

Using Your SensaTONE For PFS



Before first use of the SensaTONE, please familiarise yourself with the 'Precautions and Contraindications' contained on page 4.

PFS - Pelvic Floor Stimulation

- Switch the unit on by pressing the Power Key button. The SensaTONE will always start up in Mode A.
- The SensaTONE has four preset programmes:
 - Mode A** - Urge Incontinence
 - Mode B** - Stress Incontinence
 - Mode C** - Mixed Incontinence
 - Mode D** - After Care
- Select the mode most appropriate for your type of incontinence by pressing the 'MODE' key. Please refer to page 9 if you are unsure of which mode to use.
- Now begin by pressing the 'Intensity Up' key. Each time you press this key, you will see the intensity level increase on the LCD.

- Carefully continue to press 'Intensity Up' key until you comfortably feel your muscles contracting. If the sensation feels too strong, simply press the 'Intensity Down' key to minimise the feeling.
- Modes A, B and C all have fixed programme times. The SensaTONE will automatically switch off once the programme is complete. Mode D does not have a fixed programme time. Refer to page 9 for more information about Mode D.
- After use, always remember to ensure that the SensaTONE is switched off. Then remove the SensaTONE probe from your body, disconnect the leads and then clean it in accordance with the instructions found on page 6 or in the SensaTONE probe instruction manual.



The SensaTONE should **NOT** be used:

- During pregnancy.
- During the menstrual period.
- If you suffer a urinary or vaginal infection.
- At the same time as a barrier contraceptive device such as a diaphragm or cervical cap.
- Until 12 weeks after childbirth.

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PFS - Frequently Asked Questions

- How long will it take to see results?**
 - The amount of time varies from woman to woman; it is also dependent on the type of incontinence from which you are suffering.

STRESS Incontinence - improvement comes slowly with the building of muscle fibre and nerve sensitivity. This can take up to 2 months.

URGE Incontinence - improvements are made by reducing the false signals sent by the bladder to the brain. Results can be seen in as little as 14 days.

MIXED Incontinence - improvements are made by building the muscle fibre and nerve sensitivity as well as reducing the false signals being sent to the brain. This can take slightly longer, but you should be able to notice a difference within 21 days.

If you have any further questions on incontinence or need some advice, contact The Bladder and Bowel Foundation on:



Reg Charity
1085095

Nurse helpline: (+44) (0)845 345 0165
Counsellor helpline: (+44) (0)870 770 3246
e-mail: info@bladderandbowelfoundation.org
web: www.bladderandbowelfoundation.org

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Choosing The Right PFS Mode

There are three types of incontinence, all of which can be treated with the SensaTONE:

- Urge incontinence (MODE A)** - occurs with a strong, sudden and uncontrollable urge to urinate.
- Stress incontinence (MODE B)** - occurs when sneezing, coughing, laughing, lifting or during exercise and causes a small amount of urine to leak.
- Mixed incontinence (MODE C)** - a combination of urge and stress incontinence.

Frequency Of Use

Below is a guide showing how often to use each PFS mode on your SensaTONE. If your muscles

Programme	Length	How often
Mode A	30 mins	1-2 times a day
Mode B	30 mins	Once a day or every other day depending on severity
Mode C	45 mins	Complete the programme once a day
Mode D	-	Please see 'Using Mode D' above

DO NOT EXCEED TREATMENT TIMES UNLESS ADVISED BY A MEDICAL PROFESSIONAL.

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Specifications

All outputs have 200µs pulse width. For the Urge, Stress and Mixed mode, the output pulses are alternatively switched on and off for 5 seconds.

Programme	Display	Output Frequency/Duration
Urge	A	5Hz / 3 mins 10Hz / 5 mins 15Hz / 5 mins 20Hz / 5 mins 15Hz / 5 mins 10Hz / 5 mins 5Hz / 2mins Total time = 30 mins
Stress	B	10Hz / 5 mins 35Hz / 5 mins 50Hz / 10mins 35Hz / 5mins 10Hz / 5mins Total time = 30 mins
Mixed	C	10Hz / 5mins 20Hz / 5 mins 30Hz / 5 mins 40Hz / 5mins 50Hz / 5mins 40Hz / 5mins 30Hz / 5mins 20Hz / 5mins 10Hz / 5mins Total time = 45 mins
After Care	D	Frequency Modulation Frequency increases from 2 Hz to 10 Hz in 4 secs. and then back to 2Hz in another 4 secs. Total cycle = 8 secs Total time = 45 mins
Output Channel		Single Channel
Output Waveform		Bi-phasic rectangular
Output Voltage		0-40V adjustable in 14 steps across a 500 ohm load
Output Intensity		0-80mA adjustable in 14 steps across a 500 ohm load
Automatic Power Off		5 minutes
Battery		2 x 1.5V AAA Batteries
Battery Low Detect		2.2V±0.1V

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start to ache, or you have any problems using the SensaTONE, please contact your medical adviser.

Using Mode D – After Care

This is an optional mode and can be used as follows:

- Directly after treatment with the SensaTONE, provided you are not experiencing any muscle fatigue.
- As a maintenance mode after you have been using the sensatone on a regular basis and have experienced an improvement in your condition.

Please note that there is no recommended treatment time for this mode. It is at your discretion. It is suggested that it is used no more than between 15-30 minutes per day.



Instructions for use
SensaTONE



ISO 9001 ISO 13485
EC DIRECTIVE 93/42/EEC Annex V

Body Clock Health Care Ltd

108 George Lane, South Woodford
London E18 1AD

Tel (+44) (0)20 8532 9595

Fax (+44) (0)20 8532 9551

www.bodyclock.co.uk

e-mail customercare@bodyclock.co.uk

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This manual is recyclable

body clock

The SensaTONE from Body Clock is an ultra simple, yet powerful digital Pelvic Floor Stimulator (PFS). This compact, stylish unit has been designed for use by women of all ages to help strengthen pelvic floor muscles and to treat incontinence.

Like all other muscles in your body, the more you stimulate them, the stronger they become. Women with strong pelvic floor muscles enjoy greater control over their bladder, increased vaginal tone and greater sensation during intercourse.

One in three women suffers from some form of incontinence during her life. It can occur at any time, most commonly after childbirth. The severity of incontinence can vary.

Before you use the SensaTONE, it is important that you read this manual carefully; it contains all

of the information you need to ensure you are using the unit safely and correctly.

Explanation Of Symbols On Unit



Equipment providing a particular degree of protection against electric shock particularly regarding allowable leakage currents having a BF type (floating) applied part.



Warning – refer to accompanying documents i.e. these instructions.



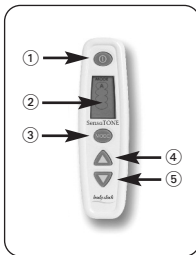
Denotes a product which must be disposed of safely.



This symbol indicates the serial number of the device and includes the year of manufacture. The serial number can be found in battery compartment of this device and also on the outer packaging.

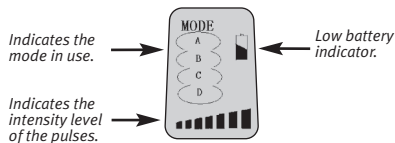
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Controls On The SensaTONE



- Power Key** – Turns the SensaTONE on and off.
- User Display** – Indicates the mode in use and the intensity level (also see diagram below).
- Mode Key** – Switch between programmes A, B, C and D.
- Intensity Up** – Increases the intensity of the pulses.
- Intensity Down** – Decreases the intensity of the pulses.

User Display



Additional Functions

Load Detector – If the vaginal probe becomes detached, the intensity will drop back to zero.
Low Battery Indicator – A flashing battery symbol will be shown on the display.
Automatic Power Off – When the unit intensity levels are zero, and the SensaTONE has not been in use for about 5 minutes, the unit will shut off automatically.

