Using Your SensaTONE for Men For PFS

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

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.

e) 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 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 anal probe from your body, disconnect the leads and then clean it in accordance with the instructions found on page 6 or in the anal probe instruction manual.

The SensaTONE for Men should not be used:

- If you suffer a urinary or bowell infection or any tissue damage or if you have a recent local surgical scar.

Choosing The Right PFS Mode

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

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.

Prog	Length	How often?
Mode A	30 minutes	1-2 times a day
Mode B	30 minutes	Once a day or every other day depending on severity
Mode C	45 minutes	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.

Instructions for use

SENSATONE™ FOR MEN

body clock

Frequently Asked Questions

Q **How long will it take to see results?**

A It varies and depends on the type of incontinence.

STRESS Incontinence - improvement comes slowly with the building of muscles which 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 reducing false signals being sent to the brain. This can take slightly longer, but you should be able to notice a difference within 21 days.

Q **What does it feel like?**

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

Q **Is it suitable for use by all men?**

A All men can use it provided none of the contraindications apply.

Q **Are there any side effects?**

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

Troubleshooting

1. Check if the unit is turned on. If so, turn it off before taking any further steps.
2. Then replace the batteries. Turn the device on. If it does not function at all, return the device for repair.
3. If your unit switches on but does not appear to be operating properly or there are changes in the performance of your equipment, first replace the batteries. IIf there is no improvement, turn off the device. Check that the leadwires and probe are properly connected.
4. If there is no improvement, replace your probe with a new one from Body Clock.
5. If your device still does not appear to function properly or the performance is still changed turn off the unit, pack it away safely and contact the manufacturer for advice and assistance or return the device to the manufacturer.

If you have further questions on incontinence or need some advice contact the **Bladder and Bowel Foundation** on:
Helpline:
(+44) (0)845 345 0165
e-mail: info@bladderandbowel foundation.org
web: www.bladderandbowel foundation.org

Technical Specification

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.

Prog / 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
AFTERCARE / **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
Operating Environment range	0 °C to 40 °C, 30% to 75% R.H.; 700 hPa to 1060 hPa
Storage & Transport range	0 °C to 40 °C, 30% to 90% R.H.; 700 hPa to 1060 hPa
Applied Part	Anal Probe
Classification of protection against electric shock	Internally Powered
IP Classification	IP22
Mode of Operation	Continuous
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 / Battery Life	2 x 1.5v AAA Batteries / Approx 110hrs
Battery Low Detect	2.2V±0.1V

Guarantee

Your SensaTONE for Men machine is guaranteed for a period of 1 year against manufacturer's defects. Please record purchase details in the space provided below for your record purposes. The guarantee does not include leads, electrodes, probes or battery.

Date of purchase:.....

Invoice number: .....

body clock

Body Clock Health Care Ltd
108 George Lane, South Woodford,
London E18 1AD United Kingdom
www.bodyclock.co.uk
+44(0)20 8532 9595

EC REP
EU Representative:
Saverine Medical Ltd
North Point House
North Point Business Park
Old Mallow Road,
Cork, Ireland

MedEnvoy Global B.V.
Prinses
Margrietplantsoen 33 -
Suite 123, 2595 AM
The Hague The
Netherlands

recycle
Recycling of batteries, electrical and electronic equipment (WEEE). Dispose of used batteries and device safely using official recycling facilities. To find your nearest recycling centre, contact your local council, or visit www.recycle-more.co.uk

CE
1639

Model: D-BC06TB
STFM-IFU-1
Jan 2024 (9)

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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.

Please keep device away from sprays of water or rain.

Denotes a product which must be disposed of safely.

SN — Indicates the device serial number found in the battery compartment and outer packaging. It includes the year of manufacture (YOM) which appears as two digits after the letters FD e.g. FDXX. The digits following the YOM identify each individual device.

EC REP — EU Representative.

IP22 — The first number 2: Protected against solid foreign objects of 12.5 mm diameter and greater. The second number 2: Protection against vertically falling water drops when enclosure tilted up to 15°on either side of the vertical.

Indicates the medical device manufacturer.

LOT — Indicates the manufacturer's batch code so that the batch or lot can be identified.

CE XXXX — This CE mark symbol indicates the conformity of products where a Notified Body has performed conformity assessment and the reference number for that Notified Body appears as four digits below the symbol.

Contents

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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.

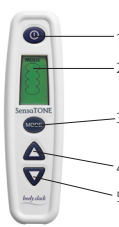
Precautions and Contraindications

1. Do NOT use the SensaTONE for Men 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. Do NOT use the SensaTONE for Men if you are suffering from any urinary or bowel infection.
4. Never use the SensaTONE for Men to mask undiagnosed pain since this could require urgent treatment.
5. Do not use if suffering from an infection or tissue damage or if you have a recent local surgical scar.
6. Remove probe after treatment.

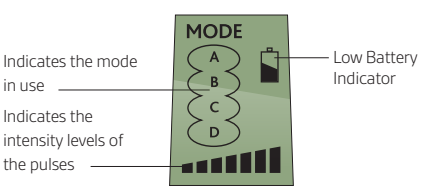
General Precautions

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. Only use specified batteries/ electrodes/leadwires.
6. Do NOT drop on hard surfaces.
7. If damaged, do not use. Return to supplier.
8. Remove batteries when not in use.
9. Do NOT use while driving or operating dangerous machinery or while using a microwave.
10. Keep out of the reach of children.
11. Do NOT place probe near the eyes, in the mouth, over the front or sides of the neck, across the head, heart. 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 Do not use on infants or people not capable of expressing their intentions.
12. The patient is the intended operator of this device.
13. Warning: No servicing or maintenance should be undertaken while the ME equipment is in use.
14. The operator may change the batteries under normal circumstances following the instructions on page 6.
15. The operator may maintain the device and it's accessories only according to these instructions.
16. The operator should NOT attempt to dismantle, open up or repair this device but should return it to the manufacturer for assistance. Only the manufacturer is entitled to repair this device.
17. The operator of this device shall NOT touch the battery terminals wand the patient simultaneously.
18. Be aware of the risk of strangulation from leadwires. Do not use this device while asleep.
19. Do not ignore any allergic reaction. If any irritation develops stop using the device. Seek medical advice immediately.
20. Keep this device away from lint and dust. Long term exposure may affect the connection with the sockets or battery connectors.
22. Do not expose this device to direct sunlight. Long term exposure may cause the device to crack.
23. Loosely connected probes, damaged leadwires or sudden changes in contact may cause brief, involuntary muscle movements.

Controls On The SensaTONE for Men



1. Power Key – Turns the device on and off.
2. 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.
4. Intensity Up – Increases the intensity of the pulses.
5. Intensity Down – Decreases the intensity of the pulses.



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 about 5 minutes, the unit will shut off automatically.

Setting Up Your SensaTONE for Men

Check you have the following contents:

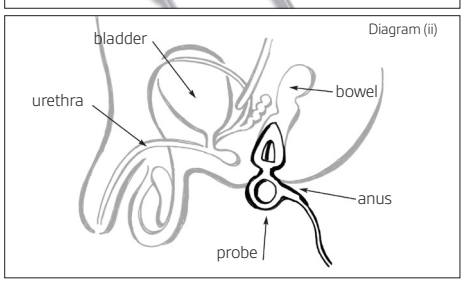
- 1 x SensaTONE for Men unit
- 1 x SensaTONE for Men anal probe*
- 1 x Leadwire
- 1 x Lubricant gel sachet
- 1 x Neck cord
- 1 x Carrying pouch
- 1 x Instructions
- 2 x AAA Batteries

The Assembly Stage

1. Ensure the SensaTONE for Men 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 anal 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 for Men. 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 into the anus while 'bearing down' as if passing a stool. The 'RING' part of the anal probe should remain external to the anus at all times. There is no need for precise orientation. See diagram (ii) on page 7.
9. You are now ready to begin stimulation.

*Only use Body Clock SensaProbe 4M anal probes (probes with a minimal electrode surface area of no less than 3.5cm² on either side).

Useful Diagrams



IMPORTANT

- The SensaProbe 4M 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.

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.

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