Treatment protocol QRS®-PelviCenter and Erectile Dysfunction & Premature Ejaculation

1. Introduction

This document describes the standard treatment protocol for treating Erectile Dysfunction and Premature Ejaculation with the QRS®-PelviCenter.

The treatment protocol is meant for doctors and nurses/ operators.

Please refer to other documents for:
- detailed explanation and training program of the QRS®-PelviCenter
- detailed treatment protocol Stress Urinary Incontinence
- detailed treatment protocol Urge Urinary Incontinenec

The contents of this document are:
1. Introduction
2. General notes on QRS®-PelviCenter, frequently asked questions (FAQ)
3. Treatment protocol QRS®-PelviCenter and ED & Premature Ejaculation

Appendix:
1. Relevant clinical trial literature about proven effects of Pelvic Floor Muscle training on improving sexual function men
2. Other relevant literature in relation to Erectile Dysfunction
3. Literature in relation to improving sexual function of women
4. Relevant literature in relation to the effects of QRS®-101 on Erectile Dysfunction
5. Kegel exercises. How to identify the right muscles and how to do the Kegel exercises.

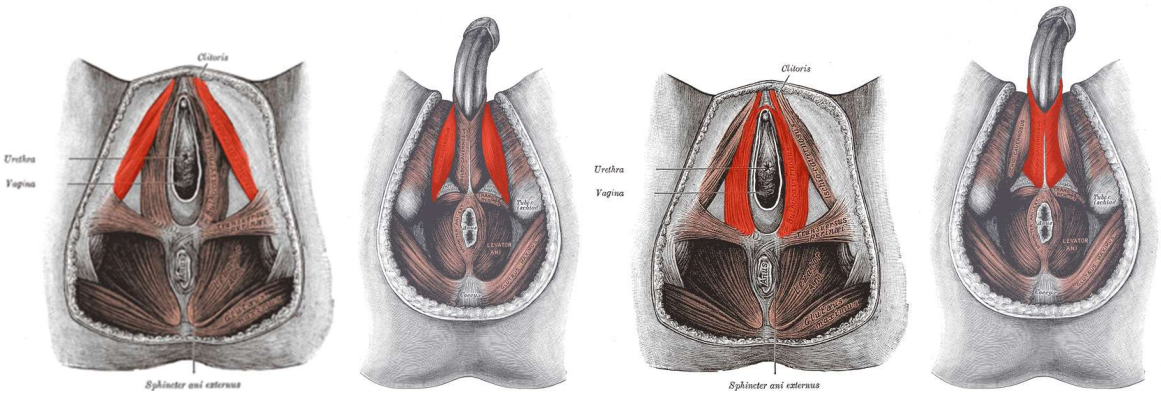
2. General notes QRS®-PelviCenter

2.1 Explanation to the customer. How does the QRS®-PelviCenter help for ED?

2.1.1 Automated training of the Pelvic Floor Muscles

- The PelviCenter is *automatically* training the muscles of the Pelvic Floor. Specifically it automatically trains the 1) coordination, 2) function and 3) strength of the pelvic floor muscles. It can be used as complementary treatment in all indications where Kegel exercises are prescribed as a treatment.

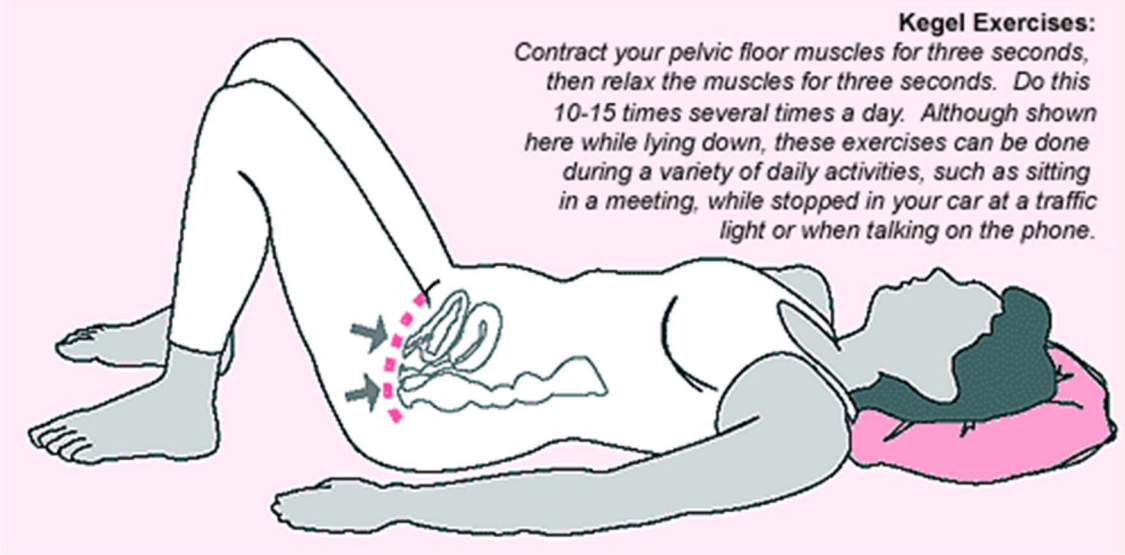
- **What are Pelvic Floor Muscle Exercises ("Kegel exercises")?**
  - Many men do not know that they have Pelvic Floor Muscles (PFM); they do not know where they are; they do not know what they are doing; they do not know how to train those muscles. However, Pelvic Floor Muscles (PFM) are one of the biggest set of muscles in the human body and have very important functions.
    - Support (slow-twitch = type I = red muscles) (70%):
      - PFMs carry the weight of the upper body including the spinal cord. Weakening of the Pelvic Floor muscles is one of the causes of lower back pain. PFMs also carry and support the urinary and reproductive organs.
    - Action (fast-twitch = type 2 = white muscles) (30%):
      - PFMs play an important role in closing the urethra in case of increased abdominal pressure, thereby ensuring that the person does not loose urine.
      - PFMs play an important role in sexual function. In pumping the blood into the penis, in ensuring that the blood stays in the penis, in maintaining and sustaining a strong erection, in ejaculating the semen.
  - 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)



- Training of the Pelvic Floor Muscles is similar to training of other muscle groups in the human body.
    - Many questions that a customer has about QRS®-PelviCenter training or of training of the Pelvic Floor Muscles can be answered by comparing to the training of other muscle groups. For example questions such as
        - "how long can I do PelviCenter training?";
        - "how many treatments can I do per week?";
        - "can I do only 1 treatment per week or per month instead of 2 or 3 per week?";
        - "how quickly will I notice results?";
        - "do I have to come back after completing the QRS®-PelviCenter treatment program?"
        - "is QRS®-PelviCenter training safe?"
        - "can I increase the intensity of the training already on the first treatment?"
        - "can I do 40 minutes of PelviCenter training instead of just 20"?
        - "is it more effective to do short duration, high intensive anaerobic exercises (6-10 reps, total 20-30 sec) or is it more effective to do longer aerobic based repetitions for endurance?"
    - QRS®-PelviCenter training is training of the Pelvic Floor Muscles
    - Training of Pelvic Floor Muscles is similar to training of other muscle groups in the human body (e.g. the biceps in the upper arm or legs).
    - Training of muscles requires the repetitive Contraction and Relaxation of muscles.
    - Muscles get tired very quickly and normally a person can not train intensively his/ her muscles for more than 20 minutes.
    - QRS®-PelviCenter training is a very intensive training of the muscles and customers must not underestimate the intensity of the training. Especially when using higher frequencies the pelvic floor muscles get tired very quickly. Many customers feel PelviCenter as a comfortable treatment and think that they can easily do higher frequencies or longer duration or do QRS®-PelviCenter training every day. This is a mistake. Especially in the beginning the customers must start slowly to avoid that muscles get tired and become painful the next day. If muscles get tired the customer will initially notice a decrease of the function of the muscles instead of an improvement. In other words: If a customer uses the QRS®-PelviCenter to improve his sexual function but when he is too ambitious in the beginning, he will notice after the first treatments a deterioration in his sexual function rather than an improvement. This effect is normally only short term and after a few days the customer will then start to notice the improvement in sexual function.

2.1.2 What are Kegel exercises?

- Kegel exercises (Pelvic Floor Muscle Training) have been used in Europe and USA for the last 60 years as the most important conservative (= non surgical) 'first line treatment' in treating pelvic floor disorders such as Urinary Incontinence (UI), Women Sexual function, and Men Erectile Dysfunction (ED).
- An important cause of UI and ED is the weakening of the muscles of the pelvic floor.
- In order to improve, customers are recommended to do "self-exercises" of the PFM (Pelvic Floor Muscles).
- More information about Arnold Kegel:
  - Arnold Kegel was an American gynecologist (1894-1981)
  - Arnold Kegel popularized exercises of the PFM to improve sexual and urinary health of women after childbirth
  - 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.
  - Additionally, Kegel recognized that surgery to correct vaginal, urethral, and rectal incompetence could be facilitated by preoperative and postoperative PFMT to improve the texture, tone, and function of the perineal muscles.
- Kegel exercises are not only for women but also for men
  - Experts in female pelvic health have widely adopted PFMT. Females are often introduced to Kegel exercises at their first gynecology visit and thereafter the exercises are reinforced at many other visits, particularly during pregnancy and postpartum, whereas men do not see urologists for routine well care.
  - Men have similar pelvic floor muscles as do women, with the potential for parallel benefits to urinary and sexual health. However, most men are unfamiliar with PFM exercises, and urologists do normally not envision their role as instructors of PFM training.



2.1.3 Why are Kegel exercises important to customers suffering from ED?

- Definition Erectile Dysfunction:
  - Erectile Dysfunction is defined as "...the inability <to get or maintain> a <rigid> erection of the penis during sexual intercourse..."
  - It is important to note that ED is not only about "getting" an erection but also about "maintaining and sustaining" an erection.
- Getting an erection:
  - In order to get an erection, various factors are of importance. In particular the relaxation of the smooth muscles and subsequent flow of blood into the penis ['smooth' muscles are the muscles which are not controlled by the brain; this as opposed to 'skeletal' muscles which can be contracted voluntary after instruction by the brain]
- Maintaining a rigid erection and ensuring strong ejaculations:
  - What many people do not realize, however, is that an important factor to maintain a rigid erection is that the (skeletal) muscles of the pelvic floor ensure that the blood stays in the penis and thus avoid venous outflow.
  - Also, strong pelvic floor muscles (especially the Ischiocavernosus muscle and also the Bulbospongiosus muscle) are of key importance in the contractions during ejaculation, and thereby are a key factor in the force and satisfaction of the sexual climax.
    Many men when they get older suffer from decreased ejaculatory force.
  - Stronger pelvic floor muscles result in the man having more control over the muscles during sexual intercourse and thereby also helping to delay an ejaculation and thereby helping with Premature Ejaculation.
  - Every man (and woman) loses about 2% of the strength of the pelvic floor muscles each year.
    Especially when the man only has limited sexual activity (limited "training") the muscles loose their strength very quickly ["Use it or loose it"]
  - If you want to be able to have a strong sexual performance, it is important to improve the function and strength of the relevant pelvic floor muscles.
    This can be done by self-training (Kegel exercises) supported with QRS®-PelviCenter training.

2.1.4 Kegel exercises have been proven effective in improving sexual function

- The importance of strong pelvic floor muscles for sexual activity has been proven by various clinical research in Europe, amongst others in UK (Dorey), Belgium (Prof. Van Kampen), Germany (Prof. Sommer).
  - Please refer to appendix 1 to this document for a listing of relevant clinical trials about the effect of Pelvic Floor Muscles exercises on improving sexual function.
- One important conclusion of the studies carried out in Europe is that a significant part of men who suffer from ED have so-called "venous-occlusion dysfunction". This means that the muscles are too weak to ensure that the blood stays in the penis. The study of Prof. Sommer from Germany reported that up to 60% of men with ED have a problem with "venous-occlusion dysfunction" caused by weak pelvic floor muscles. Kegel exercises and QRS®-PelviCenter training are particularly useful and effective in this group of men suffering from ED. Please refer to the appendix.

2.1.5 3 problems with Kegel exercises:

- Kegel exercises have thus been proven for more than 60 years to be effective in improving sexual performance not only of men but also of women.

  However, there are 3 key problems with Kegel exercises:

  1) Many men (and women) find it very difficult to identify the right muscles that need to be trained.

  And thus they need the help of a trained doctor who can show them the relevant muscles in an uncomfortable way. Uncomfortable means that, in addition to digital palpation or biofeedback, often doctors need to touch the genital areas of the customer to help the customer identify the muscles.

  Also, importantly. Please note that, until now (before QRS-PelviCenter), Kegel exercises can not be effectively explained without either digital palpation or biofeedback. Evidence shows that based on verbal instruction alone, only 50% of the patients/customers were able to correctly do the Kegel exercises; and 25% of the patients after verbal explanation of Kegel exercises even displays incontinence or ED promoting effort ('bearing down rather than drawing up the pelvic floor muscles'). If you carry out Kegel exercises in the wrong way it can have a negative rather than positive effect.

