



Treatment Procedure

Device:	QRS 1010 PelviCenter V 1.2
Release company:	QRS International AG
Date of release:	1.3.2013
Treatment:	Erectile Dysfunction

1. Initial diagnosis by a doctor

Each Patient who would like to use the PelviCenter should first consult a doctor to clarify any incompatibilities with the treatment. The treatment is a very strenuous muscle training, which can strain blood circulation. Special caution is recommended in elderly or debilitated people. The doctor should confirm that the patient can cope with an increased cardiovascular load.

2. Consultation with the patient

The staff which should advice the patient into the machine and the treatment should be a well-trained and instructed medical professional, like a doctor, physiotherapist, nurse etc.

The staff should explain the patient the basic function of the machine, how it works and how the expected feelings for the patients would probably be. Especially older people will be a little bit scared about the unusual feelings, sensing it the first time. In such a case, a lot of sensitivity is necessary to gain the trust of patients.

Although the treatment is usually very well tolerated, there's still no medical procedure that may have not **side effects**. And although these side effects rarely occur, the patients still must be informed and enlightened. An appropriate form is made available by QRS.

IMPORTANT

It is absolutely essential to inform the patients about the **contraindications**. A special form with a list of contraindications is provided. This information must be done quit and slow so that the patient can accurately understand each point of the list of contraindications. Understanding of the patient must be ensured by control issues.

3. Signing the risk disclosure statement by the patient

To protect the patients' rights and to ensure that you are complying with your duty to inform the patient, it is necessary to **fill out and sign a consultation** form by you and the patient. This form has to include the list of contraindications. This form has to be kept by the operators of the treatment center.

IMPORTANT

For legal reasons it is prohibited to treat a patient without a prior filled in and signed form of the above mentioned form of consultations.

4. Performing the treatment – Find the right patient setup on the chair

Before starting with treatments on an active chair, the following preconditions will be **strongly recommended**

- Empty bladder
- Replacing wet pads
- Removal of body jewelry between knee and neck (chains, rings, piercings, etc.)
- Removal of watches, car keys, credit cards, pagers, mobile phones and coins

If patient is using the **light therapy** option during the training, it is necessary to lowering the via-head mounted unit to the lowest position the patient felt comfortable.

If the patient is **using oxygen** during the treatment, the staff has to put a new, disinfected oxygen mask on the provided tub. The patient should then put the mask on and should then calmly breath through the mask.

IMPORTANT

Very important is to have the right **seating position**. If you have a backward leaning position on the chair, you have strong contractions of the Gluteus Maximum. The right position is an **easily forward inclined position**.

5. Identifying the individual start intensity of the patient

Basically, in a treatment with PelviCenter similar considerations has to be applied as they are known from the sports physiology.

The treatment must start with an individually determined basic level of intensity. And then, when the treatment goes on, the intensity has to be improved in a reasonable way.

But who can we determine the individual basic intensity of a patient.

- We start treating the patient with a low frequency signal (for example 5 Hz) and with the lowest intensity of 20 %.
- Then we talk about the feelings and we ask the patient, whether he can withstand the intensity well or not.
 - o If the patient can tolerate the level well, we ask for the possibility of increasing to next level
 - o If it's OK we will take 40 % as the starting level
 - o If it's not, we go back to 20 %

IMPORTANT:

Never start with a basic level more than 40 %

IMPORTANT:

Patients are often very ambitious.

But due to the fact that patients are often not very experienced with exercising and feeling their pelvic floor muscles, they often overestimate themselves.

The result is then often soreness and other unidentifiable pain syndromes in the urogenital track.

So advice your patients to be a little bit ambitious, because it is important for a successful treatment, but to much.

6. Performing the treatment – Treatment plan for an individual treatment

The treatments are structured in programs. Each treatment lasts 25 Minute. All of the treatment programs have a defined plan of operating. This program is fixed and cannot be changed by staff or patient. Individually changeable is the individual level of intensity, a patient is accepting and using, but not the structure of the program during the 25 minutes of treating.

