QRS International AG

QRS Pelvicenter rPMS

Repetitive peripheral magnetic stimulation
Neuromuscular pelvic floor training

Pelvic floor therapy

Manual for rPMS Therapists

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Welcome to the QRS Pelvicenter rPMS

The QRS Pelvicenter rPMS is an effective treatment alternative for all symptoms related to pelvic floor muscle weakness.

rPMS offers either good or very good prospects of success without the need for any stressful invasive intervention or any adverse side-effects of medicinal treatment.

If urinary incontinence is caused by weak pelvic floor musculature or irritable conditions of the bladder, or is accompanied of muscular pain symptoms affecting the pelvic or trunk region, a significant improvement or a complete remission of symptoms can be achieved in the majority of cases.

rPMS treatment is very well received by most patients, i.e. there is very good compliance. There is no need to undress and no need to insert a vaginal or rectal probe. Treatment is administered with the patient seated in a passive position.

A wealth of scientific studies, in many cases carried out to the most stringent standards, but also extensive practical experience, demonstrate that there is no single more effective alternative to the conservative treatment of stress incontinence than rPMS. Treatment results are also unequivocal for OAB syndrome and urge incontinence.

Several other rPMS indications that are still classified as “experimental” are currently being tested. The evidence gathered so far is very promising. If you are interested in updates on products or know-how, please send an informal e-mail to beratung@pelvicenter.com.

We have endeavoured to provide you with an informative manual on QRS Pelvicenter rPMS. We understand that you may require additional information.

Please do not hesitate to contact us if you have any questions.

Your QRS Team

Table of contents

1. QRS Pelvicenter quick start guide and features

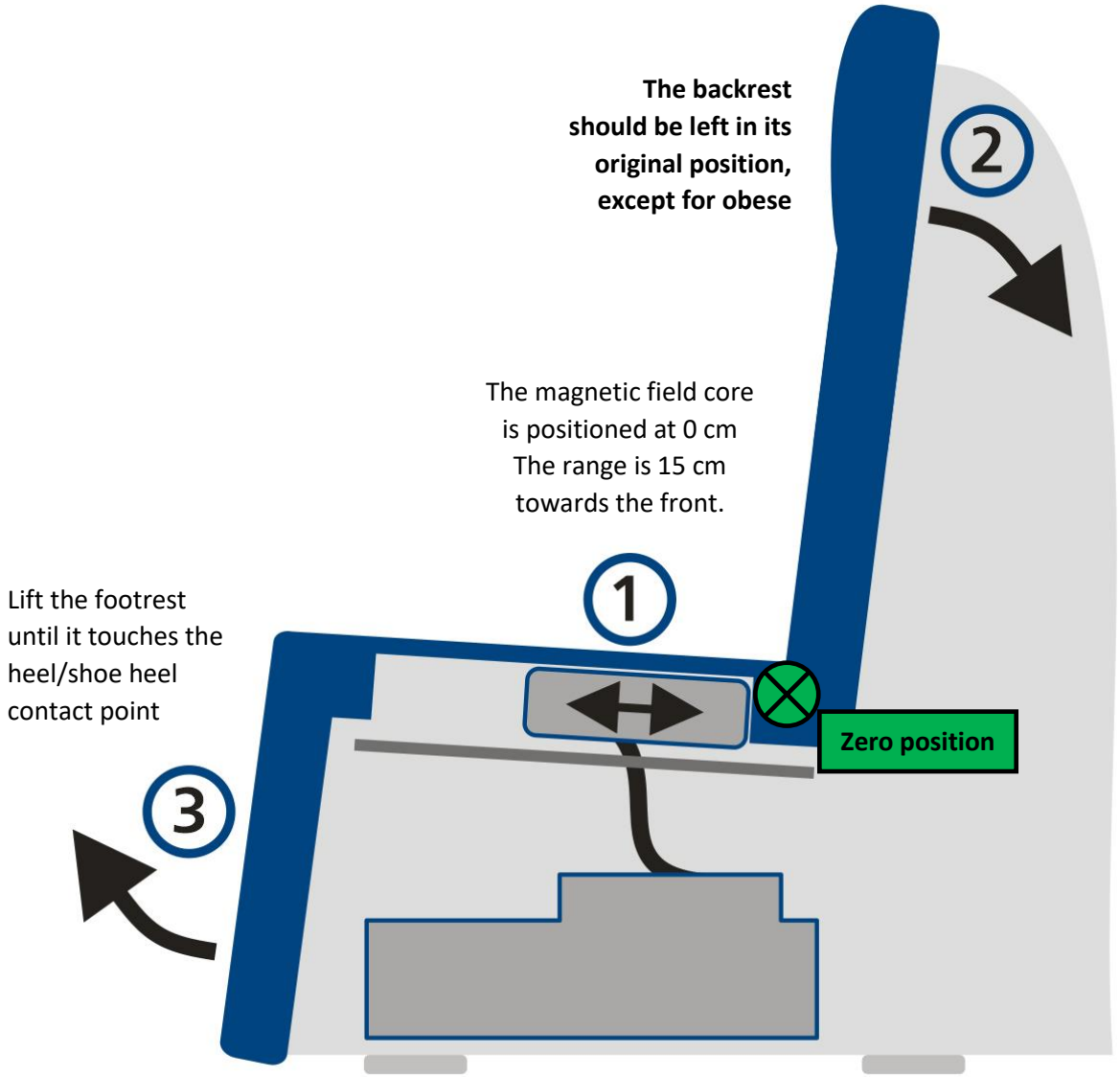
A	**Light dome**, light therapy 10,000 lux, can be lowered until it is in front of the face,	for use in parallel with treatment for any existing depression
B	**Backrest**, can be moved back	to provide a comfortable sitting position for obese patients
C	**Oxygen generator**, oxygen therapy 5 l/min, 40%, adaptor for inhalation mask/nasal cannula	Improvement of oxygen partial pressure whilst exercising and of capillary flow rate after training
D	Control console for all settings	incl. pause/restart button for therapy
E	**Footrest**, can be moved upwards	to relax the thigh muscles
F	QRS Pelvicenter rPMS **effective field**, 18 cm range in front and behind	to allow precise positioning of the treatment field beneath the patient's pelvic floor
G	XXL **seat** with a width of 65 cm	also suitable for obese patients
H	Chip card unit	for importing the key chip card or a programme chip card
I	Water-resistant	synthetic leather, wipe-clean upholstery

1.1. Adjustable elements

The magnetic field core (1) can be moved forwards and backwards electronically for precise positioning of the effective field underneath the relevant pelvic floor areas.

NOTE: The zero position of the magnetic field core's motor carriage is located on the backrest (see following diagram, green dot). Gluteal muscles are stimulated in the zero position. If the magnetic field core is moved forwards, the range is shown on the control panel display in centimetres.

The backrest (2) and footrest (3) can be adjusted electronically to ensure a comfortable sitting position for the patient.



Graphics: (1) Magnetic field core with motorised carriage for electronic positioning, (2) adjustable backrest, (3) adjustable footrest.

