QRS PELVICENTER

USER MANUAL
BASIC MODEL

The present manual was made and provided by the QRS Magnovit AG and checked for correctness. Nevertheless, it raises no claim to completeness. All information and data are subject to be changed without previous announcement.

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Pictograms

Warning!
The warnings have absolutely to be followed!

Attention!
Follow the instructions!

Note!
Information which simplify your work.

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1 Introduction

1.1 Intended use

The **QRS® Pelvicenter** serves an adjuvant treatment of incontinence with a muscle stimulation **by the "REPETITVE PERIPHAL MAGNETIC STIMULATION" (rPMS). The rPMS procedure is based on the** Faraday's principle of the magnetic induction so that a pulsating magnetic field is generated. The electrotherapy works as an external contraction support by stimulation of nerve cells.

1.2 Indications

The typical application of the Transpelvine Magnetic Stimulation TPM is:

- Strengthening the pelvic floor muscles
- Recovery after pregnancy
- Incontinence:
  - **Stress Incontinence**
  - **Urge Incontinence / OAB syndrome**
  - **Mixed Incontinence**
  - **Faecal Incontinence**
  - **Early rehabilitation after prostatectomy**
- Erectile Dysfunction
- Back-, muscle- or bone- pain within the therapy region of Pelvicenter

1.3. Patient Setting

- Empty bladder
- Replacing wet pads
- Removal of hearing aids
- Removal of body jewelry between knee and neck (chains, rings, piercings)
- Removal of watches, car keys, credit cards, pagers, mobile phones and coins

1.3 Device overview

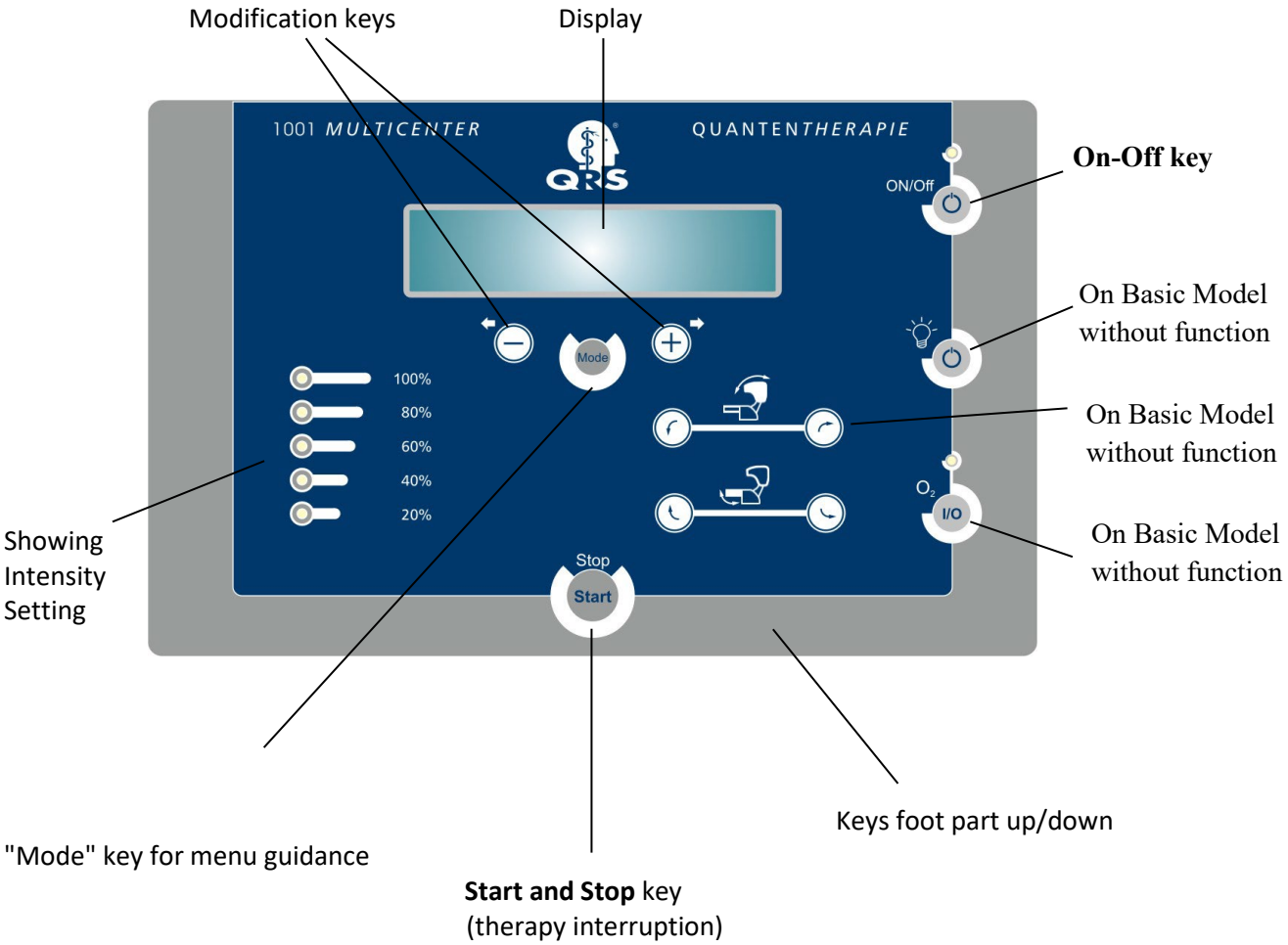
A	Electronic moveable back section
B	Washable textile leather
C	Left control panel with chipcard slot
D	Big size seat with 65 cm
E	Electronic moveable rPMS magnetic flux stimulator 16 cm
F	Electronic moveable Footer
G	Right control panel for adjusting therapy settings