  2) When the man knows which muscles to train it is very important that the man is motivated and committed enough to do these exercises every day 3 times per day and every time minimum 20 times (so minimum 60 exercises per day).

  3) It is difficult to increase the intensity of the training.
  When self-training other muscle groups of the human body (e.g. the muscles of the upper arms) it is possible to intensify the treatment by using heavier weights.
  When self-training the Pelvic Floor Muscles this is very difficult to do.

Note: QRS-PelviCenter helps effectively with all 3 inherent problems of Kegel exercises:

1) One session of QRS-PelviCenter helps the customer to immediately identify where the relevant pelvic floor muscles are. So that he/ she can continue doing the Kegel exercises themselves at home.

2) QRS-PelviCenter treatment is highly comfortable and does not require commitment. During a 20 minute treatment there are at least 100 repetitive muscle contractions (and relaxations)

3) With QRS-PelviCenter it is easy to intensify the treatment by increasing the load (the intensity of the magnetic field).

2.1.6 How to do Kegel exercises?

- Doing Kegel exercises is not easy and requires the support of a trained doctor or physiotherapist. There are two important points:
  - First the customer must learn to identify and feel the right muscles. Many people do not know that they have pelvic floor muscles, do not know what the purpose is of these muscles and do not know where they are or how to train them. There is a risk that customers start training the wrong muscles (for example the muscles of the abdomen). Training the wrong muscles can lead to aggravation of the problem of sexual dysfunction.
  - Second, the customer must be committed to do the exercises every day, 3 times per day and minimum 20 exercises per time (minimum 60 per day). This requires active involvement of the customer. Many men and women do not have the time or motivation to do this.
  - Please refer to appendix 4 for a detailed explanation of how to do the Kegel exercises for men.

2.1.7 **Complementary**:

- It is important to explain to the customer that the QRS®-PelviCenter treatments are complementary to Kegel self-exercises. And complementary to some other ED treatments. Often customers starting with the QRS®-PelviCenter treatment will feel and decide for themselves that they can reduce or stop with certain medication (and thus reduce the negative side effects) or other treatment. But QRS-doctors will never advise to stop with a treatment prescribed by the family doctor of the customer.
- If the customer wants to realize quick results it is recommended that the customer does not only do PelviCenter treatments in the clinic. It is recommended that the customer also carries out regular exercises at home.
- Also, QRS®-PelviCenter treatment can be used together with other treatments. For example with the QRS®-101 Home System. Or with natural & homeopathic solutions which improve sexual function.

2.1.8 How quickly can results be expected from the QRS®-PelviCenter treatment?

- Every customer is different. But in general, if a customer starts intensive exercise (both QRS®-PelviCenter 2 or 3 times per week and self-exercises at home) then the customer must start to feel good improvements after 3 weeks.
  "Good improvements" means that an individual with untrained muscles will be able to achieve measurable strength gains resulting from "learning" how to use the muscle.
- If the customer only carries out QRS®-PelviCenter treatments and does not do self-exercises, then the recommended treatment program is 16 treatments.
- Additional note: Clinical trials have shown the following:
  - A lot of customers suffering from ED already notice a subjective improvement after the 1st treatment. However, clinical improvement is often realized after about 9 or 10 treatments.

- Additional note:
  - Often men suffering from ED are looking for a "quick" solution. Often a man prefers to "take a drug with immediate effect" rather than having to follow a treatment of 16 times whereby the customer has to come back to the clinic 16 times.
  - Although this is understandable behaviour it is stressed that a lot of these "quick-fix" solutions only treat the symptoms and they do not treat the underlying causes of the ED. QRS®-101 and QRS®-1010 PelviCenter treatment are focused in treating the causes of ED.
    And an important cause for ED is the weakening of the muscles which result in blood flowing out too quickly from the penis.
  - It is therefore recommended for customers to use the QRS®-PelviCenter treatment complementary to other treatments.

2.1.9 Can we give a guarantee to the customer?

- Kegel exercises (manual or via QRS®-PelviCenter) will result in strengthening of the Pelvic Floor muscles. This can be measured. But the customer will also be able to feel it. The customer will be able to feel more control and strength in his muscles during sexual activity. And will have ejaculations with more force.
- Apart from that, please note that no medical solution is able to give guarantees since there will always be customers/ customers who can not be helped by the medical solution. Especially in the case of Erectile Dysfunction.
- ED can have many different causes and for some causes it is clear that the QRS®-PelviCenter will not be able to help. Often a patient suffering from ED has more than 1 cause for the ED. If the cause is "venous occlusive dysfunction" then real positive effects are expected from the QRS-PelviCenter treatment. If there are also other causes then the customer must be advised to follow another treatment. Please refer to the next paragraph for information about customers where the QRS®-PelviCenter treatment will have limited positive effect.

2.1.10 Customers where the QRS®-PelviCenter will have limited effect

- QRS®-PelviCenter is not the magical solution for all customers suffering from Erectile Dysfunction. ED can have many causes. And very often for one patient there is more than one cause for the ED. In some situations the customer must be advised to follow other treatments rather than the QRS®-PelviCenter treatment. Or the customer must be advised to use QRS®-PelviCenter only as a complementary treatment in addition to other treatments. This is especially the case in the following situations:
  - ED which is caused by non-vascular and non-muscular causes:
    - Psychogenic (depression, anxiety, marital discord)
    - Endocrinologic (hormonal abnormalities, testosterone, thyroidism)
    - Pharmacologic (ED as the side effects of certain medication, e.g. alpha & beta blockers, anti depressants).
    - Severe neurogenic disease, for example:
      - ED which is the result of long-term diabetes (i.e. 10 to 15 years). Long term diabetes has a negative effect on both the peripheral nerves and the blood vessels/ capillaries in the penis and pelvic floor. QRS®-PelviCenter works via stimulating the nerves (which in turn trigger a contraction of the muscles). If there is no intact nervous system in place then the QRS®-PelviCenter treatments will have limited effect. In those cases it is advised to follow other treatments. And we must avoid to raise high expectations to the customers.
  - Important: Please note that a customer who suffers from ED, there is often more than one cause for his ED. It is thus possible that QRS-PelviCenter "cures"/ significantly improves one important cause but that the customer still has a problem with sexual performance because of other reasons.
    - The doctor must make a detailed analysis of the customer before starting of the QRS-PelviCenter treatments and clearly analyze the different causes. And prescribe other treatment for the other causes.
    - Note that research in Germany has shown that 35% to 60% of the men suffering from ED have a problem with "Venous Occlusive Dysfunction" (research F. Sommer). This is where QRS-PelviCenter is very effective. But it is possible that the customer also has other causes such as cardiovascular disease (resulting in various things including the narrowing of blood vessels) or diabetes (resulting in 'destroying' of the nerves and the blood vessels). QRS has solutions to treat some of the other causes (for example QRS-101 which is very effective in treating Cardiovascular disease and the key symptoms of diabetes) but customer must thus not expect that QRS-PelviCenter is the solution for all the causes of ED.

2.1.11 More information on the function of Ischiocavernosus and Bulbospongiosus muscle

- The BC and the IC muscles are of particular importance during the erectile process. These PFMs activate and engage during penile erections, and their contractions:
    - Help prevent the exodus of blood from the penis
    - Enhance penile rigidity
    - Allow for intracorporeal pressure to far exceed systemic systolic pressure
- The Bulbospongiosus muscle:
    - supports and maintains pressure within the turgid corpus spongiosum and glans.
- The Ischiocavernosus muscle (IC):
    - The IC supports, stabilizes, and compresses the corpora cavernosa, impeding the return of blood to maintain pressure and rigidity within the corpora cavernosa.
    - The IC supports the penile crura, the foundational support that, when robust, allows a more “skyward” angling erection.
    - The 1909 Gray’s Anatomy labeled the IC muscle the “erector penis”.

2.1.12 Recommended 16 treatments of 20 minutes in total – 2 or 3 treatments per week

2.1.12.1 Standard treatment program is 16 treatments

- The customer is advised to sign up for a full package of 16 treatments to be completed in a 5 to 8 week period.
- Experience with QRS®-PelviCenter in clinics/ hospitals and in clinical research have shown that in general, 16 or 18 treatments is the most effective in improving sexual function. Clinical research shows that, on average, customers start to feel clinical measurable improvement after about 9 or 10 treatments.
    - Very important is that the customer tries to get to high intensity levels. Customers who complete the 16 treatments and are only on 20% or 40% of the maximum intensity of the QRS®-PelviCenter have a lower chance of improvement than customers who are on 80% or even 100% after 16 treatments. For the doctor/ operator it is therefore important to motivate the patients to use the PelviCenter at higher intensities.
    - Not every customer is the same. Some customers will feel significant improvements in sexual function already after a few treatments. This happens often in the case of men after nerve sparing Radical Prostatectomy. However, it is also possible that some customers need 18, 20 or 24 treatments.

2.1.12.2 Normally 2 or 3 treatments per week

- QRS®-PelviCenter training is intensive training of the muscles of the Pelvic Floor
- Training of the pelvic floor muscles is similar to training of other muscles of the human body. For example training of the biceps in the gym/ fitness center.
- For a person with untrained muscles it is normally not possible to do intensive training for more than 20 minutes per day. Or to do intensive training every day. Normally when a customer goes for the first time to the gym/ fitness center to train the muscles of the abdomen or upper arm, he will not be able to go to the gym the next day because his muscles are tired and need to rest.
- This is the same with QRS®-PelviCenter training. The QRS®-PelviCenter training is more intensive to the muscles than customer tend to think. Especially when using high frequencies (i.e. 40 or 50 Herz) the muscles get tired very quickly. Therefore the recommendation is as follows:
    - For new customers with untrained pelvic floor muscles, to do only 2 treatments in the first week. Minimum one day of rest in between the treatments. Also, start with low frequencies to warm up the muscles and to first focus on improving of the coordination and function of the muscles. Avoid being too ambitious and going to too high frequencies or intensities in the first treatment. Customers will complain the next day of muscle soreness and the results of training too intensively will result in a temporary deterioration of the sexual function rather than an improvement (because the muscles will be tired and weakened).
    - For customers who have been doing 2 or 3 treatments it is possible to do for example 3 or more treatments per week. The general advise is to take one day of rest in between the treatments (i.e. treatment on Monday, Wednesday, Friday). If the patient wishes to do treatment every day, the general advise is for him to check in the morning whether he has muscle soreness from the last treatment. If yes, then it is advised to wait one or two days.

- Q&A:
  - Question: Can customers do only 1 treatment per week or 1 treatment per month?
  - Answer:
    - This is not recommended. In general, 1 QRS®-PelviCenter treatment per month is not sufficient to build strength of the muscles. It is comparable to going one-time per month to the fitness room to train the muscles of the abdomen or upper arm. If the customer wishes to see quick results it is recommended to do 2 or 3 treatments per week. If a customer is not able to do more than 1 treatment per week then it is important that the customer carries out some self-exercises at home (Kegel exercises) during the days that he is not taking the QRS®-PelviCenter training.

2.1.12.3 Focus on short duration, high intensity anaerobic muscle contractions

- Training the pelvic floor muscles is similar to training other muscle groups in the human body.

- After the age of 25 the human body loses between 1% and 2% of muscle mass every year:
  - Increase of muscle mass until age of 25. Fast muscle growth during puberty, especially men, especially fast growth based on testosterone.
  - Between 25 and 30 muscle mass stabilizes
  - Between 30 and 50 decrease of muscle mass by about 1% per year. Often the person is losing muscle mass and gaining fat mass. Density of muscle is higher than density of fat.
  - After 50 faster decrease of muscle mass, especially after menopause.
  - After age of 70, people get very vulnerable to stay in the hospital. A stay in the hospital of 7 days can already result in a decrease of muscle mass by 15% or more.
  - Important principle in relation to muscles: “Use it or loose it!”. Men and women who do not regularly use their pelvic floor muscles (i.e. not have regular sexual activity) will find that the muscles will quickly lose their strength and function. Here QRS-PelviCenter can help by first restoring function and coordination after which subsequent treatments can result in improved strength.

- In principle there are two different sort of muscle exercises:
  - Endurance training (marathon). High use of oxygen (aerobic). Not at maximum load. Focuses mainly on type 1 slow twitch muscles and produces little lactic acid. Effect on building muscle strength is minimal.
  - Short and high intensity anaerobic training (sprinting, weight lifting), for example 6 to 10 repetitions in 20 to 30 seconds at maximum load. Limited use of oxygen, energy production via glucose. Focus on type 2 fast twitch muscles. Fast twitch type 2 muscles contract quickly and more powerful and have greater potential for increase in muscle mass.