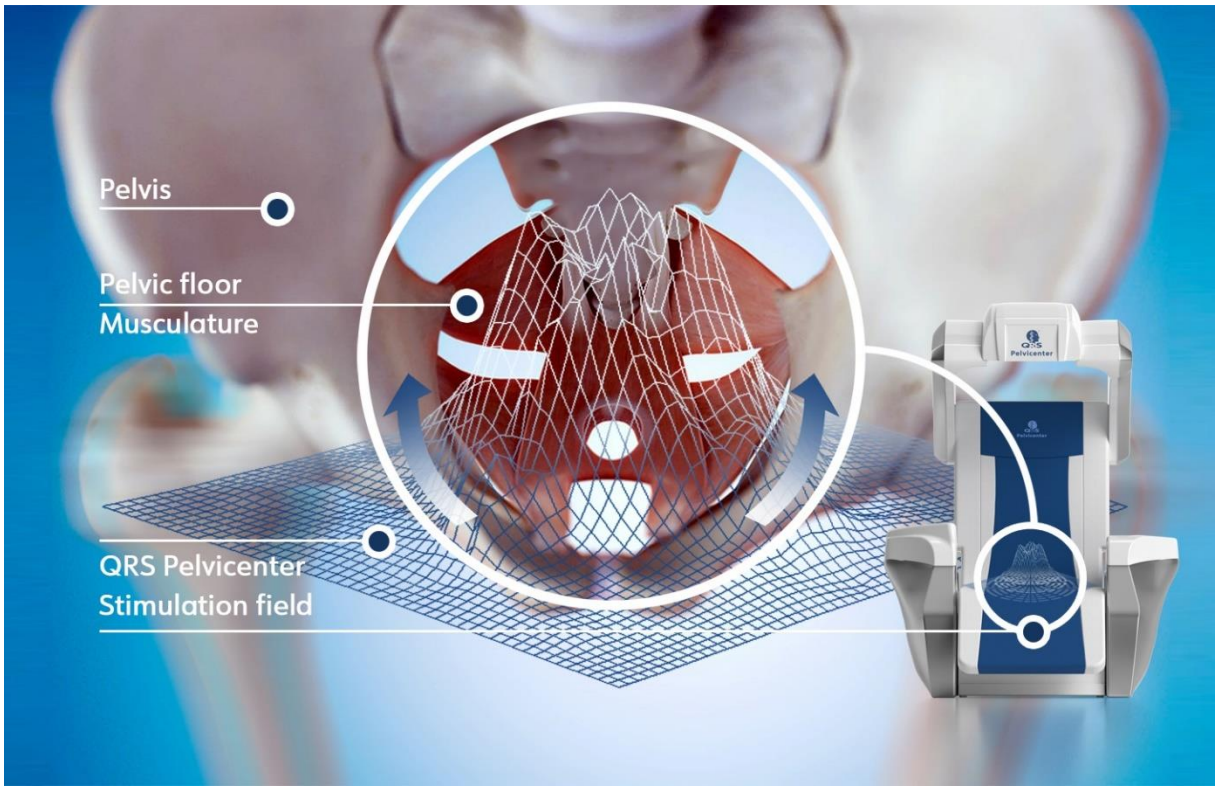
2. Introduction to the QRS Pelvicenter rPMS

The QRS 1010 Pelvicenter is a very efficient muscle stimulator which delivers neuromuscular therapy to a weak pelvic floor or a degenerated pelvic musculature and all its associated adverse consequences.

The overarching procedural concept is called PMS (pulsed magnetic stimulation). This therapeutic method is NOT comparable to conventional pulsed electromagnetic field therapy (PEMFT). The procedure itself is described by the technical term “rPMS” (repetitive peripheral magnetic stimulation).

Based on the physiological characteristics of conventional pelvic floor exercises as well as vaginal and rectal electrostimulation, a neuromuscular strengthening effect is produced by an electromagnetic field in the high Tesla range (3.3 Tesla output power).

rPMS is similar to electrostimulation. The Pelvicenter rPMS triggers the same effect at the target site as electrostimulation, i.e. it induces muscle fibres to contract in response to nerve impulses. The effect is produced by a magnetic field and does not require any physical contact, which allows a much deeper and wider target area to be exercised.



Graphics: Illustration of the “stimulating effect” of the QRS Pelvicenter’s rPMS signal on multiple layers of the pelvic floor muscles, based on actual Pelvicenter laboratory magnetic field measurements.

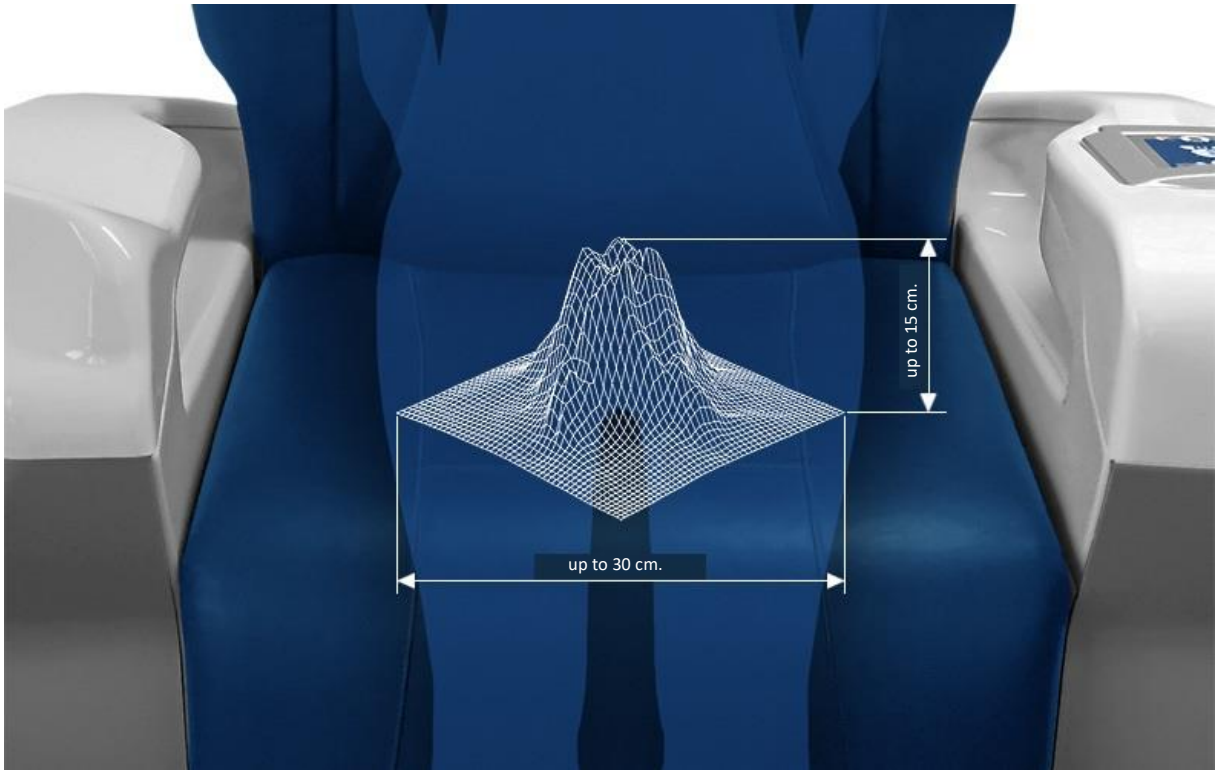
2.1. Length of a single rPMS therapy session

The typical QRS Pelvicenter rPMS therapy session lasts between 15 and 20 minutes. Longer, higher-intensity stimulation times lead to excessive muscle fatigue. Longer treatment times do not, therefore, increase muscle strength; rather, they have a counterproductive effect.

NOTE: We recommend that each therapy session should last 15 minutes. Ideally, a “warmup” with low and increasing intensities should be carried out for the first 1–2 minutes at the start of each session.

The rPMS is not continuous, but consists of repeated stimulation phases interspersed with short pauses. The Pelvicenter has a pre-set stimulation time of 8 seconds and a pause time of 4 seconds. Some indications require different settings.

2.2 rPMS effective field penetration depth and width



Graphics: At maximum intensity, the effective field's maximum range extends to a width of up to 30 cm and a depth of up to 15 cm.

The effective field, which can be regulated up to a maximum intensity, stimulates the motor nerves, producing a large number of contractions.

NOTE: In contrast to conventional pelvic floor exercises, these muscle contractions are not produced voluntarily by the patient and moreover
cannot be controlled by the patient.

3. QRS rPMS operating principles

The rPMS functions as a “transmitter” of a high-performance magnetic field with an output of 3.3 Tesla. This is a magnetic field that can penetrate cellular tissue without resistance. The repetitive signal generated by the Pelvicenter electronics targets motor nerves, and induces them to transmit this electrical stimulus to the muscle fibres via the neuromuscular junction.

Once a specific threshold value is reached, a potential difference occurs within the motor nerves, producing an action potential and thus triggering a completely natural transmission of the stimulus. The stimulus is then transmitted to the muscle fibres through the neuromuscular junction by a neurotransmitter messenger. This means that an rPMS does not act on muscles directly, but instead creates neural “signals” which induce the muscles to contract. During rPMS-induced muscle contraction, the muscle cannot be voluntarily controlled by the patient.