To start treatment secession:

- Select the appropriate program - for **erectile dysfunction** select program number 3.
- Adjust the intensity to
 - o At the first time - the individually determined intensity of the patient
 - o all other times - the individually reached training level
- Start the treatment

The structure of the 25 minutes erectile dysfunction incontinent program (program nr. 3):

Phase 1:

Length of time: 5 minutes
Intensity: Individually determined intensity of the patient
Duty Cycle: 8 seconds active / 4 seconds break
Frequency: 5 Hz

Phase 1 is the **warm-up-phase**. This Phase is very important and aims to relax the pelvic floor muscles. It is important not to start with tense muscles. The phase shall relax the muscles, shall slowly activate the metabolism of the pelvic floor muscle structure and is to prepare the patient for the next session.

Phase 2:

Length of time: 10 minutes
Intensity: Intensity set by the patient
Duty Cycle: 8 seconds active / 4 seconds break
Frequency: 30 Hz

Length of time: 5 minutes
Intensity: Intensity set by the patient
Duty Cycle: 8 seconds active / 4 seconds break
Frequency: 5 Hz

Phase 2 is the normal training session. Patients, especially elderly or weak patients, should be monitored on a regular basis. If staff is observing that the training is too strenuous for the patient, the intensity level should be reduced.

IMPORTANT

A patient is not every day in the same good condition. It is absolutely normal, that the intensity must sometimes be humiliated on a given Day. "Less" is "more" in such a case.

Phase 3 :

Length of time: 5 minutes
Intensity: -
Duty Cycle: -
Frequency: -

Phase 3 is a special phase which lasts for 5 minutes by applying a low energy PEMF (pulsed electromagnetic field) signal. Phase 2 was a relatively intensive phase which has severely strained the heart cycle. Phase 3 activates the parasympathetic nervous system, improves the capillary microcirculation and helps to better regenerate.

7. Performing the treatment – Treatment plan for the whole treatment period

Duration of the treatment period

Patients are very individually. It is impossible to specify a general recipe. But nevertheless, based on our experiences, we can specify a reasonable amount of individual treatments to get a good result.

We recommend persons with erectile dysfunction

Treatment total:	recommended	18
Treatments per week:	minimum	2
	Maximum	3

Our experience shows, that if it is possible, 3 times a week for the duration of 6 weeks gives the best benefit to the patients.

Increase of intensity

The patient starts treatment with his individually determined starting intensity. For good results, it is strongly recommended to increase intensity during the treatment period. But it is important to do that in a reasonable way. If the patient is feeling comfortable after two or three treatment sessions with the starting intensity he should try to increase one level.

If the new level is only more exhausting than the level before, everything is OK.

If the new level is painful or is bringing the patient in an too uncomfortable feeling, decrease again. Then it is too early to increase the level.

Example of a possible treatment plans:

Treatment Nr.	Patient Nr. 1 Starting Intensity	Patient Nr. 1 current Intensity	Patient Nr. 2 Starting Intensity	Patient Nr. 2 current Intensity	Remarks
1	20%	20%	40%	40%	These are two typical processes
2		20%		40%	Each patient starts individually
3		20%		40%	Each patient increases individually
4		20%		60%	
5		20%		60%	
6		40%		60%	
7		40%		60%	
8		40%		60%	
9		40%		60%	
10		40%		60%	
11		40%		60%	
12		40%		60%	
13		60%		60%	
14		60%		80%	
15		60%		80%	
16		60%		80%	
17		60%		80%	
18		60%		80%	

IMPORTANT

People often want to be very ambitious and want to increase training frequency. It makes no sense to do more than 3 treatments a week, because of the necessary regeneration phase of muscles.



8. Final treatment discussion and final treatment documentation

At the end of the treatment period we recommend an after treatment patient survey.
An appropriate form is made available by QRS.

IMPORTANT

The medical product law requires, that any side effects that have been identified, should 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.