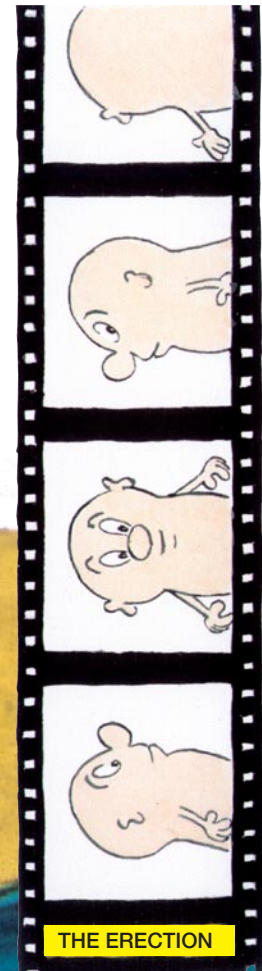
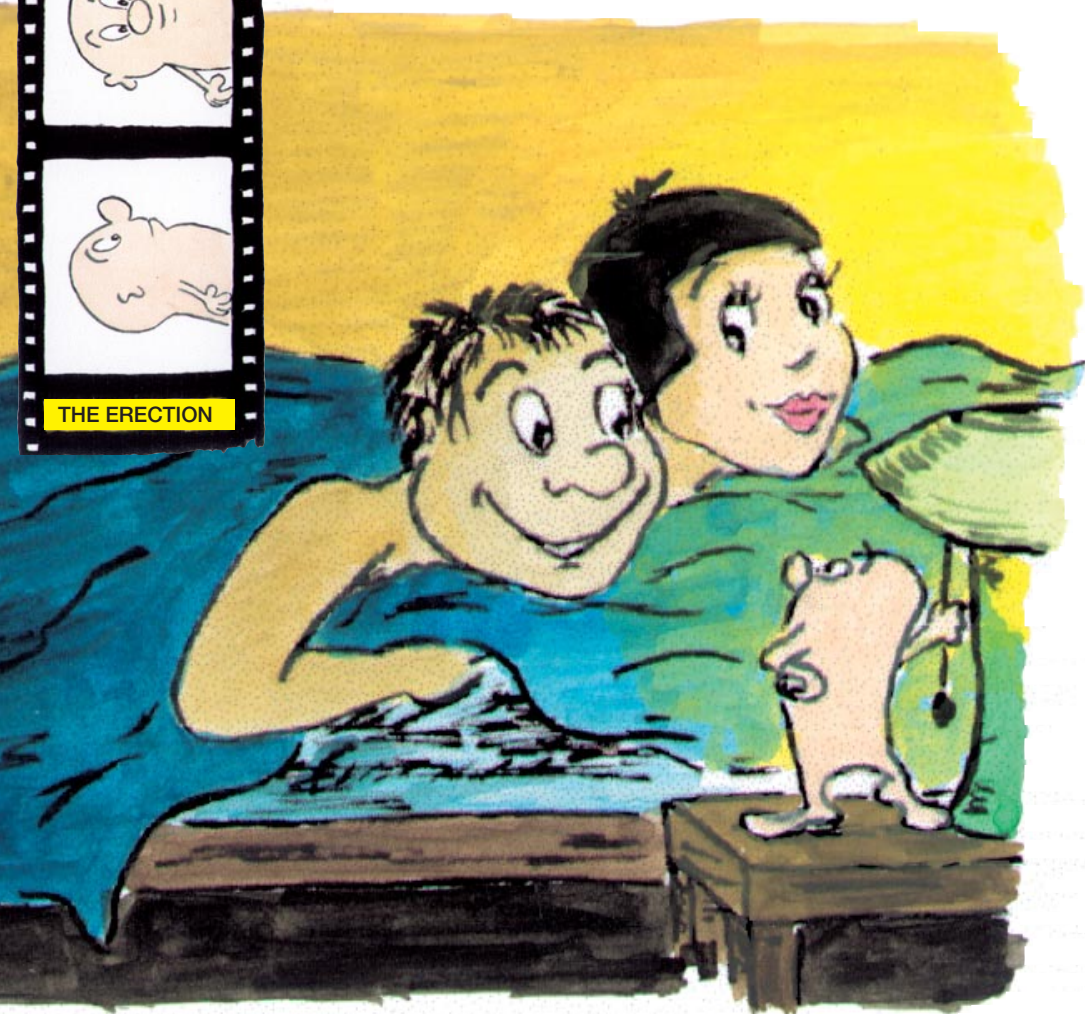


Phalli-Max

Electric stimulation appliance
for the treatment of erection disorders



THE ERECTION



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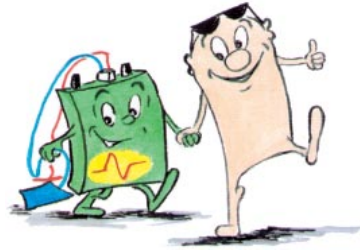
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Phalli-Max



1

Erection disorders – an introduction.

“Nearly one-in-five men in Germany today suffer from erection disorder. At this moment only one-in-three of those undergo treatment for it.” This is the introduction to a report on erection disorders dated September 27th 2000 and based on the “Cologne 8000 Men Survey”, an interview study involving 8000 men between 30 and 80 years old. The incidence of erection disorders “ at the age of 30 was approximately 2.3% and increased by the age of 80 to 53.4% ... 6.9% of the men underwent treatment.”

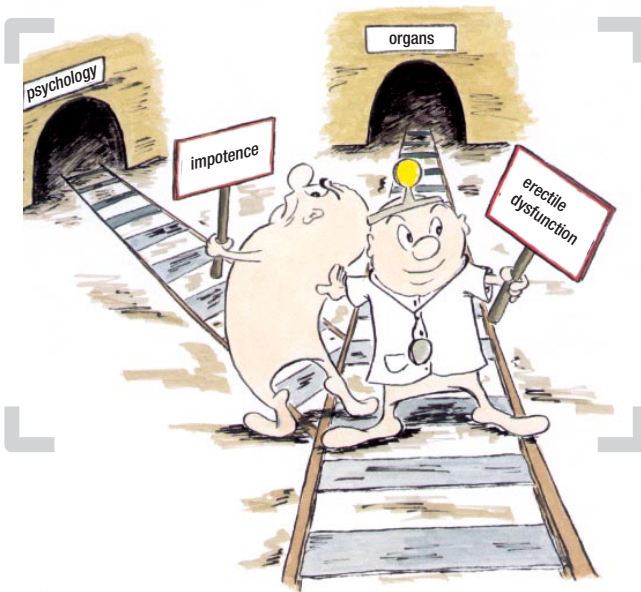
Today it is estimated that roughly 4 million persons are affected, including the unconfirmed cases.

According to the Cologne 8000 Men Survey, by the year 2030 the number will already be 5.65 million, of whom 1.8 million will be undergoing treatment. Thus it is understandable that the search for possible therapies is now intensifying!

In the eighties, there was a great upswing of research into the sexual functions of the man. Most importantly, inhibitions regarding the presentation to the public of the comprehensive results of research in the field of male sexuality were finally overcome! Numerous diagnostic methods were developed, insight was gained into the functioning of the erection and therapeutic methods were presented.

At last, erection disorders were accorded the status of a medical syndrome within the field of urology and shed their disreputability. At the same time, the term “impotence, which is

roughly synonymous with “incapacity” and a very discriminative designation, was ousted from the everyday language.



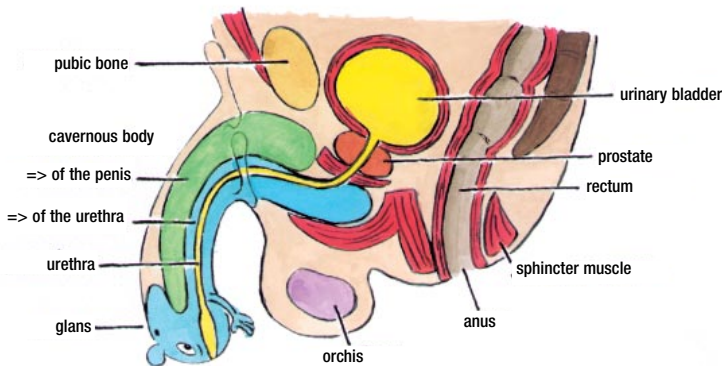
In medical terms, the problem is described as erectile dysfunction or erection disorders. Previously, men with erection disorders either did not go to the doctor with this problem at all or they were channelled towards psychiatric treatment. Thanks to the more recent research findings, it is now frequently possible to prove that there are organic causes, which made it easier to tackle the problem both for the patient as well as for the physician.

