Finetech-Brindley Bladder System

PROGRAMMING INSTRUCTION MANUAL

(Section 1 - FTM063 – Surgical Procedure Manual)

Section 2 - FTM062 – Programming Instruction Manual

(Section 3 - FTM1055 – Repair Surgery Instructions)

This programming instruction manual covers methods of programming the digital controller.

June 2020

This manual MUST be read and understood by all relevant persons prior to using the Finetech-Brindley bladder system and should be read in conjunction with the other sections.

Section 2: PROGRAMMING INSTRUCTION MANUAL

Need help?

If you need advice about any aspect of the *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 Programming Instruction Manual

Contra-indications
These notes describe situations where you should not use the *Finetech-Brindley*

Warnings and Cautions
Make sure that you understand these notes before using the *Finetech-Brindley*

Important Note
This symbol appear next to points to remember about the *Finetech-Brindley*

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

Finetech Medical Ltd
13 Tewin Court
Welwyn Garden City
Hertfordshire AL7 1AU
United Kingdom
☎ +44 (0)1707 330942
🖷 +44 (0)1707 334143
🖰 www.finetech-medical.co.uk

$C\!E$ 2797

Authorisation first issued:
10th April, 1996

1. INTRODUCTION

This manual details the programming options for the Finetech-Brindley digital *Controller*.

This **Programming Instruction Manual** is intended to be read in conjunction with the **User's Guide** (FTM061). It describes the functions of the adjustable parameters, and explains how to alter them. It does not offer any advice on the choice of parameter values for individual patients; this relies on clinical judgement which is beyond the scope of this manual.
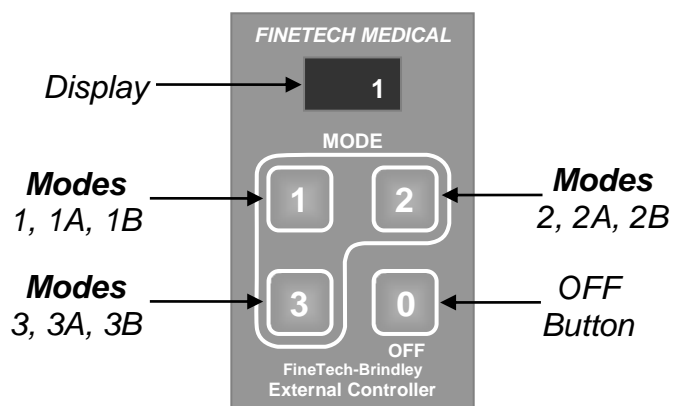
The Finetech-Brindley *Analogue Controller* is no longer manufactured as it has been replaced by the *Digital Controller* (Model BSC195). If you have an *Analogue Controller* that needs setting up, please contact Finetech Medical for assistance.

1.1 Stimulation Parameters

The action of the *Controller* can be varied within wide limits by altering the stimulation parameters. You can alter the pulse width and frequency of stimulation on channels **A**, **B** and **C** independently, as well as the amplitude and the on-time and off-time of the stimulation cycle. In addition, you can choose to start with a burst of stimulation at different settings from the main phase, and can specify a maximum duration after which the *Controller* will switch off automatically. It is also possible to arrange for pulses at a higher frequency to be interleaved between the main pulses.

1.2 Operating Modes

There are three primary modes **'1'**, **'2'** and **'3'**; typically bladder voiding, bowel evacuation and penile erection. Each **'mode'** is controlled by a complete set of parameters independently of all the other modes. Up to nine different modes can be programmed. Additional modes are **'1A'**, **'1B'**, **'2A'**, **'2B'**, **'3A'** and **'3B'**. Modes which the patient will not use can be made unavailable or 'hidden'. A hidden mode is one which the user cannot select by pressing the buttons.

Display → 1

MODE

Modes 1, 1A, 1B → 1

Modes 2, 2A, 2B → 2

Modes 3, 3A, 3B → 3

0 OFF Button

FINETECH MEDICAL
FineTech-Brindley
External Controller

2. PARAMETERS

This section describes each parameter in turn. The left column shows the name followed by the abbreviation used on the display on the *Controller*. The right column describes the function, and gives the upper and lower limits and the adjustment resolution.

2.1 General Parameters

Parameters	Display	Adjustable Value
Usable	Use	Whether a mode can be accessed by the user. By setting this to 'No' you can ensure that users cannot access stimulation modes that have not been set up for them. Options; 'Yes' or 'No'
Limit	Lim	The time (in seconds) from the start of the main stimulation until the stimulator switches itself off. (The user may still switch off at any time by pressing the '0' button). The value 0 indicates that there is no time limit; the stimulator will continue until the user switches it off or until the battery is exhausted. Minimum 10 s Maximum 2500 s (or unlimited (shown as '0') Increment 10 s

Parameters	Display	Adjustable Value
On-time	On	The period of time (in seconds) within each cycle for which the output pulses are being applied. Also known as the 'mark' time. Minimum 0.0 s Maximum 51 s Increment 0.2 s Note: If 'Off-time' is zero then this parameter is ignored.
Off-time	Off	The period of time (in seconds) within each cycle for which the output pulses are not being applied. Also known as the 'space' time. If 'Off-time' is zero, there is no cycling and the stimulation is applied continuously. Minimum 0.2 s or 0 for continuous stimulation Maximum 51 s Increment 0.2 s
Amplitude	Amp	The amplitude of the output pulses delivered on all output channels during the main stage of stimulation. Values 1, 2, 3 and 4 correspond to outputs of 10, 20, 30 and 40 V. Minimum 1 Maximum 4 Increment 1
Pulse Width	PW A PW B PW C	The width, in microseconds, of the output pulse in the main stage of stimulation. Adjustable for each channel individually. Minimum 0 µs Maximum 800µs Increment 4µs
Frequency	Fr A Fr B Fr C	The pulse repetition frequency, in Hertz, in the main stage of stimulation. Adjustable for each channel individually. Minimum 2 Hz Maximum 105 Hz Increment Variable
Interleave number (Advanced setting)	I# A I# B I# C	The number of additional pulses to be delivered at equally spaced periods between the main pulses on a particular output channel. Interleaved pulses are entirely optional and would normally be set to zero. Minimum 0 Maximum 2 Increment 1
Interleave pulse width	IP A IP B IP C	The pulse width of the interleaved pulses. Adjustable for each channel individually. Minimum 0 µs Maximum 800 µs Increment 4 µs
Pre-fatigue duration	PDur	The duration, in seconds of the pre-fatigue stage of the stimulation. Pre-fatigue is entirely optional. By setting this parameter to zero, stimulation will proceed immediately to the main stage and all other pre-fatigue parameters are ignored. Pre-fatigue stimulation is always continuous. Minimum 0 s (i.e. no Pre-fatigue stimulation) Maximum 240 s (4 minutes) Increment 1 s

Parameters	Display	Adjustable Value
Pre-fatigue amplitude	PA	The amplitude of the pulses in the pre-fatigue stage of stimulation. Values 1, 2, 3 and 4 correspond to outputs of 10, 20, 30 and 40 V. Minimum 1 Maximum 4 Increment 1
Pre-fatigue pulse width	PP A PP B PP C	The width of the pulses in the pre-fatigue stage of stimulation for each output channel. Minimum 0 µs Maximum 800 µs Increment 4 µs
Pre-fatigue frequency	PF A PF B PF C	The frequency, in Hertz, of the pre-fatigue stimulation for each output channel. Minimum 2 Hz Maximum 105 Hz Increment Variable

2.2 Interleave Pulses

The 'interleave' facility enables you to modify the physiological action of the stimulation by inserting one or two additional pulses between successive normal pulses. The additional pulses may have a different width and amplitude from the normal pulses. You can, for example, alternate pulses of high amplitude and low width with pulses of low amplitude and greater width.

> **Note**
> This facility is available only in the main stage of stimulation, not the pre-fatigue stage.

Limits on Frequency

When single interleave pulses are used, the overall frequency is twice the main frequency; when double interleave pulses are used, the overall frequency is three times the main frequency. Because of internal timing constraints, the interleave facility cannot be used with all available frequencies. If you set the Interleave Number parameter to a number that is not available at the selected frequency, then the actual frequency will be rounded to the next lower frequency which does accommodate the required interleave number. For example, if the main frequency is 30Hz, then the option of having two interleaved pulses is not available. If you request two interleave pulses, then the actual frequency of the main pulses will be rounded down to 28Hz; the overall frequency will be 84Hz. This rounding will be done when the stimulator actually starts running; the stored parameter will not be affected, and will still be displayed as 30Hz.

Power Limit

There is a limit to the total power the *Controller* can deliver to the *Transmitter Block*. The higher frequencies can only be used if the Amplitude and Pulse Width parameters are relatively low.

3. PARAMETER ADJUSTMENT

There are two methods of adjusting the parameters: using the four push buttons on the *Controlle*r, or using a personal computer and running SARLINK.

3.1 Using the Buttons
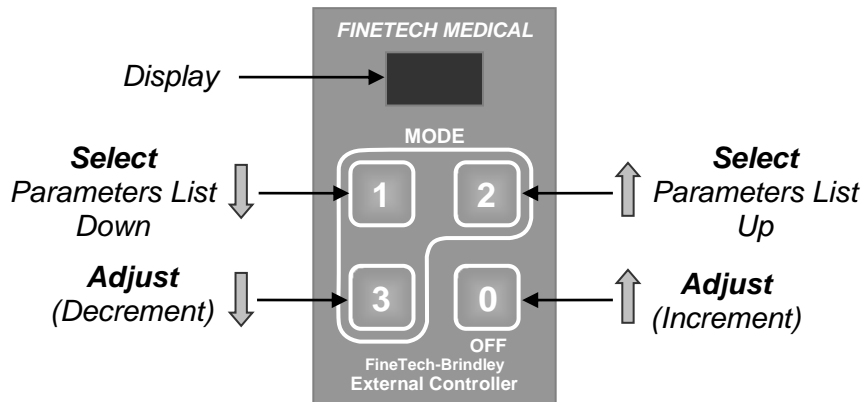
Making an Adjustment

To obtain access to the parameter adjustment facility, it is necessary first to enter the 4-digit access code: and select the Mode that you wish to change.

- Press and hold the OFF button with your right hand
- Enter the 4-digit code with your left hand; do NOT release the OFF button.
- After correct PIN: entry, the display will show **'Mode'**.

Access Code

1332

The access code is used to prevent unauthorised tampering by users as this could result in harmful stimulation. Do NOT disclose this information to the patient.