NOTE: A muscle always reacts on the “all-or-nothing principle”, i.e. an above-threshold rPMS stimulus is invariably a maximum stimulus. The selected frequency can however determine whether a muscle contracts only once or whether the contraction is sustained (physiologic tetanus).

Mechanoreceptors in the musculature detect the neuromuscular rPMS stimulus and transmit it to the central nervous system (CNS). This triggers a learning process and new neural connections are created (cortical expression in the somatosensory cortex), which enable improved muscle control of the pelvic floor muscles. This means that during a series of rPMS therapies, the CNS learns to control the treated muscle area in a powerful, focussed manner.

NOTE: The intensity of the muscle contraction achieved can be controlled by the intensity settings, which can be adjusted on the QRS Pelvicenter in 5 steps (ranging from 20 to 100%). The rPMS signal can be adjusted to create everything from a mild tingling sensation all the up to a pelvic floor contraction of the maximum (required) strength.

3.1. Transmission of stimulation to muscle cells

The electrical stimulus is transmitted to the muscle cell by means of a magnetic field through what is known as the neuromuscular junction.

Description of the neuromuscular junction
The neuromuscular junction is a chemical synapse which is a 20 to 50 nm gap, consisting of a motor neuron axon terminal on one side and a portion of muscle cell membrane on the other. To transmit a neural stimulus, the neurotransmitter acetylcholine is released into the synaptic cleft and subsequently bound by nicotinic receptors. Both the axon terminals and the membranes are entirely unfolded, allowing the increase in surface area to potentiate transmission of the signal.

The axon of the nerve cell branches out into the perimysium (a sheath of connective tissue that groups muscle fibres into bundles). The longer the branches, the greater the number of muscle fibres that are amenable to treatment. A motor nerve fibre innervates between 3 to 2,000 muscle fibres (motor units), as a function of the number of its branches, which depends on whether the muscle group coordinates fine motor or gross motor control.

3.2. Effect on motor nerves

The resting potential of peripheral nerve cells ranges from -65 to -75 mV, whereby changes of as little as +10 to +20 mV already trigger nerve cell depolarisation. An electromagnetic rPMS, produces a potential difference which consequently leads to depolarisation and produces an action potential that

primarily acts on the thick, myelinated, fast-twitch nerve fibres.
(A-alpha fibres, diameter 10 to 20 µm, twitch speed 60 to 120 m/s, which corresponds to type I of the Lloyd/Hunt classification). These mixed sensorimotor nerves do not receive any afferent pain signals, which means that rPMS stimulation is completely painless.

Small diameter, unmyelinated pain fibres (C-fibres, diameter 0.5 to 1.5 µm, 0.5 to 2m/s) are generally not activated by the rPMS. Sacral nerve fibres of the parasympathetic nervous system (C-fibres) also remain unresponsive for the same reason.

An rPMS-induced polarisation decreases the membrane potential of the adjacent neurons, so that the first pre-set pulse propagates like a chain reaction to the neuromuscular junction and onwards to the respective muscle fibres. This results in a powerful muscle contraction which is proportional to the intensity and frequency used.

Tetanic contractions (i.e. sustained muscle contractions) of the type I fibres (slow-twitch muscle fibres) occur at frequencies greater than 20 Hz (the fused contraction frequency).

A fused contraction frequency of 50 Hz also induces a sustained contraction of type II fibres (fast-twitch muscle fibres), by means of which their maximum strength of contraction can be attained.

The strengthening of muscles should not be based on exercising slow-twitch muscle fibres (type I), since fast-twitch muscle fibres (type II) are essential for exercising the pelvic floor. However, using a combination of frequencies, depending on the indication, can be a helpful option.

Each frequency, nonetheless, is capable of producing a proprioceptive input to the body map centre of the CNS, even at minimum intensity.

NOTE: The frequency selected for rPMS determines which of the two types of muscle fibres is preferentially stimulated. It is therefore helpful to choose the right setting to achieve the maximum therapeutic benefit. For more information on setting the correct frequencies, intensities, and other parameters, refer to the Stimulus Configurations section on page 20.

3.3. Effect on proprioception

Proprioceptors (sensitive to depth and position) are sensors responsible for constantly providing positional and movement information about the body. Proprioceptors are found in muscles and tendons and provide information about the position of the joints, the speed and direction of a change in position and the force deployed to achieve this change.

NOTE: In addition to their function of coordinating muscle movements, proprioceptors are also responsible for cortical mapping of the somatosensory cortex.

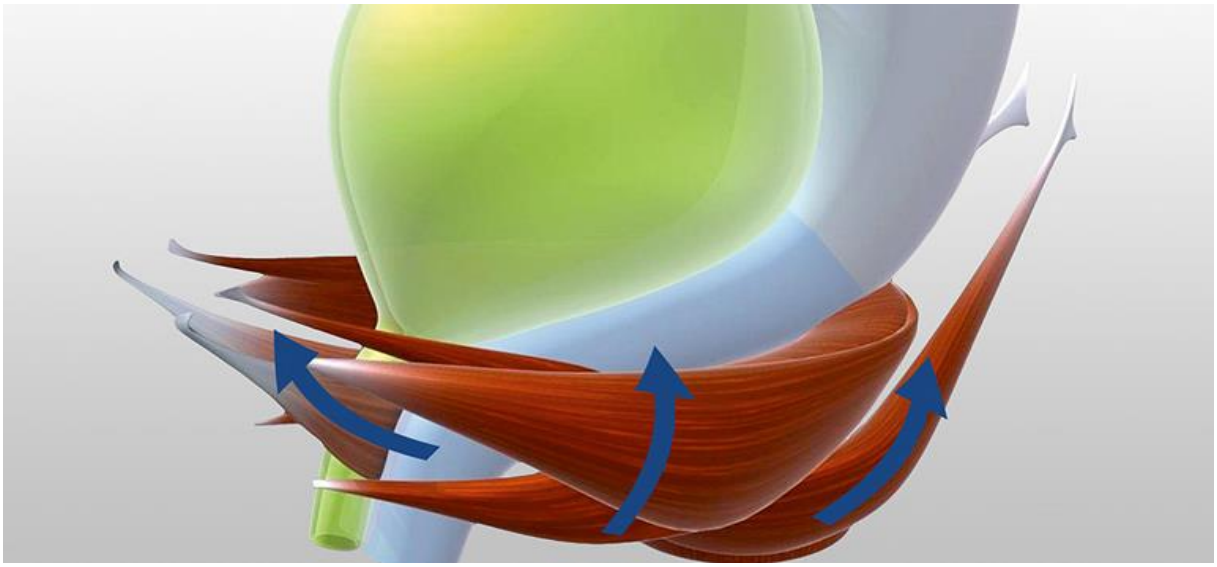
This means that the repetition of identical movements shapes and expands this area. The brain reacquires the coordination of movements in areas stimulated by the RPMS.

3.4. Stimulation of proprioceptive sensory neural pathways

When the rPMS produces action potentials on sensorimotor nerves (type 1a/b), the afferent fibre components also respond accordingly. They form part of the reflex arc, a neural signal which is transmitted towards the cortex through (small diameter) neural pathways that conduct nerve impulses slowly.

Since the original signal has already been received, there is a kind of duplicate transfer of information to the cortex: first through the rPMS-induced contraction of muscle fibres and ligaments, and secondly through the simultaneous, direct rPMS-mediated stimulation of the afferent sensory neural pathways. rPMS-mediated coordination training is achieved by repeating motor impulses. It is irrelevant whether exercises are based on a concentric or an isometric contraction.

Because conventional pelvic floor exercises only train an isolated isometric contraction, the musculature can only generate a small proportion of the maximum possible strength of muscle contraction. In contrast, because rPMS does not determine the sequence in which muscle fibres are recruited, muscles are therefore recruited collectively, meaning that all the muscles in a compound unit contract.



Graphic: When a single pelvic floor muscle is stimulated electromagnetically through the rPMS, all other muscles of the compound unit contract as well.

3.5. Circuitry of the motor cortex

Repeated rPMS training sessions reinforce the circuitry of the motor cortex and demonstrate the neuroplasticity of the CNS The underlying sensory motor influx thereby compensates for and replaces the lost physiological, proprioceptive afferent projections required for active movements.

