

Product description QRS®-PelviCenter





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I. Summary

QRS®-PelviCenter/ QRS®-CoreCenter

QRS®-PelviCenter/ QRS®-Core Center is a unique, proprietary medical device from Germany which **automatically** trains the **Coordination, Function** and **Strength** of the **Pelvic Floor Muscles** and related muscles such as the **Thighs**, the muscles of the **hipbone** area and the **glutes**.

Also, importantly, since all “**Core muscles**” are connected, the QRS®-PelviCenter has also a positive effect on training the **Transversus Abdominus** and the **Multifidus**, 2 muscles which play a very important role in **Spinal Segmental Stability**.

Complementary in all indications where Kegel exercises are prescribed

QRS®-PelviCenter can be used both as a **complementary** and as a “stand-alone” treatment in treating all indications where Pelvic Floor Muscle exercises (“Kegel” exercises) are prescribed as the first line conservative treatment.

Kegel exercises have been prescribed by doctors since more than 60 years as the first-line treatment against Urinary Incontinence and various other Pelvic Floor Disorders. Kegel exercises have been proven to be effective in many clinical trials. Not only in relation to Stress Urinary Incontinence but also in relation to many other pelvic floor disorders, including Sexual Function/ Erectile Dysfunction.

Kegel exercises are effective but there are some inherent issues which make it difficult to carry out the Kegel exercises correctly. Similarly, in relation to lower back pain, it is impossible for a person to train themselves the muscles responsible for spinal segmental stability because these muscles are too deep and too small (i.e. the Multifidus). This is where QRS®-PelviCenter, or QRS®-CoreCenter, as a complementary treatment, proves its effectiveness.



High quality professional Clinical Trials

Various high quality Clinical Trials have been carried out with the QRS®-PelviCenter. This document presents the summary findings of a Level 1 Double Blind RCT (including 6 and 12 month follow-up) carried out between 2013 and 2016 on Stress Urinary Incontinence (120 patients who each received 16 sessions on the PelviCenter)

The conclusions are very important as follows:
(see detailed results in the Appendix of this document)

1. Statistical significant differences as compared to Sham on ALL outcome measures:

- QRS®-PelviCenter is the first and only system using Magnetic Stimulation which has proven in a Double Blind RCT that is realizing statistical significant differences as compared to Sham on ALL outcome measures and not only directly at the end of the 16 sessions but also in the 6 months follow-up AND 12-month follow up (12 months after the last treatment). Previous ExMI systems have never been able to prove this.

2. Effect of QRS-PelviCenter is NOT just temporary but remains longer term

- Very important in the study is the 6 month and the 12 month follow-up. The results of the 12 month follow-up are almost the same as the results when measured directly after the end of the last (16th) session. This study proves that there is only a very small deterioration in the success rates in the year after the QRS-PelviCenter treatment program. Please note that in this study QRS-PelviCenter was compared with Sham. Patients did NOT do any additional self-Kegel exercises. Patients did NOT follow any QRS-PelviCenter maintenance treatment after the end of the 16 sessions. This indicates that the results of QRS-PelviCenter can be even better when:
 - i. When patient is asked to do self Kegel exercises complementary to the QRS-PelviCenter treatment program
 - ii. When patient is offered a maintenance program after the end of the 16th session (for example 1 or 2 times maintenance per month)

3. Comparison to Kegel exercises and to other conservative treatments:

- Studies on Kegel exercises show a reduction on ICIQ-UI-SF score of between 3.4 and 3.7 (with biofeedback) points, when measured directly at the end of the 3 or 6 month training program. This 3.4 - 3.7 is below the “≥ 5 points threshold”. Generally patients are only motivated in a treatment if it realizes minimum 5 points reduction on ICIQ-UI-SF. QRS-PelviCenter realizes reductions of between 5.63 and 7.13 (when measured 12 months after the last session ! !). Minimum 68% of PelviCenter patients have reduction ≥ points when measured 12 months after the last session.
- Please note that Kegel exercises normally show poor results in RCTs when measured in 12 month follow-up (because most patients do not have the motivation to continue with the exercises on a daily basis).

4. Comparison of QRS®-PelviCenter to surgery:

- The success rates of QRS®-PelviCenter (for example measured by a reduction on the ICIQ-UI-SF score) in the 12 month follow-up comes close to the success rates of surgery [*reduction on ICIQ-UI-SF after 12 months between 5.63 and 7.13 ; ICIQ UI SF reduction with surgery is between 10.43 and 11.65*]. These success rates can be further improved if the number of sessions are increased (clinical trial was based on 16 sessions of 20 minutes) or in case the QRS®-PelviCenter is used complementary to other treatments (i.e. when the patient is encouraged to do some self Kegel exercises at home in addition to the QRS®-PelviCenter training). So the results of QRS®-PelviCenter come close to the success rates of surgery but without the complications and pain and risks from surgery.
- Remember:
 - i. Blaivas JG reviewed 1.000 published studies on midurethral slings and reported serious complications after surgery of 20.9% (5.6% requiring further surgery and 15.3% were refractory to treatment)
 - ii. Healthcare database survey in the USA reported sling revision/removal due to mesh erosion and urinary retention of 3.7% (n=188.454) and repeated surgery of 14.5%
 - iii. Epidemiology study reported high presence of co-morbidities
 - iv. About 75.000 federal lawsuits in the USA against transvaginal mesh manufacturers due to false and misleading information about the products effectiveness and safety.

5. QRS-PelviCenter = the most effective non-surgical solution against Stress UI:

- The success rates prove that QRS®-PelviCenter is now the most effective non-surgical treatment against Stress Urinary Incontinence. Reduction in ICIQ UI SF score with QRS®-PelviCenter in the 12 month follow-up is between 5.63 and 7.13. No other conservative treatment is able to realize a reduction of minimum 5 points, not when measured directly at the end of the treatment and not when measured in a 12 month follow-up.

6. QRS-PelviCenter = What the patient wants

- The study on QRS®-PelviCenter showed a high acceptability and high % of patients who reported significant benefits.
- Between 90% and 95% of patients do not want surgery, even when their doctor has strongly advised them to do surgery.
- Up to 93% of the patients who had PelviCenter treatment reported 12 months later that they felt “better” or “very much better”.
- The conclusion seems to be that, especially for Moderate Urinary Incontinence (ICIQ-UI-SF between 6-12), QRS-PelviCenter is the best option and preferable to surgery. QRS®-PelviCenter is the best solution from a patient perspective point of view.

QRS-PelviCenter = Repetitive Peripheral Muscle Stimulation (rPMS)



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Low back pain & spinal segmental stability:

- VIII. Low Back Pain & Spinal Segmental Stability

Improvement sexual function:

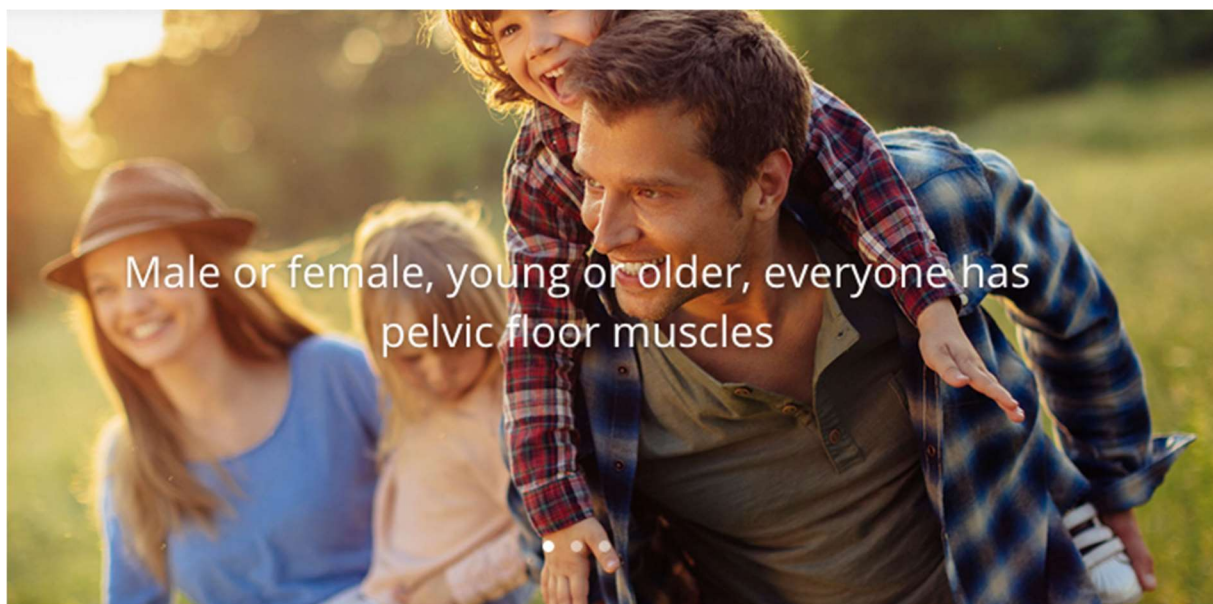
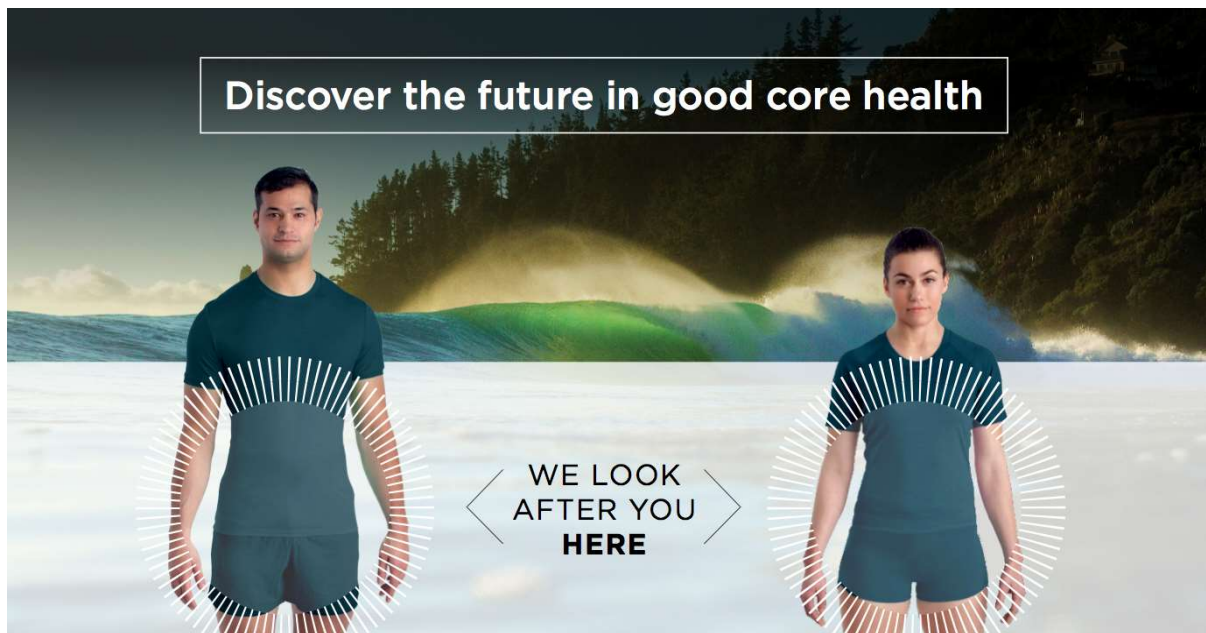
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QRS® - Unique Medical Devices aimed at treating Chronic Diseases

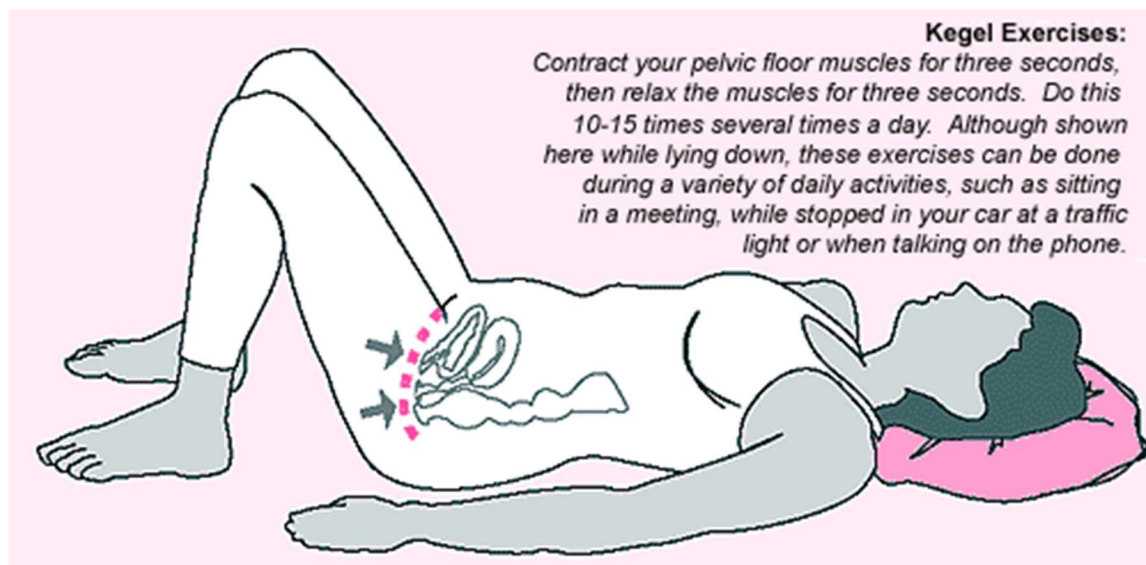
II. Introduction: QRS®-PelviCenter and Kegel exercises

QRS®-PelviCenter:

- QRS®-PelviCenter is **automated** training of the muscles of the Pelvic Floor. QRS®-PelviCenter muscle training results in improved **coordination, function** and **strength** of the Pelvic Floor Muscles (PFM)
- QRS®-PelviCenter can be used as a **complementary** treatment in all indications where Kegel exercises/ Pelvic Floor Muscle Training is effective.

Kegel Exercises:

- Pelvic Floor Muscle exercises are known as “Kegel” exercises.
- Arnold Kegel (American gynecologist):
 - Arnold Kegel popularized in 1948 exercises of the PFM for women to improve sexual and urinary health after childbirth.
 - Arnold Kegel employed the principle of functional restoration of a segregated group of muscles – well established in orthopedics, neuromuscular, and plastic surgery and physical medicine and rehabilitation, applying it to the PFM
 - Arnold Kegel recognized that surgery to correct vaginal, urethral, and rectal incontinence could be facilitated by preoperative and postoperative PFMT to improve the texture, tone, and function of the perineal muscles.
- Now Kegel exercises are used either as first line conservative treatment or as complementary treatment in the following pelvic floor disorders:
 - Improving sexual and urinary health after childbirth
 - Stress Urinary Incontinence
 - Overactive Bladder & Urge Urinary Incontinence
 - Erectile dysfunction
 - Male incontinence and ED after prostatectomy
- Kegel exercises have been proven to be effective in many clinical trials.
 - Not only in Urinary Incontinence but also in ED



- However, Kegel exercises have three inherent problems:
 - 1) **Most persons are not able to identify / feel their pelvic floor muscles**
 - a. Patients are often not able to feel or identify their Pelvic floor muscles and thus they do not know which muscles they have to train and how.
 - b. For that they often need a trained physiotherapist who helps them identifying the right muscles. This is often done in an uncomfortable way (i.e. touching the genital organs). Also the physiotherapist needs to regularly check the patient to ensure he/ she is still carrying out the exercises correctly.
 - c. Please note that it is very important to train the right muscles. If patient trains the wrong muscles (i.e. abdominal muscles) then there is a risk that the incontinence issue gets worse rather than improves.
 - 2) **Carrying out Kegel exercises requires daily active commitment**
 - a. A patient must be willing to do active training every day for 3 times per day for a long period of time. Many patients, especially older patients do not have the energy or time to do this. Often patients start ambitiously with the Kegel training exercises and they are realizing some initial benefits but then after a few months they get disappointed by the low results in relation to the efforts or expectations, and they decide to stop the exercises.
 - 3) **Not easy to intensity the training**
 - a. As with any type of muscle training, after being able to carry out the exercises at low intensity (which helps with improving the function), the patient must be motivated to strengthen the intensity of the exercises (stronger muscles can only be realized by gradually increasing the intensity of the exercises). With persons doing their own Kegel exercises at home it is very difficult to increase the intensity of the training.
- Additional issues with Kegel exercises:
 - From a urologist point of view, the task of teaching PFMT is labor-intensive, and office visits do not allow sufficient time to adequately instruct patients with respect to PFM anatomy and function, the proper technique of PFMT, and the application of the exercises to the specific problem.

Summary:

- 1) QRS-PelviCenter is automated training of the **muscles of the Pelvic Floor** and of related muscles such as the **thighs**, the **hip-bone** and the **glutes**. and of other “Core” muscles such as the **Multifidus** & **Transversus Abdominis** (the last 2 muscles have a very important role in spinal segmental stability and avoiding lower back pain)
- 2) Pelvic Floor Muscle Training (PFM) has been known since 1948 as “Kegel exercises” and is the most important conservative (non-surgical) first-line treatment in treating many pelvic floor disorders.
- 3) Kegel exercises, when carried out correctly, have been proven to be effective by many clinical trials, including Urinary Stress Incontinence and Erectile Dysfunction.
- 4) However, Kegel exercises (self-exercises) have some inherent issues. As a result of this, it is very difficult to carry out the Kegel exercises correctly.
- 5) QRS-PelviCenter solves these inherent issues of Kegel exercises and can be used as complementary treatment in all indications where Kegel exercises are prescribed.
- 6) Functionally, the QRS-PelviCenter is using repetitive Peripheral Muscle Stimulation (rPMS) and the repetitive muscle contractions and relaxations results in improved **coordination**, **function**, and **strength** of the Pelvic Floor Muscles.
- 7) QRS-PelviCenter has been proven in high quality Clinical Trials. This document includes the results of a Double Blind Random Clinical Trial on 120 women suffering from Stress Urinary Incontinence. Importantly, this double blind study did not only measure the results directly after the end of the 16 sessions. But instead it waited for 1 year after the last PelviCenter treatment. This double blind RCT proves beyond doubt that QRS-PelviCenter is the most effective non-surgical solution against Stress Urinary Incontinence.



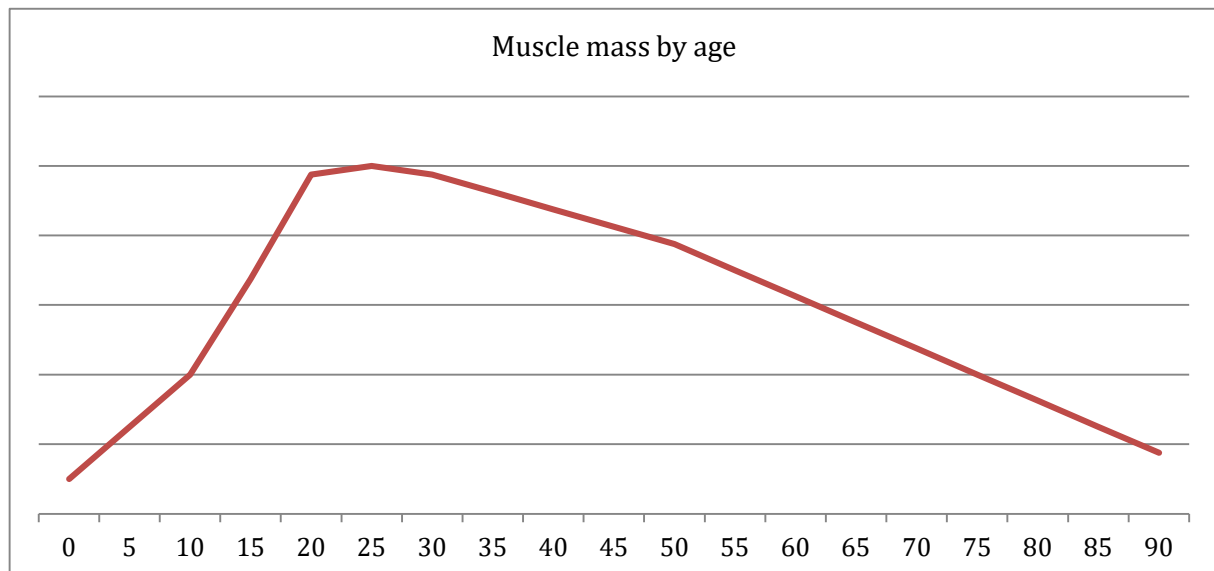
III. Additional notes on Muscle Training

Introduction:

QRS®-PelviCenter is automated training of the muscles of the Pelvic Floor
Training of Pelvic Floor muscles is similar to training of other muscle groups in the human body.

The human body of an adult person consists for about 35%-42% of skeletal muscles. Muscle mass normally grows until the age of 25 or 30 after which the muscle mass normally starts to decrease with about 1% per year and after the age of 50 even faster. The losing of function and strength of muscles is a key cause for many chronic diseases. In order to maintain function and strength of muscles it is important to regularly use them or train them ("use it or loose it!")

A QRS-PelviCenter training program follows the key principles of muscle training.



QRS®-PelviCenter/ QRS®-CoreCenter = Automated Training of Muscles

Training of Function, Coordination and Strength of muscles of Pelvic Floor, Thighs, hipbone, glutes and other core muscles including MultiFidus



QRS® - Evidence Based Magnetic Applications

Key principles of muscle training:

- Principle of “**progressive overload**”. Gradually “train” your muscles to handle bigger ‘load’ = higher intensities. The QRS®-PelviCenter has various intensity levels and the customer/patient is encouraged to gradually increase to the highest intensities. Increasing the strength of the exercises is not possible via own-self Kegel exercises.
- Principle of first focusing on learning to use the muscle before focusing on building strength.
 - QRS®-PelviCenter treatment programs are starting with low intensities to focus on **improving ‘coordination’ and ‘function’** of Pelvic Floor muscles. Only later with higher intensities will the focus be on building strength
 - Similarly, in relation to lower back pain, the focus must first be on re-training and improving the function of the relevant muscles. The muscles responsible for Spinal Segmental Stability (i.e. the Multifidus) are small deep muscles and not focused on strength. Often in people suffering from lower back pain, the function of these muscles has changed.
- Building strength of muscles can only be realized by **high intensity, short duration anaerobic exercises at maximum load**.
 - The focus is on the fast-twitch type 2 muscle fibers which have a greater potential for increase in mass.
 - Training for Strength (focused on type 2) such as sprinters and weight lifters, is different than training for endurance (focused on type 1 slow twitch muscles).
 - The Pelvic Floor consists for about 70% of slow twitch (=support) and 30% of fast-twitch (=action) muscles. QRS®-PelviCenter is able to train both muscle groups but each requires a different treatment program.
- Principle of “**warm-up**” and “**cool-down**”. QRS®-PelviCenter treatment programs ensure start at low frequencies to warm-up the muscles following by short duration high intensity/high frequency training at maximum “load”. And followed by a “cool-down” phase at lower frequencies and making use of the patented QRS®-PEMF technology to ensure improvement of blood flow and relaxation.
- The principle of “**co-contraction**”
- The principle of training muscles in a **concentric, excentric** and **isometric** way
- The principle of “relaxation” which is important after each muscle contraction



IV. Technical Details on Electro Magnetic Stimulation & QRS®-PelviCenter

What is the underlying technology of the QRS®-PelviCenter

QRS® PelviCenter makes use of the underlying technologies of Q-rPMS and ExMI.

- rPMS = Repetitive Peripheral Muscle Stimulation.
- ExMI = Extracorporeal Magnetic Innervation.

How does Electromagnetic Stimulation work?

The QRS®-PelviCenter produces a highly focused, time-varying magnetic field that penetrates deep into the perineum, stimulating innervation of the pelvic floor muscles by activating all branches of the pudendal and splanchnic nerves, which provokes muscle contraction.

The working of Pulsed Electro Magnetic fields in human tissue is as follows:

- High electric currents are applied to a surface stimulation magnetic coil which is integrated in the QRS®-1010 PelviCenter.
- These electrical currents generate pulsed electro magnetic fields,
 - Repetitive, short magnetic field pulses with a duration of 200 to 500µs and a magnetic flux density of up to 1 Tesla.
- At the tissue level, these time varying electro magnetic fields induce electrical eddy currents by an ion flow in the soft tissues of the pelvic floor.
- This flow of ions establishes differences in voltage between two spatial points (depolarization of resting motor neurons).
- If the voltage gradient is sufficiently strong and the change of field is rapid, membrane depolarization occurs.
- This membrane depolarization generates an action potential along adjacent peripheral nerve tissue. The action potential propagates naturally down the axon through the usual Na⁺ and K⁺ ion fluxes.
- After these impulses reach the motor endplate, the pelvic floor muscle respond by contracting. Unless the output pulse rate exceeds the ability of the muscles to contract and relax, the muscles contract and relax with each pulse.

In other words:

Magnetic stimulation has been developed for the non-invasive stimulation of the central and peripheral nervous system.

It is the nerves that are most sensitive to electrical depolarization by a changing magnetic field.

When the nerve is a motor nerve, depolarization will cause a propagating impulse that will release neuro- transmitters at the motor end plates and provoke muscle contraction.

QRS®-Germany - Technical leader in Magnetic Stimulation since 1990

Impact of QRS®-PelviCenter on human tissue and on the Pelvic Floor

Muscle contractions

Magnetic stimulation of peripheral nerves provoke muscle contractions and facilitate the stimulation of autonomic and somatic nerve pathways in the pelvic floor. Motor evoked potentials are triggered in the pelvic sphincter muscles.

Impact on slow-twitch and fast-twitch fibers

The QRS®-PelviCenter helps the patient to learn how to use certain muscles, resulting in improved function and coordination between the muscles of the Pelvic Floor and increased strength (hypertrophy).

The QRS®-PelviCenter trains both the fast-twitch (type II) and the slow-twitch (type I) muscle fibers (via different frequencies and intensities).

Thereby it ensures that PFM are able to respond better to a sudden increase in intra-abdominal pressure.

And also ensures improving of the resting urethral closure pressure.

How does QRS®-PelviCenter lead to improved Coordination of the PFM?

The Pelvic Floor Muscles are a highly complex set of muscles.

For the function of the Pelvic Floor Muscles it is important that the muscles work together in a coordinated manner.

