



QRS 1010 PelviCenter



Automated pelvic floor muscle training



The QRS®-1010 PelviCenter has been successfully used in treating a wide range of lower urinary tract and pelvic floor disorders, including:

- ◆ Stress Urinary Incontinence
- ◆ Urge Incontinence, Bladder Overactivity and Mixed Incontinence
- ◆ Postprostatectomy urinary incontinence with men
- ◆ Erectile dysfunction (Male) & reduced sexual function (female)
- ◆ Postpartum pelvic floor rehabilitation
- ◆ Pelvic Pain Syndrome, Interstitial cystitis
- ◆ Fecal incontinence



QRS® - Restoring health, Alleviate Pain, Extend Lives

Introduction

This brochure provides a description of the QRS®-PelviCenter, a unique therapy system based on Extracorporeal Electromagnetic Stimulation which automatically trains the muscles of the Pelvic Floor and thereby significantly helps restoring continence and improving sexual function.

This brochure is meant for specialists. It describes the *indications and contra-indications* for using the system. And it describes how a typical treatment is provided.

The QRS®-1010 PelviCenter provides you with a unique system for your clinic and allows you to offer a new highly effective solution to your patients. Please contact one of our representatives to learn more and to try the PelviCenter for yourself.

The Pelvic Floor



The power from within

The QRS®-PelviCenter

The QRS®-PelviCenter is a medical device which automatically trains the Pelvic Floor Muscles (PFM) via standardized programs, based on Magnetic Stimulation. It is a non-invasive and pain free therapy. Patient can be on the treatment fully clothed, comfortably, while reading a newspaper. The QRS®-PelviCenter makes use of a strong homogenous magnetic field which is able to penetrate deep into the Pelvic Floor and thereby to stimulate all surrounding nerves and train each relevant muscles.

Weaknesses in the strength and coordination of the Pelvic Floor Muscles (and the supporting fascia & ligaments) and subsequent prolapse of the urinary and reproductive organs is generally accepted as the most important reason for Urinary & Fecal Incontinence and also is one of the key underlying causes of Erectile Dysfunction.

Doctors generally recommend Pelvic Floor Muscle exercises as first line of treatment. These are normally self exercises (i.e. Kegel) with the help of specialized Pelvic Floor physiotherapists, but these self-exercise have some obvious disadvantages. The QRS®-PelviCenter takes away these disadvantages and allows for automated, standardized and highly effective training of the PFM (Pelvic Floor Muscles)

The result is sharp improvement in strength and coordination of the muscles resulting in a faster rehabilitation of *continence and sexual function*.

The QRS®-PelviCenter 4-step-therapy

The QRS®-PelviCenter with the 4-step therapy is based on the TPM Transpelvine Magnetic Stimulation system that works simultaneously with oxygen insufflation, a light therapy in the visible spectrum and neurotransmitter activation using low-intensive PEMF

pulsed electromagnetic field therapy. The therapy can be used to treat pelvic floor weakness (urinary and / or fecal incontinence) and erectile dysfunction as well as irritation of the bladder.

