



evoStim[®] UG

Dual channel therapy unit
for perineal electrical stimulation (PES)
using intra-vaginal or intra-anal probes

User guide
of D.M. REF: evoStim UG
(Rev. 7-2020)

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1

Description and intended use

evoStim® UG is a dual channel electrical stimulator specifically designed for perineal stimulation with vaginal or anal probes. It is easy to use without sacrificing the flexibility and performance.

The touch-screen and the unique rotating knob offer a friendly interface either for professional or home use.

evoStim® UG offers a further advancement in the effectiveness and the comfort of perineal stimulation. The automatic wave-shape, independent for two channels, according to the type of probe selected (with ring or lateral electrodes), allows the best comfort and optimal therapeutic results with any kind of probe on the market. The Intellistim® function on the 5 default programmes enables the user the ability to change the operating frequency without

having to vary all the other parameters. Up to 10 pre-set editable programmes may be associated to each-one of the 5 touch-buttons. Pelvic floor or perineal stimulation is a popular method for treating incontinence.

Pelvic floor electrostimulation successfully restores continence, especially in female patients.

Pelvic floor electrostimulation is normally applied using vaginal electrodes (probes), characterised by at least two electrodes, often in the form of rings.

The aim is to stimulate the group of perineal muscles, especially the pubo-coccygeal and pubo-rectal muscles.

Intended use

evoStim® UG is a unit for perineal stimulation (PES), with dual-channel output, for professional use or usable directly by the patient on the advice of a professional operator.

Indications: Prevention or treatment of incontinence, in the treatment of pain and spasticity of the pelvic muscles, using perineal probes or surface electrodes.

2 Introducing P.E.S.

Perineal Electrical Stimulation (P.E.S.) has been observed and demonstrated by many researchers:

- **Strengthening the pelvic floor** - Electrostimulation improves muscle activity. When the Oxford score (pubococcygeal test) gives a value of 1 or 2 (1= just perceptible contraction, 2= weak contraction), vaginal electrostimulation has been found to be very effective, quickly producing an improvement by at least 2 points. P.E.S. improves in two ways, by increasing muscle tone and improving circulation in the pelvic area.

- **Effect on the urethral closure pressure** – A significant increase of the urethral closure pressure has been reported by some researchers (Dr. PIGNE' - BOURCIER).
- **Effect on the vesical tone** - A significant improvement of vesical compliance has been observed, along with a considerable reduction of the non-inhibited contractions of the detrusor. An improvement of the cystometric capacity has also been observed.

3

Indications of P.E.S.

3.1 - Stress incontinence,

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 sec. (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.

3.2 - Urge incontinence,

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.

3.3 - Mixed Incontinence,

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, 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.

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CONTRAINDICATIONS

PLEASE READ CAREFULLY:

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

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

In the following circumstances, evoStim® UG 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.

3. .

IF IN DOUBT, CONSULT YOUR PHYSICIAN.

5

WARNINGS and PRECAUTIONS

1. Carefully read the User's manual 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 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 a patient with reduced sensitivity.
8. Keep the device and its accessories out of reach of children, the mentally impaired 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 a 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 a 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 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 47, respect to a radio frequency communication device (RF transmitters, mobile phones, remote controls).
17. DO NOT use the unit on a patient on 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 appliance on a patient on which it is used simultaneously a monitoring instrument of physiological parameters (ECG or other type). It could be affected by electrostimulation.
19. The equipment can deliver electrical pulses with a current density higher than $2\text{mA}_{\text{rms}} / \text{cm}^2$.
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® UG 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 perineal probes (vaginal or anal) on different patients. The probes are for personal use. This is to avoid the transmission of venereal diseases or other far more serious diseases.

The evoStim® UG package should contain the following parts:

Q.ty	Code	Description
1	EVO-UG	Unit evoStim® UG
1	CV/evoStim_kit_T-UG	2 Gray bipolar cables with protected 2mm banana termination and mini axial connector. Length 99cm.
1	BAT/LR03-03	Kit 3 AAA alkaline batteries 1.5 V. (LR03)
1	ESTIM-KEY	Key for battery compartment opening
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	ESim_bag	Padded bag.
1	ISTRU-evoStim UG	Ures manual for MD evoStim UG.
1	Sonda perineale.	The vaginal probe model PERIPROBE Minima (RU/VMINIMA) is normally supplied, unless otherwise requested by the customer.

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

7 HOW TO ASSEMBLE 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 push in the direction of arrow (a) (DO NOT turn the key!); Lift-off the battery cover; Insert the three batteries supplied (b), observing the



polarity shown on the bottom of the battery compartment

- (c). Close the battery-compartment with the cover
(d).

Note: The unit may not work if one or more batteries are inserted in reverse. To test, press the ON / OFF button ① for 2 seconds, the LCD screen will switch-ON and will show some numbers and characters. Try then to press the ON / OFF button, holding it down for 2 seconds to check that the unit turns off.

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 one or both lead wires and insert the plug(s) into either of the outlets, located at the base of the unit. If only using one lead wire, insert into



the CH1 outlet as marked on the unit (27, 28).

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.



7.4 - PLACEMENT OF THE PROBE

Moisten the insertable body of the probe with tap water or water based gel, to improve the conductivity of electrodes. Gently insert the probe in the vagina or anus (according to the probe model), following the instructions included in the package of the probe or the doctor's suggestions.

7.5 - USING THE UNIT

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

7.6 - Type of probe Vs. wave-shape

The lead wire of each channel has two terminations with 2mm plugs, one RED, one BLACK. 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.

If you are using a probe with 2 electrodes only, 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

Controls Reference

The ergonomics of **evoStim®** UG unit is based on the rotation of the upper knob ① (to change the stimulation intensity or the value of various parameters) and the press of the button integrated in the same (to turn on, turn off or pause the unit). Increase or decrease of the intensity or any other parameter must first be enabled by touching the appropriate area of the touch display (touch-screen).

The upper knob

Functions of the encoder (the knob) is to allow selecting programmes, as well as setting and adjusting any parameters of the selected programme.

The push-button integrated in the knob allows the following operations:

- **switch-ON/OFF** the unit (push and hold for 2 seconds);

- **Pause the unit** (by briefly pushing down the button, then push again to resume), also useful as emergency push-button;
- **Start the session.** Push the button, provided that at least one channel intensity is set to an intensity different from zero;
- **Resume the started session** when an electrode alarm (open-circuit) has been solved (restored the output circuit/connection);
- **Restore the factory parameters**, when pushed-and-held for 2 seconds in combination with one of the touch-areas ⑪ or ⑫ or ⑬, as described in 8.2.13 (only before starting a session).

will not apply the normal operation of such button rather it will light-ON the backlight for 10 seconds.

Continuous short **RED** flashes when open-circuit is detected in the output.

Continuous short **GREEN** flashes when the unit is paused.

Continuous short **YELLOW** flashes when the unit is in editing.

The backlight of the display

An RGB or multi-colour backlight helps reading the LCD display in low light environments and helps the patient to understand the different situations, provided that it has been enabled through the touch-button ⑮.

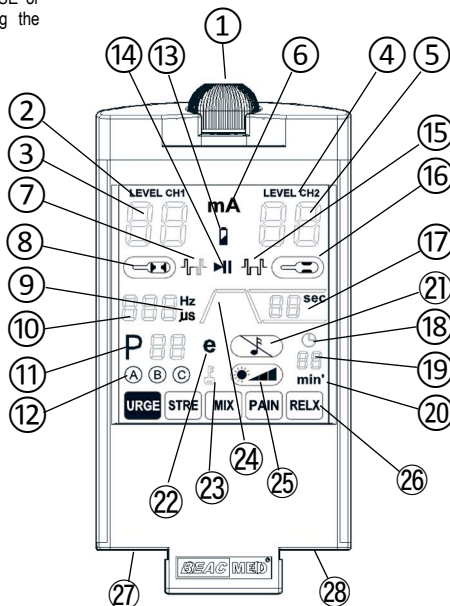
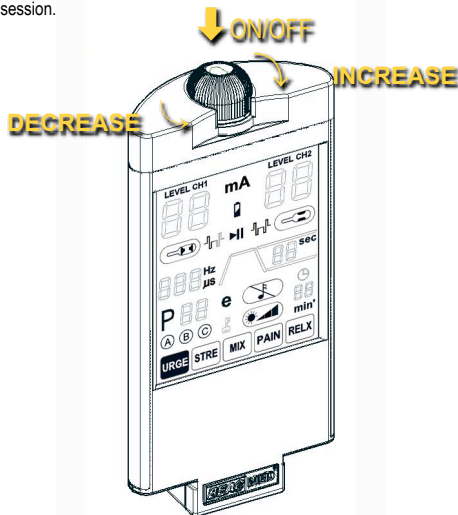
Here below the different situations/colour of backlight:

A **BLUE** light for 10 seconds when the units is switched-ON and every time the screen is touched, when the environment is dark. It means that, when the ambient light is not enough to read the display, the first touch of a button

Description of the commands (with reference to the paragraphs of chapters 8.1 and 8.2):

- ① - Upper rotating knob with push button;
- ② - Label stimulation LEVEL of CH1 (§ 8.1.4.);
- ③ - Stimulation level CH1 (touch-area) (§ 8.1.5.);
- ④ - Label stimulation LEVEL of CH2 (§ 8.1.4.);
- ⑤ - Stimulation level CH2 (touch-area) (§ 8.1.5.);
- ⑥ - Symbol mA (touch-area). (§ 8.1.4.);
- ⑦ - Symbol wave-shape CH1 (touch-area) (§ 8.1.3);
- ⑧ - Type of probe connected to CH1 (touch-area) (§ 8.1.3);
- ⑨ - Symbol Freq. (Hz) and Pulse-width (μ s) (§ 8.2.5, § 8.2.6);
- ⑩ - Value Freq. / Pulse-width (touch-area) (§ 8.2.5, § 8.2.6);
- ⑪ - Number of programme in use (touch-area) (§ 8.2.8.);
- ⑫ - Sub-programmes A B C (touch-area) (§ 8.2.12.);
- ⑬ - Symbol low battery indicator (§ 8.1.11);
- ⑭ - Symbol of PAUSE state (§ 8.1.7);
- ⑮ - Symbol wave-shape CH2 (touch-area) (§ 8.1.3);
- ⑯ - Type of probe connected to CH2 (touch-area) (§ 8.1.3);
- ⑰ - Time of stimulation cycles steps (touch-area) (§ 8.2.3 and § 8.2.4);
- ⑱ - Symbol of "clock" (§ 8.2.7);
- ⑲ - Session time display (touch-area) (§ 8.2.7);
- ⑳ - Symbol "min" (§ 8.2.11);
- ㉑ - Buzzer enabling touch-area (§ 8.1.8);
- ㉒ - Symbol "edit" (touch-area) (§ 8.2.6, § 8.2.7);
- ㉓ - Symbol LOCK state (§ 8.1.6);
- ㉔ - Steps of stimulation cycle (touch-area) (§ 8.2.3 / § 8.2.4.);
- ㉕ - Back-light adjusting (touch-area) (§ 8.1.10);
- ㉖ - Quick selection Buttons (5 touch-area) QB (§ 8.1.3);
- ㉗ - Channel 1 outlet CH1
- ㉘ - Channel 2 outlet CH2

Main functions of the upper knob: Press-and-hold down to switch ON/OFF. Press to START THE SESSION, PAUSE/RESUME. Turn to INCREASE or DECREASE the selected parameter or UNLOCK commands during the session.



8.1 - QUICK START

8.1.1 - Switch-ON the unit

Press for 2 seconds the button integrated in the upper knob ①. When the unit is ON, if the session does not start, the unit automatically turns off within 5 min.

8.1.2 - Quickly select a programme

Tap one of the five rectangular areas (QB) at the lower side of the display. The name of the selected QB will appear in reverse (with a dark background). Willing to change the programme linked to the selected button, read the section 8.2.8.

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

8.1.3 - The probe type selection

The type of probe selected defines the waveform administered on each channel. By touching the area ⑧ or ⑯, you can select the type of probe (or the position of electrodes of the probe) for either CH1 or

CH2. The wave-shape will accordingly change and symbols ⑦ or ⑮ will show the wave-shape operating respectively on CH1 and CH2 (see also section 7.6).

The same probe type used in the last session, will be automatically selected when the unit is switched-ON again.

8.1.4 - Set the stimulation level and start

After selecting a programme, (URGE - STRESS - MIXed - PAIN - RELax), and after connecting the cables and applied the probe, tap the area ③; Setting will remain enabled for 3 seconds while the label ② will flash. Then turn the knob clockwise to attain a strong but not bothering stimulation. If you are also using CH2, repeat the operation by touching the area ⑤. In this case, wishing to simultaneously adjust the levels of CH1 and CH2 (only if the same type of probe has been selected), instead of touching the areas ③ and ⑤, touch the symbol "mA" ⑥, both labels ② and ④ will flash to indicate that the rotation of the knob will act on both

channels. Briefly press the button ① to start the session.


8.1.5 - Open-circuit safety cutout

If the stimulation level is increased while the output circuit is open or the resistance of load is too high, the safety cutout will activate and the intensity level of the open channel will be forced to 0. The safety cutout will take place, for example, when the probe has not been connected to the lead wires or it has not been inserted or the probe has not been moistened and then there is a poor contact with the body.

To visually show the safety cutout, the intensity value displays ③ o/a ⑤ will flash and the backlight will flash in RED (unless disabled).

8.1.6 - 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  (②) will appear on the display.

To unlock the controls, turn for at least 1/4 turn the knob clockwise. To temporarily unlock the intensity change, tap the ③ area for CH1 or ⑤ for CH2, then turn the knob clockwise (to increase) or counter-clockwise (to decrease) until obtaining an energetic stimulation but not bothering.

8.1.7 - Temporarily stopping the session (PAUSE)

During the session, you can temporarily stop it to modify a parameter.

Briefly press the button ① to pause the session. The pause state is visually reported by the symbol  ⑭ 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 chapter 8.2 for details).

To resume the session, briefly press the button ①.

8.1.8 - Enable/Disable the "buzzer"

If the "buzzer" is enabled, you will hear a short beep every time you touch a sensitive area of the display. Furthermore, an acoustic signal will mark a safety cutout as well as the end of the session. The "buzzer" is normally enabled, willing to disable it, touch the area ②1.

For optimal use, we recommend you leave the "buzzer" activated.

8.1.9 - Change the backlight intensity

By touching the area ②5, 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.

8.1.10 - Switch-OFF the unit

If the session is regularly started, when the session ends, the unit will automatically turn off. To switch-OFF the unit, press for 2 seconds the button integrated in the knob ①.

8.1.11 - Replacement of batteries

When the batteries are exhausted, the symbol  appears on the display. The symbol flashes when the battery level is sufficient to end the session in progress, while it remains lit steadily if the batteries need to be replaced. It is necessary to replace all 3 batteries with as many new ones of the same type (§ 7.1).

8.2 - ADVANCED OPERATION

8.2.1 - ON/OFF + Pause

The encoder push-button allows to switch-ON and switch-OFF the unit as well as START the session and PAUSE the stimulation in case of emergency. When a session is paused, it is possible to edit the running programme or even select another one. Furthermore it allows to re-store the factory parameters as described in 8.2.13. Here below basic functions:

- To switch-ON the unit, hold down the push-button for at least 2 seconds;
- To re-start the preview sequence, (before starting the session) briefly push it;
- To pause the unit, (during the session) briefly push it and push again to continue the session;
- To switch-OFF the unit, hold down the key for at least 2 seconds.

8.2.2 - Programme Preview sequence

Further to the session time, a stimulation programme is characterised at least by: Frequency

and Pulse-width. When the stimulation programme includes a rest time, then the programme is characterised also by the following parameters: Rise time, Plateau time, Fall time, Rest time. For easiness, the Rise-Plateau-Fall times may be gathered in the "Action time".

The preview sequence is aimed to show in sequence all the operating parameters of the loaded programme.

It will take place any time the unit is switched-on, if the loaded programme includes a REST time.




For the first 4 seconds after switching-ON the unit, the 2 digits display ⑰ will show in sequence the parameters Action time (for 2 seconds) and Rest time (for 2 seconds). Simultaneously, the display ⑩ will show the Frequency (for 1 second) and the pulse-width (for another second) taking place either during the Action time or the Rest time. Of course the symbols "Hz" and "µs" ⑨ will coherently switch-ON during the preview sequence.

During the preview sequence the displays ③ and ⑤ as well as the labels ② and ④ and the label ⑥ will be OFF. Setting the stimulation level can

start only after the preview sequence ends, when the displays ③ and ⑤ will show 00 and the symbols ②, ④ and ⑥ will be ON.

To reviewing the preview sequence after its termination, briefly push the encoder push-button and the preview sequence will start again.


8.2.3 - Visualise Cycle-steps values

Before starting the session (that is to say before adjusting the stimulation levels) the lasting time of each-one of the 4 cycle-steps (Rise-Plateau-Fall-Rest), characterising the selected programme, may be shown on the display ⑰. To switch from one to the next cycle-step, touch the area underlying the symbols of the cycle () ⑳ or the display ⑰. After the session has started, the cycle-steps will automatically progress. Again for easiness, during the session, only the Action time () which includes Rise-Plateau-Fall and the Rest time () will be shown. The value of Action time and Rest time will be then shown on the display ⑰ but the value will not be steady rather it will count-

down to show the remaining time of either the Action time or the Rest time when they take place.

8.2.4 - Edit one or more cycle-steps time

After the preview sequence and before starting the session (eg. before adjusting the stimulation level) the lasting time of each-one of the 4 cycle-steps (Rise-Plateau-Fall-Rest), characterising the selected programme, may be edited (except for the five default programmes P10-P20-P30-P40-P50, which are automatically controlled by the IntelliSTIM® function). Repeatedly touch the area underlying the symbol ㉔ or the display ⑰, as described in the previous paragraph, to visualise the parameter to edit;

- touch the “e” label ㉔ to enable the programme editing; it will flash to show the editing state.
- touch the area underlying the symbols  or the display ⑰ to allow editing the shown parameter, the symbol “sec” will flash for 5 seconds;
- change the value shown by turning the rotating encoder or leave it unchanged if you prefer.

- touch again the same area to switch from one to the next cycle-step and then edit them one-by-one if required.
- touch the “e” label ② to disable the programme editing, it will stop to flash.
After the session has started, it is no longer possible to change any parameter unless the unit is paused.

If one or more of the cycle-steps parameter of the selected programme have no longer the factory setting (has been changed by the user) the programme number ⑪ will slowly flash.

8.2.5 - Visualise Frequency or Pulse-width values

Either, before or after starting the session, by repeatedly touching the area underlying the display ⑩, the Frequency and Pulse-width values are shown in toggle on the display ⑩; symbols “Hz” or “µs” ⑨ will be shown accordingly in toggle.
After the session has started, if the selected

programme includes the Rest time, the Frequency or Pulse-width shown on the display ⑩ will change according to either the Action time and the Rest time.

8.2.6 - Edit Frequency a/o Pulse-width

After the preview sequence and before starting the session (eg. before adjusting the stimulation level) the Frequency a/o the Pulse-width, characterising the selected programme, may be edited.

The Frequency is editable in any programme (except P60 to P99 which are non-editable) while the Pulse-width cannot be edited on the five default programmes (P10-P20-P30-P40-P50) because under the IntelliSTIM® function.

1 - Visualise the parameter Frequency as described in 8.2.5.

2 - Touch the symbol “e” to enable the programme editing, it will flash to show the editing state. When editing is enabled (symbol “e” blinking) the first touch of area underlying the display ⑩ will not produce the alternative visualisation of Pulse-width rather will allow editing the shown parameter (Frequency) for 5

seconds and that state will be shown by the symbol “Hz” ⑨ flashing.

Adjust the value during that time by means of the rotating knob ①. If you don't want to adjust also the Pulse-width, leave the rotating knob steady for 3 seconds and editing procedure will stop.

If you want to adjust also the Pulse-width, touch again the area underlying the display ⑩ while symbol ⑨ is still flashing, the symbols “μs” will appear then flashing for 5 seconds, the 3 digit display will show the Pulse-width. During that time change the Pulse-width value by means of the rotating knob ①. After 3 seconds the knob is steady, change is disabled. Touch the symbol “e” to disable the programme editing, it will stop to flash.

After the session has started, it is no longer possible to change any parameter, neither with the unit in pause state.

If the Frequency and/or the Pulse-width of the selected programme have no longer the factory value (has been changed by the user) the symbol ⑨ will slowly flash.

8.2.7 - Change the session time.

Session time is one of the parameters of each programmes. The default session time is shown in minutes on the 2 digits display ⑱. Changing of session time is allowed before the session starts or when the unit is paused. To permanently change its value:

1. touch once the “e” label ㉔ to enable editing;
2. then touch once the 2 digits value/area ⑱, the clock symbol ⑱ (⌚) will flash for 5 seconds;
3. during that time you may change the value by turning the rotating knob; after 3 seconds the knob is steady, adjusting will be disabled.

If the session time of the selected programme has no longer the factory value (has been changed by the user) the programme number ⑪ will slowly flash.

During the session, the display ⑱ will count down and then it will show the remaining session time instead of the pre-set session time.

To modify the lasting of current session time, do the same but skip the step 1.

8.2.8 - Select a programme

When the unit is switched-ON, the last used programme is loaded. The 5 “touch-buttons” at the lower side of the LCD display define the “AIM” of the treatment. The selected button will result with the dark back-ground and the text OFF. The selected programme will operate on both channels. Touch one of them to select a different aim:

URGE (linked by default to P10, may be linked instead to P11-P12-P13-P14-P15-P16-P17-P18-P19),

STRE (linked by default to Programme 20, may be linked instead to P21-P22-P23-P24-P25-P26-P27-P28-P29),

MIX (linked by default to programme 30, may be linked instead to P31-P32-P33-P34-P35-P36-P37-P38-P39),

PAIN (linked by default to Programme 40, may be linked instead to P41-P42-P43-P44-P45-P46-P47-P48-P49),

RELX (linked by default to Programme 50, no alternative programme link allowed).

For linking a different programme to the selected aim Quick Selection areas:

- touch the area underlying the label “P” and the two digit numbers ⑪, the symbol **P** will flash for 5 seconds;
- during that time the programme shown on the two digit display ⑪ may be changed, within the range allowed by the selected aim button, by turning the upper knob; after 3 seconds the encoder will remain steady, the adjustment will be disabled.

Aim selection and/or Programme selection are allowed only before starting a session or when the unit is paused. Selecting a different programme will reset the stimulation intensity of both CH1 and CH2. Details of programmes are reported in chapter 9.

8.2.9 - Select a programme outside the “aims” allowed range

If you want to use a different programme, not included in the 5 x 10 “aim” ranges, it is also possible to prepare a totally new programme by using the range P0---P9. To access the P0---P9

range of programmes:

Touch the area underlying the label “P” or the two digit numbers ⑪ twice, both the P and the two digits display will flash for 5 seconds and all the 5 aims labels will be OFF. During that time the programme shown on the two digit display ⑪ may be changed, in the range P0--- P9, by rotating the upper knob ①; after 3 seconds the rotating knob is steady, the adjustment will be disabled.

To use the programmes “out of range” they have to be completely edited because simple basic parameters have been inserted in their factory setting.

Also the selection of a programme “out of range” will be saved when the unit is switched-OFF.

8.2.10 - Adjust the stimulation level

Before starting a session, it is necessary to adjust the output stimulation level. If both levels of CH1 and CH2 are left to 00, the session cannot start.

The output stimulation level has to be adjusted after having connected the probe and inserting it ready for the session.

- Touch the 2-digits display ③, the label ② will flash for 5 seconds and during that time adjusting stimulation level of CH1 will be enabled;
- while label ② is flashing, turn the rotating knob to obtain the most comfortable stimulation level.
- Touch the 2-digits display ⑤, if also CH2 has to be used, the label ④ will flash for 5 seconds and during that time adjusting the stimulation level of CH2 will be enabled;
- while label ④ is flashing, turn the rotating knob to obtain the most comfortable stimulation level.

To simultaneously adjust the level of both channels CH1 and CH2, instead of touching the area underlying the display ③ and/or ⑤, touch the area underlying the symbol “mA” ⑥.

Both labels ② and ④ will flash for 5 seconds and during that time adjusting the stimulation level of both CH1 and CH2 will be enabled.

The stimulation level may be adjusted, in the same way, even during the session but only after having unlocked the unit.

8.2.11 - Start the session

After having adjusted the output stimulation level, the session must be activated within 10 seconds. To start the session, briefly push the button on the upper knob, the symbol “min” ⑩ will flash and the display ⑨ will start to count-down the session time.

To prevent any unwanted action or command, 10 seconds after starting the session, the touch-screen will be locked and backlight turn-OFF to preserve battery power. The symbol ② will be shown. To unlock the unit, turn clockwise the upper knob a few degrees (5 steps), the backlight will turn-ON and the symbol ③ will disappear.

Leaving the encoder steady and the touch screen untouched, after 10 seconds the unit will lock again.

8.2.12 - Restore the factory settings

As described above, any changes performed on one or more parameters of one or more programmes will be automatically saved.

If the user wishes to reset to the factory settings one programme, one mode/aim range or the whole set of programmes, there are 3 different procedures:

Reset a programme to factory settings:

- Select the programme to reset
- touch and hold the area underlying the label “P” or the two digit numbers ⑪ and simultaneously push-and-hold the upper knob exactly as per switching-OFF the unit.

Instead of switching-OFF, the unit will remain ON and all the parameters of the selected programme will be restored to the factory settings.

Reset an aim range (10 programmes):

- touch and hold one of the 5 quick selection areas ⑫ whose programmes have to be reset and simultaneously push-and-hold the upper knob exactly as per switching-OFF the unit.

Instead of switching-OFF, the unit will remain ON and the 10 programmes associated to the selected selection area will be restored to the factory settings.

Reset the whole set of editable programmes (60 programmes):

- touch and hold the “e” symbol ② and simultaneously push-and-hold the upper knob exactly as per switching-OFF the unit.

Instead of switching-OFF, the unit will remain ON and the 60 programmes associated to all the 6 quick selection areas (modes/aims) will be restored with the factory settings.

9

THE PROGRAMMES

9.1 - Grouping of programmes

The 5 touch-area (or touch-buttons) allows a quick selection of a programme according to the therapeutical aims. A default programme is linked to each one of 5 touch button as described in 8.2.8.

P10 to P19 are for urge incontinence and they are visible when the aim **URGE** is selected and then they may be associated to the touch-button **URGE**.

P20 to P29 are for stress incontinence and they may be associated to the touch-button **STRE**.

P30 to P39 are for mixed incontinence and they may be associated to the touch-button **MIX**

P40 to P49 are for perineal pain treatments and they may be associated to the touch-button **PAIN**








P50 is for relaxation of pelvic musculature and it is associated to the touch-button **RELX**.

All the programmes from 10 to 50 (except the default programmes 10-20-30-40-50 which are under the IntelliSTIM® function) may be edited (Frequency, Pulse-width, Rise time, Plateau time, Fall time and Rest time may be changed and changes will be saved even after removing the batteries). Programmes 10, 20, 30, 40 and 50 are assisted by the IntelliSTIM® function and then it is not required to modify the Pulse-width nor the Action/Rest time ratio according to the Frequency changes because that is automatically adjusted by the IntelliSTIM® function.

P0 to P9 are free programmes totally editable and basically they are not associated with any of the “aim” touch-buttons. Furthermore they are not assisted by the IntelliSTIM® function. By default, programmes P0 to P9, are set with a standard Frequency 10 Hz, Pulse-width 250 µs and no rest time. All their parameters may be locally changed and the changes will be retained.

9.2 - Key list of symbols used in the programme tables.

F (F1) = Frequency (in Hz)

-  = Pulse Width, in $\mu\text{sec.}$ (micro-seconds)
-  = RISE Time (sec.)
-  = STIM Time (sec.)
-  = FALL Time (sec.)
-  = REST Time (sec.)
- F**  = Frequency during rest (Hz.)
-  = Session time (min')

9.3 - Programmes for URGE incontinence (URGE touch-button)

Default programme is P10 and is subject to automatic adjusting function IntelliSTIM®: Frequency is 10 Hz adjustable from 1 to 20 Hz. Pulse Width will automatically change according to a reverse proportionality.

Stimulation is continuous; no rest periods will happen. Session time default value is 40 min. (adjustable in steps of 5 min from 5 up to 90 min or C = Continuous). For setting to C the session time, turn the rotating knob counter-clock wise. Changes of the session time will be retained.

Instead of P10, a different programme selectable from P11 to P19 may be linked to the URGE touch-button. They are editable by the user and changes will be retained. The pulse-width is not subject to the automatic adjusting.

P	F (Hz)	↔ (µs)	🕒
10 (default)	10	200 (auto)	40
11	5	250	40
12	5	350	40
13	10	150	40
14	10	300	40
15	10	400	40
16	15	150	40
17	15	350	40
18	20	150	40
19	20	350	40

9.4 - Programmes for STREss incontinence (STRE touch-button)

Default programme is P20 and is subject to automatic adjusting function IntelliSTIM®. Frequency is 50 Hz adjustable from 25 to 150 Hz. Pulse Width and ACTION/REST ratio will automatically change according to the frequency.

Instead of P20, a different programme, selectable from P21 to P29, may be associated to the STRE touch- button. They are locally and totally editable by the user (they are not under the Intellistim® function) and any change will be retained.

Programmes from P20 to P29 may be used to stimulate the pelvic floor, by a perineal probe, in the treatment of stress incontinence.

The appropriate selection within the different programmes will allow the best muscular recruitment without discomfort for the patient. Frequencies above 50 Hz must be used with caution; if uncomfortable, it is advised to reduce the frequency.

P	F (Hz)	↔ (µs)	↗ (sec)	↖ (sec)	↘ (sec)	↙ (sec)	F↘ (Hz)	⌚ (min')
20 (def.)	50	250	0	2	0	4	3	20
21	50	250	0	3	0	6	3	20
22	50	250	0	4	0	8	3	20
23	60	250	0	3	0	8	3	20
24	75	200	0	2	0	5	3	20
25	75	200	0	3	0	8	3	20
26	75	200	0	4	0	10	3	20
27	100	150	0	2	0	6	3	20
28	100	150	0	3	0	10	3	20
29	120	150	0	2	0	12	3	20

9.5 - Programmes for MIXed incontinence (MIX touch-button)

Default programme is P30 and is subject to automatic adjusting function. Default Frequency is 35 Hz adjustable from 25 to 150 Hz. Pulse-Width and ACTION/REST ratio will automatically change according to the frequency.

By default, session time is 30 min (adjustable in steps of 5 min from 5 up to 90 min)

Instead of P30, a different programme, selectable from P31 to P39, may be associated to the MIX touch-button.

They are editable by the user (they are not under the Intellistim® function) and any change will be saved.

Programmes from P30 to P39 can be used in incontinence treatment, when you have to treat simultaneously urge and stress incontinence. The type of incontinence is called MIXED INCONTINENCE. The selection of the most appropriate programme must be performed according to the dominance of one or the other of components.

P	F (Hz)	↔ (µs)	⌚ ↗ (sec)	⌚ ↖ (sec)	⌚ ↘ (sec)	⌚ ↙ (sec)	F ↗ (Hz)	⌚ (min')
30 (def.)	35	250	0,3	3	0	6	10	30
31	35	250	0,3	3	0	6	10	30
32	35	250	0,3	4	0	8	5	30
33	35	250	0,3	5	0	10	10	30
34	50	200	0	2	0	8	10	30
35	50	200	0	3	0	10	10	30
36	50	200	0	4	0	15	10	30
37	75	150	0	2	0	10	10	30
38	75	150	0	3	0	15	10	30
39	75	150	0	4	0	20	10	30






9.6 - Programmes for PAIN (PAIN touch-button)

Default programme is P40. Default Frequency is 70 Hz adjustable from 1 to 150 Hz; Pulse Width will automatically change according to the frequency (from 50 to 250 μ s).

Stimulation is continuous; no rest periods will happen.

By default, session time is 30 min (adjustable in steps of 5 min from 5 up to 90 min or Continuous). For setting to C the session time, turn the rotating knob counter-clock wise. Instead of P40, a different programme, selectable from P41 to P49, may be associated to the MIX touch-button. They are locally and totally editable by the user and any change will be retained.

Programmes from P40 to P49 are suitable to reduce pelvic pain, by means of either internal electrodes (vaginal probe) or surface electrodes.

P	F (Hz)	\leftrightarrow (μ s)	 (sec)	 (sec)	 (sec)	 (sec)	F \rightarrow (Hz)	 (min')
40 (def.)	70	50	0	60	0	0	-	30
41	20	150	1	3	1	3	-	30
42	30	150	1	4	1	4	-	30
43	40	50	1	60	0	0	-	30
44	50	50	1	60	0	0	-	30
45	60	50	1	60	0	0	-	30
46	80	50	1	60	0	0	-	30
47	90	50	1	60	0	0	-	30
48	100	50	1	60	0	0	-	30
49	120	50	1	60	0	0	-	30

9.7 - Programme for RELAXATION (RELX touch-button)

Default programme is P50. Default Frequency is 1 Hz adjustable from 1 to 4 Hz;

Stimulation is continuous; no rest periods will happen.

The session time is 30 min (adjustable in steps of 5 min from 5 up to 90 min or Continuous). For setting to C the session time, turn the rotating knob counter-clock wise.

Programme P50 is suitable to reduce a spastic contracture of pelvic muscles.

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Technical features:

Output: 1 to 99 mA_{pp} in steps of 1 on a standard load 1K Ω (with a pulse width of 200 μ s).

Frequency – adjustable from 1 to 150 Hz \pm 5%.

Pulse Width – adjustable from 50 to 400 μ s. in steps of 10 (\pm 5%).

Output wave-shape: selectable between “bi-phasic symmetrical” pulses and “bi-phasic symmetrical alternated”.

RISE time - 0 to 5 sec. In steps of 1 sec. (\pm 0,1 s.).

PLATEAU time - 1 to 60 sec. In steps of 1 sec. (\pm 0,1 s.).

FALL time - 0 to 5 sec. In steps of 1 sec. (\pm 0,1 s.).

REST time - 0 to 60 sec. In steps of 1 sec. (\pm 0,1 s.).

REST frequency - 0 to 10 Hz. (\pm 1%).

Supply voltage 4,5 V by 3 alkaline batteries 1,5 Volt type AAA (LR03).

Battery life: 20 hours average (variable according to the programme and the output level set).

Session time: selectable from 5 to 90 min' in steps of 5 (\pm 1 s.) or Continuous.

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.

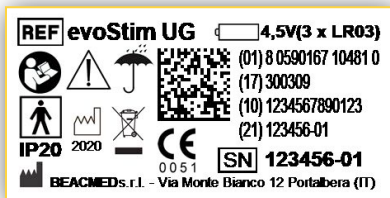
Patient circuit output connection: 2 channels with micro axial connectors to which to connect the supplied cables ending with a 2mm protected plug.

Protection against the penetration of solids and liquids:

- evoStim is classified IP20: objects larger than 12.5mm cannot penetrate the enclosure, it is not protected against the penetration of liquids.
- evoStim inserted in the evoPouch is classified IP22 as it is also protected from dripping.

11

Labelling and symbols



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).



Reference to the catalogue



Follow the user guide.



Applied parts type BF



The appliance emits energy in the form of electrical impulses.



Battery powered



Serial number



Manufactured by:



Manufactured on:



Keep dry



Degree of protection against the penetration of solids and liquids.

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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 (§ 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	12.2a - Be sure to properly press the shutdown button and hold it for at least 2 seconds (§ 8.1.10).	12.2aa - Remove the batteries from the battery compartment and wait at least one minute before reinserting them (§ 7.1). Otherwise contact the manufacturer.
12.3 - Few minutes after switching on, the device switches off.	12.3a - If the unit is switched on, but a programme was 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 (§ 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 follow the steps specified in the user manual (§ 8.1.4 - § 8.1.5 and § 8.1.6).	
	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 lead wires. 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.
12.5 - 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.

Sign	Comments / Probable causes	Suggested remedies
12.6 - Strange symbols randomly appear on the display.		12.6aa - Try to replace the batteries (§ 7.1). If the problem persists, contact the manufacturer or distributor.
12.7 - The buzzer cannot be heard.	12.7a - Make sure it has not been disabled (8.1.8).	12.7aa - If the problem persists, contact the manufacturer or distributor.
12.8 - Stimulation is no longer felt by the patient and the backlight flashes red (if enabled).	12.8a - 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.	12.8aa - 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.
12.9 - No longer feel any stimulation, the symbol ⑭ is lit on the display and the backlight slowly blinks green (if enabled)	12.9a - The device is in the state of "PAUSE" (§ 8.1.7). Maybe you have inadvertently pressed the button integrated in the ① upper knob.	12.9aa - To resume the session just briefly press the ① button.

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13

CLEANING AND MAINTENANCE

13.1 Clean 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.

13.2 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.

13.3 Cleaning and maintenance of perineal probes

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

14

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 programme of collection and recovery for this product.

Recommended separation distances between portable and mobile RF communication equipment (RF) and the EvoStim® UG unit

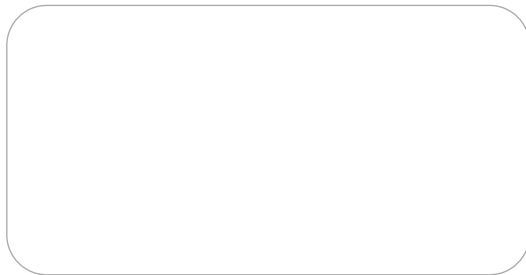
The evoStim® UG unit is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the evoStim® UG can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (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



www.beacmed.eu

Distributor:



ISTRU-evoStim UG - Rev.7-2020-EN