The next step is that erection disorders were no longer relegated to the status of general indisposition but are recognized as an illness. Now, however, before talking about erection dysfunctions, we are going to explain the normal functioning of an erection.

2

How does an erection function?

For an erection, many factors are important, both psychological and organic. However, particularly important is the cavernous body, which is composed of three parts: the two lateral chambers of spongy tissue, called the "Corpora Caverosa" and the median column of erectile tissue surrounding the urethra, called the "Corpus Spongiosum". These tissues can be imagined like sponges composed of cavernous tissue and in which are embedded muscle fibres. This creates vascular spaces which, sexually stimulation occurs, become engorged with blood. Simultaneously, the out-flow of blood from the vascular spaces becomes congested so that, as a result, the penis becomes hard and erected. The whole process is controlled almost entirely involuntarily by reflexes from the brain and the central nervous system in the spine. By "involuntarily", we mean that the erection itself cannot be controlled at will.

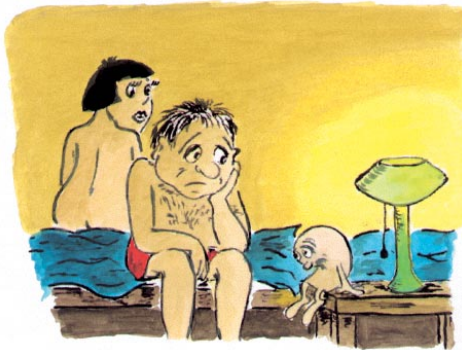


Furthermore, the muscle layers at the base of the pelvis play an important part in maintaining the erection. These muscles close at the bottom of the pelvic bone and support the intestines. These layers, in the case of a man, are intersected, among other things, by the rectum but also by the urethra, nerves, blood vessels and muscles. If the sphincter muscles are tensed, the anus and the urethra, for example, are closed. At the same time, however, blood vessels coming from the cavernous body are constricted, thus impeding the return flow of blood. In this way the pressure in the cavernous body can be increased.

The base of the pelvis comprises muscles which can be tensed and relaxed at will, thus, therefore, they can be consciously trained!!

3 What are the outward symptoms of erectile dysfunction?

There are multifarious causes and symptoms of erectile dysfunction. The observations of the persons affected are correspondingly varied. Nevertheless, there are circumstances that are described directly or indirectly by all patients.

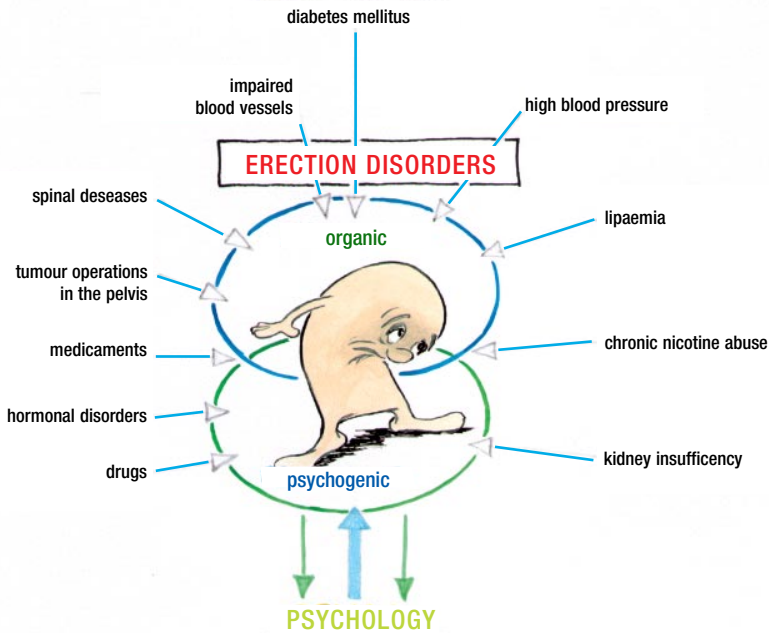


Common to all in connection with a failed erection are the feelings of fear, embarrassment, shame, anger, desperation and disappointment. Furthermore, the wish to be able again to satisfy the sexual desires of his partner is often in the foreground. To rectify these circumstances is the highest priority for the patient, who is then only too willing to instigate therapeutic measures, using medicaments or medical appliances to counteract the organic disorder. In this, however, the psychological component is frequently disregarded.

