



# CONTENTS

1. Description and use destination . . . . .	2
2. Indications for PFS . . . . .	4
3. Indications for IVES . . . . .	6
4. CONTRAINDICATIONS. . . . .	8
5. TERMS OF USE . . . . .	10
6. OPERATION . . . . .	13
7. PROGRAMMES. . . . .	24
8. SPECIFICATION . . . . .	25
9. GENERAL INFORMATION . . . . .	26
10. CONNECTION OF PROBES . . . . .	28
11. WARRANTY. . . . .	29
12. Information for disposal of the product	32

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# 1 Description and use destination

LogiSTIM® EM-19UG is a dual channel perineal stimulator suitable to be directly used by the patient but perfectly suitable even to professional use, being extremely easy without sacrificing flexibility and performances.

## ***Destination of use***

LogiSTIM® EM-19UG can be used under a doctor prescription and the supervision of a doctor or a qualified professional therapist, to perform PFS (Pelvic Floor electroStimulation), through intra-cavitary electrodes (vaginal or anal) or to apply Intra-Vesical electrical stimulation (IVES), through sterile trans-urethral catheters.

Pelvic floor or perineal stimulation is a popular method for treating incontinence.

Pelvic floor electrical stimulation 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.

After the first session cannot be expected great benefits. We can expect some therapeutic effects after many sessions (at least 30, supplied at alternated days). Occasional glaring improvements, after the initial sessions, must not lead the operator or the patient to suspend the therapy.

### ***Friendliness for personal use***

With a program locked by the doctor (Doctor-lock state) the patient is just demanded to place the probe and adjust the intensity. If not in the lock state, it is quite easy, for the patient, to select one of the 9 preset programs.

### ***Flexibility for professional use***

For professional use, further to the 9 preset program, 1 free program is available for creating custom protocols. LogiSTIM® EM-19UG offers a very



## **12. 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.

Crop and send only in the case of defective unit.

comfortable stimulation, suitable to treat even patients poorly supporting electrical stimulation.

Due to the dual channel, the unit can be used in combination with the vaginal or anal special probe.

## **2** Indications for PFS (Pelvic Floor electrical 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.

**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,

**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 **LogiSTIM® EM-19 UG**

Serial n°.....

Date of purchase:

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



## 11. 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 LogiSTIM® supplier. Note: only our authorized service agents should carry out Repairs of the LogiSTIM® EM-19UG units.*

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

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.

### 3 Indications for IVES (Intra-Vesical electrical Stimulation)

Detrusor instability / Detrusor areflexia idiopathic or induced by:

- **M. Parkinson**
- **Multiple Sclerosis**
- **incomplete spinal cord injury,**
- **nerve lesion by oncologic pelvic surgery**
- **Diabetes mellitus**
- **Enuresis nocturna**
- **Myelomeningocele**

IVES consists on supplying positive monophasic pulses, through a metallic electrode embedded in a trans-urethral vesical catheter and a surface counter-electrode, externally applied to the skin of the supra-pubic region. According to recent experimental studies, IVES activates bladder mechanoreceptors. The afferent stimuli reach the spinal sacral cord via A-delta-fibres. The optimal detrusor reaction was found to be at 20 Hz (10-90 Hz); the optimal single pulse duration was 1-2 ms. The electrical circuit between the metallic internal electrode (embedded in the catheter) and the external counter-electrode is closed through the liquid in the bladder. Such liquid can be made by the post-micturition residual liquid (urine) or by saline solution, specifically introduced through the urethra. The quantity of saline solution to be introduced should be 100 ml for adult patients and 50 ml for children. If the post-micturition residual liquid should be exploited, as conductive mean, it is imperative to apply the electrical stimulation after at least 1 hour after the

## 10. 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.*

## 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.

last micturition. Sessions will be daily and will last 30 min'.



## CONTRAINDICATIONS BEFORE USE PLEASE READ

### THE FOLLOWING:

#### ***General contraindications of electrical stimulation:***

Do not use LogiSTIM® EM-19UG 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 LogiSTIM® EM-19UG 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.

## ***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).

## ***Contraindications of Intra-Vesical electrical stimulation.***

Specific contraindication of SIV is the complete denervation of detrusor.

**Particular attention must be placed to the hygiene of urethral catheter; it must be absolutely sterile.** The failure to comply with these criteria could lead to serious infections of the lower urinary tract.

**IF IN DOUBT CONSULT YOUR THERAPIST.**

## **9. 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.

## 8. 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.

Rectangular monophasic

**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.

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

## 5 TERMS OF USE

The LogiSTIM® EM-19UG 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 LogiSTIM® EM-19UG pack should contain the following:

- **1 LogiSTIM® 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.

## Preparing the LogiSTIM® EM-19UG unit.

Assembly of the LogiSTIM® EM-19UG is very easy and requires only five steps.

**STEP 1 - BATTERIES:** Remove the belt clip, then the cover of the batteries compartment. Insert two batteries, as shown on the diagram inside the battery compartment. Re-apply the battery cover.

Note: Your LogiSTIM® unit will not function if the batteries are inserted incorrectly. To check, press the ON/OFF button once and the LCD display will start up. Having made this check press the button again, and hold it down for at least two seconds, 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.

down, the “AUX” and “MENU” keys for at least 4 seconds, To return to the normal operating mode, push again and hold-down the keys ” Ch2▼” and “ AUX”.

## 7. PROGRAMMES

F Hz	P µs	☺→	☺←	☺↗	☺↘	F↵	0 0	⏻
<b>P0 - FREE - MANUAL</b>								
<b>P1 - URGE (urge incontinence)</b>								
10	250	34	0	2	2	0	0 0	30
<b>P2 - URGE (urge incontinence)</b>								
20	250	33	10	3	0	0	0 0	30
<b>P3 - STRESS (stress incontinence)</b>								
35	250	3	6	0	0	3	0 0	20
<b>P4 - STRESS (stress incontinence)</b>								
50	250	2	46	0	0	3	0 0	20
<b>P5 - URGE+STRESS (mixed incontinence)</b>								
35	250	3	6	0	0	10	0 0	20
<b>P6 - URGE+STRESS (mixed incontinence)</b>								
50	250	2	8	0	0	20	0 0	20
<b>P7 - RELAXING (myorelaxing)</b>								
2	400	34	0	2	2	0	0 0	8
<b>P8 - PREVENTION (After childbirth prevention) (not before 6-8 weeks after childbirthing)</b>								
10	250	11	1	3	3	0	0 0	10
50	250	2	4	0	0	5	0 0	10
<b>P9 - PROPRIOCEPT (proprioception)</b>								
10-100	250	2-5	0-6	0-3	0-3	0-3	0 0	15

## ***Open circuit detection***

Only when the probe is correctly linked to the unit and has been inserted in the vaginal (or anal) cavity, the unit is enabled to supply electrical stimulation. When one or both of the electrodes of the probe do not touch the skin or contact is broken, the output level of the corresponding channel will immediately drop to zero. In that case, the probe symbol will flash and it will be impossible to increase the intensity until the contact will be re-established. If you cannot increase the intensity, even after having re-established the contact, try to decrease before and then increase it. In case, switch-OFF the unit and restart it. If the unit continues to detect "open circuit", try to replace the leads.



## ***Cumulative time recording***

By simultaneously pushing and holding, for at least 4 seconds, the keys " **Ch2** ▼ " and "**AUX**", 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

**STEP 2 - LEADS:** Decide whether you wish to use the unit with one lead or two (one lead suitable for single circuit probe, two leads suitable for a double circuit probe).

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 (slightly wet the hand in case of very dry skin). Increase the intensity only while stimulation is taking place.

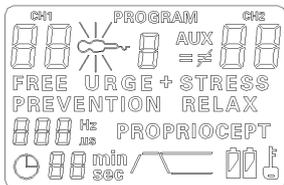
**STEP 4 - POSITION OF PROBE:** Insert the probe (vaginal or anal), according to the suggestions of your therapist and to the user guide of the probe.

**STEP 5 -** Read the next section on "Operation", and decide how to use the unit for the treatment.

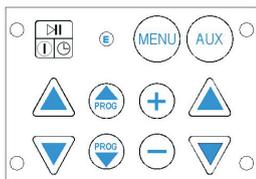
# 6 OPERATION

Operation of the LogiSTIM® EM-19UG unit is controlled by buttons on the keyboard, and the LCD display shows what is happening.

## The display



## The keyboard



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

## Parameter retention

Should, during the session, one or more parameters of the manual program M0 (except the intensity) 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 (unless in LOCK or PROGRAM LOCK state).

## Session time

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

buttons; the unit will then lock. The user will be only allowed to:

- **Set the intensity**

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 blink on the right lower corner of the display.

### ***The Program-LOCK function***

Simultaneously push and hold, for at least 4 seconds, the **+** and **CH2 intensity ▼** 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)**
- **Set the intensity**

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 appear on the right lower corner of the display.

## **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 and hold it, for at least 2 seconds to switch-OFF the unit. 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 symbol “clock” will flash, to show that time counting is suspended), until the ON-OFF key will be briefly pushed again. During the PAUSE state, the 2 digit display, at the lower left side of the display, will show the time remaining before the session will end (the symbol “min” will be ON, during the PAUSE state). In the PAUSE state all the output channels will result zeroed, while the intensity will be progressively (3 sec) restored when the PAUSE state will be ended. During the PAUSE state any change is disabled and only the ON-OFF key will be active.

Even in the PAUSE state, if the ON-OFF key is pressed for more than 2 seconds, the unit will switch-OFF.



### The buttons “PROG”:

They are for selecting one of the 10 programs, amongst them the Programs 1 to 9 are preset type (but temporarily editable), the program 0 is FREE type, that is to say, fully, permanently editable and available for the user to introduce a custom program.

When program 0 is selected, it is possible making the parameters of Ch2 (AUX) different from the parameters of ch1 (of course within some limitations).

When one of “PROG” keys are pressed, the output level goes immediately down to zero.

### **Preview ACTION/REST sequence**

When the unit is switched-on, or when a different program is selected, if the program has a REST time (REST time value different from 0), the so-called ACTION/REST preview sequence, will take place. The ACTION/REST preview will last 3+3 seconds. For the first 3 seconds, the frequency value, forecasted



### CH1 and CH2 intensity keys (▲/▼):



Push them to set the intensity values of each channel.



### The small “Edit” key,

It is embedded in the enclosure, within the ON/OFF and the MENU keys. When briefly pushed, it introduces the “Edit” phase, enabling the +/- to be used for modifying the Main Frequency or the parameter selected through the MENU key



### The “AUX” key

Not in use in this version of unit. In a special version of the unit, it could be used to set the parametrs of CH2 different from the parameters of CH1. However that feature will be limited to the program 0.

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

Simultaneously push and hold, for at least 4 seconds, the **+** and **CH1** intensity **▼**

disabled again. Any parameters change of a pre-set program will be anyhow temporary; the original value will be restored when a different program will be selected or when the unit is switched OFF and ON again.

Within the selectable and editable parameters, the parameter "wave-shape" offers the following 3 choices:

**Bi-phase symmetrical pulse**, represented with the symbol 

**Bi-phase alternated pulse**, represented with the symbol 

**Mono-phase pulse**, represented with the symbol 

#### "+/-" keys



They are used to change the value of the Main Frequency or of the parameter selected, through the MENU key. +/- keys can be enabled only by pushing the "E" small key.



during the ACTION time, is shown, on the 3 digit display, at the left, (symbol Hz is ON), while on the 2 digit display, at the lower-left corner, the ACTION time = RISE+PLATEAU+FALL time will be shown (the sec symbol is ON, along with

the ACTION symbol ). For the remaining 3 seconds, the REST time will be shown (the sec symbol is ON, along

with the REST symbol ) and, on the 3 digit display, will be shown the value that the Frequency will assume, during the REST phase. After that, in the 2 digit display, the session time will be shown (symbol "min" and symbol "clock" are ON). If the program has no REST time (REST time = 0), the above described sequence, for preliminarily showing the ACTION/REST time and the ACTION/REST frequency will not take

place; in that case the symbol , at the lower side of LCD, will be ON. During the preview sequence, intensity setting of both channels will be disabled,

as like as any other commands. The intensity display of Ch1 and Ch2 will be OFF.

### ***Changing the main frequency of the selected program***

The Main frequency value (we mean Frequency during the ACTION time) of any program is always shown, on the 3 digit display, at the left side of the display (the symbol "Hz" is permanently ON). The frequency value can be changed, by means of the +/- keys, simply previously briefly pushing the E (Edit) key to enable the editing phase. In the editing phase, the symbol "Hz" will flash and the user is allowed to change the value, through the +/- keys; the editing phase will be terminated, if the +/- buttons will remain inactive for 6 seconds.



#### **"MENU" key**

Use it if you wish to check the value of every parameters of the selected program. As explained in the previous paragraph, on the 3 digit display, at the left side of the screen, it is normally shown the value of

the main frequency, that is to say "the frequency during the ACTION phase. By repeatedly pushing the MENU key, on the 3 digit display, will be sequentially show, the value of the following parameters:

- **Frequency during the ACTION phase (Hz)**
- **Frequency during the REST phase (Hz)**
- **Pulse width (µsec)**
- **ACTION time (sec)**
- **REST time (sec)**
- **RISE time (sec)**
- **FALL time (sec)**
- **Wave-shape**
- **Session time (min')**

#### ***Parameters editing:***

The shown parameter value cannot be changed, unless the edit phase is enabled. When the parameter to be changed is shown, briefly push the small E key and you will be allowed to change it, through the +/- keys. Once the E key has been pressed, if any change will not occur, after 6 seconds, the +/- keys will be