evoStim® P

Therapeutic unit
for perineal reeducation
by electrostimulation and
biofeedback (pressure)

User guide

of M.D. REF: evoStim P
(Rev. 7-2020)

BEAC MED

CONTENTS

1 Description and intended use

evoStim® P is a therapeutic unit intended for perineal electro-stimulation and pressure biofeedback, suitable for direct use by the patient but also perfectly suitable for professional use, offering a great ease of use without sacrificing flexibility and performance.

1.1 - Intended use

evoStim® P is a unit for electrostimulation and pressure biofeedback, 1 output channel (electrostimulation), 1 input channel (pressure), for professional use or usable directly by the patient on the advice of a professional operator (Physiotherapists , Gynaecologists, Urologists, Physiatrists, Midwives).

Indications: Prevention or treatment of incontinence, by means of perineal probes or surface electrodes.

Perineal electro-stimulation is carried out by means of a vaginal or anal probe, characterised by a pair of electrodes. The therapeutic goal is the improvement of voluntary control of the perineal musculature (in case of stress incontinence) or the reflex inhibition of the detrusor muscle (in the case of urge incontinence).

We should not expect immediate benefits, after the first session. The main results will be obtained after repeated sessions (at least 30, administered daily or on alternate days, depending on the seriousness of the problem). Any amazing improvements, after the first sessions, should not induce the operator or the patient to discontinue the treatment.

This user guide provides information for the safe use of this equipment and guidance on perineal electrostimulation and how effective this treatment can be.

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2 Indications of perineal electrostimulation

2.1 - Stress incontinence,

It is frequently due to sphincter deficiency.
Symptoms include leaking of urine, caused by a strain (such as coughing, rising from a chair, etc), in absence of detrusor activity. Stress incontinence is usually treated with relatively high frequency electrical pulses, from 35 to 100 pulses per second (p.p.s.) depending on patients and therapist preference, this exercises the phasic components of the muscle fibres which provide strong but short contractions. The treatment should be performed for about 20 minutes daily starting with relatively short work periods and gradually building up endurance by increasing the contraction time as the muscles strengthen. Pulse widths may be selected between 100 to 400 microseconds, depending on the patient.

2.2 - Urge incontinence

It is caused by detrusor instability. Here the most appropriate frequency is between 5 and 10 Hz, with a pulse-width of between 250 and 400 microseconds. The treatment is best performed on a daily basis for the first week, then 2 to 3 sessions per week for the next 3 or 4 weeks. The therapy may be conducted at home.

2.3 - Mixed incontinence

It accounts for about 40% of all cases of incontinence and is characterised by episodes of incontinence when straining, along with or alternating with episodes of incontinence due to detrusor instability causing urgency. Depending on the predominance of the first or the second kind of incontinence (stress or urge), one can decide to use a relatively high frequency for greater effect on the muscle tone or lower frequencies to give

greatest effect on detrusor inhibition. Urge incontinence usually responds more quickly than stress so this is usually treated first. Alternatively two treatments per day, one for urge and the other for stress may be carried out.

3 Indications of perineal biofeedback

Perineal Biofeedback (BF) is an active therapeutic technique consisting in the fine and real-time graphical visualisation (and/or audible emission) of voluntary muscle contractions/relaxation by the patient.
The therapeutic aim is the improvement of voluntary control of the perineal muscles. The patient is visually (visual feedback) and acoustically (audible feedback) made aware of the contraction level of its perineal muscles (pubococcygeus and puborectalis), acquired by means of a silicone balloon integrated in a special vaginal probe.
The conscious appraisal of the performed work determines the effectiveness of the BF treatment.

We can identify 2 pathological situations each corresponding to a biofeedback techniques:

3.1 - Recruiting Biofeedback

The patient has a PC test (test of pubococcygeus) degree 1 or lower, with "recruitment" problems of the perineal muscles. The adopted technique will be called indeed "recruitment biofeedback."
Despite being very low the acquired signal, corresponding to the performed contraction, the level can not even reach the first target of the smallest range and the patient, through repeated free contractions, will try to find the "key" for more effectively recruiting the fibres of perineal muscle, and attaining the central target.

3.2 - Training Biofeedback

The patient has a PC test (test of pubococcygeus) of 1 or greater, with problems of "control" of perineal muscles. The patient is able to reach the central target, even using a medium range (end-of-scale), but has a poor fine control of muscles such as not being able to contract "in time" for a sudden

increase in abdominal pressure due to coughing or an effort. The patient, in this case, is "guided" to perform multiple contractions of ever-increasing degree, through visual and acoustic stimuli, rewarding the achievement of higher goals by increasing the Full-Scale (FS).

Perineal biofeedback is not an alternative treatment to perineal electrostimulation, but a complementary treatment, indicated when the patient, while managing to weakly contract the perineal muscles, is unable to sufficiently control them in cases of sudden increases of abdominal pressure (coughing or sudden efforts).

4 CONTRA-INDICATIONS

PLEASE READ CAREFULLY:

In the following circumstances, evoStim® must NOT be used:

- During pregnancy.
- If you have a heart pacemaker or serious heart rhythm problems.
- If you are driving or operating machinery.

In the following circumstances, evoStim® P can be used with caution:

1. If you have epilepsy, consult your doctor before using.
2. On children under 12, apply only under medical supervision.