- Note:
  - Please note that the pelvic floor muscles consist normally of about 70% type 1 (='slow twitch') muscles and for 30% of type 2 (= 'fast twitch') muscles:
  - Type 1 slow twitch red muscles (70%):
    - Technically:
      - Presence of oxygen binding protein myoglobin
      - High profusion of blood, high density of capillaries
      - Fibers suited for endurance; slow to fatigue; slow contraction
      - Oxidative metabolism to generate ATP ("aerobic"); high density of mitochondria
    - Function:
      - Maintain body posture; keep pelvic organs in place; also external sphincter mainly consists of type II ensuring constant tone to maintain urethral pressure > bladder pressure. Also the slow twitch muscles are responsible for protecting against prolapse of the pelvic organs.
  - Type 2 fast twitch white muscles (30%):
    - Technically:
      - Absence of myoglobin (iron)
      - Fibers efficient for short bursts of speed and power
      - Use both oxidative metabolism and (faster) anaerobic metabolism, relying on glycolytic enzymes
      - These fibers are quick to fatigue (produce lactic acid)
    - Function:
      - Driven by reflexes; objective to cope with pressure (i.e. sneeze/cough) and quickly shut off the flow of urine. For sexual function the muscles responsible for orgasm (Ischiocavernosus and Bulbospongiosus) are mainly fast twitch muscles. QRS-PelviCenter training for ED will focus on increasing strength of these fast twitch muscles.

  - Important question: Can fiber types be converted? Is it possible for a man who has 80% slow twitch and only 20% fast twitch to convert the slow twitch to fast twitch muscles?
    - The answer is: NO, BUT it is possible to "train up the fibers of a particular type". Remember that growth of muscles is NOT due to growth of new muscle cells but only due to the increased size of existing cells. This means a couple of things:
      - Every man is different. Genetically, some men are borne with high percentage of fast twitch muscles and they are naturally born to become sprinters or power lifters. Other men are born with high percentage of slow twitch fibers and they are naturally born to be good at endurance sports such as marathon. Men who in the past had strong muscles which have now weakened will find it easier to regain strength then men who had not so many muscles. In relation to sexual function, some men have naturally an advantage by having higher % of fast twitch muscle fibers. However,…
      - It is possible to train only the fast twitch muscle fibers (or conversely only the slow twitch muscle fibers) but it is very important that the correct training program is followed. Slow

twitch muscles are trained by long endurance training at less than maximum intensity. Fast twitch type 2B muscle fibers are trained effectively only by doing a small number of repetitions at maximum intensity (5-8RMs). This means that with QRS-PelviCenter treatment customers who only want to treat ED must not "overdo" it by doing too many sessions behind each other. QRS-PelviCenter leads to quick tiring of the fast twitch muscles and if customers do not take sufficient rest in between the treatments then the muscle fibers are not able to recuperate and it will result in a loss of strength instead of an increase in strength.

- Important conclusion:
  - If you want to gain muscle mass, and especially in the case of improving sexual function, then you have to focus on the strength of the fast twitch muscles of the pelvic floor, then it is important to focus the PelviCenter treatment on short duration, high intensity anaerobic exercises. So this means: using higher frequencies (50 Herz) and trying to get to as high intensities as possible (maximum load) and doing the exercise every time for short duration (20 minutes in total).

- Please note also the principle of "progressive overload".
  - Progressive overload is a fundamental principle for success in strength training.
  - Progressive overload is the gradual increase of stress placed upon the body during exercise training. The body adapts and becomes more resistant to stress.
  - This is similar to PelviCenter muscle training. It is important to start at a certain intensity and then every treatment try to build up the intensity progressively.
  - Progressive overload results in muscle hypertrophy (increase in the size of the muscle cells); in the development of stronger and denser bones, ligaments, tendons, cartilage; it increases the blood flow to the exercises regions of the body (for example the sexual organs); and it stimulates the nerve connections between the brain and the muscles.

2.1.12.4 Maintenance training (after completion of the 16 treatments):

- Q&A:
  - Question: After completing of the 16 treatments, will ED be cured for long term? Do I have to come back?
  - Answer: See below.
- QRS®-PelviCenter treatments will result in strengthening the muscles of the Pelvic Floor. This will result in positive effects on the sexual function.
- After completion of the treatments, the customer must make sure that his pelvic floor muscles stay "in shape". Keeping your pelvic floor muscles in shape can be done in a variety of ways. Regular sexual activity will help in keeping the muscles strong. Also, the customer can do Kegel or other physical exercises.
- For older customers who do not maintain the strength of their muscles themselves, it is recommended to follow a "QRS®-PelviCenter maintenance treatment program". In those cases it is advised to do a QRS®-PelviCenter treatment 2 times per month.
- Maintenance treatment is not always necessary.
  - For example in the case of men after Radical Prostatectomy. Here the QRS®-PelviCenter treatment is focusing on restoring the coordination and function of the peripheral nerves and muscles.
  - Also, men who are able to keep their muscles in shape, either via Kegel self exercises; or via regular sexual intercourse ("use it or loose it") will normally not have to come back for more treatments.

2.2 About how the QRS®-PelviCenter works

2.2.1 How exactly does the QRS®-PelviCenter treatment work? (functionally)

- If a person wants to train his or her muscles he needs to do this by so-called "repetitive Peripheral Muscle Stimulation" (rPMS). rPMS means that a muscle must be repetitively contracted and released (relaxation). With the QRS®-PelviCenter the muscles of the Pelvic Floor are repetitively contracted and released. Under a standard QRS®-PelviCenter program of 20 minutes the muscle is contracted 100 times. This can be increased by changing some of the parameters of the PelviCenter.
- Additional note:
  - Please note that Relaxation of the muscles is equally important than the Contraction of the muscles. In customers suffering from Pelvic Floor disorders it is often very important to learn how to relax the muscles (for example in the case of Premature Ejaculation, part of the customers suffering from PE have Pelvic Floor muscles which are too tight and here the focus must be on relaxing of these muscles).

2.2.2 How exactly does QRS®-PelviCenter work technically?

- The QRS®-PelviCenter makes use of Magnetic Stimulation.
- A pulsating magnetic field is created which changes via a certain frequency (number of pulses per second = Herz).
- This changing magnetic field creates an electricity flow in the nerves. Electricity flow means that ions are moving from one side of the nerve to the other side (the side which connects them with the muscles)
- The nerves are connected to the muscles and respond by contracting the muscles.
- After the magnetic field is released the nerves and the muscles relax.

Thus: Pulsating Magnetic Field → Electricity Flow → Nerves → Muscle contractions

2.2.3 QRS®-PelviCenter is 100% safe with no negative side effects

2.2.3.1 Contra-indications

- Key contra-indications:
  - Metal implants in the hip area; also spirals in the vaginal area
  - Pregnancy
  - Pacemaker
  - Surgical surgery since less than 3 weeks (wounds not healed yet)
  - Severe cardiac arrythmia
- Other relative contra-indications:
  - Epilepsy ; Acute urinary tract infection ; Menstrual
  - Painful hemorrhoids ; Febrile infection

It is recommended to the doctor that a small poster displaying all the contra-indications is displayed next to the QRS®-PelviCenter.
This allows an additional check on the contra-indications by the nurse/operator of the QRS®-PelviCenter and by the patient himself.

2.2.3.2 100% Safe:

- The QRS®-PelviCenter has obtained FDA approval both in Europe (CE) and in USA as a medical device. In order to get the FDA QRS has had to meet various requirements in relation to safety.
- Please note that the QRS®-PelviCenter is a medical device and can only be used in a hospital/ clinic environment, operated by a doctor.
- The doctor is responsible for checking the contra-indications and in ensuring that the system is used in accordance with the instructions.
- Technically, please note that, QRS®-PelviCenter uses Magnetic Field therapy and this is something different than electrical stimulation. Electrical stimulation is by definition more painful since it directly affects the nerves. Magnetic stimulation only indirectly affects the nerves (by the creation of an electricity flow in the nerves). More importantly, Magnetic fields are able to penetrate human tissues and bones etcetera without a problem and without causing pain.
- Last important note: Please note that the intensity of a magnetic field decreases very quickly when moving further away from the magnet.. As a result, the intensity of the magnetic field is highest at the coil and when the magnetic field touches the bottom part of your pelvic floor. However, when at about 9 cm height, there is almost no magnetic force remaining. This also means that the impact of the QRS®-PelviCenter will not reach the heart area or the area of the pacemaker. In technical terms:
  - the intensity of a magnetic field diminishes in proportion to the square of the distance from its source
  - the flux density is at least 0.4 tesla and the peak discharge (190 microsec) is approximately 10,000 tesla/ sec.

2.2.3.3 No negative side effects:

- QRS®-PelviCenter has been used for many years by many doctors.
- There are no negative side effects reported.
- Only possible side effect is that customer can complain about some muscle soreness after the treatment. This happens normally after the 1st or 2nd treatment when the customer has been too ambitious and using too high intensities.
- Please note that muscle soreness is a positive sign showing that the treatment is working and impacting the muscles.

2.2.3.4 Attention point: Blood Pressure

- The QRS®-PelviCenter is INTENSIVE training of the muscles of the Pelvic Floor.
- The QRS®-PelviCenter uses HIGH MAGNETIC ENERGY which is transferred in part to the customer who is taking the treatment. This high magnetic energy is beneficial in treating a variety of pelvic floor and other disorders.
- But for "untrained" persons, the PelviCenter can result in a small increase in Blood Pressure. This is nothing to worry about. This is a temporary effect. And quickly after the treatment the Blood Pressure will restore to normal. But it must be noted and customer with high blood pressure must not take more than 1 treatment per day.

2.2.4 Key parameters of the QRS®-PelviCenter

2.2.4.1 Summary key parameters of the QRS®-PelviCenter

- Intensity of the magnetic field
- Frequency (number of pulses per second)
- Position of the magnetic coil
- Duration of the pulses and duration of the "off-time"

2.2.4.2 Intensity: 20%-40%-60%-80%-100%

- Start every new customer with 20%
- Do not in the first treatment be too ambitious in the intensity level that a customer thinks he can do. Initially the focus is on:
  - Warming up the muscles
  - Improving the coordination and function of the muscles. Only after improving coordination and function are we able to build strength by increasing the intensity in later treatments.
  - Avoiding pain in muscles or lower back by making the first exercise too intensive
- In subsequent treatments build up the intensity and push the customers a little bit to be more ambitious. If a customer stays too long at low intensities there is a risk that the treatment program is not so effective.
- Special note on ED:
  - The higher the intensity of the magnetic field, the more deeper the magnetic field reaches into the Pelvic Floor. This is especially relevant when treating urinary incontinence.
  - For sexual function, the two most important muscles lie very close to the superficial part of the skin. The customer can touch these muscles by putting two fingers between the scrotum and the anus. Since these muscles do not lie deep, already good effects can be realized when using only limited intensities (e.g. 20% or 40%). On the other hand, another relevant muscle is the PC muscle. This muscle lies more deeper and for this muscle it makes more sense to use higher intensities.

- More higher intensity is not always better. People who are able to cope with higher intensities on the first treatment are not by definition better than people who have much difficulty with handling even the 20%. Someone who is able to cope with higher intensities, this can be a sign of the person having stronger muscles. But it can also be a sign of a person having limited nerves, and as a result of that not being so sensitive to magnetic or other stimulation. For example, very often with long term diabetes, the nervous system has been significantly destroyed. And the patient does not feel any sensation on 20%, or 40% or even 60%. This is not a good sign. For the QRS®-PelviCenter to be effective it is important that the nervous system of the customer is still intact. The doctor or operator is advised to look at the reaction of the customer when the treatment starts at 20%. If part of the body is moving, if part of the muscles are contracting, then the QRS®-PelviCenter treatment is working. However, if the patient is sitting still and does not seem to be affected by the treatment then the doctor needs to increase the intensity and check with the patient on whether there is a nervous system dysfunction.

2.2.4.3 **Frequency (between 5 Herz and 50 Herz).** General rules as follows:

- Start a treatment with low frequencies (5 Herz to 15 Herz) to warm up the muscles.
- For nerve related issues (i.e. Urge Urinary Incontinence) stay at low frequencies.
- In situations where the muscles must be strengthened use higher frequencies (i.e. 30 Herz for ED or 50 Herz for Stress Urinary Incontinence). Also, for Erectile Dysfunction it is recommended to use higher frequencies (30 to 50 Herz). Remember that the skeletal muscles responsible for sexual function (ischiocavernosus and bulbospongiosus) mainly consist of fast twitch muscles and in order to build strength it is important to focus the training on short duration highly intensive anaerobic exercises at maximum load (high intensity and high frequency = 50 Herz).
- Remember that with low frequency (i.e. 5 Herz) the skeletal muscles such as the external sphincter and the Ischiocavernosus & Bulbospongiosus muscle are trying “to follow” the frequency (to contract and release 5 times per second). With the higher frequencies this is no longer possible and the muscle stays contracted for a period of 8 seconds (standard program).
- Also please note that 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 herz. The Pelvic Floor in general consists for 70% of “slow twitch” muscles and for 30% of “fast twitch” muscles. The “slow-twitch” muscles (responsible for carrying the weight and organs and maintaining position) have a natural firing rate of 10 to 20 herz. Fast-twitch muscles are important for being able to quickly respond (for example in ejaculation process) and have a firing rate at 30 to 60 Herz. This explains why for ED and premature ejaculation most of the treatment (but not all) must be carried out with higher frequencies.