The self-esteem of a man suffering from erection disorder is usually grievously impaired, not only by his sexual problems but also by other stress factors inherent in his professional circumstances, in his partnership relationship and from the pressures imposed by our performance-oriented society. Therefore, there may be several reasons at the root of the functional disorder.

4 What are the causes of erectile dysfunction?

In the case of erectile dysfunction, we make a principle distinction between organic and non-organic, psychogenic disorders. Possible causes of erectile dysfunction due to organic disorders may derive from the blood vessels, the cavernous body, hormonal disorders, nerve damage, muscle or connecting tissue disorders.



The most important organic causes of erectile dysfunction are in the following proportions:

- 33% Impaired blood vessels
- 25% Diabetes mellitus (excessive blood-sugar)
- 11% Spinal damaged and disease, including multiple sclerosis
- 10% Tumour operations on the pelvis
- 8% Medicament intake (e.g. anti-hypertensive medicaments, psychopharmaceuticals, antiepileptics, anti-lipaemia drugs, anti-inflammation drugs, hormones)
- 6% Hormonal disorders, (e.g. insufficiency of male hormones, excessive prolactin, thyroid diseases, diseases of the kidneys, liver diseases)
- 7% Drug abuse (marihuana, heroin)

Risk factors causing erectile dysfunction:

- Chronic nicotine abuse
- Diabetes Mellitus
- High Blood Pressure (Hypertonus)
- Lipaemia
- Chronic kidney disease (kidney insufficiency)

Considering all the possible causes, however, the psychological component must not be disregarded for every form of erectile dysfunction ultimately has an effect on the psyche. Thus it sets in motion a vicious circle that has to be broken. Only after exhaustive examination is it possible to establish the causal nexus, which is of the utmost importance for the initiation of the right therapy. In the meantime, the range of therapeutic measures is so diversified that it is now possible to select exactly what is appropriate in the individual case.

5

What are the therapeutic possibilities?

Fundamentally, the treatment of erectile dysfunction rests on two pillars: the first involves the therapy of organic causes, which ranges from the use of medicaments, to medical appliances and finally operative treatment. The second pillar comprises sex counselling and therapy which takes into account the psychiatric element.

It would explode the bounds of this brochure if one were to try to explain every process in detail.

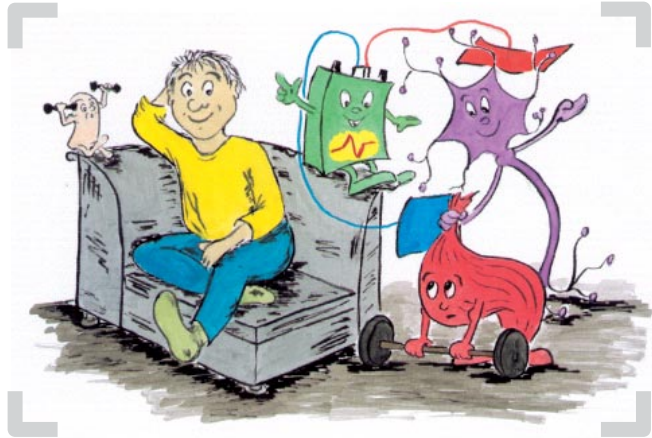
Each has its justification, advantages and disadvantages. For instance, we know medicaments and hormones that can be taken directly or that have to be injected into the penis (ETAT), vacuum-assisted erection and operative procedures, such as penis prostheses and operations on the blood vessels. But first and foremost, it is essential to carry out consistent and comprehensive research and eradication of the causes.

Among others, the treatment of erectile dysfunction by means of vacuum pumps, CBAT (Cavernous Body Auto-injection Therapy, the injection of medicaments into the cavernous body), the taking of medicaments or penis prostheses are already well-established. Here we are now going to look specifically at therapy by means of electro stimulation.

6

Electric stimulation therapy – What is it?

Electro stimulation therapy utilises low frequency, completely harmless electric current, which is normally applied to the surface of the skin by means of adhesive electrodes. There the current stimulates the nerves and the muscle cells respectively, a method that has been used for years in the treatment of pain, muscle rehabilitation and incontinence. Also for erectile dysfunction therapy, appliances of this nature have been in use since the nineties.



The therapy has been subjected to satisfactory medical researched and when correctly applied, it is:

- Simple to use
- Free of side effects
- Inexpensive
- Performed by the patient discreetly in his own home
- Without the necessity to make appointments
- Applicable without the assistance of any other person

7

The parameters of electric stimulation

Pulses form

The pulses are formed in accordance with the time duration of the individual pulse, following the direction of the current flow.

Pulse frequency

By “frequency” we understand the number of individual pulses per second; it is indicated in Hertz (Hz).

Pulse width

This is the time duration of a single pulse and essentially determines the depth of penetration of the current.

Modulation times

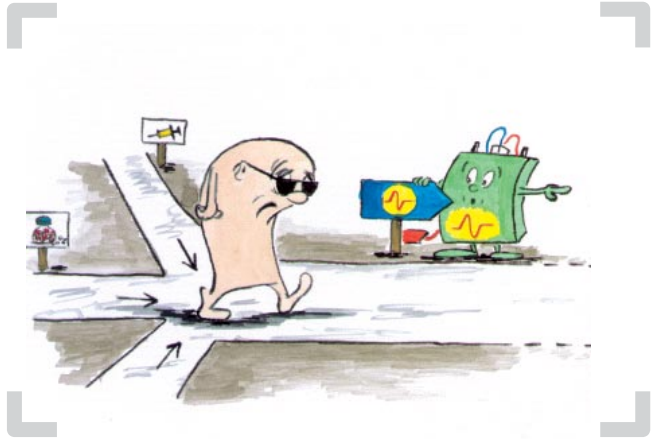
The modulation time describes the time duration of a stimulation cycle. We distinguish the upsurge time (the time taken to reach maximum current flow) , the working time (during which the maximum current flow is maintained) and the pause time (no current flow).

Intensity

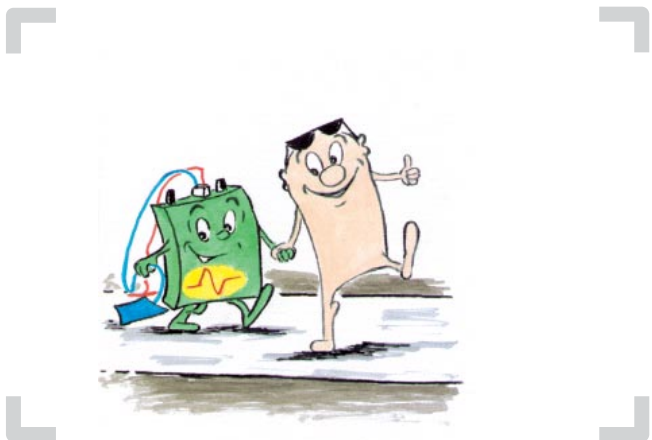
The strength of the given current is freely controllable and may be adjusted to suit the sensitivities of the individual user.

8

Electric stimulation therapy in the case of erectile dysfunction



There have been a number of very satisfactory trials on patients in the treatment of erection disorders by means of electric stimulation. These patients were invariably “hopeless cases” for whom no other non-operative therapy was available. This means that also the CBAT-therapy (i.e. the injection of medicaments into the shaft of the penis) was having no effect because the muscle cells in the cavernous body were no longer reacting. By means of electric stimulation, it was possible to reactivate these smooth muscle cells and in 23% of the cases to achieve a renewed spontaneous erection. A further 14% were able to achieve an erection after CBAT, which had previously not been possible.