Apart from the general contraindications of electrostimulation, we must consider the following criteria:

Specific contraindications of the perineal electrostimulation.

absolute:

pregnancy, kidney disease, lower urinary tract infections, tumours, post-void residual urine greater than 100 ml, vesicoureteral reflux.

subjective:

Reluctance of the patient, hyper-sensitivity to electrical stimulation.

IF IN DOUBT, CONSULT YOUR PHYSICIAN.

5 WARNINGS AND PRECAUTIONS

1. Carefully read the user guide before starting to use the unit.
2. This user guide is an integral part of the medical device; store it in a safe and protected place, possibly together with the device, to ensure the availability and readability.
3. Only use batteries AAA 1.5Volt Alkaline (LR03). The use of any other battery may damage the unit.
4. Remove the batteries when not used for prolonged periods (leaking battery acid may irreparably damage the unit).
5. The unit must not be used to treat painful symptoms of unknown origin or which have been insufficiently diagnosed.
6. Do not use the device during sleep.
7. Be careful when using the unit on patient with reduced sensitivity .
8. Keep the device and its accessories out of reach of children, the non-self-sufficient people or pets.
9. DO NOT apply electrodes on the throat or larynx nor over the carotid sinus or the sides of the neck, (the area of heartbeat detection). May increase the risk of abnormalities of blood pressure or heart rhythm.
10. DO NOT place any surface electrodes for stimulation in TRANS-THORACIC WAY. The application of the electrodes close to the thorax may increase the risk of arrhythmias or cardiac fibrillation.
11. DO NOT place any surface electrodes for stimulation in TRANS-CEREBRAL WAY. It could cause symptoms such as dizziness, nausea, vomiting, headache.

12. Do not apply the electrodes on the eyelids or around the eyes. It could affect the intra-ocular pressure
13. DO NOT place electrodes on/in the mouth. In case of inappropriate contractions may increase the risk of suffocation.
14. Avoid placing surface electrodes over any area affected by acute phlebitis.
15. DO NOT use the unit at a distance lower than 3 metres from any high frequency therapy unit (short wave or microwave) or close to a microwave oven.
16. DO NOT use the unit at a distance less than those indicated in the table on page 40, respect to a radio frequency communication device (RF transmitters, mobile phones, remote controls).
17. DO NOT the unit on a patient in which it is used simultaneously an electrosurgical high frequency device. It may increase the risk of instability of the device and / or burns under the electrodes.
18. Do not use the device on a patient on which a monitoring instrument for physiological parameters (such as ECG or others) is used simultaneously. It could be affected by electrostimulation.
19. The equipment can deliver electrical pulses with a current density higher than 2mA $_{r.m.s.}$/ cm^2.
20. Store the unit and accessories in the pouch for storage and transportation.
21. Avoid violent impact and any improper solicitation of the unit.
22. Do not expose the unit or accessories to temperature levels higher or lower than those recommended in the technical characteristics.
23. DO NOT use the unit in an ambient temperature above or below the recommended operating range.
24. DO NOT touch the unit in any way with wet hands, in order to prevent possible penetration of liquids.

25. Keep the unit dry and protect from condensation.
26. If in doubt whether liquids have penetrated inside the unit, it is advisable not to use the instrument and to send it to the manufacturer for testing.
27. Prevent the formation of condensation due to thermal sudden change.
28. In presence of condensation, avoid switching on the unit because it could be damaged.
29. In case of an evident or suspected defective operation of the unit, the user is advised to send the unit to a BEACMED authorised technical after sale Servicing Centre, for testing.
30. No repair or modification of this device or its accessories is allowed unless previously authorised in writing by the Manufacturer.
31. Avoid using the unit on more than one patient per session.
32. Use only original accessories, if supplied. If the device is used with commercially available probes, they must be CE marked, as a class IIa medical device, according to Directive 93/42/EEC MDD. Before using these special accessories, it is mandatory to carefully read the instructions for use and cleaning, which must be included in their packaging.

6 CHECKING THE PACKAGE

The therapy unit evoStim® P has been designed for a friendly but effective use. Before using it, you should carefully read the chapters: 4 - CONTRAINDICATIONS and 5 - WARNINGS and PRECAUTIONS.

PERSONAL USE OF THE PROBES!

Do not use the perineal probes (vaginal or anal) on different patients. The probes are for personal use. This is to prevent the transmission of venereal diseases or other more serious diseases.

The evoStim® P package should contain the following parts:

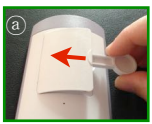
Q.ty	Code	Description
1	EVO-P	Unit evoStim® P
1	BAT/LR03-03	Kit 3 AAA alkaline batteries 1.5 V. (LR03)
1	ESTIM-KEY	Plastic key for battery compartment opening.
1	CV/evoStim_kit_P	Gray bipolar cable with protected 2mm banana termination and mini axial connector. Length 99cm.
1	ESTIM-SUPP-PGB	interlocking stand for vertical support of the unit on a horizontal surface
1	evoPouch	PVC carrying bag with necklace (IP02)
1	EStim_bag	Padded bag or rigid plastic handbag
1	ISTRU-evoStim P	User manual for MD evoStim P.
1	Sonda perineale	The probe Periprobe VAG-2STFW is provided, unless otherwise requested by the customer.

After verifying that the contents correspond to what is listed here, you can proceed to prepare your unit for the session.

7 PREPARING THE UNIT

7.1 - BATTERIES

To remove the battery-compartment cover, insert the special plastic key provided in the slot on the side of the cover and pushing in the direction of arrow ⓐ (DO NOT turn the key!); Lift off the battery cover; Insert the three batteries supplied ⓑ, observing the polarity shown on the bottom of the battery compartment ⓒ. Close the battery-compartment with the cover ⓓ.

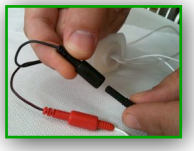


Note: The unit may not work if one or more batteries are inserted in reverse.
CAUTION!: There is a risk of explosion if the batteries are fitted incorrectly. Replace only with AAA Alkaline 1.5 volt batteries (LR03). **Do not use other batteries.** Do not mix old and new batteries. Do not dispose of the batteries in a fire and keep them out of reach of children. The batteries must be removed from the device before it is scrapped and disposed of safely. **When the unit is not used for a long time, you must remove the batteries** to avoid deterioration and leaking battery acid. This could irreparably damage the unit's electronics.

7.2 – LEAD WIRES

Unravel the gray lead wire and insert the plug(s) into either of the outlets, located at the base of the unit. If only using one lead, insert into the CH1 outlet as marked on the unit (㉔).

7.3 - CONNECT THE PROBE



Remove the probe from the bag, rinse under tap water if it is a new probe, then connect to the leads. Each lead wires should be connected as shown in the picture or according to the instruction leaflet included in the package of the probe. Also read paragraph 7.6.

If you use the balloon probe, connect (always before inserting the probe) also the tube that comes out of the probe to the corresponding tube that comes out of the equipment (Bf-P) ㉕. (only in the EVO or BIOFEEDBACK program).

7.4 - PLACEMENT OF THE PROBE

Moisten the insertable part of the probe with tap water or water based gel, to improve the conductivity of the electrodes. Gently insert the probe in the vagina (or anus), according to the instructions included in the package of the probe.

7.5 - USING THE UNIT

Read the chapter 8 (OPERATION) and use the unit according to the therapeutic aims.

7.6 - TYPE OF PROBE VS- WAVE-SHAPE

The stimulation output must be connected, by means of the included lead wire, to a probe (vaginal or anal). The cables have two endings to 2mm plug, a red and a black colour. Using “symmetrical bi-phasic pulses” (⎍), the greater effect will be felt at the electrode connected with the RED plug.

If the waveform is selected with “bi-phasic alternated pulses” (⎍⎓⎍), there will be no predominance of any of the two electrodes.

In general terms, consider the followings:

• if the probe has ring-like electrodes, the RED output of CH1 lead must be connected to the RED connector of the probe and the suitable wave shape is “symmetrical bi-phasic pulses” (⎍).

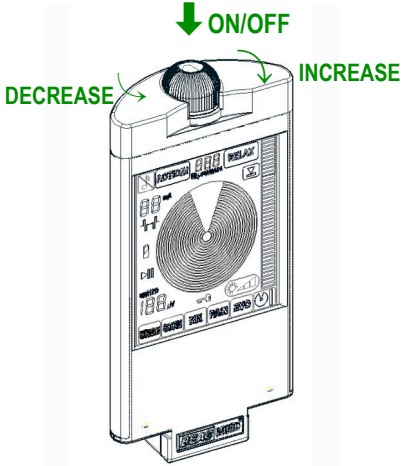
• if the probe has lateral electrodes, the suitable wave-shape is “bi-phasic alternated pulses” (⎍⎓⎍).

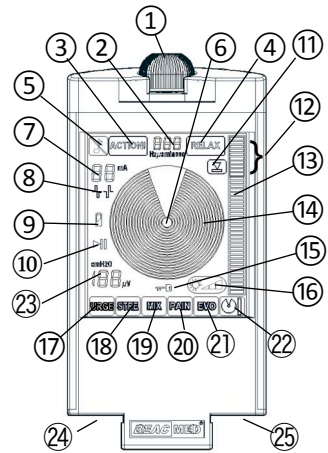
8 OPERATION

The ergonomics of evoStim® P unit is based on the rotation of the upper knob and the touch screen. Through the knob it is possible to set/ modify the stimulation intensity or the value of the various parameters; through the push-button, integrated in the knob, you can switch-ON/OFF or pause the unit. Using the touch screen you can select the programmes and variables to change.

① - Upper knob with integrated push-button
② - Parameters of the program (3 digits) (§ 8.2.2, § 2.2.3, § 8.2.4, § 8.2.5, § 8.2.6).
③ - Touch-area ACTION! (§ 8.2.5).
④ - Touch-area RELAX (§ 8.2.6).
⑤ - Touch-area buzzer enable/disable (§ 8.3.2).
⑥ - Centre of the Concentric-Circles target (CCT) (§ 8.2.8).
⑦ - Stimulation intensity (2 digits) (§ 8.1.5-8.1.7).
⑧ - Wave-shape (type of impulse) (§ 8.1.4).
⑨ - Low battery indicator (§ 8.3.3).
⑩ - Pause state indicator (§ 8.2.1).
⑪ - Touch-area reset biofeedback input (§ 10.3).
⑫ - Target zone of the linear bar-graph (§ 10.1).
⑬ - Linear Bar-Graph (BG) (§ 10.1).
⑭ - Multi-Circles target (CCT) (§ 10.1).
⑮ - Lock state indicator (§ 8.1.7).
⑯ - Touch-area backlight level (§ 8.3.1).
⑰ - Touch-area programme URGE (§ 9.3).
⑱ - Touch-area programme STRESS (§ 9.4).
⑲ - Touch-area programme MIX (§ 9.5).
⑳ - Touch-area programme PAIN (§ 9.6).
㉑ - Touch-area programme EVO (§ 9.7).
㉒ - Touch-area programme BIOFEEDBACK (§ 9.7, § 10.1, § 10.4).
㉓ - Full-scale biofeedback (3 digits) (§ 8.2.7-8.2.8).
㉔ - Stimulation output connector (§ 7.2).
㉕ - Pressure input (from the balloon) (Bf.P).