2.2.4.4 Position of the magnetic coil (0 cm to 14 cm)

- It is very important that the magnetic coil is positioned on the right position. The right position is dependent on:
  - The type of customer (fat or thin)
  - The indication, e.g.:
    - Lower back pain
    - Fecal Incontinence
    - Urinary Incontinence
    - Erectile Dysfunction.
  - Below stated are some general recommendations of the ideal position of the magnetic coil in "standard" customers. But please note that these are just general recommendations. Every customer is different.
    - Lower back pain: 0 – 2 cm
    - Fecal incontinence: 1-2 cm
    - Urinary incontinence: 3-7 cm
    - Erectile Dysfunction: 3 - 5 cm
      - Ischiocavernosus and Bulbospongosius:
      - PC muscle:
- More information on the right position for customers suffering from ED:
  - It is important to understand that the Pelvic Floor Muscles are a large and complex set of muscles.
  - The Ischiocavernosus and Bulbospongiosus muscle are the most important muscles for sexual performance. They can be found between the scrotum and the anus. The doctor or operator of the QRS®-PelviCenter system must assist in ensuring that the center of the magnetic field is positioned on the right position. The doctor/ operator can do this by showing a map of the pelvic floor muscles, by moving the magnet forward or backward with 1 or 2 centimeters and asking questions to the customer on what and where he feels the impact.
  - Please note that it is advised to, during the 16 PelviCenter treatments also change the position of the magnet a little bit so that also other pelvic floor muscles get trained. For example the magnet can be temporarily placed with the center on the penis shaft to allow for better blood circulation in the penis. And the magnet can be temporarily placed more to the back to focus more on the PC muscle.

2.2.4.5 Duration of the pulses and duration of the "off-time"

- Standard is 8 seconds pulses and 4 seconds rest (="off-time). For some customers in the beginning it is possible to start with another pattern,
- For ED and for PE (Premature Ejaculation) it is recommended to change this program after about 6 treatments and for example do part of the treatment with 4 seconds pulses and 2 seconds rest. And also to do part of the treatment with a longer duration (i.e. 10 or 12 seconds instead of 8 seconds). This follows the optimal Kegel exercise program whereby the customer is challenged to do different sorts of exercises:
  - The "basic flex": Contracting the muscles for 1 or 2 seconds and then release. At the start of Kegel exercises many men are not able to hold the pelvic floor muscles for more than 2 seconds. This exercise develops basic strength and control of the muscles.
  - The "long hard flex": A slow contraction. Squeeze as hard as you can. And hold the contraction for 3 to 5 seconds. This exercise builds longer lasting strength.
  - The "hold": A long and hard contraction. Hold the contraction and continue to squeeze for as long as you can. This exercise builds strength, control and increases the size of the muscles. This exercise is also useful for customers suffering from Premature ejaculation which gives allows the man to gain more control on delaying the ejaculation during sexual intercourse.
  - The "rapid flex". Short and very quick contractions. Very quickly squeeze and release.

2.2.4.6 Sitting position

- The sitting position of the customer in the PelviCenter is of key importance. Please refer to paragraph 3 for the standard treatment protocol. Amongst others, it is advised that the ED customer separates his 2 legs sideways (one to the left of the chair, one to the right). Thus not keep the legs together. By doing this the magnetic field simulates more directly into the relevant sexual muscles.

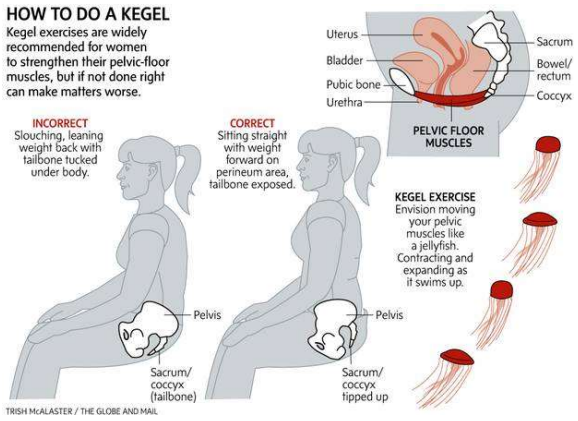
2.3 General notes on how to treat a customer

2.3.1 Initial diagnosis and prescription by a doctor:

- The QRS®-PelviCenter is a system which can be operated easily by a nurse or operator. But the initial prescription or referral must come from a doctor, e.g. a urologist, gynecologist or family doctor.
- QRS®-PelviCenter is a medical device and has been certified as a safe medical device by the both the European and the USA FDA. The 20 minute treatment is a strenuous muscle training, which can temporarily strain the blood circulation. The doctor will have to diagnose the customer and determine an individualized treatment plan.
- Contra-indications. The QRS®-PelviCenter has certain important contra-indications. It is important that both the doctor and the nurse/operator of the QRS®-PelviCenter checks the contra-indications with the customer before starting the treatment. Please refer to the list of contra-indications. The most important contra-indications are:
    - Metal implant in the hip area (ferromagnetic materials can get warm very quickly)
    - Pregnancy
    - Pacemaker (relative contra-indication)
- The doctor needs to give a clear prescription of the treatment to the customer and to the nurse/ operator of the QRS®-PelviCenter. The prescription must include:
    - Indication: for example: ED or Premature Ejaculation
    - Recommended number of treatments
    - Recommended start intensity and frequency
    - Some indication as to the position of the magnetic coil (number of centimeters away from the back of the PelviCenter). This is just an indication only and needs to be verified by the operator together with the customer during the actual treatment)
- Customers where QRS®-PelviCenter may not be helpful (long term diabetes).
    - The doctor needs to identify the customers where QRS®-PelviCenter may not be helpful. This is especially relevant in cases who are suffering from long-term diabetes. Long term diabetes destroys both the peripheral nervous system and the peripheral blood vessels. If a substantial part of the nervous system has been destroyed then it will be very difficult for the QRS®-PelviCenter to be effective.
- Customers where QRS®-PelviCenter is only complementary but where the customer needs additional treatment for underlying other causes of ED.
    - Very often ED is the result of a combination of factors. Very often ED is the result of an underlying disease such as depression, diabetes or cardiovascular. In these cases the doctor must advise not only on Kegel exercises but must advise on a treatment to cure the underlying disease (e.g. in the case of heart disease).

2.3.2 Sitting position of the customer:

- The sitting position is of key importance. The customer must be sitting upright and a little bit bent forward (angle between upper legs and upper body must be lower than 90 degrees). As a result, the gluteus muscles open up and the magnetic field reaches more deeper in the pelvic floor.
- Also please note that for improving sexual function, it is important to keep the legs spread out and thus not closed. This allows the magnetic field to more easily penetrate the relevant area.



2.3.3 Interactivity of the customer:

- QRS®-PelviCenter is COMPLEMENTARY treatment. In order to increase the effectiveness of the QRS®-PelviCenter treatment, the following is recommended:
  - To encourage the customer to also do self-exercises at home complementary to the QRS®-PelviCenter treatments.
  - To be more actively involved when doing the QRS®-PelviCenter treatment. Start counting the seconds during which there is a "rest period" (normally 4 seconds) and try to contract the muscles yourself before the start of the pulses by the QRS®-PelviCenter. Try to check whether you contracted the right muscles. By doing these exercises while sitting on the QRS®-PelviCenter your brain starts to become more actively involved and you will be able to control the muscles better when you are having sexual intercourse.

2.3.4 Ask the customer to fill out a questionnaire before the 1st treatment and after the last treatment

- Purpose is to allow for registering and measuring the improvements realized with the QRS®-PelviCenter. And as a result of that be able to offer a more professional service to our customers. And also to allow for professional doctors to analyze and review the results of the QRS®-PelviCenter. For this reason we ask every customer to fill out one form before the start of the treatment program and the same form after the end of the whole treatment program.

2.3.5 Use QRS®-PelviCenter treatment as COMPLEMENTARY treatment for ED

Erectile Dysfunction has many different causes.

Research in Germany shows that when a man suffers from ED that there are often more than 1 cause for his ED.

Research in Germany also shows that out all the men who are suffering from ED, between 35% and 60% of them are suffering from "Venous Occlusive Dysfunction". It is important to note that these patients often have also another cause for their ED.

"Venous Occlusive Dysfunction" means that the skeletal muscles are no longer able to contract the 'venes' and prevent that the blood flows out of the penis. This is caused by reduction of the strength of muscles, normally a man loses between 1% and 2% of his muscle strength every year. This results in loss of function, and strength.

The ONLY way in which you can treat this cause of ED is by training your muscles yourself. This is called "Kegel exercises". Various studies in Europe (in Germany, UK and Belgium) have PROVEN that Kegel exercises work for improving sexual function. If a man trains his muscles every day (about 250 exercises per day) he will see good improvements after 3 to 4 weeks.

However, it is not easy to do these self-exercises and it requires a lot of active commitment. The QRS®-PelviCenter is not a "Wonder cure for ED" but it does one thing very effectively. And that is to train automatically the function, coordination and strength of the pelvic floor muscles, including the muscles which are relevant for sexual function.

Management of expectations:

- Customers must not expect immediate results after one treatment. Many men are looking for a solution which helps them immediately. It happens very often that men already after one treatment have a positive effect. But real positive effects are only achieved after regular treatments (recommended 16) at HIGH intensity (100%) and at high frequency.
- Customers must also realize that QRS®-PelviCenter is complementary treatment and only targets one important cause of ED. And it is very well possible that the customer's ED has other causes as well (blood flow, smooth muscle relaxation and others).
- Also, importantly, the customer must have some basic good working nervous system and blood flow system in his pelvic floor. The QRS®-PelviCenter has limited success for patients who suffer from long term diabetes. Long term diabetes normally destroys the peripheral nervous system as well as the system of capillaries. A signal for this is when the patient/ customer is already at the first treatment not feeling the pulses of 20% or 40% intensity.

It is therefore important for the clinic to give the 20 minute QRS®-PelviCenter treatment complementary to other treatments. Including for example:

- Teaching the customer about "how to do Kegel exercises" themselves at home. And encouraging them to do these exercises for minimum 3 weeks.
- Improving blood flow and relaxation with the QRS®-101 system (in an ideal situation the customer who signs up for the QRS®-PelviCenter 16 treatments must also be encouraged to buy or rent the QRS®-101 and do two 8-minute treatments per day)
- Offering a massage to the customer after the PelviCenter treatment
- Employ female staff to treat the customer
- Offer natural herbs and homeopathic medicine.

2.3.6 Some other key summary points:

- It is absolutely essential to inform the patients about the contra-indications. A special form with a list of contra-indications must be displayed next to the PelviCenter. This information must be shared slowly with the customer so that the customer can accurately understand each point of the list of contra-indications. The doctor is responsible for building a good control process ensuring that the contra-indications are checked for every new customer.
- Customers often are very ambitious and want to increase training frequency. It makes no sense to do more than 3 treatments per week, because of the necessary regeneration phase of the muscles.
- Patients are often very ambitious and underestimate that QRS®-PelviCenter training can be very tiring for the muscles. If a customer is too ambitious in the beginning, then it can result in soreness and other unidentifiable pain syndromes in the urogenital tract. So customers must be advised to be a little bit ambitious, because it is important for a successful treatment, but not too much.
- Never start with a basic level of more than 40%.
- Very important is to have the right seating position. If you are sitting in the PelviCenter leaning backward, then you have strong contractions of the Gluteus Maximum muscles. The right position is an easily forward inclined position.
- A customer is not every day in the same good position. It is absolutely normal, that the intensity must sometimes be humiliated on a given day. "Less" is "more" in such a case.
- The medical product law requires, that any side effects that have been identified, must be reported. This applies especially for side effects, which are serious for the patient or might be. The report must be immediately sent to QRS.