TPM, Transpelvine magnetic stimulation of pelvic floor muscles



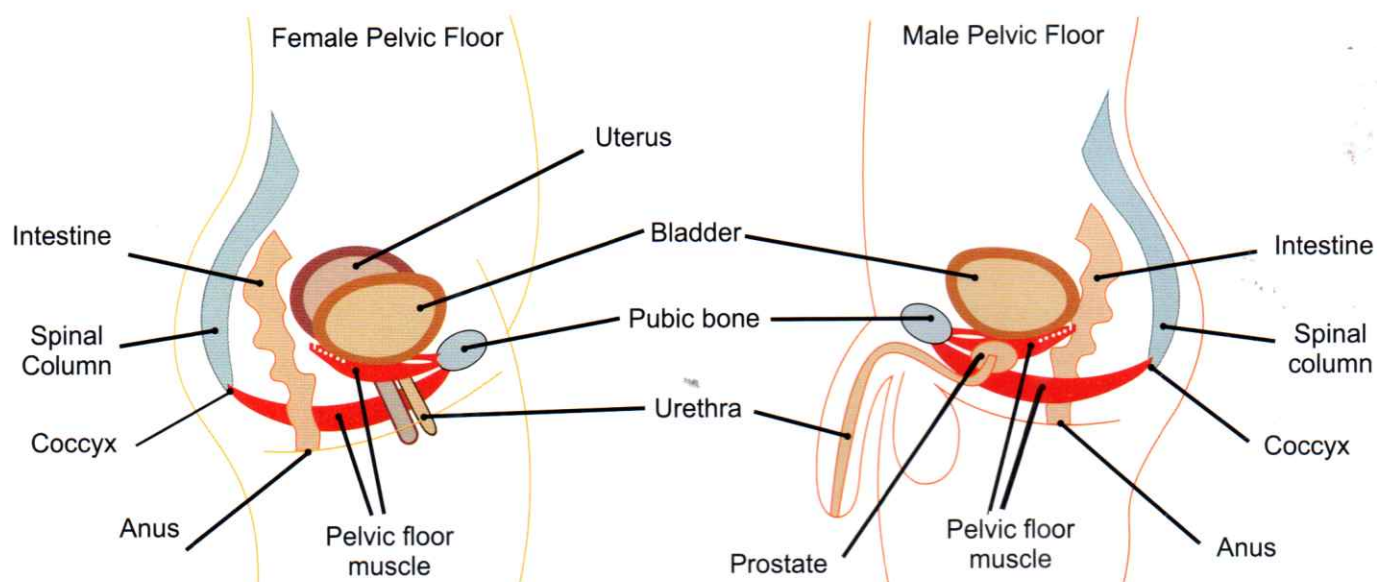
Light therapy at 10,000 lux: for the treatment of seasonal depression

Oxygen therapy during muscle activation



QRS pulsed electromagnetic field therapy

The pelvic floor muscle



The relevant muscles for ensuring continence include the internal sphincter (under involuntary control), the external sphincter and the Pelvic Floor Muscles. The external sphincter is under voluntary control of the Central Nervous System and consists of skeletal muscle fibers (losing about 2% of its strength each year). The external sphincter is primarily responsible for ensuring continence ("first line of defense").

The Pelvic Floor muscles ("second line of defense") consist of the Levator Ani and the Coccygeus. The Levator Ani consists of the Pubococcygeus muscle (PC muscle), the Puborectalis and the Iliococcygeus. The PC muscle acts as a "hammock" like muscle that stretches from the pubic bone to the tail bone.

One key function of the Pelvic Floor Muscles is to support and lift the pelvic organs. When the Pelvic Floor Muscles become weak the pelvic organs prolapse. This leads to incontinence as well as to deterioration of the sexual function.

Indications QRS®-PelviCenter

Indications are all the diseases which are wholly or partially due to:

- ◆ Weakening and/or Prolapse of the Pelvic Floor Muscles; or
- ◆ Tone of the PFM being too strong/ too tight

The QRS®-1010 PelviCenter has been successfully used in treating a wide range of lower urinary tract and pelvic floor disorders, including:

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- ◆ Fecal incontinence

In addition, the QRS®-PelviCenter has proven to be effective in other areas including sacroiliac pain in the lower back, pressure ulcers and cellulite.

QRS®-PelviCenter treatment is normally applied in combination with conservative treatments but also has exceptional results when patients follow only the PelviCenter treatments.

QRS®-PelviCenter treatment provides a useful alternative for:

- ◆ Patients doing self exercises and who have difficulty with locating the relevant muscles that need to be trained and performing a correct contraction.
- ◆ Patients who do not respond to drug therapy; or who suffer from the negative side effects of the drugs.
- ◆ Patients who are poor surgical candidates
- ◆ Patients who lack the agility to manage electrical stimulation devices
- ◆ Patients who feel uncomfortable to undress and who finds typical incontinence treatment shameful
- ◆ Patients who have a desire to avoid being continually occupied with the Incontinence problem and who do not have the stamina to comply with the daily exercise regimen.