1.5 Notes to the operating staff

The uses of the device may occur only by a medical specialist.

1.6 Description right control panel

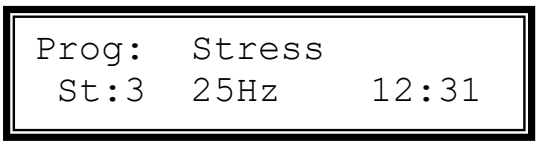
Operating field of the **QRS® - Pelvicenter**



1.6.1 Description of the Display

The **QRS ® Pelvicenter** has a 40-figure display. The shown contents, depending on the current function of the device and is described closer in chapter 3.

Display during the therapy



Meaning of the displayed parameters:
Program: Stress incontinence
Intensity: 3 (60%)
Frequency: 25 Hertz
Remaining treatment time: 12:31 minutes

!!

Note

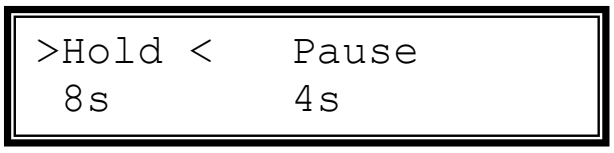
- Only with the programmed ChipCard **Individual** all parameters can be changed.
- With the programs stress incontinence, compulsion incontinence, mixing incontinence, prostatectomy / stress incontinence **only the amplitude** can be changed. Frequency, treatment duration, hold time and break are firmly given within these programs and are stored on the chip card.

Display in case of changing parameters

By a repeated pressure of the "Mode" key the focus can be put on frequency (Freq), time, hold time, break and armrest aiming. In each case, with the keys plus and minus the changeable parameters are marked by square brackets.

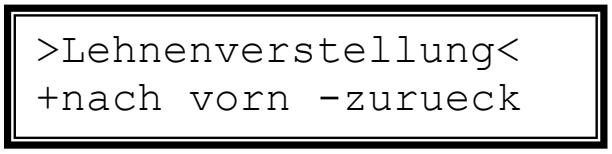
Meaning of the displayed parameters:
Ampl. Intensity: 20 – 100 %
In steps of 1 – 5 selectable

Freq. Frequency: 5 Hz – 50 Hz
In steps of 1 Hz selectable



Time Therapy time of the program
(cannot be changed)

Hold time: Flux hold time 1 – 15 seconds
In steps of 1s selectable



Pause time: Flux hold time 4 – 15 seconds
In steps of 1s selectable

Control adjustment: Forward and back

1.7 Description left control panel

The left control panel controls the on/off status of the whole system (ChipCard) but also the control of the included QRS-System. You don't need the other buttons.

Start-/Stop-key

!!

Notes

Only the On-/Off- key 

and the key 

have a function during the normal operation of the **QRS® Pelvicenter** version **QRS® 101P.**

Basic settings like the time and the language can be changed in the **QRS® 101P** by a special sequence. (see 1.7.1 and 1.7.2)

The **QRS® Pelvicenter** is **switched on** and switched off by plugging in and taking out the chip card.

With a plugged in chip card the **QRS® 101P** can be switched on and off with the On-/Off-key of the **QRS® 101P**.

1.7.1 Setting the clock

In the **QRS® Pelvicenter** is in the left armrest the **QRS® 101P** control system with a clock integrated (battery-buffered clock). This clock can set by the menu.

You get into the menu by

- switching off the device,
- if the device is turned off, press the key 

, hold this key pressed and
- turn on the device with the key 

.

  Now you are in the menu for the control of the clock and you can see the display (exemplary time):

  ```
  Time:    12:34
  ```

  A blinking Cursor is now standing at the first place of the time, in the upper example the “1”. Now you have the possibility, to increase the cipher under the cursor with the  -key or to reduce it with the  -key. With the 

-key you can confirm the current value data and come to the next input position.

  With the confirmation of the last decimal digit of the time you automatically come into the menu of the control of the date. Now you can see the display (exemplary data):

  ```
  DATE:  22.01.07
  ```

  For the control of the date please proceed as for the control of the time. With the confirmation of the final digit of the year the menu is left and the device is started in its standard functionality.

Note

- the menu for the control of the time and the data can be left at every time by pressing the 

-key. So that the settings made right now won’t be effective.
- Only the German format is available for time and date.

1.7.2 Setting the language

The user guide of **QRS® 101P** can be provided in different national languages. For the changing of the national language the operating face of the device makes available a suitable menu guidance. You can reach this menu, by

- switching off the device,
- switching off the device by pressing the key 

, holding this key pressed and
- switching on the device with the 

key.

Now you are in the menu for the setting of the national language and see the display

```
<-... DE [EN] IT ...->
```

You can move by pressing the choice keys  or  through the menu and select different national languages. The abbreviation of the current selected language is enclosed by the characters “["and"]”.

You can choose the following languages:

DE	German
EN	English
FR	French
IT	Italian
ES	Spanish
SE	Swedish

With the 

key you can confirm the current selected language, exit this menu and launch the device in its standard functionality.

Note

You can exit the menu for the chnaging of the national language at any time by pressing the 

key. Then the just carried out (defect) setting does not become effective.

1.9 Description of the display

After the plug in of the chip card the **QRS® 101P** system is started with the following notification

The messages indicate the software version, and gives you information about the current state to the operator. After the system check the **QRS® 101P** takes up communication with the **QRS® Pelvicenter** and the information indicated below is displayed.

Depending on the inserted chip card the respective patient's name and the remaining units are indicated alternating.

2 Transport and assembly

2.1 Device installation

The **QRS® Pelvicenter** is a local-bound, mains-operated device which is not moved during the appropriate use. As a setup site every level surface is suitable. The device may not be put up in front of a heater or warm blower (keep about 1m of distance). The device should stand freely, so that it can be maintained if necessary.

The device may only be set up and put into operation by an authorized service partner!

Also the transport to another setup site within an institution can only be carried out by an authorized service partner.

The device corresponds to the regulations 0750 dinars / VDE, EN 60601-1, EN 60601-1-2 and is a device of the protective class I. In the scope of the medicine product law (MDD) the device is associated to the class IIa.

The device is not determined for the operation in explosive areas. If you might work with it in anaesthesia rooms in the places at risk, the possibility of an explosion cannot be excluded.

If the patient and/or the device are in the immediate effect area of the emitter of a radio frequency-warm therapy device, a damage of the device or a danger for the patient cannot be excluded. A distance of 3m is recommended.

2.2 Power supply

The **QRS® Pelvicenter** is suitable for the connection with a mains voltage of 230 V and intended for commercial frequency of 50Hz.

Warning

To avoid the risk of an electric shock, this device can only be connected to a supply network with protective conductor.

Note

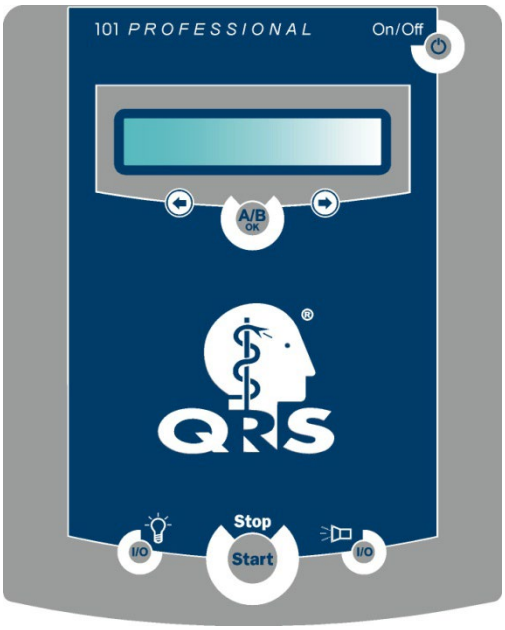
The power plug serves as a separation to the supply network. The device must be put up in such way that the power plug is accessible at any time to be able to carry out the separation of the supply network.

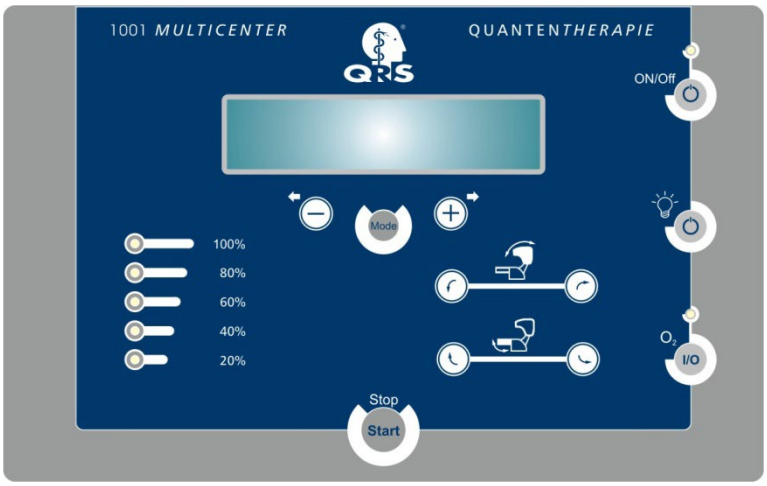
Don't use multiple sockets. If the power supply circuit does not reach up to the power socket, a lengthening circuit can be used. The cross section of this cable must be at least 3 x 1,5mm2.