2.4 Additional general notes about QRS® and Sexual Function

2.4.1 The importance of using the QRS®-101 system complementary to the QRS®-PelviCenter

About the QRS®-101 PEMF Home system:

- The QRS®-101 PEMF Home system is since 1990 the technological leader in the technology of Pulsed Electro Magnetic Frequency/ Field therapy.
- The QRS®-101 system makes use of magnetic stimulation under extremely low frequencies (normally between 1 Herz and 50 Herz) and very low intensities (maximum intensity of the Full Body mat is 30 Microtesla which is lower than the intensity of the Earth Magnetic Field of about 50 Micro tesla).
- Hundreds of clinical trials have been carried out with the QRS®-101 system since 1990. The QRS®-101 system has proven to be effective as a complementary treatment in:
    - Improving micro-circulation (= blood flow in the capillaries)
    - Improving metabolism = energy of the cells
    - Reduction of chronic diseases and chronic pains. Including reduction of blood pressure, cholesterol, stabilizing pH value, increase in oxygen intake and delivery of oxygen and nutrients to the cells, reduction of heart arrythmia.
- The QRS®-101 system is 100% safe and has no negative side effects.
- The QRS®-101 system works in a variety of ways. The QRS®-101 system strongly improves blood circulation. Red blood cells are responsible for transporting oxygen to the cells and transporting CO2 from the cells back to the lungs. When people get older there is various causes which are impacting the blood flow. Very often red blood cells are gluing together (rouleau effect) resulting in intake of less oxygen and the blood being too thick to flow through all capillaries. With only 8 minutes of QRS®-101 treatment, the blood becomes thinner and able to take in more oxygen. As a result, oxygen is delivered to all the cells and tissues that need oxygen, and CO2 is transported away from the cells, resulting in an improvement of metabolism. The QRS®-101 Home system is very effective as a complementary treatment in treating diseases where the cells and tissues require more oxygen for repair and healing.

How does QRS®-101 PEMF system help with Erectile Dysfunction:

- Oxygen and oxygen partial pressure is of key importance in the sexual function of both men and women. Oxygen is delivered via the blood to the cells. In a flaccid state, there is very little blood in the penis and thus also very little oxygen. During sexual performance (erect penis) the oxygen partial pressure increases from 40 mmHg to about 90-100 mmHg. When men get older the peak blood flow to the penis starts to decrease making it more difficult to get an erection. Also, on the longer term, a low oxygen partial pressure results in the increase of collagen fibers and a decrease of smooth muscle cells. In healthy men the ratio between collagen fibers and smooth muscle cells is about 50%-50% and this is of key importance in getting an erection. If the ratio of smooth muscle cells start to decrease it becomes more difficult to have satisfactory sexual intercourse. An important sign of reduction of oxygen partial pressure at older age is when the number of nocturnal erections are decreasing.
- How can oxygen partial pressure be increased?
    - By regular sexual activity, allowing regularly the inflow of blood and oxygen which stops the creation of collagen fibers.
    - At night during sleeping, in the REM phase. Healthy men have about 3 or 4 erectile episodes every night and this results in a good oxygenation of 1.5 to 3 hours per day.
    - With the QRS®-101 Home system.
        - The QRS®-101 system strongly improves the blood circulation. 8 minutes of QRS®-101 therapy results in the blood becoming thinner and the red blood cells binding with more oxygen. Also there is an indirect positive effect from the creation of nitric oxide which dilates the capillaries making it more easy for blood to flow in the penis.
        - The QRS®-101 system leads to strong relaxation (including assisting in the relaxation of the smooth muscle cells which are normally restricting the inflow of blood into the penis).
        - The QRS®-101 system strongly helps with sleeping disturbances. Already after 1 treatment, customers suffering from sleeping disorders will notice significant improvements in sleeping.

Please refer to the appendix of this document for some clinical trial information on the effects of QRS®-101 PEMF technology on the improvement of sexual function for men and women.

Summary: The QRS®-PelviCenter treatment improves the strength of the muscles which are needed to keep the blood in the penis and thus to maintain and sustain a strong erection.
The QRS®-101 system has a strong positive effect on blood circulation and relaxation. And can be used at home, 2 times per day for 8 minutes, complementary to the QRS®-PelviCenter treatment.

2.4.2 The positive effects of QRS®-PelviCenter treatment on the peripheral nerves

Good sexual function is dependent on good working blood vessels, muscles and peripheral nerves.

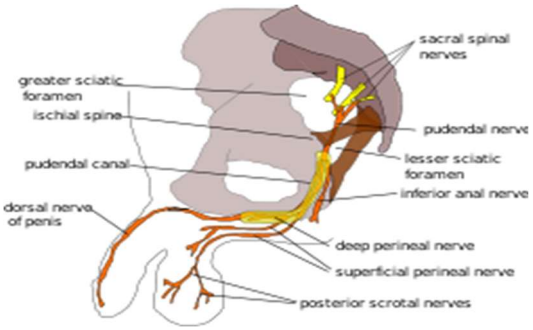
Penile erection is often a spinal reflex. This means that after stimulation of the erectile tissue the peripheral nerves between the spinal cord and the penis start the process of erection (without involvement of the brain). In technical terms: most sensory neurons do not pass directly into the brain but synapse in the spinal cord. The spinal cord activates spinal motor neurons.

For good sexual function it is of key importance that all the peripheral nerves and muscles of the pelvic floor must work in a coordinated way. The most important peripheral nerves for sexual function are as follows:

- Pudendal nerve (part of the somatic nervous system, meaning it is under voluntary control by the brain, and it innervates skeletal muscles such as the external sphincter, the PC muscle and the Ischiocavernosus and Bulbospongiosus muscle.
- Other pelvic nerves (part of the parasympathetic nervous system, meaning it is under involuntary control, not controlled by the brain but acting 'on its own' after stimulation).

The QRS®-PelviCenter uses magnetic stimulation which has a positive effect in improving the communication and coordination of all the relevant peripheral nerves of the Pelvic Floor.

Below is a picture of some of the key peripheral nerves in the pelvic floor of a man.



2.4.3 The relationship between Erectile Dysfunction and the "Post Micturation Dribble"

General notes:

- The "Post Micturition Dribble", or also called the Post Void Dribble (PVD) occurs immediately or shortly after completing urination, when urinate that remains pooled in the urethra drips out.
- PVD is the most common type of Urinary Incontinence for men.
- PVD can happen to men of any age but it more commonly occurs after age 40.

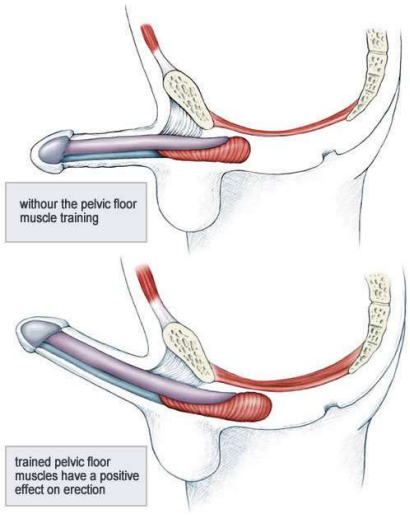
Pelvic Floor Muscle Training, QRS®-PelviCenter and Postvoid Dribbling:

- 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.
- Customers 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.
- Studies in Europe [(e.g. Dorey et al (see literature references)]:
    - Demonstrated the effectiveness of PFMT for PVD.
    - 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.

Often Post Void Dribbling is an important sign of muscles weakening and thereby of Erectile Dysfunction. QRS®-PelviCenter Pelvic Floor Muscle training will have positive effects both on PVD and on ED.

2.4.4 Men who are having difficulty maintaining an upright penis

- Young men typically have a penis, which, during erection, points upward to the stomach, and often curve a little bit so that the head touches the area on or near the stomach. This is a sign of strong muscles and good blood flow. The blood gets strapped in the penis by the strong muscles who do not allow the blood to flow out.
- When men get older, often the erect penis does no longer point upwards.
- This is caused by the weakening of the pelvic floor muscles and by the stretching of the ligaments which connect the penile muscles to the pubic bone.
- Pelvic Floor Muscle training and QRS®-PelviCenter training can help reverse this effect or can prevent this from happening.



2.4.5 Some important notes on Premature Ejaculation

- Some basic notes on PE:
  - 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 an ejaculation
  - If the customer is able to voluntarily contract the Pelvic Floor Muscles this will help control ejaculation.

- The doctor/ nurse needs to explain to the customer that stronger Pelvic Floor Muscles will help the customer with getting more control on the ejaculation during sexual intercourse and will help the customer in closing the relevant muscles to avoid ejaculation.
  - "Having weak pelvic floor muscles is the most common physical cause of premature ejaculation"
  - Your pelvic muscles essentially control when you will ejaculate and they even allow you to hold back your ejaculation
  - The stronger your Pelvic floor muscles, the more control you will have over when your ejaculation will occur which means that you will become able to last exactly how long you would like in bed.
  - The best way to make those muscles stronger, is with Kegel exercises.

- With PE it is very important that the correct QRS®-PelviCenter treatment program is used, especially in relation to frequency and the on-off time of the pulses and relaxation. It is advised to not follow only one standard program for 16 treatments but to change the program regularly. This means:
    - Start with higher frequency (30 to 50 Herz) and a standard "on-off" time of 8 seconds pulses and 4 seconds rest. This is the core part of the treatment for both ED and premature ejaculation. These short duration high intensity anaerobic exercises focus on building strength of the type 2 fast twitch muscles responsible for sexual function (ischiocavernosus and bulbospongiosus).
    - Use every treatment 5 to maximum 10 minutes to change the program a little bit, for example:
        - Change the "on-off" time to "4-2" or "2-1"……and then for 5 minutes change the "on-off" time to for example "12-6" or even higher.
            - NOTE: This is no longer possible with the new version of the QRS-PelviCenter. The new version has a so-called "ramp-up" functionality, meaning that the intensity of the pulses build up slowly in 3 or 4 seconds until the maximum. In the new version of the PelviCenter the minimum stimulation possible is 5 seconds.
        - Use a lower frequency (for example 5 or 10 Herz) for maximum 5 minutes per treatment.
- Premature ejaculation sometimes (not always) has to do with pelvic floor muscles which are too tight (instead of too weak).
    - In those cases, part of the PelviCenter treatment and accompanying Kegel exercises must focus on relaxation of Pelvic Floor Muscles.
    - In those cases, part of the PelviCenter treatment must be carried out not only at high frequencies (having an effect on the fast-twitch muscles) but also at low frequencies.
    - In those cases, the customer must be explained about so-called "Reverse Kegel" exercises (see appendix nr 3)
        - Instead of trying to make the movement of stopping the "pee" during urination, try the movement of pushing out the pee with extra force.
        - Instead of the movement of trying to stop the stool from coming out of the anal sphincter, train the movement of forcefully pushing out the imaginary stool.

2.4.6 QRS®-PelviCenter and improving the ejaculatory force

- 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 optimizes:
    - Ejaculatory volume
    - Force of ejaculation

- Intensity of sexual climax

2.4.7 QRS®-PelviCenter is a service, not a system

Many men suffering from ED look towards the QRS®-PelviCenter as a new ***system*** which will ***cure*** ED after one or two treatments.

- QRS®-PelviCenter is not the magical system. It offers a SERVICE to customers suffering from ED or PE. A complementary SERVICE which allows for automated training of the Pelvic Floor Muscles. And thereby treating and helping to resolve an important underlying cause of ED (QRS-PelviCenter treats the cause rather than the symptoms).
- Customers must understand that they have to use QRS®-PelviCenter complementary to other treatments against ED. In particular, customers must learn about the importance of Pelvic Floor Muscle training and be encouraged to do Kegel exercises themselves at home. Also, customers must continue to work in trying to resolve underlying causes of ED, such as cardiovascular and diabetes issues.

2.4.8 Improving the sexual function not only of men but also of women

- The QRS®-PelviCenter does not only have positive effects on the sexual function of men.
- But also on the sexual function of women.
- Women have the same muscles as men.
- The key relevant muscles for women are also the Ischiocavernosus muscle and the Bulbospongiosus muscle.
- The Ischiocavernosus muscle:
  - compresses the back of the clitoris erectile tissue (corpus cavernosum clitoridis)
- The Bulbospongiosus muscle (musculus constrictor Vulva)
  - Contributes to clitoral erection
  - Contributes to the feelings of orgasm
  - Closes the vagina/ Vulva
  - Produces the rhythmic contraction typical for female orgasm
  - Note that this muscle is often cut in preparation for the delivery of a child (episiotomy)
- Other positive effects of QRS®-PelviCenter Pelvic Floor Muscle training on women:
  - Positive effects on reducing Urinary Incontinence, both Urinary Stress Incontinence and Urinary Urge Incontinence.
    - Stress Urinary Incontinence is the most common form of Incontinence for women. There is only one cause for Stress Urinary Incontinence and that is the weakening of the Pelvic Floor Muscles (for example after pregnancy or after menopause). Pelvic Floor Muscle Training has been the most important first line treatment for Stress Urinary Incontinence. QRS®-PelviCenter training has positive effects on treating Stress Urinary Incontinence
    - Urge Urinary Incontinence…..
  - Can help with reduction of cellulite and improve the “contour” of the buttocks
  - Can help with the reduction of pain in the lower back.
  - Please note that all the above have indirect positive effects on the sexual function of women.

2.4.9 How does the QRS®-PelviCenter differ from other methods to treat Erectile Dysfunction?

QRS®-PelviCenter and shockwave therapy

- Shockwave therapy:
  - Shockwave therapy uses energy from acoustic waves to trigger a process called neovascularization in certain parts of the body. When neovascularization occurs, new blood vessels form. This helps improve blood flow to the region. Improving blood inflow into the penis is of key importance in the process of getting an erection.
  - The shockwave device is placed on 5 different parts of the penis shaft and the treatment is focused on the blood vessels in the penis. During one treatment of 20 minutes each part is treated for 3 minutes in which 300 shocks are administered.
  - The standard treatment program involves a total of 12 treatments divided over a 9 week period (2 times per week in week 1, 2, 3, 7, 8 and 9).
- QRS®-PelviCenter:
  - QRS®-PelviCenter treatment is focused not on the penis shaft but on the pelvic floor muscles.
  - The treatment is focused in particular the ischiocavernosus and the bulbospongiosus muscles (the muscles which you can feel between the scrotum and the anus). But it also focuses on all other Pelvic floor muscles, including the important PC muscle.
  - The QRS®-PelviCenter also focuses on all peripheral nerves between the spinal cord and the penis. Getting an erection is often a spinal reflex (stimulation of the nerves of the penis result in getting an erection without the involvement of the brain). And it is important that the peripheral nervous communication is in tact.
  - The focus of the QRS®-PelviCenter treatment is to strengthen the muscles and these muscles are very important for keeping the blood flow in the penis. And thereby for maintaining and sustaining a rigid erection. Also, these muscles are very important for ensuring strong ejaculatory force/ strong ejaculations.
  - QRS®-PelviCenter is particularly very effective with men where the ED is caused by “venous-occlusive dysfunction”. And research shows that between 35% and 60% of ED patients have some form of “venous-occlusive dysfunction”. In this group of patients there is no doubt that QRS®-PelviCenter treatment is more effective than shockwave therapy.
  - QRS®-PelviCenter treatment is fully non-invasive. No need to undress. Highly comfortable.
  - QRS®-PelviCenter is using magnetic stimulation rather than electrical based shockwave. And Magnetic fields are able to penetrate muscles much deeper and wider and without any pain.

QRS®-PelviCenter/ QRS®-101 and PDE5 inhibitors:

- Currently there are 3 dominant drugs on the market which work via so-called "PDE-5 inhibition":
  - Sildenafil (Viagra) (March 1998)
  - Vardenafil (Levitra) (Aug 2003)
  - Tadalafil (Cialis) (Nov 2003)
- How do these drugs work?
  - During sexual stimulation, the body produces cGMP
  - cGMP is important because it dilates the blood vessels (via Nitric Oxide) in the penis and thereby allowing blood flow to the penis.
  - However cGMP is normally quickly broken down in the body by PDE5.
  - PDE5 inhibitors stop that process resulting in more blood flow to the penis and better erection.
- Side effects of these drugs:
  - Headache, indigestion, back/ muscle pain, nose/ear/eyesight
  - Side effects more common with persons aged over 50 and/ or suffering from diabetes, hypertension, coronary artery disease, hyper lipidemia or smoking.
  - Risk in combination with nitrate medication
- Other relevant points:
  - Price is relatively high
  - The drugs treat the symptoms but do not treat the causes.
  - Does not work for everyone
- Comparison QRS®-101 and QRS®-PelviCenter:
  - QRS®-101 realizes similar effects as the PDE-5 inhibitors. It relaxes the smooth muscles, it dilates the blood vessels (via nitric oxide) and thereby helps in a natural way to improve blood flow into the penis.
  - QRS®-101 and QRS®-PelviCenter treat some of the underlying causes of ED:
    - QRS®-101 has positive effects in treating arteriosclerosis/ coronary heart disease and also in relation to controlling blood sugar levels.
    - QRS®-1010 PelviCenter helps in strengthening the muscles which are of key importance in maintaining and sustaining a strong erection. PDE5 inhibitors can help in getting an erection, but, especially if the customer has "venous-occlusion dysfunction", the customer needs to either do Kegel exercises or use the QRS®-PelviCenter to help maintain & sustain a strong rigid erection.

2.4.10 What customers will benefit from QRS®-PelviCenter and what customers will have limited effects of QRS®-PelviCenter

What customers will benefit from QRS®-PelviCenter treatment?

- Persons where the doctor has advised the patient to do Pelvic Floor Muscle Training/ Kegel exercises.
- Men with "venous-occlusive dysfunction". Which means that the blood flows out of the penis too fast and the customer is not able to keep a sufficiently rigid erection for a long time. A study in Germany (Prof. Sommer) showed that 60% of ED patients are suffering from weak pelvic floor muscles which are not able to keep the blood in the penis.
- Men who are noticing a reduction in the ejaculatory force.
- Men who have difficulty getting an erection with an "upright angle" (pointing towards the abdomen).

- Other:
    - Patients who suffered from ED for more than 6 months
    - Attempted intercourse 4 times on 4 different days and had an unsuccessful rate of more than 50%
    - Patients who completed the International Index of Erectile Function (IIEF) and had a domain score at 6 to 20 (denoting mild to moderate ED)
    - Patients who completed Rigidity Scale (RS) and score is <= 2 (denoting slight to moderate rigidity)
    - Patients who have non-neurological pathology

In what kind of circumstances are the patients expected to have limited results from the QRS®-PelviCenter treatment

- ED caused by a psychological issue (depression, marital discord)
- Any cause of ED other than vascular related
- Any unstable medical, psychiatric, spinal cord injury, penile anatomical abnormalities
- Clinically significant chronic hematological disease
- Cardiovascular conditions that prevent sexual activity
- History of heart attack, stroke or life-threatening arrythmia within the prior 6 months
- Cancer within the past 5 years
- Anti-androgens, oral or injectable androgens
- Use of any treatment for ED within 7 days of screening.

2.4.11 Additional notes in relation to improving sexual function

Check with the customer what kind of medication he is using

Erectile Dysfunction is often a negative side effect of certain medications. For example:

- Medications for treating hair loss, e.g. finasteride (Propecia/ Proscar)
- Medications for treating enlarged prostate/ urinary tract symptoms, e.g. dutasteride (Avodart). These drugs reduce the amount of dihydrotestosterone circulating in the blood.
- Medications used to treat depression. Selective serotonin reuptake inhibitors.
- Medications to treat high blood pressure. Beta blockers and diuretics.

Diabetes:

Men who have diabetes are 2 to 3 times more likely to also have ED than men without diabetes. Poorly regulated blood sugar can damage the nerves and small blood vessels that control erections and allow blood flow to the penis.

High blood pressure:

Healthy blood vessels and sufficient blood flow are essential to getting and keeping an erection. Uncontrolled hypertension damages blood vessels in the body, making them less elastic and less able to transport blood.

Also, some of the medications used to treat high blood pressure have negative side effect on sexual function and aggravate the erectile dysfunction.

High blood pressure can be reduced by non-pharmaceutical solutions. For example by life style changes, such as exercise. Or by using the QRS®-101 home system.

Depression:
More than 60% of people with severe depression may experience sexual problems.
Depression does not only reduce the libido/ interest in sex. But it affects the chemicals in the brain which have a role in stimulating blood flow to the penis.
Also, some anti depressants, such as selective serotonin reuptake inhibitors (SSRIs) can cause sexual problems too.

Natural solutions which have a positive effect on sexual function and reducing ED:
QRS®-PelviCenter and QRS®-101 system are effective as a complementary treatment in treating Erectile Dysfunction.
It is recommended to use QRS®-PelviCenter and QRS®-101 complementary to other solutions.
In particular complementary to physical exercise and to natural solutions.
These include the following:

- Avoid stress. Ensure good relaxation and sleep.
- Physical exercise. Gives more confidence, energy and blood circulation.
- Avoid processed baked products and other foods loaded with sugar and saturated trans fats (they raise blood sugar and disturb blood circulation)
- Avoiding diary food (diary food can affect oxygen levels in your blood due to lactic acid)
- Eat garlic & onions
- Eat ginseng
- Eat bananas
- Eat chilies (expands the blood vessels)
- Eat fish with Omega 3 (salmon)
- Eat oysters (zinc can help increase sensitivity or create hormones; but be careful of the toxins)
- Eat goji berries (reduces temperature and high temperature is main reason for low sperm count)
- Pumpkin seeds; Walnuts (Omega 3); asparagus, Maca, dark chocolate
- Coffee; little bit of red wine (anti-oxidants); Porridge

3. Standard treatment protocol QRS®-PelviCenter for Erectile Dysfunction

Summary:

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, bulbospongosius/ ischiocavernosus
Sitting position	straight 80 degrees to front, spread open your legs
Number of sessions	16 sessions
	2 to 3 times per week

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) 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 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 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.

First treatment of a new customer

1) Check the contra-indications
   a. Metal implant in the hip area.
   b. Pacemaker
   c. Pregnancy
   d. Pelvic Floor surgery < 3 weeks (wounds not yet fully healed)
   e. Severe cardiac arrythmia
   f. Epilepsy
   g. Other relative contra-indications: menstrual; acute urinary tract infections; painful hemorrhoids; febrile infection.

   It is advised to put a visible poster of the contra-indication next to the QRS®-PelviCenter so that both the nurse/ operator and the customer are reminded of this and are able to check whether some of the contra-indications are applicable to the customer.

   Also check whether the patient is suffering from any other chronic diseases. From the viewpoint of managing expectations, it is important to exclude patients who are suffering from long term diabetes. Depending on the state of their peripheral nervous system the QRS-PelviCenter may be less effective for this group of customers.

2) Let the customer fill out a Questionnaire or ask him verbally some questions:
   a. Ask the customer some basic questions about his sexual function
   b. Ask the customer whether he suffers from any diseases underlying ED such as Cardiovascular or Diabetes. More than 50% of ED is caused by an underlying disease such as heart disease (arteriosclerosis) or diabetes. It is important to identify the underlying cause / causes of the Erectile Dysfunction.
      i. If the customer is suffering from arteriosclerosis, explain that ED is often the first symptom of arteriosclerosis. Plaques start to form on the inner walls of the capillaries in the penis resulting in poor blood circulation in the penis.
      ii. If the customer is suffering from diabetes, explain to the customer that long term diabetes (i.e. 10 years) leads to deterioration of peripheral blood vessels and nerves. If the diabetes is too serious and if the customer does not have any good functioning nervous system left then it will be difficult for the QRS®-PelviCenter to help the customer.

   Purpose of the questionnaire is to identify the causes and background of the ED.
   Second important purpose of the questionnaire is to allow for measuring the results of the QRS®-PelviCenter treatment after ending of the 16 treatment program.
   The customer is requested to fill out the same questionnaire at the end of the 16 treatment program.

3) Discuss with the customer the detailed QRS-PelviCenter training program.

a. Remember that every customer is different. We all have slightly different responses to a muscle exercise program. It is important for the doctor to make a good judgment of the customer and especially about his condition. Does the customer only want to improve sexual function? Does the customer only want to focus on improving ejaculatory force and ability to delay ejaculation? (requires the focus on fast twitch muscle fibers). Does the customer also have issues with urinary incontinence? (requires the focus also on slow twitch muscle fibers).

4) Drink some water before the start of the QRS®-PelviCenter treatment.
   a. Mineral water includes electrolytes which will be affected by the magnetic fields and will have a positive effect on the treatment. Also it will help in avoiding dehydration of the body and the muscle cells.
   b. Magnesium is key supplement which increases the effectiveness of QRS®-PEMF.

5) Empty your pockets:
   a. Remove credit card and mobile phone from the pocket of the customer.
   b. Remove body jewelry in hip area (chains, rings, piercings)
   c. Optionally can remove watch, car keys, coins

6) Explain to the customer the procedure
   a. Explain that the PelviCenter will not hurt or be painful. But that the customer has to prepare for the initial set of pulses which initially can give a " strange" feeling.
   b. Explain the customer that the treatment will start at low intensity and at low frequency (and the nurse must double check the starting intensities and frequencies before clicking on the start button)

7) Make sure that the customer sits in the right position in the QRS®-PelviCenter
   a. As much to the back as possible
   b. Sitting a little bit to the front. The angle between upper legs and upper body must be less than 90 degrees. The customer is thus not allowed to sit 'relaxed' behind. The customer is thus not allowed to sit with his back against the back of the PelviCenter cushion.
   c. Spread the legs wide open. For ED it has proven to be more effective if the customer spreads his legs. For Urinary Incontinence it is possible for the customer to keep his/ her legs together but for treating ED, in ensuring an optimal impact on the ischiocavernosus and bulbospongiosus and the deeper lying PC muscle it is important to spread the legs.
   d. Check the position of the magnetic coil (0-14 cm). Make sure that the magnet is directed on the spot between the anus and the penis. Help the customer in identifying this spot by showing a picture of the pelvic floor muscles. Normally this best position is between 3 cm and 5 cm. But for certain patients it can be different.

8) Before starting the treatment, check that the starting position is 20% and 15 Herz.
   a. Be careful of just starting the system without checking.
   QRS®-PelviCenter remembers the last treatment of the previous customer and maybe this customer was on high intensity.

9) Start the QRS®-PelviCenter treatment at low intensity (20%) and low frequency (i.e. 5 or 10 or 15 Herz).
   a. This is important to warm up the muscles and to stimulate the nerves of the autonomous nervous system.
   b. This is especially important for the first treatment of the customer.
   c. However, it is important to understand that customer must not stay too long on the low frequencies or low intensities. For sexual function it is important that the strength of the fast twitch muscles is increased and this can only be done by short duration high frequency training at maximum load (high intensity of magnetic field). It is thus important that most of the treatment is focused at high frequencies (30 to 50 Herz). Also follow the principle of "Progressive Overload" (gradually over the course of a 16 treatment program build up the intensity of the magnetic field)

10) Look at the customer and see whether and how he/she responds to the PelviCenter
    a. Normally the customer must jump up a little bit. This means that the nerve system of the customer is still in tact and that the QRS®-PelviCenter has effect.
    b. Sometimes the customer is not responding. This can be an indication that part of the nervous system has been destroyed, for example due to long term diabetes. In that case it is advised to move the intensity a little bit up until the customer visible responds to the Magnetic Field pulses.

11) Check the position of the magnetic coil.
    a. It is important that the operator/ nurse checks for every patient the exact position of the magnetic coil. The QRS®-PelviCenter reminds the position of the last customer and it is very likely that this position is not the same position which is necessary for the other customer. Practice learns that Operators/ nurses often forget to check the position of the magnetic coil.
    b. The center of the magnetic coil must be directed on the center of the Pelvic Floor or on the relevant sexual muscles (ischiocavernosus and bulbospongiosus muscle).
    c. If the position is not good then this will have a negative effect on the effectiveness of the training.
    d. In order to check the right position, ask the customer where he feels the magnetic coil.

12) Explain the customer about Kegel exercises.
    a. Explain the customer that one of the key causes of ED and of PE and of reduced ejaculatory force and reduced rigidity of an erection is the weakening of the Pelvic Floor Muscles.
    b. Explain that Kegel Exercises = Pelvic Floor Muscle training has been proven to be effective in treating ED and PE.
    c. Explain the customer that QRS®-PelviCenter is automated training of the Pelvic Floor muscles but that, in order to reach fast results, it is recommended that the customer also carries out self exercises at home.
    d. Explain the customer how to identify the relevant muscles (with help of the QRS-PelviCenter)
    e. Explain the customer on how he can train himself his muscles every day at home.

13) Ask the customer to be more actively involved in the QRS-PelviCenter treatment
    a. The first or second treatment it is all right for the customer to sit and passively follow the magnetic pulses and thereby the muscle contractions which are automatically triggered by the PelviCenter.
    However in order for the PelviCenter treatment to be more effective it is encouraged that the customer tries to pay attention clearly to which muscles are being contracted.
    And then the customer is encouraged to try and contract the muscles himself/ herself, just before the automated contraction of the PelviCenter.
    So the customer is encouraged to count the seconds of rest time ("off time", normally 4 seconds) and just before the PelviCenter starts contracting again then the customer is encouraged to contract himself the muscles as strong as possible.
    In this way the customer will not only become more aware of where his/ her pelvic floor muscles are but also the male customer will be able to control these muscles better during sexual function and for example delay the ejaculation.

14) Encourage the customer to do Kegel exercises him/ herself at home
    a. Remember that QRS-PelviCenter is complementary treatment. The customer is advised to do 2 or 3 treatments per week. Ideally the customer also tries to do every day the Kegel exercises at home. The customer will see very quick results, normally within the first 3 weeks of treatment.

15) Progressive load
    a. An important principle of building muscle strength is 'progressive load'. If the customer is confident with the PelviCenter treatment at a certain intensity and frequency, the customer must be encouraged to go to higher intensities. This will also have the effect that not only the superficial bulbospongiosus and ischiocavernosus will be trained but also the more deeper lying other pelvic floor muscles.

16) Register clearly the per customer and per treatment what parameters have been used for the treatment (what intensity levels and what frequencies). This is important information for the next treatment but is also important to evaluate the results of the treatment program in a later stage.

17) Register regularly the progress of the QRS-PelviCenter treatment. For example after every 4 sessions asking the patient to fill out a standard sexual function questionnaire. Do not stop after 4 or 8 treatments. Building muscle strength requires time and can normally not be realized in 4 or 8 treatments. This is especially relevant because for building strength it is important that the customer has used the QRS®-PelviCenter for various treatments at the highest intensity (100%). Normally it takes the customer between 4 to 10 treatments to reach this 100%. The lower intensities (20%-40%) will be beneficial in improving the coordination and function of the muscles but in order to build sustained strength it is important to follow various settings at 100% intensity.

18) Discuss with the customer the other causes of his ED. Advise solutions for the other causes or symptoms.

Remember:
QRS-PelviCenter training is training of the muscles of the pelvic floor.
All the principles which are normally used for muscle training are also applicable for effective QRS-PelviCenter training. This means:

- Every customer is different. And every customer requires a specific training program.
- The principle of Overload. If you want to realize the goals of muscle training then it is important to do the exercises at a greater than normal stress.
- The principle of Progression.
    - Customer must gradually and systematically increase the workload/ the intensity of the QRS-PelviCenter training. Only that will result in improved strength. If the Overload (intensity) is increased too quickly then it can result in injury or muscle damage. Another example: It is better to try to do training regularly (every day) instead of only in the weekends.
    - Also, the principle of Progression stresses the need for proper rest and relaxation. Continual stress on the body and constant overload will result in exhaustion and injury. You must not train pelvic floor muscles hard all the time, as you will risk overtraining.
- The principle of adaptation.
    - The body is clever and is able to adjust to increased physical training. After a certain point of time, the body will find it easier to do the QRS-PelviCenter muscle exercises and uses less energy to carry out these exercises. In order to realize continued improvement it is important to change the training program a little bit.
- The principle of use and disuse.
    - “use it or loose it”. If a man does follow the QRS-PelviCenter training but he then does not regularly “ use it” then after some time the muscle fibers will start to decrease again. Men who regularly have sexual intercourse (who thus regularly “train” their muscles) have lower risk of losing strength of the relevant muscles.
- The principle of specificity.
    - If you want to train a certain muscle or achieve a certain goal the QRS-PelviCenter training protocol must be focused on that muscle and that goal.

Appendix 1: Clinical trials proving the effect of Kegel exercises on improving sexual function

- Mamberti Dias et al, 1991
  - 210 patients. 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]*
- Schouman and Lacroix, 1991
  - 20 patients. 55% reported complete response.
  - Results not so positive. Only small sample size. No information on drop-out rates.
    - *[Schouman M., Lacroix P. Apport de la rééducation pelvi-périnéale au traitement des fuites veino-caverneuses. Ann Urol. 1991;25:92-93]*
- Claes and Baert, 1993 (Belgium)
  - 78 patients. Follow up period 4 to 12 months. Drop out rate 14%. Of remaining group 86% had complete response (51%) or improved ED (35%)..
  - Complete response 50% of patients who completed the PFM training
    - *[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]*
- Study 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.
- Colpi et al, 1994
  - 59 patients. Follow up period 9 months. High drop out rate 44%. Of the remaining group 64% had complete response or improved ED...Not clear why there was such a high drop out rate.
  - 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, Scroppo 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]*
- Claes et al, 1995 (Belgium)
  - 122 patients. 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]*
- Marijke van Kampen et al (Belgium)
    - *[Marijke Van Kampen, Willy de Weerdt; 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 isssue 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 reslts 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 2: Other relevant literature & research about Erectile Dysfunction

Some other relevant literature on the process of sexual function and getting & maintaining an erection.

1. Penile Erection requires 2 vascular events:
   - Normal erection is based on:
     1) Increase of blood flow to the penis. And at the same time:
     2) Blocking the venous outflow of blood
   - This process is started by nerve impulses, triggered by various stimuli (e.g. lust/ libido/ fantasies/ touch), which result in relaxation of the smooth muscle cells.
   - References:
     - *Jünemann KP, Persson-Jünemann C, Alken P. Pathophysiology of erectile dysfunction. Semin Urol (US) 1990; 8: 80-93*
     - *Jonas U, Thon WF, Stief CG, Erectile Dysfunction. Springer Verlag, Berlin, 1991.*
     - *Levine LA. Diagnosis and treatment of erectile dysfunction. Am J Med. 2000;18:298-305*
       - *"…*Alternations in the flow of blood to and from the penis are thought to be the most frequent causes of erectile dysfunction…"

2. For getting an erection = improving the blood flow to the penis it is important that the penile erectile tissue (= smooth muscle cells) remains of high quality

- A long term reduction of the oxygenation of the Corpus Cavernosum is an important factor in men getting Erectile Dysfunction:
  - *Tarhan F, Kuyumcuoglu, U, Kolsuz A, Ozgul A, Canguven O. Cavernous oxygen tension in the patients with erectile dysfunction. Int J Impot Res 1997;9:149-53*
- Oxygen partial pressure is of key influence on the collagen fiber content. In a healthy corpus Carvernosum the ratio between smooth muscle cells to connective tissue is about 50%-50%. With low oxygen partial pressure the collagen fibers are growing resulting in a lower percentage of smooth muscle cells. When during sexual function, the oxygen pressure increases and this stops the growth of collagen fiber.
  - *Mersdorf A, Goldsmith PC, Diederichs W, Padula CA, Lue TF, Fishman IJ, Tanagho EA. Ultrastructural changes in impotent penile tissue: a comparison of 65 patients. J. Urol 1991; 145: 749-85*
  - *Moreland RB. Is there a role of hypoxemia in penile fibrosis: a viewpoint presented to the Society for the Study of Impotence. Int J Impot Res 1998; 10: 113-20*
  - *Border WA, Ruoslahti E. Transforming growth factor beta in disease: the dark side of tissue repair. J. Clin Inv 1992; 90: 1-7*
  - *Wespes E, de Goes PM, Schulman CC. Age-related changes in the quantification of the intracavernous smooth muscles potent men. J Urol 1998; 159 (Suppl): 99*.

3. Some of the causes of ED when people get older

1. When men get older the percentage of smooth muscle cells as compared to connective tissue fibers is decreasing. The key cause is lower oxygen partial pressure. Oxygenation is increased during sexual activity and also during sleeping. This explains the morning erection phenomena.
    a. See literature references above.
2. When men get older, the systolic peak flow is decreasing.
    a. *Chung WS, Park YY, Kwon SW. The impact of aging on penile hemodynamics in normal responders to pharmacological injection: a Doppler sonographic study. J Urol 1997; 157: 2129-31*
3. Reduction of the rigidity of the erection.
    a. This is fully due to a "venous-occlusion dysfunction". The blood flows too quickly out of the penis. This, in turn, is fully due to weakening of the skeletal muscles, the Ischiocavernosus muscle and the Bulbospongiosus muscle.
    b. About 20-35% of patients with ED has a problem with "venous-occlusion dysfunction".
        i. *Porst H. Erektile Impotenz. Ätiologie, Diagnostik, Therapie. Enke-Verlag, Stuttgart, 1987.*
        ii. *Porst H. Pharmakoangiographie und Pharmakoangiodynographie des Penis bei erektiler Dysfunktion. Urologe A 1990; 29: 120-5*
        iii. *Wespes E, Schulman CC. Venous impotence: pathophysiology, diagnosis and treatment. J Urol. 1993;149:1238-1245*
    c. The Ischiocavernosous muscle can increase the intracavernous pressure on the erectile tissue, when the nerves of the muscles are stimulated
        i. *Michal V., Simana J, Rehak J, Masin J. Haemodynamics of erection in man. Physiol Bohemoslov 1983; 32-497-9.*
        ii. *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*
    d. 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.
        i. *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*
        ii. *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*
    e. 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.
        i. *Kawanishi Y, Kishimoto T, Kimura K, et al. Spring balance evaluation of the ischiocavernosus muscle. Int J Impot Res. 2001;13:294-297*
    f. Kawanishi et al determined that there are statistically significant differences in IC function between patients with intact erectile function and those with ED with respect to stroke length, duration of contraction, and maximal contractile force.
        i. *Kawanishi Y, Kishimoto T, Kimura K, et al. Spring balance evaluation of the ischiocavernosus muscle. Int J Impot Res. 2001;13:294-297*

g. About Bulbospongosius muscle:
    i. When contracted the Bulbospongosius 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.
    ii. The bulbospongiosus muscle has a prominent role in ejaculation (PE)
        1. *Dorey G, Speakman MJ, Feneley RC, et al. Pelvic Floor exercises for erectile dysfunction. BJU Int. 2005;96:595-597*

h. About the pubococcygeus muscle:
    i. Kegel AH. Sexual functions of the pubococcygeus muscle. West J Surg Obstet Gynecol. 1952;60:521-524

<u>Studies about Premature Ejaculation and Pelvic Floor Muscle training:</u>

- *La Pera G, Nicastro A. A new treatment for premature ejaculation: the rehabilitation of the pelvic floor. J Sex Marital Ther. 1996;22:22-26*
    - La Pera et al demonstrated the effectiveness of PFM rehabilitation 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.
- *Piediferro G, Copli EM, Castiglioni F, et al. Premature ejaculation. 3. Therapy. Arch Ital Urol Androl. 2004;76:192-198*
    - Piediferro et al showed that physiotherapy was successful in the management of PE associated with pelvic floor dysfunction
- *Pastore AL, Palleschi G, Leto A, et al. A prospective randomized study to compare pelvic floor rehavilitation and dapoxetine for lifelong premature ejaculation. Int J Androl. 2012;35:528-533*
    - Pastore et al compared 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 ejaculatory control. Although dapoxetine resulted in greater increases in intravaginal latency time as compared with those treated with PFMT, the authors concluded that PFMT is a promising therapeutic option for PE.
- *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.
- Additional notes:
    - Further studies are needed. Although there are positive findings, there remain a lot of unanswered question as to the exact mechanism. For example what is the mechanism controlling the ejaculatory reflex. And does ejaculatory inhibition occur on the basis of contraction or on the basis of relaxation of the Bulbospongiosus/ Ischiocavernosus muscle.

Other relevant studies on Pelvic Floor Muscle training & improving sexual function:

- *Kegel AH. The nonsurgical treatment of genital relaxation. West, Med & Surg. 1948;31:213-216*
- *Kegel AH: The physiologic treatment of poor tone and function of the genital muscles and of urinary stress incontinence. West J Surg Obstet Gyne. 1949;57:527-535*
- *Kegel A. Progressive resistance exercise in the functional restoration of the perineal muscles. Am J Obstet Gynecol. 1948;56:238-248*
    - Applied exercises can enhance PFM strength, tone, durability, and responsiveness, since muscle increase in strength in direct proportion to the demands placed upon them
- *Kegel AH: The physiologic treatment of poor tone and function of the genital muscles and of urinary stress incontinence. West J Surg Obstet Gyne. 1949;57:527-535*
    - The Pelvic Floor Muscles, as with all skeletal muscles, are subject to the force of adaptation.
- *Newman DK, Wein AJ. Office-based behavioral therapy for managing of incontinence and other pelvic disorders. Urol Clin North Am. 2013;40:613-635*
    - The Pelvic Floor Muscles consist of muscle fibers of which 70% are slow-twitch type 1 (fatigue-resistant fibers that maintain static tone) and 30% are fast-twitch type 2 (resistant-prone fibers that are capable of active contraction). A decrease in the number of fast-twitch fibers can occur with aging, inactivity, and nerve innervation damage
- *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 refactory time
        - Less rigid erections
        - Adequate rigidity but premature loss of erections
        - Inability to achieve an erection.
- 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*
- There is a lot of similarities between coronary heart disease and Erectile Dysfunction. The prevalence of both increases with similar percentages when men get older. Very often ED is a first symptom of coronary heart disease. Physical exercise has been proven to have a positive effect in reducing coronary heart disease. Also ED can be prevented by physical exercise.
    - *Sommer F. VigoRobic – Potenter durch gezieltes Fitness training, Meyer & Meyer Verlag, Aachen, 2000*
    - *Hollmann et al, 1994*

More quotes on the role of Pelvic Floor Muscles in sex:

- 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 organism 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: Literature on sexual performance of women:

- 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 September 2015:
    - 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 summarizes 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 overall 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".

Please refer to treatment protocol QRS®-PelviCenter for improving sexual function of women. Purpose of this document is to give treatment protocol for improving sexual function of men.

Appendix 4: Some studies on the effectiveness of QRS®-101 in improving sexual function

Study on QRS-PEMF (low magnetic intensity) = NOT QRS®-PelviCenter !

- *Shafik, A., El-Sibai, O and Shafik, A. (2000) Magnetic stimulation of the cavernous nerve for the treatment of erectile dysfunction in humans. Int J Impot Res 12: 137-141; discussion 141-132:*
    - Study of 32 patients with neurogenic ED and 20 healthy volunteers. A magnetic coil was placed over the dorsal aspect of the penis in the vicinity of the symphysis pubis. For 10 minutes, magnetic stimulation at 40% intensity and 20 herz frequency, 50 seconds on and 50 seconds off, led to gradual increases in length and diameter until full erection was achieved; the penis became firm, rigid and pulsatile. Incorporeal pressure also increased significantly at full erection. The study demonstrated that magnetic stimulation is a simple, noninvasive method that could induce phallic engorgement and indicated this therapy might be suitable for patients with ED.
- *Pelka, R. Jaenicke, C. And Gruenwald, J. (2002): Impulse magnetic-field therapy for erectile dysfunction: a double-blind, placebo-controlled study. Adv Ther 19: 53-60*
    - Double blind, placebo-controlled study. Study assessed the efficacy of 3 weeks of impulse magnetic-field therapy for ED. A total of 20 volunteers who suffered from ED or orgasmic disturbances were included. The results suggested that impulse magnetic field therapy improved erectile function at certain forms and doses (10 minutes, magnetic stimulation at 40% intensity and 20 Hz frequency, 50 seconds on and 50 seconds off). In the active-treatment group, all efficacy endpoints were significantly improved. With 80% reporting increases in intensity and duration of erection, frequency of genital warmth, and general well-being. The remaining 20% who experienced minor improvements, were found to have an influenza-like infection after the study that may have influenced their results. No side effects were reported.

Appendix 5: How to Identify & how to do pelvic floor muscle exercises for men ("Kegels")

Step 1: How to IDENTIFY the pelvic floor muscles for men

<u>The Ischiocavernosus and Bulbospongiosus muscle</u>
The first step to be able to do pelvic floor exercises for men effectively is to find and identify the appropriate muscles around the anus and the urethra. Most men are not able to identify or feel the relevant muscles and need help by a trained doctor or physiotherapist.

- Identify the most important muscles:
    - Method 1: Feel with 2 fingers in the space between "anus" and "scrotum". Here are the relevant muscles for sexual performance. Normally in this area there is not so much fat so it is relatively easy to feel the muscles, especially when trying to contract the muscles.
    - Method 2: When you go to the toilet for urination, try stopping the urination for 5 or 10 seconds. The muscles you now contract are the key muscles which are relevant for controling the "pee" as well as for controlling the ejaculation. In training the Kegel exercises (step 2) you can 'mimic" this movement. But do not do this exercise everytime during urination.
    - Method 3: Try to imagine that there is a small towel on your penis. And now try to imagine that you want to carry your scrotum and penis up. Close your eyes and try to lift up your scrotum. The muscles that you are now using are the muscles that need to be trained.
- Identify all other relevant pelvic floor muscles:
    - Start by laying comfortably on your back or side, knees bent with the muscles of your thighs, bottom and stomach relaxed.
    - Anal sphincter: Tighten the ring of muscle around your anus by *imagining* you are stopping a bowel motion- without squeezing your bottom. Note the difference between the anus (the sphincter) and the bottom (your buttock muscles). Relax and let go.
    - External Urinary Sphincter: Tighten the muscles around the urethra – *imagine* you are stopping the flow of urine midstream. Relax and let go.
    - Now try to "lift " the scrotum, pull up inside the pelvis – as if you are walking into the cold ocean! Relax and let go.

Important: The QRS®-PelviCenter is very effective in helping customers identify where the Pelvic Floor Muscles are. A doctor does not need to help the customer in an "uncomfortable" way by touching the genital area of the customer and pointing out the muscles. Instead, when a customer is sitting in the PelviCenter he will feel immediately what muscles are being contracted, and released.

STEP 2: How to DO the pelvic floor muscle exercises for men

Key notes:

- ONLY start doing these exercises after you have been able to IDENTIFY the right muscles.
- Many men start exercising the wrong muscles and then there will be no positive effect on sexual function. Men should not train the muscles of the buttocks, abdominals or thighs. You must not squeeze buttocks, thighs or suck in your tummy (abdominals).
- It is also important to keep breathing normally during the exercises. Try to breath "from the inner core".
- Once you can feel your pelvic floor muscles working, you can exercise them.
- Try to do the exercises every day 3 times per day in total minimum 60 times (3 sessions of 20). But in the beginning do not overdo it. If you overdo in the beginning you will get some muscle pain and you will not experience the increased strength in the first few days.
- 4 types of exercises:
    - Start with the "Basic Flex"
        - Simple contraction of the Pelvic Floor Muscles
        - Squeeze and hold the contraction for 1 to 2 seconds and then release.
        - At first many men are not able to hold for more than 2 seconds.
        - This exercise develops basic strength and control of the muscles
    - The long "Hard Flex"
        - Slow contraction
        - Squeeze as hard as you can
        - Hold for 3 to 5 seconds
        - This exercise builds longer lasting strength
    - The "Hold"
        - This is a long hard contraction.
        - Do not release at the end but continue to squeeze for as long as you can. Increases the strength.
        - Count how many seconds you can comfortably hold, then release and relax. You should have a definite feeling of 'letting go'. Over time, gradually increase the hold time to 10 seconds.
        - Repeat this up to maximum of 8 to 10 squeezes, resting for 10 seconds after each tightening of the muscles.
        - This exercise builds strength, control and increases the size of the muscle.
        - This exercises is particularly relevant for customers suffering from Premature Ejaculation. During sexual activity the customers can hold this muscle for a longer time to avoid premature ejaculation.
    - The "Rapid Flex".
        - Not 8 seconds or more followed by 4 seconds rest. But much shorter.
        - Very quick. Very quickly squeeze and release.
        - This exercise will train the "Fast switch" muscles.
        - The "rapid flex" contractions are also very important for ED and PE. Do not only focus on long "hold" contractions but always try to also do 5 to 10 short, strong squeezes in quick succession.

<u>Comparison. Below were the instructions used in the study of Dorey (UK) in 2003:</u>

- Tighten your pelvic floor muscles as strongly as possible
  (as if to prevent flatus from escaping)
- Attention on ability to retract the penis and lift the scrotum, to make sure the Bulbospongosius and Ischiocavernosus muscles are working strongly.

- Emphasis on gaining a few maximum contractions (3 when lying, 3 sitting and 3 standing), minimum 2 times per day, rather than prolonged repetitions.
- Some sub-maximal pelvic floor work was advised while walking, to increase muscle endurance.
- Also, tighten your pelvic floor muscles after voiding urine whilst still poised over the toilet, as a way of working the ischiocavernosus muscle to eliminate the urine from the bulbar urethra.

<u>Another technique for doing Kegel exercises: Imagine</u>

- Start with lying on the floor with your knees bent upward and together. Your arms and hands are lying next to your body on the floor. Do not move your hipbones.
    - Imagine that you want to pull up your scrotum, up to the belly, and up to the lungs.
    - Imagine that you have a small towel on your penis and try to lift up this towel.
    - Imagine that you want to lift the right side of your scrotum to your left hand; and vice versa, imagine that you want to life the left side of your scrotum to your right hand.
- After you are able to do this exercise then make the exercise a little bit more difficult by:
    - Doing the same exercise by taking the knees apart from each other. So still lying on the floor with your knees bent but now the knees are not together.
    - Doing the same exercise by putting one of the legs straight pointing in the air (not on the ground)
    - Doing the same exercise while sitting. Sit upright on a firm chair. Repeat the above actions and feel as if you are lifting your anus, scrotum and penis away from the chair. Relax and let go.
    - And later doing the same exercise while standing or walking. the same action of closing or tightening the anus, urethra and lifting the scrotum. Try cupping your scrotum in your hand and "lift" it off your hand – do you feel the pelvic floor muscles tighten? Also, look in the mirror and if you are doing the exercise correctly you should see that your scrotum is lifting up a little bit. And the penis will retract of move up a little bit to the pubic bone.
    - Not only focus on the scrotum (Ischiocavernosus & Bulbospongiosus muscle) but also try to tighten and draw in the muscles around the anus and urethra. Remember that pelvic floor muscles are a large and complex set of muscles which have to work together in a coordinated manner and you should avoid training only one or two separate muscles. A proper pelvic floor exercise for men or contraction is a combination of all these actions: Squeeze and tighten the anus, stop the flow of urine and lift the scrotum.

<u>Reverse Kegel exercises:</u>

Some men suffering from PE have Pelvic Floor Muscles which are too tight.
In that situation the focus of Pelvic Floor Muscle Training must focus on relaxation of the muscles.
One method to achieve relaxation is via so-called "reverse Kegel exercises", as follows:

- Instead of trying to make the movement of stopping the "pee" during urination, try the movement of pushing out the pee with extra force.
- Instead of the movement of trying to stop the stool from coming out of the anal sphincter, train the movement of forcefully pushing out the imaginary stool.