Finetech-Brindley
Sacral Anterior Root Stimulator

CPC2
USER GUIDE

August 2021

This guide MUST be read and understood by all relevant persons prior to using the Finetech-Brindley Sacral Anterior Root Stimulator (SARS).

Need help?

If you need advice about any aspect of your *Finetech-Brindley SARS* please:

- email us at info@bioinduction.com
- contact us or your distributor via our website www.finetech-medical.co.uk
- telephone us on +44 (0)1707 330942

Key to Symbols used in this *User Guide*

Contra-indications

These notes describe situations where you should not use your *Finetech-Brindley SARS.*

Warnings and Cautions

Make sure that you understand these notes before using your *Finetech-Brindley SARS.*

Important Note

This symbol appears next to points to remember about your *Finetech-Brindley SARS.*

The *Finetech-Brindley* SARS has been manufactured in the United Kingdom since 1982 by:

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Authorisation first issued:
10th April, 1996

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Table of Contents

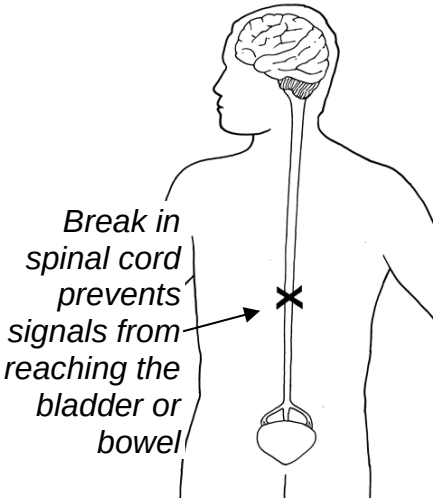
1. Introduction

This *User Guide* provides information for the safe use of your *Finetech-Brindley Sacral Anterior Root Stimulator (SARS);* for you, your family, your care givers and your doctor/surgeon/clinician.

2. How does the Finetech-Brindley SARS Work?

Functional Electrical Stimulation (FES) is a method used to enable otherwise paralysed muscles to function. The *Finetech-Brindley SARS* uses FES to stimulate the nerves which connect the spinal cord to the bladder and bowel. This allows people with complete spinal cord injuries to empty their bladder when they decide to ("on demand") leaving only a small amount of urine in the bladder. The stimulator can also be used to aid in bowel evacuation and, in some men, to stimulate penile erection.

In order to achieve control of the bladder and bowel, electrical signals normally travel from the brain down the spinal cord to the nerves that control these functions. In the case of spinal cord injury, this path is broken. The brain still sends the signals, but they do not reach the bladder or bowel.



The stimulator sends low levels of electrical energy directly to the nerves that control the bladder and bowel below the point of the spinal cord injury. If these nerves are healthy, the electrical signals cause the muscle of the bladder and bowel to contract.

What are the sacral nerves?

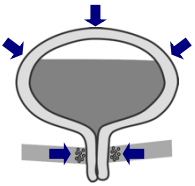
The nerves that connect the spinal cord to the bladder and bowel are located at the lower end of the spine in an area called the "sacrum". The nerves that exit the spinal cord through the sacrum are called ***sacral nerves***.

How does the Finetech-Brindley *SARS* empty the bladder?

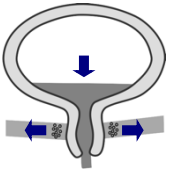
Two things must happen for a person to empty their bladder. First, the pressure inside the bladder must increase. The muscle which squeezes the bladder is known as the ***detrusor urinae***. Second, the valve at the base of the bladder, the ***external urethral sphincter,*** must open to allow the urine to flow out.

In most situations, stimulation of the sacral nerves causes the bladder to be squeezed which increases the pressure inside it. But, during stimulation, the external urethral sphincter stays closed. To open the sphincter, the stimulation must be turned off.

The *Finetech-Brindley SARS* sends the electrical signals (stimulation) in bursts, with gaps between them. In the gaps, the bladder is still squeezed but the external urethral sphincter has relaxed. Urine empties out of the bladder in spurts during these gaps.



Here, the bladder is squeezed, but the sphincter is closed. Urine cannot flow.



Here, the bladder is still squeezed, but the sphincter is open allowing urine to flow in spurts.

What is a *Rhizotomy*?

A ***rhizotomy*** is a surgical procedure in which some nerves are permanently cut. For best results from the *Finetech-Brindley SARS*, some of the nerves that carry sensation impulses from the bladder and bowel to the spinal cord may be cut.

A ***rhizotomy*** is usually performed during the same operation in which your *Finetech-Brindley SARS* is implanted. Combining the implantation with a ***rhizotomy*** can have the following benefits:

- Removes the reflexes from the bladder and bowel which can cause a dangerous rise in blood pressure (a condition known as ***autonomic dysreflexia***)
- Removes the reflex contractions of your bladder (which may cause ***reflex incontinence***) stopping the movement of urine from the bladder into the kidneys, decreasing the risk of kidney damage
- Improves the ability of the bladder to contain urine (known as ***bladder capacity***)
- Improves the flow of urine

Disadvantages of the ***rhizotomy*** procedure are:

- Loss of reflex erections (those from physical touch) in men who had those types of erection
- Loss of reflex ejaculation (from physical touch) in men who had this type of response
- Loss of sensation or “feeling” (if present) in the regions controlled by the sacral nerves (such as the anus and buttocks).
- A decrease in movement of stool through your body (known as ***bowel motility***).

How Does the *Finetech-Brindley SARS* Affect Leakage of Urine?

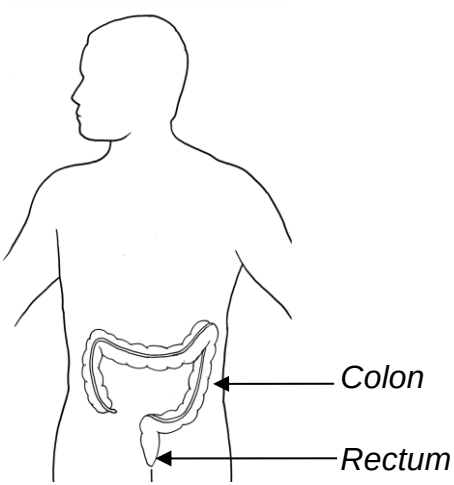
Leakage of urine, known as incontinence, can be caused in several ways. A common problem in spinal cord injury is large unpredictable leaks. This results from a reflex that causes the bladder to contract when there is urine in the bladder, called ***reflex incontinence***. The *rhizotomy* removes these reflex contractions.

Small leaks, resulting from bending forward or coughing, may also occur and are known as ***stress incontinence***. The *Finetech-Brindley SARS* may improve continence because it empties the bladder more completely.

How Does the *Finetech-Brindley SARS* Aid in Bowel Emptying?

As with the bladder, appropriate stimulation of the sacral nerves causes a rise in pressure in the rectum and some parts of the colon. For bowel emptying, it is typical to stimulate the sacral nerves for periods of 10 seconds, separated by pauses (gaps) of 20 seconds.

