



PierenFemme

ELECTROSTIMULATOR FOR THE TREATMENT OF INCONTINENCE

# ABBREVIATED INSTRUCTIONS

- » Connect the electrodes to the cable.
- » Take up a comfortable position.
- » Insert the probe or affix the electrodes.

1

- » Connect the cable to the device.

2

- » Switch on the device.

3



» Select the desired program.

# 4

» Set the required intensity.

# 5

- » Switch off the device when the therapy has been completed.
- » Remove the probe or detach the electrodes.
- » Clean the probe or re-affix the electrodes to the foil.

# 6





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## Introduction

### *Incontinence – what is it?*

Incontinence is regarded as the involuntary release of urine, faeces or both: Millions of people suffer from this condition.

### *The most common types and causes of incontinence*

Where stress or strain type incontinence is involved there occurs firstly the release of urine in the form of droplets or jets and this occurs later also when the body is at rest. For the most part it is women who are affected.

Stress type incontinence is divided into three categories according to the degree of severity:

- I: Involuntary urine release arising from sudden body strain resulting from, for example, coughing, laughing, sneezing.
- II: Involuntary urine release arising from mild body strain resulting from, for example, walking, climbing stairs or lifting objects.

III: Involuntary urine release when standing, without changes of pressure in the abdominal cavity and finally also when reclining.

The cause of stress incontinence is a dysfunction of the closure system, mostly as a result of untrained or over-stretched muscles of the pelvic floor, for example, following a difficult childbirth. An age related hormone deficiency is also frequently a contributory factor for women.

With urge type incontinence there arises a strong urge to urinate often even where small amounts of urine are involved and which can lead to premature urination. The cause of urge type incontinence is an over-active urinary bladder triggered by the nervous system. Mixed stress and urge incontinence types are common.

Lastly, there is what is known as the reflex incontinence whereby uncontrolled urination is involved. It occurs, inter alia, as a result of spinal cord injuries.

### *The most common types and causes of faecal incontinence*

Faecal incontinence can also be divided into three categories according to the degree of severity:

Grade 1: Uncontrolled release of wind,

Grade 2: Uncontrolled release of wind and thin, liquid faeces,

Grade 3: Uncontrolled release of solid faeces.

Faecal incontinence can be caused by an impairment of the muscular closure system. It occurs after childbirth, with laceration of the perineum or other injuries resulting from, for example, operations on the pelvic floor/sphincter. Muscular degeneration is also age related.

A reduction in rectum sensitivity with a lack of signals regarding the level of faecal fullness and solidity can lead to incontinence. The cause is injuries to the nerves, inter alia arising from operations for haemorrhoidal disorders.

### *Treatment of incontinence*

The type of treatment for incontinence is contingent on the causes and includes medicament, physiotherapy such as pelvic floor exercises, electrical current stimulation treatment and surgery. In any event it is necessary, before starting treatment, to be examined by a doctor for diagnosis purposes.

### *Treatment by means of electrical current stimulation*

Electrical current stimulation therapy is appropriate in the area of urinary incontinence primarily as a treatment for stress and strain related incontinence and/or their mixed forms. In the area of rectal incontinence it is particularly suitable for the muscular related forms. In this type of therapy the nerves and muscles in the area of the pelvic floor are stimulated by means of a weak electrical current. The current is applied via electrodes placed on the skin or via sensors located in the vagina/rectum.

The treatment can be carried out in conjunction with other therapies such as perineal gymnastics and medication or as a separate, sole application.

## Purpose of use

The PierenFemme is a medical product. It serves for the transcutaneous and transmucosal electric stimulation of feminine muscles and nerves in order to reduce discomfort and pain associated with incontinence. Please do not use it for any other purpose.

**Caution:** Incontinence or pain can be caused by serious disorders in the body and must therefore be investigated by your doctor. Even when the use of the PierenFemme has had good results it does not mean that the underlying cause of the illness has been eliminated. In particular, please take note of the vaginal and anal probe contra-indications.

## Instructions regarding safe use of the device

***For your own safety it is important that you read carefully and observe the following instructions:***

- » The PierenFemme may only be used with original accessories.
- » Keep the device well away from water and other fluids. For easier insertion, the vaginal or anal probes can be lightly moistened with water.
- » Never use the PierenFemme if it is not functioning correctly or is damaged.
- » To avoid possible interactions, the PierenFemme should not be used adjacent to or on other electronic devices. If this is not possible, the functioning of such devices must be monitored during operation to ensure that they continue to function correctly.
- » Avoid placing electrodes in such a position that the current flow traverses the coronary region.
- » The device may only be connected to one patient at any one time.
- » The device may not be used when machines are being operated or during other activities which require

heightened attention levels. This particularly applies to the activity of driving.

- » Do not drop the PierenFemme, do not use improperly, do not expose to extreme temperatures or high levels of humidity (use only in a temperature range of 10°C-40°C and a relative air humidity below 90 %).
- » Special care is necessary when the PierenFemme is being used in the vicinity of children.
- » After use please store the PierenFemme in its original packaging to protect against damage and contamination.

### *Warnings*

- » Electronic devices which generate high frequency current (for example mobile phones, microwave ovens, high frequency surgical instruments) can affect the function and current output of the PierenFemme. Please avoid simultaneous use of such devices.
- » The electrodes should not be smaller than 2 cm<sup>2</sup>.

### *When should the PierenFemme not be used or used only after consultation with the doctor (contra-indications)?*

- » In general, treatment with the PierenFemme is a very agreeable procedure but in the event of the following contra-indications the device should not be used, or only after consultation with your doctor:
  - » Patients with implanted electronic devices such as heart pacemakers.
  - » During pregnancy.
  - » Patients suffering from cardiac rhythm disorders.
  - » Patients subject to seizures (epilepsy).
  - » Patients with malignant illnesses in the area of application.
  - » Patients with skin/mucous illnesses in the area of electrode affixation.
  - » Patients with metallic implants in the area of the flow of electrical current.
  - » Patients with metallic intra-uterine contraceptive devices (spiral).
  - » Patients with hyper-sensitivity in the treatment area.
  - » Patients with serious, local inflammations.

- » Children under the age of 5 or patients suffering from dementia.
- » With anal probes, patients with serious haemorrhoidal disorders.
- » Electrodes must not be affixed to wounds and diseased skin areas.
- » The physician should be consulted in cases of reddening, burning, itching or blistering under the electrodes or in the vicinity of the electrodes. Slight skin reddening of short duration in the area of the electrodes following stimulation is quite normal because blood circulation has been improved by the effects of the stimulation.
- » Muscular pain or aching can occur as a result of too intensive a muscular stimulation. To avoid this, and, in particular with regard to the initial treatment session, it is recommended to begin with short and not too intensive stimulation.

*What side effects can occur when the device is used correctly?*

Treatment using the PierenFemme is easy and uncomplicated. The device delivers agreeable and effective therapy.

The following side effects can occur:

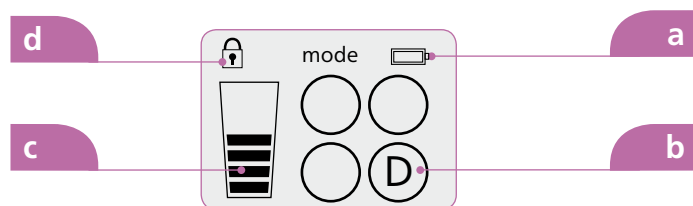
- » Pain: Can arise if the application is too intensive or existing pain can be exacerbated. In order, as far as possible to avoid pain, it is desirable to operate with weak electrical current over a short period during the first therapy session.
- » Skin or mucous incompatibility can occur as a reaction to the electrodes, the electrode gel or the electrical impulses.

## Operating elements

All settings can be made with the keys. The various operating modes are shown on the display.

1. Display
2. ON/OFF key
3. Mode/program switch
4. Intensity +
5. Intensity -
6. Output socket

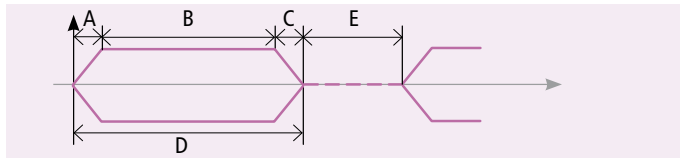
- a. Battery charge level
- b. Display of the selected program A – D
- c. Electric current intensity
- d. Interlocking active



## Description of the programs

### Program A: Urge type incontinence

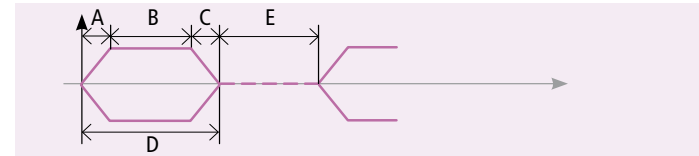
Parameter:	Impulse width	250 $\mu$ s
D	Frequency	12,5 Hz
A	Muscle tensioning time	1 s
B	Application time	5 s
C	Muscle relaxation time	1 s
E	Muscle at rest	3 s
	Therapy time	20 min



### Program B: Stress type incontinence

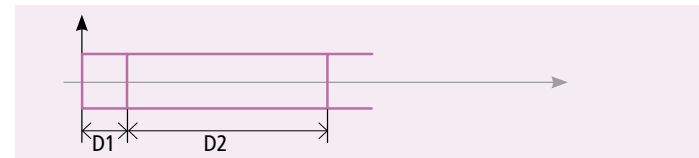
Parameter:	Impulse width	250 $\mu$ s
D	Frequency	50 Hz
A	Muscle tensioning time	1 s
B	Application time	3 s
C	Muscle relaxation time	1 s

E	Muscle at rest	5 s
	Therapy time	20 min



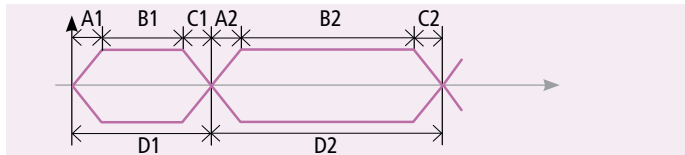
### Program C: Mixture 1 type incontinence


Parameter:	Impulse width	250 $\mu$ s
D1	Frequency	50 Hz
D2	Frequency	10 Hz
D1	Application time	0,5 s
D2	Application time	2 s
	Therapy time	$\infty$

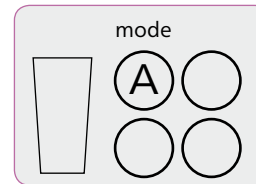


**Program D: Mixture 2 type incontinence 2**

Parameter:	Impulse width	250 $\mu$ s
	D1 Frequency	27 Hz
	A1 Muscle tensioning time	1 s
	B1 Application time	3 s
	C1 Muscle relaxation time	1 s
	D2 Frequency	10 Hz
	A2 Muscle tensioning time	1 s
	B2 Application time	8 s
	C2 Muscle relaxation time	1 s
	Therapy time	20 min

**Operating the PierenFemme****Starting**

The device is switched on with the key . The PierenFemme starts with the program which was last used. If interlocking is active (please see the section on “Interlocking the device”), there appears the key symbol on the upper right-hand side of the display.

**Using vaginal and anal probes**

The probes are first positioned in the rectum/ vagina. Then connect the cable double plug with the PierenFemme. Only now switch on the device.

### *Using self-adhesive electrodes*

Firstly connect the self-adhesive electrodes to the individual connections on the cable and then the cable with the double plug to the PierenFemme. Affix the electrodes to the application area and switch on the device.

### *Connecting vaginal and anal probes and electrodes to the device*



*Connecting the device with the anal probe*



*Connecting the device with the vaginal probe*



*Connecting electrodes to the device*

## How do I effect stimulation?

### Program selection

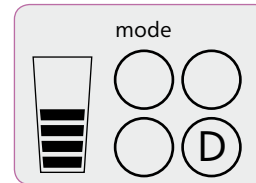
Changing to the next program is effected by means of the key **M**. However, this is only possible providing the device in the unlocked condition. Initially a standard program identified by A to D will run. The switching sequence is A → B → C → D → A. Confirmation with key **M** during the therapy in operation will terminate the treatment.

### Starting the stimulation

Once the desired program has been selected with the key **M** or a locked device has been started directly with the desired program, stimulation can be started with the key **+**.

### Setting the intensity

The channel intensity can be set at all times to an agreeable level using the modification keys **+** **−**. The intensity of the output voltage can be varied in 14 steps. If the electrodes are not properly connected to the device or not positioned correctly on the skin, the intensity is reduced to zero in three output voltage steps.



**Please note:** The PierenFemme is equipped with an additional safety component.


### Stopping the stimulation

Stimulation can be discontinued at any time with the key **M** or the key **⊙**. After expiry of the total program running time, the stimulation stops automatically.


### Interlocking the device

Select the required program with the key **M** (please see the section „Description of the Programs“). If the key **−** is now depressed and held down, the device will be locked and in the upper left-hand corner of the displays there appears the symbol **🔒**. All device functions are now unavailable with the exception of the stimulation in respect of the selected program. The same key combination is used to unlock the device.

### *Switching off the device*

The device is switched off with the key . If the voltage in the battery has fallen below a critical value or if apart from the stimulation no key has been depressed for a period of two minutes, the device switches off automatically and this is confirmed by the sounding of an acoustic signal.

### *Inserting/Changing the batteries*

If the voltage in the batteries falls below a critical value (less than 2.2 V) and a battery symbol appears in the upper right-hand corner of the display , the PierenFemme switches off automatically and/or the device cannot be switched on again. In this case it is necessary to insert a new battery into the device.

Please ensure that the PierenFemme is switched off when changing batteries.



1. Open the battery compartment cover (on the rear side, down) by sliding in the direction of the arrow.
2. Remove the used batteries from the compartment.
3. Insert two new batteries into the battery compartment and ensure the polarity is correct.
4. Close the battery compartment.

**Please note:** Please do not throw used batteries into the household waste system. Batteries must be disposed of in accordance with the regulations which means they must be brought to the communal battery disposal facility.

## Therapy instructions for the patient

- 1 Take up a comfortable position
- 2 Affix the electrodes or insert the probe
- 3 Connect the cable to the device
- 4 Switch on the device and select the desired program
- 5 Set the required intensity
- 6 Switch off the device when the therapy has been completed
- 7 Detach the electrodes or remove the probe
- 8 Re-affix the electrodes to the foil or clean the probe

## Probe placement

**Tip:** This type of training functions well when stimulation by means of skin electrodes is hindered by overweight.

For the treatment of stress incontinence women can select either the vaginal or the anal probes.

For the treatment of other types of urinary incontinence the vaginal probe is preferable.

Faecal incontinence is treated with the anal probe.



*Placement of the vaginal probe*



*Placement of the anal probe*

## Electrode placement

Various, comparable electrode placement options are available for the treatment of incontinence.

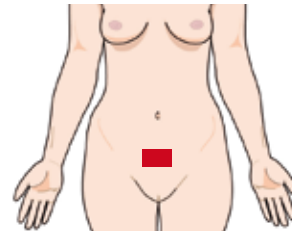
### Placement with self-adhesive electrodes

Here is differentiated between positive electrodes (anode) and negative electrodes (cathode).

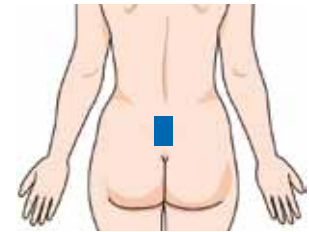
Please note: Electrodes in various sizes are available.

### 1. Placement above the pubic bone and the anal cleft

Select the placement so that a perceptible twitching in the muscle is effected.



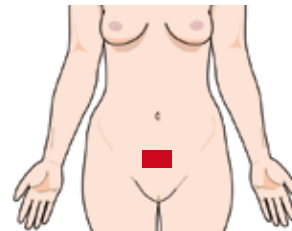
Anode (red)



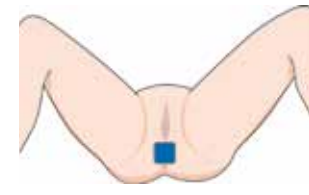
Cathode (blue)

### 2. Perineal placement

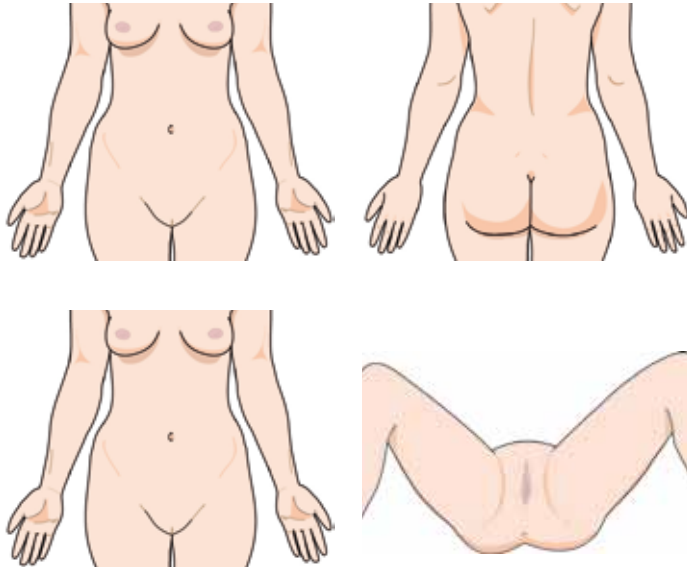
Place the anode (red) above the pubic bone and the cathode (blue) on the perineum as illustrated below.



Anode (red)



Cathode (blue)

**Body schematic****General information****Symbols**

Attention: Read accompanying documents, especially user manual!



Type BF applied part



Date of manufacture



Catalogue number



Serial number



Environment

Do not dispose of the appliance with the normal household waste at the end of its life, but hand it in at an official collection point for recycling. By doing this you will help to protect the environment.

**CE0197** By labelling with CE mark, the manufacturer asserts that the product fulfills all relevant requirements of the respective EC Directives. A conformation

assessment process has been successfully completed. The identification number in respect of the conformation assessment process is given in accordance with the CE labelling of the relevant notified body.

## Technical Data

Single channel nerve stimulator with outputs, constant voltage characteristics, output short circuit switching (AKS) and 4 integrated programs.

### Technical data

Output voltage 0-60 Vpp (on 500  $\Omega$  real)

Frequency range 10-50 Hz

Impulse width 250  $\mu$ s

Voltage supply 2 x 1.5 V AAA batteries

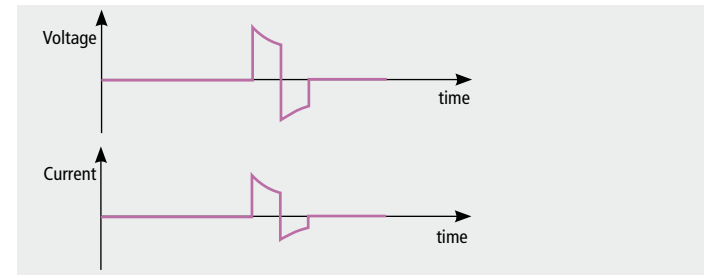
Modulation type Amplitude modulation with „impulse envelope curve“

Dimensions 120 x 34 x 20 mm

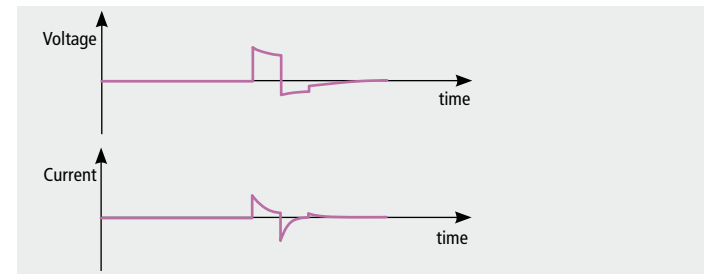
Weight Approx. 40g

### Impulse form

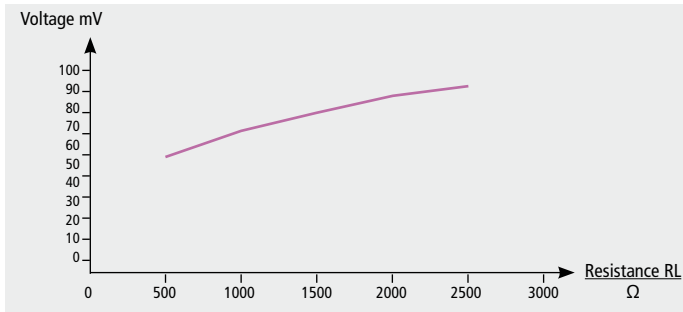
Biphasic symmetric rectangle, direct current neutral, 250  $\mu$ s, adjustable in 14 steps of intensity.



*On a load of 500  $\Omega$  real*



*On load ANSI/AAMI Standard*



*Output voltage change contingent on the load resistance*

### ***New settings, modifications and repairs***

The manufacturer can only be held responsible for safety and performance of the device providing new settings, modifications or repairs have been carried out by persons who have been authorised by the manufacturer to engage in such activities and also that the device has been used in accordance with the instructions contained in the instruction manual.

### ***Switching circuits, spare part lists and setting instructions***

On request we would be pleased to make available to your suitably qualified personnel our switching circuits, spare parts lists and setting instructions.

### **Warranty**

Legal right of warranty is applied according to German Civil Code.

### **Guarantee**

The manufacturer issues a guarantee of 12 months from the date of purchase.

The guarantee does not apply in the following cases:

- » damage due to improper handling
- » defects the customer is aware of on the date of purchase
- » damage caused by the customer
- » for wearing parts and consumable supplies like, for instance, electrodes, batteries and cables.

## Care and cleaning

No particular care and cleaning is necessary for the PierenFemme. The device and cables can be cleaned with a soft, fluff-free cloth. It is important that no moisture penetrates the interior of the device. If, nevertheless, moisture is present, the device must be subjected to a technical check.

## Classification

The above named product has been classified as Class IIa in accordance with Appendix IX of the Directives 93/42/EEC for medical products.

## Technical safety checks

We recommend a technical safety check on the PierenFemme every 24 months.

The technical safety check comprises:

1. Checking that the accompanying documentation is at hand and contains the operating instructions together with the medical product book.
2. Checking the equipment for completeness.
3. Sight check
  - For mechanical damage on the device and accessories,
  - Completeness of stickers on the device,
  - If the keys are working properly.
4. Functional safety
  - Checking that the control dial cannot be over-wound,
  - Checking the output signals at a load resistance of 500 W (voltage),
  - Checking the frequencies,
  - Checking the modulation depth.

Safety evaluation must be carried out by qualified persons who possess the necessary medical/technical knowledge of the device. The name of the person who has carried out the check and the relevant date must be entered in the medical book.

## Combination

The PierenFemme may only be combined with all the accessories listed in the operating instructions.

## Delivery content

Article	Quantity	Item no.
PierenFemme	1	462126
Cable type 5.15	1	106351
Vaginalprobe V2B	1	103025
AAA batteries	2	450780-11
Operating Instructions	1	451600-0336
Brochure Incontinence	1	451730-0051

## Optional accessories

### *Vaginal and anal probes*

#### Technical data

Composition	Probes: ABS (except anal probe TL1R)
Electrodes	Inox 316L
Delivery content	All probes incl. 120 cm cable and double plug
Manufacturer	Pierenkemper GmbH

### Application

Vaginal and anal probes for the treatment of incontinence. The probes are designed for personal use by only one person. They are to be used exclusively with a device which has been designed to provide vaginal and anal stimulation. This includes, for example, the Pierenkemper device PierenFemme. Since 1991 several thousand ABS probes have been distributed worldwide. In line with normal therapeutic use no allergies or comparable reactions have been observed.

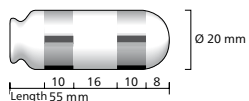
### Care

After use, please clean the probes with water or alcohol (for example with a concentration of 70%) or use a disinfection solution based on Glutaraldehyde.

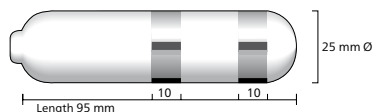
For reasons of hygiene, anal and vaginal probes have been designed for use by one person only, that is the owner. We cannot therefore accept claims or complaints resulting from use by any other persons.

Article	Quantity	Item no.
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Vaginal probe VATT	1	101464
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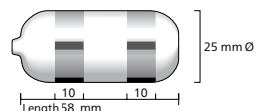


Vaginal probe V21B	1	101466
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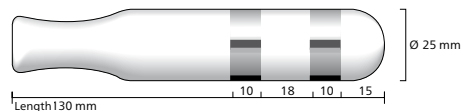
Article	Quantity	Item no.
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Vaginal probe TAM	1	101465
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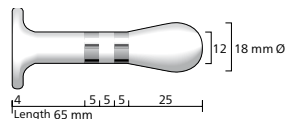


Vaginal probe V2B	1	103025
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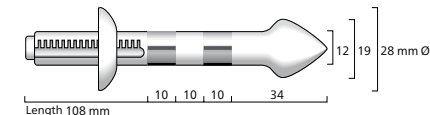
(contained in the delivery consignment)



Anal probe TL1R	1	101462
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Anal probe 12C	1	101463
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### Self-adhesive electrodes

#### Technical data

Composition	Electrically conductive and adhesive mass
Serice life	80 - 100 applications
Colour	grey/black
Manufacturer	Pierenkemper GmbH

#### Application

Skin electrodes for the treatment of incontinence and pain. The electrodes are affixed directly to the skin in the treatment area. But do not affix to diseased skin or wounds. The electrodes are self-adhesive electrodes which are designed for multi-use.

**Tip:** Clean the area of skin to which the electrodes should be affixed of sweat, moisture or dirt and do not apply ointments or creams to this area prior to treatment.


**Important:** Do not affix electrodes to parts of the skin which are irritable or diseased.

**Important:** If you want to change the placement of an electrode please first switch off the device for a short time.

Possible residues from the self-adhesive electrodes on the skin can easily be removed using soap and water.

#### Care

For reasons of hygiene the electrodes should only be used by one patient. After each use please re-affix the electrodes in the foil and replace in the bag. The electrodes will last longer if they are stored in a cool location (for example a refrigerator). When used correctly they should be usable many times. Adhesiveness can be restored by moistening the surfaces with water.

Article	Quantity	Item no.
Stimex, round 32 mm Ø	4 pieces	281004
		
Stimex, round 50 mm Ø	4 pieces	281005



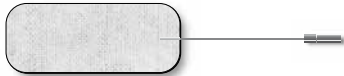
Stimex, 50 X 50 mm                      4 pieces                      281006



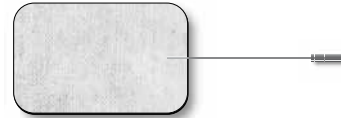
Stimex, 50 X 90 mm                      2 pieces                      281007



Stimex, 50 X 130 mm                      2 pieces                      281008



Article	Quantity	Item no.
Stimex, 80 X 130 mm	2 pieces	281009



**Cable**

Article	Quantity	Item no.
Electrode cable type 5.15, 2 mm plug	1 piece	106351





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