After correct PIN entry
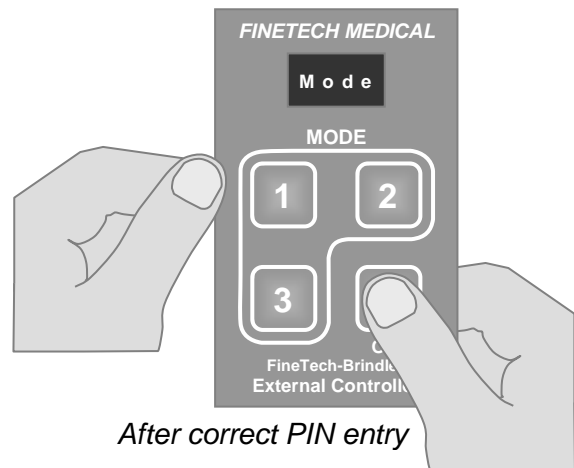
- While continuing to hold the OFF button, press the button for the required mode. (For one of the alternate modes, press the required button two or three times, e.g. press button 1 once for mode 1, twice for mode 1A, three times for mode 1B). Normally the stimulation modes are set as follows:
  - o Mode 1   Micturition
  - o Mode 2   Defaecation
  - o Mode 3   Erection

- The display will then indicate the selected mode

e.g. Select Mode 1
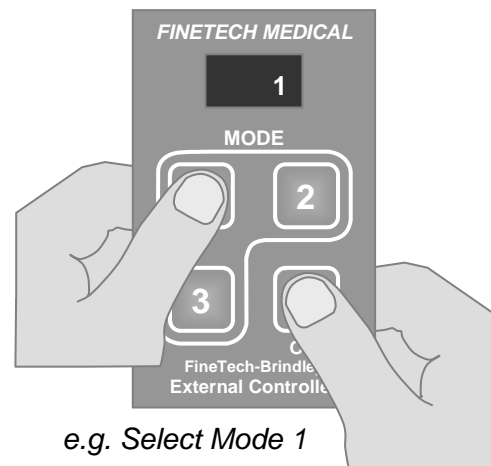
- Release the OFF button
- The display will indicate the selected mode
- Press the OFF button again to confirm that this is the mode you want to adjust stimulation parameters. Any other button will turn the *Controller* off.

Once the Mode has been confirmed, the display will start showing the first parameter.
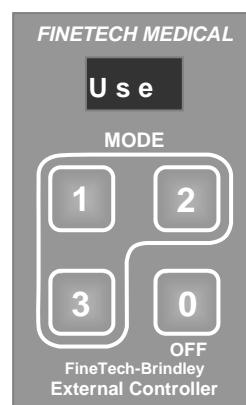
When no button is pressed, the display <u>alternates between the *Parameter* and the *Value*</u> of the selected parameter, at one second intervals.
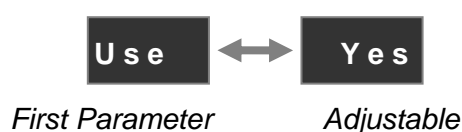
Select a Parameter using buttons 1 or 2; these take you up and down the list of parameters.

Then adjust the value by pressing buttons 3 (Down) or 0 (Up). Continue in this way adjusting as many of the parameters as required. All the buttons will repeat if held down for more than a second.
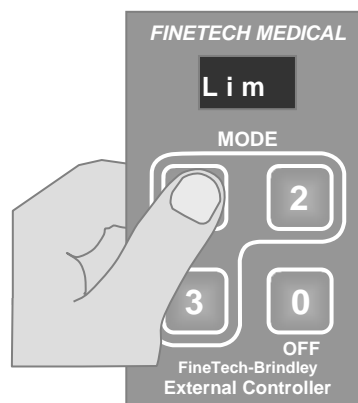
Finally, store the new values and <u>switch off</u> the stimulator by pressing buttons 1 and 2 together.

1ˢᵗ Parameter selected

First Parameter   *Adjustable*

2ⁿᵈ Parameter selected
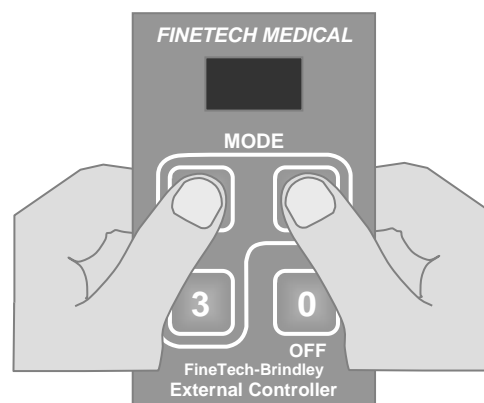
***Switch off** by pressing buttons 1 and 2 together*

Changing Mode

It is not possible to change mode while adjusting the parameters. To access a different mode, you must <u>switch off and then re-enter the 4-digit access code</u>. Since the Off button is now used to alter parameter values, it does not now switch off the stimulator. Instead, you switch off by <u>pressing buttons 1 and 2 together</u>.

Abbreviated Names

Since the display can only show four characters, the names of the parameters are shown in abbreviated form. Here is a list of the abbreviations.

Use	Whether the mode can be accessed by the user
Lim	Main stimulation time limit
On	On-time ('mark')
Off	Off-time ('space')
Amp	Amplitude of main stimulation
PW	*Pulse width of main stimulation
Fr	*Frequency of main stimulation
I#	*Interleave number
IP	*Interleave pulse width
PDur	Pre-fatigue duration
PA	Pre-fatigue amplitude
PP	*Pre-fatigue pulse width
PF	*Pre-fatigue frequency

Parameters marked * are adjustable independently for each output channel.

3.2   Using a PC (SARLINK)

The Controller can also be programmed using a computer and the provided software called **'SARLINK'**. There are a number of benefits in using SARLINK; there is no need to enter a PIN number, and you can easily change modes, additionally the computer screen shows all the parameters for one mode together. You can print a list of all the current settings for filing in the patient's notes and you can easily test the action of the stimulation.

System Requirements

In order to run SARLINK the following hardware is required:
- IBM-compatible PC, running DOS 3.1 or later,
- Windows 95/98, XP, Vista and OS/2 can also be used,
- Serial Communications Lead (BSD199),
- a copy of the program 'SARLINK.EXE'.

Install SARLINK

To install SARLINK on your PC's hard disk, simply copy the file **SARLINK.EXE** into any directory. But it is good practice to create a folder calls 'SARLINK' in the Program Files directory:

Step 1: Create a new folder called 'SARLINK' in the Program Files directory.

C:\Program Files\SARLINK
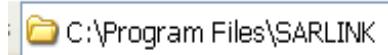
Step 2: Copy SARLINK.EXE to the SARLINK folder.

C:\Program Files\SARLINK   copy SARLINK.EXE

Step 3: Create a short cut to SARLINK.EXE
You can run SARLINK by double clicking on SARLINK.EXE, but it is more convenient to have a shortcut on the Desktop. Right click on SARLINK.EXE and select 'Create Shortcut' from the drop down menu to create a shortcut.
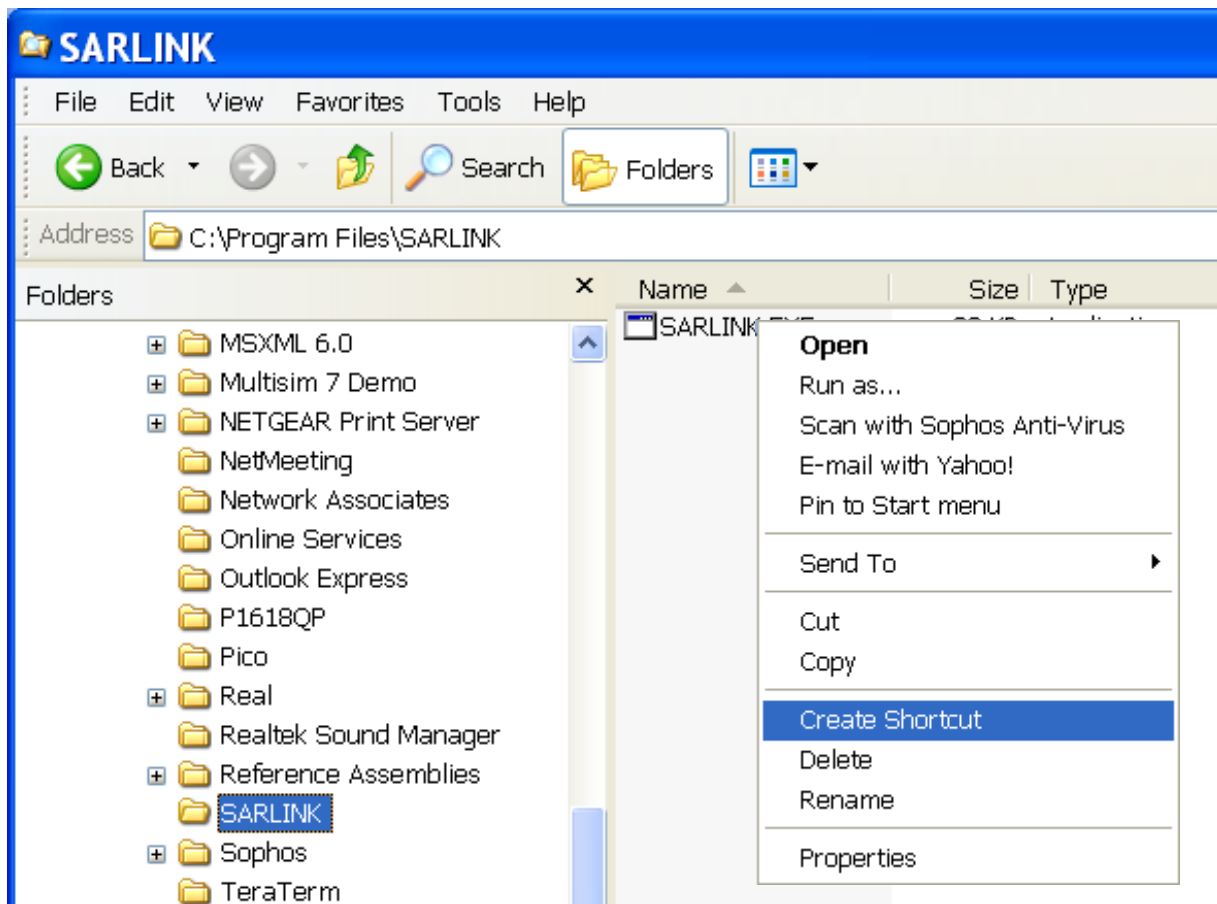
Step 4: Move 'Shortcut to SARLINK.EXE' to your Desktop
You can move the shortcut by clicking and dragging it to your Desktop or using the cut and paste method.
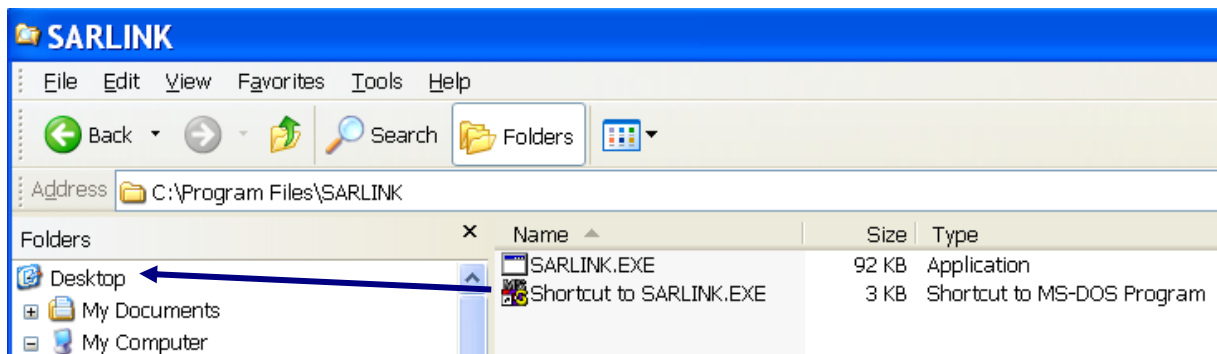
Connection

To connect the Controller to the PC, plug the *Serial Communications Lead* into the *Controller* (it will only fit into the correct socket) and plug the other end of the lead into a serial port on the PC. This will probably be marked 'Serial 1', 'Serial 2', 'Com1' or 'Com2'. Make a note of the number of the port (probably 1 or 2, possibly 3 or 4). It is recommended that you use port 1 if it is available. The lead has a 9-pin plug at the PC end. Some older PCs use 25-pin serial sockets, in which case you will need to use an adapter or the one provided.

> **Caution**
> For connection to the PC only use the Finetech-Brindley *Serial Communications Lead* as this has been specifically designed to ensure safety in use and incorporates full electrical isolation.

Serial Communications Lead
(1.8m Long)

Isolation Box
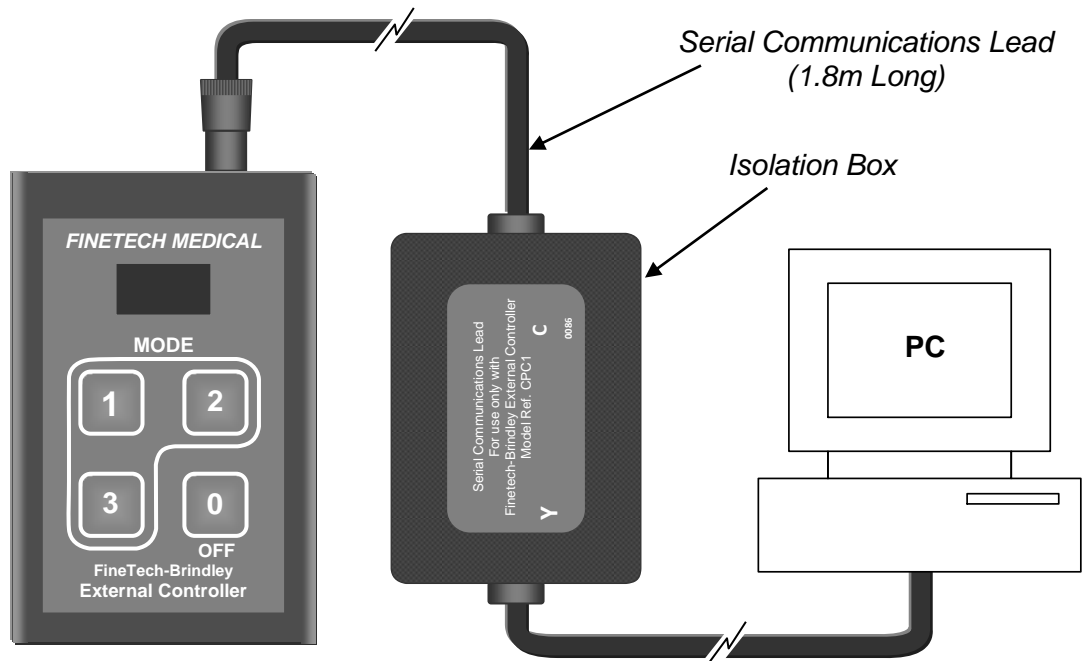
Running SARLINK

Before running SARLINK, connect the PC to the stimulator (see above) and switch on the stimulator. If you don't have the transmitter block connected, it will show 'ERROR 2', you can still change the parameters but you cannot perform a stimulation test. Press the 'S' key to put the Controller into Adjust mode where you can make change to the settings.

SARLINK is a DOS program not a Windows application. When SARLINK is running, you can return to your Windows applications by pressing [Alt+TAB]. In order to exit SARLINK press [Alt+x].

If you have created a shortcut on your Desktop, you can run SARLINK by double clicking on the SARLINK icon on you your Desktop (Note that you can rename your Shortcut to your preferred name). If the Serial communication lead is connected to port 1, you don't need to change any settings.

Double click on icon to run SARLINK

If you are using port 2 or higher, you need to add the port number at the end of the command line. Right click on the Shortcut icon on your Desktop and select 'Properties' then click on the 'Program' tab. Add a space and the port number at the end of the command line and click OK.

    Example: Cmd line: C:\PROGRA~1\SARLINK\SARLINK.EXE 2

SARLINK Properties

Misc | Compatibility | Security | Summary
General | Program | Font | Memory | Screen

SARLINK.EXE

Cmd line: C:\PROGRA~1\SARLINK\SARLINK.EXE 2

Working: C:\PROGRA~1\SARLINK

Batch file:

Port Number

Shortcut key: CTRL + ALT +

Run: Normal window

☑ Close on exit

Advanced... | Change Icon...

OK | Cancel | Apply

Open
Scan with Sophos Anti-Virus

Send To ▶

Cut
Copy
Paste

Create Shortcut
Delete
Rename

Properties
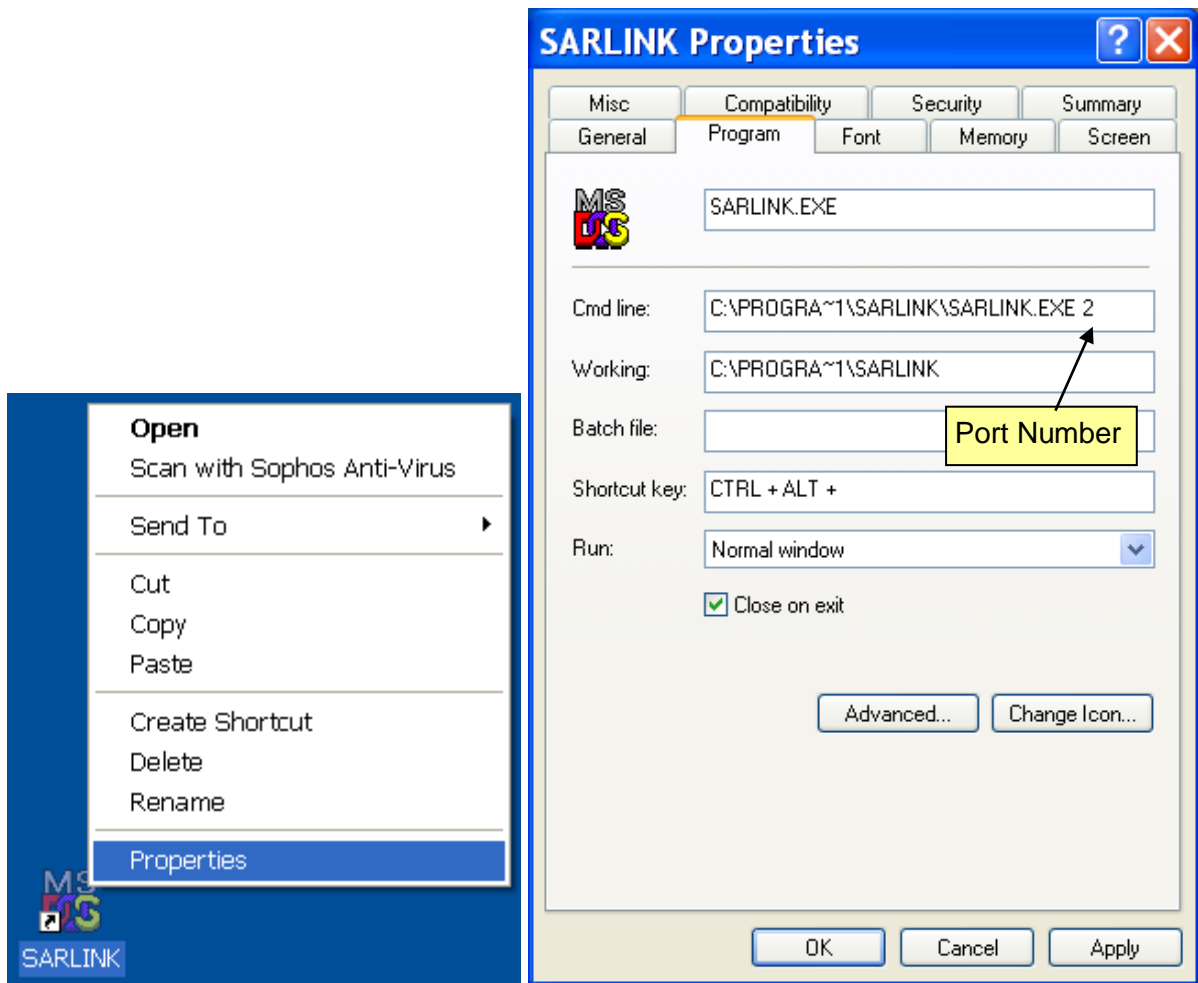
SARLINK

SARLINK User Interface
When SARLINK is running, the screen appears on a PC as shown below:

menu   *parameter selector*   *mode indicator*   *state indicator*

+Inc   -Dec   Print   [F1]:Help   [alt_x]:quit   Mode: 1   **State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes		
Main stimulation time limit (s)	0		
Main stimulation on-time (s)	4.0		
Main stimulation off-time (s)	1.0		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width (µs)	200	200	200
Main stimulation frequency (Hz)	25	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	4		
Pre-fatigue pulse width (µs)	200	200	200
Pre-fatigue frequency (Hz)	25	25	25

The frequency for the main stimulation output (Hertz)

message window

Menu	Shows the keys which may be pressed in order to perform various actions.
State indicator	Indicates the current state of the Controller, which may be Adjust, Pausing, Pre-fatigue, Main Stimulation, Charging or Error. By pressing 'S' you can start stimulation. The stimulator will then advance automatically through the stages as determined by the duration parameters. By pressing 'S' again, you can force the stimulator to advance immediately to the next stage: Adjust to Pre-fatigue, Pre-fatigue to Main, Main to Adjust. It is also possible to use the 'S' key to reset an Error state and return to Adjust.
Mode indicator	Shows which mode the displayed parameters apply to. It is the same as the number shown on the front of the Controller. To cycle through all the modes, press M. Note that modes which are hidden (not available to the user) may also be selected in this way.
Parameter selector	Indicates which parameter is currently selected and may be modified. You move the selector around the screen using the arrow keys. In this example, the frequency on channel A is selected.
Increment and Decrement	The value of the indicated parameter can be incremented or decremented by pressing I or D, or by pressing '+' or '–'. Every parameter has a permitted maximum and minimum value which it is not possible to exceed. Note: it is only possible to change parameter values in 'Adjust' mode and not during stimulation.
Print	Press 'P' to print the parameters. A further menu will offer the choice of: Printer only, File only, Both file and printer, Neither. If you select Printer or Both, the current screen will be copied to the printer. If you select File or Both, you will be prompted for a file name, and then the screen will be copied to the file. This can later be inserted into a word processor document; the file type is 'plain ASCII'
Help	The F1 key displays a screen of help information.

Communication Errors

If there is any error in the communication between the stimulator and the PC, then the parameters will be blanked from the screen, and the message window will display "***Stimulator not responding***". This can happen for a number of reasons: the *Controller* is switched off, the *Serial Communications Lead* is unplugged at either end or the lead is plugged into the wrong socket on the PC. If using a serial port other than Com1, it is necessary to add the port number to the command line.

Disconnect the Controller from the PC

If the controller is disconnected from the PC while in Adjust mode, it will remain in this mode; to turn it off, press button 1 and 2 together. If the controller is disconnected from the PC while in Stimulating mode, it will remain stimulating; to turn it off, press the OFF button.

4. EQUIPMENT REQUIRED

In order to set the parameters for a patient, the following equipment is required:

- 3-way Foley catheter
- Cystometry equipment (Pressure transducer and chart recorder)
- Blood pressure monitor
- Patient's external Finetech-Brindley Bladder Control equipment (*Controller, Transmitter Lead and Transmitter Block).*

Optional equipment includes:
- PC with SARLINK software
- *Serial Communications Lead*
- Printer

These optional items allow the clinician to set parameters more easily and to keep a paper record of the final stimulation parameters.

5.   PARAMETER SETUP/ADJUSTMENT PROCEDURE
5.1   Cystometry
Single-channel water Cystometry
Single channel cystometry requires a manometer to measure pressure in cmH_2O.

> **Information**
> *A Foley catheter keeps the line in position when the patient is being turned.*
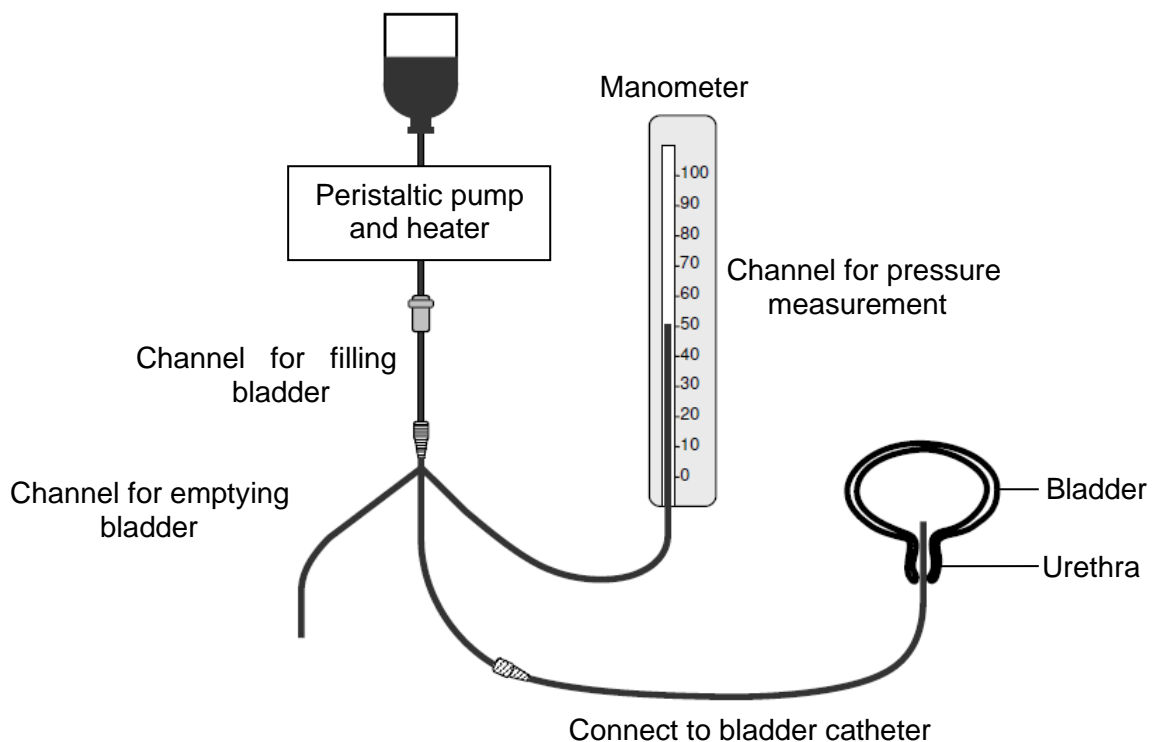
Multi-channel Cystometry
Multichannel cystometry carried out in the clinic requires a urine flow meter, 2 (or 3) transducers, and an electronic subtraction unit to derive detrusor pressure from the vesical and abdominal pressures ($P_{det} = P_{ves} - P_{abd}$), a recorder with printout, and an amplifying unit. Pressure measurements are in cmH_2O; Flow measurements in ml/s.

> **Information**
> *A Foley catheter keeps the line in position when the patient is being turned.*

Peristaltic Pump and heater

Bladder

Rectum

Intravesical Pressure (P_{ves})

Pressure Transducers

Intra-abdominal Pressure (P_{abd})
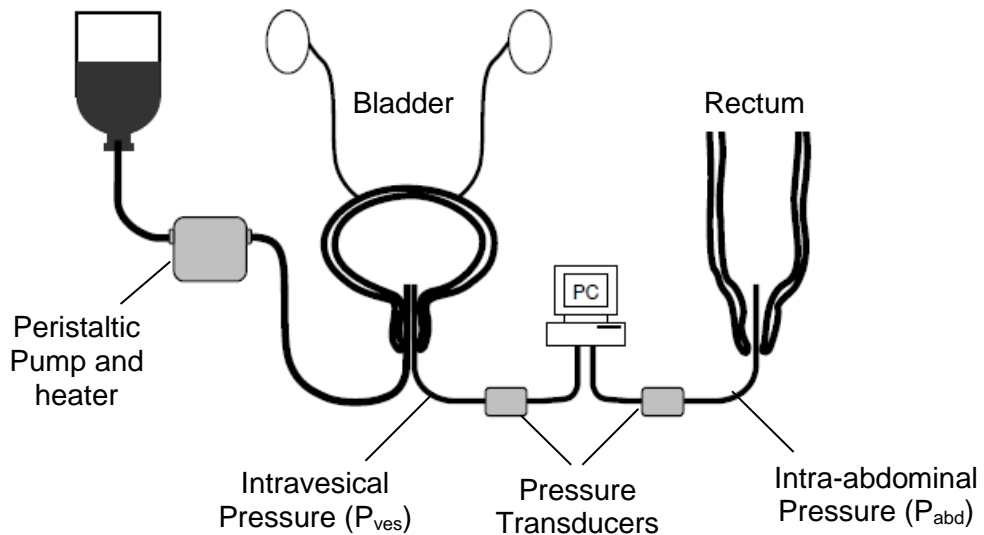
5.2 Preparing for the Tests

- Ensure that the *Controller* is fully charged.
- Identify the position of the implanted receiver using palpation. If palpation is unsuccessful in locating the implanted receiver, X-ray screening must be used.
- Mark the position of each of the receivers on the dressing or skin.

Locations of receivers marked on dressing/skin
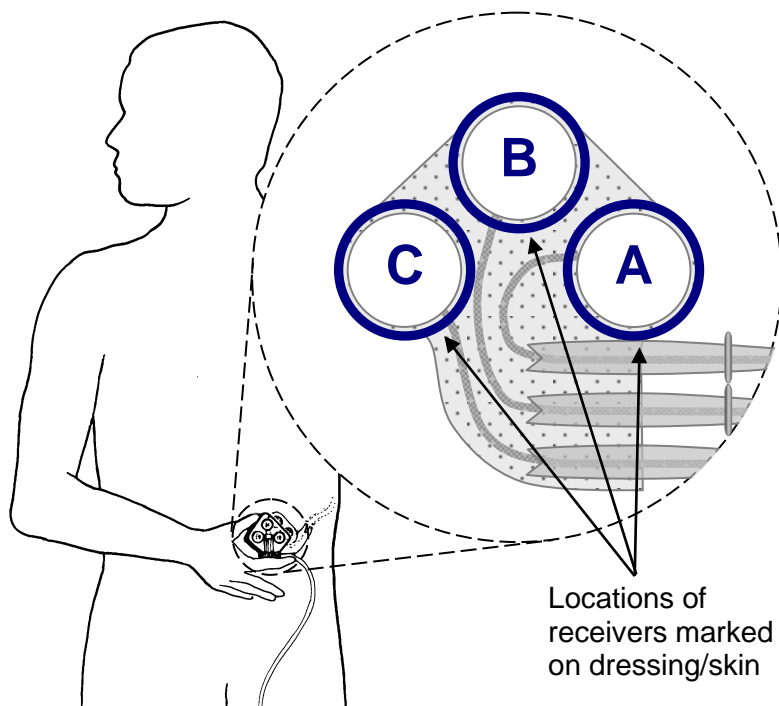
- Insert a 3-way Foley catheter in the usual manner.
- Empty residual volume from bladder with catheter
- Connect the catheter in order that the bladder can be:
  - o filled with saline at 37°C to reflexive volume (between 200ml and 400ml) at a maximum flow rate of 20ml/minute
  - o emptied via a flow meter
  - o connected to a pressure transducer with chart recorder.

If a second pressure transducer and a recording facility for monitoring the difference between two transducers are available, a second transducer can be used for a balloon in the upper

vagina or, for a man, in the stomach. The difference channel will then have the usual cystometric significance, but with fluctuations in abdominal pressure being cancelled out. The rectum cannot be used for this purpose, because sacral root stimulation causes contraction of rectal smooth muscle. Usually it is unnecessary to cancel out fluctuations in abdominal pressure, because in most patients, sacral root stimulation will not affect the abdominal pressure. In the few that it does affect, abdominal muscle contractions can usually be distinguished from detrusor contractions by their time-course.

5.3 Initial Testing

In order to examine the bladder response to stimulation, it is usually sufficient to test each pair of spinal roots at a single frequency and at the same amplitude. Stimulation parameters should be sufficient to stimulate all or nearly all the preganglionic fibres to the bladder. To achieve this, the main stimulation amplitude should be set to 3 and the frequency should be roughly 25 Hz. The main stimulation pulse width should be set to between 200 µs and 500µs (about 200µs for a thin patient, about 350µs for a patient with an average amount of subcutaneous fat and about 500µs for an obese patient).

- Program the *Controller* with a test set of parameters for each channel e.g. Mode 1 only stimulates A, Mode 2 only stimulates B and Mode 3 only stimulates C. Example configurations are shown below for the various levels of subcutaneous fat on the patient. (SARLINK has been used in this instance, but all changes can be made using the buttons if necessary).

Mode 1: (settings for testing channel A of a thin patient)

menu　　*parameter selector*　　　　*mode indicator*　　*state indicator*

+Inc　-Dec　Print　[F1]:Help　[alt_x]:quit　　　**Mode:** 1　　**State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes		
Main stimulation time limit (s)	600		
Main stimulation on-time (s)	4.0		
Main stimulation off-time (s)	0.0		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width　(µs)	200	0	0
Main stimulation frequency (Hz)	25	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	1		
Pre-fatigue pulse width (µs)	40	40	40
Pre-fatigue frequency (Hz)	20	20	20

The frequency for the main stimulation output (Hertz)

Mode 2: (settings for testing channel B of an average patient)

menu parameter selector mode indicator state indicator

+Inc -Dec Print [F1]:Help [alt_x]:quit   Mode: 2   **State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes		
Main stimulation time limit (s)	600		
Main stimulation on-time (s)	4.0		
Main stimulation off-time (s)	0.0		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width (µs)	0	350	0
Main stimulation frequency (Hz)	▉ 25 ▉	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	1		
Pre-fatigue pulse width (µs)	40	40	40
Pre-fatigue frequency (Hz)	20	20	20

The frequency for the main stimulation output (Hertz)

Mode 3: (settings for testing channel C of an overweight patient)

menu parameter selector mode indicator state indicator

+Inc -Dec Print [F1]:Help [alt_x]:quit   Mode: 3   **State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes		
Main stimulation time limit (s)	600		
Main stimulation on-time (s)	4.0		
Main stimulation off-time (s)	0.0		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width (µs)	0	0	500
Main stimulation frequency (Hz)	▉ 25 ▉	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	1		
Pre-fatigue pulse width (µs)	40	40	40
Pre-fatigue frequency (Hz)	20	20	20

The frequency for the main stimulation output (Hertz)

- Fill the bladder with the patient's reflexive volume (typically 150-200ml) of warmed saline.
- Connect the *Transmitter Block* to the *Controller* using the *Transmitter Lead*

- Press '1' on the *Controller* to activate Mode '1'.
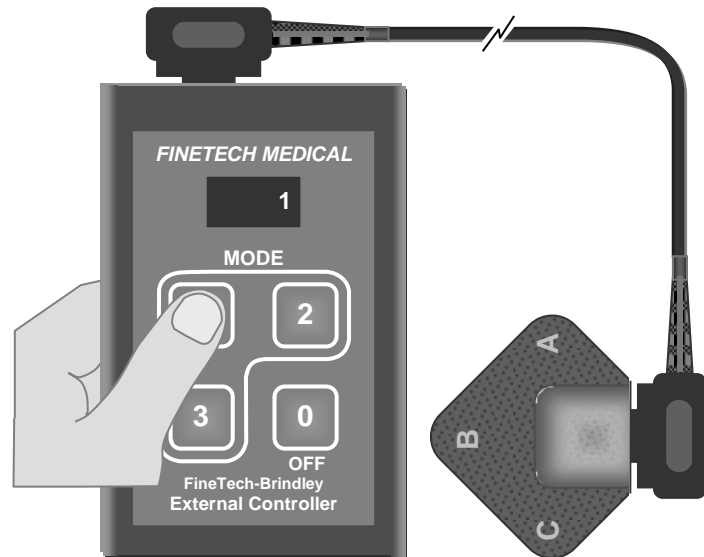
- Hold the *Transmitter Block* over the markings of the implant-receivers on the skin/dressing for 15 seconds, monitoring the bladder pressure. If very high pressure is attained (i.e. over 130 cm H_2O for men and over 110 cm H_2O for women) pull the *Transmitter Block* away from the patient immediately.

Place the Transmitter unit over the markings on the skin/dressing
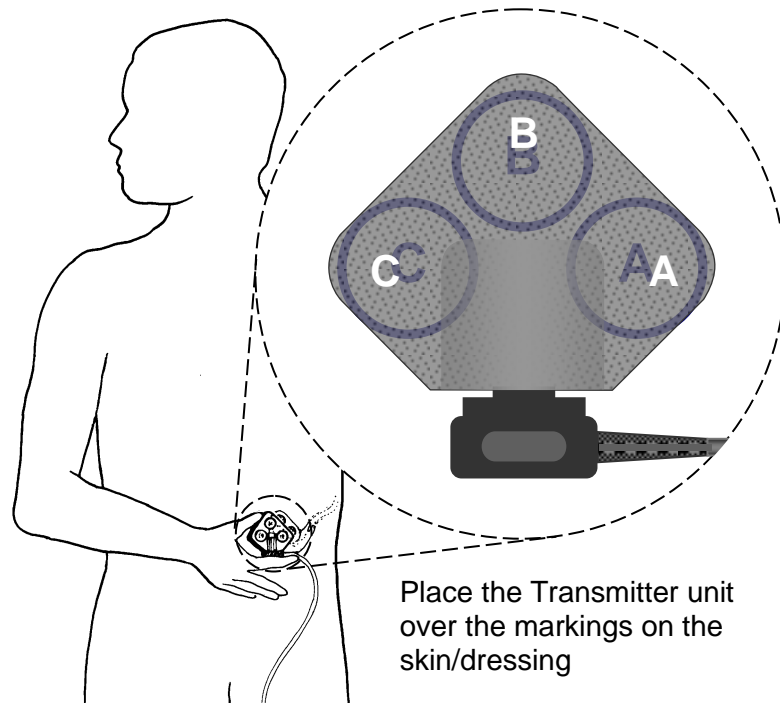
- Switch the *Controller* off by pressing the 'OFF' button.
- Repeat the monitoring of the bladder pressure with mode 2 and, for 3-channel implants, mode 3.

5.4   Setting a Micturition Stimulation Programme (Typically Mode 1)

First-Time Settings
If a 2-channel implant is being used or Mode 3 of the initial testing gave neither bladder pressure nor pelvic floor contraction, program the following stimulation parameters as a starting point:

	A	B	C
+Inc -Dec Print [F1]:Help [alt_x]:quit		**Mode:** 1	**State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes	200 for a thin patient	
		350 for an average patient	
Main stimulation time limit (s)	600	500 for an obese patient	
Main stimulation on-time (s)	3.0		
Main stimulation off-time (s)	6.4		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width (µs)	200	200	0
Main stimulation frequency (Hz)	25	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	1		
Pre-fatigue pulse width (µs)	40	40	40
Pre-fatigue frequency (Hz)	20	20	20

The frequency for the main stimulation output (Hertz)

If a 3-channel implant is being used and Mode 3 of the initial testing gave either bladder pressure or pelvic floor contraction, program the following stimulation parameters as a starting point:

menu   *parameter selector*   *mode indicator*   *state indicator*

	A	B	C
+Inc -Dec Print [F1]:Help [alt_x]:quit		**Mode:** 1	**State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes	200 for a thin patient	
		350 for an average patient	
Main stimulation time limit (s)	600	500 for an obese patient	
Main stimulation on-time (s)	3.0		
Main stimulation off-time (s)	6.4		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width (µs)	200	200	200
Main stimulation frequency (Hz)	25	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	1		
Pre-fatigue pulse width (µs)	40	40	40
Pre-fatigue frequency (Hz)	20	20	20

The frequency for the main stimulation output (Hertz)

Initial Testing
The program must now be tested whilst recording bladder pressure:
- Fill the bladder with the patient's reflexive volume (typically 150-200ml) of warmed saline.
- Connect the *Transmitter Block* to the *Controller* using the *Transmitter Lead*
- Press '1' on the *Controller* to activate Mode '1'.

- Hold the *Transmitter Block* over the markings of the implant-receivers on the skin/dressing whilst monitoring the bladder pressure. If very high pressure is attained (i.e. over 130 cm H_2O for men and over 110 cm H_2O for women) pull the *Transmitter Block* away from the patient immediately.

The trace obtained should roughly resemble this:

Bladder Pressure

- Switch the *Controller* off by pressing the 'OFF' button.
- Some urine/saline is likely to leak round the outside of the catheter, but efficient micturition is not to be expected.
- If, in a man, an inconvenient degree of penile erection is caused, channel C (where used) can be switched off.

Initial Pressure Adjustment
- Maximum pressure occurs in the gaps between bursts and minimum pressure occurs during the bursts. The highest pressure is usually attained during the gap between the third and fourth or between the fourth and fifth bursts.
- If this highest pressure is between:
    - 80 - 120cm H_2O in a man
    - 60 - 100 cm H_2O in a woman

Refill the bladder, if necessary, to ensure there is 100ml of saline/sterile water within it and then remove the catheter.

If the highest pressure obtained is outside of these ranges, follow the adjustment chart below:

```
┌─────────────────────────┐         ┌─────────────────────────┐
│   PRESSURE TOO LOW?      │         │   PRESSURE TOO HIGH?     │
│   <80 cm H₂O for men     │         │   >120 cm H₂O for men    │
│   <60 cm H₂O for women   │         │   >100 cm H₂O for women  │
└─────────────────────────┘         └─────────────────────────┘
```

PRESSURE TOO LOW?
<80 cm H_2O for men
<60 cm H_2O for women

PRESSURE TOO HIGH?
>120 cm H_2O for men
>100 cm H_2O for women

| Change On-time to 6 seconds | Change On-time to 2.4 seconds |

| Wait 2 minutes |

| Repeat trial, refilling bladder if necessary |

YES ← Pressure in range? → **NO**

DONE **REFER TO ADJUSTMENT CHARTS IN SECTION 7**

Initial Urine Flow Adjustment

- With the catheter removed, press **'1'** on the *Controller* to activate **Mode '1'**.
- Hold the receiver over the markings of the implant-receivers on the skin/dressing and observe the pattern of urine/saline flow.

A visual assessment is generally better than using a flow meter. The bladder is typically emptied in less than two minutes. There should be a smooth flow of urine/saline during the gaps between the bursts of stimulation (recognisable by watching the feet, perineum or penis). If the flow is irregular, refer to the adjustment charts in Section 6.

0 10 20 30 40 50 60 70
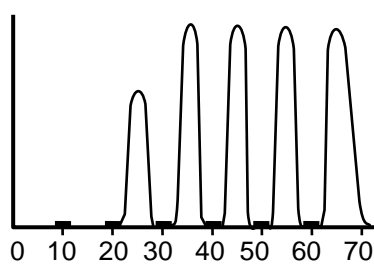
(i) Smooth Urine Flow

0 10 20 30 40 50 60 70
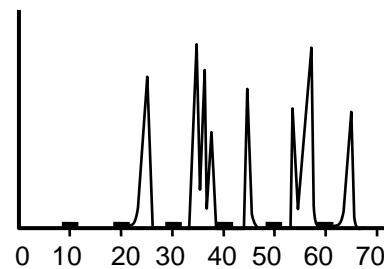
(ii) Irregular Urine Flow

▬ = *Burst of stimulating pulses time (seconds)*

- If the flow is smooth, adjust the Main stimulation on/off-time parameters as necessary:
  - If the flow from the preceding burst has not quite ceased when the next starts, the Main stimulation off-time is set correctly.
  - If the flow has definitely ceased, the Main stimulation off-time should be reduced.
  - If the flow is interrupted during a strong stream of urine/saline, caused by closure of the sphincter, the Main stimulation off-time is too short.

Checking Post Void Residual (PVR) Volume

- When urine/saline flow has stopped, check the residual volume using a straight catheter or ultrasound.
  Clinical judgement should be used to determine if the residual volume is low enough. A Post Void Residual (PVR) of less than 50ml is the recommended target. If this is not achieved, please refer to the Adjustment Charts in section 6.

Keeping a Record of the Settings

- Once acceptable parameters have been set, a note/printout of the settings should be taken for future reference. A form has been provided for recording the settings.

5.5   Setting a Defaecation Stimulation Programme (Typically Mode 2)

Strong stimulation of S3 or S4 usually, and of S2 sometimes, causes a rise in rectal pressure with latency of about 6 seconds and duration about 25 seconds. It will also cause contraction of the anal sphincter. The anal sphincter contraction has a much shorter latency than the rectal contraction, and ceases promptly when stimulation ceases. It is often followed by a fall in anal sphincter pressure to below the resting level. This fall is slow, and it is probably mainly due to inhibition of anal smooth muscle. A programme for bowel emptying should aim to achieve as high as possible a rectal pressure at the time when the anal sphincter is fully relaxed. If all channels of the implant are used together, at the strength needed for bladder emptying, in bursts of 10 seconds followed by pauses of 20 seconds, this will be roughly achieved.

A more accurate programme can be set up for each patient individually if anal sphincter pressure and rectal pressures are recorded simultaneously. If the duration of bursts and pauses for defaecation is critical, then the patient will have to time them him/herself, using a watch. The patient starts and stops the bursts by using the relevant program mode (usually mode 2) and the '0' (Off) button or by moving the *Transmitter Block* alternately into and away from its proper position over the *Receivers*. Often, however, there is a fair range of burst lengths and gap lengths that will suffice. If so, an appropriate combination can usually be achieved by setting as shown:

	menu	parameter selector		mode indicator	state indicator

+Inc	-Dec	Print	[F1]:Help	[alt_x]:quit	**Mode:** 1	**State:** Adjust

	A	B	C
Mode available to user (Yes/No)	Yes		
		200 for a thin patient	
Main stimulation time limit (s)	600	350 for an average patient	
Main stimulation on-time (s)	8.0	500 for an obese patient	
Main stimulation off-time (s)	17.0		
Main stimulation amplitude (1-4)	3		
Main stimulation pulse width (µs)	200	200	200
Main stimulation frequency (Hz)	25	25	25
Interleave number (0-2)	0	0	0
Interleave pulse width (µs)	0	0	0
Pre-fatigue duration (s)	0		
Pre-fatigue amplitude (1-4)	1		
Pre-fatigue pulse width (µs)	40	40	40
Pre-fatigue frequency (Hz)	20	20	20

The frequency for the main stimulation output (Hertz)

Besides the immediate rise of rectal pressure, stimulation of sacral anterior roots causes an increase in colonic activity. In about 50% of patients, use of the implant as described above expels faeces from the rectum. In the remainder, it fails to do this, but is nevertheless useful because it moves faeces from the pelvic colon into the rectum, and thus makes manual evacuation quicker and more complete.

An Adjustment chart is available in Section 6.

5.6   Setting an Erection Programme (Typically Mode 3)

First try a frequency of around 8Hz and an amplitude setting of level 4, continuously. Test S2 alone, then S3 alone. Usually S2 is the main erectile root. If S2 and S3 both give incomplete erection, try them together. Each test should be continued for at least 3 minutes; implant driven erection can come on very slowly, but when established it stays constant until stimulation ceases. If S2 without S3 gives adequate erection, it is probably the best choice for the practical program even if adding S3 improves the penile rigidity, because leakage of urine is less likely with S2 alone.
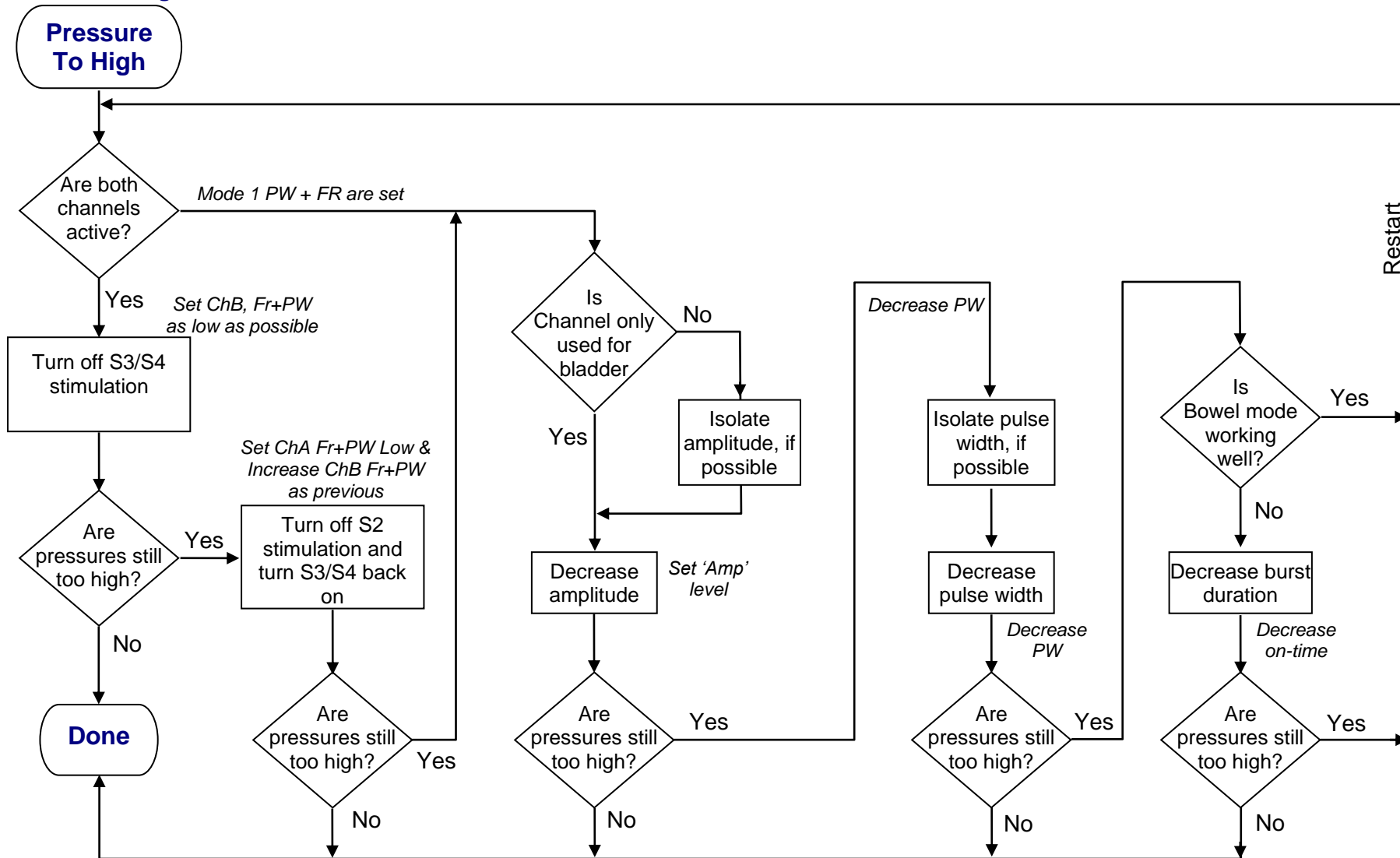
8Hz is below tetanic fusion frequency for lower limb muscles and will make the patient shake. If he finds the shaking too disturbing, the frequency can be increased. At around 12Hz there will be less shaking and at around 18Hz probably none. If erection is poor with an amplitude setting of level 4 at the pulse duration appropriate for bladder and bowel activation, it may be possible to achieve good erection by setting a greater main stimulation pulse width.
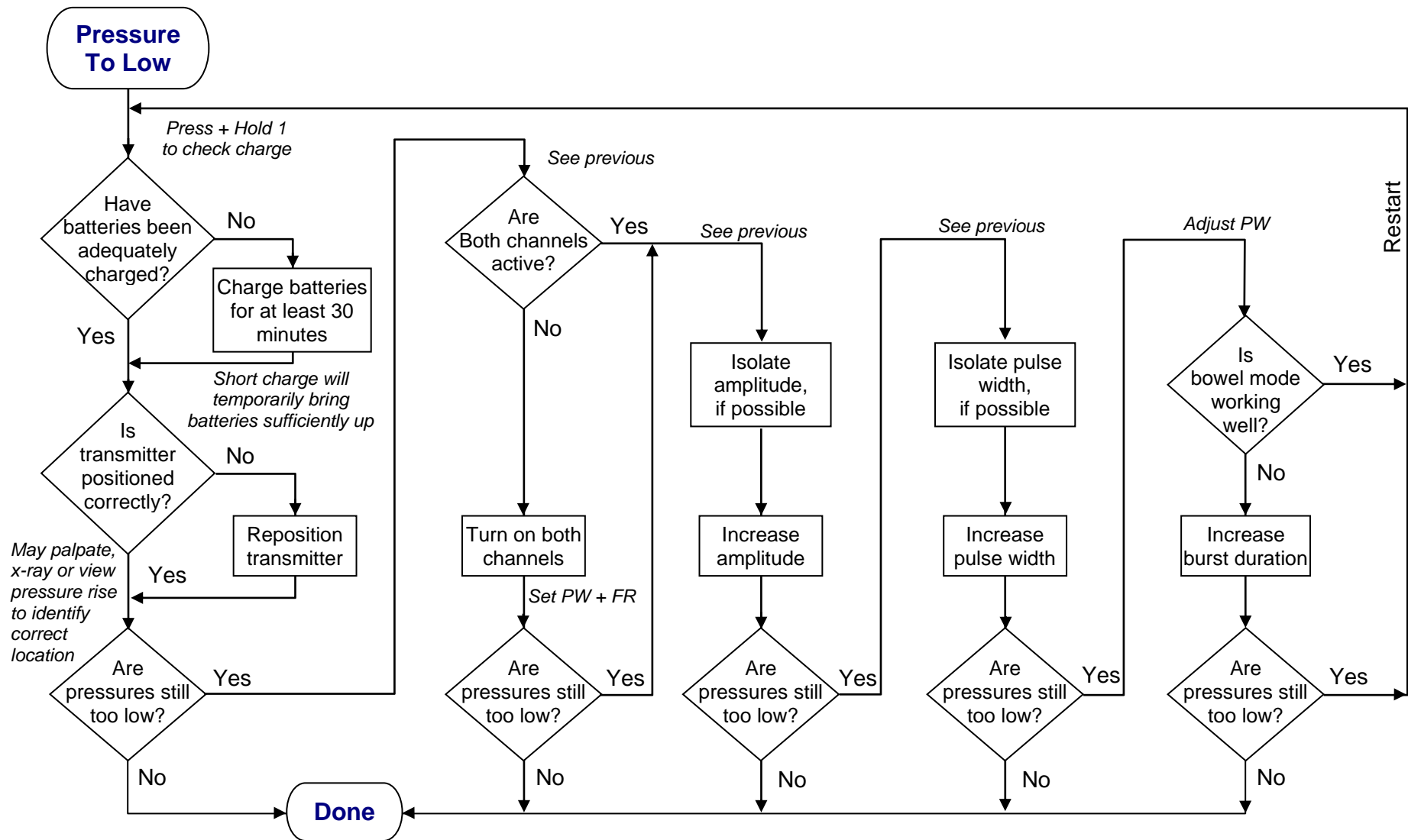
6.   ADJUSTMENT CHARTS

This section contains flow charts to assist in modifying stimulation parameters in three key sections:
- Adjusting bladder pressure
  - Pressure too High
  - Pressure too Low
- Adjusting Post Void Residuals (PVR)
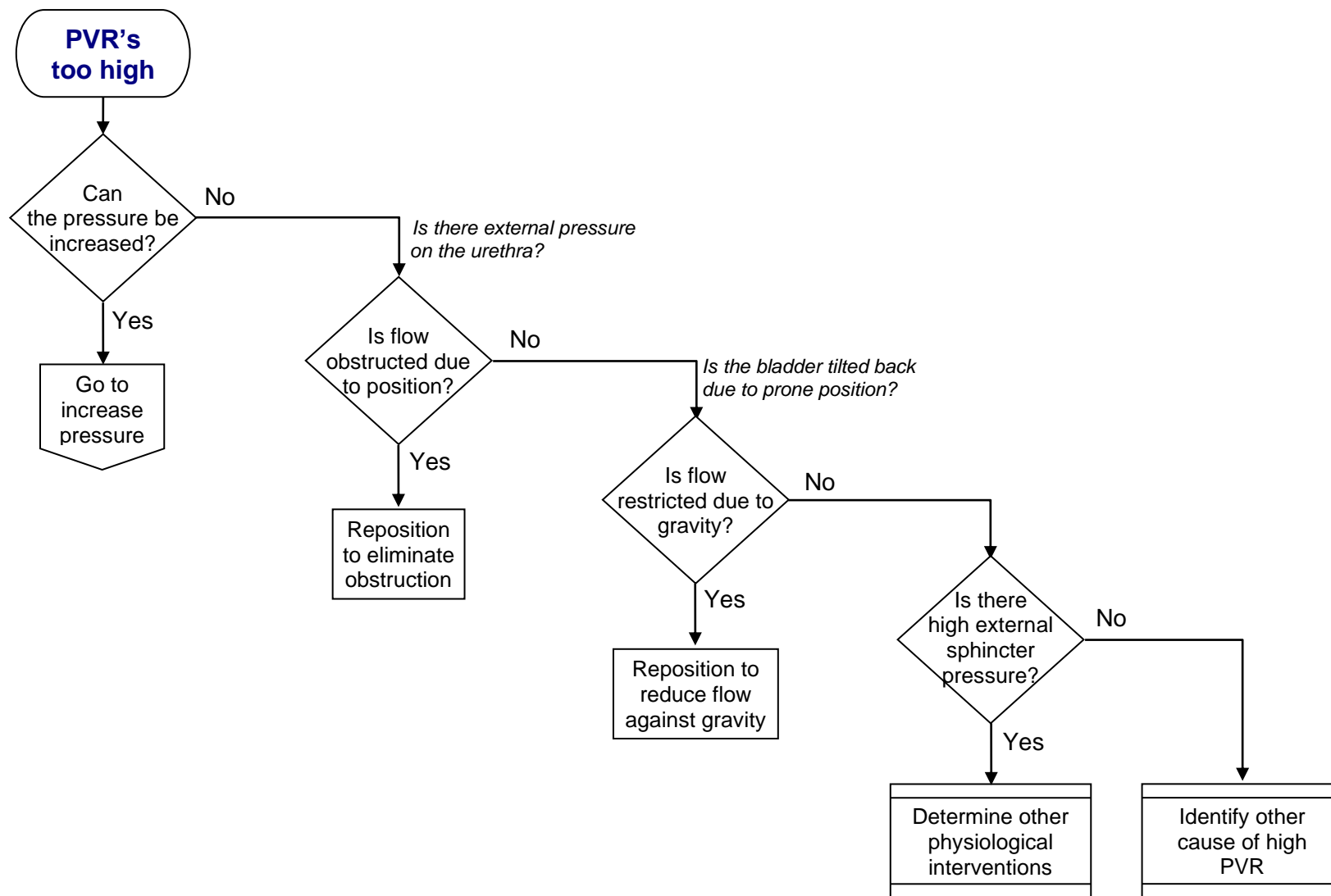- Adjusting urine flow
- Adjusting bowel mode
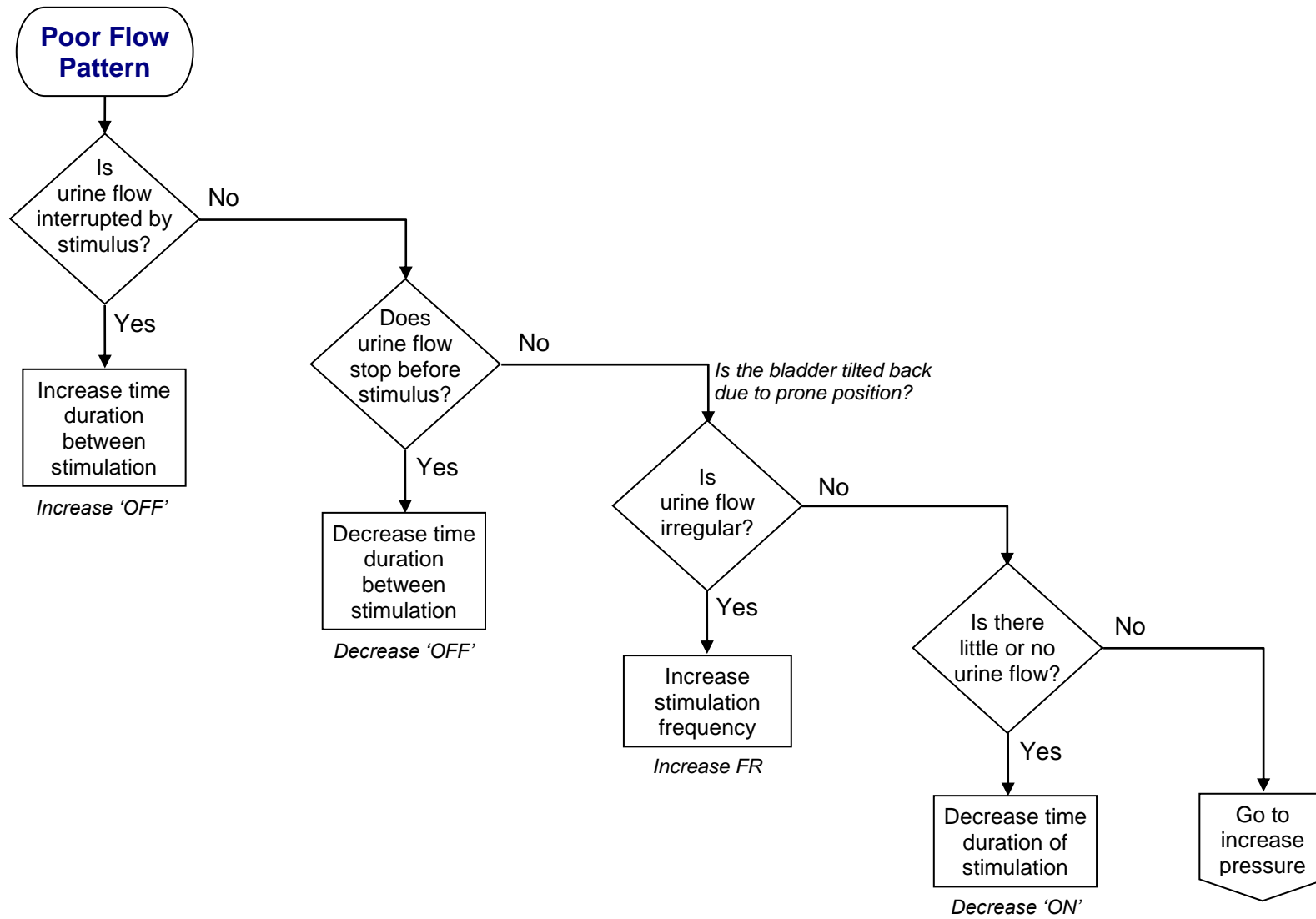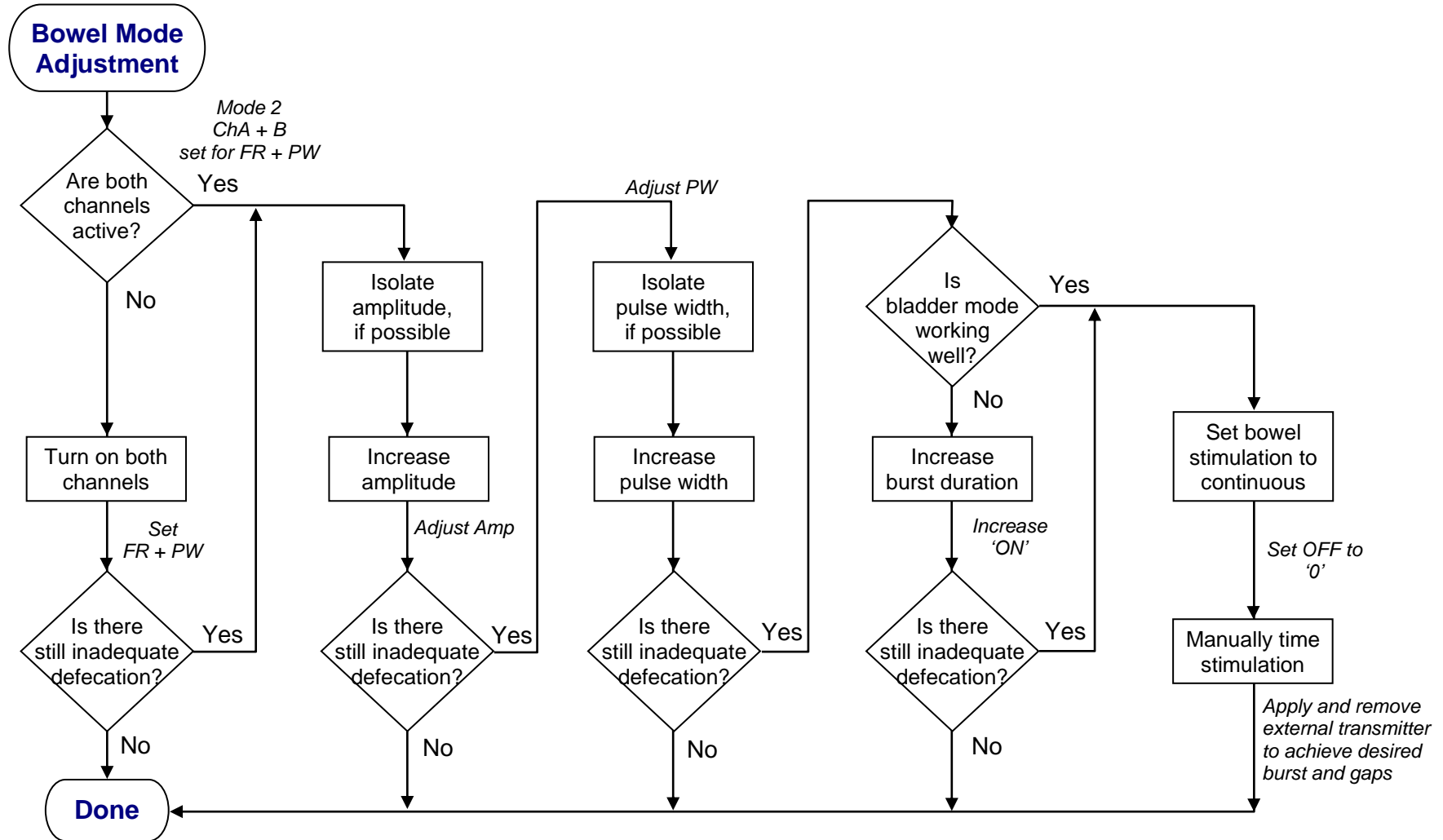
6.1 Adjusting Bladder Pressure
Pressure Too High.

```
┌─────────────┐
│  Pressure   │
│   To High   │
└─────────────┘
```

Are both channels active? — Mode 1 PW + FR are set →

Yes ↓ — *Set ChB, Fr+PW as low as possible*

Turn off S3/S4 stimulation

Are pressures still too high?

- **Yes** → *Set ChA Fr+PW Low & Increase ChB Fr+PW as previous* — **Turn off S2 stimulation and turn S3/S4 back on**
- **No** ↓ → **Done**

Are pressures still too high? — **Yes** / **No**

Is Channel only used for bladder
- **No** → **Isolate amplitude, if possible**
- **Yes** → **Decrease amplitude** — *Set 'Amp' level*

Are pressures still too high? — **Yes** / **No**

Decrease PW → **Isolate pulse width, if possible** → **Decrease pulse width** — *Decrease PW*

Are pressures still too high? — **Yes** / **No**

Is Bowel mode working well?
- **Yes** →
- **No** ↓ → **Decrease burst duration** — *Decrease on-time*

Are pressures still too high? — **Yes** / **No**

Restart

Pressure Too Low.

Pressure To Low

Press + Hold 1 to check charge

Have batteries been adequately charged?

No → Charge batteries for at least 30 minutes

Short charge will temporarily bring batteries sufficiently up

Yes

Is transmitter positioned correctly?

No → Reposition transmitter

Yes

May palpate, x-ray or view pressure rise to identify correct location

Are pressures still too low?

Yes

No → Done

See previous

Are Both channels active?

Yes → *See previous*

No

Turn on both channels

Set PW + FR

Are pressures still too low?

Yes

No → Done

Isolate amplitude, if possible

Increase amplitude

Are pressures still too low?

Yes

No → Done

See previous

Isolate pulse width, if possible

Increase pulse width

Are pressures still too low?

Yes

No → Done

Adjust PW

Is bowel mode working well?

Yes

No

Increase burst duration

Are pressures still too low?

Yes

No → Done

Restart

6.2   Post Void Residuals

```
        ┌──────────┐
        │  PVR's   │
        │ too high │
        └──────────┘
             │
             ▼
        ╱Can       ╲    No
       ╱ the pressure ╲ ────────────┐
       ╲ be increased? ╱            │   Is there external pressure
        ╲            ╱              │   on the urethra?
             │ Yes                  ▼
             ▼                ╱Is flow      ╲   No
        ┌──────────┐        ╱ obstructed due ╲ ──────────┐
        │  Go to   │        ╲ to position?   ╱           │  Is the bladder tilted back
        │ increase │         ╲            ╱              │  due to prone position?
        │ pressure │              │ Yes                  ▼
        └──────────┘              ▼                ╱Is flow       ╲   No
                            ┌──────────┐         ╱ restricted due to ╲ ──────────┐
                            │Reposition│         ╲ gravity?         ╱           │
                            │to eliminate│        ╲              ╱              ▼
                            │obstruction│              │ Yes            ╱Is there       ╲   No
                            └──────────┘              ▼                ╱ high external    ╲ ──────┐
                                                ┌──────────┐          ╲ sphincter        ╱       │
                                                │Reposition to│        ╲ pressure?      ╱        │
                                                │reduce flow  │             │ Yes                │
                                                │against gravity│           ▼                    ▼
                                                └──────────┘         ┌──────────┐        ┌──────────┐
                                                                     │Determine other│    │Identify other│
                                                                     │physiological  │    │cause of high │
                                                                     │interventions  │    │PVR           │
                                                                     └──────────┘        └──────────┘
```

6.3 Urine Flow

Poor Flow Pattern

↓

Is urine flow interrupted by stimulus?

— No →

Yes ↓

Increase time duration between stimulation

Increase 'OFF'

Does urine flow stop before stimulus?

— No →

Yes ↓

Decrease time duration between stimulation

Decrease 'OFF'

Is the bladder tilted back due to prone position?

↓

Is urine flow irregular?

— No →

Yes ↓

Increase stimulation frequency

Increase FR

Is there little or no urine flow?

— No →

Yes ↓

Decrease time duration of stimulation

Decrease 'ON'

Go to increase pressure

.

6.4   Bowel Mode

```
                    ┌─────────────────┐
                    │   Bowel Mode    │
                    │   Adjustment    │
                    └─────────────────┘
                             │
                             ▼
                       ╱─────────╲         Mode 2
                      ╱ Are both  ╲        ChA + B
                     ╱  channels   ╲  Yes  set for FR + PW
                     ╲   active?   ╱──────────────────────────►
                      ╲           ╱
                       ╲─────────╱
                             │ No
                             ▼
                    ┌─────────────────┐
                    │  Turn on both   │
                    │    channels     │
                    └─────────────────┘
```

Mode 2 ChA + B set for FR + PW

Adjust PW

┌─────────────────┐   ┌─────────────────┐
│   Isolate   │   │   Isolate   │
│   amplitude,   │   │   pulse width, │
│   if possible   │   │   if possible   │
└─────────────────┘   └─────────────────┘

Set FR + PW

┌─────────────────┐   ┌─────────────────┐   ┌─────────────────┐
│   Increase   │   │   Increase   │   │   Increase   │
│   amplitude   │   │   pulse width   │   │ burst duration │
└─────────────────┘   └─────────────────┘   └─────────────────┘

Adjust Amp   *Increase 'ON'*

Is bladder mode working well? — Yes — Set bowel stimulation to continuous

Set OFF to '0'

Is there still inadequate defecation? — Yes / No

Manually time stimulation

Apply and remove external transmitter to achieve desired burst and gaps

Done

7. PROBLEMS AND ERROR CODES

If the *Controller* detects an error it will immediately stop stimulation and display '**Err**' followed by a number. The meaning of the various error codes is shown below along with the action which should be taken.

Error Code	Action
Err1 - battery very low	Put *Controller* on charge.
Err2 - low output current	Check that *Transmitter Lead* is not damaged and is properly connected to the *Transmitter Block* and *Controller*.
Err3 - current after end of pulse	Internal fault - return to supplier.
Err4 - stimulation too high	The requested level of stimulation is too high - you must reduce overall output amplitudes.
Err5 - HT supply under-voltage	Internal fault - return to supplier.
Err6 - HT supply failure	Internal fault - return to supplier.
Err7 - HT supply over-voltage	This can occur if Modes are switched too quickly. Turn off and try desired Mode again. If problem persists return to supplier.
Err8 - assertion failure	Internal fault - return to supplier.
Err9 - reset monitor	This indicates that the previous shut down of the *Controller* was abnormal - switch off the *Controller* and try again. If the controller was shut down due to battery low, charge it up and try again.
Battery Protection Circuit	The Lithium Ion battery used in the *Controller* has an electronic protection circuit built into it. This protects against over discharging the battery. If this is activated the battery will switch itself off and the *Controller* will not respond to any button presses. In order to reset the protection circuit the *Controller* must be briefly put on charge.

8. GRAPHICAL SYMBOLS

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.
🚶	Degree of protection against electric shock – Type BF Electrically 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.
(((•)))	The System includes an RF *Controller* that intentionally applies RF electromagnetic energy for treatment.
REF	The catalogue number of the unit.
SN	Serial number of the unit.
LOT	Manufacturing batch code of the assembly.
🏭	Manufactured by Finetech Medical Ltd.
📅	Date of manufacture; year and month. YYYY-MM
⧗	Date of sterility expiry; year and month. The use by date; 2 years duration is standard. YYYY-MM
STERILE	Sterile by steam or dry heat.
⊘	Do not use if package damaged.
⊘	Do not reuse.
☀	Protect from heat.
☂	Protect from moisture.
🌡	Storage conditions.
⏻	Power button (On/Off)

9. **FORMS**

FINETECH BRINDLEY STIMULATOR SETTINGS			
Patient Name:	Surgery Date:	Hospital No:	Etiology:
Implant Type:	Extradural [ ] Intrathecal [ ]	2 channel [ ] 3 channel [ ]	Clinician:
User Guide: FTM061 Surgical Procedure Manual: FTM063		Implant S/N:	Controller S/N:

Mode(s) available to user:

1 [ ]	1A [ ]	1B [ ]	2 [ ]	2A [ ]	2B [ ]	3 [ ]	3A [ ]	3B [ ]

Mode (1, 1A, 1B, 2, 2A, 2B, 3, 3A, 3B)			
Time limit (sec)			
On time (sec)			
Off time (sec)			
Amplitude (1 to 4)			

	Ch A	Ch B	Ch C	Ch A	Ch B	Ch C	Ch A	Ch B	Ch C
Pulse width (µs)									
Frequency (Hz)									
Interleave									
Number (0 to 2)									
Pulse width (µs)									
Pre-fatigue									
Duration (s)									
Amplitude (1 to 4)									
Pulse width (µs)									
Frequency (Hz)									

10. INDEX

11. NOTES