2.3 Turning on the device

Put the programmed chip card into the slot of the **QRS® 101P** in the left armrest.

After the system check the **QRS® 101P** indicates alternating the patient's name programmed on the card and the remaining credit. The operating feature of the **QRS® Pelvicenter** in the right armrest turns into standby.





left armrest **QRS ® 101P** operating feature

right armrest **QRS ® 101P** operating feature

In the shown example on top, Fritz Mustermann should be treated. For him an intensity with the level 3 is given, a frequency of 25 hertz and a duration of treatment of 10 minutes. - Change request the time display in the window and the duration of treatment in the text on the standard of 20 minutes!

The patient should take a seat on the chair. If the oxygen flow is released, an oxygen mask must be connected and put on the patient.

The inclination of the foot part can be set individually on the patient. For this the key „move foot part upwards“ can be pressed as long as the patient has reached a comfortable position for his legs.

The head part can be moved down if the patient should also receive a light therapy. For this, the key „head part down“ can be pressed until the head part is completely lowered down.

Now the therapy can be started with help of the start key on the **QRS® Pelvicenter** operating feature.

After pressing the start key, following functions become active:

- The incontinence therapy starts with the parameters which are stored on the card.
- If the light therapy on the card is released, the light therapy starts
- If the oxygen flow is released, the additional oxygen flow starts

At the end of the treatment duration all running therapies are switched off. If a **QRS® 101P** magnetic field therapy on the chip card is released, now this one is started. The applicator for this therapy is integrated into the back support.

At the end of the treatment duration of the magnetic field, the therapy stops and a beep in the **QRS® 101P** is audible. This beep signals the end of the treatment of all therapies.

All movable parts like head part, foot part and back support are moving back in their start positions.
Now the patient can leave the **QRS® 101P**.

2.4 Interruption of the therapy

The therapy can be interrupted at any time using the 

key on the **QRS® 101P** or using the 

key on the **QRS® Pelvicenter** operating feature.

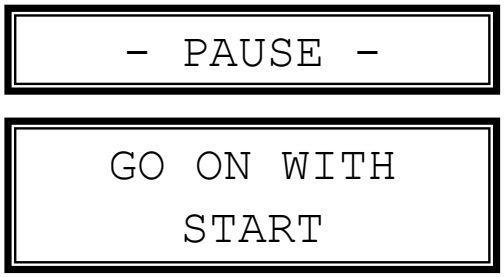
Note

If the therapy is interrupted, all movable parts are moving back in their start position and must be set again, to continue the therapy.

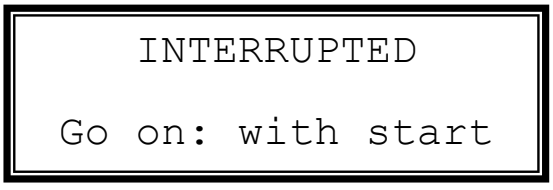
During the therapy interruption the device cannot be switched off with the 

key.

During the therapy interruption following messages can be seen alternating on the **QRS® 101P**.



During the therapy interruption following messages can be seen on the **operating feature QRS Pelvicenter QRS® 101P**



The therapy can be continued by another pressing of the 

key.

2.5 Switching off the device

After all therapies are done and the patient has left the **QRS® Pelvicenter**, the **QRS® Pelvicenter** can be switched off.

For this you pull out the programmed chip card from of the card slot of the **QRS® 101P** in the left armrest. The **QRS® 101P** automatically switches off immediately and the display becomes black. The disconnection of the operating feature in the right armrest occurs with delay.

Note

The **QRS® Pelvicenter** can also be switched off with the 

key on the **QRS® 101P**. After pressing this key the **QRS® Pelvicenter** behaves exactly like when you pull out the chip card.

During the therapy the 

key on the **QRS® 101P** is locked.

Note

The **QRS® Pelvicenter** can also be switched off with the 

key on the operating feature in the right armrest of the **QRS® Pelvicenter**. After pressing this key the **QRS® Pelvicenter** switches off itself immediately and the display becomes black. In addition, the **QRS® 101P** must be switched off with the 

key.

During the therapy the 

key on the operating feature in the right armrest of the **QRS® Pelvicenter** is locked.

Note

If the chip card is going to be pulled out of the card slot in the left armrest of the **QRS® 101P** during the running therapy, the **QRS® Pelvicenter** switches off immediately for safety reasons.
All movable parts are moving back to their start positions.

2.6 Warning board

The warning board delivered with the device (033-7-0051) must be attached near the device well visibly.

2.7 Removal from service

No other measures are necessary accepting the separation of the power supply for the removal from service.

3. Functional characteristics

3.1 Basic functions

Basically the **QRS® Pelvicenter** is activated by inserting the chip card into the card slot of the **QRS® 101P**.

The therapy is started by pressing the 

key and can be interrupted or stopped at any time by pressing repeatedly. The device moves back all movable parts in their start position and has to be adjusted again, in case of a continuation of the therapy, if necessary.

During the application, the time counts backwards on the display. Thus you can read the remaining time during the treatment on the display.

3.1.1 Setting the flux intensity

The **QRS® Pelvicenter** offers the setting of the application intensity in 5 steps from 20% to 100%.

The selected level is displayed on the display as a numerical value (1-5) under Ampl. and in addition is indicated, in the intensity display on the left of the connecting panel as % value.

Press the 

key to get into the menu prompt of the display. The display Ampl. flashes on and off. With the keys.... +.... and....-... you can carry out the desired % setting.

By pressing the 

key repeatedly you can get back into the menu prompt to select other functions.

If no further input is occurred with use of the …+…and …-… keys, while the display flashes, the device shifts back automatically after 5 seconds into the standard display setting and takes over the last entered value.

Note
The intensity of the therapy should be started with a low intensity, increasing carefully.

Note
The parameters described in the following chapters from the 3.1.2 to the 3.1.3 are adjustable only with the **Individual** Program.

- Only with a programmed therapy card **Individual** all parameters can be changed.
- With the programs stress incontinence, urge incontinence, mixing incontinence, Prostatectomy/stress incontinence only the amplitude can be changed. Frequency, duration of treatment, hold time and break are firmly given with these programs and are saved on the chip card.

3.1.2 Setting the flux frequency

The **QRS® Pelvicenter** offers the setting of the frequency in 1-Hz steps from 1Hz to 50Hz.

The selected frequency is indicated on the display as a numerical value under Freq.

Press the 

key to get into the menu prompt of the display. By pressing the key repeatedly, the display Freq. flashes. With the keys.... +.... and....-... you can carry out the desired frequency setting in 1-Hz steps, if necessary accelerated by pressing the key constantly.

By pressing the 

key repeatedly, you get back into the menu prompt of the display and can select the further menu items.

If no further input is occurred with use of the …+…and …-… keys, while the display flashes, the device shifts back automatically after 5 seconds into the standard display setting and takes over the last entered value.

3.1.3 Setting the Application duration

The **QRS® Pelvicenter** offers an application duration of 20 minutes. In addition, you can set the active application intervals and the passive break intervals in 1-second steps.

3.1.4 Setting the Hold- and Pause- Time

Press now the 

key another time. On the display the display preservation time. flashes.

In this setting you are able to adjust the duration of the active application intervals (1 - 15 seconds) by pressing the.... +... and....-.... keys.

Press now the 

key another time. On the display the display break.flashes. In this setting you are able to adjust the duration of the break times (1 - 25 seconds) between the application intervals by pressing the.... +... and....-.... keys.

With a repeated pressure of the 

key you get back into the menu prompt of the display and can select the further menu items.

If no further input is occurred with use of the …+…and …-… keys, while the display flashes, the device shifts back automatically after 5 seconds into the standard display setting and takes over the last entered value.

3.1.5 Setting the position of the back support

The **QRS® Pelvicenter** offers the possibility to adjust the inclination of the back support. The adjustment can be bent from 90° to the bearing surface up to 25° to the back and this is the basic adjustment after having turned on the device.

Press now the 

key another time. On the display following note can be seen:

```
Backrest inclination
+forwards -backwards
```

In this adjustment you are able to change the inclination of the back support by pressing the.... +... and....-.... keys.

By a repeated pressure of the 

key you get back in the menu guidance of the display and can select the further menu items.

If no further input is occurred with use of the …+…and …-… keys, while the display flashes, the device shifts back automatically after 5 seconds into the standard display setting and takes over the last entered value.

3.1.6 Setting the position of the Flux Generator

The **QRS® Pelvicenter** offers the possibility to adjust the position of the flux coil in the seat backwards and forwards.

Press now the 

key another time. On the display the following note can be seen:

```
>Coil Position<
+forwards -backwards
```

In this adjustment you are able to change the position of the flux coil by pressing the.... +... and....-.... keys.

By pressing the 

key repeatedly, you get back in the menu prompt of the display and can select the further menu items.

If no further input is occurred with use of the …+…and …-… keys, while the display flashes, the device shifts back automatically after 5 seconds into the standard display setting and takes over the last entered value.

3.1.7 Setting the footrest position

The **QRS® Pelvicenter** disposes of the possibility to shift the footrest and thus to offer the patient a comfortable position during the application.

You can adjust the footrest by switching on the device and pressing the Up- and Down-keys.

!!

Note

The device has a built-in security barrier if the footrest section bumps into an obstacle during the motion. The device stops the motion and stays in the current position. It can be started again, when the obstacle has been removed.

3.2 Notes for the therapy

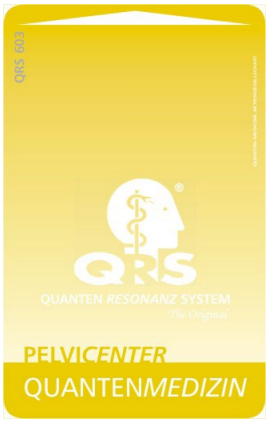
In the **QRS® Pelvicenter** the control device **QRS® 101P** is integrated. This device runs the complete system with the support of a programmed treatment card. Insert the card in such way into the card slot of the **QRS® 101P,** that the writing is visible upwards and the white arrow shows in the direction of the card slot.

For determination of the individual therapy parameters of a patient, the doctor can carry out a 2-minute treatment with help of an assay therapy card, with which the therapy parameters can be adapted.

Then these parameters for the treatment of every patient will be transferred on the patient's card from the doctors card with a program system (PC, card reader and software). The program and the card reader are a component of the **QRS® Pelvicenter** system and are installed by the introduction on a PC or notebook. The provided operating instructions for the card preparation program, describes the necessary levels for the programming of the patient-related chip cards.

On the chip card, the parameters for the entire treatment are stored. The release of the QRS magnetic treatment is initiated by plugging in the chip-card.

- Intensity
- Frequency
- Duration
- Hold/Pause- Time
- Position of the Flux-coil



If the intensity has been changed during a therapy, this new value will be stored in the card and is preset until the next treatment as a parameter on the card. If the card has been removed during a therapy, all single therapies are interrupted and the movable parts moving back into their starting position. - Then the remaining therapy time gets lost!

After inserting the chip card, the name of the patient and the remaining units are showed alternating.

Chip Card **QRS® - Pelvicenter**
to release the treatment

4. Therapy

4.1 Incontinence therapy

For this the patient has to sit comfortably on the chair. The therapy should be started with a low intensity. It should generally be pleasant for the patient. The patient feels muscle stimulation in the area of the pelvic ground up to the muscles in the thigh, if necessary also up to the breech and lower back.

- Only start the therapy if the patient has taken the right seat position.
- By the first application the therapy should be started with lower intensity.
- It generally should be pleasant for the patient.
- Point out to the patients the fact that they can interrupt the therapy with the start / stop key at any time.

Notes

- The patient has to be prepared for the muscle stimulation or muscle contraction.
- The patient should empty his/her pockets so that no magnetic data carriers can be erased or other items will be effected negatively.

Warning

The patient can be treated only by sitting down and with consciousness, in other positions the treatment must be interrupted.

5. Trouble shooting

The **QRS® Pelvicenter** can recognize most of malfunctions by themselves and indicates suitable announcements on the display. Some of these malfunctions can be solved by the user without help.

The following description classifies malfunctions roughly in those which can be indicated with an understandable announcement on the display and those which are not indicated or not understandable.

For all mistakes the symptoms are described and - if possible - also the cause and remedial actions.

Always get in contact with the manufacturer or service of your distributor, in case of doubts!

For all uses, which go beyond the described measures and/or operating steps in chapter 2 and 3 of this manual, the power plug has to be drawn from the power outlet and/or from the device-sided small power socket!

5.1 Error messages on the display

CARD INVALID

The chip card does not show any credit, if it is inserted in a wrong way or is damaged mechanically.

Check whether the chip card is inserted correctly. Insert the card in the card slot of the **QRS® 101P** that the script shows upwards and the white arrow in direction of the card slot. Check the credit of the chip card. Check the chip card for damage.

If all measures don't lead to success, contact your service partner or distributor.

APPLICATOR DEFETIVE

No electricity flow is possible through the applicator. The applicator or his connecting lead is defective.

Please get in contact with your service partner or distributor.

ERRORCODE: nn

The control device has recognized a mistake with support of its self-test.

Switch off the control device and switch it on again after some seconds. In case of a permanent, or already several times appeared malfunction, please get in contact with your service partner.

Please, note the error code >> nn << and report it to your service partner!

5.2 Malfunctions

Symptom	Cause / Measure
The device cannot be switched on, the display stays dark and empty.	Check whether the power outlet and the power cable lead voltage. Contact if necessary your service partner.
While connecting the device to the main power supply, a steady alarm sound is audible from the control device **QRS® 101P**.	The program memory of the control device has wrong contents. Contact your service partner.
Every time after turning on of the control device **QRS® 101P,** the display shows the menu for time settings.	The clock of the control device is powered by a battery (the *regular* life span averages more than 5 years). The battery is empty and has to be replaced. Contact your service partner.

6. Maintenance

The performance, reliability and the safety properties of the device are guaranteed only with designated use, according to the operating instructions. Security examinations, servicing works, repair and changes may be carried out only by an authorized person and or one an authorized service provider. The components, which influence the security of the device can be replaced only with original spare parts in case of malfunction. The electric room installation must correspond to the demands of VDE/IEC.

The device doesn’t contain any parts which have to be maintained by the user.

6.1 Battery exchange of the control device

The battery exchange in the control device can be carried out only by an authorized service partner.

6.2 Safety controls

6.2.1 Statutory requirements and regulations

The operator of an active medical device - according to appendix I and II of the "medical device directive" - must keep a device logbook covering all parameter during use and to do a documentation of the following described safety controls.

Note

In countries beyond the EU the medical device directive must follow country guidelines.

6.2.2 Performance of safety checks

We recommend an examination of the device all 12 months by a certified service partner according to §6 of the medical device directive.

The examination should contain at least the following criteria:

- Electrical safety check
- Examination of the device on external integrity
- Examination of all display and operating elements in respect of damages
- Examination of all inscriptions in respect of legibility
- Test according to the test plan of the manufacturer

6.3 Cleaning, disinfection and care

For the cleaning and disinfection of the device and the accessories no cleaning materiel should be used which contains amounts of carbolic acid derivatives, alcohol, chlorine compounds or peracetic acid.

We recommend clean the device with a soft, slightly moistened cloth. In case of stronger soiling, a mild, household cleaning liquid can be used for sensitive plastic surfaces.

Disinfectants on aldehyde basis are recommended. The device is ***not*** suited for heat sterilization or for the sterilization with gases.

Caution

Before every cleaning or disinfection unplug the power supply out of the socket!

In case of damages of the upholsterer or other case parts, please get in contact with a service Partner which is authorized by the manufacturer or your distributor!

The device is suited for wiping disinfection. It has to be observed that no liquids enter the device. In no cases shall the plug or socket get wet. For cleaning or disinfection the device may not be drizzled.

Control unit, seat and leather

Use commercial cleaning liquids for plastics. Wipe off only with humid cloth.

Please pay attention to the fact that no sharp objects are pressed into the bearing surfaces. The system should not be exposed to direct solar irradiation and be protected against frost.

6.4 Dispose of the device and accessories

This medicine device can’t be disposed with the domestic waste according to the law WEEE (electronics and electronics old devices order). The device has to be sent back to the manufacturer for the disposal. The manufacturer has the obligation to guarantee the disposal for the devices brought in traffic. This is also marked by the sign WEEE (crossed out waste bin) on the type tag.

The oxygen masks have to be thrown into the plastic waste bin.

7. Contraindications and safety precautions

7.1 Contraindications

With the following contraindications the therapy must not be applied

- Pregnancy
- Electronic or metallic implants between knee and neck
- Epilepsy
- Surgical operations since less than 4 weeks
- Severe cardiac arrhythmias

With the following contraindications the therapy should not be applied:

- Menstrual
- Acute urinary tract infection
- Painful hemorrhoids
- Febrile infection

7.2 Patient safety

Warning!
Patients with electronic implants like pacemakers, defilibrators, insulin pumps or similar, are not allowed to be therapied by Pelvicenter.

Warning!
Patients with metal implants like female hormone spiral, hip replacement, screws, nails, etc. are not allowed to be therapied by the Pelvicenter.

Warning!
Before using the Pelvicenter put off or get rid of all metal or electronic parts on or in your body like

- credit cards
- jewelries, rings
- watches
- keys
- mobiles
- wallet
- cameras
- generally all metal things

7.3 Systems safety

Warning!

- Don’t put the system close to high energy or ultrahigh frequency generators. Please keep a distance of 3m.
- The device is not identified for the operation in explosive areas. If it is used in anesthesia rooms, the possibility of an explosion cannot be excluded.
- In case of every recognizable operational disturbance please immediately get in contact with a competent person or an authorized service partner.

7.4 Usage by children or teenagers

Warning!

An application on children and teenagers **is not allowed!**

7.5 Safety precautions and cautionary notes

Warning!

- You should start the therapy when the patient has taken the right seat position.
- If it is the first application, the therapy should be started with low Intensity. It generally should be pleasant for the patient.
- Point out the fact to the patients that they can interrupt the therapy with the start / stop key at any time.

Note!

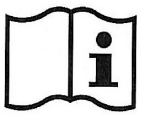
- The patient has to be prepared for the muscle stimulation/muscle contraction.
- The patient should empty his pockets, so that no magnetic data carriers can be erased or destroyed.

Warning!

The patient can be treated only by sitting down and conscious, in any other position the treatment must be interrupted.

8. Explanation of the used signs

CE Conformity sign with the identifying number of the notified body for medical products.



Attention!
Follow the operating instructions!

Application part ungrounded, protection degree Type BF

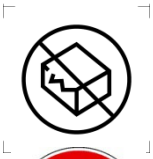
This product complies with WEEE Directive 2002/96/EG about electric- and electronic old devices (waste electrical and electronic equipment WEEE).

Caution, strong magnetic field!

Magnetic recordings on check cards, credit cards and other magnetic data carriers can be erased or destroyed.

Warning!
Keep away from open fire!
During an oxygen dose no open fire or smoking.

Not for reuse.



Warning!
Don’t use if the packing is damaged.

Warning!
Patients with electronic implants like heart pacemaker, insulin pump or defibrillator are not allowed to be treated by Pelvicenter.

Warning!
Patients with metal implants like artificial joints, coil or screws are not allowed to be treated by Pelvicenter.

Warning!
The patient can be treated only by sitting down and conscious, in any other position the treatment must be interrupted.

9. Technical data

Main voltage and frequency:	230V ~, 50Hz
Power consumption:	max. 1265 VA
Fuse:	2× T6,3A L 250V
Battery (in **QRS® 101P):**	CR2032
Output signal:	
Magnetic field incontinence seat Field strength:	 Maximal 2T
Magnetic field back support Field strength:	 Maximal 3V, 170mA, 40µT
Light therapy module Power Light intensity:	 2x36 watts 10000 Lux at a distance of 20 meters
Oxygen dose and concentration	 87-96% by 0.5 to 5l/min
MDD-device class:	IIa
Safety class:	I
Protection degree:	B
Protection against ingress of water:	IPX0
Dimensions:	187cm × 134cm × 173cm
Weight:	180kg
Secure burden of work:	135kg
Display:	Dot-Matrix 2x40 characters (**QRS® 101P** 1x16)
Environmental condition	Operation of the device: Temperature range: +13°…+30° Relative air humidity: 30-75% Transport and storage: Temperature range: +5°…+50° Relative air humidity: <90%, non condensed

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10. Accessories

Article description	Order number
QRS® - Pelvicenter BASIC Standard scope of supply: **QRS® Pelvicenter** incl. operating panel Operating instructions + warning board Mains feeder	033-0-1003
Operating instructions **QRS® - Pelvicenter** Operating instructions for the construction of the chip card software	033-7-0044 033-7-0052
Chip card **QRS® - Pelvicenter**	033-8-0016
Mains lead	011-4-6001
Construction of the card software	033-0-7000
Warning board	033-7-0051

11. Appendix

Notes according to the EG-directive for the medical device directive

The **QRS® Pelvicenter** is a mains-powered magnetic field therapy device of protection class **I**.

The device is in accordance with the EG directive for medical device (93 / 42 / EWG) and, carries the CE sign with the registration number of the notified body for medical devices. The according graphical symbol is placed on the type tag.

The **QRS® Pelvicenter** is a device of the class **IIa** according to the medical device directive**.**

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

- the device is used according to the operating instructions;
- the electrical installation of the location where the device will be used, meets the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- mountings, enhancements, re-adjustments, 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 MDD .

Technical support may be obtained by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life as scheduled by the manufacturer is 10 years.

The **QRS® Pelvicenter** is an electronic device. For disposal the according regulations for electronic devices have to be observed. Incidentals have to be disposed with residual waste.

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

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

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

Further EMC-comments can be found in the chapter „Warnings and Safety Precautions" of this operating instruction as well as in the technical information of the two following pages.

According to the EMC comments for medical products we **are obligated by law** to provide the following information.

Guidance and manufacturer's declaration of the electromagnetic emissions

The equipment is intended for use in the electromagnetic environments specified below. The consumer of the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF-emissions according to CISPR 11	Group 1	The equipment uses RF energy only for its internal function. That's why the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF-emissions according to CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2 (*)	Class a	
Voltage fluctuation/ flicker emissions according to IEC 61000-3-3 (*)	Complies	
(*) note: the requirement is merely necessary for devices with a power consumption between 75 watts and 1000 watts.		

Guidance and manufacturer's declaration of the electromagnetic immunity

The equipment is intended for use in the electromagnetic environments specified below. The consumer of 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**
Discharge of static electricity (ESD) according to IEC61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The pavement should be made out of wood or concrete or be covered with ceramic tile. If the pavement is covered by synthetic materials, the relative humidity should be at least 30%.
Electrical fast, transient/bursts according to IEC 61000-4-4	±2 kV for gridlines ±1 kV for input- and output lines	±2 kV for gridlines ±1 kV for input- and output lines	The quality of the mains power should correspond to the typical environment of a store or hospital.
Surge voltage according to IEC 61000-4-5	±1 kV outer to outer conductor ±2 kV outer conductor to earth	±1 kV outer to outer conductor ±2 kV outer conductor to earth	The quality of the supply voltage should correspond to the typical environment of a store or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	<5% U_τ for ½ cycle (>95% invasion) 40% U_τ for 5 cycles (60% invasion) 70% U_τ for 25 cycles (30% invasion) <95% U_τ für 5 s (>5% invasion)	<5% U_τ for ½ cycle (>95% invasion) 40% U_τ for 5 cycles (60% invasion) 70% U_τ for 25 cycles (30% invasion) <95% U_τ für 5 s (>5% invasion)	The quality of the supply voltage should correspond to the typical environment of a store or hospital. If the user demands a continual function, also in case of interruption of the energy supply, it is recommended to connect the device to an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of 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 of the electromagnetic immunity

The equipment is intended for use in the electromagnetic environments specified below. The consumer of 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 radio units have not to be used in a minor distance than the recommended separation distance, which is calculated with help of the following equation. **Recommended separation distance:**
Conducted RF disturbance variable according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF disturbance variables according to IEC 61000-4-3	3 V/m 80 MHz bis 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
			P as the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d as the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distance 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 to avoid interferences by means of minimum separation distances between the portable and mobile RF communication equipment, like recommended below, according to the maximum output power of the communication equipment.

Rated power of the transmitter (W)	Separation distance according to the transmission 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

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