A series of stimulations, which should be carried out in accordance with the recommended stimulation configurations (see page 20), enables the activation of previously idle muscle fibres in the body map centre of the cortex. This means that any naturally occurring cortical demands on the pelvic floor will in future be fulfilled by all available pelvic floor muscles. This has the additional advantage of also stimulating and "co-exercising" the gluteal muscles (gluteus maximus, medius and minimus) and parts of the thigh muscles. As a result, the cortical mapping and the coordination ability in this area is also strengthened and improved.

3.6. rPMS-induced muscle growth

Passive rPMS muscle stimulation cannot exactly reproduce the full extent of real movements as a sequence of interactions between different muscle groups. In terms of its effect on muscle growth, however, there is no difference when compared to active, "natural" strength training.

An *in vitro* study on human muscle cells harvested from biopsies demonstrated that rPMS induced a 44% increase in cell differentiation rate compared to 26% in the untreated control group. Furthermore, in the above study PGC-1 alpha protein increased significantly, reflecting the increased adaptation of the muscle to training. Similarly, acetylcholinesterase mRNA and protein synthesis increased twofold, reflecting enhanced synapse activity.

More details about PGC-1 alpha:
PGC-1 alpha regulates the adaptation mechanisms of endurance training and therefore significantly influences metabolism and muscle function. As part of its other roles, it increases muscle endurance by regulating the formation and breakdown of lactate.

3.7. rPMS and faulty feedback

During active pelvic floor training, a considerable proportion of patients cannot consciously contract their pelvic floor despite being given careful verbal instructions. Instead, they (unintentionally) use their gluteal muscles, thighs and abdominals to compensate when exercising.

This (incorrectly) enhances the cortical mapping of these muscles in the CNS, while the already weak CNS area of the pelvic floor barely strengthens. A possible consequence of this faulty feedback loop is that the pressure exerted on the bladder itself and on the bladder closure mechanisms is increased and is therefore counterproductive. rPMS generally eliminates this type of faulty feedback.

3.8. Decreased effectiveness of rPMS

The effectiveness of rPMS is nevertheless reduced if pelvic floor nerves have been damaged by surgery, if there are urinary tract anomalies or recurrent urinary tract infections.

NOTE: The premature discontinuation of therapy also has a negative effect on results. Even though therapy may already prove effective after a few sessions, the recommended number of therapy sessions should not be reduced. A rapid positive response can be quickly reversed as a result of an insufficient number of therapy sessions.

4. rPMS indications

➔ Women
- Stress urinary incontinence (SUI)
- Urge incontinence/overactive bladder (OAB)
- Postpartum
- Pelvic pain syndrome (PPS)
- Sexual dysfunction/anorgasmia

➔ Men
- Urge incontinence/overactive bladder (OAB)
- Stress urinary incontinence (SUI) following prostatectomy
- Erectile dysfunction following a prostatectomy
- Pelvic pain syndrome (PPS)
- Erectile dysfunction (ED)

➔ Experimental
- Core strength
- Sarcopenia/age-related muscle loss
- Gluteal muscle exercises

4.1. Absolute contraindications

➔ Pregnancy
The influence of the strong rPMS magnetic field on the embryo has not been investigated and cannot therefore be determined. It is therefore imperative to firmly refuse treatment to pregnant women.

➔ Prior surgeries/wound healing phase
rPMS can be used without any further measures from 4 weeks after surgery and successful wound healing and from 10 days after catheter removal following a prostatectomy.

➔ Severe cardiac arrhythmia or epilepsy
Although rPMS has no direct influence on cardiovascular disease or unpredictable epileptic seizures, the risk is too significant to warrant its use if these conditions are present.

➔ When using oxygen therapy, please note its contraindications!

4.2. Relative contraindications

Caution and medical supervision are advised if the patient has been fitted with a:

➔ Metallic or electronic implant which is located in the effective field region

When in doubt, a prior review of the implant specification is necessary, depending on the implant.

NOTE: If there is any uncertainty about one of the following implants, the therapist is requested to contact us. Our contact details can be found on the cover and penultimate page of this manual.

- Metallic Implants *(Risk of the metal heating up)*
  Metallic implants located in the trunk region and up to 10 cm above the knee joint can, depending on the type of metal or alloy, become hot or warm due to the magnetic field generated. Surgical implants, however, present little risk of warming.
- Electronic implants (risk of magnetic field interference)
  Depending on the interference field shielding, electronic implants may give rise to complications. This specifically affects neurostimulators, cardiac pacemakers, cardioverters, defibrillators, bladder pacemakers and insulin pumps. Newer devices which have a high degree of interference field shielding are not affected.

➔ Intrauterine device
Contractions of the pelvic floor can alter the position of an intrauterine device, irrespective of the material it is made of.

NOTE: rPMS therapy should only be administered if the patient can be observed! In certain circumstances, ultrasound examinations are recommended to check the position of the intrauterine device.

4.3. Undesirable side-effects

Approximately 5% of patients report undesirable side-effects. These are, nonetheless, relatively insignificant. They include:

➔ Pain affecting the gluteal musculature and the hip bone region

Comment: In most cases this can be largely avoided by lowering the intensity setting during the initial phase of the therapy series.

➔ A burning sensation when passing urine or a yellowish vaginal discharge in the absence of any signs of infection.

NOTE: When pooled with data on undesirable side effects from studies in the USA, Japan, Korea and Turkey, the undesirable effects are so minimal that rPMS can be described as a well-tolerated, painless procedure which is virtually free of side effects.

5. Treatment of an rPMS patient

Successful rPMS pelvic floor therapy with the QRS Pelvicenter is not “directly” contingent on the patient's motivation or physical capacities. After all, the patient does not necessarily have to actively participate in the sense that they are required to carry out physical exercises. The patient is expected to remain seated during the treatment.

As the patient does not have to do any sensory awareness training or exercises during QRS Pelvicenter therapy, subjective patient satisfaction is high, which is reflected in good patient compliance.

NOTE: In contrast to active pelvic floor exercises, there is no learning or sensory awareness phase, because the patient on the QRS Pelvicenter becomes aware of their pelvic floor muscles using rPMS in a matter of a few minutes.

5.1. Therapy schedule

Before starting therapy, the patient should be informed that keeping to the agreed appointments is of utmost importance to the success of the therapy. During the first 5 to 10 sessions, a high degree of adherence to set appointments is crucial, particularly at the beginning of rPMS therapy, otherwise the success of the therapy will be jeopardised.

NOTE: Most indications require 2 to 3 therapy sessions per week. We recommend scheduling 3 therapy appointments per week in order to ensure that at least two therapy sessions are completed if one of the weekly appointments is cancelled.

Some indications, such as postpartum BDNF stimulation or Pelvic Pain Syndrome, require daily therapy sessions (5 times a week), albeit over a shorter overall time period of 10 days (10 sessions) or up to two weeks (12 sessions).

In these cases, the patient is advised to keep to all scheduled appointments and to choose a convenient time frame to ensure continuity of therapy.