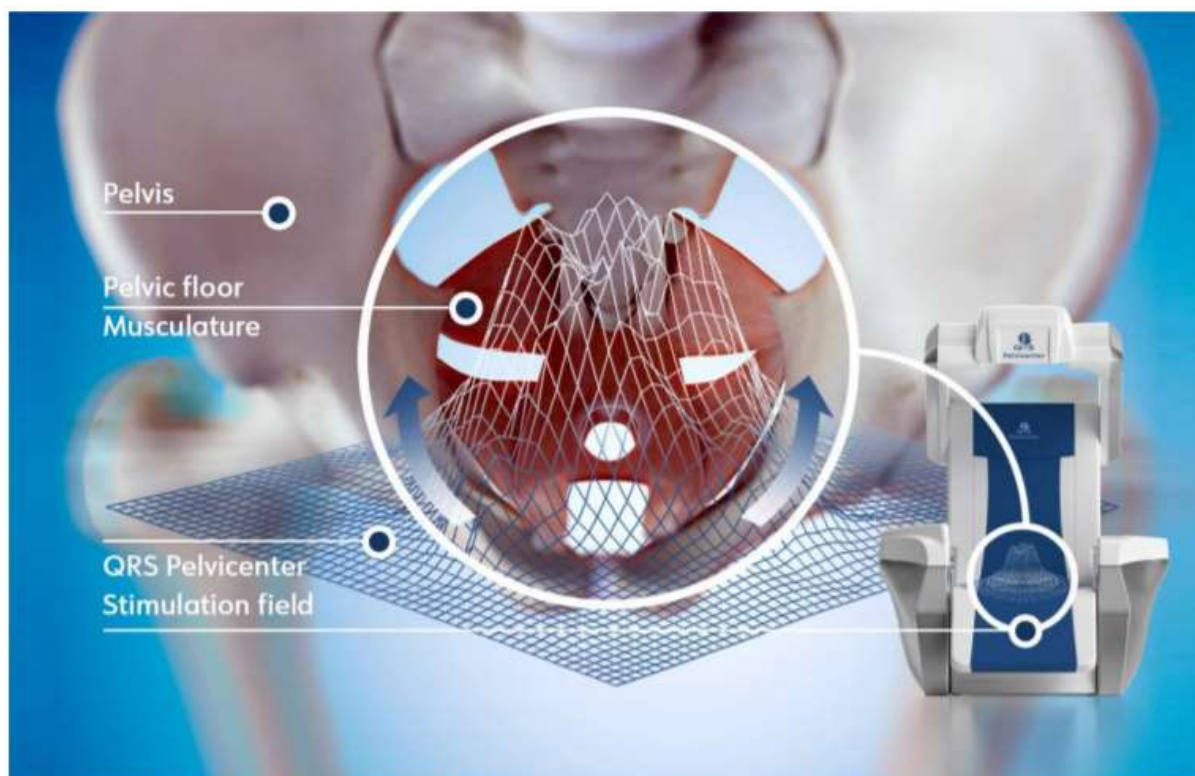
The PelviCenter does not selectively exercise individual muscles, but affects the entire muscle system of the pelvic floor and muscles in the hip, buttock and thigh region.

All important muscles are strengthened at the same time; the muscles that are the weakest due to a lack of activity are strengthened particularly effectively.

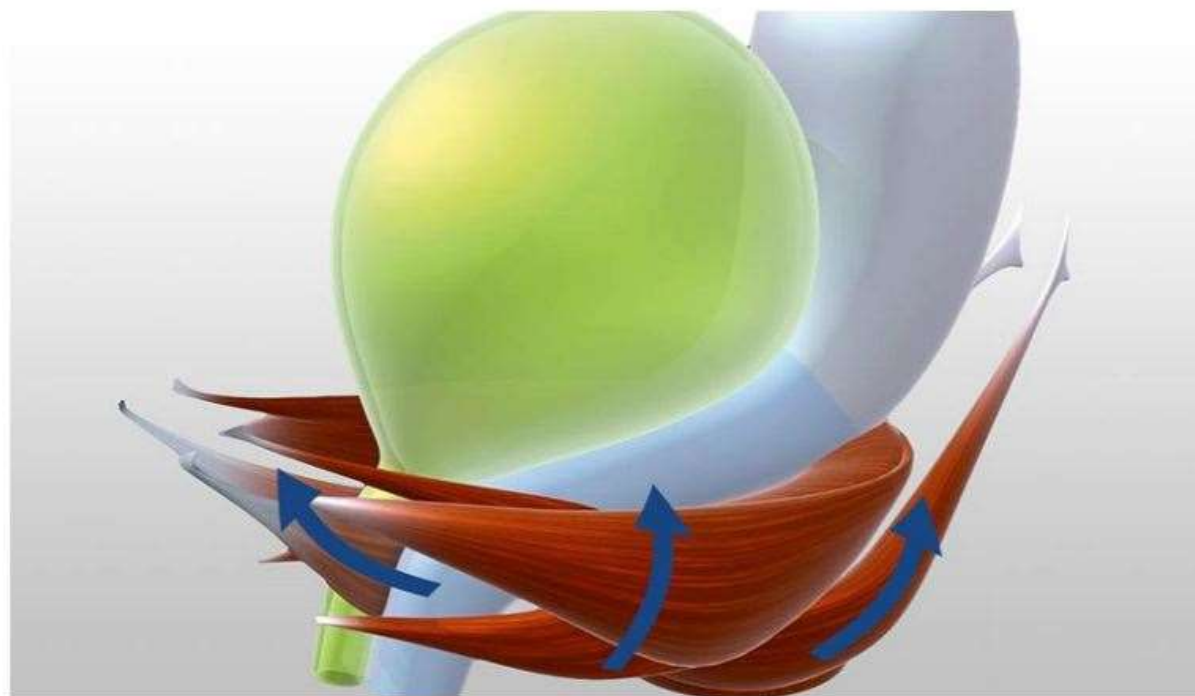
This significantly improves the requirements for regaining specific muscle coordination.

As a result of the depolarization of the motor nerves, the extracorporeal magnetic stimulation also causes an intracorporeally generated return flow of proprioceptive data to the brain.

It has been shown that an internal return flow of sensory information, generated through external stimulation, is able to change the cortical representation in the long-term; in addition it is able to improve the personal perception and controllability of individual muscle functions and indirectly also their coordination.



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.



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



V. QRS®-PelviCenter as compared to old versions of the ExMI technology

Introduction:

The technology of ExMI (“Extracorporeal Magnetic Innervation”) in the treatment of Stress Urinary Incontinence has been introduced in 1999 in the USA (obtained FDA approval in USA in 1999).

Many clinical trials were carried out. Despite the fact that there were many positive patient testimonials, the technology was never fully accepted by the professional urologists/ (uro)-gynecologists/ physiotherapists. This is mainly based on the fact that the old ExMI technology has never been able to prove in professional Double Blind RCTs that it was effective (statistical significant differences as compared to “sham”).

QRS®-Germany has in the last 10 years carried out a lot of Research & Development and has strongly revolutionized the technology. The result is that there is now, for the first time, high quality professional Double Blind Clinical control Trials proving, beyond doubt, the effectiveness of the technology of Magnetic Stimulation in treating Pelvic Floor Disorders.

The high quality Double Blind RCTs do not only show statistical significant improvements and statistical significant differences as compared to “sham” directly after the end of a 16 session treatment plan [something which has never been proven by the old ExMI systems]

But importantly, also after 6- and 12 month follow-up.

Based on the evidence of the double blind RCTs, the QRS®-PelviCenter is now the most effective non-surgical solution against Stress Urinary Incontinence and other Pelvic Floor disorders.

The paragraph below describes some of the key improvements that QRS®-PelviCenter has introduced to ensure that it is now a unique and highly effective complementary treatment against Urinary Incontinence and other pelvic floor disorders.

QRS®-PelviCenter = What the patient wants

QRS®-PelviCenter in comparison with the old ExMI technology

Old ExMI technology

QRS®-PelviCenter has strongly revolutionized the technology.

The first ExMI systems focused on treating Urinary Incontinence were introduced in 1998 in the USA.

Many clinical trials were carried out by the results were often “inconclusive”.

Although many systems were installed at family doctors and although many patients with Stress Urinary Incontinence realized improvement in their symptoms, the professional Urologists/ Urogynecologists/ Physiotherapists did not accept the technology as being effective.

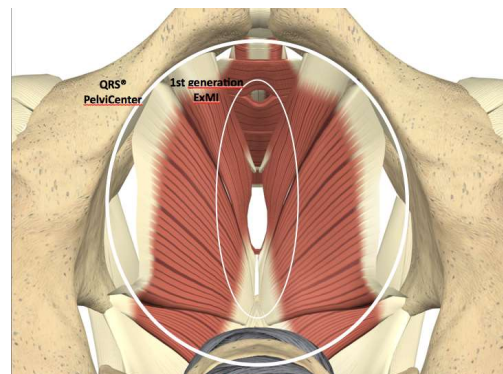
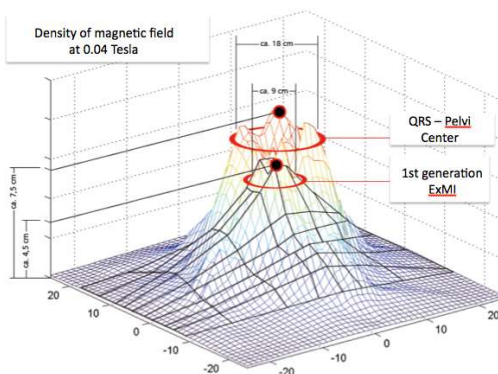
The QRS®-PelviCenter is no longer comparable to the old ExMI technology and systems. The focus of QRS® is to work closely together with professional urologists/ gynecologists/ physiotherapists and carry out professional high quality clinical trials to prove the effectiveness of the treatment.

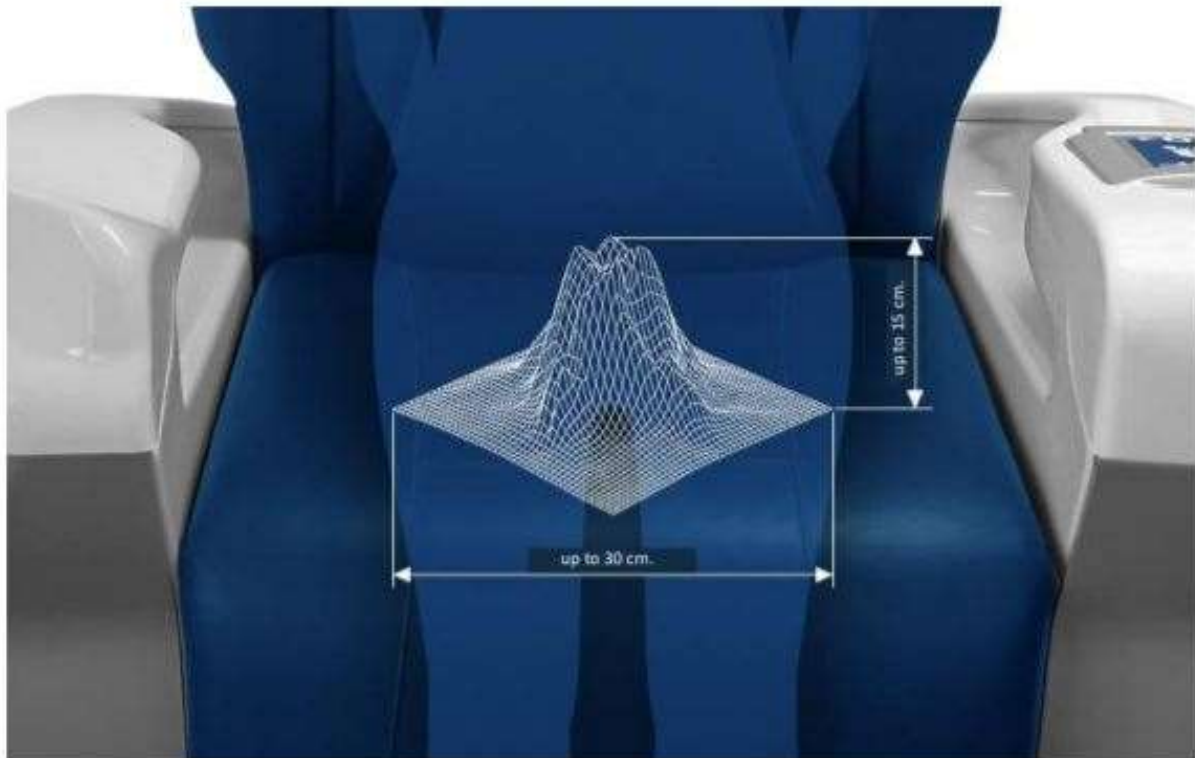
Proprietary declaration QRS®-PelviCenter

Some of the key improvements that QRS® has implemented and which make QRS®-PelviCenter a truly unique and proprietary system are as follows:

1. Much stronger and much more homogenous stable magnetic field.
 - a. Use of 4-arm Magnetic Coil System instead of 2 arm
 - b. Much less energy loss: Apart from the important improvement that QRS-PelviCenter operates with much stronger magnets, there is another important difference: Technologically, the QRS®-PelviCenter has much less losses and so the energy will be better transported to the patient.
 - c. The QRS®-PelviCenter does not get so hot. The QRS®-PelviCenter can be used much longer at full energy than the previous ExMI systems. It is possible to operate the QRS®-PelviCenter continuously for 8 or more hours per day and this was not possible with the previous ExMI systems. Some older ExMI systems can only be used for 10 or 20 minutes after which they require a “cooling-down” phase.
 - d. Also, the QRS®-PelviCenter produces a much more stable Magnetic field. The performance of previous ExMI systems was not stable and often fluctuating because of the high energy losses.
 - e. Pulselength of the QRS®-PelviCenter are much longer. This is another important point of why the QRS®-PelviCenter produces better stimulation. Older ExMI versions do use only short pulselength because higher pulselength produces more energy losses.

2. Thus reaching much deeper and much wider in the pelvic floor
 - a. Old ExMI systems produced a magnetic field like a “knife-form” or “needle form”, in length-side of the chair. QRS® produces a “bell-form” in length and width-mid from the chair. The “illuminated” volume is thereby much bigger. The result is that the QRS®-PelviCenter activates more regions in the body and this stimulates not only more muscles but also deeper into the body.
 - b. Training ALL muscles of the Pelvic Floor resulting in more effective training of **Coordination** of the muscles and this is very important in re-learning how to use the pelvic floor muscles.
 - c. Training not only the muscles of the Pelvic Floor but also some of the important “Core” muscles including the muscles of the **thigh** (hamstrings, quadriceps), of the **hip-bone** and of the **glutes**. The result is that QRS®-PelviCenter is not only effective in treating Urinary Incontinence but can also be used for other indications including Core Stability training exercises (training the important “MultiFidus” and “Transversus Abdominis” muscles).





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.

3. Much better stable performance:
 - a. The QRS®-PelviCenter does not get so hot. The QRS®-PelviCenter can be used much longer at full energy than the previous ExMI systems. It is possible to operate the QRS®-PelviCenter continuously for 8 or more hours per day and this is not possible with the previous ExMI systems. No “cooling-down” phase necessary with QRS®-PelviCenter. It is possible to treat more than 30 patients per day (at 20-25 minutes each) without any problem.
4. Movable magnetic coil, allowing the possibility to position the magnet exactly on the right position.
 - a. The magnetic coil can be positioned exactly on the right position depending on the size of the patient and of the indication (lower back pain, fecal incontinence, urinary incontinence, erectile dysfunction). The coil can be moved between 0 cm (calculated from the back/ spinal cord) to 14 cm. In combination with the various frequencies and intensities we can target all relevant pelvic floor muscles (for example the PC muscle or the more superficial ischiocavernosus and bulbospongiosus muscle).

5. “Ramp-up” functionality, which creates a gradual increase of the intensity and this is more comfortable for the patient (no painful “shock” effect) and also more effective.
6. Various other Functional improvements including:
 - a. Possible to operate with a chipcard and program the chipcard with the exact treatment program for the specific indication, thereby ensuring that the nurse and patient use the most optimal treatment program.
7. High quality clinical trials (see also appendix for detailed results of studies):
 - a. Various high quality Random Clinical Trials have been carried out with the QRS®-PelviCenter which prove the effectiveness. Availability of double blind RCT which prove beyond doubt, not only the effectiveness of the system directly after the end of 16 sessions, but also proving statistical significant improvements and differences as compared to “sham” on ALL outcome measures both 6 months and 12 months after the end of the last PelviCenter session ! ! !
 - b. Note that QRS® has been the first and only company to prove beyond doubt, the effectiveness of its system in a high quality double blind clinical trial. Note that with the previous versions of the ExMI technology (since 1998), many clinical trials were carried out but never has there been any double blind Random Clinical Trial proving beyond doubt that the technology was effective. QRS®-PelviCenter is the first system which has been able to prove that. Please refer to the paragraph on clinical trials.
8. Able to treat other indications with QRS®-PelviCenter:
 - a. Stress Urinary Incontinence
 - b. Other Pelvic Floor disorders (other than Stress Urinary Incontinence) including:
 - i. Urge & Mixed Urinary Incontinence, Overactive Bladder
 - ii. Sexual function men & women
 - iii. Fast rehabilitation after prostatectomy (men)
 - iv. Fast rehabilitation after pregnancy (women)
 - v. Fecal incontinence
 - vi. Pelvic Pain
 - c. But also very successful in treating Lower Back Pain.
 - i. Many patients experience already after 1 single session with QRS®-PelviCenter significant improvements in the pain and in the functionality of their lower back pain.
 - d. Spinal Stability
 - e. Cellulite
 - f. Osteoporosis (magnetic stimulation has strong positive impact on bone growth)

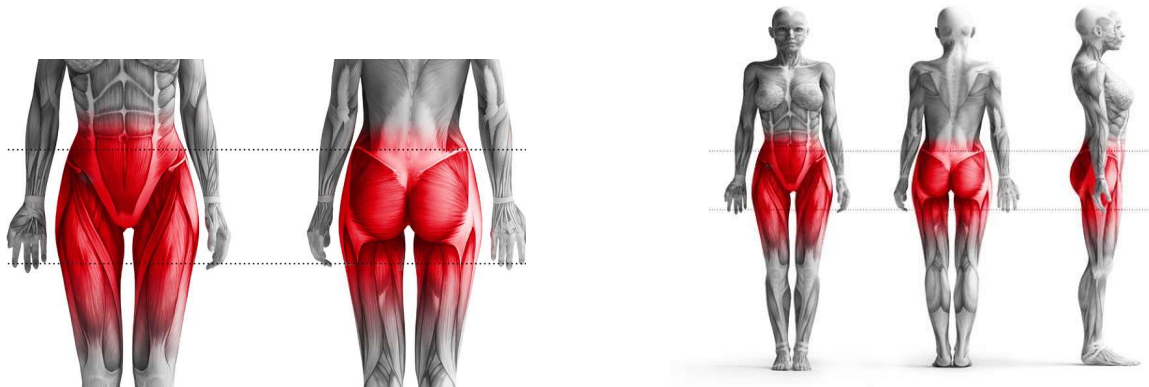
Summary of the comparison of QRS®-PelviCenter with old ExMI technology:
See next page

Summary of the comparison of QRS®-PelviCenter with old ExMI technology:

With QRS®-PelviCenter you feel real muscle contractions IN the pelvic floor

Important is for doctors to test the QRS®-PelviCenter as compared to the older ExMI systems. All doctors who tested the QRS®-PelviCenter confirmed that the PelviCenter has much more power and stimulates the muscles much better. **With the QRS®-PelviCenter you feel Real Coordinated Muscle Contractions IN the Pelvic Floor** and that was not always the case with the previous version of the ExMI technology (with the previous ExMI versions, urologists often concluded that the system was only contracting superficial muscles such as the glutes).

The QRS®-PelviCenter/ CoreCenter is working on ALL “Core” muscles.



QRS® - First choice before Surgery and Pharmaceuticals

**Why do elderly persons have higher risk of falling and breaking a leg?
Because of weak core muscles**

**What do all profesional sports people need in order to ensure top performance?
→ Strong Core muscles ;**

What is the number 1 reason for lower back pain and why does back pain keep coming back? Because of weak/ non-functioning core muscles

VI. QRS®-PelviCenter Pelvic Floor Muscle Training and Stress Urinary Incontinence

Key causes for Stress Urinary Incontinence include:

- Weakening of urethral sphincters. Total number of skeletal muscle fibers decreases 7 fold as women progress from 15 to 80 years of age (2% per year)
- Problems with urethral support. Pelvic floor muscles act as second line of defense in closing the urethra by pushing the urethra against the pubic bone. However, if the pelvic floor muscles are weakened and/or the supporting ligaments/ fascia get stretched the pelvic floor muscles are no longer able to support the urinary and reproductive organs and are no longer able to push the urethra against the pubic bone, resulting in incontinence.

Stress Urinary Incontinence and Kegel exercises:

Kegel exercises have been used since the 1950's in treating Stress Urinary Incontinence with women.

Studies Extracorporeal Magnetic Innervation & Stress Urinary Incontinence:

The technology of ExMI has been introduced in the market since 1998.

Since 1998 more than 75 studies have been carried out and published.

Most of these studies are low quality studies but show that Magnetic Stimulation has positive effects on Stress Urinary Incontinence and Urge Urinary Incontinence.

However, the old technology of ExMI has never been able to prove its effectiveness in a double blind Random Clinical Trial.

This is also the reason why professional urologists have never accepted the technology.

However, QRS® has strongly revolutionized the technology (see other paragraph in this document for a description of the improvements) and QRS has been carrying out double blind RCTs which have proven, beyond doubt, that QRS-PelviCenter is the most effective non surgical solution against Stress Urinary Incontinence.

Studies QRS®-PelviCenter and Stress Urinary Incontinence:

Various high quality studies have been completed. Amongst others in:

- Malaysia. Double Blind Random Clinical Trial (level 1) with 12 month follow-up
- India, New Delhi. Study on 90 patients suffering from Stress UI, Urge UI and ED
- University of Vienna, Austria. RCT 360 patients from elderly care homes.
- Germany: Study by Dr. Zellner focused on Incontinence after Prostatectomy

Various other studies are underway.

Please refer to separate paragraph for results of these studies.

Double Blind MultiCenter Random Clinical Trial Penang, Malaysia SUI

QRS®-International has carried out between September 2013 and March 2015 a Double Blind Random Clinical Trial on 120 female patients suffering from Stress Urinary Incontinence.

In April 2016 the university finalized the study report for the 12 month follow-up measurements (12 months after the patients had received the last treatment with the QRS-PelviCenter).

This was a MultiCenter study carried out by 6 private hospitals in Penang, Malaysia. Leading doctor is Dr. Liong Men Long from the Island hospital in Penang. Researcher was Dr. Renly Lim.

The Study Design has followed the highest quality standards (internationally level 1 and Level 5 on the JADAD score, which is the highest quality level possible in international clinical trials).

120 patients were randomized in 2 groups (phase 1):

- Active: 60 patients received 16 real PelviCenter sessions on the QRS®-PelviCenter.
- Sham: The other 60 patients received 16 “sham” treatments.

After phase 1 (above), patients who were not fully cured were given the option to do 16 real Active treatments on the QRS®-PelviCenter.

- 41 patients of the original “Sham” group chose to do 16 Active sessions. Thus during the ‘open label study’ a total of 101 patients received 16 active Pelvicenter sessions (60 of the original group and 41 of the Sham group).
- 24 patients of the original “Active” group decided to do an additional 16 sessions with QRS®-PelviCenter. This group included mainly patients with Severe Urinary Incontinence who had realized improvements with the 16 sessions with PelviCenter but who had not yet been fully “cured”.

Measurements were made on all important outcome measures including:

- Number of patients who realized a decrease on ICIQ-UI-SF total score of minimum 5 points
- Objective Cure (no leak after 1 hour pad test)
- Subjective Cure
(answer “never” on question: “how often do you leak urine?”)
- Severity
(measured via “ICIQ_UI-SF Total score”, scale 0-21)
- Frequency (average number of leaks per day)
- Pad Weight
- PGI-I
(% of patients reporting “significant benefits”)
- Quality of Life
(measured via ICIQ-LUTSqol score, scale 19-76)
- Improvement Sexual Function
- Adverse events



In total 5 study reports have been issued by the University of Malaysia:

1. Report double blind Study of 120 patients directly after the 16 sessions.
 - a. This report was presented at the SIU (Societe Internationale d'Urologie) in Melbourne in October 2015. See detailed findings in the appendix.
2. Report Patient Perception QRS-PelviCenter (presented at EUA, European Urology Association, in Munich March 2016):
 - a. Conclusion: QRS®-PelviCenter was proven to be well-accepted, well-tolerated, and effective for treatment of Stress Urinary Incontinence.
 - b. 90% of patients would recommend the treatment to friends; 95% did not experience adverse effects; 83% experienced no pain. 82% was satisfied or completely satisfied after 16 sessions. 95% of patients would not consider surgical options even if they require further treatment for their condition.
3. 6 month follow-up report (October 2015)
 - a. Measurements were made 6 months after the last QRS®-PelviCenter session.
 - b. The report has been presented at the AUA in San Diego, USA in May 2016
 - c. Conclusion: on ALL outcome measures 6 months after last session there is:
 - i. Statistical significant differences as compared to baseline
 - ii. Statistical significant differences as compared to sham
4. Report Sexual Function women (double blind study and results measured 6 months after the last session as compared to baseline and as compared to sham).
 - a. The report is presented at the AUA in San Diego, USA in May 2016
 - o Conclusion of the report: QRS®-PelviCenter improves sexual function of both the female subjects and their partners.
5. Report 12 month follow-up (April/ May 2016)
 - a. Measurements were made 12 months after the last QRS-PelviCenter session.
 - b. The report will be presented at the UAA (Urology Association of Asia) in Singapore in July 2016.
 - c. The report will be published in the European Urology Journal (Journal with the highest ranking in the world; only accepts high quality studies with 12 month follow-up)
 - d. Conclusion: on ALL outcome measures 12 months after last session there is:
 - i. Statistical significant differences as compared to baseline
 - ii. Statistical significant differences as compared to sham

Please refer to appendix for detailed results of the Study.

Please refer to separate Powerpoint Presentation for further analysis.

Publication Study in Journal of Urology:



The screenshot shows the homepage of The Journal of Urology, the official journal of the American Urological Association. The header includes the journal title in large red letters, the AUA logo, and a navigation bar with links like 'Articles & Issues', 'Collections', 'Multimedia', 'News', 'For Authors', 'Journal Info', 'Subscribe', and 'AUA'. Below the navigation bar is a search bar with a dropdown menu set to 'All Content' and a 'Search' button. The main content area features a 'Previous Article' link, a central 'Articles in Press' link, and a 'Next Article' link. A red banner below these links states: 'To read this article in full, please review your options for gaining access at the bottom of the page.' Below this is a dark blue bar labeled 'Article in Press'. The article title is 'Randomized Controlled Trial of Pulsed Magnetic Stimulation for Stress Urinary Incontinence: 1-Year Results'. The authors listed are Renly Lim, Men Long Liong, Wing Seng Leong, Nurzalina Abdul Karim Khan, and Kah Hay Yuen.

Full link to the Study Report on:

[http://www.jurology.com/article/S0022-5347\(16\)31795-5/fulltext?rss=yes](http://www.jurology.com/article/S0022-5347(16)31795-5/fulltext?rss=yes)

Identification details:

- PII: S0022-5347(16)31795-5
- DOI: 10.1016/j.juro.2016.11.091
- Reference: JURO 14216

**QRS®-PelviCenter – Most effective Non-surgical solution
against Stress Urinary Incontinence and other Pelvic Floor disorders**

Publication Study in Journal of Urology:
Summary of the publication below:

Abstract

Purpose

Despite significant differences in success rates between surgical and non-surgical treatments for female stress urinary incontinence (SUI), a few cross-sectional surveys reviewed that most patients still prefer the latter. We evaluated the efficacy of the under-studied non-surgical treatment using pulsed magnetic stimulation (PMS) in female SUI.

Materials and methods

This randomized, double-blind, sham-controlled study involved 120 female SUI subjects aged at least 21 years old. Treatment involved PMS, 2 sessions per week for 2 months (16 sessions). After 2 months, subjects could opt for 16 additional sessions regardless of initial randomization. The primary response criterion was a 5-point reduction in International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form (ICIQ-UI SF). Key secondary response criteria included objective and subjective cure, supplemented by other secondary criteria. Follow-ups were conducted at months-1, 2, 5, 8 and 14.

Results

At 2 months, 45 of 60 subjects (75%) in the active versus 13 of 60 subjects (21.7%) in the sham arms were treatment responders ($p<0.001$). After 2 months, 24 (40%) subjects from the active and 41 (68%) from the sham arms opted for additional active PMS. At 14 months, subjects who received 32 sessions of active PMS had the highest percentage of treatment responders ($n=18/24$, 75.0%), followed by those who received 16 sessions ($n=26/36$, 72.2% and $n=28/41$, 68.3%) and those who did not receive any active PMS ($n=4/19$, 21.1%) ($p<0.001$).

Conclusions

The encouraging long-term response rates show that PMS is an attractive non-surgical alternative to patients who do not want to undergo surgery.

Full link to the Study Report on:

[http://www.jurology.com/article/S0022-5347\(16\)31795-5/fulltext?rss=yes](http://www.jurology.com/article/S0022-5347(16)31795-5/fulltext?rss=yes)

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VII. QRS®-PelviCenter and Overactive Bladder (OAB)

Some basic notes about Overactive Bladder (OAB):

OAB = Detrusor Instability.

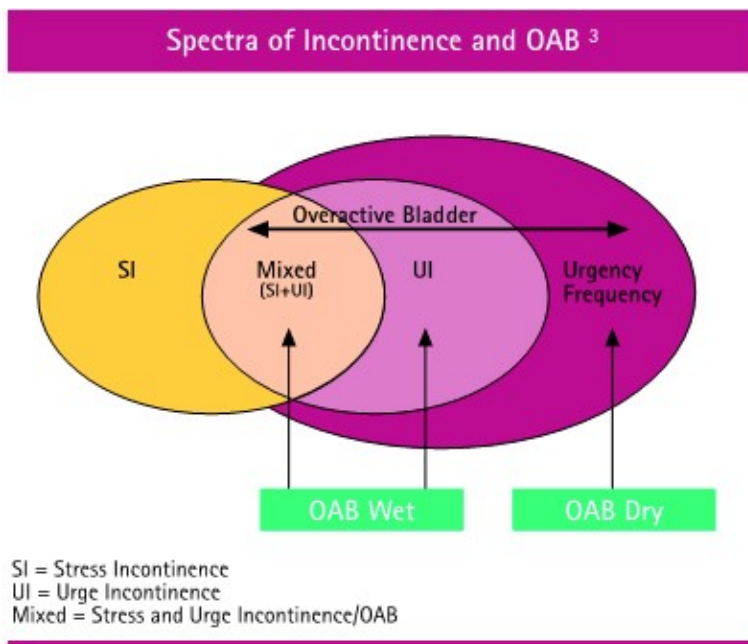
OAB has 4 key symptoms:

1. Urgency:
 - Urgency is the most important symptom of OAB
 - Definition of urgency: sudden, compelling desire to pass urine which is difficult to defer
 - = OAB dry
2. Frequent urination (but: the amount of urine that is passed when there is an urgent need to urinate is relatively small with OAB)
3. Frequent interruptions of sleep because of the need to urinate (nocturia)
4. Urinating unintentionally followed by an urge to continue (urge incontinence)
 - Involuntary loss of urine occurring for no apparent reason while feeling urinary urgency.

Relationship between OAB, Urgency, and Urge Incontinence:

- OAB patients normally have urge but may or may not have leak
- Urge incontinence patients have both urge and leak.
- Urgency and Urge Incontinence are symptoms of OAB.

See graphical overview below.



Overactive Bladder and Pelvic Floor Muscle Training:

- The American Urological Association guidelines for OAB recommend that clinicians offer fluid management, bladder training, bladder control strategies, and Pelvic Floor Muscle Training as first-line therapy to all patients with OAB.
- Bladder training is focused on training patients to recognise the contractions or the planned contractions of the detrusor muscle (e.g. in the case of hand washing, key in the door; rising from sitting; running water; cold or rainy weather) and to teach the patients to respond by deploying their (skeletal) Pelvic Floor Muscles at the same time. This is the so-called „quick-flick“ technique whereby the PFMs are rapidly pulsed 3-5 times at the time when urgency is perceived. Quick rhythmic flicks of the PFM can preempt the involuntary bladder muscles before they contract; or diminish or abort it after urination has begun.

Effect of QRS-PelviCenter on suppression of involuntary detrusor activity

[QRS®-PelviCenter therapy leads to a suppression of involuntary detrusor activity while increasing bladder capacity and compliance.](#)

This is realised by various effects on neurological pathways including pelvic floor afferents, autonomic efferents and somatic motor fibers.

- Activation of [hypogastric nerve](#) (activation of inhibitory hypogastric sympathetic neurons)
- Stimulates [sympathetic fibers](#), particularly those that maintain smooth muscle tone within the internal sphincter.
- Stimulates of the [pudendal nerve](#) afferent branches which consequently create an inhibitory spinal reflex through vesico-inhibitory pathways at the S3 nerve root.
- Strengthening of the external sphincter which leads indirectly to detrusor relaxation.
 - Pelvic floor muscle contraction is known to cause relaxation of the detrusor, most likely through reflex inhibition of parasympathetic neurons. Also, as the dorsal clitoral nerve lies in close proximity to the stimulating coil there will be stimulation of afferent sensory fibers which can also cause bladder relaxation.
- Repetitive maximal contraction of the levator muscle complex facilitates the transformation of „fast-twitch“ to „slow-twitch“ muscle fibers. This reconditioning of the skeletal muscle has a positive indirect effect on Bladder Overactivity.

Additional notes on Overactive Bladder and Urge Urinary Incontinence:

Bladder Function and Pelvic Floor Activity are integrated.

Bladder Function and Pelvic Floor activity influence each other in a facilitatory or inhibitory way.

- Stimulation of the hypogastric plexus (originated in the spinal segment) result in:
 - Relaxation of the detrusor muscle
 - Contraction of the internal sphincter, inhibiting urination
- Stimulation of the parasympathetic nerves (originating in S2-S4) has the opposite effect:
 - Contraction of the detrusor muscle
 - Relaxation of the internal sphincter

See literature references in the appendix to this document

Effects of QRS-PelviCenter Magnetic Stimulation on OAB & Urge Urinary Incontinence (based on clinical trials):

- Frequency:
 - Reduction in number of urinary incontinence episodes (voids) as recorded in bladder diary
- Urgency: Reduction in the number of urgency episodes per 24 hours
- Increase in bladder volume:
 - Increase in the mean and maximum voided volume per micturition (mL)
 - Increase in the maximum cystometric capacity (measured by urodynamic study)
- Reduction in nocturia
- Increase in the Quality of Life (for example measured via the V-8 OAB questionnaire; or the IPSS QOL Index)
- Severity: Reduction total score ICIQ-UI-SF



XIII. Low Back Pain and Spinal Segmental Stability

Introduction

QRS-PelviCenter is very effective in treating Non Specific Low Back Pain. Especially in the important subgroup where lower back pain is caused by segmental instability.

QRS-PelviCenter is in these cases more effective than self-training or physiotherapy training (so called “Core Stability Exercises”).

This is because responsible for segmental stability is not the global muscles (the superficial muscles that you can feel with your hands) but instead the local small deep muscles (e.g. MultiFidus and Transversus Abdominus).

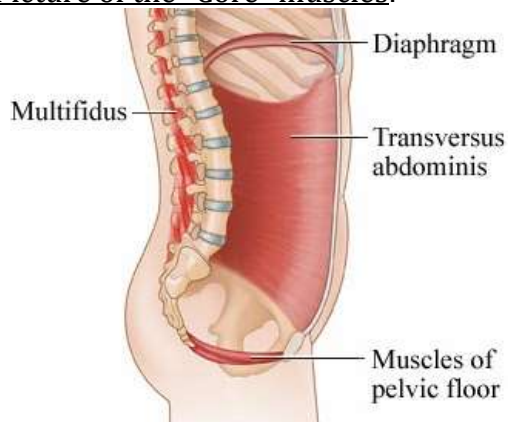
The function of these small and deep muscles can only be trained effectively with magnetic stimulation.

Lower Back Pain and Functional (Segmental) Stability:

Stabilizing system consists of 3 subsystems:

- **Structural Stability** = Passive
 - [Vertebrae; Facet Joints; Intervertebral Discs; Spinal ligaments; Joint capsules; Passive muscle support]
 - Important: Contrary to common belief there is no relationship between lower back pain and damages in structural stability. Without muscles (= Functional Stability, see below) the spinal cord is unstable.
- **Functional Stability** = Active muscles.
 - most important muscles for **Functional (Segmental) Stability** are small local deep slow-twitch muscles, the “Core Muscles”:
 - Transversus Abdominus
 - MultiFidus
 - Pelvic Floor
 - Diaphragm
 - Lack of movement results in atrophy of these local muscles and thereby loss of function (these muscles are not so strong and not focused on strength). One important function that these muscles are losing is the “**feed-forward**” function (function whereby Transversus Abdominus normally reacts before a movement and before the movement of other muscles (e.g. Deltoideus).
 - Important: **Lumbar Segmental (Functional) Instability is considered to represent a significant sub-group within the chronic low back pain population (L4-L5-S1).** “Instability” = Lack of control of movement. Muscle control = Pain control (White & Panjabi 1990)
- **Control** (Central & Peripheral nervous system)

Picture of the “Core” muscles:



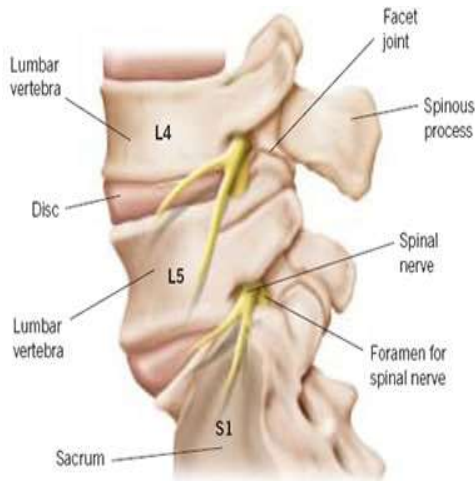
Lower back pain and Pelvic Floor Muscle Exercises:

- Various studies have proven a strong association between lower back pain and pelvic floor muscle dysfunction. The association is stronger than the association between lower back pain and high BMI or inactivity. People suffering from pelvic floor disorders have a higher risk of lower back pain than people with inactivity or with high BMI. The 2 strongest co-morbidities for lower back pain are Pelvic Floor dysfunction and respiratory dysfunction.
- Only limited studies have been carried out on the effectiveness of pelvic floor muscle training on lower back pain. More research is needed. However, it is clear that all “Core” muscles are related and have to work together.
 - The Pelvic Floor is co-active connected to Transversus Abdominis and Multifidus. Training of the Transversus Abdominis indirectly trains the pelvic floor. And training of the pelvic floor has a positive effect on segmental stability (Sapsford et al 2001).
 - Also, stimulation of thigh muscles has a positive effect also on other core muscles including “Multifidus” and abdominal muscles.

Lower back pain and “core stability” exercises:

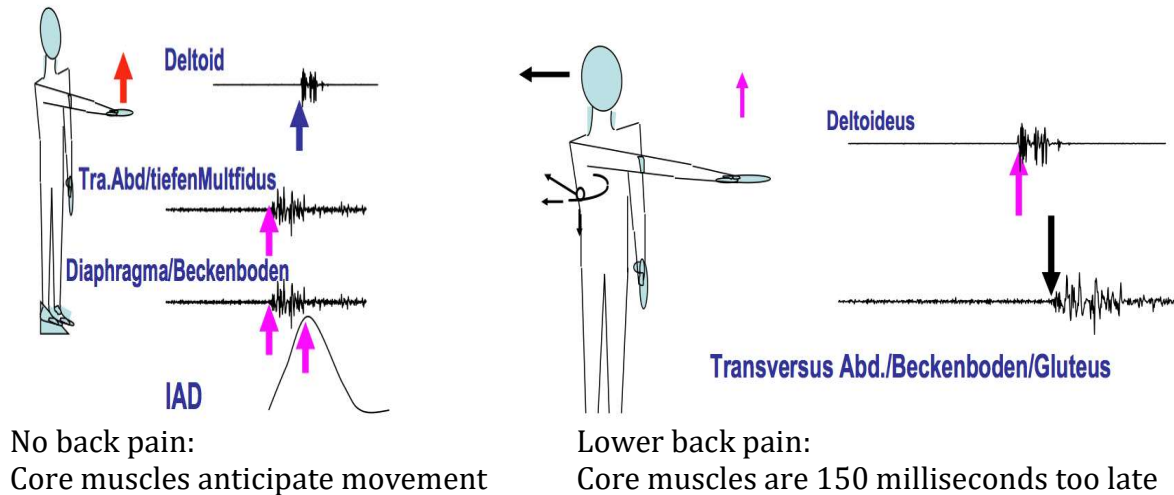
- In Europe/ USA, patients with lower back pain are routinely referred to physiotherapy
- Most common treatment in Europe/ USA of physiotherapists against Lower Back Pain is ‘muscle activation’ / ‘core stability’ exercises.
- Many studies have been carried out on “core stability” exercises. Studies do show that “core stability” exercises have a positive effect but inconclusive evidence as to whether “core stability” exercises are more effective than normal physical exercise.
- The key reason why “Core Stability exercises” are not always effective and often not more effective than normal physical exercises is because it is very difficult to self-train the relevant muscles and only a skilled physiotherapist is able to do effective treatment. This is because:
 - Responsible for spinal stability is not the global (superficial) muscles but the deep small local muscles, in particular the “Multifidus” and the “Transversus Abdominis”.

Additional key notes on Spinal Segmental Stability:



- Spinal Segmental Instability is defined as an abnormal response to applied loads, characterized by movement of spinal segments beyond the normal constraints.
- Instability of the lumbar spine often occurs in L4-L5 or L5-S1
- Distinction between “global muscles” and “local muscles”:
 - Global muscles are the long superficial strong muscles that you can feel between the shoulders and the pelvic floor. These muscles are not connected to the spinal cord. They are not responsible for segmental stability but instead focus on movement and balance (e.g. Obliquis externis; Rectus Abdominis; Erector Spinae)
 - Local muscles are the small deep slow-twitch muscles connected on the segments. They center around the joints and protect the joints from stress. These “Core” muscles focus on segmental stability (Transversus Abdominis; Multifidus; Obliquis internis; Rotators). You can not train these local muscles in a fitness studio. These muscles are not focused on strength. Training of these muscles must focus on improving function/ control
- The Transversus Abdominis and the Lumbar Multifidus are the Primary Stabilizers
 - An important function of these small muscles is to anticipate the movement of other muscles. This is called the “feed-forward” mechanism. Normally these muscles are moving before any other body muscles are moving to ensure spinal stability.
 - In patients suffering from Lower Back Pain the muscle function has changed. This change is due to various reasons including atrophy, lower number of capillaries, increased connective tissue and fat, and change in spindle function.
 - The QRS-PelviCenter uses magnetic stimulation which penetrates deep into the human body and is able to train these deep small muscles that a patient can not train him/herself. The focus is on restoring the function of the Multifidus and Transversus Abdominus and all the other core muscles. In particular the focus is on restoring the “feed-forward” mechanism.

Picture “Feed-Forward” mechanism (Urguhart 2005)



Literature References:

- See appendix

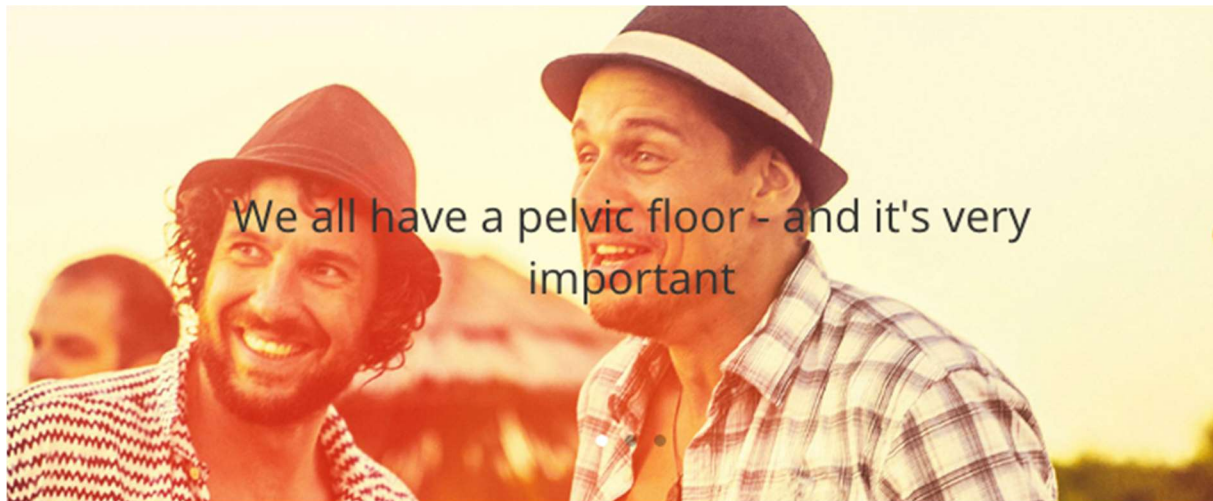
Let's Talk About It: Back & Pelvic Pain



Pain in your lower back, pelvic floor and/or groin can be excruciating and debilitating. Many people simply learn to 'put up with it', avoiding activities that trigger spasms or pain such as exercise and lifting, and even sex. Some turn to prescription medication to mask the pain. But many people can significantly improve their situation by having a strong and fully functioning core and pelvic floor. At the Coregood Institute we specialise in treating the issues that weaken a person's pelvic floor. We do this using a range of treatment solutions including the latest leading edge technology from Germany, the PelviCenter. It's non-invasive and easy – and you do it fully clothed. So call us today to talk about living a less painful, more active life.

Enjoy a better life with a strong and fully functioning core.

IX. QRS®-PelviCenter and Erectile Dysfunction



Please refer to separate document “Treatment Protocol QRS®-PelviCenter and Erectile Dysfunction & Premature Ejaculation” for detailed list of all clinical trials demonstrating the effectiveness of Pelvic Floor Muscle training on improving sexual function of men and women.

The following are some of the key authors who have done detailed studies into demonstrating the effectiveness of Pelvic Floor Muscle Training on reducing Erectile Dysfunction (see appendix for detailed listing of clinical trials):

- Dorey G et al (UK)
- Van Kampen et al (Belgium)
- F. Sommer et al (Germany)

The key conclusions of these studies are as follows:

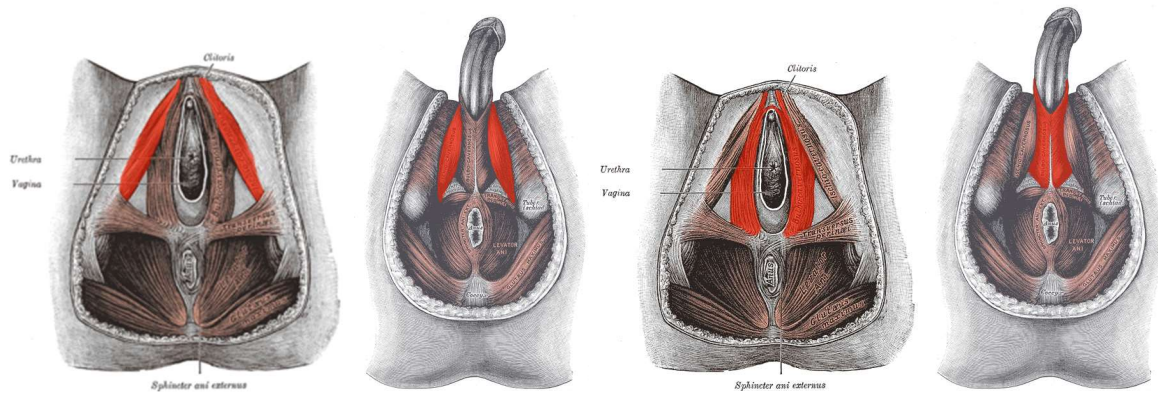
- There are many potential causes of ED, the most common denominator is blood flow. The importance of blood flow for sexual function consists of two parts:
 - Blood must flow into the penis
 - Blood must stay in the penis and must not flow out too quickly
- Various studies in Europe show that between 35% and 60% of patients suffering from ED are suffering from so-called “Venous Occlusive Dysfunction”. This means that their skeletal muscles (ischioavernosus and bulbospongiosus muscle) are too weak to keep the blood trapped in the penis. The result in increased refractory time, less rigid erections, premature loss of erections, the inability to achieve an erection and reduction in ejaculatory force.
- Pelvic Floor Muscle Training and QRS®-PelviCenter is especially effective in this group of patients (“venous-occlusive dysfunction”). Please note that QRS®-PelviCenter is not “the wonder solution against all ED”. Often a man who suffers from ED has various causes underlying his ED. QRS®-PelviCenter helps with one important cause which is called “venous occlusive dysfunction”.

Please refer to separate document for more details.

Relevant Pelvic Floor muscles for improvement of sexual function of men and women:

■ The most important Pelvic Floor Muscles relevant for sexual function are:

- **Ischiocavernosus muscle** (picture 1 and 2 below)
- **Bulbospongiosus muscle** (picture 3 and 4 below)
- **PC muscle** (deeper in the Pelvic Floor)



X. QRS®-PelviCenter and Premature Ejaculation

Reduction of force of ejaculation when men get older

- Changes in ejaculatory function are commonly experienced with aging. Ejaculation and orgasm often become less intense, with diminished ejaculatory force and seminal fluid volume
- The bulbospongiosus muscle is responsible for propelling semen after emission. A weakened bulbospongiosus muscle may result in semen dribbling with diminished force or trajectory. A strong bulbospongiosus muscle can generate powerful contractions that can forcibly ejaculate semen at the time of climax.
- The stronger the bulbospongiosus muscle, the better the capacity for maximal engorgement of the corpus spongiosum, urethral pressurization, and ejaculation. The intensified ejaculation resulting from a robust bulbospongiosus muscle may enhance the orgasm that accompanies the physical act of ejaculation.
- Pelvic floor muscle training may optimize ejaculatory volume, force, and intensity of sexual climax.



About Premature Ejaculation

- Premature Ejaculation is the most common male sexual disorder and is a very prevalent condition among urology patients.
- Weak pelvic floor muscles make it difficult to delay a ejaculation
- If the patient is able to voluntarily contract the Pelvic Floor Muscles this will help control ejaculation
- See literature overview (appendix to this document). Studies show the effectiveness of Pelvic Floor Muscle training in delaying ejaculation and thus in treating PE.
- However, more research is required:
 - How exactly is the precise mechanism controlling the ejaculatory reflex?
 - Is control of Premature Ejaculation the result of stronger contracting of the Ischiocavernosus & bulbospongiosus muscle or is it due to relaxation of these muscles?

XI. Improvement Sexual Function (women)

Please refer to appendix for Clinical Trial report (double blind placebo controlled RCT with 1 year follow-up) proving that QRS®-PelviCenter has a positive impact on the sexual function and satisfaction of women.



XII. Other indications where QRS-PelviCenter is helpful as complementary treatment

QRS®-PelviCenter and Pelvic Pain

QRS-PelviCenter is effective in treating parts of CP/CPPS.

How is QRS®-PelviCenter being able to treat part of CP/CPPS

- Pelvic pain is an indication which has many different causes, some of these causes are still unknown.
- Despite its uncertain etiology there is some evidence that the symptom complex found in CPPS may be founded at least in part in pelvic floor muscular dysfunction and/or neurogenic hypersensitivity/inflammation. Some research has shown that the application of a rapidly changing electromagnetic field applied noninvasively to the perineum of the subject may result in neural excitation and pelvic floor muscle stimulation to a degree that breaks the cycle of tonic muscular spasm and neural hypersensitivity/inflammation, thereby, restoring more normal pelvic floor muscular activity.
- Results in treating patients suffering from CP/ CPPS with QRS®-PelviCenter/ Pelvic Floor Muscle training are mixed. QRS®-PelviCenter can be effective as a complementary treatment for certain parts of Pelvic Pain.
- The optimal management of category III CP/CPPS is unknown, treatment strategies include alpha-blockers, anti-inflammatory agents, hormonal manipulation, phytotherapy, physiotherapy, and chronic pain therapy. Pelvic Floor Muscle Training and QRS®-PelviCenter can be a useful component of this multimodal approach. And Pelvic Floor muscle training/ QRS®-PelviCenter has been proven to be effective in treating part of the Pelvic Pain cases, but is not effective in all cases.

Pelvic floor muscle training for Pelvic Floor tension Myalgia

- About Pelvic Floor Tension Myalgia:
 - Tension myalgia of the levator ani can be a factor in chronic prostatitis or chronic pelvic pain syndrome (CP/ CPPS). When the levator exists in a hypercontractile and hypertonic state, it can cause pelvic, urogenital, and rectal pain: tightness and spasticity; and adverse effects on sexual, urinary, and bowel function. This neuromuscular dysregulation of the pelvic floor and/ or perineum can be triggered by stress and other circumstances.
- How do PFMT and QRS®-PelviCenter help in treating Pelvic Floor Tension Myalgia:
 - In the management of tension myalgia, it is fundamental to foster relaxation of the spastic levator muscle. PFMT serves not only to increase the strength of the levator and other PFMs but also to instill awareness of and to develop proficiency in relaxing the involved muscles as one cycles through contraction and relaxation phases. The relaxing aspect is an equally important component of the PFMT program as is the contracting phase and is the key to managing levator spasticity.

QRS-PelviCenter and Interstitial Cystitis (Painful Bladder Syndrome)

What is IC?

- A chronic condition in which you experience bladder pressure, bladder pain and sometimes pelvic pain
- With IC the nerve communication between the bladder and the spinal cord via the pelvic nerves gets mixed up, resulting in the patient feeling the need to urinate more often and with smaller volumes of urine than most people.

How effective is Pelvic Floor Muscle Training in treating the symptoms of IC?

- 75%-80% of IC is related to Pelvic Floor Disorders (Dr. Robert Moldwin USA)
- American Urological Association (2010) gave guidelines for treating IC.
 - 1st line of defense includes diet changes and reducing of stress
 - 2nd line of defense includes physiotherapy, medications (Amitryptiline/Elmiron) and Bladder installation medications)

QRS-PelviCenter and endometriosis

See separate document



QRS-PelviCenter and Feecal Incontinence

Standard treatment program QRS-PelviCenter and Feecal Incontinence:

- QRS-PelviCenter is effective as a complementary treatment in treating Feecal Incontinence.
- Measurement before:
 - Test the strenght and endurance via direct digital muscle assessment or via Peritron device (Manometry) (more accurate). If the strength is lacking then the patient is a very good candidate for QRS-PelviCenter treatment.
- Position the coil:
 - Focus on the Anal Sphincter.
 - Normally about 0-2 cm for women. And 3 cm for men. But this depends on patient size and dimensión. So it is best to rely on patient verbal feedback to gain a direct anal contraction. The fluteals will fire very firmly also
- Intensity:
 - The key focus is building strength.
 - Ideal program is to use 35 Herz (not 50Herz). 35 Herz realizes a smooth peak contraction but a little less fatigue.
- Nr of sessions:
 - Recommendation is to do 16 treatments of progressive intensity and strengthening.
 - Whilst avoiding that the patient gets delayed muscle soreness, the sooner the patient is able to reach the maximum stimulus/ workout, the better the result.
 - Base recommendation for any form of incontinence is 16 sessions, 2-3 weekly. It is important to have 1-2 days between sessions to allow for recovery, repair, and muscle adaptation.
- Complementary:
- Some notes about Stool:
 - The EAS (External Anal Sphincter) is designed to hold back solid and not so well suited to hold back loose stool. Thus it is best to ask the patient about stool type and bowel habit.
- QRS-PelviCenter complementary to dietary advise:
 - Dietary advise to reduce inflammation/ irritation
 - Probiotics to balance the microbiota and decrease dysbiosis is very important
 - Education on correct toileting posture
- Some attention points:
 - Be careful when treating patients with anal fissure or haemorrhoids. MEbo repair ointment is natural and is particularly effective at reducing irritation and promoting healing. The patient can apply it directly on the EAS.

QRS®-PelviCenter and reduction of Cellulite

QRS®-PelviCenter, when used as a complementary treatment, can have a positive effect on tightening the buttocks/ glutes and reducing cellulite.



Before and After:



Standards treatment program QRS-PelviCenter and Cellulite:

- Normally a customer takes a course of 16 treatments. The standard rule when using QRS-PelviCenter (for example for Urinary Incontinence) is that the customer can do maximum 1 treatment of 20 minutes per day (QRS-PelviCenter treatment is much more intensive for the muscles then people think and doing 2 treatments on a day will lead to delayed muscle soreness). However this rule does not apply when treating Cellulite skin (assuming that each session focuses on a different part of the body/ different part of the cellulite skin).
- In a typical treatment plan the customer is normally provided 2 treatments of 20 minutes in 1 hour. However the position of the magnetic coil is different in each of the 2 sessions, so for example:
 - 20 minutes focus the magnetic coil on the left part of the buttocks (or thighs)
 - 5 minutes rest
 - 20 minutes focus the magnetic coil on the right part of the buttocks

XIII. Differences between QRS®-PelviCenter and Electric Stimulation

There are a few important differences between Magnetic Stimulation and Electric Stimulation:

- Electrical stimulation directly stimulates the nerves. Magnetic stimulation generates an ion flow and eddy currents to which nerve tissue is particularly sensitive.
- Spatial distribution of the Magnetic field is larger and has the space of a hollow “dough-nut” in contrast to the limited “bull’s eye” field that is created by electrical stimulation.
- Most importantly, a magnetic field is unaffected by tissue impedance and can thereby reach deeper into the Pelvic Floor. Electrical stimulation requires relatively high voltages at the skin to compensate for decay as the current traverses soft tissue and bone.
- Electrical stimulation is more painful and some clinical tests show that with electrical stimulation the episodes of incontinence can increase rather than decrease.

QRS®-PelviCenter therapy is non-invasive and does not require any probes, skin preparation, or physical or electrical contact with the skin surface.



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Fitnesshaus Liechtenstein

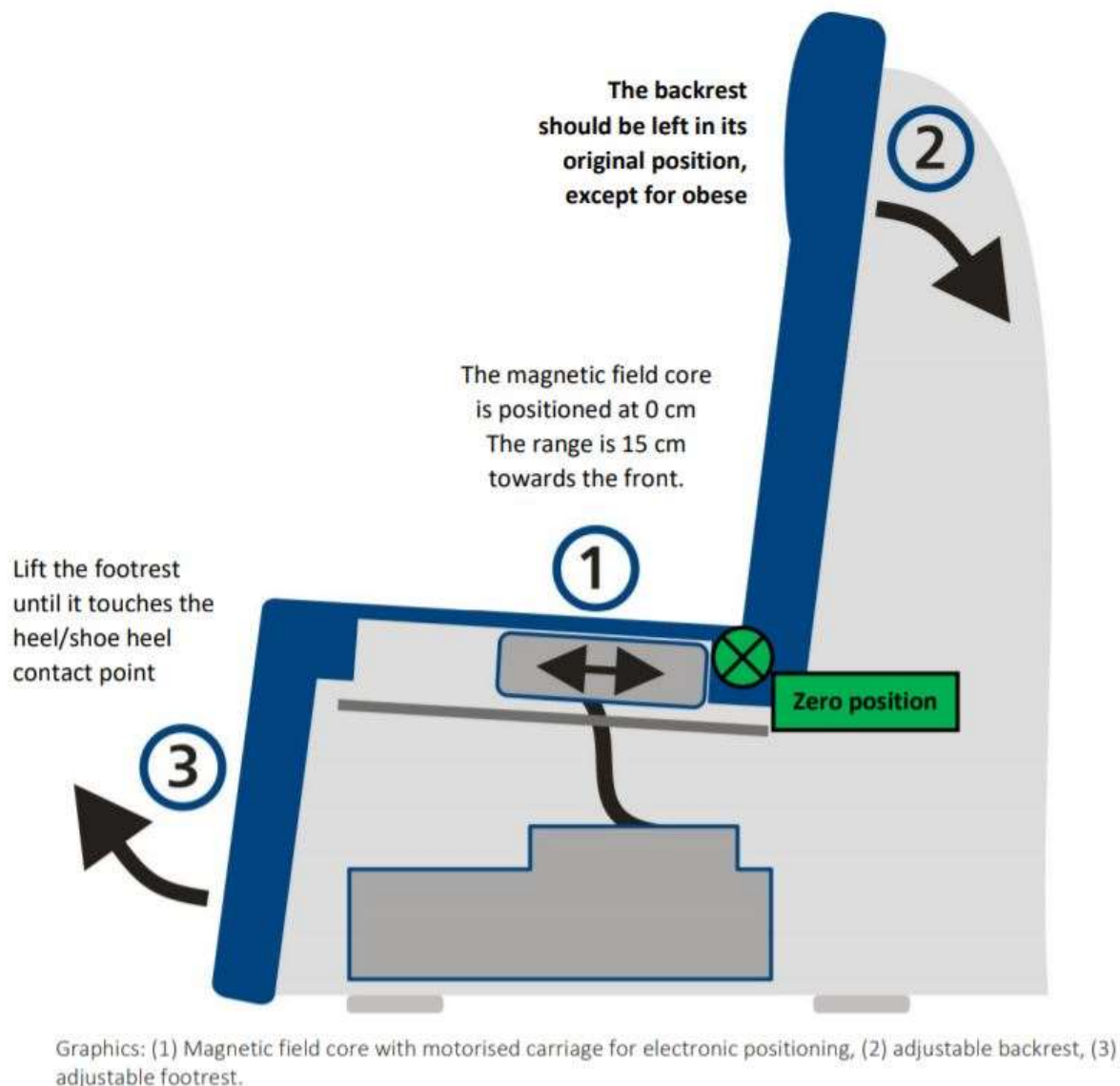
HOW TO OPERATE THE QRS-PELVICENTER

XIV. Getting Started



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

Image PelviCenter from the side



Key notes:

- The Magnetic Coil (1) can be moved from the back (positioned directly under the spinal cord) towards 15 cm to the front. The exact position is dependent on the Indication that you wish to treat (e.g. Lower Back Pain, Urinary Incontinence, Fecal Incontinence, Sexual Function, training of the Thigh Muscles) and on the type of person.
- The backrest can be put to the back (into reclining position) but for most indications this is not used. Most indications such as Urinary Incontinence require that you sit upright, and preferably a little bit inclined towards the front (angle between your upper legs and your upper body less than 90 degrees). For treating Lower Back Pain sometimes we let the back rest recline so that the QRS stimulation directly “hits” into the relevant muscles of the lower back (in particular the “Multifidus”)

Contra-indications PelviCenter

General key notes on contra-indications:

- Please note that the QRS-PelviCenter is a Medical Device. And thus requires the involvement of Medical Doctors.
- **Each new Patient will first require a diagnosis and referral by a Doctor, preferably a Uro-gynecologist, a urologist or a gynecologist.**
- The diagnosis must define what type of Urinary Incontinence (e.g. Stress, Urge, Mixed) or what other indication (e.g. lower back pain, sexual function) the customer is suffering from.
- Then only the Medical doctor is allowed and able to define the exact treatment protocol. In no situation is it allowed for the customer to make a self diagnosis or to try and treat themselves the condition that they think they are suffering from.
- After defining the treatment protocol, the actual treatment can be administered by the Nurses or Operators who have followed QRS Training and who have been certified as "QRS Authorized Representatives"
- **Of key importance, both for the Medical Doctor (who diagnose the patient and who define the treatment protocol) as well as for the QRS nurses/operators (those who administer the treatment) is that they both check on Contra-indications before starting the QRS-PelviCenter treatment.** Below is a list of Absolute and Relative Contra-indications.
- Also it is recommended that every person who is admitted to the PelviCenter treatment signs a "**Consent Form**" in which they declare that they understand about the PelviCenter treatment including about the Contra-indications and the possible undesirable side-effects.
- Also, it is the responsibility of doctor and of patient to observe the patient during each individual treatment and during the treatment program. QRS can provide the doctor with an App whereby all treatments can be registered including any remarks/ feedback from the customer.

Absolute Contra-indications:

- **Pregnancy: Do NOT use the QRS-PelviCenter when you are pregnant !!**
- Metallic or electronic implant which is located close to the Pelvic Floor (e.g. thighs/ upper legs/ lower back)
 - Risk of 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. Most metal implants are made of titanium which does not have the risk of heating up, however, see next point.
 - **Risk of the connective material (metal implants) heating up !!:**
 - Please note that the issue is not only that some materials can become hot during rPMS treatment, another key issue is that the connections between the implants and the bones can be damaged severely. So for example titanium implants have the advantage that they do not become hot, however still there is a serious risk that the connective material between the titanium implant and the bone becomes heated.

- Risk of magnetic field interference with electronic implants:
 - 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. Note however that newer devices have a high degree of interference field shielding and thus are not affected.

Relative Contra-indications:

- Prior Surgeries/ wound healing phase
 - We recommend that rPMS (repetitive Peripheral Muscle Stimulation) can be used from 4 weeks after surgery and successful wound healing and from 10 days after catheter removal following a prostatectomy.
 - Please also note that QRS-101 Therapy System can be used immediately after surgery to ensure more faster and more precise wound healing.
- Severe cardiac arrhythmia and epilepsy:
 - QRS-PelviCenter is 100% safe and has no direct influence on either cardiovascular health or unpredictable epileptic seizures. However, from an insurance point of view, depending on the situation (e.g. country), we recommend not to do treatment on a customer suffering from severe arrhythmia or epilepsy. Also we recommend that every new customer signs a form at the beginning of the treatment program whereby they sign off for having understood the contra-indications of the PelviCenter and the possible undesirable side-effects.
- Intrauterine devices:
 - Contractions of the pelvic floor can alter the position of an intrauterine device
 - 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.

Possible undesirable side-effects of QRS-PelviCenter:

- Pain and soreness affecting the muscles of the glutes and hip bone:
 - QRS-PelviCenter has been proven by professional studies to be well tolerated and free of side effects. However sometimes persons report some minor undesirable side-effects. It is stressed that these side effects occur mainly when the doctor or patient is “overdo-ing” the treatment by starting with too high intensities and especially by doing too long treatments and too often. The side effects are similar to side effects experienced with normal muscle training. If you start the muscle training with too high intensities or if you do too many exercises per day/week then you will suffer from muscle soreness resulting in muscles becoming tired and painful.
- A burning sensation when passing urine, or a yellowish vaginal discharge in the absence of any signs of infection.

SAFETY NOTICE

As stated earlier in this document, it is the responsibility of both the Doctor (who makes the diagnosis of the patient and who determines the treatment plan) as well as of the QRS Certified Nurse/ Operator (who administers the treatments in accordance with the treatment plan as defined by the doctor) to check the Contra-indications. For that reason it is recommended to print out the Safety Notice (below) and keep this print out next to the PelviCenter so that both the Operator/Nurse and the customer/patient can read the Safety Notice while sitting on 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.

XV. Key parameters QRS®-PelviCenter

Key parameters of the QRS®-PelviCenter are as follows:

1. Intensity of magnetic field (amplitudes)
2. Frequency (5 Herz / 10 Herz / 50 Herz)
3. Duration of magnetic pulses versus “off” time (8 seconds ‘on’ and 4 seconds ‘off’)
4. Duration of the treatment (20 minutes/ 15 minutes?)
5. Position of magnetic coil & sitting position
6. Number of treatments per week/ number of treatments in total program



Image Control Unit PelviCenter below:



Please note:

- QRS-PelviCenter can only be operated by a Chipcard (which acts like the “key”)
- Normally Customer will be supplied with various “unlimited cards” which can be pre-programmed (e.g. unlimited card of 20 minutes or unlimited card of 4 minutes for demonstration purposes).
- Light therapy and Oxygen therapy is Optional.



Sub 1: QRS®-PelviCenter and intensities (amplitudes)

The magnetic coil of the PelviCenter has intensities of up to 0.4 Tesla.

Please note that this is the intensity at the coil.

The potential of the magnetic field decreases sharply with the distance from the coil (factor 3).

If the 'buttocks' (the 'glutes' / 'gluteus maximus') of the patient is about 10-15 mm away from the magnetic coil then only about half a Tesla (500 millitesla) remains for these superficial muscles.

Other superficial muscles which are directly stimulated include the ischiocavernosus and bulbospongiosus muscles.

With further distance (i.e. sphincter muscles) the intensity decreases even further.

The QRS®-PelviCenter has 5 different intensities:

- 20%
- 40%
- 60%
- 80%
- 100%

Special “ramp-up” functionality of QRS®-PelviCenter:

The QRS-PelviCenter has a special software whereby the intensity of the magnetic pulse is started gradually.

When the patient starts with 20%, the QRS®-Pelvicenter impuls builds up slowly towards the 20% (2 or 3 seconds).

This instead of a sudden shock (in a fraction of a milli-second from 0 to 20%).

The advantage is not only that the QRS®-PelviCenter treatment is more comfortable for customers.

But more importantly, the effectiveness of the treatment is increased, because it allows some time for the nerves and muscles to build up the contraction.

Sub 2: QRS®-PelviCenter and frequencies

QRS® frequency therapy

The QRS®-PelviCenter has standard predefined therapy programs.

For example a program for Stress, for Urge and for Mixed Urinary Incontinence.

These programs deliver a train of magnetic pulses of a certain intensity (amplitude), frequency, duration, as well as with an “off” time (recuperation) duration.

Each program uses a different range of proven frequencies.

In addition, the doctor or operator is able to change the frequencies manually.

Some general guidelines and attention points are as follows:

“Fusion frequency”

The QRS®-PelviCenter provokes muscle contractions.

A single pulse generates a single contraction, or brief muscle twitching.

Repetitive sending of pulses causes repetitive muscle twitching.

Of key importance is the frequency used.

When using lower frequencies (i.e. 5Hz to 10Hz), the muscles are still able to follow this frequency resulting in repetitive muscle twitching.

Once a specific frequency, the so-called “fusion frequency” has been reached, the individual contractions can no longer be distinguished from one another and the muscle enters into a “tetanised” state. Depending on the muscle type, this state occurs between 15 and 25Hz.

Urge Incontinence/ Overactive Bladder, most effective between 5Hz and 10Hz

- The sacral afferent nerves, particularly the autonomic nerves of the pelvic organs are poorly myelinated (A delta) or unmyelinated fibers, which conduct current at a slow rate of 5 to 20 Hz
- Low frequencies (1-5Hz) generate twitch contractions, allowing little sustained tension to develop in the muscle

Stress Incontinence 20 Hz to 50Hz

- Slow-twitch muscle fibers have a natural firing rate of 10 to 20Hz. Fast-twitch fibers fire at 30 to 60Hz. Fast twitch fibers are highly effective in quickly responding to a sudden increase in intra-abdominal pressure. Slow-twitch fibers ensure improving of the resting urethral closure pressure.
- In a healthy muscle, at frequencies of approximately 30Hz, muscle contractions usually become fused or tetanized, so that a smooth contraction is apparent.

General note on what frequency to use with QRS-PelviCenter:

In general, when the focus is to improve the strength of muscles, the QRS-PelviCenter treatment must be carried out at high frequencies (between 35 Herz and 50 Herz). However, in most cases it is recommended to use only 35 Herz since 50 Herz has a higher risk of delayed muscle soreness.

Mixed incontinence, combined program:

- 10 minutes low frequency (5Hz to 10Hz) + 10 minutes high frequency (20 to 50 Hz)

Fatigue:

- Fast twitch (type II) fibers fatigue more rapidly than slow twitch (type I) fibers. Therefore the QRS®-PelviCenter allows for sufficient relaxing time in between the series of pulses.
- Frequencies of greater than 40Hz may cause undue fatigue. At lower frequencies, less fatigue occurs
- Chronic stimulation may increase the relative number of slow-twitch fibers, by helping to transform fast-twitch fibers to slow units, which can sustain the contraction longer.

Sub 3: About the “off”-time:

- The “off” time is defined as the period of rest between the various series of individual pulses. The ratio of stimulation time to rest time is called the duty cycle. QRS®-PelviCenter allows the setting of the required duty cycle. A typical duty cycle is approximately 1:2. The patient’s diagnosis and degree of muscle weakness must be considered when identifying a suitable duty cycle for initiation of the electrical stimulation program. In case of weakness or neurologic impairment, a ratio of 1: 3 may be appropriate. As muscle strength or endurance improves, the ratio of “on-to-off” time may be decreased.
- QRS®-PelviCenter allows the doctor to easily adjust the duration of pulses and the duration of rest. Standard treatment programs of QRS®-PelviCenter (20 minutes) works with a duty cycle of 2:1 (8 seconds stimulation time followed by 4 seconds of rest time).

XVI. A typical treatment program with the QRS®-PelviCenter:

Please note the following:

- Every individual patient is different. There is not a standard program which works the same for all patients. The QRS-PelviCenter is a medical system and the doctor needs together with the patient needs to defined the optimal treatment program (including number of treatments, position magnetic field, sitting position, intensity, frequency of the magnetic field).
- Despite this, QRS® has developed various standard treatment protocols for each relevant indication (e.g. Stress UI, Urge UI, ED, Lower Back Pain, Cellulite). Please refer to separate documents.
- Below is an overview of a „typical“ treatment program for a patient. Based on a standard program of 16 treatments (of 20 minutes each).
- Please refer to the next paragraph for detailed explanation of the key attention points during a treatment program with the QRS-PelviCenter.

Treatment	Intensity	Frequency Stress UI	Frequency Urge UI	Frequency ED
1	20%	35-50 Hz	10Hz or 5Hz	30-50Hz
2	20%	35-50 Hz	10Hz or 5Hz	30-50Hz
3	40%	35-50 Hz	10Hz or 5Hz	30-50Hz
4	40%	35-50 Hz	10Hz or 5Hz	30-50Hz
5	60%	35-50 Hz	10Hz or 5Hz	30-50Hz
6	60%	35-50 Hz	10Hz or 5Hz	30-50Hz
7	80%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
8	80%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
9	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
10	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
11	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
12	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
13	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
14	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
15	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz
16	100%	Max 35 Hz	10Hz or 5Hz	Max 35 Hz

Some key points in relation to use of intensities & frequencies: See next page.

When using intensities 80% or 100%, then do not use frequency higher than 35 Herz.
Do not change the 8 seconds „ON“ and 4 seconds „OFF“ durations.

Some key points in relation to use of intensities & frequencies:

- Intensity:
 - Not too ambitious with intensity on 1st or 2nd treatment. To avoid muscle pain. Focus 1st and 2nd treatment on improving FUNCTION of muscles. After 2nd treatment be more ambitious (focus now on STRENGTH) and try to push the patient as quickly as possible to 100%. Patient must at least do 6 treatments at 100% at the end to ensure LONG term results.
- Stress Urinary Incontinence: High Frequencies = 35 to 50 herz (building muscles)
 - When the focus of the treatment program is to build strength, then one must use higher frequencies (between 35hz and 50hz). From a theory point of view 50 herz may be better, however, from a practical point of view, often 35herz is more comfortable than 50 Herz. The risk with 50 Herz ist hat the muscles become too tired too quickly. With 35 Herz it is possible to reach smooth peak contraction without fatigue for the muscles.
 - Important: When using intensities 80% or 100%, then do not use frequency higher than 35 Herz. System requires too much energy with risk of malfunction. Also the energy can be too much for the patient.
- Urge Urinary Incontinence: Low Frequencies = 10 herz or 5 Herz (= relaxation) ;
- Mixed Urinary Incontinence (Urge & Stress):
 - 10 minutes low frequencies; 10 minutes high frequencies
- Cellulite:
 - Use high frequencies (35 to 50 Herz)
 - Customer can do 2 treatments of 20 minutes behind one another. First treatment focusing the stimulation on the left buttocks; then 5 minutes rest and second treatment of 20 minutes focusing on right buttocks.
- Lower Back Pain:
 - Use Low frequencies when focusing on the Multifidus muscle. Multifidus is a small muscle and does NOT respond to strength training (strength training = high frequencies). Focus of QRS®-PelviCenter treatment for lower back pain is to improve the FUNCTION of the multifidus and other muscles.
 - Also focus part of the LBP treatment on the pelvic floor & thigh muscles. Now use Higher frequencies. Strengthening of pelvic floor & thigh muscles has indirect positive effect on Lower Back Pain.
- Do NOT change the standard 8 seconds „ON“ and 4 seconds „OFF“ duration.
- Note that the QRS-PelviCenter is NOT a wonder „system“ which can cure all diseases. QRS-PelviCenter is complementary treatment. And during one treatment the „system“ can only focus on 1 disease at a time. Patient must not expect that during one treatment he/ she will realize benefits both on incontinence, back pain, cellulite, sexual function etcetera. Each indication has its own treatment program (managed by the software, the parameters and sitting position). Customer must choose for which indication he/ she wishes to follow treatment.

XVII. Additional notes which are important in realizing high effectiveness of QRS-PelviCenter training



- 1) Medical Check by a qualified doctor
 - a. QRS-PelviCenter is a medical system.
 - b. Normally each new patient first has a consult with a doctor (or after a referral by another doctor). For the following reasons:
 - i. To check the contra-indications
 - ii. To determine the indication and severity of the indication (for example Stress UI, Urge UI, Mixed UI, severe, moderate)
 - iii. To check the causes of the disease (for example Erectile Dysfunction bet he cause of an underlying disease such as cardiovascular disease or diabetes which will require treatment).
 - iv. To determine the treatment program (number of treatments, intensity, frequency, position of the magnetic coil).
- 2) Check the contra-indications before the start of the treatment
 - a. QRS-PelviCenter is a medical system. And requires for a professional doctor to analyse the patient and to determine the treatment program.
 - b. See the list of contra-indications. The most important contra-indications are:
 - i. Pregnancy
 - ii. Metal implants in the hip-bone area
 - iii. Pacemaker

3) Checks before the treatment

- a. Remove jackets and coats
- b. Patients should void their bladder as much as possible
- c. Ensure incontinence pads used are dry
- d. Remove hearing aids prior to commencing the treatment
- e. Remove purses/ wallets from pockets**
 - i. Please note that there is a risk that PelviCenter will impact the information on the bank cards with a magnetic strip
 - ii. Also, there is a slight risk that coins will start to get hot and that they will interfere with the electromagnetic fields of the PelviCenter
- f. Remove Mobile Phones**
 - i. Mobile phones and PelviCenter both use electromagnetic fields and their fields will interfere with each other.
- g. If customer uses Oxygen therapy during the PelviCenter treatment then provide a new or disinfected oxygen mask to the patient.

4) Time per treatment = 15 to 20 minutes

- a. The standard time per treatment is set at 20 minutes. After the 20 minutes the QRS-PelviCenter has a 5 minute „relax“ program in which it uses its patented and proven QRS-PEMF „relax and blood flow improvement“ technology of the QRS-101 system.
- b. It is strongly advised NOT to do treatment longer than 20 minutes per day. The QRS-PelviCenter treatment is more intensive and more tiring for the muscles than the patient will think. If the patient continues with the training for too long a time, there is a risk that the muscles get tired resulting in a (temporary) deterioration of the condition instead of an improvement.
- c. Building strength of muscles requires a high intensive, short duration training at „maximum load“. Normal sports physiology is based on doing short repetitions (10 to 15) at maximum load and then allow the muscles to rest.
- d. Older patients may want to start the first 3 to 5 minutes with low frequencies so that they can „warm up“ the muscles, followed by 12 or 15 minutes of intensive training at high frequencies and at the end „cooling down“ for 3 minutes to low frequencies. See further information below.
- e. It is recommended to combine the QRS-PelviCenter treatment with other treatments, for example an intensive RELAX treatment on the QRS-101 of 25 minutes directly after the QRS-PelviCenter treatment.

- 5) Number of treatments needed in the full QRS-PelviCenter treatment program
 - a. Every patient is different and the optimal treatment program must be set by the doctor depending on the exact condition. However, in general (standard treatment program), based on evidence from Clinical Trials, it is recommended that a patient completes 16 treatments.
 - b. In general a patient will realize good positive results after 6 treatments. However, in order to ensure long term results the patient is advised to complete 16 sessions. Normally a woman after 6 treatments on the Pelvicenter is on an intensity level of 40% or 60%. This is not enough to ensure sustained strength for a long term period. Normally a woman after 10 treatments is reaching intensity level of 100%. Just 1 or 2 treatments at 100% is not enough to ensure sustained strength for a long term period. It is recommended that the woman completes 16 sessions, the last 5 or 6 of which at 100% intensity level.
 - c. Not in all cases do patients need 16 treatments.
 - i. For example women after pregnancy or men after prostatectomy normally need only about 6 to 8 treatments. Here the focus is on restoring coordination and function of the muscles (rehabilitation).
 - ii. However, in other cases, patients must complete 16 sessions. For example women after menopause who have been suffering for some time with Urinary Incontinence. Focus is on building strength.
 - d. In some cases patients need more than 16 sessions (e.g. 24 or 32).
 - i. In cases of severe urinary incontinence it is possible that patients need some additional treatments to realize further improvements after ending of the 16 sessions.

- 6) First treatment: Start the first treatment at low intensities and low frequencies
 - a. Frequencies:
 - i. Start the first treatment the first 5 minutes with low frequency (5 to 15 herz). This is necessary to warm-up the muscles.
 - b. Intensity of the magnetic field:
 - i. Start on the 1st treatment with low intensities (20% or 40%).
 - ii. Patients must be ambitious but not be too ambitious in the first treatment (so do not try to go immediately to 80% or 100% intensity).
 - iii. If the patient is too ambitious on the first or second treatment it can result in some muscle pain the next day.
 - iv. Please note that in the 1st and 2nd treatment the focus is on improving the **coordination** and the **function** of the muscles. For improving the function it is not necessary to use high intensities.
 - v. In a later stage the focus will shift to improving the **strength** of the muscles and for this it is crucial that the patient tries to do the treatment at as high an intensity as possible.

- 7) After 1st or 2nd treatment, the patient must be more ambitious and be motivated and pushed to go to higher intensities. Improving the strength of pelvic floor muscles is best realized at high intensities.
 - a. For example: Patients who follow a 16 treatment program who only reach intensity level 60% after 16 sessions will have lower effectiveness than patients who reach 100% intensity.
 - b. Other example: Patients who realise 100% after 10 sessions and then stop the treatment program will have lower effectiveness than patients who continue until completion of the 16 session program with 100%. If you only reach 100% in the last session then you need to continue a few more sessions at 100% to ensure that the positive effects of the QRS treatment remain long term.
 - c. In other words: In order to realize the most effectiveness of the whole treatment program (e.g. 16 treatments) it is important that the customer moves as fast as possible to the highest possible intensities and carries out as many treatments as possible at the highest intensities, however, in the first and second treatment the customer must not be too ambitious and first get used to the signal and thus avoid unnecessary muscle tiredness and muscle pain.
- 8) Patient must do minimum 2 treatments per week.
 - a. This can also be increased to 3 treatments depending on the strength of the pelvic floor muscles of the patient.
 - b. Important:
 - i. It is important that the patient/customer keeps to the agreed appointments and thus makes minimum 2 or preferably 3 treatments per week. If the patient does not stick to this therapy schedule then there is less guarantee of success of the treatment program, the success of the treatment program will be jeopardized.
 - c. In general it is recommended to keep one day of rest between each treatment.
 - i. Patients must not underestimate the intensity of the pelvic floor muscle training.
 - ii. Pelvic floor muscle training is similar to training of other types of muscles in the human body, including the biceps muscles of the upper legs or upper arms.
 - iii. Pelvic floor muscles (especially the type 2 fast twitch muscles) get tired very quickly and this is one reason why a treatment of 20 minutes is the maximum.
 - iv. During the days of rest it is recommended that, complementary to PelviCenter treatment, the customer/ patient performs himself/herself some manual Kegel exercises at low intensity.

- d. If a patient insists and he wishes to come for Pelvicenter training every day, then ask the patient that he/ she can only come back the next day if he/she does not feel any muscle pain in the morning. Note that if you „overdo“ the training (too long at too high intensities and too many treatments per week) then the effect will be counter productive and the patient will initially experience a deterioration of his/ her condition instead of an improvement.
- e. Additional note:
 - i. Note that some indications, such as postpartum BDNF stimulation or Pelvic Pain Syndrome require daily therapy sessions (5 times a week over a period of 10 days = 10 sessions or over a period of 2 weeks = 12 sessions)

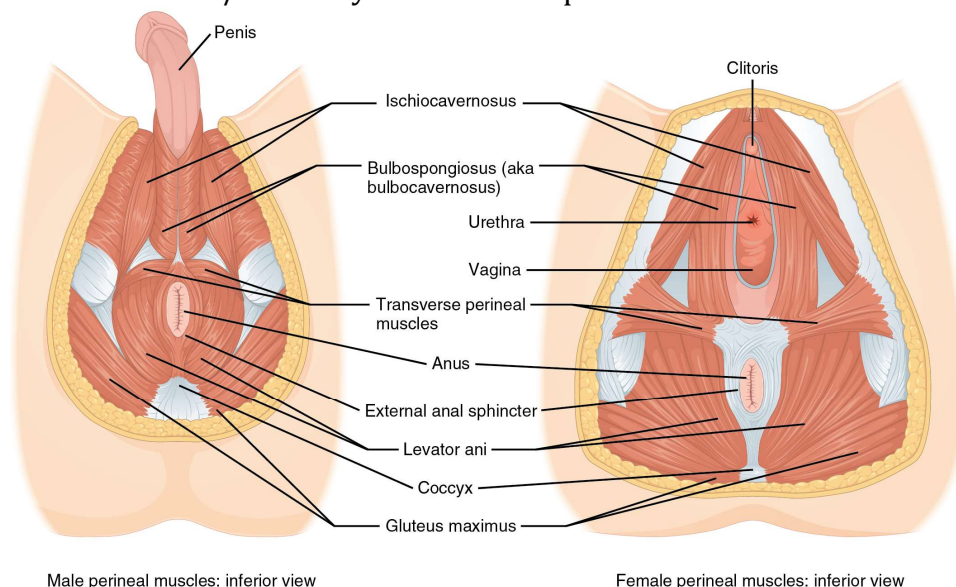
9) Use QRS-PelviCenter as complementary treatment.

- a. It is NOT necessary for the patient to do self-Kegel exercises complementary to the QRS-PelviCenter treatment. Our clinical trials are based on patients who only followed the 16 PelviCenter sessions and who did not do any other treatment. And the results are very good.
- b. However, despite the fact that it is not necessary to do self exercises, from a „customer service point of view“ we recommend to also explain the patients about self „Kegel exercises“. QRS-PelviCenter will quickly show positive results but patients who want to realize even faster results are encouraged to do some own Kegel exercises complementary to the PelviCenter treatment. The effectiveness will increase if the patient complementary to the PelviCenter treatment also does manual Kegel exercises at home 3 times per day.
- c. From a „customer service point of view“ it is recommended that the clinic inform all patients about Kegel exercises, about the importance of carrying out these exercises, about how to identify the relevant muscles and how to carry out the exercises. Stimulate the patients to do some exercises themselves at home.
- d. Patients will realize results faster if they do both the PelviCenter treatments in the clinic and also the exercises at home.

10) Sitting position is of key importance.

- a. For Urinary Incontinence:
 - i. Patient must sit upright and a little bit bent forward whereby the angle between the upper legs and the upper body is less than 90 degrees. This opens up the gluteus maximus muscles and allows for the pelvic floor to enter directly into the pelvic floor.
 - ii. Thus do not move the backrest of the Pelvicenter to the back. Keep the backrest set relatively straight.
 - iii. The entire gluteal and back region must have full contact. A large area of the patient's back should rest against the backrest. The patient must maintain this posture and avoid forming a hunched back as a result of the buttocks sliding away during the course of the treatment.

- b. When treating Erectile Dysfunction it is required for the patient to spread wide his legs while sitting on the PelviCenter. This allows more direct stimulation of the Pelvic floor muscles responsible for sexual function.
- c. When treating lower back pain, the treatment must focus on 2 parts:
 - i. part of the treatment can focus on the pelvic floor (similar position to treating urinary incontinence). Note that an important cause of LBP is the weakening of the Pelvic floor and thigh muscles. By focusing the treatment on these muscles the LBP will improve.
 - ii. part of the treatment must focus on direct stimulation of the multifidus muscle in the lower back. This means you have to change the sitting position:
 1. a) moving the magnetic coil to the back (0 cm) directly under the spinal cord; and by
 2. b) change the sitting position by leaning backwards on the pelvicenter. So that the magnetic coil is now very close to the lower back (L4-L5-S1). It also helps if you lift up one or both of your legs.
- d. Sit with your body centered on the seat surface
 - i. 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
 - ii. Only in the situation of treatment of cellulite/ improvement of the glute area, then it makes sense to move position (e.g. to left or right) and let the rPMS stimulation focus on one of the glutes/buttocks first and later changing position to focus the stimulation on the other glutes
- e. Tool to help customer in identifying the right position.
 - i. It often helps to show the customer a picture of the Pelvic Floor (for example picture below) and ask the customer to identify the various muscles in his/ her body based on this picture.





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

11) Check the position of the magnetic coil:

- a. The magnetic coil must be positioned exactly on the area where the treatment is required.
- b. For patients suffering from lower back pain, the magnetic coil must be on the back (under the spinal column).
- c. Patients suffering from fecal incontinence, the magnetic coil must be positioned under the anal area.
- d. Patients with urinary incontinence, the magnetic coil must move a little bit to the front under the urinary external sphincter muscle.
- e. And patients suffering from erectile dysfunction, the magnetic coil must be positioned under the bulbospongiosus and ischiocavernosus muscle. Please note that these 2 muscles are superficial muscles which do not lie so deep (you can feel them yourself). So initially you do not need high intensities to stimulate these 2 muscles. Higher intensities you can use to stimulate the PC muscle (which lies deeper) which also has an important function in sexual function.
- f. General note:
 - i. Experience has shown that the optimum position can be set more precisely when at least the 2nd intensity level (40% output) is selected. For slim patients, in most situations the position of the coil should be between 4cm and 8cm.

12) It is recommended to motivate the patient to be more actively involved during the QRS-treatment.

- a. Instead of sitting passively and let the peripheral muscles automatically contract when the stimulation starts, it is recommended that the patient counts the seconds of the „off time“ and prepares for the moment of contraction. Then just before the magnetic stimulation starts again, to actively (voluntary by the brain) contract the muscles of the pelvic floor. In this way the patient is also forced to more actively feel where the relevant pelvic floor muscles are and how to contract these muscles. This will help the patient in carrying out the exercise manually at home (Kegel exercises)

13) Additional notes for improving sexual function:

- a. For improving sexual function, it is recommended during the course of the treatment program to sometimes change the duration of the „stimulation time“ (standard 8 seconds) versus the „off time“ (standard 4 seconds). After about 10 treatments it is recommended to do part of the treatments with shorter times (i.e. 2 seconds stimulation and 1 seconds off time) and part of the treatments with longer times (i.e. 12 or 16 seconds). The longer times help with creating more strength.

14) Relaxation of the muscles is equally important as contraction of the muscles.

- a. Patients must not try to reduce the „off time“. Increasing coordination, function and strength of pelvic floor muscles require the repetitive contraction and relaxation of the muscles. Some patients have pelvic floor muscles which are too tight and here the focus must be on relaxation.

15) „Maintenance treatment“ after the end of the 16 sessions

- a. Our clinical trials prove that the positive effects of QRS-PelviCenter remain for a very long term. In general, maintenance treatment is not required. However, in some cases it is recommended to do „maintenance treatment“ = 1 or 2 treatments per month after the completion of the full program. An important principle is „Use it or loose it!“. Meaning if the patient after the completion of the PelviCenter program regularly uses the pelvic floor muscles then there will not be any deterioration (for example younger women). But if the persons have limited physical activity and do seldom use their pelvic floor muscles then it is recommended to do „maintenance treatment“ after the completion of the program (for example older women).

The long term effects of QRS-PelviCenter treatment & maintenance therapy

QRS® has recently completed a high quality Double Blind Placebo Controlled RCT in Penang, Malaysia on 120 patients.

Part 1 of the study was focused on the results of QRS®-PelviCenter as compared to Sham directly after the end of the 16 sessions.

Part 2 of the study was focused on measuring the results 6 and 12 months after the end of the last session.

So in the 12 months after the last PelviCenter session, patients did not follow any additional Pelvicenter (no „maintenance“ treatment) or any other treatment (no self Kegel exercises).

The results are very good.

There is almost no „relapse“.

The results of the 12 month follow-up are almost similar to the results at 6 month follow-up and the results when measured directly after the end of the 16 sessions.

This is a clear and strong indication that the positive effects of QRS-PelviCenter remain long-term. Please see the detailed report of the Clinical Study.

Please refer to the paragraph on clinical trials.

About QRS®-PelviCenter „maintenance“ therapy after the completion of the 16 sessions

Normally QRS® standard treatment protocol requests the patient to do between 1 and maximum 2 maintenance sessions per month after completion of the full 16-session treatment protocol.

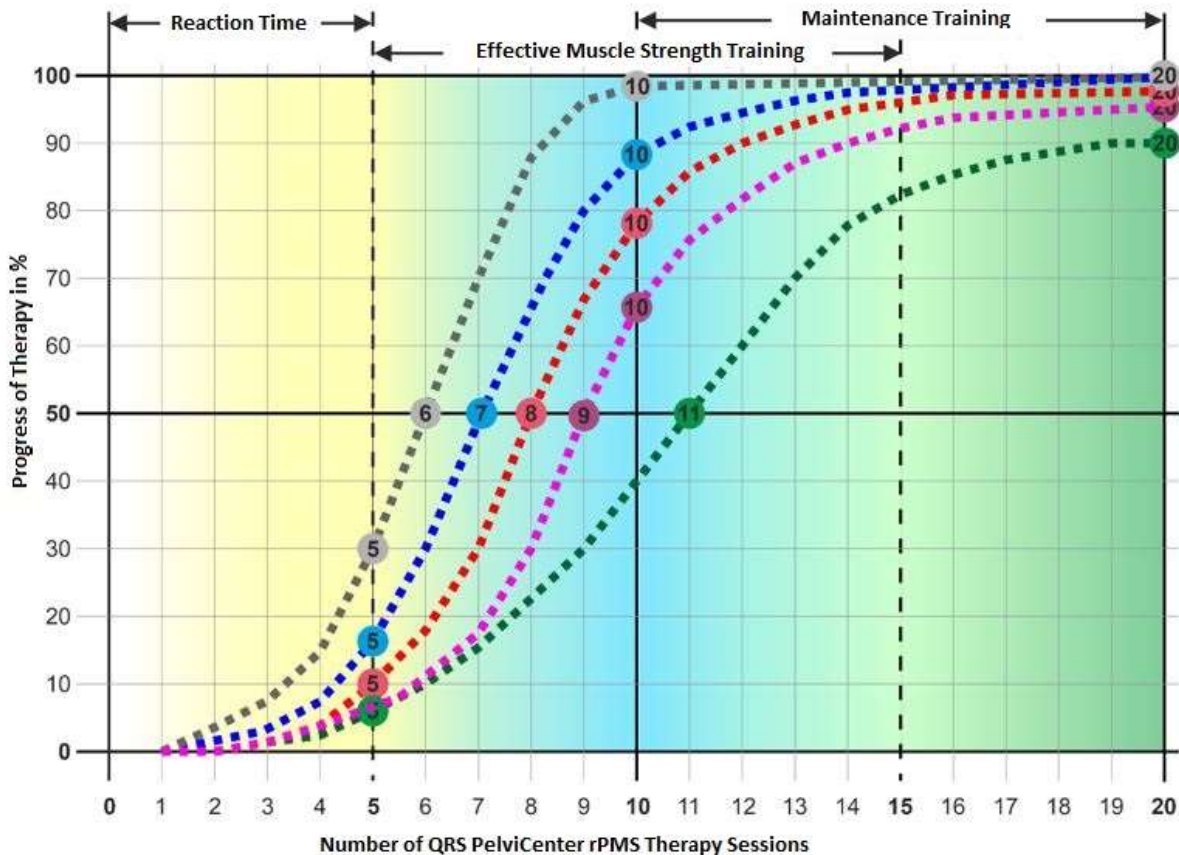
However, this maintenance therapy is not in all cases necessary and experience shows that it is relevant mainly for the elderly patients who do not do much physical exercise and do not regularly use the muscles.

Important advise after the 16 session QRS® treatment protocol is to „use it or loose it“. A large part of the patients/ customers who follow QRS®-PelviCenter treatment have benefit from re-learning how to use the pelvic floor muscles and regaining strength after which they keep using the muscles regularly in daily life or via self-Kegel exercises. In these cases no QRS®-PelviCenter maintenance therapy is required.

In general the following can be said:

- For some type of patients (younger patients) and some type of indications (i.e. rehabilitation after pregnancy or after radical prostatectomy) the focus of QRS-PelviCenter training is mainly on restoring coordination and function of the pelvic floor muscles. After the QRS-PelviCenter training program the patient is able to maintain strength of the muscles via normal daily activities and does not have to return.
- However in other cases, especially for elder persons, women after pregnancy it is recommended to continue doing „maintenance“ treatment on the QRS-PelviCenter (1 or 2 times per month) in order to maintain the strength of the pelvic floor muscles. Remember that training the Pelvic Floor muscles is similar to training any other group of muscles. If the muscles are not used regularly they will start to loose strength.

Additional graph in relation to Managing of Expectations



The graph above shows the following:

- Initially the customer must not expect big improvements after the first or second therapy session. Initially the focus of the rPMS (repetitive peripheral muscle stimulation) therapy is on improving the FUNCTION and COORDINATION of the Pelvic floor muscles. Normally during the first few treatments we start with low intensities and do not yet reach the highest intensity levels
- Normally all customers report a positive improvement after 6 therapy sessions.
- Starting after about 6 therapy sessions, the progress of each subsequent session is more faster. Now normally most customers/ patients are at about 80% or 100% intensity. The focus is now no longer on improving function and coordination, but instead the focus is on improving strength.
- Almost all customers report after 10 therapy sessions a SUBSTANTIAL improvement. However we strongly recommend not to stop after 10 sessions. In order to ensure LONG TERM success it is important to continue at least until 16 therapy sessions. All our clinical trials are based on 16 treatments.
- Our long term studies show that normally after 16 treatments, there will be long term positive effects lasting at least 12 months to 3 years. However, we still recommend that the patient/ customer does some self-exercises during this period, e.g. remains active („use it or loose it“). Also for those people who are overweight we recommend to try and loose weight.
- In the graph above, the green line represents those patients who started off with a higher frequency severity and frequency or Urinary Incontinence and/or a more serious prolapse. These type of customers will require more therapy sessions.

Summary key points when doing a treatment with QRS-PelviCenter:

- 1) Always first check the contra-indications
- 2) Start first treatment at low intensity and low frequency.
 - a. Just to get the feeling. To improve the coordination & function of the muscles.
 - b. After the 1st or 2nd treatment, motivate the customer to increase the intensity as much as possible (but the customer must not feel any pain, so normally the increase from 20% to 100% takes between 6 and 10 sessions).
- 3) Determine the indication:
 - a. Urge Urinary Incontinence: 10 Herz or 5 Herz**
 - b. Stress Urinary Incontinence: Between 35 Herz and 50 Herz.**
 - i. When you reach 80% or 100% intensity, do not go higher than 35 Herz
 - ii. Theoretically 50 Herz is better to build strength, but 50 Herz results in the muscles quickly getting tired and thus resulting in delayed muscle soreness. In order to avoid that one can choose to use 35 Herz instead.
- 4) Lower Back Pain: Focus the stimulation on 2 parts:
 - a. Pelvic floor muscles and thigh muscles (15 minutes)
 - i. Use high frequencies (35-50 Herz). Similar to treatment of Stress Urinary Incontinence.
 - b. Direct stimulation of the lower back (multifidus) (15 minutes)
 - i. Use low frequencies, between 5 and 30 herz. The multifidus is a small muscle and does not respond to strength training.
- 5) For long term results it is important to complete the full program (normally 16 treatments).
 - a. Patients can stop earlier if they want but in that case we can not guarantee long term results.
- 6) Notes:
 - a. Always check the position of the magnetic coil. The position of the coil must be different for every patient (fat or thin) and for every indication (lower back pain, fecal incontinence, stress incontinence, sexual function). If position of the magnetic coil is not good, customer will not get the expected benefit from the QRS-PelviCenter treatment.

Appendices:

Appendix 1. Information on Clinical Trials

- 1.1 Results Double Blind RCT Stress UI 12 month follow-up
- 1.2 Other clinical trials: Please ask your QRS representative

Appendix 2. Technical details and ISO certificates

- 2.1 Technical details: ISO certificate 13485
- 2.2 Full Quality Assurance System EC Certificate
- 2.3 Technical details & dimensions

Appendix 3. Key statements & literature references

- 3.1 Literature references SUI & Magnetic Stimulation
- 3.2 Literature references OAB/Urge & Magnetic Stimulation
- 3.3 Literature references Lower Back Pain & Spinal segmental stability
- 3.4 Literature references Erectile Dysfunction & Kegel exercises
- 3.5 Literature references Premature Ejaculation & Kegel exercises
- 3.6 Literature references Rehabilitation after prostatectomy
- 3.7 Literature references Improving sexual function women
- 3.8 Literature references Pelvic Pain & Kegel exercises
- 3.9 Literature references Post micturation dribble & kegel exercises

Appendix 4. Additional notes from QRS-Germany Corporate Head Office

- 4.1 Notes on how QRS-PelviCenter works
- 4.2 Notes on treatment protocol various Indications

Appendix summary results Double Blind RCT Penang Malaysia AFTER 12 months

Summary Study QRS-PelviCenter in Penang Malaysia

University: School of Pharmaceutical Sciences, University of Science Malaysia;
 Ms Dr. Renly Lim (PhD)
Hospitals: Dr. Men Long Liong, urologist Island Hospital (Penang, Malaysia)
 + Lam Wah Ee Hospital + 4 other private hospitals

Objective of the Study:

Compare



Population/ Basic Parameters:

Indication: Stress Urinary Incontinence
Average age 52 years
BMI 52.6 (normal 18-25)
Prolapse 12% stage 0; 53% stage 1; 35% stage 2
Duration: 23% > 10 yrs; 20% between 5 and 10 yrs
Severity: Moderate (ICIQ UI SF 6-12): 75%
 Severe (ICIQ UI SF 13-18): 25%

Number of patients in Double Blind RCT with 6 and 12 month follow-up

4 subgroups:	Code 01	Code 03	Code 02	Code 00	Total
Start number of patients					120
Randomization	36	24	41	19	120
16 sessions	16 ACTIVE PelviCenter sessions	16 ACTIVE PelviCenter sessions	16 SHAM sessions	16 SHAM sessions	
drop-outs	-3	0	0	-2	-5
Completed 16 sessions	33	24	41	17	115
16 additional sessions	NO additional PelviCenter session	16 additional PelviCenter sessions	16 Real PelviCenter sessions	NO additional sessions	
	Total 16 Active PC sessions	Total 32 Active PC sessions	Total 16 Active PC sessions	Total 0 Active PC sessions	
	No self-Kegel exercises Patients only follow PelviCenter treatments				
	No maintenance treatments in the 12 month period				
more drop outs	0	-1	-1	-3	-5
Completed 6 month follow-up	33	23	40	14	110
more drop outs	-2	0	0	-2	-4
Completed 12 month follow-up	31	23	40	12	106

Drop outs are reported in the Study as "failure" ; Without the "drop outs" the results of the study are even better.

LEVEL 1 RCT

Randomized - Double Blind - MultiCenter 6 months follow-up & 12 months follow-up

First Clinical Study on Magnetic Stimulation
which realises the highest quality level on Jadad Clinical Trial score

First study which proves in Double Blind study that Magnetic Stimulation (QRS-PelviCenter) realizes:

- Statistical Highly Significant improvements as compared to Sham
- Statistical Highly Significant improvements as compared to Baseline on ALL outcome measures
 - a) measured directly after the end of the 16 sessions
 - b) measured 6 months after the end of the last session
 - c) measured 12 months after the end of the last session

Comparison with Kegel exercises and other Conservative solutions:

- This study proves that QRS-Magnetic Stimulation is the most effective non-surgical solution against Stress Urinary Incontinence
- Only QRS-PelviCenter is reaching reductions of between 5.6 and 7.1 on the scale of ICIQ-UI-SF (12 months after completion of the 16 sessions)
- Other conservative solutions do not reach a 5 point decrease on the ICIQ UI SF scale, not after the treatment, not after 12 months (5 point is the threshold perceived as clinically meaningful by patients)

Important advantage QRS-PelviCenter over Kegel exercises:

- Studies on Kegel exercises show a reduction of ICIQ-UI-SF of between 3.4 (without biofeedback) and 3.7 (with biofeedback). (when measured directly at the end of the 6 month Kegel training program) (this 3.4 to 3.7 is below the threshold of 5 points)
- Studies on Kegel exercises show very low result in 12 month follow-up (most patients do not have the motivation to continue the training)
QRS-PelviCenter shows longer term duration and realises reductions of between 5.6 and 7.1 (without any maintenance treatment in last 12 months)

Effect of QRS-PelviCenter remains long-term:

- The results in "12 month follow-up" are almost the same as "6 month follow-up" and as compared to "result measured directly after the end of the 16 sessions"
Note that during the 12 month period, patients did not do "maintenance treatment" and also did not do any "self-Kegel exercises"

Comparison QRS-PelviCenter with surgery:

- The success rates of the QRS-PelviCenter come very close to the success rates of Surgery. But without the risks and complications of surgery.
- Many patients do not want surgery.
QRS-PelviCenter is a good alternative, especially for Moderate UI (16 sessions is enough and can be done in 4 to 8 weeks)
(16 sessions is enough and can be done in 4 to 8 weeks)

1. ICIQ-UI-SF Score

ICIQ-UI SF (primary outcome measure of this study):

Number and % of responders (patients who realise ≥ 5 points decrease on ICIQ UI SF scale) :

% of 60 persons Code 01 & 03 who respond after 8 sessions	35,0%
% of 60 persons Code 01 & 03 who respond after 16 sessions	75,0%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	61,1%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	75,6%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	79,2%
Follow-up 12 mths: Code 01 (31 persons - 16 sessions) 26 out of 31	72,2% 83,9%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions) 28 out of 40	68,3%
Follow-up 12 mths: Code 03 (23 persons - 32 sessions) 18 out of 23	75,0%

ICIQ-UI SF Total score (0-21):

ICIQ-UI SF Total Score at Baseline Code 01 & 03 (60 patients)	9,93
ICIQ-UI SF Total Score after 16 sessions Baseline Code 01 & 03 (60)	4,21
Reduction ICIQ-UI SF 'Total score' Code 01&03 after 16 sessions	-5,72
Code 03 (23 persons). Further reduction in 16 more sessions	-1,50
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	-6,05
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	-6,16
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	-7,19
Follow-up 12 mths: Code 01 (31 persons - 16 sessions)	-7,13
Follow-up 12 mths: Code 02 (40 persons - 16 sessions)	-5,63
Follow-up 12 mths: Code 03 (23 persons - 32 sessions)	-6,80

ICIQ-UI SF Overall Impact of UI (1-10):

ICIQ-UI SF Overall impact at Baseline Code 01 & 03 (60 patients)	5,02
ICIQ-UI SF Overall impact at 16 sessions Code 01 & 03 (60)	1,82
Reduction ICIQ-UI SF 'Overall Impact' Code 01 & 03 after 16 sessions	-3,20 -/- 63.7%
Code 03 (23 persons). Further reduction in 16 more sessions	-1,00
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	-3,51
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	-3,37
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	-3,46
Follow-up 12 mths: Code 01 (31 persons - 16 sessions)	-4,21
Follow-up 12 mths: Code 02 (40 persons - 16 sessions)	-3,05
Follow-up 12 mths: Code 03 (23 persons - 32 sessions)	-3,24

What is the ICIQ-UI-SF score?

(International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form)

The ICIQ-UI Short Form is a questionnaire for evaluating the frequency, severity and impact on quality of life (QoL) of urinary incontinence in men and women in research and clinical practice across the world. This short and simple questionnaire is also of use to general practitioners and clinicians in both primary and secondary care institutions to screen for incontinence, to obtain a brief yet comprehensive summary of the level, impact and perceived cause of symptoms of incontinence and to facilitate patient-clinician discussions.

1. Please write in your date of birth: _____

2. Are you (tick one): ☐ Female ☐ Male

3. How often do you leak urine? Check one box.

<input type="checkbox"/> Never	(0)
<input type="checkbox"/> About once a week or less often	(1)
<input type="checkbox"/> Two to three times a week	(2)
<input type="checkbox"/> About once a day	(3)
<input type="checkbox"/> Several times a day	(4)
<input type="checkbox"/> All the time	(5)

4. How much urine do you usually leak, whether you wear protection or not?
Check one box.

<input type="checkbox"/> None	(0)
<input type="checkbox"/> A small amount	(2)
<input type="checkbox"/> A moderate amount	(4)
<input type="checkbox"/> A large amount	(6)

5. Overall, how much does leaking urine interfere with your everyday life?
Circle a number between 0 (not at all) and 10 (a great deal.)

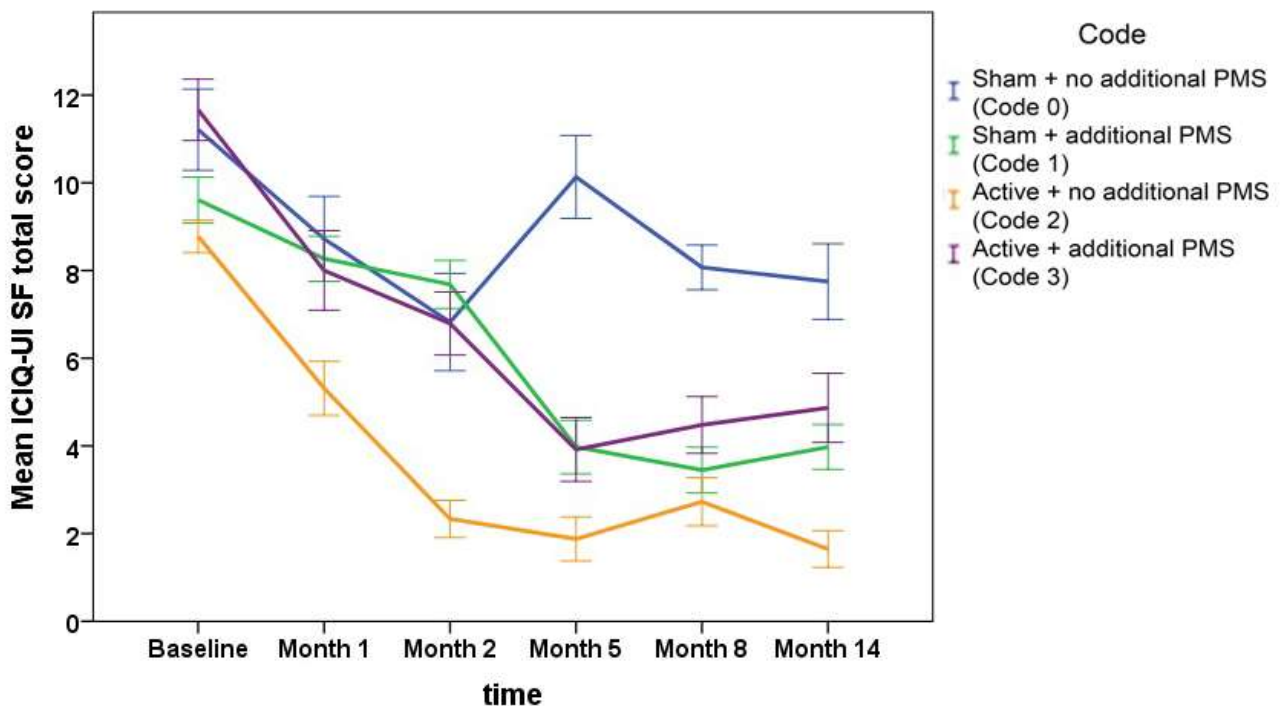
0	1	2	3	4	5	6	7	8	9	10
Not at all										A great deal

Total ICIQ Score (Question 3 + 4 + 5)	
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Important overview of the reduction in ICIQ-UI-SF

Picture below provides an overview of the reduction in ICIQ-UI-SF with QRS®-PelviCenter, measured after 8 treatments (1 month), measured after 16 treatments (2 months), and measured 12 months after the end of the last treatment (month 14).

Key conclusion from the picture below is that there is almost no deterioration in the ICIQ-UI-SF score in the 12 months in which the patient does not do any QRS-PelviCenter treatment.



A 5 point decrease on the ICIQ-UI SF scale is the threshold perceived as clinically meaningful by patients.

Directly after 16 PelviCenter treatments, 75% of patients realize a reduction on the ICIQ-UI SF scale of minimum 5 points.

12 months after the last PelviCenter treatment, a minimum of 68% are still reporting a reduction on ICIQ-UI SF with more than 5 points as compared to baseline (t=0).

The ICIQ-UI SF score is the important scale to measure the severity of the Urinary Incontinence.

The Baseline measurement at t=0 for the Active group was 9.93.

(75% of patients had Moderate Incontinence; ICIQ UI SF 6-12)

25% of patients had Severe Incontinence, ICIQ UI SF 13-18)

When measured directly after the 16 sessions, the average reduction was **5.72** (from 9.93 to 4.21).

More importantly, 12 months later, the average reduction was **between 5.63 and 7.13**

Thus proving that positive effects of QRS-PelviCenter remain, even without maintenance therapy.

Comparison QRS-PelviCenter to Kegel exercises:

Normally QRS-PelviCenter is used COMPLEMENTARY to Kegel exercises.

In this study patients received PelviCenter treatments and they did NOT do any Kegel exercises.

- Reduction ICIQ-UI-SF directly after 6 months of Kegel	-3,40
- Reduction ICIQ-UI-SF directly after 6 months of Kegel&biofeedback	-3,70
- Reduction ICIQ-UI-SF 12 month follow-up after Kegel	LOW
- Reduction ICIQ-UI-SF QRS measured 12 months follow-up	- 5,63 --> - 7,13

Comparison QRS-PelviCenter to Surgery:

The reduction in ICIQ-UI-SF realised by QRS-PelviCenter comes very close to reductions realised by surgery. But QRS-PelviCenter realises those results without the complications, risks, adverse effects and pain.

- Reduction ICIQ-UI-SF QRS measured 12 months follow-up	- 5,63 --> - 7,13
- Reduction ICIQ-UI-SF SIMS Mini Sling	-10,43
- Reduction ICIQ-UI-SF TVT-O	-11,65

2. Objective Cure & Subjective Cure

Objective Cure:

% responders of 60 persons of Code 01 & 03 after 16 sessions	41,7%
% responders of 41 persons of Code 02 after 16 PelviCenter sessions	53,7%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	66,7%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	56,1%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	41,7%
Follow-up 12 mths: Code 01 (31 persons - 16 sessions) 24 out of 31	66,7% 77,4%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions) 24 out of 40	61,0%
Follow-up 12 mths: Code 03 (23 persons - 32 sessions) 11 out of 23	45,8%

Subjective Cure:

% responders of 60 persons of Code 01 & 03 after 16 sessions	31,7%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	47,2%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	36,6%
Follow-up 12 mths: Code 01 (31 persons - 16 sessions) 20 out of 31	55,6% 64,5%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions) 12 out of 40	29,3%
Follow-up 12 mths: Code 03 (23 persons - 32 sessions) 6 out of 23	25,0%

ICIQ-UI SF = 0

% of 60 persons with ICIQ-UI SF = 0 after 16 sessions	21,7%
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"Objective Cure" is measured by Pad test and is defined as
"a leakage of less than 1 gram on the pad test"

Follow-up measurement 12 months after last PelviCenter session
shows the Objective Cure rate is between 46% and 77%.

Especially for "Moderate UI" the Objective Cure comes very close to
Surgery. But without the complications and risks of Surgery.

Transobturator slings: Objective & subjective cure: 85% & 82%
Retropubic slings: Objective & subjective cure: 87% and 84%

When measured directly after the 16 Active PelviCenter sessions:

- Minimum of 32% of patients answered "Never" on the question
"How often do you leak Urine?"
(this % is higher with Moderate UI and lower with Severe UI)

When measured 12 months after the last Active PelviCenter treatment:

- A minimum of 25% of patients (group 03) is even 12 months after
the last PelviCenter session still answering "Never" on the question
"How often do you leak urine?".
This percentage is even 64% for the 31 patients in group Code 01

22% of the 60 Active patients had ICIQ-UI SF of ZERO after 16 PelviCenter
sessions.

3. Frequency

IEF (Frequency)

Number and % of responders (= patients who realise $\geq 50\%$ reduction in number of leaks):

% responders of 60 persons of code 01 & 03 after 16 sessions	76,7%
% responders of 23 Severe UI persons after 32 sessions (code 02)	87,5%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	80,6%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	65,9%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	79,2%

Follow-up 12 mths: Code 01 (31 persons - 16 sessions)	27 out of 31	75,0%	87,1%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions)	24 out of 40	58,5%	
Follow-up 12 mths: Code 03 (23 persons - 32 sessions)	17 out of 23	70,8%	

Average number of leaks per day (IEF):

Average nr of leaks Baseline Code 01 & 03 (60 patients)	1,77
Average nr of leaks after 16 sessions Code 01 & 03 (60)	0,36 -/- 80%
Average nr of leaks after 24 sessions Code 03 (24)	0,00 Zero leaks !

Reduction in number of leaks:

Reduction for 57 persons Code 01 & 03 after 16 sessions	-1,41 -/- 80%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	-1,23 -/- 92.5%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	-1,08 -/- 82.5%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	-2,12 -/- 87.6%

	Baseline	After 6 mths	After 12 mths	Reduction
Follow-up 12 mths: 01	1,33	0,10	0,07	-1,26 = -/- 94.8%
Follow-up 12 mths: 02	1,31	0,23	0,20	-1,11 = -/- 84.8%
Follow-up 12 mths: 03	2,42	0,30	0,35	-2,07 = -/- 85.5%

QRS-PelviCenter results in a statistically highly significant decrease of number of leaks/ day.

12 months after last session between 58% and 87% of PelviCenter patients report decrease of $\geq 50\%$ of nr of leaks per day

12 months after last session on QRS-PelviCenter, patients report that the reduction in number of leaks per day as compared to baseline is between 85% and 95%

4. 1 hour pad test

1 hour pad test

Number & % of responders (= patients who realise $\geq 50\%$ reduction in pad weight):

% responders of 60 persons of group 01 & 03 after 16 sessions	81,7%
% responders of 41 persons of code 02 after 16 sessions	90,2%
% responders of 24 persons of code 03 after 32 sessions	95,8%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	83,3%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	82,9%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	87,5%

Follow-up 12 mths: Code 01 (31 persons - 16 sessions)	27 out of 31	75,0%	87,1%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions)	34 out of 40	82,9%	
Follow-up 12 mths: Code 03 (23 persons - 32 sessions)	20 out of 23	83,3%	

Average pad weight (gram):

Average pad weight (gram) at Baseline Code 01 & 03 (60 patients)	10,90
Decrease pad weight (gram) 16 sessions Code 01 & 03 (60)	-8,30 -/- 76.1%
Average pad weight (gram) after 16 sessions Code 01 & 03 (60)	2,60
Average pad weight (gram) after 32 sessions Code 03 (24)	0,50

Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	-6,14 -/- 79.5%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	-7,69 -/- 83.0%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	-12,63 -/- 80.6%

	Baseline	After 6 mths	After 12 mths	Reduction
Follow-up 12 mths: 01	7,72	1,58	1,48	-6,24 = -/- 80.8%
Follow-up 12 mths: 02	9,27	1,58	1,98	-7,29 = -/- 78.7%
Follow-up 12 mths: 03	15,67	3,04	2,22	-13,45 = -/- 85.8%

Even 12 months after the last PelviCenter session, minimum 83% of the patients have a reduction in their pad weight of more than 50%.

Highly significant reductions in pad weight (gram).

For Severe UI (code 03) reduction from 15.67 grams (baseline, $t=0$) to 0.5 grams after 24 PelviCenter sessions.

12 months after the last PelviCenter session there is still a reduction of minimum 78% of pad weight (=total loss of urine per day)

5. PGI Significant benefits and Quality of Life

PGI-I (significant benefits)

% responders of 60 persons of Code 01 & 03 after 16 sessions	65,0%
% responders of 41 persons of Code 02 after 16 sessions	78,0%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	58,3%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	70,7%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	79,2%
Follow-up 12 mths: Code 01 (31 persons - 16 sessions) 29 out of 31	80,6%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions) 25 out of 40	61,0%
Follow-up 12 mths: Code 03 (23 persons - 32 sessions) 19 out of 23	79,2%

12 months after last PelviCenter session between 61% and 93% of patients report feeling "better" or "very much better"

Quality of Life:

1) ICIQ-LUTSqol "Total Score" (scale 19-76)

Total score for ICIQ-UI SF at Baseline (t=0) Code 01 & 03 (60)	38,55
Total score for ICIQ-UI SF after 16 sessions Code 01 & 03 (60)	29,82
Reduction Code 01 & 03 after 16 sessions (60)	-8,73
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	-12,98
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	-13,51
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	-11,32
Follow-up 12 mths: Code 01 (31 persons - 16 sessions)	-13,95
Follow-up 12 mths: Code 02 (40 persons - 16 sessions)	-11,92
Follow-up 12 mths: Code 03 (23 persons - 32 sessions)	-10,18

12 months after the last PelviCenter session, there is a highly statistical significant improvement of about 35% in Quality of Life as compared to baseline.

2) ICIQ-LUTSqol "Overall Impact" (scale 1-10)

Overall Impact for ICIQ-UI SF at Baseline (t=0) Code 01 & 03 (60)	
Overall Impact for ICIQ-UI SF after 16 sessions Code 01 & 03 (60)	
Reduction group A after 16 sessions (60)	
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	-3,38
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	-2,85
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	-3,96
Follow-up 12 mths: Code 01 (31 persons - 16 sessions)	-3,27
Follow-up 12 mths: Code 02 (40 persons - 16 sessions)	-2,73
Follow-up 12 mths: Code 03 (23 persons - 32 sessions)	-3,45

6. Incontinence Severity and Pelvic Floor Muscle Strength

Incontinence severity

(nr of patients who improved minimum 1 level on ICIQ-UI-SF severity scale)

(4 levels: Light = 0-5 ; Moderate = 6-12 ; Severe = 13-18 ; Very severe = 19-21)

% responders of 60 persons of Code 01 & 03 after 16 sessions	81,70%
Follow-up 6 mths: Code 01 (33 persons - 16 sessions)	75,00%
Follow-up 6 mths: Code 02 (40 persons - 16 sessions)	82,90%
Follow-up 6 mths: Code 03 (23 persons - 32 sessions)	87,50%
Follow-up 12 mths: Code 01 (31 persons - 16 sessions) 27 out of 31	80,60%
Follow-up 12 mths: Code 02 (40 persons - 16 sessions) 34 out of 40	75,60%
Follow-up 12 mths: Code 03 (23 persons - 32 sessions) 20 out of 23	83,30%

82% of persons moves to minimum 1 lower severity level after only 16 treatments [4 levels: Slight (1-5); Moderate (6-12); Severe (13-18); Very Severe (19-21)]
12 months later this is still more than 75% of the patients.

Pelvic Floor Muscle Strength:

(measured with Perineometer)

	Baseline measurement t=0	improvement after 16 sessions (60)	improvement after 12 mth code 01	improvement after 12 mth code 02	improvement after 12 mth code 03
Maximum contraction (cmH ₂ O)	23,98	5,70	6,07	5,40	8,70
Average contraction (cmH ₂ O)	16,59	5,97	6,01	5,63	8,32
Duration of contraction (cmH ₂ O)	5,88	1,60	2,18	1,95	1,76

Despite the inherent issues of Perineometer, QRS-PelviCenter was able to prove statistical significant differences as compared to sham in 6 month and 12 month follow-up.
In future studies we must use "Urodynamic Bladder Pressure Test" system instead of Perineometer pelvic floor muscle strength

12 months after the last session the Pelvic Floor Muscles are still between 25% and 50% stronger than at baseline. Muscles have not become weaker in the last 12 months.

7. Summary results Double Blind RCT with 1 year follow-up QRS-PelviCenter

QRS-PelviCenter proved statistical significant differences as compared to Sham 12 months after last treatment. On ALL outcome measures. See tables below.

Table 3 Responder analysis (binary outcome measures) at month-14.

Outcome, frequency (%)	Sham + no additional PMS (0 PMS) (n=19) (Code 0)	Sham + additional PMS (16 PMS) (n=41) (Code 1)	Active + no additional PMS (16 PMS) (n=36) (Code 2)	Active + additional PMS (32 PMS) (n=24) (Code 3)	p-value*			Overall p-value*
					Code 1 versus 0	Code 2 versus 0	Code 3 versus 0	
ICIQ-UI SF	4 (21.1)	28 (68.3)	26 (72.2)	18 (75.0)	<0.001	<0.001	0.001	<0.001
Objective cure	2 (10.5)	25 (61.0)	24 (66.7)	11 (45.8)	<0.001	<0.001	0.007	<0.001
Subjective cure	0 (0)	12 (29.3)	20 (55.6)	6 (25.0)	<0.001	<0.001	<0.001	<0.001
Incontinence episode frequency	3 (15.8)	24 (58.5)	27 (75.0)	17 (70.8)	0.005	<0.001	0.004	<0.001
1-hour pad test	3 (15.8)	34 (82.9)	27 (75.0)	20 (83.3)	<0.001	<0.001	<0.001	<0.001
Incontinence severity	6 (31.6)	31 (75.6)	29 (80.6)	20 (83.3)	<0.001	<0.001	0.001	<0.001
PGI-I	2 (10.5)	25 (61.0)	29 (80.6)	19 (79.2)	<0.001	<0.001	<0.001	<0.001

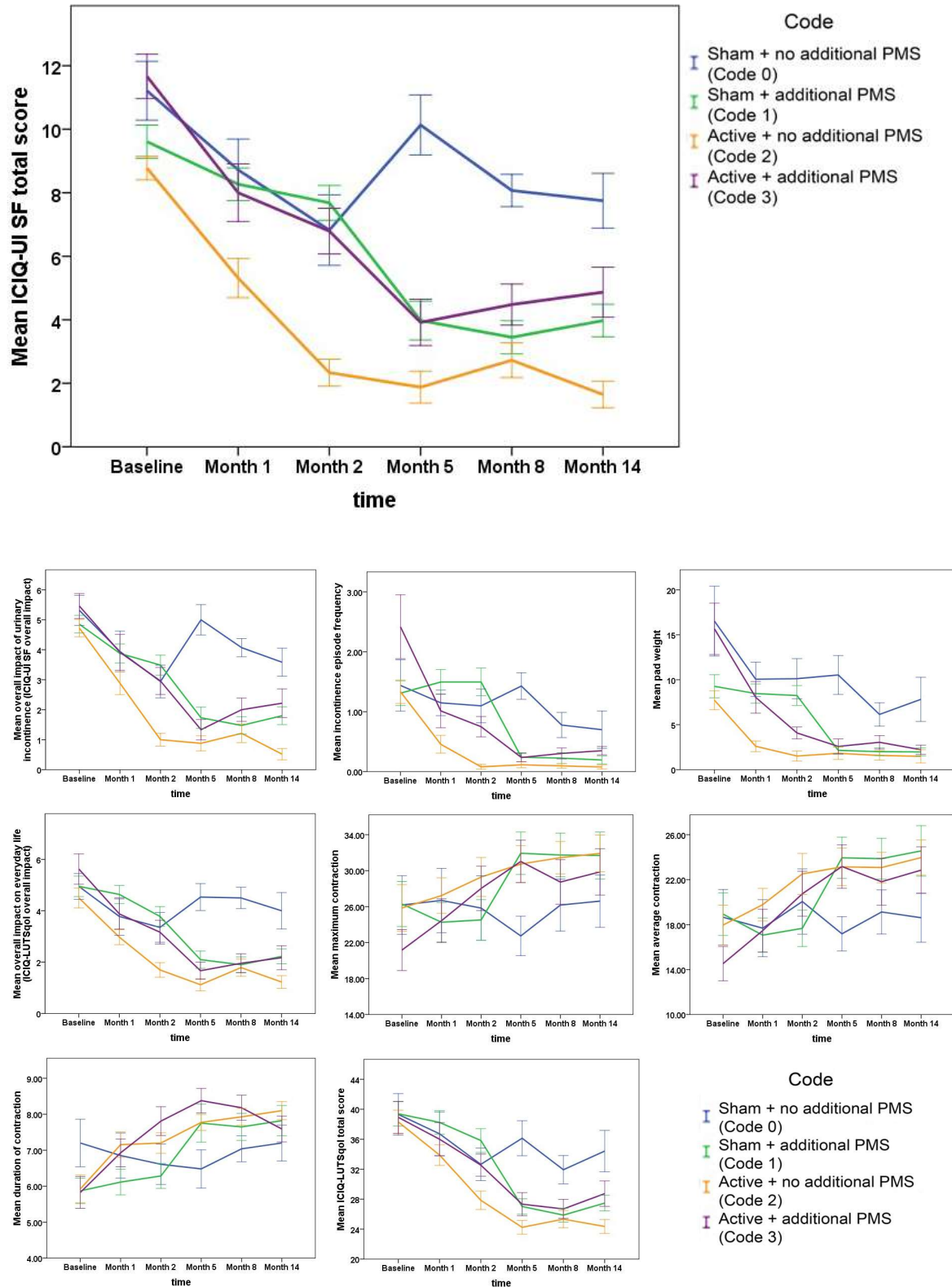
*p-value based on generalized linear mixed model (binary logistic regression).

Table 4 Mean changes in subjective and objective outcome measures (continuous variables) at month 14.

Outcome, mean \pm SE	Sham + no additional PMS (0 PMS) (n=12) (Code 0)	Sham + additional PMS (16 PMS) (n=40) (Code 1)	Active + no additional PMS (16 PMS) (n=31) (Code 2)	Active + additional PMS (32 PMS) (n=23) (Code 3)	p-value*			Overall p-value*
					Code 1 versus 0	Code 2 versus 0	Code 3 versus 0	
ICIQ-UI SF								
Overall impact of UI	-1.73 \pm 0.71	-3.05 \pm 0.43	-4.21 \pm 0.47	-3.24 \pm 0.56	0.027	<0.001	0.019	<0.001
Total score	-3.46 \pm 1.21	-5.63 \pm 0.73	-7.13 \pm 0.80	-6.80 \pm 0.95	0.027	0.001	0.002	<0.001
Incontinence episode frequency	-0.74 \pm 0.38	-1.11 \pm 0.22	-1.26 \pm 0.24	-2.07 \pm 0.29	0.323	0.270	0.003	0.009
1-hour pad test	-8.71 \pm 2.36	-7.29 \pm 1.39	-6.24 \pm 1.53	-13.45 \pm 1.82	0.981	0.611	0.019	<0.001
Pelvic floor muscle function								
Maximum contraction	0.44 \pm 4.85	5.40 \pm 2.92	6.07 \pm 3.22	8.70 \pm 3.84	0.002	<0.001	<0.001	0.550
Average contraction	-0.04 \pm 3.71	5.63 \pm 2.23	6.01 \pm 2.46	8.32 \pm 2.93	<0.001	<0.001	<0.001	0.523
Duration of contraction	0 \pm 0.87	1.95 \pm 0.53	2.18 \pm 0.58	1.76 \pm 0.69	0.003	0.001	0.014	0.220
ICIQ-LUTSqol								
Overall impact	-0.95 \pm 0.76	-2.73 \pm 0.46	-3.27 \pm 0.51	-3.45 \pm 0.60	0.002	<0.001	<0.001	<0.001
Total score	-4.90 \pm 3.02	-11.92 \pm 1.82	-13.95 \pm 2.01	-10.18 \pm 2.39	0.004	0.001	0.044	0.007

*p-value based on linear mixed models.

The positive effect of QRS-PelviCenter is a long-term positive effect.
See pictures below from the clinical trial:



Appendix 2.3 Technical Details & Measurements

Please also refer to paragraph 9 of the Operating Manual

Manufactured in country:	Germany
Medical device category (EU):	Class IIa
Protection class:	I
Protection grade	B
Encapsulation	IPX0
Dimension (cm) (H*L*W)	187 * 134 * 173
Weight (kg)	90 kg
Max load (kg)	130 kg
Powerplug/ input voltage	230V/6A / 50 herz
Output current/ power consumption	Max 1265 VA
Power max (W)	1350W
Fuse:	2 * T6, 3A L 250V
Output signal (field strength):	
• Maximum coil intensity:	3.3 Tesla (measured at coil)
Output signal of optional applicators:	
• Magnetic field back support:	Maximal 3V, 170mA, 40micro tesla (QRS-PEMF RELAX therapy)
• Battery including in QRS-101P	CR2032
• Light therapy (light intensity):	2*36 watts (10.000 Lux at distance of 20 meters)
• Oxygen dose and concentration:	87-96% by 0.5 to 5l/min
Environmental condition:	
• Operation of the device	
○ Temperature range (°C)	+13° +30° C
○ Relative air humidity (%)	30-75%
• Transport and storage:	
○ Temperature range (°C)	+5° +50° C
○ Relative air humidity (%)	<90%, non condensed

Information about measurements and weight of QRS Pelvicenter for shipping purposes						
Type of shipment	Size and number boxes	HS Code for customs	QRS Pelvicenter Premium 033-0-1002 QRS-1010	without light without oxygen 033-0-1002/2 QRS-1013	without light with oxygen 033-0-1002/1 QRS-1012	with light without oxygen 033-0-1002/3 QRS-1011
Via Courier	1 pallet 120 * 80 *158 cm + 1 box 120 * 80 * 94 cm	90189084	190 kg	140 kg	160 kg	175 kg
Via Airflight	2 wooden boxes 2 * 120 * 80 * 160cm	90189084	360 kg	310 kg	330 kg	355 kg

<div data-bbox="199 271 614 488"> <p>Hersteller: gbo Medizintechnik AG D-64668 Rimbach</p> <p>CE 0123</p> <p>QRS PelviCenter 033-0-1001 SN:1234 Patent-EP0594655</p> </div> <div data-bbox="199 495 614 712"> <p>Ausgangswerte: TPM: max. 1800 Apeak 6.50Hz O2: max. 6l/min bei 98 % QRS-Therapie: max. 3V / 170mA / 40µT Lichttherapie: 10.000 Lux bei 0,2m</p> <p>Achtung starkes Magnetfeld! Uhren, Handys, Scheckkarten etc. fernhalten!</p> </div>	<p>Important note:</p> <ul style="list-style-type: none"> Hospital is responsible for providing stable electricity. If stable electricity can not be guaranteed, hospital has to install Uninterrupted Power Supply (UPS).
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Key functionalities/ modules:

- Core of QRS®-PelviCenter:
 - High intensity electromagnetic field generator:
 - Intensity in 5 steps from 20% to 100%
 - Frequency between 5 Herz and 50 Herz
 - Chipcard controlled (including pre-defined treatment programs)
 - Ramp-up functionality
 - Movable magnetic coil
 - Black & white washable leather
 - Integrated QRS®-101 PEMF relax therapy
 - Adjustable foot rest/ adjustable back rest
- Optional modules:
 - Oxygen therapy (87%-95% oxygen with 0.5 to 5.0 liter/minute)
 - Light therapy (2*36 Watt, 10.000 Lux within 20 cm distance)



Appendix 3.1 Literature references:

About magnetic stimulation in relation to Stress Urinary Incontinence:

- Stimulation of the peripheral nerves with a pulsed magnetic field provokes muscle contractions
 - *Bickford RG, Fremming BD: Neuronal stimulation by pulsed magnetic fields in animals and man. Digest of 6th International Conference on Medicine and Electronics Biology and Engineering, Tokyo 1965, p112*
- Magnetic pulses facilitate the stimulation of autonomic and somatic nerve pathways in the pelvic floor, without the use of electrodes.
 - *Evans BA: Magnetic stimulation of the peripheral nervous system J Clin Neurophysiol 8: 77-84, 1991*
- Magnetic fields applied to the S2-S4 nerve roots trigger motor evoked potentials in the pelvic sphincter muscles.
 - *Opsomer RJ, Guerit JM, Wese FX, Van Cangh PJ: Pudendal cortical somatosensory evoked potentials J Urol 135: 1216-128, 1986*
 - *Eardley I, Nagendran K, Kirby RS, Rowler CJ: A new technique for assessing the efferent innervation of the human striated urethral sphincter. J Urol 144: 948-951 1990*
 - *Jost WH, Schimrigk K: A method to determine pudendal nerve motor latency and central motor conduction time to the external sphincter. Electroencephalogr Clin Neurophys 93:237-239, 1994*
- High-frequency, or continuous, magnetic stimulation of S3, delivering up to 20 pulses/ sec, produces clinically useful stimulation of the pelvic floor musculature, increased pressure in the anal canal, and contraction of the external sphincter.
 - *Craggs MD, Sheriff MKM, Shah PJR, et al: Responses to multi-pulse magnetic stimulation of spinal nerve roots mapped over the sacrum in man. J Physiol 483:127, 1995*
- Repetitive maximal contraction of the Levator ani muscle leads to transformation of fast-twitch into slow-twitch striated muscle fibers.
 - *Kralj B: Conservative treatment of female stress UI with functional electrical stimulation. Eur J Obstet Gynecol 85:53-56, 1999*
- Magnetic stimulation acts through several neurological pathways that contribute to coordinated micturition. Pelvic floor afferents, autonomic efferents, and somatic motor fibers play a role in supplying the pelvic floor musculature and striated sphincters.
 - *Craggs MD, McFarlane JP, Foley SJ, et al: Detrusor relaxation following suppression of normal voiding reflexes by magnetic stimulation of the sacral nerves. J Physiol 53:501P, 1997*

Appendix 3.2: Literature references:

Statements in relation to Overactive Bladder including Urge Incontinence (1)

- About effect of Pelvic Floor Muscle Training on OAB:
 - The American Urological Association guidelines for OAB recommend that clinicians use fluid management, bladder training, bladder control strategies, and PFMT as first-line therapy to all patients with OAB
 - Gormley EA, Lightner DL, Burgio KL, et al: American Urological Association/ Society for Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction. *Diagnosis and treatment of OAB (non-neurogenic) in adults: AUA/SUFU guideline. J Urol. 2012;188 (Suppl 6):2455-2463*
 - Pelvic Floor Muscle contractions play an important role in inhibiting urgency and urgency incontinence, and PFMT helps stimulate inhibitory reflexes between the PFM and the detrusor muscle
 - Godec C, Cass AS, Ayala GF. *Bladder inhibition with functional electrical stimulation. Urology. 1975;6:663-666*
 - The „quick flick“ is a technique in which the Pelvic Floor Muscles are rapidly pulsed 3-5 times at the time when urgency is perceived.
 - Price N, Dawood R, Jackson SR, *Pelvic floor exercise for urinary incontinence: a systematic literature review. Maturitas. 2010;67:309-315*
- Detrusor instability results from imbalances between facilitative and inhibitory signals within the voiding reflex
 - Schmidt RA, Jonas U, Oleson KA, et al: *Sacral nerve stimulation for the treatment of refractory urinary urge incontinence. J Urol 162(2):352-357, 1999*
- Suppression of involuntary detrusor activity by magnetic stimulation is explained by at least two effects on the autonomic balance. These are activation of pudendal nerve afferents blocking parasympathetic detrusor motor fibers through the spinal reflex arc and activation of inhibitory hypogastric sympathetic neurons
 - Linsstrom S, Fall M, Carlsson CA, Erlandson BE: *The neurophysiological basis of bladder inhibition in response to intravaginal electrical stimulation. J Urol 129:405-410, 1983*
- Magnetic stimulation inhibits the involuntary contractions that characterize detrusor hyper-reflexia lowering the magnitude of bladder contractions while increasing bladder capacity and compliance.
 - Sheriff MK, Shah PJ, Fowler C, et al: *Neuromodulation of detrusor hyper-reflexia by functional magnetic stimulation of the sacral roots. Br J Urol 78:39-46, 1993*
- Sacral magnetic stimulation acutely suppresses idiopathic detrusor instability
 - McFarlane JP, Foley SJ, DeWinter P, et al: *Acute suppression of idiopathic detrusor instability with magnetic stimulation of the sacral nerve roots. Br J Urol 80:734-741, 1997*

Appendix 3.2 Literature references

Statements in relation to Overactive Bladder including Urge Incontinence (2)

- Magnetic Stimulation is effective in treatment of Urge Incontinence (2013):
 - Magnetic Stimulation leads to reflex inhibition of detrusor contraction by the activation of afferent fibers within the pudendal nerve by 3 actions:
 - Activation of hypogastric nerve
 - Direct inhibition of the pelvic nerve within the sacral cord
 - Supraspinal inhibition of the detrusor reflex

Tomonori Yamanishi, Osamu Yokoyama, Yukio Homma, Kasaku Yasuda Multicenter, randomized, sham-controlled study on the efficacy of magnetic stimulation for women with urgency urinary incontinence (August 2013)
- Functional magnetic stimulation, developed as an alternative to electrical stimulation, has been used as a safe and non-invasive intervention for urgency incontinence. A greater inhibition of detrusor overactivity has been reported in magnetic stimulation than in electrical stimulation in a urodynamic study.
 - *Yamanishi T, Yasuda K, Suda S et al. Effect of functional continuous magnetic stimulation for urinary incontinence. J. Urol. 2000; 163: 456–459.*
 - *Yokoyama T, Fujita O, Nishiguchi J et al. Extracorporeal magnetic innervation treatment for urinary incontinence. Int. J. Urol. 2004; 11: 602–6.*
 - *Almeida FG, Bruschini H, Srougi M. Urodynamic and clinical evaluation of 91 patients with urinary incontinence treated with perineal magnetic stimulation: 1-year followup. J. Urol. 2004; 171: 1571–5.*
 - *But I, Faganelj M, Sostaric A. Functional magnetic stimulation for mixed urinary incontinence. J. Urol. 2005; 173: 1644–6.*
 - *Chandi DD, Groenendijk PM, Venema PL. Functional extracorporeal magnetic stimulation as a treatment for female urinary incontinence: “the chair”. BJU Int. 2003; 63: 539–42.*
 - *Voorham-van der Zalm PJ, Pelger RC, Stiqqelbout AM et al. Effect of magnetic stimulation in the treatment of pelvic floor dysfunction. BJU Int. 2006; 97: 1035–8.*
 - *Yamanishi T, Sakakibara R, Uchiyama T et al. Comparative study of magnetic versus electrical stimulation on inhibition of detrusor overactivity. Urology 2000; 56: 777–81.*

Appendix 3.2 Literature references

Statements in relation to Overactive Bladder including Urge Incontinence (3)

Bladder Function and Pelvic Floor Activity are integrated.

Bladder Function and Pelvic Floor activity influence each other in a facilitory or inhibitory way.

- Stimulation of the hypogastric plexus (originated in the spinal segment) result in:
 - Relaxation of the detrusor muscle
 - Contraction of the internal sphincter, inhibiting urination
- Stimulation of the parasympathetic nerves (originating in S2-S4) has the opposite effect:
 - Contraction of the detrusor muscle
 - Relaxation of the internal sphincter

Van Balken MR, Vergunst H, Bemelmans BLH. The use of electrical devices for the treatment of bladder dysfunction: a review of methods. J Urol 2004;172:846-51

The innervation of the pelvic floor and external sphincter comes from the segments S2-S4, which partially explains the interaction at the spinal level, being much higher and supra-spinal complex interaction.

DeGroat WC, Kawatani M. Neural control of the urinary bladder: possible relationship between peptidergic inhibitory mechanisms and detrusor instability. Neurourol Urodyn 1985;4:285-300

The proper functioning of the bladder and internal sphincter depends on the delicate balance between inhibitory and facilitory stimulus.

injury of peripheral nerve fibers involved in the integration of these interrelationships or injury of the involved central nervous system,

causes urinary voiding dysfunction of emptying/storage of the bladder,

depending on the severity of impaired balance

between facilitation and inhibition of micturition

Van Balken MR, Vergunst H, Bemelmans BLH. The use of electrical devices for the treatment of bladder dysfunction: a review of methods. J Urol 2004;172:846-51

Other relevant literature in relation to Urinary Incontinence:

- *Craggs MD, McFarlane JP, Knight SL, et al: Detrusor relaxation of the normal and pathological bladder. Br J Urol 79 (suppl 4):58-59, 1997*
- *Yamanashi T, Yasuda K, Suda S, et al: Effect of functional continuous magnetic stimulation for urinary incontinence. J Urol 163:456-459, 2000*
- *Sand PK, Richardson DR, Staskin SE, et al: Pelvic floor stimulation in the treatment of genuine stress incontinence: A multicenter placebo-controlled trial. Am J Obstet Gynecol 173:72-79, 1995*
- *Galloway NTM, El-Galley RES, Sand PK, et al: Extracorporeal magnetic innervation therapy for stress urinary incontinence. Urology 53(6):1108-1111, 1999*
- *Carlan SJ, Bhullar A: Follow-up of patients who underwent extracorporeal magnetic innervation therapy for urinary incontinence: 2.9 years after initial treatment. Poster presentation, International Bladder Symposium, Washington DC, March 8-11, 2001*
- *Bavendam T, Braddon L, Carlan S, et al: Impact of extracorporeal magnetic innervation on quality of life in the treatment of stress urinary incontinence. Abstract presentation American Urological Association, Atlanta, GA, April 2000.*

Appendix 3.3 Literature references

Association between Pelvic Floor Dysfunction and Lower Back Pain

International research shows that there is a strong association between pelvic floor disorders and lower back pain. Studies show that people who are suffering from Pelvic Floor Dysfunction have a higher risk of Lower Back Pain than people with inactivity or with high BMI.

- One study showed that 78% of women with Lower Back Pain also reported Urinary Incontinence.
 - *Urinary incontinence in women with low back pain. Eliasson K¹, Elfving B, Nordgren B, Mattsson E. Man Ther. 2008 Jun;13(3):206-12. Epub 2007 Mar 23.*
- Another study from 2010 showed that individuals with low back pain have a significant decrease in pelvic floor function as compared to individuals without low back pain.
 - *Arab A, Behbahani R, Lorestani L, Azari A. Assessment of pelvic floor muscle function in women with and without low back pain using transabdominal ultrasound. Manual Therapy. June 2010;15(3):235-239*
- A large study from 2006 followed 38.050 women over a 5 year period and concluded that people who suffer from Pelvic Floor Dysfunction have a higher risk of lower back pain than people who are overweight (high BMI) or than people who do only limited physical exercises (walking).
 - *Smith M., Russell A., Hodges P. Disorders of breathing and continence have a stronger association with back pain than obesity and physical activity. Australian Journal of Physiotherapy. March 2006; 52(1)11-16*
 - <http://www.sciencedirect.com/science/article/pii/S0004951406700575?np=y>
- Another study from 2013 in Australia showed that 57% of women with lower back pain also suffered from Pelvic Girdle Pain and from Pelvic Floor Dysfunction.
 - *Van Wingerden et al (2013)*

Let's Talk About It: Back & Pelvic Pain



Enjoy a better life with a strong and fully functioning core.

Pain in your lower back, pelvic floor and/or groin can be excruciating and debilitating.

Many people simply learn to 'put up with it', avoiding activities that trigger spasms or pain such as exercise and lifting, and even sex. Some turn to prescription medication to mask the pain.

But many people can significantly improve their situation by having a strong and fully functioning core and pelvic floor.

At the Coregood Institute we specialise in treating the issues that weaken a person's pelvic floor. We do this using a range of treatment solutions including the latest leading edge technology from Germany, the PelviCenter. It's non-invasive and easy – and you do it fully clothed.

So call us today to talk about living a less painful, more active life.

Appendix 3.4 Literature references

Clinical studies proving the effectiveness of Kegel exercises on Erectile Dysfunction

- Mamberti Dias et al, 1991
 - 210 patients suffering from ED started PFM training. 53% reported complete response (cured). 21% improved and 26% failure. No information on drop-out rates.
 - [Mamberti-Dias A, Bonierbale-Brancherau M. Therapy for dysfunctioning erections: four years later, how do things stand? *Sexology*. 1991;1:24-25]
- Claes and Baert, 1993 (Belgium)
 - 78 ED patients started PFM training. Follow up period 4 to 12 months. Drop out rate 14%. Of remaining group 86% had complete response (51%) or improved ED (35%).
 - [Claes H, Baert L. Pelvic floor exercise versus surgery in the treatment of impotence. *Br J Urol*. 1993;71:52-57]
 - [Claes H, Van Hove J, Van de Voorde W, et al. Pelvi-perineal rehabilitation for dysfunctioning erection: a clinical and anatomo-physiologic study]
 - Prof. Dr. H. Claes and L. Baert (Belgium, 1993):
 - A group of 150 men suffering from ED followed a training program of 5 times. After only 5 times, 42% of men were satisfied with the outcome and did not need additional treatment for ED.
- Prof. Dr. Colpi et al, 1994
 - 59 ED patients started PFM training. Follow up period 9 months. High drop out rate 44% (men did not want to do Kegel exercises every day). Of the remaining group 64% had complete response or improved ED.
 - Interesting conclusion of this study: Age was not a determining factor for the success of physical therapy.
 - Colpi et al studied PFM contractility in men with and without ED using electromyography, demonstrating that PFM voluntary activity is more efficient in men with normal erectile function as compared with a matched group of men with ED, supporting the concept that PFM efficiency is related to erectile capability.
 - [Colpi GM, Negri L, Scropo FI, Grugnetti C. Perineal floor rehabilitation: a new treatment for venogenic impotence. *J Endocrinol Invest*. 1994;17:34]
 - [Colpi GM, Negri L, Nappi RE, Chinea B. Perineal floor efficiency in sexually potent and impotent men. *Int J. Impot Res*. 1999;11:153-157]
- Prof. Dr. Claes et al, 1995 (Belgium)
 - 122 patients started PFM training. 4-12 month follow up. 12% drop out rate. Of the remaining group. 80% had either complete response (46%) or improved (34%) ED.
 - [Claes H, Van Kampen M, Lysens R, Baert L. Pelvic floor exercise in the treatment of impotence. *Eur J Phys Med Rehabil*. 1995;5:135-140]
- Prof Dr. Marijke van Kampen et al (Belgium)
 - [Marijke Van Kampen, Willy de Weerd; Hubert Claes, Hilde Feys, Mira De Maeyer, Hendrik Van Poppel Treatment of Erectile Dysfunction by Perineal Exercise, Electromyographic Biofeedback, and Electrical Stimulation. *Phys Ther*. 2003; 83:536-543]
 - 51 patients with ED were treated with Pelvic floor exercises, biofeedback, and electrical stimulation. No control group.
 - Drop out rate 17%. Of the remaining group 57% had regained a normal erection and another 21% improved.
 - Other interesting conclusions of this study:
 - The study concluded that pelvic floor muscle training is most favorable in men with „venous-occlusive dysfunction“. The key conclusion of Prof. Van Kampen: Physical therapy can contribute to the improvement of erectile dysfunction by decreasing venous outflow. Contraction of the pelvic floor muscles results in higher pressure at the base of the penis.

- There were 9 patients in the study where the ED was caused by psychological issue and none of these 9 had a positive result from the physical therapy.
 - Age, duration of the ED, and other sexual problems or other causes of ED had no influence on the results of the study.
- More information:
 - Patients attended an individual physical therapy session once a week over a period of 4 months.
 - First started with training the muscles in a supine position with the knees flexed. Later the exercises were done with the patient sitting or standing. The patient was asked to perform short (1 second) and long-lasting (6-10 seconds) contractions of the target muscles. 30 contractions in the morning; 30 in the afternoon and 30 in the evening.
 - The first improvement in the duration of the erection occurred between 1 and 12 weeks after the beginning of the therapy.
 - The mean time for duration of the erection to be noted was 3.9 weeks.
- Study Dorey (UK) 2003:
 - A group of 55 men with ED problems. The men carried out pelvic floor muscle exercises for 3 months. 40% of men had regained normal erectile function. 36% had improved. Other 24% did not improve but can be due to the fact that they did not consistently carry out the exercises.
 - [Dorey G, Speakman MJ, Feneley RC, et al. Pelvic floor exercises for erectile dysfunction. *BJU Int.* 2005;96:595-597]
- Study F. Sommer Germany 2001:
 - Study of 12 months with a control group. One group was carrying out pelvic floor muscle training. The study showed a significant improvement in systolic peak flow and an significant improvement in erection capability, measured by standardized questionnaires such as IIEF.
 - [Sommer F; Bloch W., Klotz T, Engellmann U. Aging male – Prävention der erektilen Dysfunktion durch Hyperoxygenierung des Corpus cavernosum. *Urologe A* 2001; 40 (supple 1); 41]
- Study F. Sommer Germany:
 - Study on 124 men with ED who were suffering from “venous-occlusive dysfunction”. Part of the ED patients got Viagra. Other part was carrying out pelvic floor muscle training. 80% of the group who started with pelvic floor muscle training reported improvement after 16 weeks, whereas 72% of the group who were taking Viagra reported improvement.
 - Sommer F, Raible A., Caspers HP, Schoenenberger A, Engelmann U. Eine konservative Methode zur Behandlung von erektilen Funktionsstörungen bei impotenten männlichen Patienten. *Urologe A* 2002; 41 (supple): 11 (P 3-7)
 - Sommer F, Raible A, Bondarenko B, Caspers H-P, Esders K, Batsch G, Schoenenberger A, Engelmann U. A conservative treatment option of curing venous leakage in impotent men. *Eur Urol* 2002; 1 (suppl): 153
 - Sommer F, Graf C. “sports meets medicine – Urologie und Sport – Lifestyle, Sexualität, Onkologie und Sport”. Cuvillier-Verlag, Göttingen, 2002.
- One of the important conclusions of the studies above is that Pelvic Floor Muscle training is particularly effective when the cause of ED is due to so-called “venous-occlusive dysfunction” [the muscles are not strong enough and blood flows away too quickly from the penis]. [The study of Prof. Sommer from Germany found that between 35% and 60% of ED cases have their origin in this “venous-occlusive dysfunction”.](#) And PFM training helps.

Appendix 3.4 Literature references

Statements about importance of strong skeletal muscles on sexual function of men

Important statement from QRS®: QRS-PelviCenter is NOT the revolutionary system which can „cure“ all Erectile Dysfunction.

ED has many different causes. And very often a man who suffers from ED has 2 or more reasons which cause his ED.

One important reason for ED is the so-called „venous occlusive

- *Andrew L. Siegel Pelvic Floor Muscle training in males: Practical applications (Urology 84:1-7, 2014):*
 - Although there are many potential causes of ED, the common denominator is insufficient blood flow to fill the corpora, or alternatively, sufficient arterial blood flow but poor venous trapping due to venous-occlusive disease, both issues often (but not completely) caused by a decline in the capacity for smooth muscle relaxation. This results in a spectrum of erectile difficulties including:
 - Increased refractory time
 - Less rigid erections
 - Adequate rigidity but premature loss of erections
 - Inability to achieve an erection.
- About 20-35% of patients with ED has a problem with “venous-occlusion dysfunction”.
 - *Porst H. Erektile Impotenz. Ätiologie, Diagnostik, Therapie. Enke-Verlag, Stuttgart, 1987.*
 - *Porst H. Pharmakoangiographie und Pharmakoangiodynographie des Penis bei erektiler Dysfunktion. Urologe A 1990; 29: 120-5*
 - *Wespes E, Schulman CC. Venous impotence: pathophysiology, diagnosis and treatment. J Urol. 1993;149:1238-1245*
- PFM voluntary activity is more efficient in men with normal erectile function as compared with a matched group of men with ED.
 - *Colpi GM, Negri L, Nappi RE, et al. Perineal floor efficiency in sexually potent and impotent men. Int J Impot Res. 1999;11:153-157*
- The **Ischiocavernosus muscle** can increase the intracavernous pressure on the erectile tissue, when the nerves of the muscles are stimulated
 - *Michal V., Simana J, Rehak J, Masin J. Haemodynamics of erection in man. Physiol Bohemoslov 1983; 32-497-9.*
 - *Lavoisier P, Courtois F, Bornes D Blanchard M. Correlation between intracavernous pressure and contraction of ischiocavernosus muscle in man. J. Urol. 1986;136:936-939*
- It has been proven that the **Ischiocavernosus muscle** is of essential importance in the realizing of supra-systolic intracavernous pressure. And as a result of that on the rigidity of the Penis during an erection.
 - *Derouet H, Nolden W, Jost WH, Osterhage J, Eckert RE, Ziegler M. Treatment of erectile dysfunction by an external ischiocavernous muscle stimulator. Eur Urol 1998; 34: 355-9*
 - *Sommer F, Block W, Klotz T, Engelmann U. Aging male – Prävention der erektilen Dysfunktion durch Hyperoxygenierung des Corpus cavernosum. Urologe A 2001; 40 (supple 1): 41*

- The **Ischiocavernosus muscle** stabilizes the erect penis and inhibits venous return to help maintain penile rigidity and intracavernosal blood pressures that far exceed systemic systolic blood pressures. Kawanishi et al determined that there are statistically significant differences in Ischiocavernosus function between patients with intact erectile function and those with ED with respect to stroke length, duration of contraction, and maximal contractile force. There are statistically significant differences in function of Ischiocavernosus muscle between patients with intact erectile function and those with ED with respect to stroke length, duration of contraction and maximal contractile force
 - Kawanishi Y, Kishimoto T, Kimura K, et al. *Spring balance evaluation of the ischiocavernosus muscle. Int J Impot Res. 2001;13:294-297*
- About **Bulbospongiosus muscle**:
 - When contracted the Bulbospongiosus muscle engorges the glans and corpus spongiosum, expels residual urine from the bulbar urethra, and ejaculates semen from the urethra at the time of climax. The bulbospongiosus muscle has a prominent role in ejaculation (PE)
 - Dorey G, Speakman MJ, Feneley RC, et al. *Pelvic Floor exercises for erectile dysfunction. BJU Int. 2005;96:595-597*
- About the **pubococcygeus muscle**:
 - i. Kegel AH. *Sexual functions of the pubococcygeus muscle. West J Surg Obstet Gynecol. 1952;60:521-524*

More statements on the role of Pelvic Floor Muscles in sexual function:

- Lack of arousal and “frigidity” due to weak pelvic floor and laxity is associated with decreased sexual sensation” (Kegel 1952)
- Weak muscles provide insufficient activity necessary for vaginal friction of blood flow (Graber, Kline-Graber, 1979)
- Pelvic floor contractions are used during early arousal to increase vasocongestion and physical sensations (Messe and Geer, 1985, Colpi, et al, 1999)
- Initiation of orgasm is characterized by Pelvic Floor contractions with an interval of 8ms (Masters and Johnson, 1966, Masters, 1994)
- Orgasm is triggered by firing of stretch receptors in the Pelvic Floor Muscles caused by vasocongestion (Sherfey, 1974)
- Pelvic Floor Muscle function enhances blood flow to the penis. Contraction of the IC and BC muscles compresses the deep dorsal vein of the penis, keeping it erect (Dorey, 2004)
- During orgasm rhythmic contraction of the pelvic floor muscles is perceived as pleasurable
- Pelvic floor muscles are active during ejaculation (Shafik, 2000)

Appendix 3.5 Literature references

Statements in relation to Kegel exercises and Premature Ejaculation:

- A voluntary contraction of the Pelvic Floor Muscles helps control ejaculation
 - *Dorey G. Pelvic Dysfunction in Men. John Wiley & Sons, Ltd;2006:158*
- Pelvic floor muscle rehabilitation is effective in the management of PE, teaching patients to recognize and tone the muscles involved in controlling the ejaculatory reflex, resulting in 11 of 18 patients (61%) being cured.
 - *La Pera G, Nicastro A. A new treatment for premature ejaculation: the rehabilitatio of the pelvic floor. J Sex Marital Ther. 1996;22:22-26*
- Physiotherapy is successful in the management of PE associated with pelvic floor dysfunction
 - *Piediferro G, Copli EM, Castiglioni F, et al. Premature ejaculation. 3. Therapy Arch Ital Urol Androl. 2004;76:192-198*
- Antonio Pastore (Italy) et al 2 studies:
 - 1: comparison of PFM rehabilitation with on-demand treatment with the selective serotonin reuptake inhibitor dapoxetine. 11 of 19 patients (57%) treated with rehabilitation were able to achieve ejaculator control. Although dapoxetine resulted in significantly greater increases in intravaginal latency as compared with those treated with PFMT, the authors concluded that PFMT is a promising therapeutic option for PE:
 - *Pastore AL, Palleschi G, Leto A, et al. A prospective randomized study to compare pelvic floor rehabilitation and dapoxetine for lifelong premature ejaculation. Int. J Androl. 2012;35:528-533*
 - 2: Other study of Antonio Pastore (Italy) on 40 men suffering from PE:
 - 40 men got Pelvic Floor Muscle Training for 12 weeks
 - Conclusion: average ejaculation time improved from 31.7 seconds to 146.2 seconds. 33 of 40 men improved within 12 weeks. Only 5 showed no significant improvement.

Appendix 3.6 Literature references

Statements in relation to ED & Incontinence after Radical Prostatectomy:

- The early application of PFMT after radical prostatectomy has been shown to have a beneficial impact on the recovery of erectile function in terms of duration and severity of ED
 - Prota C, Gomes CM, Ribiero LHS, et al. Early postoperative pelvic floor biofeedback improves erectile function in men undergoing radical prostatectomy: a prospective, randomised, controlled trial. *Int J Impot Res.* 2012;24:174-178
- About use of PFMT before radical prostatectomy (preventative):
 - Porru D, Campus G, Caria A, et al. Impact of early pelvic floor rehabilitation after transurethral resection of the prostate. *Neurourol Urodyn.* 2001;20:53-59
 - Sueppel C, Kreder K, See W. Improved continence outcomes with preoperative pelvic floor muscle strengthening services. *Urol Nurs.* 2001;21:2012-210
 - Parekh AR, Feng MI, Kirages D, et al. The role of pelvic floor exercises on post-prostatectomy incontinence. *J Urol.* 2003;170:130-133

Appendix 3.7 Literature references

Statements in relation to QRS®-PelviCenter and Female Sexual Function:

- Can stronger pelvic floor muscle floor improve sexual function; Lior Lowenstein; Ilan Gruenwald; Irena Gartman; Yoram Vardi (May 2010: International Urogynecology Journal)
 - 176 women who complained about sexual dysfunction were included in the study. Women with strong or moderate PFM scored significantly higher on the FSFI orgasmic and arousal domains than women with weak PFM. The duration of PFM contraction was correlated with FSFI orgasmic domain and sexual arousal. The study suggests that both the orgasm and arousal function of women are related to better PFM function.
- Study carried out on QRS-PelviCenter in Penang, Malaysia between September 2013 and March 2015 (+ 12 month follow-up, finalized in April/ May 2016):
 - Study on 120 women, double blind Random Clinical Control Trial (RCT). Highest possible quality standard in clinical trials (Level 5 on JADAD score). Study results presented at the AUA (Urology Association in USA May 2016). Patients received 16 treatments with QRS-PelviCenter and then measurements were made at baseline (before start of the treatments), directly after 16 treatments, and 6 months after the end of the last treatment (6 month follow-up). A comparison was made with a Sham group who received 16 Sham treatments on QRS-PelviCenter (patients had the psychological idea that they were receiving the real PelviCenter treatment but in fact they did not receive the real treatment). This report summarises the conclusion of the 6 month follow-up. Measurement was done with various questionnaires including the “Golombok Rust Inventory of Sexual satisfaction” questionnaire (GRISS, range 0-96; the GRISS questionnaire is highly recommended by the ICS) and the questionnaire on oversall sexual experience “over the past 4 weeks, how satisfied have you been with your overall sexual life?” Questionnaires were not only filled in by the women but also by their male partners. The conclusions were very clear. 6 months after the end of the last PelviCenter treatment there were statistically significant improvements and statistically significant differences between the QRS-PelviCenter group and the sham group. The overall conclusion of the study is that “QRS-PelviCenter improves sexual function of both the female subjects and their partners. Increasing the number of PelviCenter sessions from 16 to 24 or 32 may further improve female sexual function”.

Appendix 3.8 Literature references

Statements in relation to Chronic Pelvic Pain Syndrome/ Chronic Prostatitis (CPPS/CP)

- 2 RCTs have demonstrated the effectiveness of pelvic floor rehabilitation in painful bladder syndrome (Fitzgerald et al, 2009 feasibility study and 2012 full trial):
 - Outcome of the study: 59% and 57% respectively responded to Pelvic Floor Training interventions addressing tissue dysfunction only.

Paick et al (2006):

- Magnetic stimulation does not only lead to depolarization of the motor nerves (causing a propagating impulse that will release neurotransmitters at the motor end plates and provoke muscle contraction). But depolarization also occurs in sensory afferent fibers and autonomic nerves that regulate local blood flow and other factors.
 - *More effects of extracorporeal magnetic innervation and terazosin therapy than terazosin therapy alone for non-inflammatory chronic pelvic pain syndrome: a pilot study; J-S Paick1, SC Lee1 and JH Ku2, Seoul, South Korea (2006)*
- Magnetic Stimulation offers a new approach for pelvic floor stimulation that improves CP/CPPS. A longer follow-up is required to determine how long the benefits of treatment will last and whether retreatment will be necessary. In addition, the next step in future research will be to determine possible mechanisms of action of Magnetic Stimulation and to identify factors influencing the outcomes. The early results suggest that Magnetic Stimulation combined with α - blocker therapy
 - *Paick et al (2006) More effects of extracorporeal magnetic innervation and terazosin therapy than terazosin therapy alone for non-inflammatory chronic pelvic pain syndrome: a pilot study. Prostate Cancer and Prostatic Diseases 9,261-265.*
 - http://www.nature.com/pcan/journal/v9/n3/pdf/4500881a.pdf?origin=publication_detail

Row et al (2005):

- Despite its uncertain etiology there is some evidence that the symptom complex found in CPPS may be founded at least in part in pelvic floor muscular dysfunction and/or neuro- genic hypersensitivity/inflammation. Our research shows that application of a rapidly changing electromagnetic field applied noninvasively to the perineum of the subject may result in neural excitation and pelvic floor muscle stimulation to a degree that breaks the cycle of tonic muscular spasm and neural hypersensitivity/inflammation, thereby, restoring more normal pelvic floor muscular activity.
 - *A prospective, randomized, placebo controlled, double-blind study of Pelvic Electromagnetic therapy for the treatment of chronic pelvic pain syndrom with 1 year of follow up. E. Rowe, C. Smith, L. Laverick, J. Elkabir, R O'n Witherow, E. Patel, St. Mary's hospital London, UK (2005) ; J Urol. Jun:173(6):2044-7*
 - <http://www.ncbi.nlm.nih.gov/pubmed/15879822>
 - *Results: A total of 21 men with a mean age of 47.8 years (range 25 to 67) were analysed. Mean symptom scores decreased significantly in the actively treated group at 3 months and 1 year ($p < 0.05$), unlike the placebo group, which showed no significant change ($p > 0.05$). Sub analysis of those receiving active treatment showed that the greatest improvement was in pain related symptoms.*
 - *Conclusion: The novel use of pelvic floor electromagnetic therapy may be a promising new noninvasive option for chronic pelvic pain syndrome in men.*

Other literature references on Chronic Pelvic Pain and Magnetic Stimulation:

- By breaking the cycle of pelvic pain muscle spasm and neural inflammation through magnetic stimulation, normal pelvic floor muscular activity can be reinstated. Repeated magnetic stimulation of the pelvic floor and pelvic organs might temporarily or permanently relieve symptoms in men with CP/CPPS, especially chronic pelvic pain.
 - *The Efficacy of Extracorporeal Magnetic Stimulation for Treatment of CP/CPPS – Patients who do not respond to pharmacotherapy. Tae Heon Kim, Deok Hyun Han, Won Jin Cho, Hyo Serk Lee, Hyun Wook You, Chang Myon Park, Dong-Soo Ryu, Kyu-Sung Lee (South Korea, 2013)*
- A study with 11 patients suffering from CP/CPPS showed that 8 of 11 patients (72%) improving in either pain or Chronic Prostatitis Symptom index scores, indicating a role for pelvic floor and neuromuscular re-education. The success of PFMT was based on the principle that maximal muscle contraction induces maximal muscle relaxation, a „meditative“ state between muscle contractions
 - *Nadler R. Bladder training biofeedback and pelvic floor myalgia. Urology. 2012;60(Suppl 6A):42-43*
- A study by Clemens J. et al. Confirms that a formalised program of neuromuscular re-education of the pelvic floor muscles together with interval bladder training can provide significant and durable improvement in objective measures of pain, urgency and frequency in patients with CPPS.
 - *Clemens J. et al. (2000) Biofeedback, pelvic floor re-education, and bladder training for male chronic pelvic pain syndrome. Urology Vol56, Issue 6: 951-955*
- A study by Duclos A. Et al. (2007): Given current data, we favour a complete examination of the patient followed by multimodal therapy. In a treatment naive patient, a 2–4 week course of antibiotics is reasonable, but should not be continued if cultures are negative and there is no improvement in symptoms. If cultures are negative, we then use a combination of an alpha blocker (tamsulosin, alfuzozin) and anti-inflammatory phytotherapy (quercetin and bee pollen, for instance 1 capsule of Q-Urol (Farr Labs, Santa Monica CA) twice daily) for 6–12 weeks. If not successful, we use neuromuscular therapies such as pelvic muscle physical therapy, amitriptyline or gabapentin. In patients who don't respond to conventional therapy and have prostatic stones on transrectal ultrasound, we use an anti-nanobacterial therapy such as Calciclear (Calgenex Corp, Tampa FL). In the minority of patients who do not improve with these therapies, referral to a pain management specialist is appropriate.
 - *Duclos A et al. (2007) Current treatment options in the management of chronic prostatitis. Therapeutics and Clinical Risk Management Aug;3(4):507-512*
- A study by Kim et al (2013): The finding of this study demonstrate that extracorporeal magnetic stimulation is effective in terms of the primary endpoint, total and pain scores of the National Institutes of Health Chronic Prostatitis Symptom Index. This is an important finding because CP/CPPS is one of the most difficult conditions in urologic practice.
 - *Kim et al (2013) The Efficacy of Extracorporeal Magnetic Stimulation for Treatment of Chronic Prostatitis/Chronic Pelvic Pain Syndrome Patients Who Do Not Respond to Pharmacotherapy. Urology 82:894-898*
 - [http://www.goldjournal.net/article/S0090-4295\(14\)00028-4/fulltext](http://www.goldjournal.net/article/S0090-4295(14)00028-4/fulltext)

Appendix 3.9 Literature references

Statements in relation to Pelvic Floor Muscle training for Postvoid Dribbling

General notes:

- PVD occurs immediately or shortly after completing urination, when urinate that remains pooled in the urethra drips out.
- PVD can happen to men of any age but it more commonly occurs after age 40.

Pelvic Floor Muscle Training, QRS®-PelviCenter and Postvoid Dribbling:

- Pelvic Floor Muscle Training & QRS®-PelviCenter can help create a powerful Bulbospongiosus muscle and help increase the capability to empty the urethra. The Bulbospongiosus muscle is responsible for emptying the urethra. Strong contractions of the Bulbospongiosus muscle compress the bulbar urethra, displacing the urine within distally. Patients suffering from PVD are instructed to train their pelvic floor muscles and vigorously contract the PFM several times after completing urination to empty the bulbar urethra.
- Dorey et al demonstrated the effectiveness of PFMT for PVD.
- Dorey et al recognized an association between ED and PVD and concluded that these issues are parallel problems, one sexual and the other urinary – both manifestations of PFM weakness and amenable to improvement by PFMT.

Literature references:

- PFMT is effective in treating Post Micturation Dribble:
 - Dorey G, Speakman MJ, Feneley R, et al. Pelvic floor muscle exercises for treating post-micturation dribble in men with erectile dysfunction: a randomized controlled trial. *Urol Nurs.* 2004;24:490-512
- There is an association between ED and Post Micturation Dribble. Both issues are parallel problems, one sexual and the other urinary – both manifestations of PFM weakness and amenable to improvement by PFMT.
 - Dorey G, Speakman MJ, Feneley RC, et al. Pelvic floor exercises for erectile dysfunction. *BJU Int.* 2005;96:595-597

Appendix 4. Additional notes from QRS-Corporate Head Office

Appendix 4.1 Notes on how QRS-PelviCenter works

Some additional notes on how QRS-PelviCenter works:

- QRS-PelviCenter transmits a magnetic field with an **output of 3.3 Tesla**
- The magnetic field penetrates cellular tissue without resistance.
- The pulsating magnetic fields target the motor nerves and induces them to transmit electrical current to the muscle fibers with the neuromuscular junction
- Once a specific threshold value is reached, an Action Potential is triggered in the motor nerves. This results in muscle contractions which can not be voluntarily controlled by the patients. PelviCenter thus works on the nerves which trigger muscle contractions.
- Depending on certain frequency, the muscle will either contract (and relax) multiple times (e.g. with low frequencies, such as 5 Hz, the muscle will contract and relax 5 times in a second); or alternatively will remain contracted until the stimulation is finished (such as with high frequencies, e.g. 50 Hz = physiologic tetanus)
- Involvement of Central Nervous System (CNS): Mechanoreceptors in the musculature detect the neuromuscular rPMS stimulus and transmit it to the 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. Thus during a series of rPMS therapies, the CNS learns to control the treated muscle area.
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Appendix 4.2 Notes on treatment protocol various 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.

General notes on frequencies:

Most comfortable frequency to start QRS treatment	15 to 20 Hz
Warm-up of muscles	15 to 20 Hz
Muscular loosening effect	15 to 20 Hz
Treatment of myofascial problems	15 to 20 Hz
Cool-down at end of training	5 to 10 Hz
Relaxation of nerves	5 to 10 Hz
Optimization nerve communication	5 to 10 Hz
Urge Incontinence/ OAB	5 to 10 Hz
Stimulation of Central Nervous System (CNS)	5 to 50 Hz
Sacral afferent nerve stimulation (poorly myelinated (A-delta) fibers)	5 to 20 Hz
Endurance training / exercise type 1 fibers - focus on aerobic energy production - focus on improving blood circulation type 1 fibers - focus on muscles which support organs & upper body	20 to 25 Hz
Strength training/ fast twitch type 2 fibers - focus on anaerobic energy production - focus on muscles for short bursts of power - focus on building strength of muscles	35 to 50 Hz

- Please note that High Frequencies work better for training fast twitch, type 2 muscles (which is for example important for training the external sphincter muscle for ensuring closure of the uretra to prevent against urinary incontinence). However, importantly, please note that higher frequencies cause undue fatigue and type 2 muscle fibers fatigue very quickly. It is therefore important to do this intensive training only during limited amount of time. One other reason for this (apart from muscles becoming tired) is that long stimulation of the fast-twitch muscle fibers at high frequency will result in fast twitch fibers converting to slow twitch fibers (meant for support) because slow twitch fibers can sustain the contraction longer. **Therefore we recommend that each treatment session for strength training (high frequencies) is maximized to 15 or 20 minutes.**
- 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.

4.2.1 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.

Postpartum – Pudendal nerve 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.

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.

4.2.2 Stress Urinary Incontinence (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.

Stress Urinary Incontinence

Treatment duration	Intensity	Frequency	Position coil	nr treatments	Other notes
7.5 to 10 minutes	- first only 20% & 40% (improving function) - then to 80% & 100% (improving strength)	5 to 10 Hz 80 & 100%: 35Hz	Front third of the Pelvic Floor	Minimal 16 for serious UI increase to 32 2 to 3* p. week	16 is essential to ensure long term results - stimulation 8 sec - pause 4 sec

Additional notes:

- Stress Urinary Incontinence for women often happens **after Pregnancy**
- Also SUI for women often happens **after Menopause**. Note that the strength of muscles (including pelvic floor muscles) start to decrease with about 2% per year after menopause. **It is therefore strongly recommended to start PelviCenter training already a few years before entering into menopause.** Thereby you will be able to maintain good muscle mass and good functioning of the pelvic floor muscles and thus PREVENT yourself against some of the negative effects of Menopause. In this situation, as preventative treatment, we recommend the same protocol as “maintenance treatment” and that is to use QRS-PelviCenter 2 times per month).

- **Maintenance program for Stress Urinary Incontinence:**

- For everybody who is suffering from SUI after menopause, we recommend first to do a full “Rehabilitation program” by using QRS-PelviCenter at least 16 times.
- After the “rehabilitation”, despite the fact that Studies have proven that QRS-PelviCenter has a long term positive effect, still we recommend that you follow a “Maintenance Program” after that. **We recommend a maintenance program of 2 treatments per month** (24 treatments per year).
- Note that such a maintenance program is normally not so important for younger women (e.g. who suffered of SUI after pregnancy/ child birth) because for them they will most likely on a daily basis restart using their pelvic floor muscles and thereby do not need so much the special QRS-PelviCenter treatment for maintenance. Remember what was mentioned in this document in relation to the muscles involved in sexual function: “use it or loose it!”

4.2.3 Urge Urinary Incontinence (UII) and Overactive Bladder (OAB)

4.2.3.1 UII & OAB women

rPMS for urge urinary incontinence (UII) 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.

OAB/ Urge Urinary Incontinence

Treatment duration	Intensity	Frequency	Position coil	nr treatments	Other notes
15 to 20 min (maximum 20)	- first only 20% & 40% - later slowly to 80% & 100%	5 to 10 Herz !	Middle of the pelvic floor	Minimum 10 2 to 3* p. week	Often improvement noticeable after 1 treatment - stimulation 8 sec - pause 4 sec

Key note:

- QRS-PelviCenter has good positive effects for Urge Urinary Incontinence. Also it is able to improve some (not all!) of the symptoms of Overactive Bladder. Important is to use LOW frequencies (between 5 Herz and 10 Herz). However, in case the customer also suffers from a weak pelvic floor then part of the stimulation must also include higher frequencies (35 to 50 Herz). Normally a customer suffering from Urge Incontinence will notice improvement in the symptoms already after 1 or 2 treatments (e.g. the number of times he/ she has to go to the toilet during night time)

Additional notes:

- 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.

4.2.3.2 UUI & OAB 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.

Treatment protocol. See under UUI & OAB Women.

4.2.4 Mixed Urinary Incontinence (MUI) (women and men)

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

4.2.4.1 MUI Women

Mixed Urinary Incontinence

Treatment duration	Intensity	Frequency	Position coil	nr treatments	Other notes
7.5 to 10 minutes	start with 20% / 40% slowly build up to 60%/80%/100%	5 to 10 Hz	Middle of the Pelvic Floor	Minimal 14 Optimal 20	Minimum 16 to ensure long term results
7.5 to 10 minutes	start with 20% / 40% slowly build up to 60%/80%/100%	up to 60%: 50Hz 80&100%: 35Hz	Front third of the Pelvic Floor	2 to 3* p. week	- stimulation 8 sec - pause 4 sec

4.2.4.2 MUI 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

4.2.5 Stress Urinary Incontinence following a prostatectomy (men)

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.

4.2.6 Sexual Function (men & women)

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

4.2.6.1 Erectile Dysfunction – venous leak/ musculus ischiocavernosus/ 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.

Improving Sexual function Men

Treatment duration	Intensity	Frequency	Position coil	nr treatments	Other notes
15 to 20 min (maximum 20)	- first only 20% & 40% - then higher than 60%	20/40/60%: 50 Hz 80%&100%: 35 Hz	Perineum (between anus & scrotum)	Minimum 16 2 to 3* p. week	- stimulation 8 sec - pause 4 sec Also use QRS-101 !!!!
			cavernosal fibrosis: also focus on anterior pelvic floor		

4.2.6.2 Erectile Dysfunction – Cavernosal Fibrosis

See separate document for detailed Treatment Protocol

4.2.6.3 Erectile Dysfunction – Premature Ejaculation

See separate document for detailed Treatment Protocol

4.2.6.4 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.

Improving Sexual function women

Treatment duration	Intensity	Frequency	Position coil	nr treatments	Other notes
15 to 20 min (maximum 20)	- first only 20% & 40% - then higher than 60%	20/40/60%: 50 Hz 80%&100%: 35 Hz	Middle and front third of the Pelvic Floor	Minimum 16 2 to 3* p. week	- stimulation 8 sec - pause 4 sec Also use QRS-101 !

4.2.7 Lower Back Pain/ Core Stability

See separate document for detailed Treatment Protocol

4.2.8 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.

Pelvic Pain Syndrome

Treatment duration	Intensity	Frequency	Position coil	nr treatments	Other notes
15 to 20 min (maximum 20)	- first only 20% & 40% - then higher than 60%	20 Hz	Anterior pelvic floor	Optimal 10 5* p. week	- stimulation 5 sec - pause 20 sec Also use QRS-101 !

Standard treatment protocol QRS-Pelvicenter and Urinary Incontinence

	Urge Urinary Incontinence (UII)	Stress Urinary Incontinence (SUI) after pregnancy	Stress Urinary Incontinence (SUI) after menopause	Mixed Urinary Incontinence (UII and SUI)
Therapy duration	15 to 20 minutes	15 to 20 minutes	15 to 20 minutes	20 minutes
Intensity	Start low, later high	Start low, later high (to level 5 or 6)	Start low, later high (to level 5 or 6)	Start low, later high (to level 5 or 6)
Frequency	5 to 10 herz	35 to 50 Herz	35 to 50 Herz	10 minutes 35 to 50Hz 10 minutes 5 to 10Hz
Position of coil	under urinary spincter	under urinary spincter	under urinary spincter	under urinary spincter
Sitting position	straight 80 degrees to front	straight 80 degrees to front	straight 80 degrees to front	straight 80 degrees to front
Number of sessions	Minimum 6 to 16 2 to 3 times per week	Minimum 6 to 16 2 to 3 times per week	16 to 24 2 to 3 times per week	16 to 24 2 to 3 times per week

Please note:

- 1) Use QRS-Pelvicenter as complementary therapy
 - a. In the case of Urge Urinary Incontinence, use QRS-Pelvicenter complementary to QRS-101 Therapy system in order to help relax bladder nerves and communication between bladder and spinal cord
 - b. In case of Stress Urinary Incontinence, use Pelvicenter in combination with self Kegel training exercises. Use the Pelvicenter first of all to help identify the relevant muscles that need to be contracted. Then during the therapy do not use QRS Pelvicenter as passive therapy but stimulate to contract the relevant muscles yourself each time the stimulation of Pelvicenter starts. Also practice the exercises yourself at home
- 2) Follow the basic rules of muscle training:
 - a. Start first session with low intensities, focus on improving function and coordination. Do not overdo the therapy in the beginning (maximum 20 minutes and at reasonable intensities) or else you get muscle soreness and temporary loss of function.
 - b. After improved function, then build up as quickly as possible in strength (to level 5 and 6) for SUI and use between 35Hz and 50Hz
 - c. When reaching the highest intensity level, continue at least 6 sessions at highest intensity level to ensure long term results (clinical studies are based on 16 sessions of 20 minutes)
 - d. After the 16 sessions, maintain function and strength by regularly using the muscles or by doing 2 maintenance sessions per month). Use Pelvicenter also for preventative therapy (a few years before start of menopause)
- 3) Above protocols are guidance only. Every patient is different. Exact protocol can only be defined by medical doctor after diagnosis of patient.

Standard Treatment protocol QRS Pelvicenter and Sexual Dysfunction:

	Erectile Dysfunction (ED)
Therapy duration	15 to 20 minutes
Intensity	Start low, later high (level 5 or 6)
Frequency	35 to 50 Hz
Position of coil	under PC muscle, bulbospongiosus/ ischiocavernosus
Sitting position	straight 80 degrees to front, spread open your legs
Number of sessions	16 sessions
	2 to 3 times per week

Please note:

- 1) Use QRS-Pelvicenter only as complementary therapy, and managing of expectations:
 - a. Men who suffer from ED often suffer from at least 2 or 3 different causes of this ED. Between 35% and 60% of men who suffer from ED suffer from “Venous occlusive Dysfunction” as at least one of the causes of ED. At least 80% of men who suffer from ED who do pelvic floor muscle training realize positive effects. But it is possible that the man also has other causes of the ED (e.g. psychogenic (depression, anxiety, marital discord), endocrinologic (hormonal abnormalities, testosterone, thyroidism), pharmacologic (ED as the side effects of medication, e.g. alpha & beta blockers, anti-depressants), neurogenic.
 - b. One important positive effect of Pelvicenter is that men feel which are the relevant muscles for sexual function and how to contract them. It is important that men do not take the therapy only passively but are actively taking part in their brain trying to contract and control the muscles. Also men taking certain medication (e.g. anti-depressants) will have lower effectiveness of the QRS Pelvicenter and QRS-101 therapy.
 - c. Patients with severe diabetes (damaged blood vessels and peripheral nerves) will find less positive effects of Pelvicenter and will need higher intensities than other men.
 - d. It is recommended that patients who follow 16 sessions QRS Pelvicenter that they also use QRS-101 Therapy system at home. This strongly improves circulation and relaxation.
- 2) Follow the basic rules of muscle training:
 - a. Start first session with low intensities, focus on improving function and coordination. Do not overdo the therapy in the beginning (maximum 20 minutes and at reasonable intensities) or else you get muscle soreness and temporary loss of function.
 - b. After improved function, then build up as quickly as possible in strength (to level 5 and 6) for SUI and use between 35Hz and 50Hz
 - c. When reaching the highest intensity level, continue at least 6 sessions at highest intensity level to ensure long term results
- 3) Above protocols are guidance only. Every patient is different. Exact protocol can only be defined by medical doctor after diagnosis of patient. Please check detailed protocol QRS Pelvicenter and Sexual Function.

Standard Treatment protocol QRS Pelvicenter rehabilitation after Radical Prostatectomy

	Rehabilitation after Radical Prostatectomy
Therapy duration	15 to 20 minutes
Intensity	Start low, later high (level 5 or 6)
Frequency	35 to 50 Hz
Position of coil	under urinary sphincter
Sitting position	straight 80 degrees to front, spread open your legs
Number of sessions	minimum 6 recommended 16 for long term positive results 2 to 3 times per week

Notes:

- 1) Therapy can only start after wound healing
- 2) Use QRS-Pelvicenter Therapy as complementary therapy. The focus is to improve function and strength of pelvic floor muscles which most men have not trained well during their life. With the damaging/ removing of the prostate, the man falls back on this second level of defense. By training pelvic floor muscles, the man regains control on his pelvic floor muscles and thereby control on urination and sexual function.
- 3) Most men report good positive effects after 6 sessions, but it is recommended to complete full 16 sessions to ensure long term positive effects.
- 4) Use the rules of muscle training including:
 - a. start first session with low intensities (e.g. level 1 or 2) at medium frequencies (e.g. 25 to 35) with focus on training function and coordination of the muscles
 - b. after that quickly build to higher intensities with minimum frequency of 35 Herz
 - c. not more than 1 session (15 or 20 minutes) per day, give your muscles time to recuperate, do not underestimate the intensity of the training session, it is possible to do a session everyday but only in case there is no muscle soreness on the morning after the last session

Standard Treatment protocol Lower Back Pain

	Lower Back Pain
Important:	The protocol is dependent on the exact cause of the lower back pain Below we describe 3 different ways of using Pelvicenter with lower back pain
Therapy duration	20 minutes
Position of coil:	1) Under the urinary spincter, normal strength training, patient sits straight 80 degrees, high intensity, 35/50Hz 2) Directly under the spinal cord 3) Directly on multifidus muscle, patient will lie in pelvicenter, use moderate intensities and frequencies
Number of sessions	minimum 6 recommended 16 for long term positive results 2 to 3 times per week

Notes:

- 1) Important: Protocol above is for Guidance purposes only. It is important to understand that every patient is different and causes of back pain can be different from one person to the other. So for some patients the stimulation of QRS Pelvicenter must focus more on the Pelvic Floor muscles (coil placed directly under the urinary sphincter). For other patients, it is more effective to focus the stimulation more directly under the spinal cord (put the coil at 0cm directly under the spinal cord). Or to ask the patient to lie in the Pelvicenter and focus the stimulation directly on the segmental muscles around the spinal cord. The exact treatment protocol can only be defined by a Medical Doctor after diagnosis of the patient.
- 2) When the patient suffers from weak pelvic floor muscles then the focus is on training the function and strength of the pelvic floor muscles. Here it is best to use high intensities (level 5 and 6) and high frequencies (between 35Hz and 50Hz).
- 3) When the lower back pain is more caused by non function of segmental muscles around the spinal cord (multifidus muscle) then it is best to use lower frequency and lower intensity. The multifidus does not respond to strength training. The focus must be on improved function.