Side effects and contra-indications

QRS® treatment is safe. There are no negative side effects and no risk of tissue damage. However there are some cautionary measures:

Absolute Contra-Indications:

- ◆ Pregnancy
- ◆ Electronic and metal implants
- ◆ Epilepsy
- ◆ Surgical operations < 3 weeks
- ◆ Severe cardiac arrhythmia

Relative contra-indications

- ◆ Menstrual period
- ◆ Acute urinary tract infection,
- ◆ Painful hemorrhoids
- ◆ Infections in the pelvic area.

QRS® PelviCenter - The safe, effective & painless therapy



A typical QRS®-treatment plan

Role of the specialist

It is important to note that every treatment plan must be set individually for each patient. This can only be realized in close cooperation with a professional doctor, who can give a prescription on the treatment plan. One QRS®-PelviCenter treatment takes 20 minutes. The doctor does not have to be present during the treatment, the assistant can operate the PelviCenter based on the treatment prescription given by the doctor.

Each patient requires an individual therapy program

The neuromuscular structure of the pelvic floor can vary widely between individual patients, specifically with respect to the amount of functional muscle mass present and the order or disorder of activity among the resident population of motor units. For example, inducing contractions within a pelvic floor that is characterized by severely atrophic muscles requires higher thresholds, compared with a case of mildly weakened pelvic musculature. The composition of the nerve fibers targeted by the QRS®-PelviCenter may also differ widely between individual patients.

QRS®-PelviCenter allows for different therapy programs

With the QRS®-1010 PelviCenter the doctor can choose different standardized, and proven, treatment plans. For example there is a standard plan for Stress, Urge, Mixed Incontinence and for Radical Prostatectomy. The doctor can also customize an individual treatment plan by changing amplitudes, duration, frequencies of the pulses as well as the recuperation ("off") time between the series of individual pulses.

Standard treatment plan involves 16 treatments

A standard QRS®-PelviCenter treatment plan involves 18 treatments of 20 minutes each. Whereby in an optimal situation there must be 3 or 4 days between each treatment. Initial results are already noticeable after 2 or 3 treatments.

Initially the patient must start the treatment with a low intensity (i.e. 20% of capacity), and during the course of the treatment plan gradually increase, depending on the situation and progress of the patient.

Chip card functionality

The QRS®-PelviCenter allows the doctor to program the required treatment plan (including number of treatments required) on a chip card, which can be passed on to the assistant/operator. By inputting the chip card, the QRS®-PelviCenter starts the prescribed treatment plan.

Therapy for urinary
incontinence and
fecal incontinence



Improve potency and
libido

Rehabilitation after
child birth

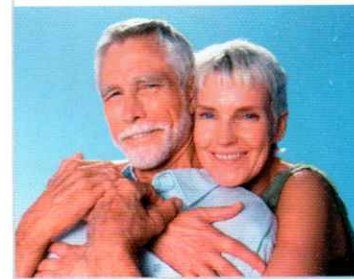


Cellulite treatment



Rehabilitation after
prostatectomy

For the general
well-being



QRS® PelviCenter Functionality



Ease of use

- ◆ Duration of treatment; 20 minutes
- ◆ No need to undress, treatment fully clothed
- ◆ Pain-free and with no side effects

Superior technology

- ◆ Top performance in high tesla range
- ◆ Built for high utilization rate
- ◆ Low noise even at high intensity

Ease of use

- ◆ Pre-set therapy programs in QRS smart card
- ◆ Easy to read instruction



Comfortable sitting position
with adjustable footrest



Easy to read control panel

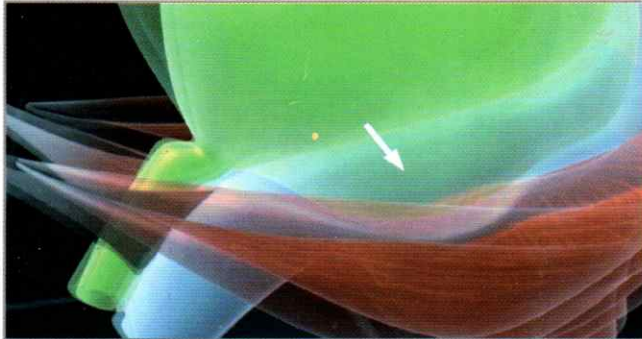
High quality leather finish



Therapy program with QRS
smart card



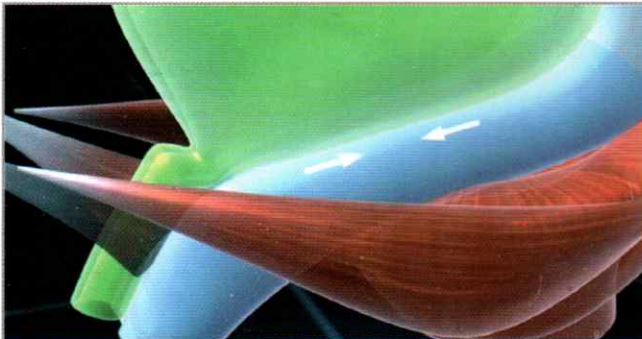
Stress incontinence therapy



The Pelvic Floor acts as a type of "hammock" and a single functional unit. If a part of the structure is weakened then the hammock has lost some of its original functional and cannot perform efficiently. As a result of stretching of the fascia and ligaments, the urinary and reproductive organs prolapse. The Pelvic Floor Muscles can no longer push the urethra against the pubic bone resulting in Incontinence (DeLancey/Petros & Ulmsten)

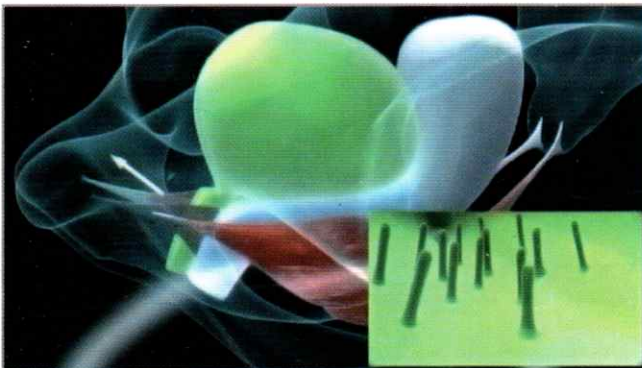


With growing age, the strength of the muscles of the external sphincter deteriorates, about 2% per year. The effect is greater with women after having given birth or after muscles and nerves have been damaged because of surgery.



The QRS®-PelviCenter treatment:

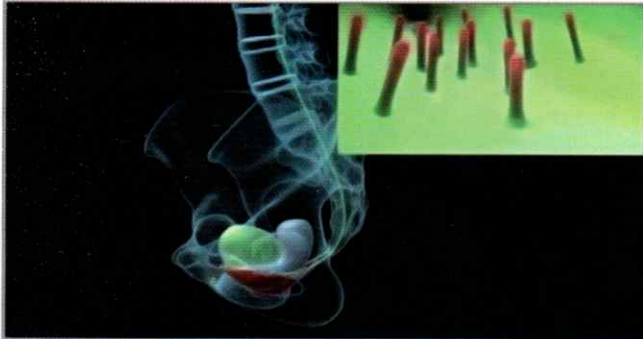
Magnetic stimulation of peripheral nerves provoke muscle contractions and facilitate the stimulation of autonomic and somatic nerve pathways in the pelvic floor. Motor evoked potentials are triggered in the pelvic sphincter muscles.



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 and strengthens both the external sphincter muscle and the muscles of the Pelvic Floor. Thereby it ensures that the Pelvic Floor Muscles are able to respond better to a sudden increase in intra-abdominal pressure. And also ensures improving of the resting urethral closure pressure.



Urge Incontinence & Bladder Overactivity



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.



The QRS®-PelviCenter therapy for Bladder Overactivity Uses low frequency, rhythmic magnetic pulses.

These reduce the overactive sensory triggers from the bladder. And also ensure inhibition of reflexes and impulses coming from the central nervous system reacting on these overactive impulses.

Rehabilitation after child birth



Vaginal delivery is an important cause of stress urinary and fecal incontinence and pelvic organ prolapse. In addition, the sexual function/ quality of vaginal climax is often affected.

The QRS®-PelviCenter treatment can assist in quickly restoring the tone of the relevant muscles. The treatments can start soon after having given birth.

A conservative continence treatment for the elderly



Urinary incontinence is one of the key problems of the elderly and affects every aspect of an elderly person's life. One of the aspects of UI is the self-imposed social isolation because of constant fear of incontinence in public, ultimately resulting in loss of self-esteem.

The economic costs of urinary incontinence to the individual and to society are enormous but the personal loss to the individual is by far the worst. Unfortunately, since urinary incontinence in the elderly is not a fatal disease, many people think it is part of the aging process.

The QRS®-PelviCenter offers a conservative treatment for the elderly in treating urinary incontinence. There is no need to implant electrodes. Only limited participation by the patient is required, as compared to active pelvic muscle exercises. QRS®-PelviCenter reaches the same improvements with Urge Incontinence as a conventional drug therapy but without the negative side effects.

QRS® PelviCenter treatment offers equal benefit to younger and older patients

Erectile dysfunction



Erectile Dysfunction can be caused by a combination of various factors including psychological, hormonal, neurologic or vascular. Key risk areas include lifestyle factors, certain diseases (i.e. Cardiovascular; Diabetes Mellitus, Parkinson), side effects of prescription drugs (i.e. anticholinergic) and hormonal factors.

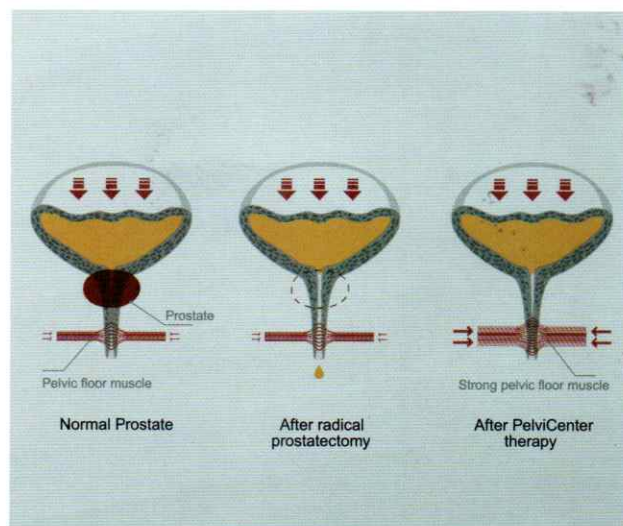
Normal penile erection (for the men) and normal sexual activity for the female requires coordinated involvement of the:

- ◆ intact central and peripheral nervous systems
- ◆ the bulbospongiosus, ischiocavernosus and pubococcygeus muscles
- ◆ normal arterial blood supply and venous outflow

The QRS®-PelviCenter works in all these areas. It activates the afferent fibers within the pudendal nerve. The pudendal nerve is of key importance to normal sexual activity, both with men and women. In addition QRS®-PelviCenter results in a sharp improvement of the tone of the relevant muscles, and has a strong positive effect on blood flow (amongst others via Nitric Oxide).

Better sexual life for men and women

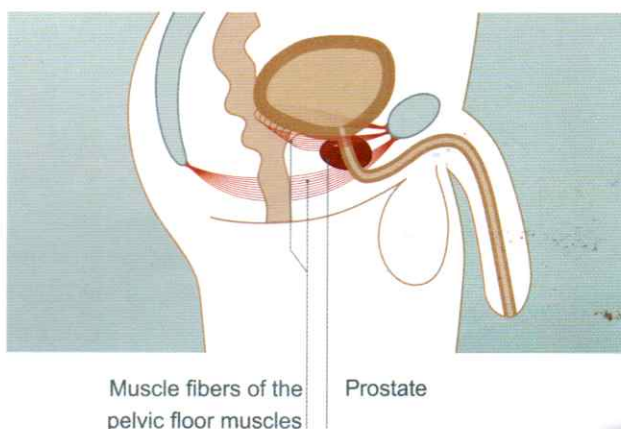
Rehabilitation after prostatectomy



Prostatectomy results in a high incidence of Urinary Incontinence and Erectile Dysfunction. Prostate removal often results in damaging soft muscle tissue and pudendal and cavernosal vessels. After prostatectomy the external sphincter becomes primarily responsible for ensuring continence. The treatment of significant sphincteric incompetence is often surgical by means of the placement of an artificial urinary sphincter.

The QRS®-PelviCenter therapy

QRS®-International has treated many patients suffering from incontinence after Prostatectomy. The QRS®-PelviCenter treatment results in a rehabilitation of the strength of the sphincter and pelvic floor muscles. Already after a few treatments do the patients notice significant improvements.



QRS®-PelviCenter – Technical Data



Dimension: 187 cm x 134cm x 173cm (HxBxT)

Weight: 120 kg

Maximum load: 135 kg

Input voltage: 230V ~, 50Hz

Output Current: max. 1265 VA

Fuse: 2x T6,3A L 250V

Output Signal

Maximum coil intensity: Maximum 2Tesla

Maximum QRS PEMF intensity: Maximal 3V, 170mA, 40μT

Light therapy module, illumination:

2x 36 Watt, 10000 Lux within 20cm distance

Oxygen output / Oxygen concentration:

87 – 96% with 0.5 to 5 l/min

Medical device category: Class IIa

Protection class: I

Protection grade: B

Encapsulation: IPX0

Environmental conditions

Operation of the device:

Temperature range +13 °C to +30 °C

Relative humidity: 30 to 75%

Transport and storage:

Temperature range +5 °C to +50 °C

Relative humidity <90%, non-condensing

Operation of the PelviCenter

- ◆ Smart card controlled
- ◆ Pre-defined treatment programs
- ◆ Intuitive menu control
- ◆ Therapy programming on the PC

Certification

Certified in accordance with Directive 93/42/EC
Medical Devices



Clinical Trials

Over the last 10 years, more than 75 studies have been carried out into various forms of electro stimulation and magnetic stimulation. In total more than 3.000 patients have been included in the clinical trials.

QRS®-International has perfected the technology and has introduced the QRS®-1010 PelviCenter.

Currently various Randomized Clinical Trials are underway in Europe, Asia, USA and in the Middle East.

In India, a Randomized Clinical Trial is carried out by the Dr. Ram Manor Lohia hospital in Delhi.

Please contact one of our representatives for more information about the status and conclusions of these trials.

About QRS® India Pvt Ltd

QRS® India Pvt Ltd is a subsidiary of QRS®-International AG, Liechtenstein. QRS®-International (previously known as "Quanten-Medicine AG") was founded in 1990 and has since been the technological leader in the field of Pulsed Electro Magnetic Field therapy. Technological leader means that:

- ◆ QRS®-International has a strong R&D department (working closely with universities from Germany and Switzerland and USA)
- ◆ All the relevant patents in the field of Magnetic Therapy are registered on the name of QRS®-International
- ◆ QRS®-International was the first in the field of Magnetic successful consumer product, the "Salut" (now the QRS®-101 home system). And continues to be the first and leading in the professional market where it launches new powerful solutions on a regular basis.

Contacts

Please contact one of our representatives who will be happy to explain you in more detail about our products.

Also, on request we can provide you with a paper explaining in detail the technical background of the QRS®-PelviCenter and how it realizes the clinical objectives as described in this brochure.

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QRS® - Evidence Based Magnetic Applications

QRS® Professional & Home Models



QRS PelviCenter

Installed at Dr. Ram Manohar Lohia Hospital, New Delhi
at Urology Department & benefitting lot of people



QRS 301 for Doctors



QRS 301 for Doctors



QRS 700 Quantum Waver



QRS 101 Therapy System

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