Functions of the upper knob: **Press** and hold the knob downwards to SWITCH ON or SWITCH OFF, simply press to START THE SESSION or PAUSE it. **Turn** the knob to INCREASE or DECREASE the selected parameter or to UNLOCK the controls during the session.





8.1 - FREQUENT OPERATIONS

Before carrying out the following operations, connect the probe to the device at least through the gray cable Ch.1 (24) and insert the probe into the vagina or anus (in the case of anal probe). For the EVO and BIOFEEDBACK programmes, the probe balloon is also used, which requires the connection of the pneumatic tube to the Bf. P input ㉕ (see also § 10.4.1).

8.1.1 Switch-ON the unit

Press for 2 seconds the button integrated in the knob ①.

8.1.2 Switch-OFF the unit

Press for 2 seconds the button integrated in the knob ①. The unit will also turn-OFF if the session does not start in 5 minutes.

8.1.3 Select a program

Touch one of the 6 rectangular areas at the lower side of the display (⑰, ⑱, ⑲, ⑳, ㉑ o ㉒).

The label of the selected program will appear in reverse.

Every time the unit is turned ON, it will automatically load the last used programme.

8.1.4 Select the type of probe in use

By touching the area ⑧, you can select the wave-shape according to the type of the probe in use:

- the simple impulse () for the probes with ring-like electrodes;
- the alternated pulse () for the probes with lateral electrodes.

The choice of the type of probe used in the last session, will be automatically loaded when the unit is switched-ON.

8.1.5 Set the stimulation level

If a program providing electrical stimulation has been selected (URGE-STRE-MIX-PAIN-EVO), after connecting and positioning the probe, tap the area **0mA** ⑦, then turn the knob clockwise to feel a strong and comfortable level of stimulation. After adjusting the stimulation level, it is required to start the session (§ 8.1.6), otherwise the

stimulation stops after a few seconds and, after a few minutes, the unit switches off.

8.1.6 Start the session

Briefly push the button ① to start the session.

8.1.7 Adjust the stimulation level during the session

10 seconds after starting the session, all the "touch" commands will be disabled (except the "Buzzer Enable / Disable" and the backlight adjusting); the symbol (⑮) will appear on the display.

Turn for at least 1/2 of a turn the knob ①, clockwise, to temporarily unlock the commands, touch the area ⑦, then turn the knob ① clockwise (to increase) or counter-clockwise (to decrease) until you feel a strong and comfortable level of stimulation.

8.1.8 - End of the session

After completing the session, make sure that the unit is turned off and then carefully remove the probe, avoiding not to pull the wires that come out of the probe, as this could damage them over time. Rinse the probe thoroughly under tap water, dry thoroughly and store in the original bag.

8.2 - OPTIONAL OPERATIONS

8.2.1 Temporarily stopping the session (PAUSE)

During the session, you can temporarily pause the programme to modify a parameter.

Briefly press the button ① to pause the session. The pause state is visually reported by the symbol ▶II ⑩ and the green back-light of the display flashing (if enabled).

In the PAUSE state, you can change: the session time, the frequency, the pulse width, the Action time, the Rest time (see the section 8.2 for details).

To resume the session, briefly press the button ①

*8.2.2 Changing the session time (min') **

Tap the area ②, the two digits flash, then rotate the knob to the desired time.

8.2.3 - Modify the frequency (Hz)

Tap 2 times the area ②, then rotate the knob to the desired value. The frequency can only be adjusted before the start of the session (§ 8.1.6) while not possible with the unit in PAUSE state.

*8.2.4 - Display the pulse width (µs) **

To view the pulse width (mS), tap 3 times the ② area, the pulse width can not be changed.

*8.2.5 - Modify the ACTION! time (s.) **

Tap the area ③, it will blink for a few seconds, ② the display ② will shows the current value of the action time (sec.). To edit it, touch area and ②, while the display is flashing, turn the knob to obtain the desired value.

*8.2.6 - Modify the RELAX time (s.) **

Tap the area ④, it will blink for a few seconds, ② the display ② will shows the current value of the action time (sec.), To edit it, touch area and ②, while the display is flashing, turn the knob to obtain the desired value.

*8.2.7 Manual adjustment of the biofeedback scale **

If the BIOFEEDBACK program has been selected, which provides for the detection of the pressure by means of a balloon probe, it is possible to adjust its sensitivity, that is the Full-Scale (FS).

Tap the area ㉓, the 3 digits will blink for few seconds, during which it is possible to change the scale by turning the knob.

*8.2.8 Automatic adjustment of the biofeedback scale **

Alternatively, the full scale (FS), that is to say the BF sensitivity, can be automatically adjusted.

After connecting the probe (§ 7.3) and properly inserted it (§ 7.4), tap the area ㉓, the 3 digits will blink for few seconds, tap the centre of the Concentric Circles Target (CCT), the 3 digits will show now the pressure value acquired by the balloon probe.

Ask the patient to perform a maximal contraction. The detected pressure value (in cmH_2O) will be automatically assumed as the new Scale.

8.2.9 - Restore the factory settings

If the default program parameters have been changed by the user, the button of the selected program is displayed on a flashing background. The parameters of the original program can be reset as follows:

- Tap and hold the virtual button of the programme to be reset (⑰, ⑱, ⑲, ⑳, ㉑, ㉒) and simultaneously push and hold the button ①.
- Release the buttons. The unit will remain ON and the virtual button of the selected programme will stop to flash.

* = Allowable only before starting the session or during the session with the unit in the PAUSE state.

8.3 - ACCESSORY OPERATIONS

8.3.1 Change the backlight intensity.

By repeatedly taping the area ⑯ the backlight intensity of the display can be selected between 4 levels:

 backlight OFF suitable for daylight.

 backlight LEVEL 1, suitable for twilight.

 backlight LEVEL 2, suitable for the dark.

 backlight LEVEL 3, suitable for the dark.

8.3.2 Enable/Disable the audible feedback (the "buzzer").

The buzzer has a double aim:

❖ when performing a biofeedback program, it provides the patient with the perception of the level of contraction voluntarily carried out.

❖ it provides the operator / patient with the acoustic perception of the activation of a "touch" command.

Tap the area ⑤ to enable/disable the audible feedback.

8.3.3 Replacing the batteries.

When the batteries are depleted, the symbol ⑨ will start flashing. To replace the batteries, see the section 7.1. If the batteries are not replaced, they will still work for some minutes, then, to prevent functional problems, the unit will automatically switch off.

9 PROGRAMMES with ELECTROSTIMULATION

5 programmes are dedicated to perineal electro-stimulation, by means of internal probes:
Programme URGE - to treat URGE incontinence.
Programme STRE - to treat STRESS incontinence.
Programme MIX - to treat MIXED incontinence.
Programme PAIN - to treat pelvic PAIN.
Programma EVO - designed to rehabilitate the pelvic floor using electrostimulation triggered by voluntary contractions.

Each programme has pre-defined and optimised parameters; However, it is possible to modify one or more parameters (except the pulse width which is automatically defined):

- Frequency (in Hz) see the section 8.2.3
- ACTION! time (in sec.) section 8.2.6
- RELAX time (in sec.) section 8.2.7

During the action time, if the probe is properly placed and the wires connected, the concentric circles of the target are activated in sequence from smallest to largest (from inside to outside).

9.1 - Open-circuit safety cutout

If, during electrostimulation, the connection of the probe is interrupted (even momentarily) or the contact with the body is not optimal, a safety device resets the stimulation intensity and visually signals the anomaly with the intermittent activation of all the circles of the target (CCT) and the backlight will **flash RED** (if enabled).
To resume electrostimulation, it is necessary to restore the connection between the unit and the probe (possibly replacing the cable, and/or restore the good contact of the probe with the body; then press the button ①.
The previously set intensity will be gradually and automatically restored.

9.2 - The session time

The typical session time of a stimulation program is 30 min'. However, you can change it from 5 to 60 min' (in steps of 5), or select continuous stimulation (the symbol C). Each programme offers a session time range, according to the intended therapeutic purpose.

9.3 - Programme URGE

Pre-set parameters
Frequency: 10 Hz. (adjustable from 1 to 20).
Pulse width: 200 µs.

Since this frequency range does not produce muscle fatigue, there are no rest periods.

9.4 - Programme STRESS

Pre-set parameters
Frequency: 50 Hz.
Pulse-width: 250 µs.
ACTION! time: 2 sec.
RELAX time: 4 sec.
Frequency during the rest time: 3 Hz
The 3 Hz frequency has a relaxing effect on the pelvic floor.

9.5 - Programme MIXED

MIX

Pre-set parameters
Frequency: 35 Hz.
Pulse-width: 200 µs.
ACTION! time: 3 sec.
RELAX time: 6 sec.
Frequency during the rest time: 5 Hz
The 5 Hz. frequency, during the RELAX time, has the function of inhibition on the bladder muscle (detrusor) and therefore effective for the URGE component of the treatment.

9.6 - Programme PAIN

PAIN

Pre-set parameters
Frequency: 70 Hz.
Pulse-width: 50 µs.

9.7 - Programme EVOCATED

EVO

Pre-set parameters
Frequency: 35 Hz.
Pulse-width: 350 µs.
ACTION! time: 3 sec.
RELAX time: 8 sec.

EVO, standing for (evoked stimulation) administers action/rest cycles of perineal electrostimulation but each cycle must be activated by the patient's voluntary contraction, upon reaching a defined threshold.
With the evoStim® P unit, the contraction performed by the patient is performed using a balloon probe (or preferably, a probe integrating electrodes and balloon). In addition to the connection of electrical stimulation, the probe must be connected together with the tube for detecting the pressure. The balloon pressure is measured in CmH_2O and is directly proportional to the contraction of the perineal muscles, detectable in

the vagina. The pre-set threshold is 8 cmH_2O and can be manually changed (§ 8.2.8). That threshold, however, will also automatically increase every three voluntary valid contractions. The ability, the will and/or the perseverance of the patient in reaching more and more thresholds makes this programme extremely effective for the functional recovery of the pelvic floor. The last threshold value reached is automatically stored at the end of the session, and will constitute the starting threshold of the next session.

The EVO programme exploits the biofeedback function of evoStim® P, by acquiring the pressure of the ballon probe and showing its value through a Concentric Circles Target (CCT) on the display.
The patient will see a number of concentric circles activated from outside to inside (from largest to smallest) proportionally to the voluntary contraction of the perineal muscles.
The easiness for the patient to turn-ON the whole target (the centre) will depend on the Full-Scale (FS). The lower the FS, the easier the exercise, and vice-versa.
Instead of the CCT target representation, it is possible to represent the voluntary contraction through the sidebar-graph. To change the selection during the session, touch the area ㉒.
For this reason, if you want to select the BFB program starting from the EVO program, you must first select a stimulation program.

The pulse-width of the stimulation programmes automatically changes from 150 to 250 µs., according to the frequency, and it can not be manually adjusted.

The frequency of STRE, MIX and EVO programmes is manually adjustable from 25 to 150 Hz. (§ 7.2.3).

By changing the frequency, ACTION and RELAX timing will automatically adjust, by virtue of the IntelliSTIM® system. However, you can edit them manually (§ 7.2.4, 7.2.5).

Vaginal probe with electrodes and balloon, model VAG-2STFW

Connection "luer-lock" tube-probe

Before using the balloon probe, for the treatment of pressure biofeedback, it is essential to connect the male Luer-lock connector of the tube that comes out of the probe to the female Luer-lock connector coming from the biofeedback equipment.
Otherwise, the balloon would deflate when the probe is inserted into the vagina, the balloon would lose its initial shape, also losing its ability to detect changes in pressure during contractions.

10 The BIOFEEDBACK PROGRAMME

The "biofeedback" mode presupposes the detection of a signal whose value varies in proportion to the muscle contraction of the area under treatment.

Perineal biofeedback takes place, with the evoStim® P unit, by means of a special probe VAG-2STFW balloon which detects the pressure exerted by the perineal muscles on the balloon itself.

The detected pressure value is not numerically displayed but on a concentric circles graph or on a linear bar graph, by means of a back-lit LCD display.

The goal for the patient is to activate all the 20 circles of the target, including the central one (or all 40 segments of linear bar).

Appropriate audible signals motivate the patient to improve the level of contraction. The therapeutic goal of biofeedback is to improve the awareness and voluntary control of the area treated by administering to the patient (in simplest form) even the slightest variations in the contraction / pressure detected.

For evoStim® P we have chosen, as the main visual feedback, the concentric circles target as it graphically emulates the closure of an orifice caused by muscle contraction.

The patient will see turning-ON a number of concentric circles (from outside to inside) directly proportional to the contraction effected by himself, also appreciating the smallest variations.

In the absence of contraction (muscles at rest) none or very few circles will appear on the target; with the rise of the contraction level, an increasing number of circles will be enabled until reaching the centre of the target.

The ability to turn-ON the whole target (the centre) will also depend on the Full-Scale (FS). The lower the FS, the easier the exercise, and vice-versa.

10.1 - Valid contraction

To be valid, a contraction should remain on the centre of the target ⑥ at least 60% of the ACTION! time. At the end of the contraction phase, a high-pitched sound, if the contraction was valid, or a low-pitched tone when the contraction was insufficient.
For those wanting to use the lateral bar-graph as visual feedback, just touch the screen area ㉒.
Unlike the concentric circles target (CCT), the bar -graph displays up to 40 lines ⑬, the 30th of which is the Full-Scale (FS). Therefore, with a FS of 30 cmH2O, variations of 1 cmH_2O will be appreciated.
If the linear bar-graph is used as visual feedback ⑬, a contraction is considered valid if it remains beyond the 30th line ⑫ at least 60% of the ACTION! time. To switch between the two types of visual feedback ⑬ ⑭ touch the sensitive area ㉒.

10.2 - Pre-set parameters of the biofeedback programme (BFB)

Full-Scale (FS): 20 cmH_2O (Editable by selecting among 20 values).
Contraction time (ACTION!): 8 sec. (editable from 1 to 20 sec.).
Rest time (RELAX): 8 sec. (editable from 1 to 20 sec.)
Type of visual feedback: 20 concentric circles targets (editable to 40 lines bar-graph).
Audible feedback: 2 KHz sound with repetition rate from 0.5 (corresponding to low contraction) to 20 Hz (corresponding to a full scale contraction). The feedback is normally Enabled (modifiable in Disabled).

10.3 - Reset of the biofeedback sensor

The pressure detected by the probe balloon may be influenced by several factors other than the perineal contraction. The signal detected when the probe is inserted and the muscles are relaxed, is almost always greater than zero. This situation is highlighted by the activation of one or more circles

of the target. If you want to make a "recruitment" or "training" biofeedback, it is better that the initial signal level is reset. The biofeedback signal reset may be performed simply by touching the symbol ⑪ while the patient is asked to relax the perineal muscles.
After the reset, the symbol ⑪ will appear in black and all the circles previously activated will turn-OFF.

10.4 - How to perform a biofeedback session

10.4.1 - Select the BFB program by touching the sensitive area ㉒. Selecting the BFB program is not allowed directly from the EVO program but you must first select one of the stimulation programmes (URGE-STRE-MIX-PAIN).
10.4.2 - Connect the tube of the probe to the pressure input **Bf-P** ㉕, by means of the pneumatic connector "luer-lock" (page 29).
10.4.3 - Insert the probe (not to introduce the probe into the vaginal cavity prior to connect the tube).
10.4.4 - With the perineal muscles completely relaxed, reset the biofeedback sensor (§ 10.3).
10.4.5 - Try to perform a maximal contraction of the perineal muscles and determine whether the level is enough to fully activate the target or even surpasses it.
10.4.6 - Depending on the number of circles activated with the maximal contraction, manually adjust (§ 8.2.7) or automatically adjust (§ 8.2.8) the Full-Scale.
10.4.7 - To start the session, after instructing the patient about the goal to attain, briefly press the button ①. The patient may attempt several contractions until it reaches the centre of the target. This stage corresponds to the "recruitment" biofeedback of and is particularly important if the perineal contraction is very weak. Once started, the session will automatically proceed, alternating contraction phases (ACTION!) to relaxation phases (RELAX).
With alternating phases, the patient will have to contract and relax, for a pre-defined number of seconds. The visual command to contract consists

in the label **ACTION!** and in the **YELLOW** back-lighting of the LCD display.
The visual command to relax instead consists in the label **RELAX** and in the **GREEN** back-lighting of the LCD display.
This phase of repeated contractions / relaxations corresponds to the “training” biofeedback (or better “repetitive training”).
During the contraction and relaxation phases, the display ② inversely scans the duration of the phases; so the patient gets ready for the next phase.
The exercise ends after the pre-defined session time (normally 30 min').

11 Technical features

Electrostimulation output: 1 to 99 mA_{pp} in steps of 1 on a standard load 1KΩ. (with pulse-width of 200 µs);
Frequency: adjustable from 1 to 150 Hz (± 5% of FS);
Frequency during rest: - 3 to 5 Hz. (± 5% of FS);
Pulse Width: automatically adjusted between 50 and 400 µs in steps of 10µs (± 5% of FS);
Output wave-shape: selectable between “bi-phasic symmetrical” pulses and “bi-phasic symmetrical alternated”;
Rise/Fall time: 0,3 to 1 s. (automatically adjusted)
PLATEAU time - 1 to 60 s. In steps of 1 s. (± 0,1 s.);
REST time - 0 to 60 s. In steps of 1 s. (± 0,1 s.)
Session time: adjustable between 5 and 90 min’ in steps of 5 min’ (± 1 s.) or Continuous;

Biofeedback scale (FS): selectable among 2-4-8-12-16-20-24-32-40-50-60-70-80-90-100 -120-140-160-180-199 cmH_2O;
Supply voltage 4,5 V by 3 alkaline batteries 1,5 Volt type AAA (LR03);
Battery life: 20 hours average (variable according to the program and the output level set).
Electrical safety: Internal supply (according to IEC 60601-1);
Overall dimensions: 73 x 147 x 25 mm;
Weight: About Kg 0,2 (including batteries);
Environment using limits: +5 / +40°C U.R.15% / 93% 700hPa / 1060hPa;
Transport and storage limits:: -25 / +70°C U.R. 93%;
Electromagnetic susceptibility: Class A according to CISPR 11;
Output connections to applied parts: 1 channel (Ch.1) with coaxial micro outlet to which connect the gray bipolar cable, ending with 2 mm protected plugs. - 1 pressure inlet channel with "Luer-lock";

Protection against the penetration of solids and liquids:
- evoStim it is rated IP20: objects larger than 12.5mm cannot penetrate the casing, it is not protected against the penetration of liquids;
- evoStim inserted in the evoPouch it is classified IP22, i.e. it is also protected from dripping.

The back-light ("BL")

An RGB or multi-colour backlight helps reading the LCD display in low lighted environments and understanding the different situations, provided that it has been enabled through the touch-button ⑯. Since the "BL" reduces the battery life, by repeatedly tapping the area ⑯, it is possible to adjust the brightness or even turn it off. In which situations may help the backlight (if enabled)?
1 - When the unit is switched-ON, the backlight is BLU to allow the user to see the onscreen controls. After 5 seconds, the blue light goes OFF but it will turn-ON again for another 5 seconds tapping the screen anywhere.

2 - When the unit is in the PAUSE state, the backlight colour is **GREEN flashing**.
3 - In the biofeedback programme, during the ACTION! phase, a **YELLOW** backlight will exhort the patient to perform a contraction.
4 - In the biofeedback programme, during the ACTION! phase, a steady **GREEN** backlight will exhort the patient to relax.
5 - In case of open-circuit detection on the output (§ 9.1) or if the contact resistance with the body is too high, a flashing RED backlight will alert the operator of the abnormal condition requiring attention and solution.

12 Trouble-shooting table

Sign	Comments / Probable causes	Suggested remedies
12.1 - The unit does not switch-ON	12.1a - Check the batteries are inserted correctly (§ 7.1).	
	12.1b - Batteries are low.	12.1bb - Replace the batteries with new ones (§ 7.1).
	12.1c - Make sure that the contacts of the battery are not missing, broken or oxidised.	12.1cc - If batteries had remained for a long time into an unused unit, some battery acid may have leaked on to the contact springs. Try to clean the contacts and replace batteries with new ones. Otherwise contact the manufacturer.
12.2 - The unit will not switch-OFF	12.1a - Be sure to properly press the shutdown button and hold it for at least 2 seconds (§ 8.1.2).	12.1aa - Remove the batteries from the battery compartment and wait at least one minute before reinserting them (§ 7.1).
12.3 - Few minutes after switching on, the device switches off.	12.3a - If the unit is switched on, but a programme not started within 5 minutes, the unit will automatically switch off to conserve battery power.	
	12.3b - The batteries are low.	12.3bb - Replace the batteries with new ones (§ 7.1).

Sign	Comments / Probable causes	Suggested remedies
12.4 - You can not adjust the intensity level of electro-stimulation.	12.4a - Be sure to carefully follow the steps specified in the user manual (§ 8.1.5).	
	12.4b - The device is equipped with a Control Lock system to prevent accidentally changing the intensity level and the parameters during the session (§ 8.1.6).	12.4bb - To unlock the controls and allow the intensity adjustment during a treatment session, make a clockwise rotation of the knob fully clockwise and then touch the intensity value, it is now possible to change the value. The control-lock system will return after 5 seconds of inactivity on the operator's controls of the unit.
	12.4c - When you try to set the intensity, the value drops to "0" and the display will flash red.	12.4cc - The output circuit connection to the patient is interrupted. Check the connection of cables and electrodes. If required, replace the cable/s. If the wires and their connection is ok, there may be insufficient contact between the electrodes and the skin. Try to moisten the gel surface of the electrodes with water and, in the case of intra-vaginal therapy, try to assume the semi-sitting position. If necessary, replace the electrodes with new ones.

Sign	Comments / Probable causes	Suggested remedies
12.5 - The unit is ON but no operations are allowed.	12.5a - Remove the batteries, wait a few minutes and re-insert them.	12.5aa - If the problem persists, contact the manufacturer or distributor.
12.6 - In the biofeedback session no pressure signal is detected.	12.6a - The device is equipped with a "zeroing" system of the pressure (§10.3).	12.6aa - Verify that "zeroing" procedure was correctly performed. Possibly, try to repeat it. In case, switch-OFF and switch-ON the unit.
	12-6b - Make sure that the probe tube is properly connected to the unit (page 29).	12.6bb - This may be a failure of the balloon probe. Try replacing the probe with a new one. If the problem persists, contact the manufacturer.
12.7 - Strange symbols randomly appear on the display.		12.7aa - Try to replace the batteries (§ 7.1). If the problem persists, contact the manufacturer or distributor.
12.8 - The buzzer cannot be heard.	12.8a - Make sure it has not been disabled (§ 8.3.2).	12.8aa - If the problem persists, contact the manufacturer or distributor.

Sign	Comments / Probable causes	Suggested remedies
12.9 - Stimulation is no longer felt by the patient. All concentric circles intermittently turn-ON on the display and the backlight flashes RED (if enabled).	12.9a - The "open circuit protection" (§ 8.1.5) intervened. The circuit connection of the unit to the patient is interrupted or the contact of the electrodes with the skin is insufficient.	12.9aa - The output circuit connection to the patient is interrupted. Check the connection of cables and electrodes. If required, replace the cable/s. If the wires and their connection is ok, there may be insufficient contact between the electrodes and the skin. Try to moisten the gel surface of the electrodes with water. If necessary, replace the electrodes with new ones.
12.10 - No longer feel any stimulation, the symbol ⑩ is lit on the display and the backlight slowly blinks GREEN (if enabled)	12.10a - The device is in the state of "PAUSE" (§ 8.2.1). Maybe you have inadvertently pressed the button integrated in the ① upper knob.	12.10aa - Just briefly press the ① button to resume the session.

Recommended separation distances between portable and mobile RF communication equipment (RF) and the EvoSTIM® P unit

The evoStim® P unit is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the evoStim® P can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum power of communications equipment.

Rated maximum output power of RF transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 KHz to 80 MHz (m)	80 MHz to 800 MHz (m)	800 MHz to 2,5 GHz (m)
0,01	0,117	0,117	0,233
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,4
100	11,7	11,7	23,3

13 Labelling and symbols

CE 0051

This product is CE marked in accordance with Annex II of Directive 93/42 / EEC / MDD, under Rule 9 of Annex IX. E 'classified as type IIa Medical Device. No. 0051 indicates the Notified Body that issued the authorisation to the CE marking.

CE Marking authorised by the Notified Body IMQ (0051)

REF — Reference to the catalogue

Follow the user guide.

Applied parts type BF

The appliance emits energy in the form of electrical impulses.

Battery powered

SN — Serial number

Manufactured by:

Manufactured on:

Keep dry

IP20 — Degree of protection against the penetration of solids and liquids.

14 Cleaning and maintenance

Cleaning the unit

To clean the unit, screen and lead wires, use a soft, slightly damp cloth (NOT soaked) in alcohol. DO NOT use water or water based cleaners.

Maintenance of the unit

Remove the batteries from the unit when it is not used for prolonged periods (the release of battery acid, could irreparably damage it). NOT allowed any repair or modification of this device or its accessories unless previously authorised in writing by the Manufacturer.

Cleaning electrodes and probes

Any electrodes and / or perineal probes supplied with or supplied as accessories to evoStim are medical devices. Please refer to the individual manuals for cleaning and maintenance.

15 Information for disposal of the product

This symbol indicates that the product (as Electric or Electronic product) must be disposed of separately from normal waste, at the end of its operational lifetime.

Please dispose of this product by bringing it to your local collection point or recycling centre for such equipment. This will help to protect the environment in which we all live. Such obligation derives from directive 2002/96/CE, opportunely applied by the governments of every country member of the E.U.. The product contains parts that can be recovered or eliminated in differentiated way, contributing to the environmental improvement. The product contains substances which, if wasted in unsuitable way, can have harmful effects on the environment and human health. The Producer is available to withdraw the product, at the end of its cycle of life, for an appropriated recovery or elimination. Please contact the BEACMED local distributor, to ask detailed information on the program of collection and recovery for this product.

www.beacmed.eu

Distributor: