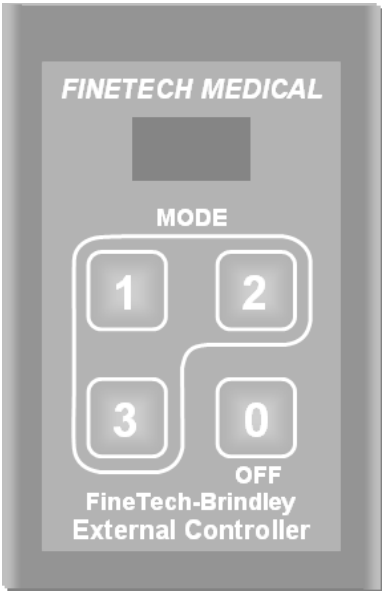
Finetech-Brindley Bladder System

USER GUIDE



June 2020

This guide MUST be read and understood by all relevant persons prior to using the Finetech-Brindley Bladder System.

Need help?

If you need advice about any aspect of your *Finetech-Brindley* bladder system 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*

Warnings and Cautions

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

Important Note

This symbol appear next to points to remember about your *Finetech-Brindley*

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

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CE 2797

Authorisation first issued:
10th April, 1996

Table of Contents

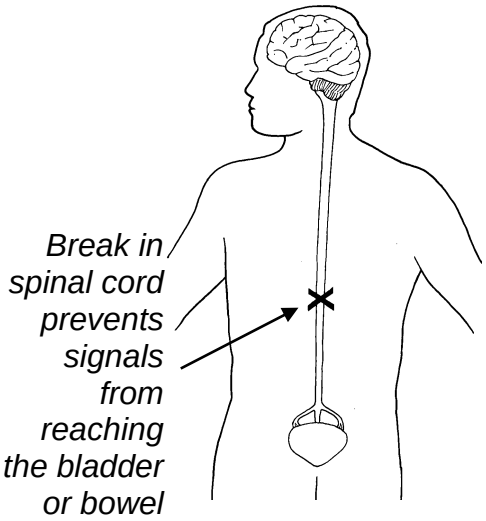
1. Introduction

This *User Guide* provides information for the safe use of your *Finetech-Brindley;* for you, your family, your caregivers and your doctor/surgeon/clinician.

2. How does the *Finetech-Brindley* Work?

Functional Electrical Stimulation (FES) is a method used to enable otherwise paralysed muscles to function. The *Finetech-Brindley* 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 *Finetech-Brindley* 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 *Finetech-Brindley* 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?

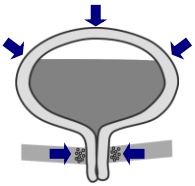
The nerves that connect the spinal cord to the bladder and bowel are located at the lower end of the spine in an area called the “sacrum”. The nerves that exit the spinal cord through the sacrum are called ***sacral nerves***.

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

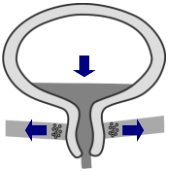
Two things must happen for a person to empty their bladder. First, the pressure inside the bladder must increase. The muscle which squeezes the bladder is known as the ***detrusor urinae***. Second, the valve at the base of the bladder, the ***external urethral sphincter,*** must open to allow the urine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

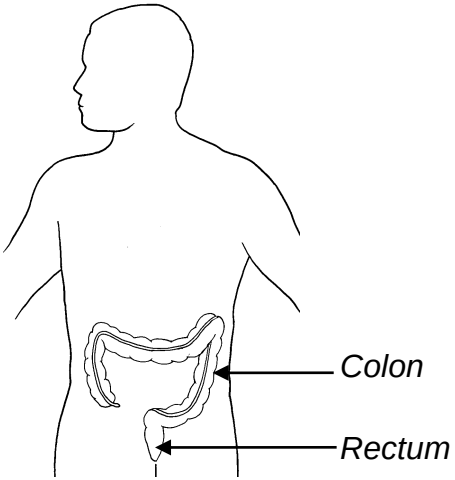
Leakage of urine, known as incontinence, can be caused in several ways. A common problem in spinal cord injury is large unpredictable leaks. This results from a reflex that causes the bladder to contract when there is urine in the bladder, called ***reflex incontinence***. The *rhizotomy* removes these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

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

How Does the *Finetech-Brindley* 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.

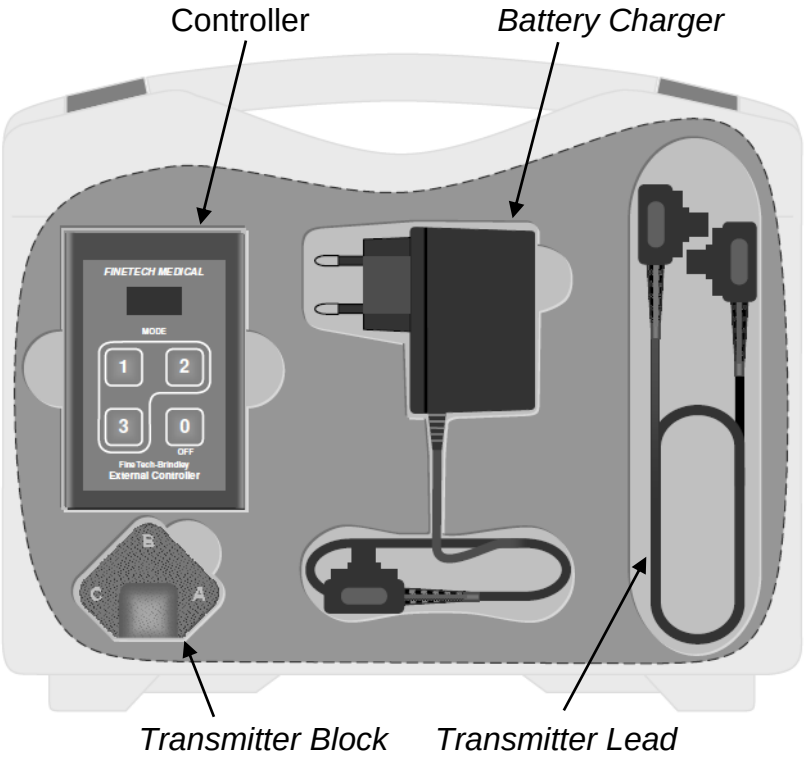


3. Components of the *Finetech-Brindley*

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

3.1 *External Components*

The external components allow you to operate and control the *Finetech-Brindley*. The external components consist of:

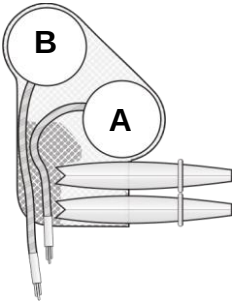


Controller	1off
Transmitter Block	1off
Transmitter Lead	2off
Battery Charger	1off
Hard Case	1off
User Guide	1off
Implant Certificate	1off

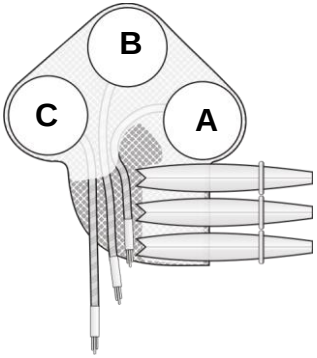
3.2 *Implanted Components*

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.

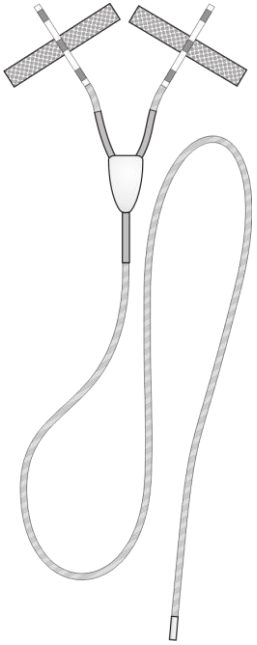


2-channel Receiver

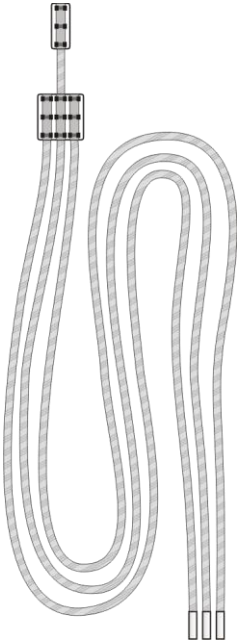


3-channel Receiver

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 intradural and an extradural electrode assembly are shown:



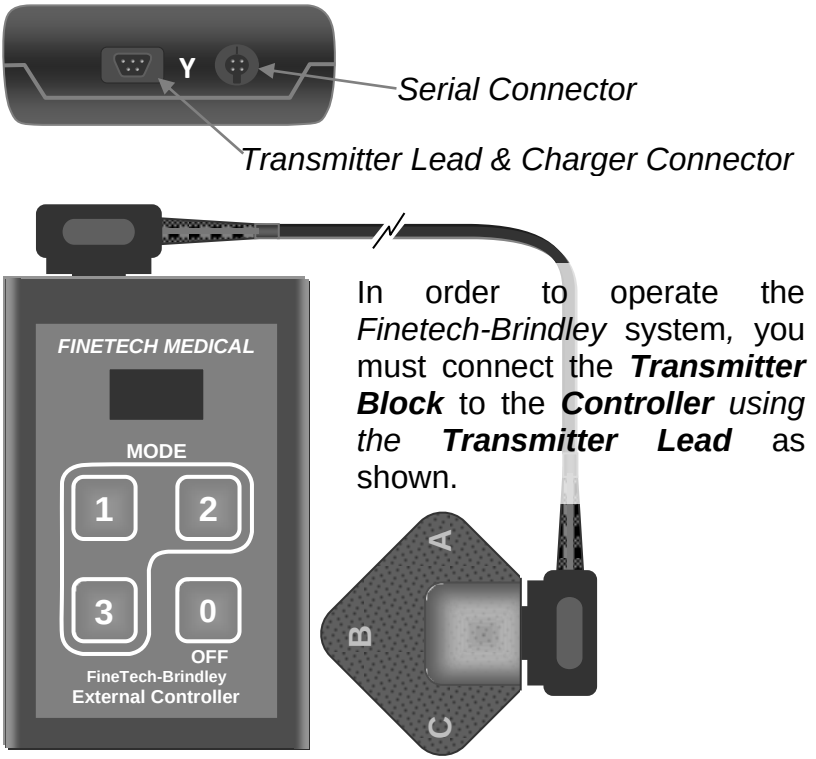
Extradural



Intradural

4. Using the *Finetech-Brindley*

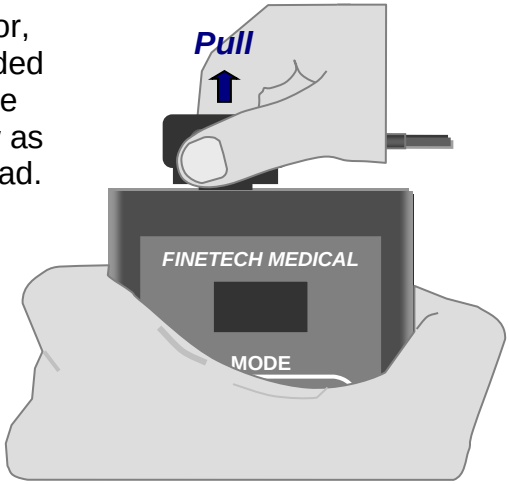
To use the *Finetech-Brindley* effectively, you will need to have an approximate **"schedule"** for using the device to empty your bladder. For example, you might use it in the morning, at lunch time, in the mid afternoon, in the evening, and before you go to bed. Similarly, you will need to establish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



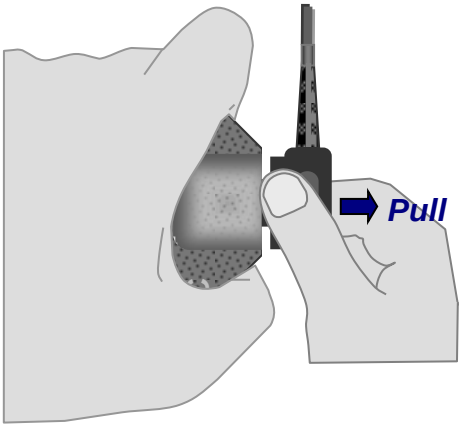
In order to operate the *Finetech-Brindley* system, you must connect the ***Transmitter Block*** to the ***Controller*** *using the* ***Transmitter Lead*** as shown.

To unplug a connector, always pull the moulded body of the plug in the direction of the arrow as shown and not the lead.

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



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

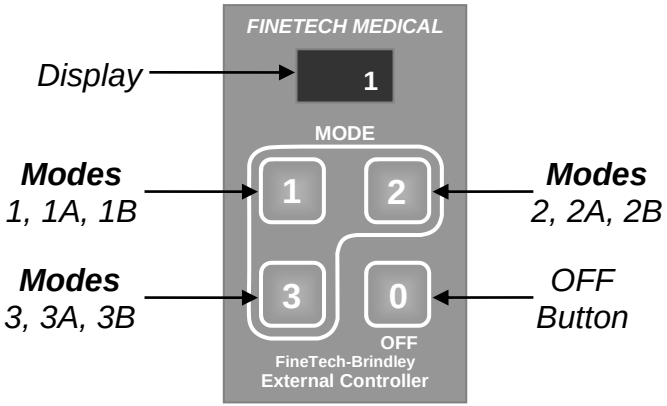


4.1 *Operating Modes*

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 *Finetech-Brindley* 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.*



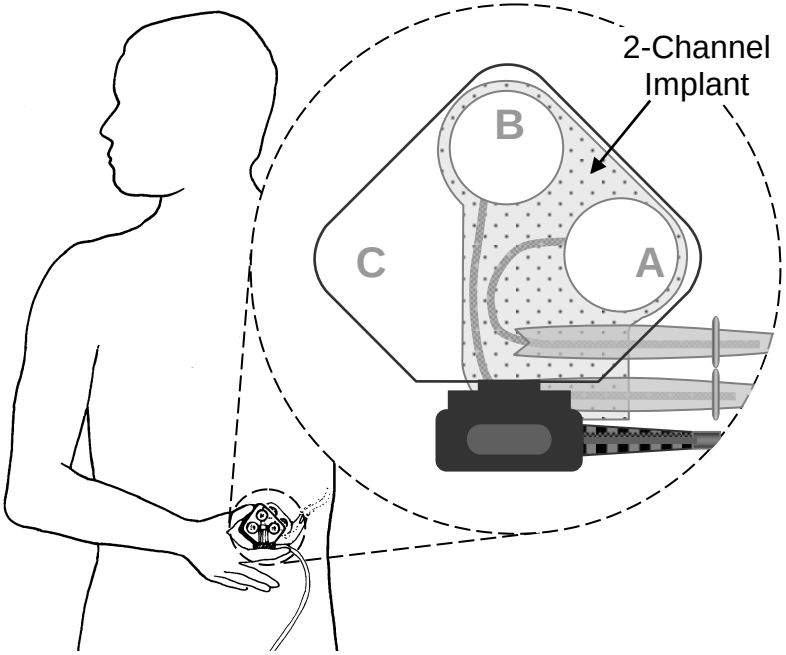
You select which Mode to use by pressing the corresponding Button. You cannot select a Mode which has not been set up for you. If you only use the stimulator for function 1, your clinician should have disabled Buttons **2** and **3**.

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.

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. *Refer to HELPFUL HINTS below for help in positioning.*

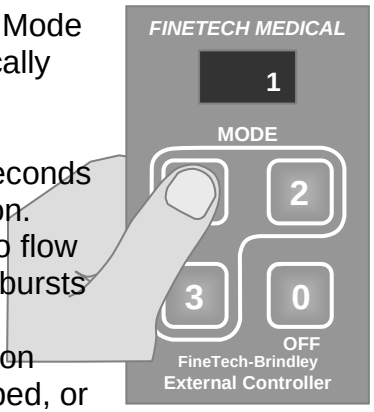


1. Place the *Transmitter Block* accurately over the *Receiver*.

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.

2. Select the appropriate Mode on the *Controller* (typically Mode 1).

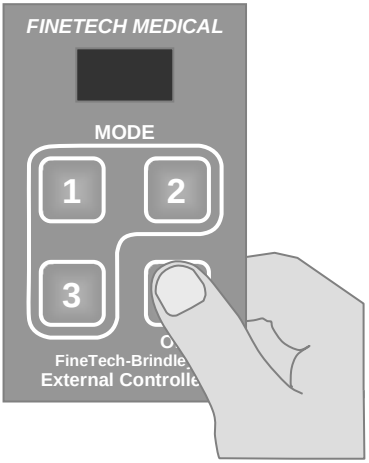
Stimulation starts a few seconds after you release the button. You should expect urine to flow out in spurts between the bursts of stimulation. Keep the *Transmitter Block* in position until the spurts have stopped, or nearly stopped.



Select Mode 1

3. Press Button **0** to stop the stimulation and turn the *Controller* OFF.

If you forget to turn the *Controller* OFF, the unit will eventually switch off automatically. This may take a long time, though, and waste the battery charge. Your clinician can adjust the amount of time that the unit will continue stimulating before switching off.



Stop stimulation

Note

You may need to turn the Controller OFF (by pressing ***'0'****), 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 system 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.

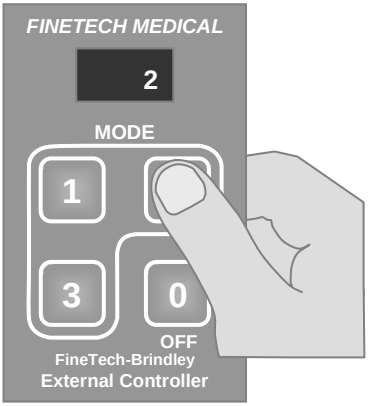
4.3 *Bowel Emptying*

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).

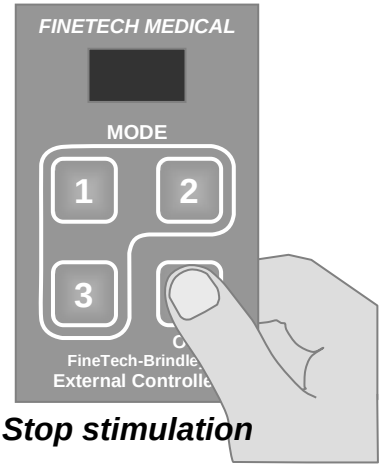
Typically, up to five minutes of stimulation is needed to empty the bowel. If stimulation does not empty the bowel effectively by itself, it may be necessary to assist stool removal manually.



Select Mode 2

3. Press Button **0** to stop the stimulation and turn the *Controller* OFF.

If you forget to turn the *Controller* OFF, the unit will eventually switch off automatically. This may take a long time, though, and waste the battery charge. Your clinician can adjust the amount of time that the unit will continue stimulating before switching off.



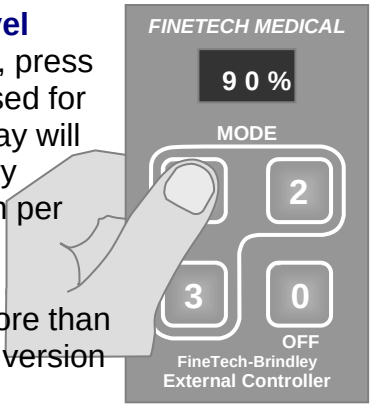
Stop stimulation

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* 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.



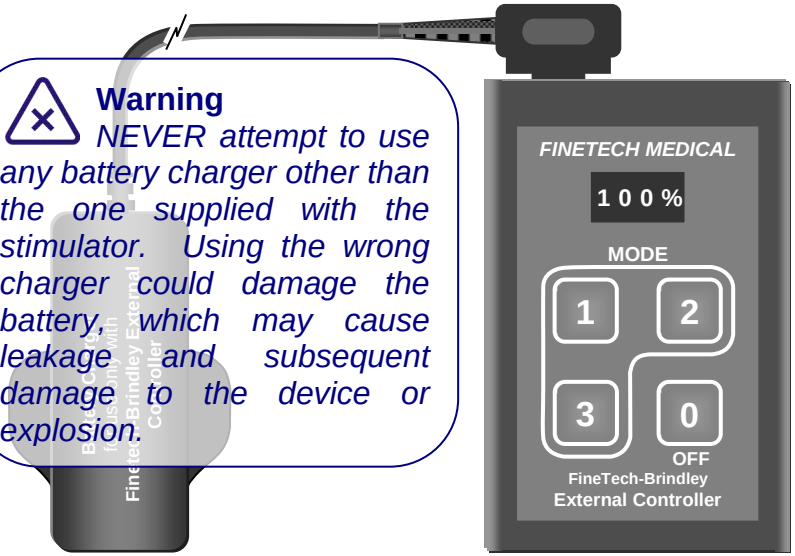
Pressing the Button for more than 4 seconds will display the version of software.

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 the warning message **'Low'**. Some while later, it will display an error message, **'Err1'**, and then switch off.

The exact level at which the battery-low warning is given depends on the level of stimulation that has been set up for you individually, and may be different for each Mode. If the stimulation levels are high, you may need to recharge the battery even though the charge indicator indicates that the battery is not yet depleted.

How to charge: To charge the battery, simply plug the *Charger* into a mains outlet and connect the output plug into the *Controller*. You will have to first disconnect the *Transmitter Lead.* 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.



Warning

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

While the battery is charging, the display on the *Controller* will show the approximate level in 10% steps. When it shows '100%', it is approaching 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. The controller will switch-off when the charge cycle is completed.

When to charge: You can charge the battery whenever you like, although it is recommended to charge around 70%. Following this charging routine will prolong the life of the battery.

The internal battery should only be used under the following conditions:

Normal use	-10°C to +55°C
Charging	0°C to +45°C

5. Care and Maintenance

Care of the system: The *Transmitter Lead* can be damaged internally by rough handling. Never kink it or wrap it tightly around the *Controller.* When unplugging, always pull the moulded connector rather than the lead.

Do not wash or submerse the *Controller* for cleaning. The outside cover 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.

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.

Repair and Maintenance: 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.

Storage and Handling: The equipment should be transported and stored within the following environmental conditions:

Temperature	-10°C to + 55°C
Humidity	0 to 90%
Pressure	70 kPa to 150 kPa

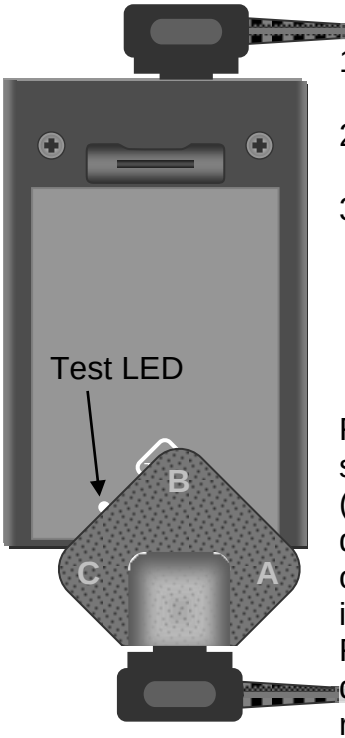
We recommend that you keep your *Finetech-Brindley* parts and/or spares within the *Hard Case* provided. Like any electronic equipment, the *Controller* should not be exposed to excessive temperatures. Do not leave it on a radiator or in a car in direct sunshine, even in the glove compartment. Although 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 back of your *Controller*.



1) Connect the *Transmitter Block* to the *Controller*.
2) Put the *Controller* into a stimulation mode.
3) Move the *Transmitter Block* over the Test Symbol on the back of the *Controller*. If working, the green test light (LED) will flash.

Remember that it may take several seconds for the test light (LED) to begin flashing. If you do not see a flashing light (LED), one of the external components is not working properly. Contact Finetech Medical or your local distributor to organise repair or replacement.

If your system seems to work sometimes but not other times, check the *Transmitter Lead*. You may have a loose connection.

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

Error Code	*Action*
Err1 Battery very low	Put the *Controller* on charge.
Err2 Low output current	Check that the *Transmitter Lead* is not damaged and is properly connected to the *Transmitter Block* and *Controller*.
Err4 Stimulation too high	Your Clinician will need to reduce the amplitude, pulse width or frequency of stimulation.
Err 3, 5, 6, 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.
Err 7 Internal faults	This can be caused by switching too quickly between stimulation modes. If this error code appears, 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.
Err 9	This indicates an abnormal shutdown. Charge the controller and try again. If the fault persists please return the *Controller* to Finetech Medical or your local distributor.

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

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 stimulator.

Other Problems: If you have any other problems with your *Finetech-Brindley*, 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 Ltd. warrants the external components of the *Finetech-Brindley* free from defects in workmanship and materials for two years from the date of implantation. Finetech Medical Ltd. 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*. Please read it carefully when considering treatment options.

Implantation Certificate (FTM081): An Implantation Certificate is issued to the patient with every *Finetech-Brindley* 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)*:** Before 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.

***MRI* Scanning Conditions:** *MRI* scanning can be performed on individuals implanted with the *Finetech-Brindley* **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 *MRI* Scanning: Patients must be closely monitored during scanning and asked to report any unusual sensations or muscle activity.

***MRI* Quality:** *MRI* quality may be compromised if the area of interest is in the same area or relatively close to the position of the implanted *Receiver*.

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*.

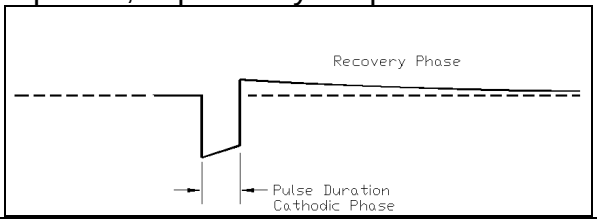
Short wave and microwave therapeutic diathermy: *Short wave and microwave therapeutic diathermy* as used by physiotherapists etc should not be used in patients implanted with the *Finetech-Brindley*.

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

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*.

Technical Specification

Parameters	Specifications
Implantable Receiver:	
Output channels	Up to 3 independent outputs
Output waveform	Biphasic, capacitively coupled waveform 
Operating frequency	Channel A – 9 MHz Channel B – 7 MHz Channel C – 9 MHz
Overall dimensions	80 x 50 x 7mm
Mass	8g
Packaging	1 Receiver, steam sterilised in double bag
Implantable Electrode Assembly:	
Dimensions	Up to 3 460mm, Ø 2mm cables with associated electrodes
Mass	6g
Packaging	Electrode Assembly, steam sterilised in double bag
Controller (Model CPC1):	
Battery type	Li-Ion 7.4V (nominal) Battery life up to 8 hours (typical stimulation settings)
Charging time	Up to 3 hours

Dimensions	100 x 65 x 25 mm
Mass	150g
Output parameters	Driver voltage 0-40V Pulse duration 0-800µs Pulse frequency 2-105Hz
Transmitter Cable:	
Dimensions	760mm
Mass	24g
Transmitter Block:	
Carrier frequency	Channel A – 9MHz Channel B – 7MHz Channel C – 9MHz
Dimensions	75 x 50 x 32mm
Mass	30g
Battery Charger (Models BSD196, 197 and 198):	
Input	100-240V AC, 250mA, 50-60Hz
Output	9.5V DC max, 500mA
Mass	100g
Lead length	1.6m
Hard Case:	
Dimensions	80 x 70 x 45 mm
Mass – complete kit	820g

9. Important Information

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

If you need to go to the doctor, physiotherapist, dentist or other healthcare specialist for any kind of therapy or procedure, it is essential that you make him/her aware of your implant and that you refer them to the section; Information for Healthcare Professionals.

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* is unknown.

Flammable anaesthetic mixture

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

Warnings and Cautions

Healthcare Professionals

You MUST notify all healthcare professionals (including your dentist) that you have a *Finetech-Brindley* and refer them to this manual BEFORE undergoing any surgical or therapeutic procedures.

Epilepsy
Use of the *Finetech-Brindley* Bladder Control System 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* 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*, you should be prepared to use this alternative method.

Damage from liquids
Do not allow the external components, cables, and attachments of the *Finetech-Brindley* to come into contact with water as this may cause damage to the system. Please contact us or your distributor if you get the *Finetech-Brindley* wet.

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

Important Note

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*

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.

Unintended stimulation

It is important to notify your doctor if you experience unintended stimulation when your *Finetech-Brindley* 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.

Electrical interference

In general the *Finetech-Brindley* 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.

10. 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.

Intradural: Situated within 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 cycles/second or Hertz (Hz).

Symbols Key

Symbol	*Description*
	Attention – Please read the manual before using.
	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. A class of protection against electric shock providing a high degree of protection regarding leakage currents utilising an isolated (floating) Applied Part.
	Class II equipment.
IPX4	Degree of protection against ingress of water (splash-proof).
	Not for disposal by municipal waste collection systems. Waste to be sorted and returned to manufacturer for recycling.
REF	Catalogue number of the unit.
SN	Serial number of the unit.

11. Index

Notes: