

Standard Treatment Protocol QRS Pelvicenter and Lower Back Pain



Introduction:

QRS Pelvicenter is a unique medical device. It is the only system which has been proven in Level 1 Double Blind Placebo-controlled Randomized Clinical Study (with long term follow-up) to be effective in automatically training the coordination, function and strength of pelvic floor and other core muscles. Thereby, when QRS Pelvicenter is used as a complementary therapy, it has proven positive effects on a variety of indications including treating a variety of sports injuries, sexual dysfunction, urinary incontinence. Also, QRS-Pelvicenter is often used for body forming purposes. One other key indication where QRS Pelvicenter is super effective is in treating lower back pain and spinal instability. QRS is even making a claim that QRS-Pelvicenter is the only system in the world which is able to not just reduce back pain in minutes without side effects, but which is also able to treat the key underlying cause of lower back pain (which is weak pelvic floor muscles and non-functioning of other local segmental core muscles (such as the important multi-fidus muscle). Other therapies (e.g., pain medication, massage) can result in temporary improvement of the symptoms (pain relief) but do not help in training the relevant muscles and the result is a high recurrence rate of lower back pain. This document provides the standard treatment protocol for treating lower back pain with QRS Pelvicenter. There are important differences as to the treatment protocol of other indications.

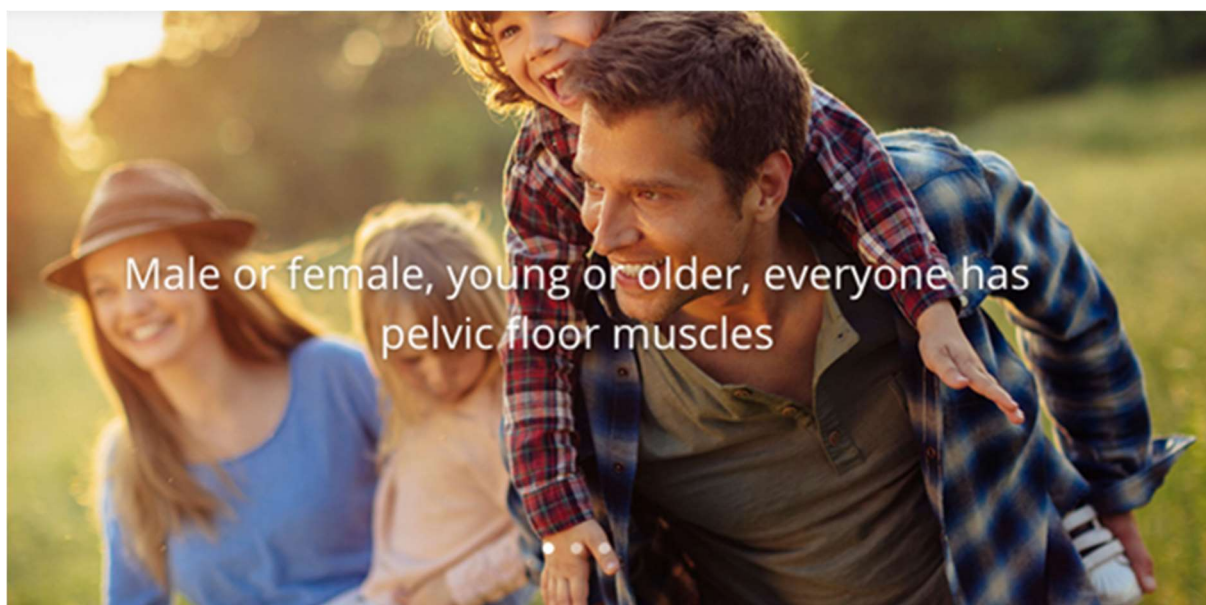
Summary treatment protocol QRS Pelvicenter and Lower Back Pain/ spinal instability:

2 different programs to be used in combination

There is not a standard program which works for everybody. Every patient is different. And the exact treatment protocol can only be defined after diagnosis by a doctor. However, in general, given the fact that various muscle groups must be treated we recommend a protocol with 2 different positions:

1. Normal STRENGTH training of the pelvic floor muscles (high intensity, high frequency)
2. Training of improved FUNCTION of Multifidus muscle by focusing on the stimulation on the spinal cord (L4/L5) (low intensity, low frequency)

Please note that we also advise the patient uses at home the QRS-101 Home Therapy System as complementary therapy.



1. Normal strength training of the pelvic floor muscles

The most important cause of Lower Back Pain is weak pelvic floor muscles. If the pelvic floor muscles (which form part of the core muscles) are weak, the pelvic floor is not able to support the weight of the upper body and the spinal cord becomes instable. Thus, the focus of the Pelvicenter therapy is on training the fast twitch muscle fibers of the pelvic floor by using high frequency (between 35 and 50 Herz) and high intensity and ensure that the patient continues to do the therapy at high intensity for various sessions to ensure long term success. In short:

- Sitting position:
 - Sit straight on the QRS Pelvicenter, slightly bending to the front (thus less than 90-degree angle between thighs/legs and the upper body) (thus do NOT put the back seat of the QRS Pelvicenter to the back and do NOT sit relaxed behind)
 - Keep the legs a little wide open from each other, left leg to the left, right leg to the right, the result is the muscles open a bit more and the stimulation reaches deeper and more effective
- Position the magnetic coil in the middle of the pelvic floor muscles, close to the urinary sphincter (depending on the size of the patient between 4 and 6 cm)
- First session:
 - start first session with focus on improving FUNCTION, with low frequency (for example 15 to 25 Herz) and low intensity (start with level 1 / 20%). After the patient feels comfortable, move the frequency to 50 Herz
- Next sessions:
 - then start step-by-step (session by session) increasing the intensity. Thus, after improving the function and coordination of the pelvic floor muscles, now in the 2nd and subsequent sessions the focus is more on improving strength by using frequencies between 35Hz and 50Hz and by using high intensities
- Number of sessions:
 - be careful not to overdo the therapy, only do 15 to 20 minutes for each session. customer can do one session everyday but only if he/she does not feel muscle pain from the previous session
 - do 16 therapy sessions. Clinical studies show that almost everybody realizes positive effects and improvements within 6 sessions. But it is important to continue the therapy and do at least 5 or 6 sessions at highest intensity so that the therapy can result in a long term sustainable positive effect on reducing the number and intensity of back pain episodes.

2. Focus the therapy on the Multifidus muscle

The second most important cause of lower back pain / spinal instability is the non-functioning of local segmental muscles, in particular the “multi-fidus”. This is a muscle which is small, and which lies deep and surrounds the spinal cord. The multifidus muscle has an important function in anticipating movements of the body and always ensuring that the spinal cord remains stable. Research shows that almost everybody who suffers from lower back pain, also have a non-functioning multifidus muscle. The patient at a certain day may not suffer from back pain, but as soon as he/ she makes a strange movement then the multifidus is too late in responding resulting in spinal instability and back pain.

Importantly the multifidus does not respond to strength training. The focus is thus on improving function which means also that it is not necessary to use high frequencies.

Treatment protocol:

- Sitting position.
 - Put the backrest of the pelvicenter to the back, resulting in the patient to lean a little bit to the back
 - Pull up your feet and place them on top of the chair. The result is that now your L4 L5 S1 is closer connected to the bottom side of the pelvic floor, directly above the magnetic coil
 - Move the magnetic coil to the back (0 cm)
 - Alternative sitting position: To sit STRAIGHT (back rest of pelvicenter straight) and position the magnetic coil directly under the spinal cord (0 cm)
- Position the magnetic coil on the back, directly under the spinal cord
- First and subsequent sessions:
 - Use LOW Frequencies and LOW to MEDIUM Intensities
 - Frequencies: remember that the multifidus does not respond to strength training. So do not use high frequencies (35 to 50 Herz). Instead focus on improving the function of the multifidus by using low frequencies (e.g., 10 Herz)
 - Intensity: The therapy must not be painful. So best to start with Level 1 / 20% and maybe increase to level 2 but it is normally not necessary to increase the intensity. The pulsating magnetic fields of QRS penetrate through the whole body.
- Number of sessions:
 - be careful not to overdo the therapy, only do 15 to 20 minutes for each session. customer can do one session everyday but only if he/she does not feel muscle pain from the previous session
 - do 16 therapy sessions. You can combine this part of the therapy also with the first part of the therapy. Thus 10 minutes focus on building strength of pelvic floor muscles (high intensity, 35 to 50Hz) and 10 minutes focus on improving function of multifidus (different sitting position, low intensity, low frequency).

Further explanation on why QRS Pelvicenter is the only therapy in the world which can treat the core cause of lower back pain and thereby is able to reduce the recurrence rate of lower back pain

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).

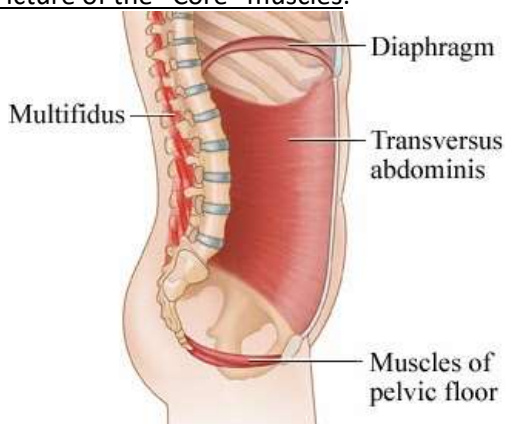
The function of these small and deep muscles can only be trained effectively with magnetic stimulation.

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:



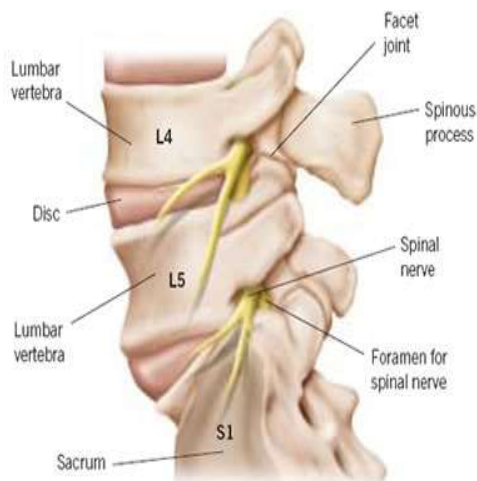
Lower back pain and Pelvic Floor Muscle Exercises:

- 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, all “Core” muscles are related and must work together.
 - The Pelvic Floor is co-active connected to Transversus Abdominus and Multifidus. Training of the Transversus Abdominus 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:

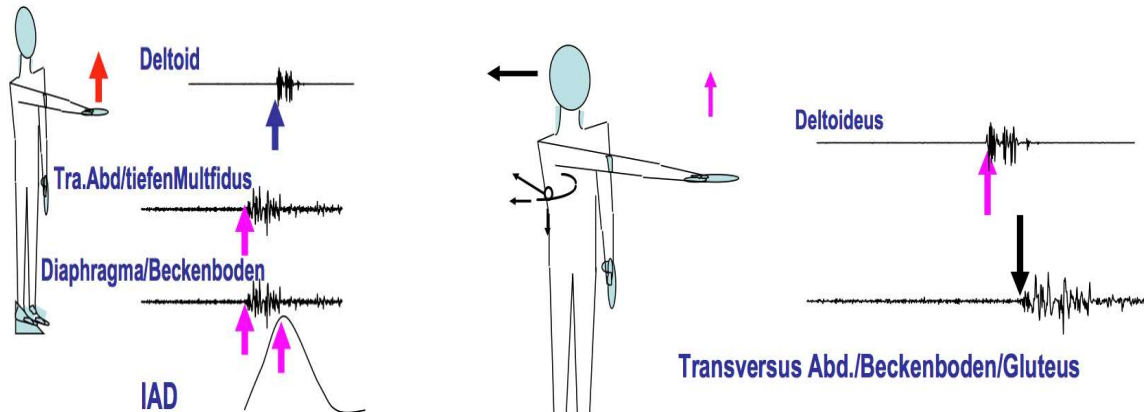
- In Europe/ USA, patients with lower back pain are routinely referred to physiotherapy
- Most common treatment in Europe/ USA of physiotherapists against Lower Back Pain is ‘muscle activation’ / ‘core stability’ exercises.
- Many studies have been carried out on “core stability” exercises. Studies do 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:



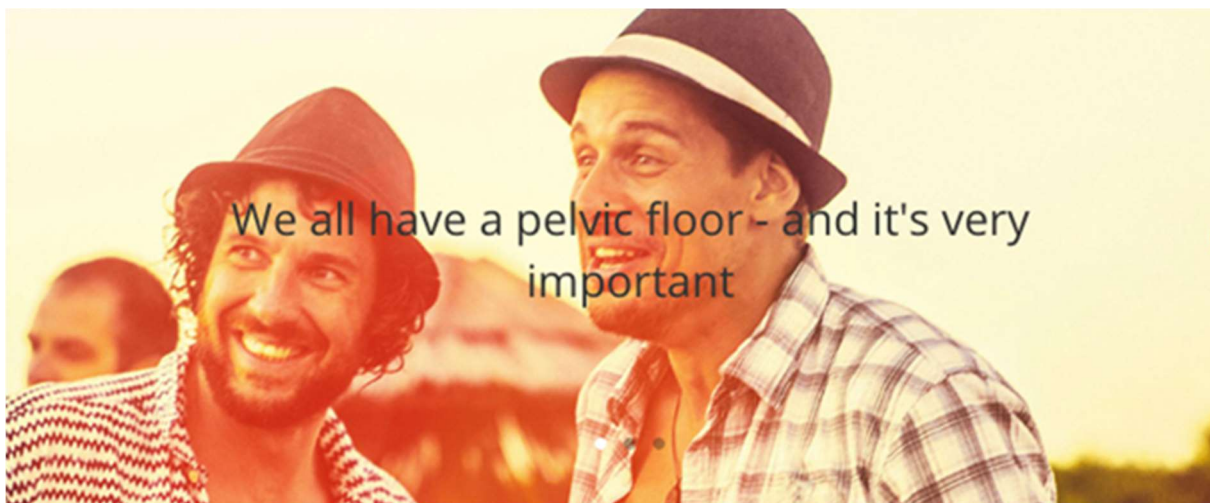
- Spinal Segmental Instability is defined as an abnormal response to applied loads, characterized by movement of spinal segments beyond the normal constraints.
- Instability of the lumbar spine often occurs in L4-L5 or L5-S1
- Distinction between “global muscles” and “local muscles”:
 - Global muscles 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. Obliques 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; obliques internis; Rotators). You cannot 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 can train these deep small muscles that a patient cannot train him/herself. The focus is on restoring the function of the Multifidus and Transversus Abdominis and all the other core muscles. The focus is on restoring the “feed-forward” mechanism.

Picture "Feed-Forward" mechanism (Urguhart 2005)



No back pain:
Core muscles anticipate movement

Lower back pain:
Core muscles are 150 milliseconds too late



About the QRS-101 Home Therapy System:

It is strongly recommended that everyone who suffers from Lower Back Pain also uses the QRS-101 System as a complementary therapy at home. QRS-101 System is the Original PEMF therapy system from Germany which has two key purposes:

1. It has been proven to be effective as a complementary therapy in treating all chronic pains and chronic diseases. If you suffer from a chronic disease, please contact your own doctor and follow exactly the protocol as prescribed by your doctor. But if you use QRS as a complementary therapy then you will always realize positive effects. For example, when suffering from Heart Disease, Neurological Disease, Lung Disease, Diabetes and all body pains. Are you suffering from Back Pain, Hip Pain, Knee Pain, Foot Pain, Neck Pain, Shoulder Pain, Migraine. Use QRS and you will realize a fast reduction of pain without side effects
2. QRS is essential PREVENTATIVE therapy for everybody. Not just for older people suffering from chronic disease. But also, for middle-aged persons, young children. 8 minutes of QRS Therapy at home gives you the same proven biological effects as that of a 2-hour daily walk. 8 minutes QRS Therapy results in a strong improvement of blood circulation, oxygenation of all cells & tissues. The result is that all your cells start producing more energy and start to function better. This means for example a reduced blood pressure if you suffer from hypertension. Or better functioning of your brain in case you want to prevent yourself or your loved ones from neurological disease.



Appendix : Summary

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 sphincter, 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 QRS-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.