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This unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENT.

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Setting Up Your SensaTONE

Check you have the following contents:

- 1 x SensaTONE unit
- 1 x SensaTONE vaginal probe
- 1 x Leadwire
- 1 x Lubricant gel sachet
- 1 x Neck cord
- 1 x Instructions

NB. batteries not included

The Assembly Stage

1. Ensure the SensaTONE unit is switched off.
2. Slide open the battery cover on the back of the unit to expose the battery compartment.
3. Insert the batteries matching the + and – terminals, according to the diagram found in the battery compartment. Replace the cover.
4. Remove the SensaTONE vaginal probe from its packaging.
5. Wash hands in soap and warm running water. Liberally wash the probe using the same method but do not soak. Rinse all soap and residue from hands and probe. Dry your hands and the probe with a clean cloth/paper towel and allow to air dry.
6. Insert the end of the leadwire into the socket at the bottom of the SensaTONE. Connect the other end of the leadwire to the probe. See diagram (i) on page 7.
7. Apply a thin coating of lubricating gel to the probe.
8. Insert the probe until the flange at the base of the probe is sited between the labia. There is no need for precise orientation. See diagram (ii) on page 7.
9. You are now ready to begin stimulation.

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Precautions And Contraindications

1. Do **NOT** use the SensaTONE if you have a cardiac pacemaker.
2. Check with your medical adviser before using if you suffer from a heart condition, undiagnosed pain, have any metal implants, or any doubts whatsoever.
3. The SensaTONE can **NOT** be used during pregnancy. You can use it from 12 weeks after the birth.
4. Do **NOT** use the SensaTONE if you suffering from any urinary or vaginal infection.
5. Do **NOT** use the SensaTONE at the same time as a barrier contraceptive device such as a diaphragm or cervical cap.
6. Never use the SensaTONE to mask undiagnosed pain since this could require urgent treatment.
7. The SensaTONE should **NOT** be used during the menstrual period.

If you have any concerns regarding use of the SensaTONE please do not hesitate to contact Body Clock Health Care on (+44) (0)20 8532 9595.

General Precautions

1. Do **NOT** use this unit without first reading these instructions.
2. Do **NOT** handle or insert probe unless the unit is switched off.
3. Do **NOT** immerse unit in liquid.
4. Do **NOT** place it close to any source of excessive heat or operate it in the presence of flammable gas.
5. Do **NOT** drop this unit onto a hard surface.
6. Do **NOT** attempt to dismantle the SensaTONE.
7. Only use specified batteries and electrodes.
8. If damaged, do not use. Return to supplier.
9. Remove batteries when not in use.
10. Do **NOT** use while driving or operating potentially dangerous machinery or while using a microwave.
11. Keep out of the reach of children.
12. Do **NOT** place the vaginal probe near the eyes, in the mouth, over the front or sides of the neck, across the head, heart.
13. Do **NOT** use in the presence of tuberculosis, malignant tumours, very high or low blood pressure, high fever or acute inflammatory disease unless under medical supervision.

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Useful Diagrams



Diagram (i)

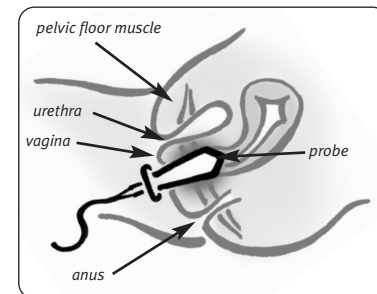


Diagram (ii)

Important

- The SensaTONE vaginal probe is single patient use **ONLY**. Additional probes and gel can only be purchased from Body Clock.
- Probes may be re-used by the same patient only.
- Wash probe as instructed before each use.
- Do **NOT** use the probe if the pack is open or damaged.

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