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## 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 taking it to your local collection point or recycling centre for such equipment. This will help to protect the environment in which we all live. This obligation is set out in directive 2002/96/CE, accepted in law by the government of every European community member country. The product contains parts that can be recovered or eliminated safely, contributing to the environmental improvement. The product contains substances which, if incorrectly disposed of, can have harmful effects on the environment and human health. The Manufacturer is available to dispose the product, at the end of its useful life as appropriate for recovery or elimination. Please contact the BEAC local distributor, for detailed information on the collection and processing of this product.

**USER name** (write in CAPITALS):

**USER address** (write in CAPITALS):

**Other USER data (Phone, Fax., E-Mail):**

**Data of the PURCHASE:**

**Details of any complaint** ( in CAPITALS):

Model **IntelliSTIM® BE-28 UG**

Serial n°.....

Date of purchase:

month:.....year:.....

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## **1. Introducing PFS (perineal re-education through electrical stimulation)**

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 object is to stimulate the group of perineal muscles, especially the pubococcygeal muscle.



## 2. Effects of PFS (Pelvic Floor Stimulation)

The different effects of electrostimulation, have 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), endo-vaginal electrostimulation has been found to be very effective, quickly producing an improvement by at least 2 points. This improvement is the result of the electrostimulation providing two separate but concurrent effects: the excito-motor action that increases muscle tone, and the vascular effect improving local circulation.

**Effect on the urethral closure pressure** – A significant increase of the urethral closure pressure has been reported by some researchers (Dr. PIGNE' - BOURCIER).

## 14. WARRANTY

*In addition to your statutory rights, the Manufacturer agrees that if any defect in materials or workmanship appears in this product within two years after the original date of consumer purchase, it will repair or at it's option replace the product in question free of charge. This applies only if the product has been used for domestic purposes and has not been damaged through misuse, accident or neglect and has not been modified or repaired by anyone other than the Manufacturer or its authorized agents.*

*If a defect appears, please check that the article is being used in accordance with instructions, if so, return it with this warranty and the Certificate of Purchase or some other proof of purchase to your nearest IntelliSTIM® supplier. Note: only our authorized service agents should carry out Repairs of the IntelliSTIM® BE-28UG units.*

**Exclusions:** The batteries must be considered excluded by this warranty, due to their exhaust during normal usage.

## **ORIGINAL ACCESSORIES**

The unit must be used only with the original accessories, supplied by the manufacturer.

Since the unit is used with internal special electrodes, for perineal stimulation therapy, they must be the original type supplied or suggested by the manufacturer; in any case they must have CE mark as Class IIa medical device, according to the 93/42/CEE Directive. The instructions for use and cleaning of accessories included in their original package must be read and followed.

**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 for PFS

#### (Pelvic Floor stimulation)

**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.

### 13. GENERAL INFORMATION

**Statement: This unit is CE Marked, according to the 93/42/CEE/MDD**



**Directive and it is classified a Medical Device class IIa.**



### PRECAUTIONS

1. Do not immerse the unit in water
2. Do not place the unit close to excessive heat
3. Use only the specified batteries: 2x 1.5volt AA Alkaline (LR6). Using of any other battery could damage the unit.
4. Do not use the unit while asleep.
5. Remove the batteries from the unit, when it is not used for long time.
6. Keep the unit away from sources of high magnetic fields such as TV'S, microwave ovens and hi-fi speakers, as these may affect the LCD screen.
6. Temperature & Relative Humidity during storage and transport : -20°C to +80°C, 8% to 80% R.H.

## 12. CONNECTION OF PROBES

### **Cables and Polarity management:**

Each channel (output) is connected to the probe (vaginal or anal) through a pair of cables, terminating with male 2mm colored connection: one red, one black.

### **General principles:**

- 1. Using the symmetrical biphasic wave shape, the strongest effect will be felt under the positive electrode (red).*
- 2. When using probes with two ring-shaped electrodes, the red connector should be connected to the proximal electrode ring (in the middle of the probe). The symmetrical biphasic wave shape should be used.*
- 3. When using probes with electrodes along the two sides, it would be better to use the symmetrical alternating wave shape.*
- 4. The second channel can be used, for example, for special double-circuit probes for simultaneous vaginal and anal stimulation.*

**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 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.

### **Mixed Incontinence**

This 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 (e.g.. 75 Hz) 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.

## 4. Product description

IntelliSTIM<sup>®</sup> BE-28UG is a dual channel perineal stimulator suitable for professional or personal use. Fifteen pre-set programs are available in the memory, ready for use. They can be modified by the therapist but any changes will be lost when the unit is switched-off, unless the program is locked. For stress incontinence, treatment consists of periods of stimulation through a vaginal or anal probe causing pelvic floor muscle contractions, these are followed by rest periods. The objective is to improve the voluntary control of the pelvic floor muscles (for stress incontinence) or to strengthen the reflex inhibition of the detrusor muscle (for urge incontinence).

PRESET programs									
20	250	30	10	3	0	0	0	0	20
F Hz	P µs	⏪	⏩	↶	↷	↸	F↶	0	⏸
<b>P8 - STRESS incontinence (STRESS)</b>									
35	250	3	6	0	0	3	0	0	20
<b>P9 - STRESS incontinence 1 (STRESS 1)</b>									
50	250	2	4	0	0	3	0	0	20
<b>P10 - STRESS incontinence 2 (STRESS 2)</b>									
60	250	2	4	0	0	3	0	0	20
<b>P11 - MIXED incontinence (MIX)</b>									
35	250	3	6	0	0	10	0	0	20
<b>P12 - MIORELAXING (RLX)</b>									
2	400	30	0	2	2	0	0	0	8
<b>P13 - POST PARTUM (P.PARTUM)</b> (starting at 6-8 weeks after childbirth)									
10	250	5	1	3	3	0	0	0	10
50	250	2	4	0	0	5	0	0	10
<b>P14 - PAIN MANAGEMENT (PAIN)</b>									
80	50	6	3	1	1	6	0	0	25
<b>P15 - PROPRIOCEPTION (SEXO)</b>									
10- 100	250	2-5	0-6	0-3	0-3	0-3	0	0	15

## 11. Available programs

Manual programs								
F Hz	P $\mu$ s					F L		
<b>Free program 0 - without IntelliSTIM® control</b>								
10	300	10	0	3	0	0		5
<b>Free program 1 - under IntelliSTIM® control</b>								
35	250	4	5	1	0	5		15
<b>Free program 2 - under IntelliSTIM® control</b>								
50	250	3	6	0	0	4		15
<b>Free program 3 - under IntelliSTIM® control</b>								
70	250	3	8	0	0	4		15

PRESET programs								
F Hz	P $\mu$ s					F L		
<b>P5 - URGE incontinence</b>								
5	250	15	0	2	2	0		20
<b>P6 - URGE 1 incontinence</b>								
10	250	30	0	2	2	0		20
<b>P7 - URGE 2 incontinence</b>								

For urge incontinence most people start noticing an improvement after 7-10 20 minute treatments and a majority are cured after 15-20 treatments. Stress incontinence requires the rebuilding of muscle strength and endurance so results take longer.

### *The IntelliSTIM® function*

There is a relationship between FREQUENCY, WORK time, and REST times as regards the physiological effect. If the frequency is changed, then work and rest times should also be adjusted to achieve the best results. For Manual Programs (M1-M3) the IntelliSTIM® system automatically adjusts work and rest times when frequency is changed. This unique feature makes it very easy to set programs without having to consider the optimum relationship between frequency, work and rest times.

## 5. Pelvic floor stimulation techniques

The stimulation level and the position of the electrodes play a key role in the success of PFS.

The patient should be placed in the modified gynaecological position and be relaxed. Once the probe has been correctly inserted, ask the patient to straighten the legs, perhaps placing a pillow under the knees, to allow the legs to remain slightly flexed. The session will proceed with the patient in the chosen position, reclining, sitting or standing.

### ***How does one know that the probe is in the right position?***

It is quite easy:

Insert the probe as far as it will go comfortably.

When using a program for obtaining pelvic floor contractions (Stress incontinence), during the contraction phase, we MUST observe that the external portion of the probe tilts

minute; Once it reaches zero, the unit will automatically shut off.

### ***Auto-switch-OFF***

When the unit intensity levels are 0 on both channels, and it has not been in use for 5 minutes, the unit will automatically switch off.

### ***Open circuit detection***

When one or both of the electrodes do not touch the skin or contact is broken, the output level of the corresponding channel will immediately drop to zero.

### ***Cumulative time recording***

By simultaneously pushing and holding, for at least 4 seconds, the keys " **Ch2 ▼**" and "**Prog**", the display will show the cumulative time the device was used since the last resetting. It is possible reset this value, by simply pushing and holding down, the "**Prog**" and "**Wave Shape**" keys for at least 4 seconds. To return to the normal operating mode, push again and hold-down the keys "**Ch2▼**" and "**Prog**".

- **Set the intensity**
- **Set the session time.**

The program-lock state will be unaffected by switching-off the unit or by removing the batteries. When the unit is program-locked, and the locked program is selected, a small symbol of a “key” will blink on the right lower corner of the display.

To Unlock a locked program, repeat the same steps made to lock it.

### ***Parameter retention***

Should, during the session, one or more parameters of a manual program M0—M3 (except the intensity and the session time) be modified, the new values will be retained, even after switching-OFF the unit or removing the batteries.

On the contrary, in the case of pre-set programs any parameter change will be lost when the unit is switched-OFF

### ***Session time***

When the treatment timer is set, it will begin to count down one minute by one

down as the contraction lifts the pelvic floor and the patient feels a muscle contraction a tightening of the pelvic floor. When the current is increased a pins and needles sensation is felt and this becomes more and more intense but when the muscles contract the stimulation feels more comfortable. Stimulation should never be too uncomfortable. It is impossible to cause damage with the Intellistim.

When using a low frequency program (for URGE incontinence), the object is not a muscle contraction so we do not look for any probe movement; one must rely on patient feedback on the position of the probe and the intensity of stimulation. The higher the intensity, the more therapeutic is the stimulation, so ask the patient to make themselves as uncomfortable as possible. During stimulation the discomfort diminishes with time and the current can be turned up further.

## 6. CONTRAINDICATIONS BEFORE USE PLEASE READ THE FOLLOWING:

### *General contraindications of electrical stimulation*

Do not use IntelliSTIM<sup>®</sup> BE-28UG unit under the following circumstances:

- **For 3 months after labour or at anytime during pregnancy.**
- **If a heart pacemaker is used or in the case of a serious heart rhythm problem**
- **While driving or operating machinery**

### *Be cautious using IntelliSTIM<sup>®</sup> BE-28UG unit under the following circumstances:*

1. In case of epilepsy, consult your doctor before using any electrical stimulation unit.
2. For children under 12, apply only under medical supervision.

## Other features

*The LOCK function - (prevents patients from changing parameters)*

Simultaneously push and hold, for at least 4 seconds, the **CH1 intensity ▼** and **T▲** buttons; the unit will then lock. The user will be only allowed to:

- **Set the intensity**
- **Set the session time.**

The locked state will be unaffected by switching-off the unit or by removing the batteries.

When the unit is locked, a small symbol of a “key” will appear on the right lower corner of the display.

### *The Program-LOCK function*

Simultaneously push and hold, for at least 4 seconds, the **CH2 intensity ▼** and **T▲** keys; only the program in use will be locked. In such state the user will be unable to change any parameters of the locked program; however one may:

- **Select another program (manual or preset)**

## 10. Specifications:

**Ch1 intensity** settings in 20 steps of 5mA, from 5mA to 100mA on a 1K $\Omega$  load (peak-to-peak value, by using a pulse width of 200 $\mu$ s)

**Ch2 intensity** settings in 20 steps of 5mA, from 5mA to 100mA on a 1K $\Omega$  load (peak-to-peak value, by using a pulse width of 200 $\mu$ s)

**Frequency (Hz):** 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150. Hz.

**Pulse width:** 50-400 $\mu$ s in steps of 50 $\mu$ s

### **Wave forms:**

Rectangular biphasic symmetrical.

Rectangular alternating biphasic.

**RISE-FALL times:** 0-5s in steps of 1s

**ACTION time:** 1-60s in steps of 1s.

**REST time:** 0-60s in steps of 1s.

**TREATMENT time:** Continuous, 10, 20, 30, 45, 60, 90 minutes

## **Contraindications of perineal electrostimulation**

### Absolute contraindications:

pregnancy, nephropathies, infections of the lower urinary tract, tumours in-situ, post-micturition residual above 100 ml, vesico-ureteral reflux, total denervation, vaginal bleeding outside the time of menstruation.

### Relative contraindications:

Hyper-sensitivity to the electrostimulation, menses (psychological contraindications).

**IF IN DOUBT CONSULT YOUR THERAPIST.**

## 7. PREPARING THE UNIT

The IntelliSTIM® BE-28UG unit has been designed to be simple and easy to use yet highly effective. Before use please read all the instructions and ensure that CONTRAINDICATIONS do not apply.

### CONTENTS:

Your IntelliSTIM® pack should contain the following:

- **1 IntelliSTIM® UG Unit,**
- **2 Leads,**
- **2 Alkaline AA1.54v (LR6) Batteries,**
- **1 Instruction Booklet (which you are reading).**
- **1 carry bag**

Having checked that all the contents are correct please proceed to assemble the unit.

the original pulse width function will return.

### To change the RAMP-DOWN time

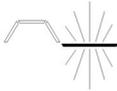


After having set the RAMP-UP time, press the FUNCTION button to bring up the blinking RAMP-DOWN symbol and set the time using the T▲ / T▼ buttons as before.

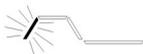
alternating synchronisation (↔) and after having set the REST time on Ch1, again press the FUNCTION button, and adjust the REST time on Ch2 by using the T▲ / T▼ buttons as before. After 6 seconds the original pulse width function returns.

**WARNING!** The REST time of Ch2 can NEVER be set lower than the WORK time. If the setting is incorrect,

the ATTENTION! Symbol  will blink on the display and the REST time on Ch2 will be shown again ready to be changed.



### To change the RAMP-UP time



After having set the REST time (or the REST Ch2 time), by again pressing the FUNCTION button, the T▲ / T▼ buttons set the RISE time which will be seen blinking. After 6 seconds,

## To assemble the unit

Assembly of the IntelliSTIM® BE-28UG unit is very easy and requires only five steps.

**STEP 1 - BATTERIES:** Remove the battery cover and insert two batteries, as shown on the diagram inside the battery compartment. Re-apply the battery cover.

Note: Your unit will not function if the batteries are inserted incorrectly.

Pull down the front cover to expose the buttons. Press the  ON/OFF button once and the LCD display will light if the batteries have been correctly inserted. Press the button again to switch the unit off.

**CAUTION:** There is a risk of explosion if the batteries are fitted incorrectly. Replace with AA Alkaline 1.5 volt batteries (LR6). 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 they should be disposed of safely.

**STEP 2 - LEADS:** Decide whether you wish to use the unit with one lead or two.

Unravel one or both leads and insert the plug(s) into either of the sockets at the top of the unit. If only using one lead, insert into the ch1 socket as marked on the unit.

**STEP 3 - PROBE:** Remove the probe from the bag and connect it to the leads

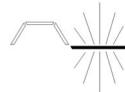
Before using on a patient test the stimulation by holding the probe in the hand. Increase the intensity only while stimulation is taking place.

**STEP 4 - POSITION OF PROBE:** Insert the probe, as described in the Section 5

**STEP 5 -** Read the next section on “Operation of the IntelliSTIM® UG Unit“, and decide how to use the unit for the treatment.

FUNCTION key within 6 seconds. The symbol of the parameter ready to be set will be seen blinking on the display. Make changes using the T▲ / T▼ buttons. 6 seconds after these keys are used the setting will return to the original pulse width function.

### To change the REST time



After having set the WORK time, press the FUNCTION button within 6 seconds and the REST time symbol will be seen blinking on the display. Using T▲ / T▼ buttons, change the time. Then after 6 seconds, the original pulse width function setting will return.

### The Ch2 REST time

Normally, the REST time is the same for both channels Ch1 and Ch2. The only exception is in M0 program. In this case, after selecting the

stimulation). Once the TREATMENT time is set, again press the FUNCTION key and see the symbol  $\Rightarrow$  will blinking on the display. Using the  $T\blacktriangle$  /  $T\blacktriangledown$  buttons, change the synchronisation between SIMULTANEOUS ( $\Rightarrow$ ) and ALTERNATING ( $\Leftarrow$ ). If a button is not pressed within 6 seconds, the buttons  $T\blacktriangle$  /  $T\blacktriangledown$  will return to their original function (pulse width).

### To change the WORK time



The WORK time of any program is preset automatically by the IntelliSTIM® system, if this is acceptable, there is then no need to modify it.

A change is possible (temporarily in the preset programs, permanently in the manual programs).

Once synchronization is set, WORK time can be set by again pressing the

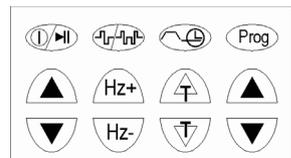
## 8. OPERATION

Operation of the IntelliSTIM® BE-28UG unit is controlled by buttons on the keyboard, and the LCD display shows what is happening.

### The display



### The keyboard



## Function of the buttons

### The ON/OFF / ►|| button.



Switches the unit ON, OFF, and PAUSES the activity as required. Press once, to switch-ON (when the unit is OFF). When the unit is ON and the intensity of both channels is 0, press the same button once more to switch OFF. When the unit is ON and the intensity of at least one channel is above 0, pressing the same button once more will PAUSE the unit, the output level of both channels go to zero, and the symbol ►|| will be displayed. To exit from the PAUSE state, push the same button once more. The level of intensity level before pausing will be restored on both channels in 2 seconds. To switch the unit OFF, while it is stimulating, push and hold-down the ON/OFF button for at least 2 seconds.

**“PROG” button:** This is for selecting Programs: 3 Manual Programs M 1, M 2, M 3 (with the Frequency, Work and Rest time)



Either the Frequency or the Pulse width can be changed and the difference will be immediately felt by the user.

With the FUNCTION button, it is possible to sequentially select some other parameters which can be then modified, using the buttons T▲ / T▼; For example:

### To change the TREATMENT time

Press the FUNCTION button once, to select the TREATMENT time. Then change it, within 6 seconds, by using the T▲ / T▼ buttons. After 6 seconds, the buttons T▲ / T▼ will return to the original function (pulse width).

For MANUAL programs changes will be saved. In PRESET programs changes will be lost when the device is switched off.

### To change the SYNChronisation between Ch1 and Ch2 (Possible only for the M0 program)

The possible selections will be ⇌ or ⇄ (simultaneous or alternating)

## 9. Starting a session

When the unit is switched-ON, the program used during the last session is ready to use again. Simply set the intensity level for each channel.

### To select a different program

Press the PROG button to select one of the other programs in memory (P05 to P12 or M0-M1-M2-M3). To switch between MANUAL programs (M) and PRESET Programs (P) the PROG key must be held down for at least 2 seconds (see section 8).

### To change the FREQUENCY

Use the Hz+ / Hz- buttons to change the frequency of the selected program. The frequency can be changed at any time, even during the preset programs.

### To change the Pulse-WIDTH

Use the T▲ / T▼ buttons to change the Pulse-WIDTH of the selected program. The Pulse-WIDTH can be changed at any time, even while the preset programs are running.

relationships automatically preserved by IntelliSTIM® ), M 0 completely free without the automatic Intellistim® adjustment; and 8 PRESET Programs.

Pressing “PROG” button successively selects programs from M00 to M03, then back to M00. Pressing and holding “PROG” button for more than 2 sec, opens the to the menu of P05-P12 PRESET programs. To again switch to the manual programs, simply press the “PROG” again for 2 seconds. When the “PROG” button is pressed, the output stops.

### Hz+ / Hz- buttons:



These buttons are pressed to modify the operating frequency. It is also possible to change the frequency while the unit is in use, for example to select more comfortable parameters.



### The T▲ / T▼ buttons:



can be used to change the Pulse-width.



### The FUNCTION button:

is used to sequentially select, and show on the display, any time-based parameters used in the stimulation program:

- **Treatment time** (⊕),
- **Synchronisation** (⇌/↔),
- **ACTION time** (⊕↗+⊕↘+⊕↙),
- **REST time** (⊕↖),
- **REST time Ch2** (⊕↖), only if ALT(↔) synchronisation has been selected.
- **RAMP UP time** (⊕↗),
- **RAMP DOWN time** (⊕↘)

Any selected parameter can be easily modified using the buttons T▲ / T▼. The symbol identifying the selected parameter is seen “blinking” on the display; should the parameter not be modified within 6 seconds using the key-buttons T▲ / T▼ the device will return to the original function.

The channels Ch1 and Ch2 are always synchronised, which means the times of work and rest are the same for both channels. The alternating mode, of Ch1 and Ch2 (⇌/↔), is possible only in the program M0. Selecting and modifying the **Synchronisation** parameter is done using the FUNCTION key, as explained above.



The buttons **intensity CH1 (▲)** and **intensity CH2 (▲▼)**:



Increase or decrease stimulation level of Channel 1 and Channel 2 respectively.



The button **Wave-shape**: can be used for changing the wave-shape, for example, to simultaneously stimulate just one or two similar muscles (contra-lateral), with the same channel.