OPERATING INSTRUCTIONS – ENGLISH

BEFORE USING THE STIMULATOR

USER INFORMATION

ADDITIONAL INFORMATION

1. INTRODUCTION

CEFAR Medical AB has been a medical supplier of electrotherapy products for more than 30 years. The company was established in Sweden in 1975 and is currently represented in large parts of the world.

The Cefar stimulators are widely used by public and private health care professionals around the world.

Electrical nerve and muscle stimulation is effective, has no side effects and it is economical. Through clinical research, areas of application for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation) are rapidly expanding. Cefar is working actively to further develop the method towards a natural treatment alternative for both health care professionals and consumers.

More information about TENS, EMS and our products can be found on our web site: www.cefar.se

CEFAR PERISTIM PRO is a dual channel incontinence stimulator for treatment and rehabilitation of incontinence. CEFAR PERISTIM PRO features seven preset incontinence program for internal use with a vaginal and/or anal probe, two preset TENS program for external use with two surface electrodes. The CEFAR PERISTIM PRO provides programming for three custom programs. The channels are simultaneous, which means that a selected program applies for both channels.

2. MEDICAL BACKGROUND

INCONTINENCE

Urinary incontinence, involuntary loss of urine from the bladder, is a problem for many people. There are two main types of urinary incontinence; stress incontinence and urge incontinence. Faecal incontinence, involuntary passage of faeces, is not often discussed, but still a common problem. Electrical stimulation through a vaginal/anal probe, or in some cases surface electrodes, is a well-tolerated treatment for urge, stress, mixed and faecal incontinence and has shown positive results in improving bladder and bowel control.

Stress incontinence

Stress incontinence is urine leakage caused by increased abdominal pressure on the bladder, such as coughing, sneezing, laughing, exercising or lifting something heavy. Stress incontinence is the most common type of incontinence and is primarily affecting women. It usually occurs when the perineal and pelvic floor muscles are weakened, for example by pregnancy, childbirth or menopause.

Urge incontinence

Urge incontinence means a sudden, strong urge to urinate followed by an immediate bladder contraction, resulting in an involuntary leakage of urine. Both men and women can be affected, particularly the elderly. One reason for this condition can be a disruption in the part of the nervous system that controls the bladder.

Mixed incontinence

Mixed incontinence is a combination of stress incontinence and urge incontinence.

Faecal incontinence

Faecal incontinence, also called anal or bowel incontinence, is the impaired ability to control passage of gas or stool. There are many possible causes of faecal incontinence, the most common is injury to the anal sphincter (ring-like muscle), for instance during childbirth or surgery, or damage to the nerves that control the anal sphincters. The condition usually becomes worse as people age.

INCONTINENCE TREATMENT

Electrical stimulation via the pelvic nerves is a recognized treatment alternative for urinary incontinence. It is also proposed as a treatment method for faecal incontinence due to pelvic floor dysfunction or a poorly functioning anal sphincter.

When treating stress incontinence, the aim of the electrical stimulation is to mirror a voluntary muscle contraction and improve the function of the pelvic floor muscles. For urge incontinence, the aim is to inhibit involuntary bladder contractions by stimulating the nerves in the pelvic floor. When treating mixed incontinence, a stimulation appropriate for both urge incontinence and stress incontinence is used. For faecal incontinence, the aim is to improve bowel control by strengthening and toning pelvic floor muscles.

3. PRECAUTIONARY MEASURES

- Inspect the equipment prior to use.
- Use the stimulator only as stated in the operating instructions.
- Use only CEFAR-approved vaginal and anal probes intended for electrical stimulation.
- The stimulator may only be operated after instructions from medically trained personnel.
- The treatment is a personal ordination. Do not lend probes or stimulator to anyone else
- Only Cefar accessories should be used with the stimulator.

WARNINGS

For internal use with a vaginal/anal probe

- People with implanted electronic equipment, such as pacemakers and intracardiac defibrillators, must not be treated with CEFAR PERISTIM PRO.
- Pregnant women must not be treated with the urology programs.
- People with extra-urethral incontinence (fistula, ectopic ureter) must not be treated with the urology programs.
- People with overflow incontinence due to outflow obstacle must not be treated with the urology programs.
- People with serious retention of urine in the upper urinary tract must not be treated with the urology programs.
- People with complete peripheral denervation of the pelvic floor must not be treated with the urology programs.
- Stimulation should not take place while the user is connected to high-frequency surgical equipment. It may cause burn injuries on the tissue, as well as problems with the stimulator.
- Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- Keep the stimulator out of reach of children.

For external use with surface electrodes

- People with implanted electronic equipment, such as pacemakers and intracardiac defibrillators, must not be treated with CEFAR PERISTIM PRO.
- Due to the location of the carotid arteries and the carotid bodies, do not stimulate the front or sides of the neck, since a drop in blood pressure can occur.
- Pregnant women should not be treated with CEFAR PERISTIM PRO during the first trimester (12 weeks).
- Stimulation should not take place while the user is connected to high-frequency surgical equipment. It may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- Keep the stimulator out of reach of children.

CAUTION

For internal use with a vaginal/anal probe

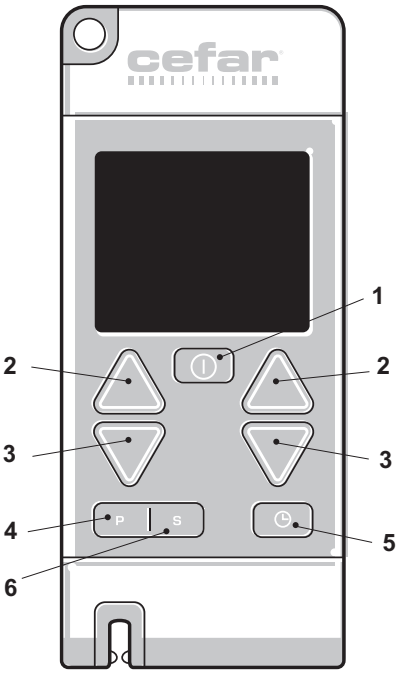
- Patients with total/subtotal prolapsed uterus/vagina should be stimulated with greatest caution.
- Patients with urinary tract infections must be treated and clear of infection before starting therapy with the urology programs. Consult your doctor.

- If tissue irritation should occur, treatment should be temporarily discontinued. If problems continue, contact your health care provider. Hypersensitivity can occur in isolated cases. The problem usually disappears when probes or gel are changed to another type.
- Observe caution when using electrotherapy at the same time as the patient is connected to monitoring equipment with body worn electrodes. The stimulation might interfere with the signals to the monitoring equipment.
- Never open the battery cover during stimulation in order to avoid electrical shock.
- Turn off the stimulation or make sure that the amplitude for each channel is 0,0 mA before touching or removing the probes. Getting electrical stimulation through the fingers is unpleasant but not harmful.
- Observe caution when stimulating in the immediate vicinity of cellular phones that are switched on, since this may affect the output power of the stimulator.

For external use with surface electrodes

- If pregnant, do not place electrodes directly over the uterus or connect pairs of electrodes across the abdomen. The reason is that, theoretically, the current could affect the foetus's heart (although there are no reports of it being harmful).
- The electrodes are only to be placed on healthy skin. Avoid skin irritation by ensuring that good contact is achieved between electrodes and skin.
- Do not use electrodes with a surface < 14 cm^2, as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities > 2 mA/cm^2.
- If skin irritation should occur, treatment should be temporarily discontinued. If problems continue, contact your health care provider. Hypersensitivity can occur in isolated cases. The problem usually disappears when electrodes or gel are changed to another type.
- Observe caution if you use the stimulator while driving, unintentional stimulation changes might extract focus from the driving and create a hazardous situation.
- Observe caution when using electrotherapy at the same time as the patient is connected to monitoring equipment with body worn electrodes. The stimulation might interfere with the signals to the monitoring equipment.
- Never open the battery cover during stimulation in order to avoid electrical shock.
- Turn off the stimulation or make sure that the amplitude for each channel is 0,0 mA before removing the electrodes. Getting electrical stimulation through the fingers is unpleasant but not harmful.
- Observe caution when stimulating in the immediate vicinity of cellular phones that are switched on, since this may affect the output power of the stimulator.

4. OVERVIEW/CONTROL BUTTONS



1. ON/OFF

- Turns the stimulator on and off.
- Turns the stimulator off even when the key lock is activated. Can be used for terminating the stimulation at all times.

2. INCREASE (left and right channel)

- Increases the amplitude (intensity of stimulation). Press and hold the button to increase the amplitude continuously.
  Note! Always increase the amplitude cautiously.
- Increases the number of minutes when setting the timer (right button).
- Used when turning the program lock on and off (left button)*.
- Scrolls through choices in programming mode (left button)*.

3. DECREASE (left and right channel)

- Decreases the amplitude (intensity of stimulation). Press and hold the button to decrease the amplitude continuously.
- Deactivates the key lock.
- Decreases the number of minutes when setting the timer (right button).
- Used when turning the program lock on and off (left button)*.
- Scrolls through choices in programming mode (left button)*.

4. PROGRAM

- Selects programs P1–P12.
- Pauses an ongoing program.
- Used when activating/deactivating the program lock*.

5. TIMER

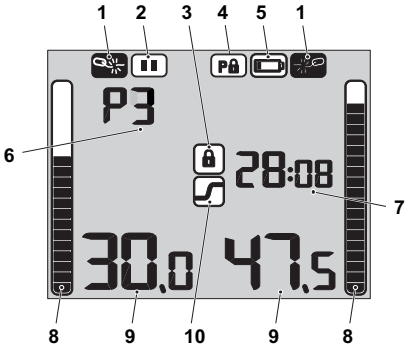
- Initiates the timer setting.

6. PROGRAMMING/CONFIRMATION*

- Turns the stimulator into programming mode for custom programs P10–P12 when pressed for 2 seconds.
- Confirms settings in programming mode.

*Professional use

4. OVERVIEW/DISPLAY SYMBOLS



1. BROKEN CIRCUIT

Broken circuit. The reason for a broken circuit may be too high resistance or cable breakage. See chapter 10.

2. PAUSE

Paused program.

3. KEY LOCK

Activated key lock. The key lock is automatically activated if no key is pressed for 10 seconds. Deactivate the key lock by pressing the left or right **DECREASE** button.

4. PROGRAM LOCK

Activated program lock.

5. BATTERY STATUS

Empty batteries. This symbol is shown when the batteries are almost empty.

6. PROGRAM NUMBER

Selected program number.

7. REMAINING TIME

Remaining program time in minutes and seconds. Time is flashing during timer setting.

8. AMPLITUDE BARGRAPH (left and right channel)

Selected amplitude as a bargraph.

9. AMPLITUDE LEVEL (left and right channel)

Selected amplitude in mA.

10.STIMULATION/REST

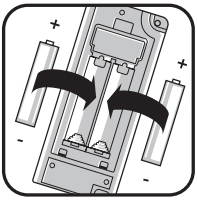
Stimulation/rest indication for programs with intermittent stimulation. The upper part of the symbol is flashing during stimulation and the bottom part during rest time.

5. OPERATION

Programs 1–7 in CEFAR PERISTIM PRO should be used with the vaginal and/or the anal probe and Programs 8–9 with surface electrodes. Program 10–12 can be configured in various ways to suit individual needs and should only be used as recommended by your health care provider.

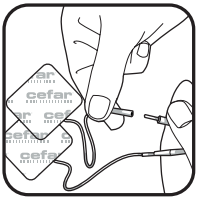
1. INSERT THE BATTERIES

Insert the batteries (see chapter REPLACEMENT OF BATTERIES).

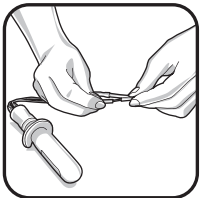


2. PLACE THE ELECTRODES/PROBES

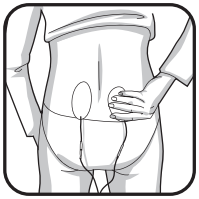
A 1. Connect the electrodes to the cable(s).



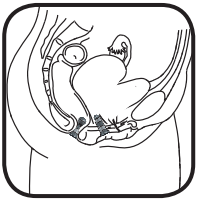
B 1. Connect the probe(s) to the cable(s).



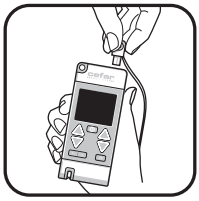
A 2. P8–P9: Attach the electrodes to your body



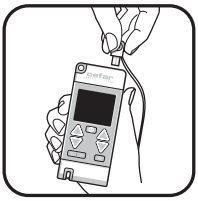
B 2. P1–P7: Insert the vaginal probe and/or the anal probe.



A 3. Connect the cable(s) to the CEFAR PERISTIM PRO.



B 3. Connect the cable(s) to the CEFAR PERISTIM PRO.



3. SWITCH THE STIMULATOR ON

Press the **ON/OFF** button ⏻ . This button can be used for terminating the stimulation at all times, even when the key lock is activated.

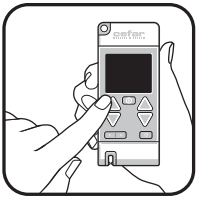
Always switch the stimulation off before removing electrodes from the skin.

4. SELECT A PROGRAM (P1–P12)

Select a program recommended by your health care provider by pressing the **PROGRAM** button P repeatedly until the program number is shown on the display.

Note! When selecting a program the amplitude must be set to 00.0 mA for both channels.

5. START THE STIMULATION



Press the **INCREASE** button △ for each channel until you reach a comfortable level of stimulation. Press and hold the button to increase the amplitude continuously.

Note! Always increase the amplitude cautiously!

Programs P1–P6: These programs have intermittent stimulation, i.e. stimulation alternates with rest time. The upper part of the stimulation/rest symbol is flashing during stimulation and the bottom part during rest time. Set the amplitude during stimulation.

The treatment time is preset, but can be changed by using the timer function, see section TIMER.

6. STOP THE STIMULATION

You can stop the stimulation before the program time has elapsed by pressing the **DECREASE** button ▽ until the amplitudes are 00.0 mA or press the **ON/OFF** button ⏻ .

An automatically activated key lock prevents unintentional changes during treatment. The key lock is activated if no button is pressed for 10 seconds. Press any of the **DECREASE** button ▽ to deactivate the key lock.

When the program is finished, Remaining time “00:00” is flashing on the display.

7. AFTER USE

Turn the stimulation off. Remove the probe(s)/electrodes. Clean the probe(s) according to the instructions included with your probes.

The last used program is saved when the stimulator is turned off and then pre-selected the next time the stimulator is turned on.

The stimulator turns off after five minutes of inactivity to spare batteries.

TIMER

The preset treatment time is set to 30 minutes, but the timer function allows you to set the treatment time yourself. You have the option to change the timing from "- -" to 60 minutes. If you choose to stay on "- -", the stimulation will go on until you stop the stimulation manually.

To set the timer:

1. Select a program and start the stimulation, see chapter OPERATION.
2. Press the **TIMER** button ◷ to initiate the timer function.
3. Increase the time by pressing the right **INCREASE** button △. The time is increased by 1 minute each time you press the button. Decrease the time by pressing the right **DECREASE** button ▽. The time is decreased by 1 minute each time you press the button. The time is flashing on the display, while setting the timer.
4. Press the **TIMER** button ◷ to confirm the timer setting.

PROGRAM PAUSE

You can pause the programs up to five minutes.

To pause a program:

1. If key lock is on, press any of the **DECREASE** buttons ▽ to deactivate it.
2. Press the **PROGRAM** button P to pause the program.

Start stimulation again by pressing the **PROGRAM** button P.

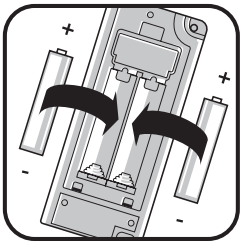
If stimulation is paused for more than five minutes, the stimulator turns off automatically to spare batteries.

6. REPLACEMENT OF BATTERIES

A battery symbol is shown on the display when the batteries are almost empty . As long as the stimulator is working normally you can continue the treatment. When stimulation feels weaker than usual or the stimulator turns off, it is time to replace the batteries.

If the stimulator is not used for some time (approximately 3 months), the batteries should be removed from the stimulator.

The stimulator operates on either two non-rechargeable 1.5 V AA batteries or two rechargeable 1.2 V AA batteries, recharged in a separate charger.



REPLACING THE BATTERIES

1. Turn off the stimulator.
2. Locate the battery compartment on the back of the stimulator.
3. Remove the battery cover by sliding it downwards about 1 cm and then lifting it upwards.
4. Remove the batteries.
5. Insert the new batteries correctly according to the polarity markings (+ and –) inside the battery compartment, see picture.
6. Replace the battery cover.
7. Dispose of the exhausted batteries in accordance with local and national regulations.

NOTE! Non-rechargeable batteries may not be charged due to the risk of explosion.

7. PROGRAMS

PRESET PROGRAMS

CEFAR PERISTIM PRO offers eight preset programs for stress, urge, mixed and faecal incontinence treatment and one preset program for relief of bladder-related pain.

Programs 1–7 should be used with a vaginal and/or anal probe and programs 8–9 with surface electrodes.

In programs 1–6 intermittent stimulation is used, which means that stimulation time alternates with rest time without stimulation: stimulation/rest/stimulation. The rest time allows the muscles to recover.

Programs 1–3

STRESS INCONTINENCE

Programnumber	Frequency	Pulse width	Stimulation time	Rest time	Recommended treatment time
P1	50 Hz	200 µs	3 s	6 s	30 minutes, 3–5 times a week
P2	50 Hz	200 µs	5 s	10 s	30 minutes, 3–5 times a week
P3	50 Hz	200 µs	10 s	20 s	30 minutes, 3–5 times a week

One cause of stress incontinence can be poorly functioning perineal muscles. Electrical stimulation of the perineal muscles with a vaginal and/or anal probe makes the muscles contract. The contractions help to identify and strengthen the weakened muscles. The stimulation must be as strong as possible without being painful, and it is helpful if the patient participates actively in the muscle contractions. The intensity should be sufficient enough to create a reflexive contraction of the anus. It is suggested that this training will be combined with the patient's own exercises for pelvic floor muscles.

Programs 4–6

MIXED INCONTINENCE

Programnumber	Frequency	Pulse width	Stimulation time	Rest time	Recommended treatment time
P4	20 Hz	200 µs	3 s	6 s	30 minutes, 3–5 times a week
P5	20 Hz	200 µs	5 s	10 s	30 minutes, 3–5 times a week
P6	20 Hz	200 µs	10 s	20 s	30 minutes, 3–5 times a week

Program 4-6 is be used with a vaginal and/or anal probe for treating mixed incontinence. The stimulation should be as strong as possible without being painful. It is helpful if the patient participates actively in the muscle contractions.

Program 7

URGE INCONTINENCE

Programnumber	Frequency	Pulse width	Stimulation time	Rest time	Recommended treatment time
P7	10 Hz	180 µs	Continuous	–	30 minutes, 2–5 times a week

Normally the bladder muscle is relaxed between evacuations. In certain kinds of urge incontinence, however, the bladder is unstable and sudden uncontrolled bladder contractions occur during the "resting phase". Urge incontinence can be treated with low-frequency constant stimulation, which has a relaxing effect on the overactive bladder. Program 8 is intended for urge incontinence treatment and should be used with a vaginal and/or anal probe. The stimulation should be as strong as possible without being painful.

Program 1–6

FAECAL INCONTINENCE

Programnumber	Frequency	Pulse width	Stimulation time	Rest time	Recommended treatment time
P1	50 Hz	200 µs	3 s	6 s	30 minutes, 3–5 times a week
P2	50 Hz	200 µs	5 s	10 s	30 minutes, 3–5 times a week
P3	50 Hz	200 µs	10 s	20 s	30 minutes, 3–5 times a week
P4	20 Hz	200 µs	3 s	6 s	30 minutes, 3–5 times a week
P5	20 Hz	200 µs	5 s	10 s	30 minutes, 3–5 times a week
P6	20 Hz	200 µs	10 s	20 s	30 minutes, 3–5 times a week

Faecal incontinence can be a result of e.g. weakened pelvic floor muscles, weakened or poorly functioning anal sphincter muscles or damage to the nerves controlling the anal sphincter muscles. In these cases electrical stimulation can be used with an anal probe to increase the tonus of the pelvic floor and the anal sphincter. The stimulation should be as strong as possible without being painful. The intensity should be sufficient enough to create a reflexive contraction of the anus. It is helpful if the patient participates actively in the muscle contractions.

Program 8

TENS (HIGH FREQUENCY) – PAIN RELIEF

Programnumber	Frequency	Pulse width	Stimulation time	Rest time	Recommended treatment time
P8	80 Hz	180 µs	Continuous	–	At least 30 minutes daily

High-frequency TENS stimulation is an effective treatment for relief of both acute and chronic pain. External stimulation with surface electrodes can be used for diagnosed pain conditions in the lower part of the abdomen, as in cystitis.

The electrodes should be placed in the painful area over the pubic region, see electrode placement picture.

Program 9

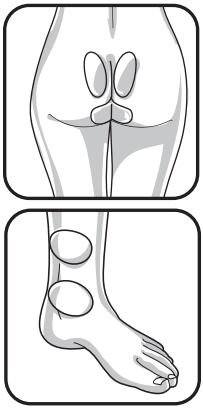
TENS (BURST) – URINARY INCONTINENCE

Programnumber	Frequency	Pulse width	Stimulation time	Rest time	Recommended treatment time
P9 Sacral nerves stimulation	2 Hz	180 µs	Continuous	–	At least 30 minutes daily
P9 Acupuncture pointsstimulation	2 Hz	180 µs	Continuous	–	30 minutes per session during at least one month. Start with 2–3 times a week and then reduce the treatment frequency.

Electrical stimulation for urinary incontinence is usually applied by a probe inserted in the vagina and/or anus. An alternative method is to use TENS to stimulate areas of the skin that are innervated by the same spinal cord segment (S2–S3) as the bladder and urethra. The stimulation is applied through surface electrodes placed on the skin between the anus and the genitals, alternatively in the lumbar region. In treatment of incontinence where the sacral nerves are stimulated, the electrodes should be placed in the region of S2–S3, see electrode placement picture. The stimulation should be strong enough to create a reflexive contraction of the anus.

Electrical stimulation of the posterior tibial nerve, via acupuncture points, has also proven to have a positive effect.

In treatment of incontinence where stimulation is applied over acupuncture points, the electrodes should be placed over SP6 and behind/beneath the medial malleolus, see electrode placement picture



CUSTOM PROGRAMS (P10–P12)

With the CEFAR PERISTIM PRO it is possible to create and store three custom programs for individual needs. To create a custom program, follow the programming procedure below. To use a custom program, follow the instructions in the chapter OPERATION. The program time is preset to 30 minutes but can be changed with the timer function, see section TIMER.

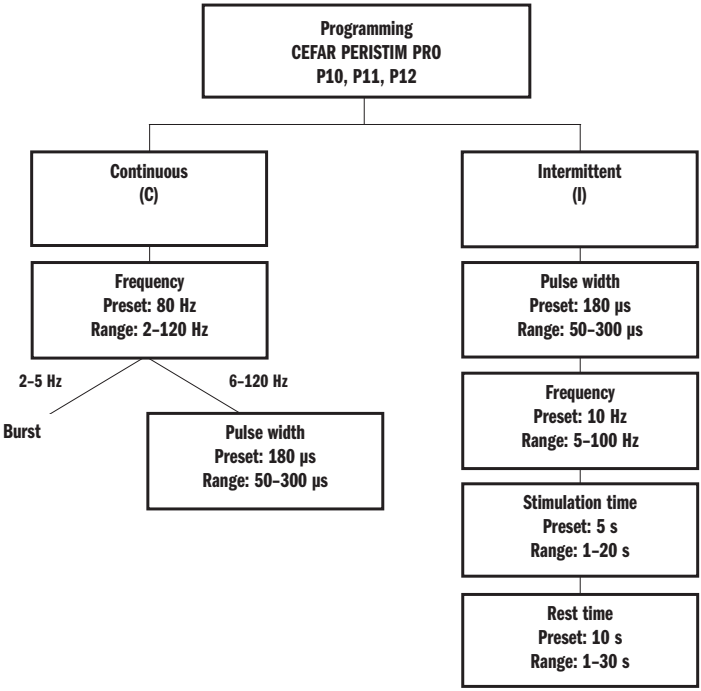
Programming

1. Press the **PROGRAM** button [P] repeatedly until Program 10, 11 or 12 is shown on the display. Select one of these programs.
2. Press the **PROGRAMMING/CONFIRMATION** button [S] for 2 seconds to enter the programming mode.
3. Press the **INCREASE (OR DECREASE)** button ▽ △ to see the two different stimulation types alternate on the display: C, I. The programming chart below shows the setting possibilities for each stimulation type.
4. Press the **PROGRAMMING/CONFIRMATION** button [S] to confirm your choice of stimulation type. You are now moved to the next stage in the programming procedure (see the programming chart).

5. A preset value is shown on the screen, but you can change it by pressing the **INCREASE (OR DECREASE)** button ▽ △ . The valid range for this value is shown in the programming chart.
6. Press the **PROGRAMMING/CONFIRMATION** button [S] to confirm your setting. You are now moved to the next stage (if any) in the programming procedure (see the programming chart).
7. Repeat step 5 and 6 until the value in the last stage is set.
8. The programming procedure is finished and you will automatically exit the programming mode. The new program is now selected and ready for use. The program is saved for future use.

A custom program can be changed by redoing the programming.

PROGRAMMING CHART



PROGRAM LOCK

The stimulator can be locked to prevent changing of programs.

To activate/deactivate the program lock:

1. Select the program you want to lock/unlock, see chapter OPERATION.
2. Press the **PROGRAM** button [P] and the left **DECREASE** button simultaneously for 2 seconds.
3. Press the left **INCREASE** or **DECREASE** button . “ON” is shown on the left side of the display when activating the program lock and “OFF” when deactivating it. (The button toggles between ON and OFF).
4. Press the **PROGRAM** button [P] to finish the program lock setting.

COMPLIANCE

Compliance gives you the possibility to monitor the use of the stimulator:

1. Turn the stimulator ON.
2. Press the **TIMER** button [◷] and the right **DECREASE** button simultaneously for 2 seconds.
3. The left side of the display shows the usage time in hours and the right side in minutes. To reset the usage time, press the right **DECREASE** button for 2 seconds.
4. Wait for 5 seconds or press **TIMER** button [◷].
5. The left side of the display shows the total usage time in hours and the right side in weeks. The total usage time cannot be reset.
6. Wait for 5 seconds or press the **TIMER** button [◷] to exit compliance mode.

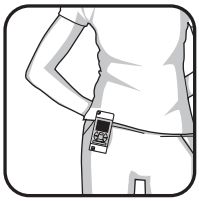
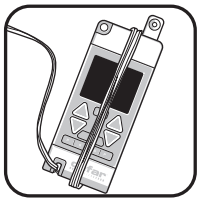
8. ACCESSORIES

You can use the CEFAR PERISTIM PRO together with vaginal and/or anal probe. The probes can be either autoclavable or non-autoclavable. Always read and follow the care and maintenance instructions delivered with the probes.

If you use the CEFAR PERISTIM PRO with surface electrodes the electrodes will eventually wear out and need to be replaced. It is recommended to replace the electrodes after approximately 20–40 times of usage.

CEFAR PERISTIM PRO comes with a neck strap and a belt clip, allowing you to wear the stimulator around your neck or on your belt and have your hands free during treatment.

For purchase information, contact your Cefar dealer or visit www.cefar.se

9. CARE INSTRUCTIONS

Taking care of and cleaning the Cefar equipment is simple with the following instructions:

- For care and cleaning instructions of probes, see probe package.
- Self-adhesive multi-use electrodes are re-moistened if necessary with a few drops of water and kept air-tight (in a plastic bag) on protective paper when they are not in use.
- Rinse the carbon rubber electrodes and the skin with water after use. Do not use detergent for the electrodes.
- Never expose the stimulator to water. Wipe it off with a damp cloth if necessary.
- Do not jerk cables or connections.
- The cables are best preserved if left attached to the stimulator between sessions.

10. TROUBLESHOOTING

THE STIMULATION DOES NOT FEEL THE SAME AS USUAL

- Check that all settings are correct (chapter OPERATION) and make sure that the electrodes are correctly placed.
- **Electrodes:** Slightly change the position of the electrodes.

THE STIMULATION FEELS UNPLEASANT

- Check that the probe/electrode cable is properly connected to the stimulator.
- **Probes:** Make sure that the probe is correctly placed with good contact. In case of irritation/inflammation in the vagina or anus, please contact your health care provider.
- **Electrodes:** The skin is irritated. For advice on skin care, see chapter PRECAUTIONARY MEASURE.
- **Electrodes:** The electrodes begin to lose their stickiness and do not stick properly to the skin. Moisten the adhesive surface with a few drops of water before placing on the skin.
- **Electrodes:** The electrodes are worn out and need to be replaced.
- **Electrodes:** Slightly change the position of the electrodes.

THE STIMULATION FEELS WEAK OR NOT AT ALL

- Check if the batteries need to be replaced, see chapter REPLACEMENT OF BATTERIES.
- **Electrodes:** Electrodes are too old and need replacement.

THE BROKEN CIRCUIT SYMBOL IS SHOWN ON THE DISPLAY SYMBOL

The broken circuit symbol indicates that the resistance is too high, or that a cable is broken. 

- A too high resistance can be caused by a bad connection between the electrodes/probes and your skin/tissue, or that the electrodes need to be replaced.
- A cable breakage can be checked by pressing the cable´s pins against one another while increasing the amplitude for the corresponding channel to 11 mA. If the amplitude now drops to 00.0 mA and  starts flashing, the cable needs to be replaced.

Note! Never increase the amplitude above 20 mA when you check for cable breaks, since this can damage the stimulator.

THE STIMULATOR IS NOT WORKING

If the error symbol appears on the display when you start the stimulator, it means that the stimulator is broken and needs to be repaired.

Note! Do not use the stimulator – contact your Cefar dealer.

Cefar will only be responsible for service and repairs performed by Cefar or a distributor appointed by Cefar.

11. TECHNICAL DATA

CEFAR PERISTIM PRO is a stimulator with two non-independent channels intended for treatment of incontinence and bladder-related pain. It has nine preset programs and three custom programs.

Treatment with electrical stimulation requires the stimulation current to penetrate the resistance of the skin and the electrode, about 1000 ohms. CEFAR PERISTIM PRO can penetrate this resistance and maintain a current of up to 99.5 mA. With a change in load from 100 to 1000 ohms, the stimulation current changes less than 10% from the set value.

The stimulator operates on either two non-rechargeable 1.5 V AA batteries or two rechargeable 1.2 V AA batteries, recharged in a separate charger.

CEFAR PERISTIM PRO

Number of channels	2 (non-independent)
Constant current	Up to a resistance of 1000 ohm
Stimulation current/channel	0–99,5 mA
Waveform	Symmetrical biphasic pulse, 100% compensated
Number of preset programs	9
Number of custom programs	3
Stimulation forms	Continuous stimulation Intermittent stimulation
Max pulse duration	300 µs
Max frequency	120 Hz
Timer	1 to 60 min/Off
Environment for storage, use and shipping	Temperature 10° C–40° C Air humidity 30%–75% Air pressure 700 hPa–1060 hPa
Power source	2 x 1.5 V AA non-rechargeable or 2 x 1.2 V AA rechargeable batteries
Current consumption for one channel, 80 Hz, 30 mA	150 mA
I r.m.s. max/channel	27 mA
Size	120 x 50 x 30 mm
Weight	ca. 180 g

KEY TO THE SYMBOLS

Read the operating instructions before to use.

Patient part type – Body Floating.

Dispose of the worn-out stimulator in accordance with local and national regulations.

One ore more of the following markings may appear on your device:

CE
0413

Complies with the European Medical Device Directive (93/42/EEC).
Notified body Intertek ETL Semko (0413).

Complies with UL 69050-1, SCA C22.2 No. 69050-1.
Certification mark issued by SGS.

INFORMATION RELATED TO ELECTROMAGNETIC COMPATIBILITY (EMC).

CEFAR PERISTIM PRO is designed to be used in typical domestic or clinical environments and approved according to the EMC safety standard of EN 60601-1-2.

CEFAR PERISTIM PRO emits very low levels in the radio frequency (RF) interval. Therefore it is not likely to cause any interference in nearby electronic equipment (radios, computers, telephones etc.).

CEFAR PERISTIM PRO is designed to withstand foreseeable disturbances originating from electrostatic discharges, mains supply magnetic fields and radio frequency transmitters (such as mobile telephones).

12. REFERENCES

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Maximal electrical stimulation of patients with frequency, urgency and urge incontinence. Report of 38 cases. *Acta Obstet Gynecol Scand 1992;71:629-631*

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Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: A multicenter, placebo-controlled trial. *Am J Obstet Gynecol Vol 173, No 1, 1995*