Using Your SensaTONE for Men For PFS



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

PFS - Pelvic Floor Stimulation

- a) Switch the unit on by pressing the Power Key button. The SensaTONE for Men will always start up in Mode A.
- b) The SensaTONE for Men has four preset programmes:
 - Mode A Urge Incontinence Mode B - Stress Incontinence Mode C - Mixed Incontinence
 - Mode D After Care
- c) 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.
- d) Now begin by pressing the 'Intensity Up' key. Each time you press this key, you will see the intensity level increase on the LCD.

PFS - Frequently Asked

Q How long will it take to see

The amount of time varies

from man to man; it is also

dependent on the type of

STRESS Incontinence -

slowly with the building

nerve sensitivity. This can

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.

improvement comes

of muscle fibre and

take up to 2 months.

URGE Incontinence -

incontinence from which you

Questions

results?

are suffering.

- e) Carefully continue to press the '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.
- f) Modes A, B and C all have fixed programme times. The SensaTONE for Men 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.
- g) After use, always remember to ensure that the SensaTONE for Men is switched off, then remove the SensaTONE for Men probe from your body. Disconnect the leads and then clean it in accordance with the instructions found on page 6 or in the SensaTONE for Men probe instruction manual.



The SensaTONE for Men should **NOT** be used if suffering from a urinary or bowel infection or tissue damage or if you have a recent local surgical scar.

8

Q What does it feel like?

A All three PFS programmes feel slightly different. In general, the feeling is that of a pleasant, tingly, squeezing sensation that contracts and relaxes the pelvic floor muscles.

Q Is it suitable for use by all men?

- A Yes, all men can use it provided none of the contraindications apply.
- Q Can you use the Sensatone for Men for Faecal (Bowel) incontinence or Nocturnal Fnuresis?
- A Yes, but you must consult with your medical adviser to determine the treatment mode which will best suit your needs.

Q Are there any side effects?

A No, it is totally drug free. There are no known side effects.

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

10



Nurse helpline: 0845 345 0165 Counsellor helpline: 0870 770 3246 info@bladderandbowelfoundation.org www.bladderandbowelfoundation.org

Choosing The Right Mode

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

- 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 for Men. If your muscles start to ache, or you have any problems using the SensaTONE for Men, please contact your medical adviser.

Using Mode D – After Care

This is an optional mode and can be used either directly after treatment (provided you are not experiencing any muscle fatigue), or, as a maintenance mode after you have been using your unit on a regular basis and have experienced an improvement in your condition.

NB. There is no recommended treatment time for Mode D. It is at your discretion. It is suggested that it is used no more than 15-30 minutes per day.

Using the Sensatone for Men for Faecal (Bowel) incontinence or Nocturnal Enuresis

The Sensatone for Men can be used for these conditions, but you must consult with a medical adviser to determine the best treatment mode prior to use.

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.

9

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	А	5Hz/3 mins 10Hz/5 mins 15Hz/5 mins 20Hz/5 mins 15Hz/5 mins 10Hz/5 mins 5Hz/2 mins 70tal time = 30 mins
Stress	В	10Hz /5 mins 35Hz /5 mins 50Hz /10mins 35Hz /5mins 10Hz /5mins Total time = 30 mins
Mixed	С	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		o-40V adjustable in 14 steps across a 500 ohm load
Output Intensity		o-8omA 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



ustructions for use

SensaTONE for Men







ISO 9001:2008 ISO 13485:2003 EC DIRECTIVE 93/42/EEC Annex V

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For accessories and consumables please visit www.bodyclock.co.uk

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11

The SensaTONE for Men from Body Clock is an ultra simple, yet powerful digital Pelvic Floor Stimulator (PFS). This compact, stylish unit has been designed for use by men 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. Men with strong pelvic floor muscles enjoy greater control over their bladder.

One in seven men suffer from some form of incontinence during their life. It can occur at any time. The severity of incontinence can vary.

Before you use the SensaTONE for Men, 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.

Contents

Precautions And Contraindications4
Controls On The SensaTONE for Men5
Display Symbols And Their Meanings5
Additional Functions5
Setting Up Your SensaTONE for Men6
Useful Diagrams7
Using Your SensaTONE for Men For PFS8
Choosing The Right PFS Mode9
Frequency Of Use9
Using Mode D – After Care9
PFS FAQ's
Technical Specification11

3

Precautions And Contraindications

- Do **NOT** use the SensaTONE for Men if you have a cardiac pacemaker.
- Check with your medical adviser before using if you suffer from a heart condition, undiagnosed pain, have any metal implants, or any doubts whatsoever.
- Do NOT use the SensaTONE for Men if you are suffering from any urinary or bowel infection.
- Never use the SensaTONE for Men to mask undiagnosed pain since this could require urgent treatment.
- Do not use if suffering from an infection or tissue damage or if you have a recent local surgical scar.

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

General Precautions

- Do NOT use this unit without first reading these instructions.
- Do NOT handle or insert probe unless the unit is switched off.
- Do **NOT** immerse unit in liquid.
- Do NOT place it close to any source of excessive heat or operate it in the presence of flammable gas.
- Do **NOT** drop this unit onto a hard surface.
- Do **NOT** attempt to dismantle the SensaTONE for Men.
- Only use specified batteries and electrodes.
- 8. If damaged, do not use. Return to supplier.
- 9. Remove batteries when not in use.
- 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 anal 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.

Controls On The SensaTONE for Men



- Power Key Turns the SensaTONE for Men on and off.
- User Display Indicates the mode in use and the intensity level (also see diagram below).
- 3) **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 anal 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 for Men has not been in use for appoximately 5 minutes, the unit will shut off automatically.

Setting Up Your SensaTONE for Men

Check you have the following contents:

- 1x SensaTONE for Men unit
- 1 x Anuform anal probe
- 1 x Leadwire
- 1 x Lubricant gel sachet
- 1 x Neck cord
- 1 x Instructions

NB. 2x AAA batteries NOT included

The Assembly Stage

- Ensure the SensaTONE for Men unit is switched off.
- Slide open the battery cover on the back of the unit to expose the battery compartment.
- Insert the batteries matching the + and - terminals, according to the diagram found in the battery compartment. Replace the cover.

- 4. Remove the Anuform anal probe from its packaging.
- 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 for Men. Connect the pins to the other end of the leadwire to the Anuform probe. See diagram (i) on page 7.
- 7. Apply a thin coating of lubricating gel to the probe.
- 8. Insert the probe into the anus while 'bearing down' as if passing a stool. The 'RING' part of the Anuform probe should remain external to the anus at all times.

 There is no need for precise orientation. See diagram (ii) on page 7.
- You are now ready to begin stimulation.

Useful Diagrams



Diagram (i)

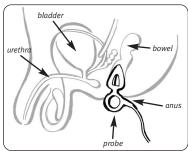


Diagram (ii)

Important

- The Anuform anal 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.

5