5.2. Before treatment

Before the initiation of rPMS treatment on the QRS Pelvicenter, the patient should note the following:

- ➔ Any jacket, coat or similar should be removed.
  Warmth may potentially accumulate in the back area
- ➔ They should void their bladder as much as possible.
  Perhaps draw the patient's attention to this at the reception desk.
- ➔ Where applicable, incontinence pads should be relatively dry.
  Otherwise we recommend that these should be replaced

➔ **Where applicable, remove hearing aids prior to commencing treatment**
These may be susceptible to interference

➔ **Remove purses/wallets from pockets**
Prevent any potential issues with cards bearing a magnetic strip

➔ **With concomitant oxygen therapy**
Provide a new or disinfected oxygen mask

5.3. Sitting on the QRS Pelvicenter

The patient sits down on the Pelvicenter. Before starting therapy, the following essential points must be considered when positioning the patient on the QRS Pelvicenter:

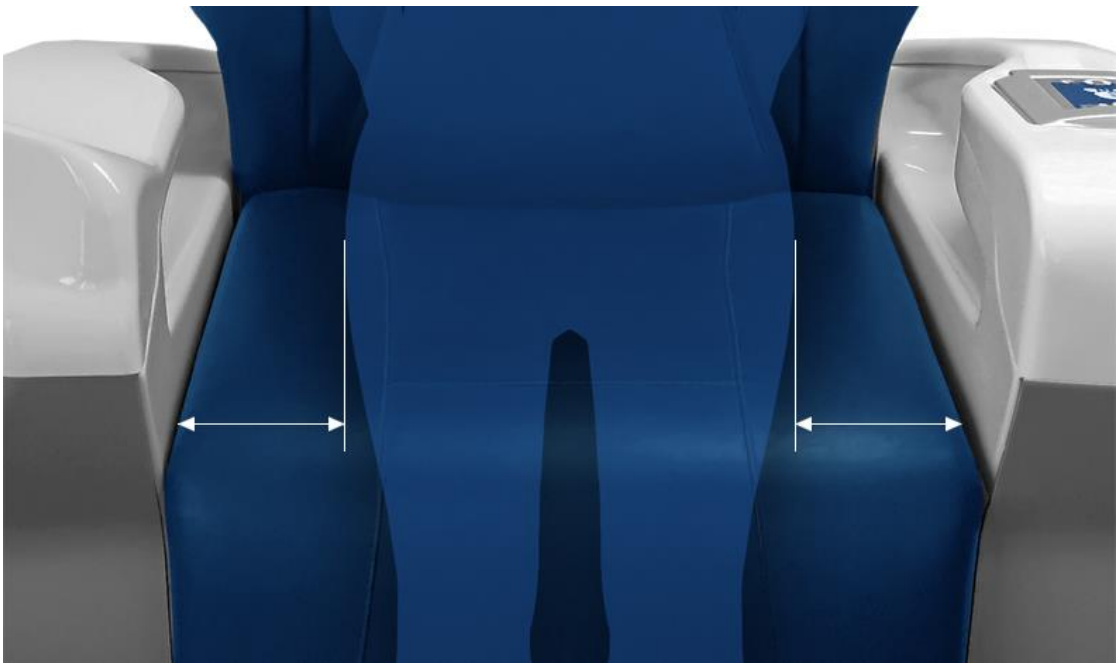
➔ **The entire gluteal and back region should have full contact**
A large area of the patient's back should rest against the backrest.

NOTE: The patient is advised to maintain this posture as far as possible and to avoid forming a hunched back as a result of the buttocks sliding away during the course of treatment. The therapist also needs to pay attention to this!

➔ **Straight, upright sitting posture**
The backrest should be set relatively straight (similar to the home position).

NOTE: If the patient is obese, we recommend moving the backrest as far back as required to reduce any abdominal pressure.

➔ **Centred position on the seat surface**
The therapist should stand in front of the device and check the centring of patient's sitting posture, and if necessary give instructions to correct the position.



Graphic: The therapist should check that the patient is sitting centrally before starting treatment.

NOTE: If the patient reports one-sided stimulation, this may be due to either the sitting position or a muscular imbalance. This reaction can often be triggered in the low intensity range. As soon as the intensity is increased, this sensation of "one-sidedness" usually disappears immediately.

➔ Engaging the leg support

To reduce muscle tension in the thigh musculature, the leg support should be raised until the ball of the foot or heel of the shoe touches it.

NOTE: After completion of therapy, the patient should wait to get up until the footrest has been (automatically) lowered completely.

5.4. First Pelvicenter session

➔ Getting used to the magnetic field signal

During the first session, the patient should be made aware that the effective rPMS field is initially applied at the lowest intensity or level 1 (20%) until the patient gets used to the magnetic signal, and it is only increased once the patient has adapted to the signal.

➔ Positioning of the magnetic field signal

During the first session (and 2nd or 3rd sessions) the optimal position of the magnetic field core with respect to the pelvic floor should be determined. This is achieved by electronically adjusting the magnetic field core underneath the seat.

NOTE: Experience has shown that the optimum position can be set more precisely if at least the 2nd intensity setting (40% output) is selected. For slim patients, the magnetic field core position will in most cases be between 4 and 8 cm.

Depending on the degree of obesity, the effect of the stimulation is reduced due to the increased distance from the magnetic field core. As the distance to the backrest, which is considered to be the zero position, is extended, the magnetic field core position also changes to between 10 and 14 cm.

➔ Setting the signal intensity

As a general rule, the slimmer the patient, the more clearly the magnetic impulses are perceived. The increase(s) in intensity should be carried out at a moderate pace for slim patients.

NOTE: Obese patients have a significantly higher signal tolerance, so they can be started at higher intensities from the outset.

Bearing in mind the recommended stimulation configurations (see page 20), the initial session should attempt to establish an intensity that is well tolerated by the patient within approx. 5 minutes (recommendation: min. 2nd step = 40%).

NOTE: If the patient is motivated, it may be possible to increase the intensity by one or two additional steps during the course of the session (e.g. after 10 minutes).

IMPORTANT: Overall, the principles of strength training apply. The sooner the musculature is able to work at high intensity, the faster the muscle growth, resulting in the therapy objectives being reached more quickly. Experience shows that men are more readily prepared to cope with higher intensities than women.

The therapist should be guided by their functional assessment of the patient's condition. If the first session is well tolerated, the intensity can be increased in the following sessions in the majority of cases without running the risk of inducing a muscular lesion.

5.5. Maximum and minimum rPMS intensity

Generally, rPMS does not activate pain fibres. Nevertheless, rPMS can be perceived as somewhat "uncomfortable" or may "need some getting used to" by some patients, especially when rPMS is applied for the first time, owing to the "suddenness" and unusual intensity of muscle contractions. This sensation is mainly due to the fact that the "magnetic" contraction effect produces a new neurological sensory experience and possibly also sudden innervation of impaired muscle fibres. It is therefore advisable to start with a minimum intensity (step 1, 20%) in the preliminary "test run", but then to increase the intensity relatively quickly up to step 3 and higher.

To ensure that as many pelvic floor muscles as possible are covered, the absolute minimum intensity required for therapeutic success is step 3 (60%). This is however very much dependent on feedback from the patient.

The therapist should inform the patient before and during therapy that "the higher the intensity, the greater the degree of muscle stimulation". Experience shows that patients and muscles adapt very quickly.

Step 6 of the Pelvicenter equals the maximum intensity with a 100% stimulation rate (for models prior to 2019 this corresponds to step 5). The maximum intensity places considerable strain on the musculature. It is therefore advisable to only use this high intensity if the patient is really comfortable with this level of stimulation. It may be advisable to only use the highest setting during the final minutes of a stimulation exercise session. This is always based on the personal and specific tolerance threshold of each individual patient.

NOTE: With a frequency setting of 50 Hz, the intensity can be set up to a maximum of step 3. This prevents overloading the stimulated musculature.

5.6. After treatment

After completion of therapy, the patient should wait to get up until the footrest has been (automatically) lowered completely. We recommend drinking a glass of water (approx. 150–200 ml) after each rPMS therapy session. The amount of water consumed after the therapy session should take into account the level of severity of the incontinence and any fluids prescribed for the patient.

NOTE: A supplement for muscle-recovery in the form of electrolytes can be added to the water (an isotonic drink).

5.7. Follow-up sessions

The success of the therapy very much depends on putting the musculature under considerable strain during rPMS sessions. This means that high intensity settings should be used relatively quickly and, where appropriate, patients should be encouraged to persist to achieve this objective.

Rule of thumb: From the 5th session onwards, rPMS stimulation should be carried out at step 4 (80%) or 5 (100%) until the last therapy session.

NOTE: Experience has shown that any initial difficulties with high intensity settings can be resolved relatively quickly.

5.8. Optimising contraction effects

The magnetic field core position determined during the first therapy session should be recorded or saved on the therapy plan. This position should be further optimised during the course of the second and third sessions. The magnetic field motor carriage should be moved back and forth in both directions to help achieve this.

NOTE: This approach gives the patient an opportunity to reconfirm the optimal position. If the previous magnetic field core position setting is not reconfirmed by the patient, this should be noted and corrected in the therapy plan.

5.9. Example therapy plans

An example of a therapy plan – treatment of stress incontinence:

No.	Date	Duration	Step	Frequency	Cycle time	Position	Light	O2	Comment
1	1.10.	15 min.	1/2	50 Hz	8/4 sec.	7 cm	no	no	1 min. Pause at 9 min.
2	3.10.	15 min.	2/3	50 Hz	8/4 sec.	9 cm	no	no	1 min. Pause at 9 min.
3	5.10.	15 min.	3/4	35 Hz	8/4 sec.	8 cm	no	no	1 min. Pause at 9 min.
4	9.10.	15 min.	3/4	35 Hz	8/4 sec.	8 cm	no	no	1 min. Pause at 9 min.
5*	11.10.	15 min.	4/5	35 Hz	8/4 sec.	8 cm	no	no	1 min. Pause at 9 min.
6	13.10.	15 min.	5/6	35 Hz	8/4 sec.	8 cm	yes	yes	1 min. Pause at 9 min.
7	17.10.	15 min.	5/6	35 Hz	8/4 sec.	8 cm	yes	yes	1 min. Pause at 9 min.
8	19.10.	15 min.	5/6	35 Hz	8/4 sec.	8 cm	yes	yes	1 min. Pause at 9 min.
9	21.10.	15 min.	5/6	35 Hz	8/4 sec.	8 cm	yes	yes	1 min. Pause at 9 min.
10	25.10.	15 min.	5/6	35 Hz	8/4 sec.	8 cm	yes	yes	1 min. Pause at 9 min.

An example of a therapy plan – treatment of urge incontinence:

No.	Date	Duration	Step	Frequency	Cycle time	Position	Light	O2	Comment
1	1.10.	8 min. 7 min.	1/2	5 Hz 50 Hz	8/4 sec.	7 cm 14 cm	no	no	Frequency change
2	3.10.	8 min. 8 min.	2/3	5 Hz 50 Hz	8/4 sec.	9 cm 14 cm	no	no	Frequency change
3	5.10.	8 min. 7 min.	3/4	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	no	no	Frequency change
4	9.10.	8 min. 7 min.	3/4	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	no	no	Frequency change
5*	11.10.	8 min. 7 min.	4/5	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	no	no	Frequency change
6	13.10.	8 min. 7 min.	5/6	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	yes	yes	Frequency change
7	17.10.	8 min. 7 min.	5/6	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	yes	yes	Frequency change
8	19.10.	8 min. 7 min.	5/6	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	yes	yes	Frequency change
9	21.10.	11 min. 8 min.	5/6	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	yes	yes	1 min. Pause at 11 min.
10	25.10.	11 min. 8 min.	5/6	5 Hz 35 Hz	8/4 sec.	8 cm 14 cm	yes	yes	1 min. Pause at 11 min.

* For an optimal training effect and a maximally effective therapy outcome, the highest intensity (step 5 or 6) should be reached by the 4th or 5th therapy session and maintained through to the last therapy session. The patient should be encouraged to achieve this by the therapist during the first few sessions.

5.10. Optional oxygen therapy

The QRS Pelvicenter provides an integrated oxygen generator to deliver oxygen during therapy sessions. The proportion of oxygen dispensed through an oxygen inhalation mask or nasal cannula after mixing with fresh air should be 40%.

This effectively doubles the proportion of oxygen normally present in ambient air.

NOTE: Administering oxygen has a positive effect on providing stimulated muscle cells with nutrients and also considerably increases tissue blood flow in the trunk region.

We recommend that you offer your patients the additional benefits of optional oxygen therapy starting halfway through the therapy plan.

rPMS activates and "boosts" muscle and tissue cell metabolism. This considerably increases the oxygen requirement and blood flow in the stimulated part of the body or muscle. A combined rPMS-O2 therapy over a period of 4 to 8 weeks can have a positive effect on capillary diameter (reduced swelling of the endothelium) and improve microcirculation.

NOTE: The certified oxygen therapy module uses a generator output of 5 litres per minute. Administration of O_2 produces a beneficial and sustained arterio-venous O_2 saturation difference that persists for 1 to 2 hours after therapy.

5.11. Optional light therapy

The QRS Pelvicenter also features a light therapy module incorporating a light hood module.

Light therapy is one of the biological approaches to anti-depression therapy. It is particularly effective for seasonal affective disorders (SADs), in other words seasonal depression, or for what are known as adjustment disorders (i.e. reactive depressions), which frequently occur in incontinence patients.

In the majority of patients, particularly those of advanced age, parallel Pelvicenter light therapy has a mood-enhancing effect.

NOTE: The certified light therapy module has a 10,000 lux output.
It does not emit UV light and corresponds to the volume of light of a summer's day.

We recommend that you offer your patients the additional benefits of optional light therapy starting halfway through the therapy plan.

6. Use of rPMS frequencies and ranges

Indication requirement and rPMS effects	Frequency or frequency range
Urge incontinence/OAB	5 to 10 Hz
Stimulation of the central nervous system (CNS)	5 to 50 Hz
Treatment of myofascial problems	15 to 20 Hz
Muscular loosening effect	15 to 20 Hz
Endurance training or exercising type I fibres*. *-> please follow the instructions below!*	20 to 25 Hz*
Excellent tissue blood flow	30 to 35 Hz
Strength training/muscle growth or exercising type I + type II fibres	35 to 50 Hz

IMPORTANT NOTE:

Values from 20 to 25 Hz correspond to the threshold stimulation (the fused contraction frequency) at which slow-twitch type I muscle fibres contract to produce tetanic muscle contractions.

But from a physiological perspective, slow-twitch type I muscle fibres should not be exercised at 20 to 25 Hz in "isolation", since muscle movement sequences always invoke fast-twitch type II fibres as well.

This means that endurance training for muscle growth should always be carried out at 35 to 50 Hz. A single "isolated" frequency of 20 Hz is "only" used for postpartum training (BDNF synthesis), for pelvic pain therapy or the treatment of peritrochanteric, and for all myofascial pain syndromes.

WARNING NOTE:
Please note that longer rPMS treatments at 20 Hz (> 3 months) may result in a shift from Type II to Type I muscle fibres. We therefore strongly advise against a longer treatment period using a narrow frequency setting between 20 and 25 Hz. However, the recommended therapy duration of 10 to 12 sessions using a 20 to 25 Hz setting (for activation of BDNF synthesis and treating PPS) is completely harmless.

7. QRS rPMS stimulation configurations

The concept of “stimulus configuration” is the “recipe” for a functionally optimised and therefore effective rPMS therapy. A stimulus configuration incorporates all optimised and harmonised therapy parameters in their entirety.

NOTE: The aim of an optimised stimulus configuration is to maximise the potential impact of the therapy and ensure the success of the treatment for the patient.

7.1. QRS rPMS stimulation configurations

The “complete configuration” takes the following parameters into account:

- **Total duration of stimulation**
  The time required for a single treatment unit/therapy session, e.g. 15 or 20 minutes.
  - Where applicable, stimulation pause with a possible frequency change (indication/type of fibre)
  - Duration of the renewed stimulation (time remaining after pause)

- **Effective field intensity**
  Strength of contraction intensity

- **Effective field frequency(ies)**
  Number of repeated cycles per second

- **Duration of individual contractions**
  Duration of the contraction in seconds incl. pre- and relaxation phases and a repeated 1.5 second tapering of the stimulation signal.

- **Pause time**
  Duration of recovery time between repetitions in seconds

- **Interval between sessions**
  Number of weekly therapy sessions to be held

- **Total duration of therapy**
  Total number of therapy sessions and (if necessary) treatment series required

NOTE: The therapist should adjust the settings during the therapy period, in order to use a stimulation figuration that is optimised as far as possible.

However, this is NOT absolutely necessary, since a stimulation configuration

is already present in the therapy room. This is because most parameters can be preset. Any changes in intensity and/or frequency should, however, take place at the specified time points.

8. Stimulation configurations for various rPMS indications

The following recommendations for therapeutic stimulation configurations are based on studies, experience and the basic principles of strength training. We suggest that you adhere to the recommended settings as far as possible.

8.1. Stress urinary incontinence (SUI) in women and men

Since there is an inverse relationship between type II fibre content and muscle strength, it is not the endurance or type I fibres that are preferentially exercised, but rather the fast-twitch muscle fibres. Since the physiologic tetanus threshold of type I fibres is lower, these fibres cannot be isolated and are therefore also exercised.

Stimulation should preferably focus on the anterior portions of the pelvic floor, although medium and posterior portions of the pelvic floor can also be exercised for short periods of time on account of rapid muscle fatigue.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Front third of the pelvic floor	Minimum: 10 Optimal: 18 2x to 3x per week

8.2. Overactive bladder/urge urinary incontinence (OAB / UUI) in women

rPMS for urge urinary incontinence (UUI) focuses on treating detrusor hyperactivity. There are two possible target options:

- **Activation of somato-sensitive fibres of the pudendal nerve**, which can block the spinal cord neurological "gate". This is used to prevent the transmission of chaotic afferent signals to the CNS (e.g. neuromodulation).

- **Exercising a potentially excessively weak pelvic floor.** The purpose of this is to help lift a prolapsed bladder caused by a structural anomaly of the pelvic floor.
  The stimulation ratio for this should be about 6:4.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 7.5 min.	≥ step 3	Frequency: 5 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 14 Optimal: 20 3x per week
Stimulation: 7.5 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Front third of the pelvic floor	

Chaotic detrusor signals to the CNS can be disrupted by an rPMS application in the 5–10Hz frequency range based on gate control theory.

In women, a prolapsed bladder is often responsible for increase in urgency, which is caused by a lack of sensory information from the pelvic floor.

Additional rPMS pelvic floor exercises at a frequency of 50 Hz should be performed in these cases, with this combination therapy not exceeding the total treatment time of 20 minutes.

8.3. Overactive bladder/urge urinary incontinence (OAB/UUI) in men

The male UUI differs from the female version insofar as a potential impact of an excessively weak pelvic floor is of little relevance in men.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 7.5 min.	≥ step 3	Frequency: 5 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 14 Optimal: 20 3x per week
Stimulation: 7.5 min.	≥ step 3	Frequency: 10 Hz Stimulation: 8 sec. Pause: 4 sec.		

8.4. Mixed urinary incontinence (MUI)

With this form of incontinence, which is common in advanced age, the duration of application is dependent on the prevalence of symptoms (urge or stress incontinence).

The frequency setting here is based on two different forms of incontinence, i.e. during a single treatment session of 20 minutes, the OAB/UUI is treated with 5 to 10 Hz and subsequently the SUI with 50 Hz.

A) Mixed urinary incontinence in women

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 7.5 min.	≥ step 3	Frequency: 5 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 14 Optimal: 20 3x per week
Stimulation: 7.5 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Front third of the pelvic floor	

B) Mixed urinary incontinence in men

In men with mixed incontinence, the urge urinary incontinence (UUI) component is more pronounced. This is why it is important to note that therapy should also be initiated with a number of mixed settings. We therefore recommend two different stimulus configurations, each used alternately on day 1 and day 2:

- ➔ Day 1: OAB/urge incontinence
- ➔ Day 2: Stress urinary incontinence
- ➔ Repeat from the beginning

Treatment day 1

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 7.5 min.	≥ step 3	Frequency: 5 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 7 Optimal: 10 1x to 2x per week
Stimulation: 7.5 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle and front third of the pelvic floor	

Treatment day 2

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 7.5 min.	≥ step 3	Frequency: 5 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 7 Optimal: 10 1x to 2x per week
Stimulation: 7.5 min.	≥ step 3	Frequency: 10 Hz Stimulation: 8 sec. Pause: 4 sec.		

8.5. Stress incontinence following a prostatectomy

Because the urethra is shortened during the surgical procedure, an essential closure mechanism is lacking after prostatectomy. This needs to be compensated for by increasing the strength of pelvic contraction (“reserve continence system”).

The stimulus configuration is therefore similar to that of stress incontinence. The start of treatment is guided by the progression of postoperative healing. rPMS should be started approximately 10 days after removal of the catheter.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Front third till middle of the pelvic floor	Minimum: 10 Optimal: 18 2x to 3x per week

8.6. Postpartum training

Postpartum rPMS training requires the use of different stimulus configurations which should be determined by considering the complexity of delivery sequelae and the period of time elapsed since delivery (stress urinary incontinence and/or faecal incontinence, genital prolapse, pelvic pain syndrome, dyspareunia, etc.)

If, for example, birth-related nerve damage is suspected, which often remains untreated, stimulation of the pudendal nerve or pro-regenerative BDNF (brain-derived neurotrophic factor) cytokine stimulation should be started as early as possible.

The general objective is not so much a rapid “healing” of postpartum urinary or faecal incontinence or an immediate relief of pain, but rather an acceleration of the body's own repair processes in order to prevent the development of chronic conditions or a deterioration of potential trauma sustained during delivery.

A) Postpartum - nervus pudendus rehabilitation/BDNF stimulation

Start: As early as possible or in line with the wound healing process following episiotomy. Even if longer application times (e.g. 40 minutes) would be optimal for the activation of BDNF growth factor synthesis, significant BDNF synthesis can still be achieved using shorter treatment times.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	≥ step 3	Frequency: 20 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 8 Optimal: 12 Every day for 14 days

B) Postpartum - urinary and faecal incontinence, anal flatus symptoms, organ prolapse

Only start treatment after completion of the entire BDNF stimulation schedule. Stimulation configurations are based on SUI application principles.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle of the pelvic floor	Minimum: 10 Optimal: 18 2x to 3x per week

8.7. Erectile dysfunction/potency problems/impotence

Penile, i.e. atherosclerotic or age-related blood influx disorders usually lead to cavernous fibrosis, which in the case of erection results in insufficient filling of cavernous bodies and a venous leak. The target region of an rPMS in these cases is the ischiocavernosus muscle, which with powerful contractions provides effective emissary vein closure and increased penile blood filling pressures.

Penile fibrosis also responds well to rPMS treatment, as an improvement in microcirculation can alter the imbalance between connective tissue and smooth muscle cells in favour of smooth muscles.

NOTE: Longer treatment times (> 8 months) must be planned for these cases.

A) Erectile dysfunction – venous leak/musculus ischiocavernosus/ musculus bulbospongiosus

As both muscles form an integral part of the pelvic floor musculature, the stimulation configuration is similar to that used for treating an SUI.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Front third of the pelvic floor/perineum	Minimum: 10 Optimal: 18 2x to 3x per week

B) Erectile dysfunction – cavernosal fibrosis

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	≥ Step 4	Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Anterior pelvic floor	Minimum: 96 Optimal: 120 3x per week

8.8. Sexual dysfunction/anorgasmia in women

Since pelvic floor muscles increase the intensity of vaginal sensitivity to penetration, so that women with a strong pelvic floor also experience more pleasure and a more intense orgasm, and since the pubococcygeus and ileococcygeus muscles generate spontaneous contractions and regulate the intensity of an orgasm, rPMS exercises should target this region of the pelvic floor.

Duration of application	Intensity	Frequency/cycle time	MF core position	Applications
Stimulation: 15 min.	until step 3 from step 4	Frequency: 50 Hz Frequency: 35 Hz Stimulation: 8 sec. Pause: 4 sec.	Middle and front third of the pelvic floor	Minimum: 10 Optimal: 18 2x to 3x per week

8.9. Pelvic pain syndrome (PPS)/peritrochanteric pain syndrome (coxarthrosis)

For myofascial pain syndrome (trigger points/formation of muscle knots), which characterises PPS, the intensity of rPMS is determined based on the degree of pain the patient can tolerate and can therefore already be increased from 20% intensity (step 1) to step 3 or 4 in the first session.

The stimulation and pause times also differ compared to those used to treat urinary incontinence. Depending on the severity and chronic character of the disease, beneficial effects can already be felt after a single session. In order to promote long-term effects, however, the treatment series provided for this purpose should be fully exploited.

Duration of application	Intensity	Frequency/cycle time		MF core position	Applications	
Stimulation: 15 min.	≥ step 3	Frequency: Stimulation: Pause:	20 Hz 5 sec. 20 sec.	Anterior pelvic floor	Optimal: 5x per week	10

9. Pelvic floor exercises to support therapy

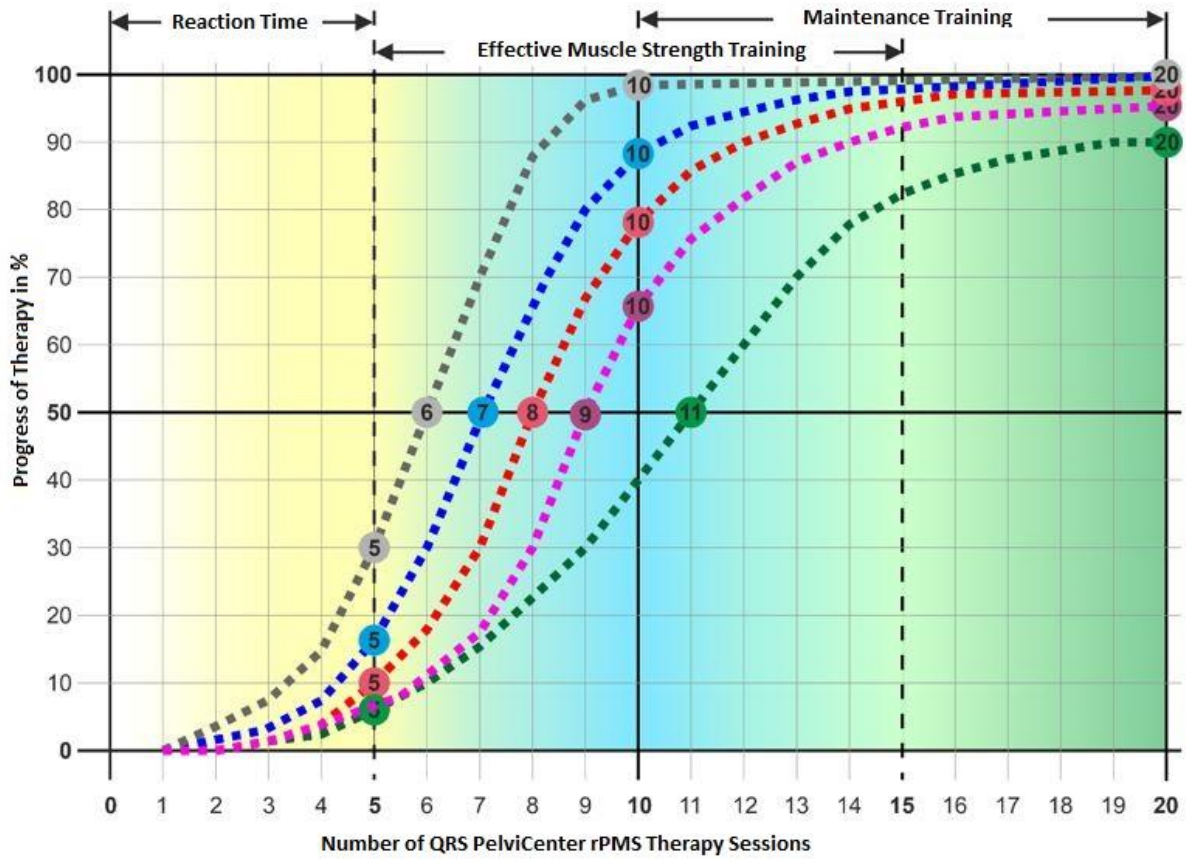
Many patients have already been taught active pelvic floor exercises at a pelvic floor centre or as part of physiotherapeutic measures. It is by no means counterproductive, but on the contrary rather beneficial, to practise previously learned pelvic floor exercises on days without training sessions (particularly if there are a number of days between rPMS sessions, e.g. on weekends). To avoid any interruption to the all-important regeneration time period, we recommend that pelvic floor exercises are not carried out with excessive force, but only with gentle exertion, in favour of more purposeful movements.

10. Therapy planning and managing of expectations

The exact number of required rPMS therapy sessions is depending on the type of Indication and the diagnosis of the situation of the patient/customer. In most situations, a customer will require at least 10 therapy sessions. In the situation of 10 rPMS therapy sessions, we advise that you complete the full therapy program in 4 weeks. And to divide the appointments (sessions) as follows:

10 therapy sessions				Up to 20 therapy sessions	
1st week	2nd week	3rd week	4th week	5th week and further	
3 sessions	3 sessions	2 sessions	2 sessions	2 sessions	2 sessions

Reason: Most patients notice a good improvement of the rPMS therapy program after 6 therapy sessions. This is due to the delayed reaction of the organism, in particular the autonomous nervous system in the process of muscle fiber formation. This is clarified via the following graph:



Notes explaining the graph above representing the progress during the therapy program:

The different color-curves in the graph above represent the progress that can be expected during a typical rPMS therapy program. The progress realized is a dynamic process. One important conclusion from the graph above is that, normally after 6 rPMS therapy sessions, most customers report a clear and good improvement in the function and initial strength of their pelvic floor muscles. In subsequent therapy sessions, each individual therapy session will result in a further and even stronger improvement.

The patient with the green curve, was suffering from a higher severity and frequency of Urinary Incontinence and/or had a more serious prolapse. When compared to other patients, the improvement is realized only in a later stage. Only after the 11th therapy session an improvement of 50% was realized. Thus this patient was not able to realize a 100% improvement after 10 and also not after 15 sessions. This patient will thus require more therapy sessions.

In summary, with a typical average patient, the following is the expectation in relation to progress of the therapy program: During the first 5 rPMS-therapy sessions, the muscles of the patients are getting used to the therapy. Initially the focus is on improving the function and the coordination of the muscles, and often in the first few therapy sessions we start the therapy at lower intensity. The result is that initially the customer/ patient notices only small improvements in strength of the muscles. Normally after 6 therapy sessions all customers who use the rPMS therapy notice real improvements and in the subsequent therapy sessions the focus is more on improving strength, thus resulting in faster improvements for each therapy session. After about 10 to 16 therapy sessions normally most customers have realized substantial improvement. All subsequent therapy sessions are important to maintain the function and strength of the muscles and to ensure long term success.

11. Maintenance and long term success

A professional follow-up study was carried out with the purpose to determine to what extent the positive effects of the rPMS therapy program would result in long term success. This follow-up study involved 104 patients suffering from Stress Urinary Incontinence who each had followed 16 rPMS therapy sessions, and who after those 16 sessions did not do any additional therapy sessions. ‚Success' was measured in terms of ‚being completely dry' or ‚being largely dry'. The conclusion of this important follow-up study is that the rPMS therapy program normally ensures long term success for minimum 12 months to 3 years.

However it is important to note that the long term success is dependent on the number of initial therapy sessions (e.g. only 10 or up to 15/20). Also the long term results are dependent on whether the customer, after ending the therapy program is actively using the muscles which have been trained („use it or loose it").

We advise that, after completing of the initial therapy program, the customer tries to regularly use the muscles, for example via self-training. And also, if the customer is suffering from being overweight, to make changes in his/ her lifestyle. Doctors working with the QRS-PelviCenter have informed us that the best long term results are realized when the customer is active and is trying to reduce his/her weight.

10. Further information (current state of research etc.)

Further information, such as detailed symptom descriptions and any related medical-scientific results as well as detailed information on the state of research about individual indications, can be found on our website at www.pelvicenter.com.

11. Contact and Support

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For technical questions or problems please contact us:
E-mail: support@qrs-international.com

11. Safety notice

You received this safety notice with the delivery of your QRS Pelvicenter.
We kindly ask you to place the safety notice provided in the vicinity of the Pelvicenter.

Warning!
Patients may only be treated when seated and conscious.

Warning!
Keep away from sources of ignition! No naked flames during oxygen therapy.

Warning!
Patients fitted with electronic implants such as pacemakers, defibrillators, insulin pumps, etc. should not be treated.

Warning!
Patients fitted with metal implants such as artificial joints, coils or screws should not be treated.

Caution, strong magnetic field!
Magnetic information stored on cheque cards, credit cards and other magnetic media may be erased.

033-7-0051 QRS Pelvicenter warning shield Version 1.2