Typically, less than five minutes of stimulation is enough to empty the rectum. In some cases, this process will not empty the rectum but does move the faeces from the colon into the rectum, making manual evacuation easier.

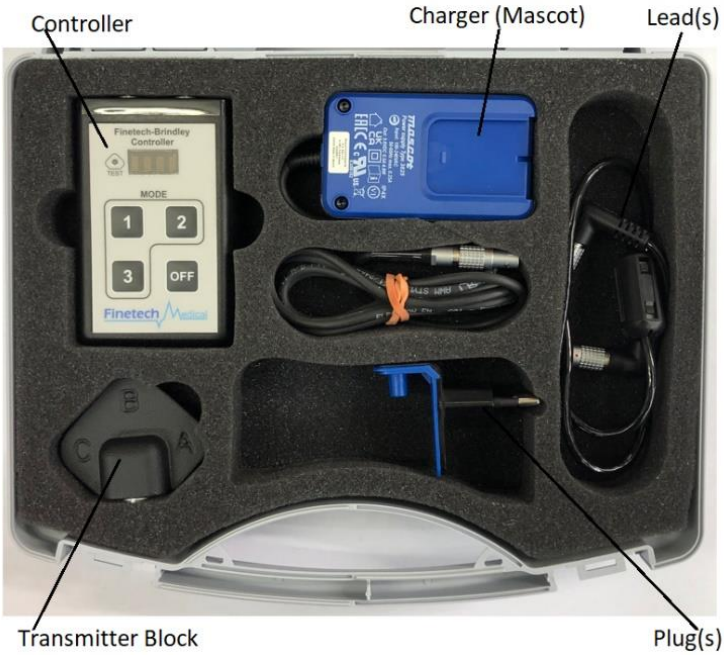


3. Components of the Finetech-Brindley SARS

Your *Finetech-Brindley* SARS is made up of **external** and **implanted** components.

3.1 *External Components*

The external parts of the *Finetech-Brindley SARS* allow you to operate and control the implanted stimulator/receiver. The external components consist of:



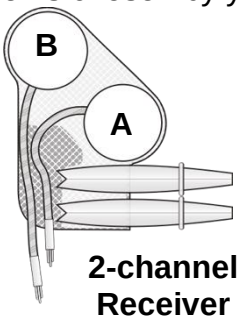
Contents of the carry case:

Parts	Quantity
CPC2 Controller	1
Transmitter Block	1
Transmitter Lead	1 or 2
Battery Charger	1
Euro plug	0 or 1
UK Plug	0 or 1
USA Plug	0 or 1
User Guide	1
Implant Certificate	1
Patient Card	1

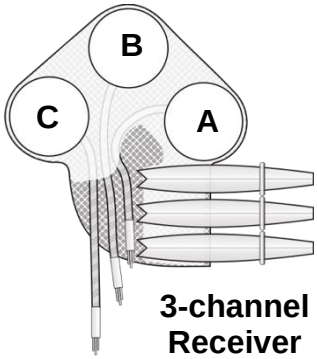
3.2 *Implanted Components*

The implanted components include the implanted ***Receiver*** and ***Electrode Assembly*****.**

The Implanted *Receiver-Stimulator* is typically implanted under the skin of your abdomen by your Surgeon. It receives signals from the external components and sends electrical signals to the nerves, which control the bladder and bowel. A suitable 2-Channel or 3-channel receiver is chosen by your surgeon.

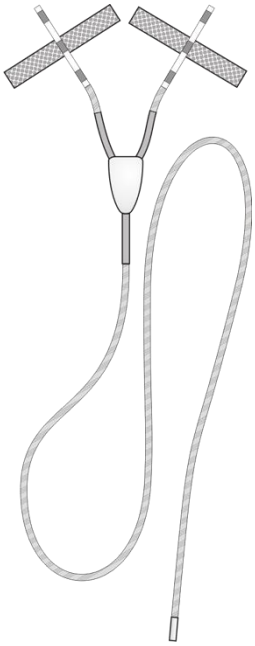


2-channel Receiver

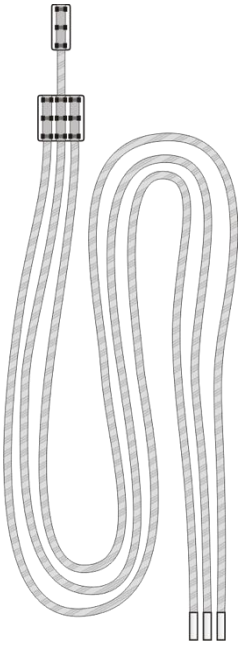


3-channel Receiver

An Electrode Assembly is connected to the implanted R*eceiver* during the implantation procedure to make a complete implant system. The electrical signals produced by the *Receiver* are carried along the leads to the electrodes. The electrodes are attached to the sacral nerves. An Intrathecal and an Extradural electrode assembly are shown below, but only one type of electrode is used; a suitable type is chosen by your surgeon:



Extradural Electrode



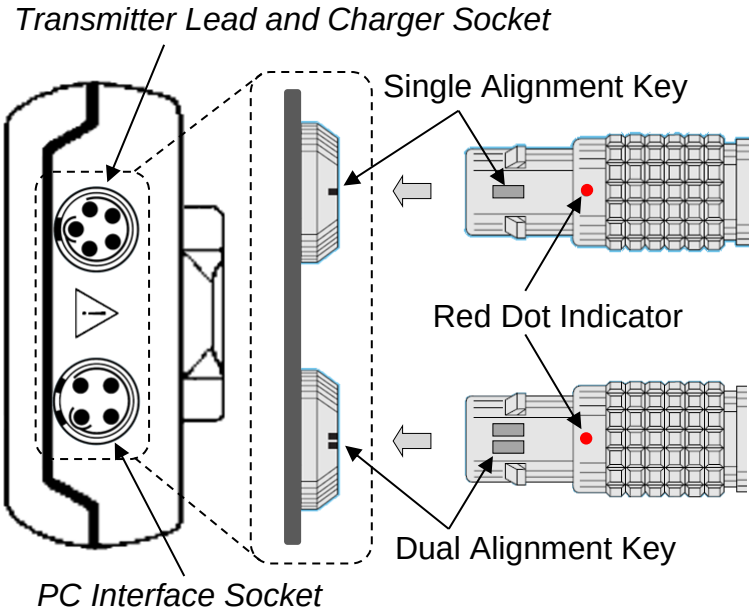
Intrathecal Electrode

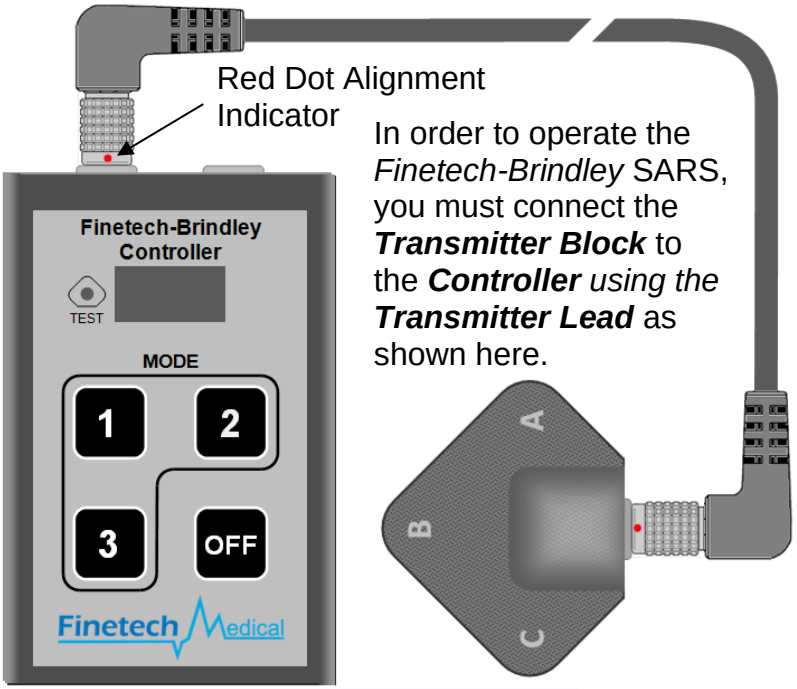
4. Using the *Finetech-Brindley SARS*

To use the *Finetech-Brindley SARS* effectively, you will need to have an approximate **"schedule"** for using the device to empty your bladder. For example, you might use it in the morning, at lunch time, in the mid afternoon, in the evening, and before you go to bed. Similarly, you will need to establish a ***"schedule"*** for your bowel routine. You and your doctor will decide on a schedule that is appropriate for you.

The Connectors

Care should be taken when plugging in the connectors. The Transmitter Lead and the Charger socket has a single alignment key, where the SARLINK-2 interface socket has a dual alignment key, it must be aligned when plugged in to avoid damage to the connector.

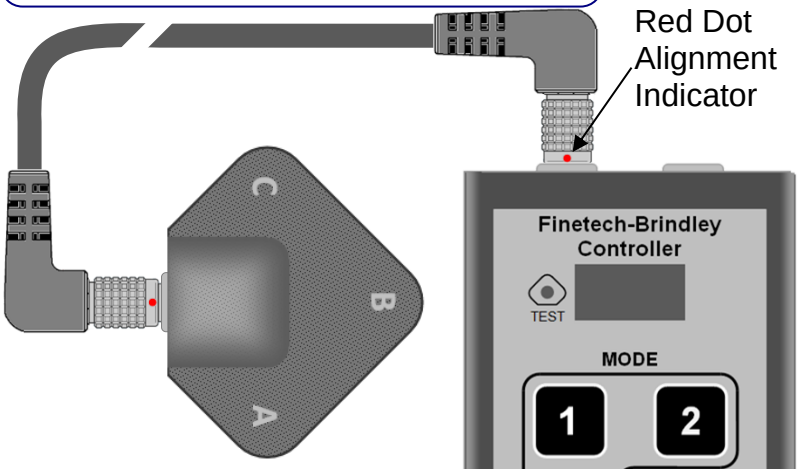




In order to operate the *Finetech-Brindley* SARS, you must connect the ***Transmitter Block*** to the ***Controller*** *using the* ***Transmitter Lead*** as shown here.

Warning
DO NOT rotate connector.
Connector CANNOT be rotated.

OR

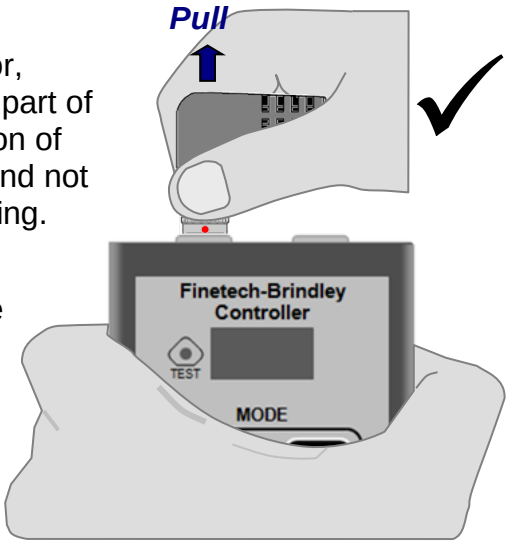


The connectors use a Push-Pull self-latching connection system, therefore the outer metal part of the connector is a moving part.

Correct Method

To unplug a connector, always pull the metal part of the plug in the direction of the arrow as shown and not the lead or the moulding.

Hold the *Controller* in one hand and pull the metal part of the plug with the other hand.

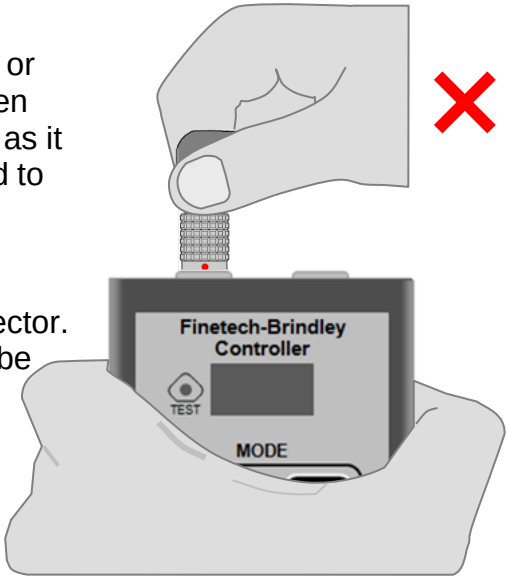


Wrong Method

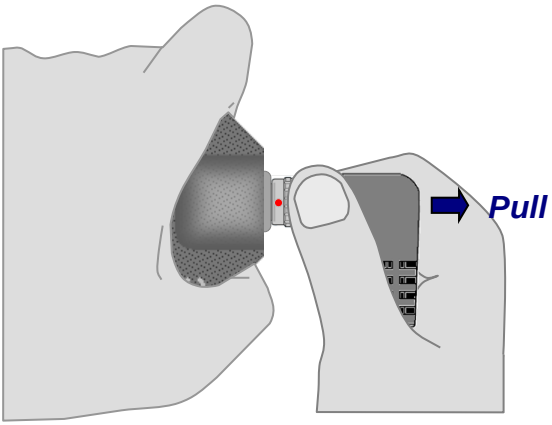
Do not hold the cable or the moulding part when unplug the connector as it could cause damaged to the connector.

WARNING:

DO NOT rotate connector. Connector CANNOT be rotated.



To unplug the connector from the *Transmitter Block*, hold the *Transmitter Block* in one hand and pull the metal part of the plug with the other hand.