9

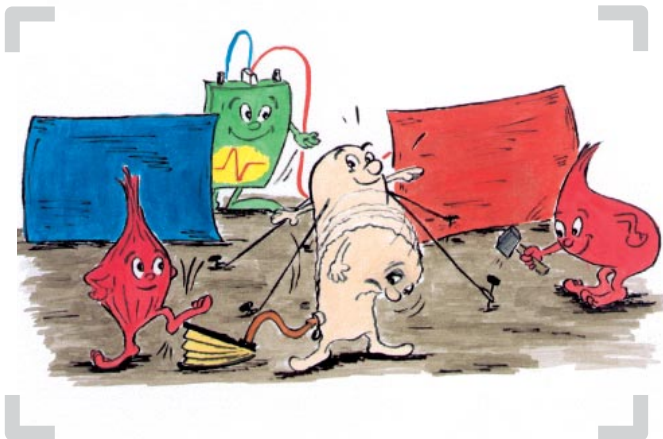
The working mechanism of electric stimulation therapy

The effect may be explained by the stimulation of the smooth muscle cells of the cavernous body.

These muscles cannot be controlled at will and are not accessible for active training. The electro stimulation, however, stimulates the nerve pulses to which the muscle cells normally react. In this way it increases their responsiveness and reaction speed.

This procedure needs a certain amount of time. The electro stimulation does not directly produce an erection. The effect of the electro stimulation therapy is rather to be seen after a period of training of the cavernous body and the muscles at the base of the pelvis lasting several months. Then an increase in the strength and duration of an erection may be seen or an erection at all, respectively, is observable.

Apart from this, by simply trigger the sphincteral muscles at the base of the pelvis, a man is able to increase the pressure in the cavernous body. In this way, it is possible to strengthen and prolong the erection.



10

The Phalli-Max therapy

Which erection disorders can be treated?

The Phalli-Max is suitable for the treatment of erectile dysfunction caused by damage to or weakness of the muscle cells in the cavernous body or at the base of the pelvis, respectively, i.e. in the case of so-called organic erection disorders. It is important to note that also in the event of a failure of the CBAT therapy, an electric stimulation therapy can lead to a renewed erection capability. If this does not suffice alone, then the application of an CBAT treatment subsequent to the electric stimulation therapy is frequently successful!

How often and how long?

An electric stimulation therapy for muscle stimulation should be applied over a period of at least three months. Some patients apply the therapy for up to one year or longer in order to increase the quality of the erection. The individual treatments should be conducted twice or three times daily for 30 minutes over at least three months; it is also possible to apply the treatment while the patient is asleep.

How does Phalli-Max work?

Pulse form

The Phalli-Max works with a two-phase current flow (positive rectangle with subsequent negative fluctuation) which is particularly safe and gentle to the skin.

Pulse frequency

The Phalli-Max incorporates three different programmes that work at fixed frequencies.

Pulse width

The Phalli-Max operates with pre-programmed pulse widths which lie between 90 and 250 μs

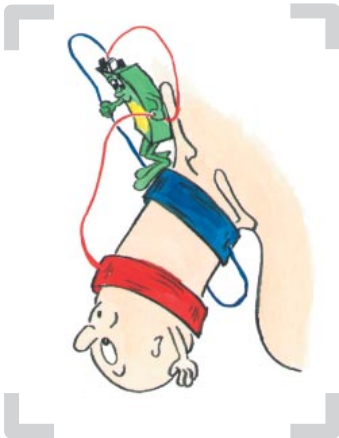
Modulation times

These are precisely adjusted to the target muscle groups. They are pre-programmed and run automatically.

*How do I use the appliance?
How do I attach the electrodes?*

The Phalli-Max provides three programmes, each for a different kind of application.

These differ also in the positioning of the adhesive electrodes, which are also described below. This is clearly illustrated in the corresponding drawings, which also show the cable connections. For this the colour of the cable (blue or red) determines the polarity and is therefore to be followed without fail.



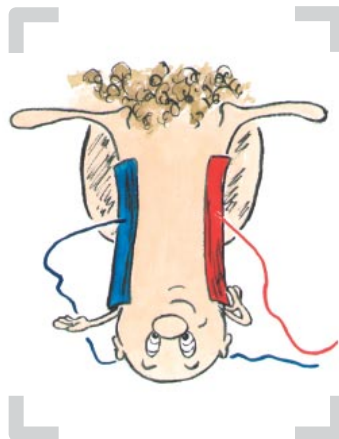
Programme 1:

To strengthen the muscle cells of the cavernous body.

Place the first adhesive electrode around the penis just below the glans, the bulbous apex of the penis. Attach the electrode to the connector at the end of the red cable. The second electrode is wrapped around the penis proximally near the root of the penis. Attach the electrode to the connector at the end of the blue cable.

Attach the second adhesive electrode the pubic hair and it to the blue cable.

Apply this programme alternately with programme 2 for 30 minutes daily.



Programme 2:

To strengthen the muscle cells of the cavernous body.

Attach the adhesive electrodes laterally at each side of the penis shaft (cable connections as desired)

Apply this programme alternately with programme 1 for 30 minutes daily.

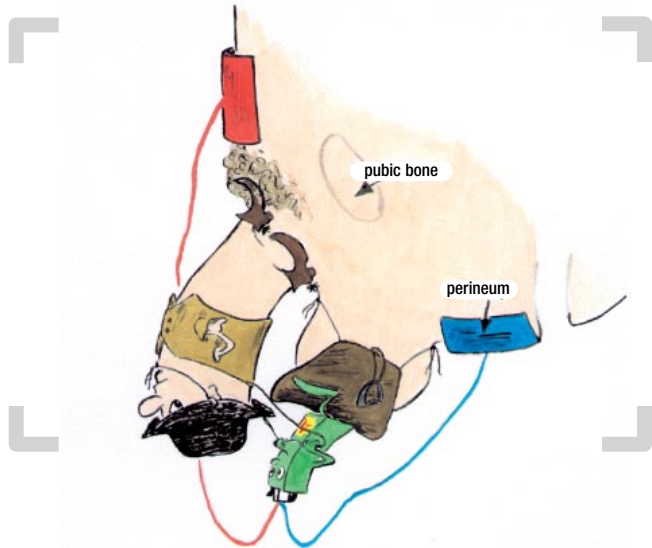
Programme 3

To strengthen the sphincter muscles

Take one electrode for the perineum (blue cable) and attach the other above the pubic hair (red cable – above the pubic bone).

Apply this programme once daily for 30 minutes.

Connect the electrodes to the electric cables, whereby it is important to heed the cable colours. Plug the cable into the appliance and select the desired programme by means of the sliding selector switch and you are ready to go. Set the intensity to a pleasant level by means of the intensity regulator and at the end of the treatment time, proceed in the reverse sequence.



programme	frequency	width	modulation times		
			ramp	work	break
1	30 Hz	90 μ s	1 s	3 s	6 s
2	10 Hz	150 μ s	1 s	2 s	4 s
3	55 Hz	250 μ s	1 s	5 s	10 s

When may I not use Phalli-Max?

You may not apply electric stimulation therapy:

- When there are inflammations, eczemas or open wounds where the electrodes are to be positioned.
- When the sensitivity of the skin is impaired, e.g. after an operation, or by nerve damage. This may preclude the accurate assessment of the electric current strength. In this case, the strength of the current should be tested on a healthy surface, such as the inside of the thigh or the underarm to make sure that the setting is correct. The intensity set in this manner must then in no case be exceeded.
- When there are malignant tumours in the pelvic region or the surrounding skin. Electro stimulation promotes the metabolism and improves the blood circulation in the tissues. Application in the vicinity of malignant tumours could therefore accelerate their growth.
- When you are using an electric pacemaker. By applying current in the region of electric pacemakers (heart pacemaker, nerve stimulators against circulatory disorders in the legs or after spinal injury) the pacemakers could be disturbed and may possibly cease functioning. In no case should you use Phalli-Max without first consulting your physician.
- If you have freshly implanted hip prostheses or bone plates operatively inserted within the last 6 weeks. Metal implants in use today (hip prostheses, bone plates, etc.) do not heat up when exposed to electro stimulation. There is no risk of "internal burns". What could happen, however, is the loosening of the implants caused by the twitching of the muscles close to the freshly operated bones.

Are there any side effects?

Side effects, given correct application, are extremely rare. The skin could react sensitively to the adhesive surface of the electrodes. These reactions normally subside, however, within hours. If not, please contact your physician. Any reaction to the current is prevented by means of special, protective circuitry. Nevertheless, the stimulation time should initially be limited to 40 minutes per session. Stiffness in the muscles is possible after applying the training programme for strengthening the sphincteral muscles. This can be avoided by increasing the stimulation time step by step. In spite of all precautionary measures, pain may develop where stimulation is applied. This can be rectified by shifting the position of the electrodes or shortening the duration of the application. Any pain will then disappear spontaneously within minutes of their occurrence.



