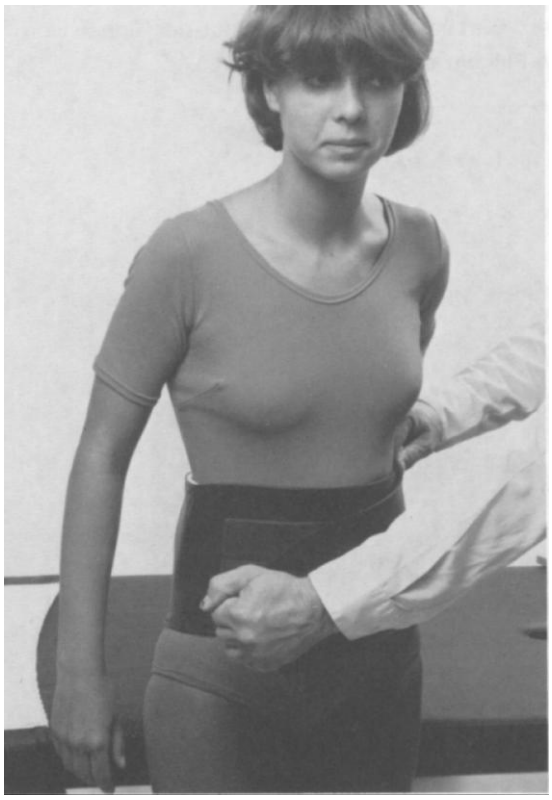
To put on the belt, first locate the bottom of the ribs and position the thorax belt so that the bottom end of the ribs is in the middle of the thorax belt between the two wings of the belt.

To fasten the thorax belt, stand sideways to the head end of the unit. Take the fastening straps of the belt in your left hand and position the belt so that the bottom end of the ribs is centered under the belt. Then place the inner belt wing across the body so that it reaches the opposite shoulder.

Holding the thorax belt in this position with the left hand, take the other wing of the belt in your right hand. Pull both ends of the belt upwards and over the rib cage so that the lower, inside part of the belt is pressed into the soft area of tissue between the ribs and the hips. It is essential that the belt does not slip under the arms and/or onto the rib cage.

To fasten the thorax belt to the bench, guide the straps into the eyelets down on the head piece (10) on the bench and tighten the equipment by pulling on the straps underneath the patient.

Adjusting the pelvic belt



It is easier to adjust the pelvic belt if the equipment is adjusted on the patient before he lies down on the bench.

The strap is at the back of the patient, between his legs. The soft side of the equipment should be facing the patient.

With the pelvic belt already adjusted and with the corresponding straps hanging freely behind the patient, the patient is correctly prepared.

Even if the pelvic belt had already been adjusted to the patient, it should be adjusted to the correct position once again after the patient lies on the bench.

Stand sideways to the feet end of the bench and take one wing of the pelvic belt in your right hand. Then place the belt diagonally across the body towards the opposite leg and press the upper, external part of the belt together in the soft area of tissue of the waist.

Take the other wing of the pelvic belt in your left hand and cross it over firmly so that the end of the belt is pressed inwards into the soft area of tissue of the waist. This will prevent the belt fromslipping while the extension unit is being used. Moreover, this position is also comfortable for the patient and will not give rise to any complaints.

To fasten the pelvic belt, fasten the belt fastener on the pelvic belt to the extension rope on the foot piece (7). Tighten the strap by placing your hand beneath it and pulling upwards.

Move the stepped bed under the knees of the patient to attain the highest position. If a lower position is required, the foot piece (7) can be lowered. Both positions help to smooth out curvature in the lumbar region.

5 Behavior in case of failures

The following failures will be indicated by the **TESI®** bench both optically and acoustically. Most of them can be remedied by following the instructions on the display. As a rule, the following applies:

1. The **TESI®** bench will not execute any incorrectly entered functions or modifications entered by pressing on the Touch Screen.
2. The acoustic error signal will sound.
3. An error message will appear on the display.

5.1 Notes

♦ Note – Only touch the screen with one single finger. Dont slide over the screen.

Cause: The Touch Screen was touched at several different points or the fingers made a sliding movement across the screen. The Touch Screen must not be operated in this way.

Suggestion:
1. Please note that the Touch Screen will only work properly if it is touched only by a single finger at a single point. If more than one finger or the ball of the thumb are placed on the active surface, this will trigger the error message shown above.
2. Confirm the message with the **Button (OK)**.

♦ Note – The rope of the cervical spine extension is at its limit. Please check that there is enough remaining space for its movement.

Cause: The extension rope has been drawn in as far as the end stop. It will not be possible to attain the desired force.

Suggestion:
1. Position the carriage to allow sufficient travel distance. Move the neck cushions on the carriage right down and then slide the carriage under the head of the patient. Hang the extension carriage on the extension bar.
2. Confirm the message by touching the **Button (OK).**
3. Reset the extension parameters.

♦ Note – The rope of the lumbar spine extension is at its limit. Please check that there is enough remaining space for its movement.

Cause: The extension rope was retracted to the end stop. It will not be possible to attain the desired force.

Suggestion:
1. Position the patient to allow sufficient travel distance.
2. Confirm the message by touching the **Button (OK).**
3. Reset the extension parameters.

♦ Note – The stepped bed is at the same height as the traction rope and could not be lowered any more.

Cause: The stepped bed cannot be lowered below the extension bar because otherwise the rope would become jammed.

Suggestion:
1. First, lower the extension height, which will enable you to further lower the stepped bed.
2. Confirm the message by touching the **Button (OK).**
3. The stepped bed can now be lowered further.

5.2 Warnings

♦ Warning – The stepped bed has been stopped! It should only be moved without load.

Cause: The stepped bed can only be moved when not under excessive load.

Suggestion:
1. The patient must remove his feet from the stepped bed.
2. Touch the **Button (OK)**.
3. Move the stepped bed into the desired position.

♦ Warning – Height adjustment for lumbar spine extension overloaded.

Cause: The lumbar spine extension height adjuster can only be moved when not under load.

Suggestion:
1. The extension bar must not be moved under load. Remove any hindrances or loads.
2. Touch the **Button (OK)**.
3. Move the extension bar to the desired position.

♦ Warning – Height adjustment for cervical spine extension overloaded.

Cause: The cervical spine extension height adjuster can only be moved when not under load.

Suggestion:
1. The extension bar must not be moved under load. Remove any hindrances.
2. Touch the **Button (OK)**.
3. Move the extension bar to the desired position.

♦ Warning – A too large meassurement difference was detected on the cervical spine extension unit.

Cause: There is a fault in the measurement of the traction power.

What to do: Contact the Service Center.

♦ Warning – A too large meassurement difference was detected on the lumbar spine extension unit.

Cause: There is a fault in the measurement of the traction power.

What to do: Contact the Service Center.

♦ Warning – The carriage motor is blocked and was stopped.

Cause: The carriage cannot be moved and was therefore stopped for safety reasons.

Suggestion:
1. Remove all unintended loads from the cover.
2. Confirm the message by touching the **Button (OK)** and try again to move the carriage by touching the Touch Screen.
3. If the message appears again, contact the Service Center.

♦ Warning – The spindle motor is blocked and was stopped.

Cause: The contact pressure adjuster for the carriage cannot be moved and has therefore been stopped for safety reasons.

Suggestion:
1. Remove all unnecessary loads from the cover.
2. Confirm the message by touching the **Button (OK)** and try to move the carriage again by touching the Touch Screen.
3. If the message appears again, contact the Service Center.

5.3 Errors

There are two possible error messages:

♦ Error - CAN: No ACK.

and

♦ Error - CAN: Timeout.

Cause: A communication error between the different internal subsystems occured.

Suggestion: Contact the service center.

5.4 Other notes

♦ Attention – The therapy was interrupted. Continue with OK.

Cause: The patient actuated the interruption switch.

Suggestion:
1. Find out why the interruption switch was actuated.
2. Confirm the message by touching the **Button (OK)**.
3. The bench will continue the massage functions if these had been active before the interruption switch was actuated. All extension parameters must be reset.

6 Maintenance

Functionality, reliability and safety characteristics of the **TESI®** bench are only guaranteed in case of proper use in accordance with the operating instructions. Safety control, maintenance work, repair work and modifications shall only be carried out by the manufacturer or the service agents authorized by him. In case of a failure, parts which influence the safety of the device shall only be replaced by original spare parts of the manufacturer. The electric installation shall be carried out in accordance with the requirements of VDE/IEC. **The device does not contain any parts which require maintenance work by the user.**

6.1 Legal provisions and requirements

The device is subject to the provisions of the Medical Device Directive. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be observed in particular. Operators of medical devices in active use are obligated to keep a book of the medical device and document all safety controls they are commited to do as described below

!!

Note!

The Medical Device Directive is only valid in countries throughout the EU.

6.2 Safety controls

The device is subject to the Medical Device Directive. The safety controls are to be carried out on the basis of this directive at 12-months intervals by a qualified service agency.

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked by the manufacturer or by a service agency authorized by him at 12-months intervals.

The check shall consist of at least the following criteria:

- Safety check of electric parts of the device
- Check of the device in respect of external integrity
- Check of all display and operating elements in respect of damages
- Check of all inscriptions in respect of legibility
- Check of the power-cable
- Check of all functions of the device

The manufacturer keeps a respective check list available.

6.3 Cleaning, disinfection and care

Warning!

Before cleaning or disinfection unplug the mains plug out of the socket!

The device is suited for wiping disinfection. Make sure that no liquids soak into the device. Under no circumstances the plug or socket must get wet. Do not sprinkle the device for cleaning or disinfection. The device is not suited for hot sterilisation or sterilisation with gases.

- To clean the imitation leather parts use a dry or damp cloth. Do not use any agents containing higher portions of alcohol. Examples for useful products to be used for cleaning are: “Mikrobac Tissues” by Hartmann/Bode or “Cleanisept Wipes” by Dr. Schumacher.

- If the imitation leather of the heating cover is wet, dry it carefully. In case you detect any damage or disturbance, the heating cover has to be repaired by the manufacturer.

- For the equipment dry cleaning is recommended.

7 Warnings and safety precautions

Warning!

- Do not pierce the heating cover accidentally.

- In case of any visible operational disturbances, please contact immediately gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG.

- Please take care that the patient does not hit the support arm or the touch panel when lying down on or getting up from the bench.

- The lumbar extension device must not be used for cervical extension.

- The bench must not be left unattended if there is a patient lying on it with extension equipment.

7.1 Contra-indications

Indication, dosage and application of an extension are realized in sole responsibility of the user. Before applying an extension the harmlessness from a specialist's, neurologist's and orthopedists's point of view must be guaranteed.

An application of the extension system is not recommended in case of

- acute inflammatory processes,
- open wounds or abscesses in the region of the vertebral column,
- bacterial bone process (osteomyelitis), tuberculosis and other inflammatory osteopathies or arthropathies,
- malign tumors.

8 Explanation of the signs used

CE 0123

CE Conformity sign

Observe the instructions for use !

Application section with protection class B

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment.

9 Technical data

Supply voltage and supply frequency:	100-240 V, 50 – 60 Hz		
Current consumption:	max. 2.3 A with 100 V max. 0.95 A with 240 V		
Mains fuses:	T 6.3 A H 250 V		
Vibration frequency:	15 – 35 Hz ± 0,5Hz		
Heating temperature:	max. 35° C at 23° C ambient temperature		
Traction power Lumbar:	max. 600 N ± 10%		
Traction power Cervical:	max. 160 N ± 10%		
Accuracy of position of extension carriage, gallows and stepped bed	± 2 cm		
Operating mode:	Continuous operation		
MDD device class:	IIb in accordance to MDD, annex IX		
Protection class:	I in accordance to IEC 601-1 / DIN EN 60601-1		
Protection degree:	B in accordance to IEC 601-1 / DIN EN 60601-1		
IP class:	IPX0		
Safe working load:	Bench: 135 kg		
	Stepped Bed: 45 kg		
	Support arm: 75k g	The handle of the support arm can be used to get up.	
Dimensions:	max. 66/175 cm(*) × 200 cm × 94 cm (Height × depth× width) (*)Height of the device without/with support arm		
Weight:	max. 80 kg without equipment		
Color:	RAL 9002 or special varnish Coat blue		
Display:	TFT-Display		
Environmental conditions:	Operation:	Temperature range +10 °C ... +35 °C Relative air humidity 30 ... 75 %	
	Transport and storage:	Temperature -10 °C ... +50 °C Relative air humidity < 90 %, non-condensing	

By request of technical personnel gbo Medizintechnik AG can offer spare part lists check lists and circuit diagrams.

The mains connector is used for all pin disconnection from the mains power supply.

gbo Medizintechnik AG reserves the right to modify the design and specification without prior notice.

10 Accessories

Article		**Article number**
TESI® ComfoTrac Scope of supply	1 Mains supply cable 1 Thorax belt 1 Pelvic belt 1 Cervical cushion, small 1 User's manual 1 DVD "Anlagevideo" ("Setup of the equipment")	018-0-0020
TESI® ComfoTrac duo Scope of supply	1 Mains supply cable 1 Thorax belt 1 Pelvic belt 1 Cervical carriage 1 Cervical cushion, small 1 User's manual 1 DVD "Anlagevideo" ("Setup of the equipment")	018-0-0030
Pelvic belt		018-0-0002
Pelvic belt, small		018-0-0003
Cervical cushion, small		016-0-0058
Cervical carriage		018-0-0040
Cervical belt		018-0-0004
Thorax belt		018-1-0001
Headphones (for hardware revision F and higher)		017-4-0005

!!

Note!

Use gbo original accessories only to guarantee the safe function of the unit.

11 Index

Notes in accordance with the EC Directive and Medical Device Directive

The **TESI® bench** is a mains operated Extension System for combined physical therapy of protection class **I**.

The device is in accordance with the EC Medical Device Directive (93/42/EEC) and therefore carries the CE sign with the registration number of the notified body for medical devices. The according graphical symbol is placed on the type plate.

According to the Medical Device Directive, the **TESI® benches** are devices of class **IIa**.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

- the device is used in accordance with the instructions for use, especially the notes concerning maintenance and cleaning of the device as described in Chapter 6;
- the electrical installation of the location where the device will be used corresponds to the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- the mountings, amplifications, readjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
- the operator regulation of this EC-directive is observed within the scope of the Medical Device Directive.

You will obtain technical support by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life scheduled by the manufacturer is 10 years.

The **TESI® benches** are electronic devices. For their disposal the respective regulations for electronic devices have to be observed.

On request, the manufacturer will provide you with further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare part lists, and adjustment instructions as far as these are of use for the qualified technical staff of the operator.

Comments on electromagnetic compatibility (EMC)
Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories my cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with them. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2 (*)	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	

(*) Note: For devices with a power consumption between 75 W and 1000 W only.

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_τ is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d=1,2\sqrt{P}$ for 80 MHz to 800 MHz $d=2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.			
Rated power of the transmitter (W)	**Separation distance according to the tranmission frequency (m)**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz $d=1.2\sqrt{P}$**	**800 MHz to 2,5 GHz $d=2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23