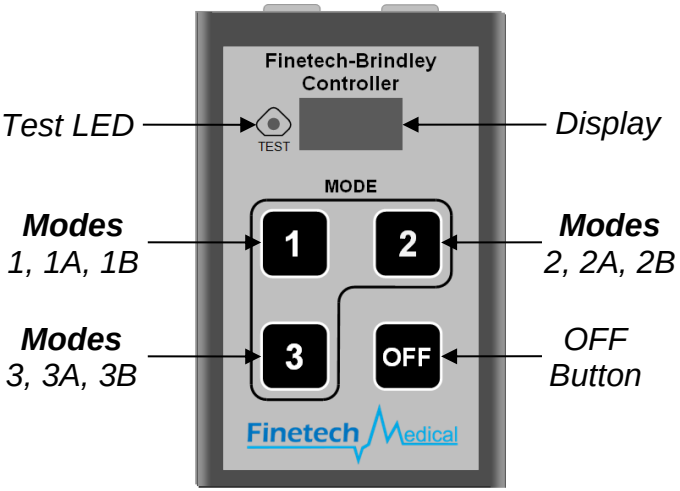


4.1 *Operating Modes*

The stimulator has been designed primarily for emptying the bladder. Some people are also able to use it to assist with emptying the bowel, and some men can use it to obtain an erection. These different functions are called **'Modes'**. Your clinician will have set up the external Controller for your own particular needs, and will have told you which Mode to use for each function.

Typical modes allocation:

- *Mode 1: Bladder emptying.*
- *Mode 2: Bowel emptying.*
- *Mode 3: Penile erection.*



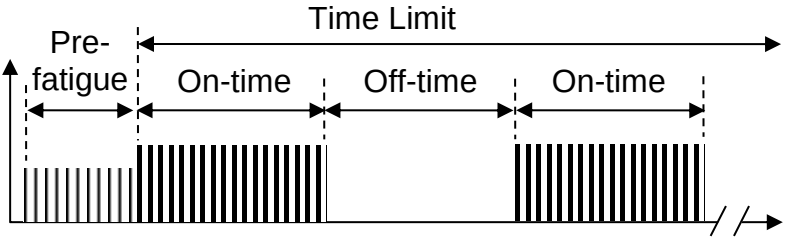
You select which Mode to use by pressing the corresponding Button. You cannot select a Mode which has not been set up for you. If you only use the Controller for function 1, your clinician should have disabled Buttons **2** and **3**.

Your clinician may have set up the unit to give alternative settings for some of the Modes. To use an alternative Mode, press the Button again. So for example:

- for Mode 2, press Button 2 once
- for Mode 2A, press Button 2 twice
- for Mode 2B, press Button 2 three times.

Stimulation Pattern

A stimulation mode may start with a Pre-fatigue period, but this is not normally used, this is then followed by the main stimulation period.



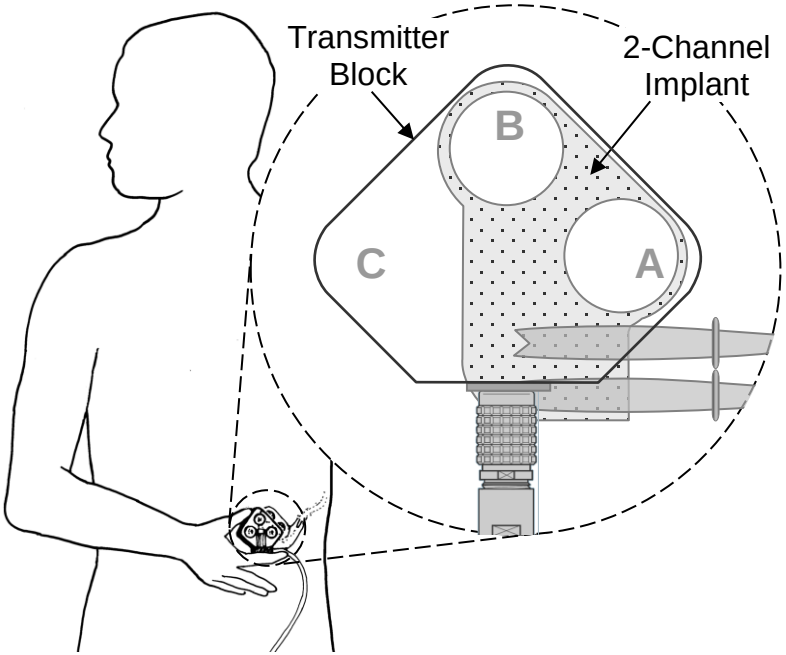
The main stimulation pattern usually consists of an On-time and an Off-time that is repeated during the whole of your stimulation period. The controller will automatically switch off at the end of the Time Limit that has been set or will operate continuously if it is set to zero. These times are set by your clinician and vary from patient to patient. The mode number on the display flashes during the On-time period and remains still during the Off-time period. There is no stimulation output during the Off-time period.

4.2 *Bladder Emptying*

Position yourself to begin your voiding program. This may involve a transfer to a commode, placement of a urinal, or assistance from a personal care attendant.

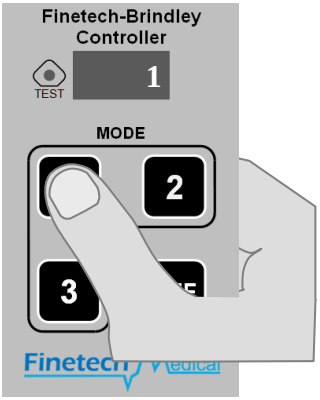
You may be able to feel the *Receiver* under the skin. Your doctor will help you learn where the receivers are and how to position the *Transmitter Block*. During the first six weeks after implantation, the implant may move slightly, but after six weeks, its position is usually very stable.

Refer to HELPFUL HINTS below for help in positioning.



1. Place the *Transmitter Block* accurately over the *Receiver*.
2. Select the appropriate Mode on the *Controller* (typically Mode 1). Press for 1 second and release.

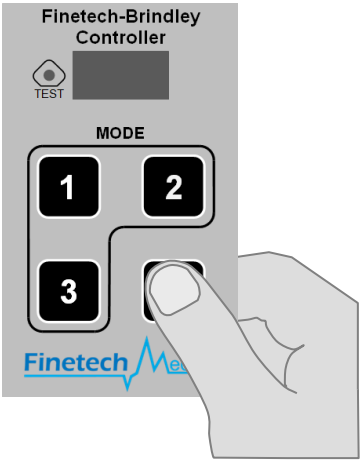
Stimulation starts a few seconds after you release the button. You should expect urine to flow out in spurts between the bursts of stimulation. Keep the *Transmitter Block* in position until the spurts have stopped, or nearly stopped.



Select Mode 1

3. Press the "**OFF**" button to stop the stimulation and turn OFF the *Controller*.

If you forget to turn OFF the Controller, the unit will eventually switch off automatically; this may take a long time and waste the battery charge. Your clinician can adjust the Time Limit that the unit will continue transmitting before switching off.



Stop stimulation

Note

You may need to turn OFF the Controller (by pressing **'OFF'** button*), wait for two minutes and then turn it back ON again. Waiting for a period of two minutes will enable your bladder to rest before beginning another series of stimulation. This may help you empty your bladder completely.*

Caution

If your urine flow pattern changes or you do not think you are emptying your bladder completely, contact your doctor immediately. If you cannot contact your doctor, use an alternative or back-up method (such as Intermittent Catheterisation) to empty your bladder.

HELPFUL HINTS

***Use of the Finetech-Brindley SARS in a wheelchair**: While sitting in a wheelchair, a man can empty his bladder into a condom catheter and leg-bag or male urinal and a female can empty her bladder into a female urinal.*

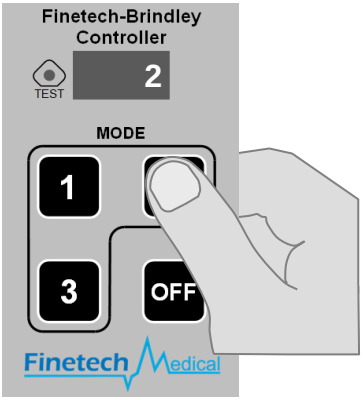
If you are a man, you may not empty your bladder completely if your wheelchair cushion is pressing against your urethra (the opening through which urine passes). You may be able to relieve this pressure if you sit further forward on the cushion, lean to one side, or, if you reduce the height of the centre of the cushion.

4.3 *Bowel Emptying*

Position yourself to begin your bowel program. This may involve a transfer to a commode or assistance from a personal care attendant.

1. Place the *Transmitter Block* accurately over the *Receiver*.
2. Select the appropriate Mode on the Controller (typically Mode 2). Press for 1 second and release.

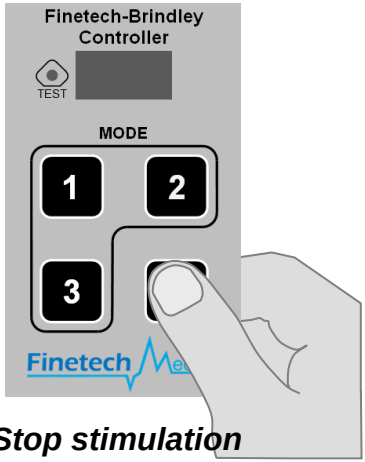
Typically, up to five minutes of stimulation is needed to empty the bowel. If stimulation does not empty the bowel effectively by itself, it may be necessary to assist stool removal manually.



Select Mode 2

3. Press the "**OFF**" button to stop the stimulation and turn OFF the *Controller*.

If you forget to turn OFF the Controller, the unit will eventually switch off automatically; this may take a long time and waste the battery charge. Your clinician can adjust the Time Limit that the unit will continue transmitting before switching off.



Stop stimulation

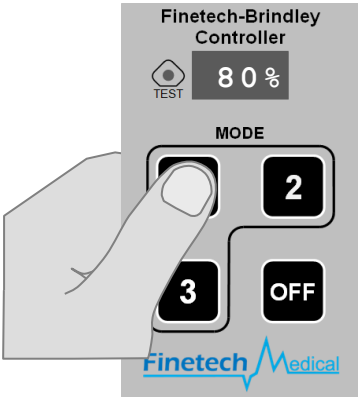
Some people may require repetition of this stimulation. In these cases, you should stimulate for 3 to 5 minutes, rest for two minutes, then stimulate again for 3 to 5 minutes. The entire bowel program (including time spent manually evacuating or cleaning) may take longer. While learning to use the *Finetech-Brindley SARS* you should continue your usual bowel medications.

4.4 *Charging the Battery*

Checking the battery level:

To check the battery level, press Button **1** and keep it pressed for a few seconds. The display will show the remaining battery capacity to the nearest ten per cent.

Pressing the Button for more than 7 seconds will display the version of firmware.

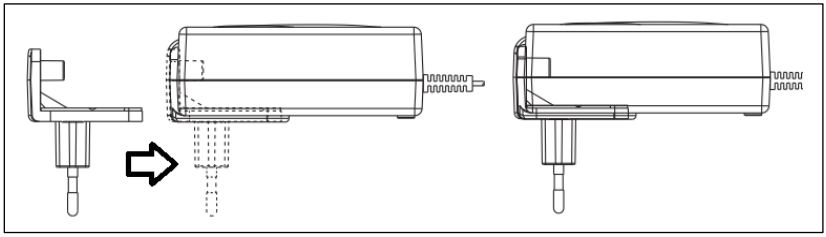


A fully charged battery will last up to 8 hours under heavy usage. With typical settings, the battery will last many days between charges; the exact period will depend on individual stimulation parameters setting. The battery may be sufficiently charged for one Mode, but still give a low warning on another Mode.

Low battery warnings: If the battery runs low while you are stimulating, the unit will display **'Low'** and flashes during stimulating. Some while later, if the battery level drops further, it will display an error message, **'Flat'** for 3 seconds then switch off. You will need to re-charge the battery before it can be used again.

Selecting and changing the charger plugs: The charger is supplied with the plug suitable for your region. Chargers with plugs for UK, Euro and USA can be supplied by contacting Finetech Medical. Standard travel adapters can be used if you travel out of your region.

Fitting a plug: First align the plug with the fitting slots on the charger body, then push the plug into the slots and slide it forward until it clicks together. Once fitted it is not built to come apart.



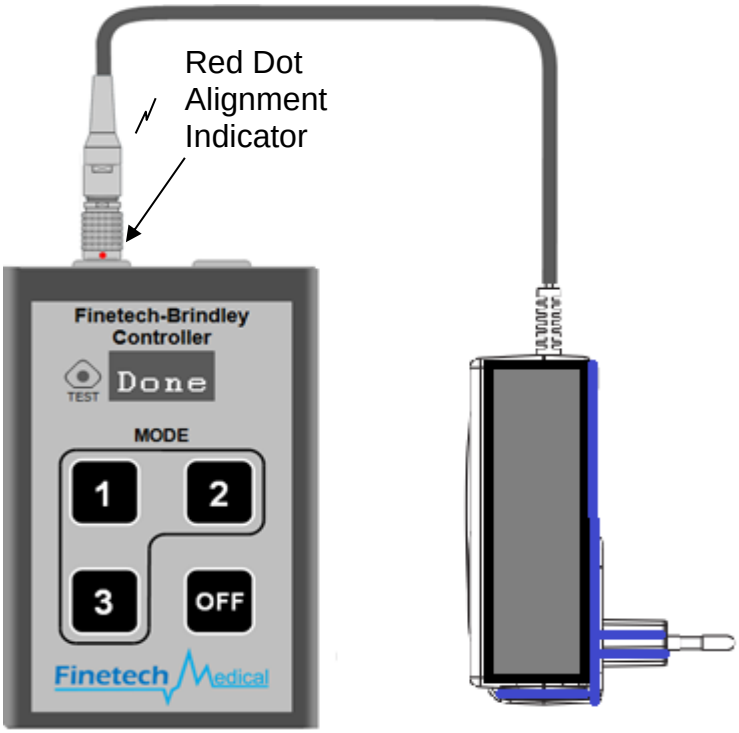
How to charge:

To charge the battery, simply plug the *Charger* into a mains outlet and plug the output connector into the charger socket on the *Controller*. You will have to first disconnect the *Transmitter Lead* from the *Controller.* While the battery is on charge, the *Controller* cannot be used for stimulating. It is normal for the *Charger* to get warm. Do not cover it or it may overheat.

While the battery is charging, the display on the *Controller* will show the approximate level in 10% steps, except when it is approaching fully charged, the display will show '95%'. When it shows 'Done', it is fully charged. A full charge takes up to 3 hours; the time will depend on the state of charge at the beginning of the charge cycle. Lithium-ion batteries do not need to be fully charged; a partial charge is better for battery life but this reduces the runtime.

Warning

NEVER attempt to use any battery charger other than the one supplied with the Controller. Using the wrong charger could damage the battery, which may cause leakage and subsequent damage to the device or explosion.



When to charge: The controller contains a Lithium-ion battery and can be charged at any time, whether at a 90% charge level or only 10%. Do not allow a nearly flat battery to be unused for more than a month or so; the battery will slowly discharge until it becomes fully discharged and this will permanently damage the battery cells.

Your controller should only be charged under the following conditions:

Charging	0°C to +40°C

Warning
Do not charge below freezing or above the maximum recommended charging temperature.

5. Care and Maintenance

Care of the system: The *Transmitter Lead* can be damaged internally by rough handling. When unplugging, always pull the body of the connector rather than the lead.

Warning
- Do not pull on the cables.
- Do not hang the *Controlle*r by the cable
- Do no wrap cables around the *Controller*
- Do not tie knots in the cables
- Do not plug any other connector into the *Controller* other the supplied parts.

Do not wash or submerse the *Controller* for cleaning. The outside of the *Controller* can be cleaned with a damp cloth. For heavier dirt or stains, a mild detergent such as dishwashing soap may be used for cleaning. Remove the soap with a damp cloth. Tape residue may be cleaned off the *Transmitter Block* by rubbing with alcohol. The cables should be wiped clean with mild detergent. Allow all items to air-dry completely before using.

Repair and Maintenance: The Controller contains no serviceable components. Do not open the *Controller* unit as it contains high voltages which can be dangerous. Internal damage could result in inappropriate stimulation. Always return it to the manufacturer or distributor for any repair or maintenance.

The battery should last for many years. If, eventually, you find that it is not holding its charge well, return the *Controller* to the manufacturer or local distributor to have a new battery fitted. The battery is a special unit, which should only be changed by authorised personnel.

Warning
Do not modify this equipment without authorisation of the manufacturer.

Storage and Handling: We recommend that you keep your *Finetech-Brindley SARS* parts and/or spares within the *Carry Case* provided. Like any electronic equipment, the *Controller* should not be exposed to excessive temperatures. Do not leave it on a radiator or in a car in direct sunshine, even in the glove compartment. Although the *Controller* is designed to withstand minor knocks, it can be damaged by being dropped from a height or subjected to severe impact. If in doubt, return it to us or your distributor for testing and repair.

Disposal of Equipment: It is recommended that any external equipment that is not required should be returned to Finetech Medical.

6. Troubleshooting

If you think that the *Controller*, *Transmitter Lead* or the *Transmitter Block* is not working properly, you should first make sure the *Controller* has enough charge by pressing and holding down Button **1** to see the remaining battery capacity.

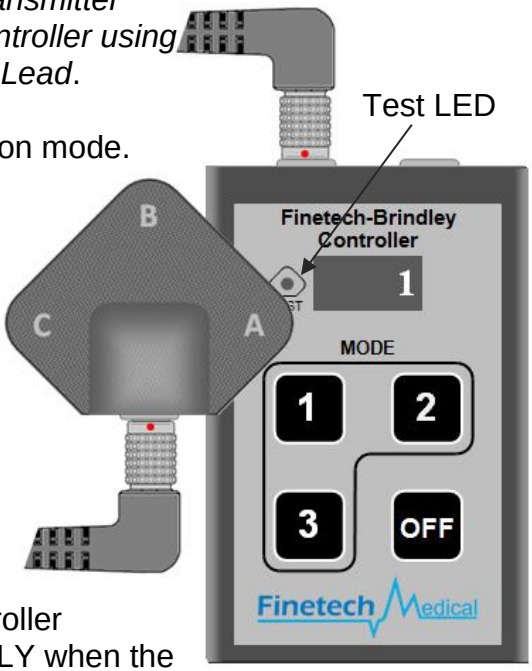
If the *Controller* is sufficiently charged, you can perform a functional test on the external equipment using the green test light (LED) on the front of your *Controller*.

1) Connect the *Transmitter Block* to the *Controller using the Transmitter Lead*.

2) Start a stimulation mode.

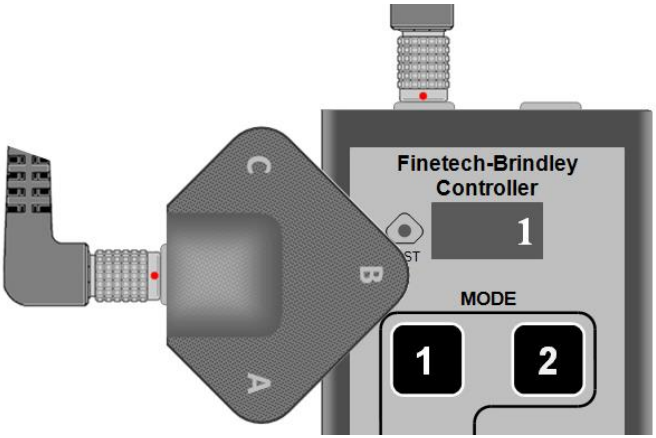
3) Move the *Transmitter Block* over the Test Symbol on the front of the *Controller as shown*. If working, the green LED test light will flash.

   Note: The Controller transmitting ONLY when the mode number is flashing.

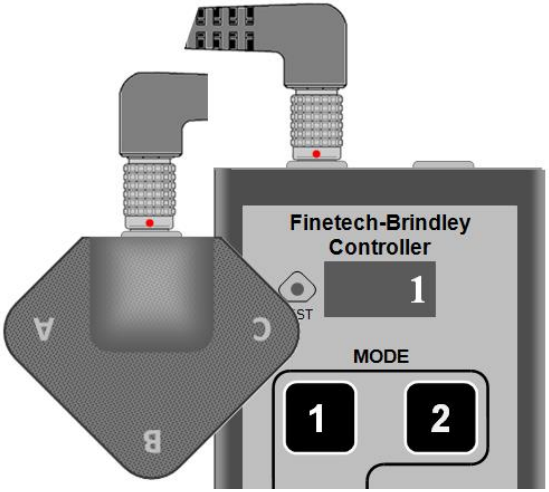


Testing Channel - A

Remember that it may take several seconds for the LED test light to begin flashing; depending on the On and Off time periods that have been programmed. If you do not see a flashing LED light, one of the external components is not working properly. Contact Finetech Medical or your local distributor to organise repair or replacement.



Testing Channel - B



Testing Channel - C

Error codes: If there is a fault with the Controller, it will stop stimulating and the display will show an *Error* code.

Error Code	Action

Flat or Low Low battery	Put the *Controller* on charge.
E 2 Low output current	Check that the *Transmitter Lead* is not damaged and is properly connected to the *Transmitter Block* and *Controller*.
E 4 High output current	Your Clinician will need to reduce the amplitude, pulse width or frequency of stimulation. If the fault persists please return the *Controller* to Finetech Medical or your local distributor.
E 3, 5, 6, 7, 8 Internal faults	If any of these error codes appear, switch off the *Controller*, leave for 10 seconds and try again. If the fault persists please return the *Controller* to Finetech Medical or your local distributor.
E 10	Charging fault. Return the *Controller and Charger* to Finetech Medical or your local distributor.

If you have any questions or concerns with the *Finetech-Brindley SARS* or need assistance, call your doctor, contact us or your distributor.

Display Flashes Low: The display flashes 'Low' during stimulation indicating the battery is getting Low. This does

not affect the stimulation output and you can continue to use it but the controller needs to be re-charged at the next opportunity.

If You Cannot Empty Your Bladder: If you think that a large amount of urine is left in your bladder after trying to empty it, you should use an alternative or back-up method to empty your bladder (such as catheterisation) until the problem has been corrected. You should also contact your doctor immediately.

Drying: If the *Controller*, the *Transmitter Block* or the *Transmitter Lead* is accidentally dropped in water, they should be carefully dried before using again. Unplug the *Transmitter Lead* at both ends, and then wipe all parts with a dry cloth or tissue. Then allow to air dry for at least eight hours.

Check that the plugs and sockets are dry before reconnecting the *Transmitter Lead*. Do not use heat or hot air such as a hair dryer, as this may damage the Controller.

Other Problems: If you have any other problems with your *Finetech-Brindley SARS*, please contact Finetech Medical or your local distributor.

Other Reasons to Contact Your Doctor: If you suspect that you have a urinary tract infection you should contact your doctor. Signs and symptoms of a urinary tract infection include one or more of the following: fever; general tiredness and weakness; strong odour, cloudy, or bloody urine; and increased leaking of urine.

7. Warranty Information

Finetech Medical Limited warrants the external components of the *Finetech-Brindley SARS* free from defects in workmanship and materials for two years from the date of implantation. Finetech Medical Limited will repair or replace, at its discretion, any product found to be defective within the warranty period. This warranty does not apply to any product which has been damaged due to misuse, or that was repaired or altered other than by the manufacturer.

8. Information for Healthcare Professionals

This section contains important information for all healthcare professionals dealing with users who have a *Finetech-Brindley SARS*. Please read it carefully when considering treatment options.

Implantation Certificate: An Implantation Certificate is issued to the patient with every *Finetech-Brindley SARS* and lists information regarding:

- The Patient
- Place of Implantation
- System Details
- Physician Remarks
- Contact Details

Please read it carefully when considering treatment options, particularly if they involve any of the following:

- X-ray
- Ultrasound
- Magnetic Resonance Imaging (MRI)
- Therapeutic ultrasound
- Shortwave and microwave therapeutic diathermy
- Microwave therapy
- Electrocautery instruments

- ENT(ear, nose, throat) or dental procedures

X-rays and Ultrasound: *X-ray*s and *ultrasound* have not been reported to affect the function of the implanted *Receiver* or *Electrodes*. However, the doctor's ability to see the tissue behind the implants may be blocked.

***Magnetic Resonance Imaging (MRI)*:**

MR Conditional

- **Preparation for Scanning:**
  - The function of each electrode should be tested prior to MRI scanning. Imaging a patient with a broken implanted lead may result in excessive heating around the break in the lead. This potential risk of scanning a patient with a broken implanted lead would have to be considered on a case-by-case basis against the benefits of scanning.
  - Patients should be advised to empty their bladders prior to MRI scanning by testing the stimulated response of each channel.
  - The patient's external equipment must not enter a room where an MRI scanner is located. The implant only operates when coupled with the external equipment.
- **Scanning Conditions:**
  MRI scanning can be performed on individuals implanted with the *Finetech-Brindley SARS* **ONLY** under the following conditions:
  - A 1.5T (Tesla) scanner with a spatial gradient of 450 gauss/cm or less can be used (this covers the majority of *MRI* scanners used today).
  - Scanners over the 1.5T (Tesla) level can be used.

- The imaging mode used must not load the patient with an average Specific Absorption Rate (SAR) of more than 1.1W/kg for a scan of 30 minutes duration.
- Unconventional or non-standard *MRI* modes must not be used.
- The use of Transmit Coils other than the scanner's Body Coil or a Head Coil is prohibited.

- **During Scanning:**
  - Patients must be closely monitored during scanning and asked to report any unusual sensations or muscle activity.
- **Image Quality:**
  - If the location to be scanned is in the same area or relatively close to the position of the implanted receiver, artefacts may compromise the quality of the image.
  - In non-clinical testing, the worst case image artefact caused by the device extends approximately 124mm^2 from the implantable receiver when managed with a gradient echo pulse sequence and a 1.5T MRI system.
  - In non-clinical testing, the worst case image artefact caused by the device extends approximately 255mm^2 from the implantable receiver when managed with a spin echo pulse sequence and a 1.5T MRI system.
- **After Scanning:**
  - The implant should be checked for correct function with the external equipment, outside of the scanning area.

Therapeutic ultrasound: *Therapeutic ultrasound* (physical therapy) should not be performed over the area

of the implanted *Receiver* or *Electrodes* since it may damage the *Finetech-Brindley SARS*.

Short wave and microwave therapeutic diathermy: *Short wave and microwave therapeutic diathermy* as used by physiotherapists etc should not be used in patients implanted with the *Finetech-Brindley SARS*.

Microwave therapy: *Microwave therapy* should not be performed over the area of the implanted *Receiver* or *Electrodes* since it may damage the *Finetech-Brindley SARS*.

Electrocautery instruments: The implanted components of the system should not be touched with ***electrocautery instruments*** (instruments used during surgery to cut tissue or to stop bleeding). Electrocautery should not be used within 1cm of the metal electrode contacts.

Ear, Nose, Throat or Dental procedures: Antibiotics may be required following ENT, dental or other “high risk” medical procedures in order to prevent infection that could spread to the implanted *Finetech-Brindley SARS*.

Contra-indications

Cardiac pacemakers

Not to be used by persons fitted with a cardiac pacemaker.

External defibrillation

The effect of external defibrillation (devices which deliver an electrical shock to the heart when it has stopped beating regularly) on the *Finetech-Brindley SARS* is unknown.

Flammable anaesthetic mixture

The *Finetech-Brindley SARS* is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Warnings and Cautions

Epilepsy

Use of the *Finetech-Brindley SARS* is not advised for users with poorly controlled epilepsy. Stop use immediately and consult your doctor if you experience any epileptic symptoms.

Pregnancy

The safety of using the *Finetech-Brindley SARS* during pregnancy or birth has not been established.

Alternative methods of emptying your bladder

It is essential that you or your carer be familiar with an alternative method of emptying your bladder (such as catheterisation). If you have any problems with your *Finetech-Brindley SARS*, you should be prepared to use this alternative method.

Damage from liquids

Do not allow the external parts of your *Finetech-Brindley SARS* to come into contact with water as this may cause damage to the system. Please contact us or your distributor if you get any of the external parts wet.

Implant care

Care should be taken not to put undue pressure on the *Implanted Receiver* and *Electrode Assembly*.

9. Information for Patients

This section contains important information regarding the safe use of the *Finetech-Brindley SARS*. Please read it carefully.

You MUST notify all healthcare professionals (doctor, physiotherapist, dentist or other healthcare specialist) that you have a *Finetech-Brindley SARS* and refer them to section 8 Information for Healthcare Professionals of this manual BEFORE undergoing any surgical or therapeutic procedures. Your external Controller, Transmitter Lead and Transmitter Block must not enter a room where an MRI scanner is located.

Electromagnetic Compatibility (EMC)

Your *Finetech-Brindley SARS* needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Notes for Surgeons and Physicians. Please read this section carefully.

The Transmitter Block and Implant receiver are tuned to a resonant frequency of 7 and 9 MHz and may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements. Exposure

to environmental or incidental sources of radio frequency energy near 7 and 9 MHz may result in a sensation of stimulation.

Portable and mobile RF communications equipment can affect your *Finetech-Brindley SARS*. It is important to notify your doctor if you experience unintended stimulation when your *Finetech-Brindley SARS* is not in use. While there have been no reports of system activation or malfunction due to electromagnetic interference (such as from retail anti-theft detectors, airport metal detectors, or other electronic devices), even after testing, it is not possible to guarantee that this will not occur. If possible, note when and where the stimulation occurred and report this information to your doctor and Finetech Medical.

In general, the *Finetech-Brindley SARS* can affect and should not be used in conjunction with other electrically powered devices. If it is suspected that it is causing interference with any other electrical device, then either move the Controller away from the device, or alternatively switch the device off for a period of time if it is practical to do so.

Use of accessories other than those supplied for the system may result in increased emissions or decreased immunity of the *Finetech-Brindley SARS*.

Skin condition

Check your skin daily for any signs of redness, swelling, or sores especially in the areas where the *Implanted Receiver* and *Electrode Assembly* are located. Call your doctor immediately if you notice any change in your skin condition.

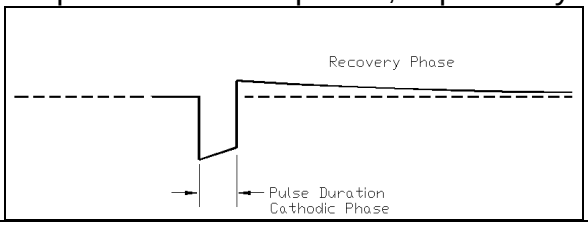
Change in health or stimulation effectiveness

It is important to stay healthy and to notify your doctor immediately if you become sick, get an infection, experience any unusual sensations or muscle contractions, or notice any change in how your bladder or bowel stimulation works.

Flying with the *Finetech-Brindley SARS*

The *Controller* should only be powered up whilst you are emptying your bladder or bowel. As the system is only used for these functions, there should be no requirement to use it during take-off and landing phases of flight.

10. Technical Specification

Implantable Receiver:
Output channels: Up to 3 independent outputs
Output waveform: Biphasic, capacitively coupled waveform 
Operating frequency: Channel A: 9MHz, Channel B: 7MHz, Channel C: 9MHz.
Overall dimensions: 80 x 50 x 7mm
Mass: 20g
Packaging: 134°C steam sterilised in double bag.
Output parameters: Pulse amplitude: up to 40V (5V steps). Pulse duration: 0-720µs (4µs steps). Pulse frequency: 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 26, 28, 30, 32, 35, 38, 42, 47 and 53 Hz.

Expected service life: 10 years.

Implantable Electrode Assembly:
Dimensions: Length 50cm, Ø2mm cables.
DC Resistance: 100 Ohms per conductor.
Mass: 6g
Packaging: 134°C steam sterilised in double bag.
Expected service life: 10 years.

Controller (BS100, Model CPC2):
Battery type: Li-Ion 7.4V (nominal) Operation time: up to 8 hours (typical stimulation settings) Cycle life: >300 cycles.
Charging time: Up to 3 hours.
Dimensions: 100 x 65 x 25 mm
Mass: 150g
Output parameters: Driver voltage 0-40V (5V steps). Pulse duration 0-720µs (4 µs steps). Pulse frequency: 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 26, 28, 30, 32, 35, 38, 42, 47 and 53 Hz.
Expected service life: 10 years.

Transmitter Cable (BS101):
Dimensions: Length=600mm
Mass: 50g
Expected service life: 2 years.

Transmitter Block (BS102):
Carrier frequency: Channel A: 9MHz, Channel B: 7MHz, Channel C: 9MHz
Dimensions: 50 x 50 x 21mm

Mass: 48g
Expected service life: 10 years.

Battery Charger (BS103):
Input: 100-240V AC, 110-250mA, 50-60Hz
Output: 9.6V DC max, 500mA
Mass: 140g
Lead length: 1.5m
Expected service life: 10 years.

Carry Case:
Dimensions: 261 x 175 x 74 mm (L x W x H)
Mass (complete kit): 850g

Storage Conditions
Storage temperature: -10°C to + 55°C Humidity: 0 to 90% Pressure: 70 kPa to 150 kPa

11. Glossary and Graphical Symbols

Functional Electrical Stimulation (FES): A method by which electrical signals provide function to otherwise paralyzed muscles.

Autonomic Dysreflexia: Reflexes from the bladder which can cause a rise in blood pressure.

Detrusor Urinae Muscle: the muscle over the top of the bladder that squeezes the bladder.

Reflex Incontinence: Large unpredictable leakage of urine resulting from a reflex that causes the bladder to contract when there is urine in it.

Stress Incontinence: Small leaks of urine from bending forward or coughing.

Bladder Capacity: The amount of urine that the bladder can hold.

External Urethral Sphincter: A valve at the bottom of the bladder which needs to open for urine to empty out of the bladder.

Extradural: Situated outside the spinal column.

Intrathecal: Introduced into the space under the membrane which covers the spinal cord.

Rhizotomy: The selective cutting of nerves.

Sacral Nerves: Nerves which travel through a lower part of the spine called the sacrum.

Stimulation: Electrical signals which cause the contraction of muscles.

Frequency: Expressed as number of stimulation pulses per second or Hertz (Hz).

EMC: Electromagnetic Compatibility

Symbols Key

Symbol	*Description*
	Read instructions before use.
	Caution: Consult accompanying documents
	Contra-indications.
	Important note.
CE 2797	CE Mark and registration number of the Notified Body for Finetech Medical Ltd.
	Type BF Electrically Isolated (Floating) Applied Part (protection against electric shock).
	Class II equipment.
IP22	Degree of protection against solids (touch by fingers >12.5mm) and ingress of water (dripping < 15 degrees from vertical).
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.
REF	Catalogue number of the unit.
SN	Serial number of the unit.
	MR Conditional

12. Index

Notes: