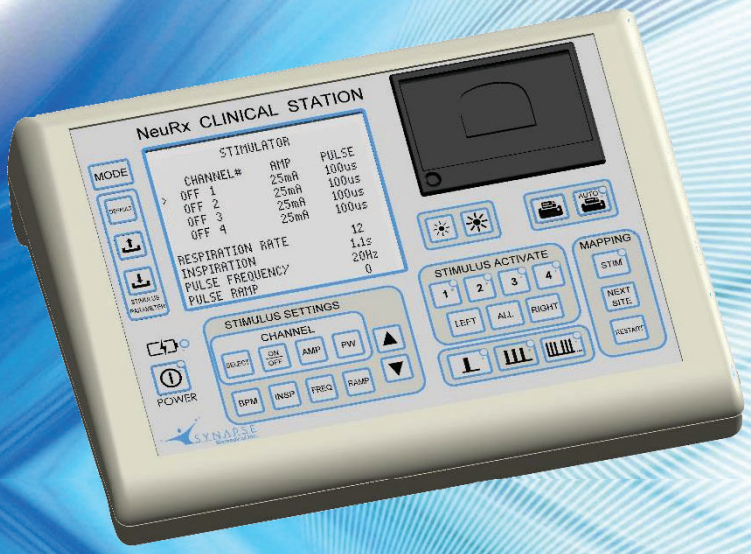
NeuRx®
Clinical Station User Manual



SYNAPSE
Biomedical Inc.

Contents

1 Overview

1.1 About this manual

This manual describes the features and functions of the Synapse Biomedical Clinical Station.

1.2 Symbols

Explanation of symbols	
	The *Warning* symbol precedes warning information that mitigates a risk that is not obvious to the operator. Indicates that a potentially hazardous situation which, if not avoided, could result in harm to the operator or patient. Powered equipment - indicates physiological effects not obvious to the user that can cause harm.
	The *Caution* symbol appears next to precautionary information when the intention is solely to inform. Indicates that a potentially hazardous situation which, if not avoided, may result in minor or moderate personal injury or property damage. This word is used to also alert against unsafe practices.
	The *Manufacturer* symbol appears next to the manufacturer's name and address.
	The *Reference* symbol appears preceding the part number for the device. The part number is a unique numeric identifier for the device.
	The *Lot* symbol appears preceding the lot number for a device. Devices manufactured at the same time using identical material and parts will share a common lot number.
	The *Serial Number* symbol appears on devices that require unique identification.
	The *Use Until* symbol appears on devices that have an indication of the date by which the device should be used. The date is expressed as the year and month, with the month referring to the end of the month.
	The *Manufactured Date* symbol appears on devices as an indication of the date of manufacture. The date is expressed as the year and month.
	The *Temperature Limits* symbol appears on actual devices as an indication of the operational temperature limits.
	The *Temperature Limits* symbol appears on packages of devices as an indication of the storage and transit temperature limits.
	The *Keep Dry* symbol appears on all packages of devices requiring to protect the packaging from potential damage.
	The *Don't Use If Packing Damaged* symbol appears on all packages of devices requiring to dispose of the device if the packaging has suffered damage.

CE 2797	The *Regulatory Marking of Conformity* symbol indicates that the device meets Medical Device Directive 93/42/EEC. This has been certified by notified body number 2797.
EC REP	The *European Community Representative* symbol indicates the identification of the authorized representative for the distribution of devices into the European community.
	The *Type BF Applied Part* symbol appears on powered equipment that connects directly to a patient. It is an indication of the degree of protection provided against electric shock, patient leakage current and patient auxiliary current.
	The *On / Off* symbol on powered equipment indicates push-button ON/OFF power control of the device.
	The *Consult Accompanying Documents* symbol appears on powered equipment indicating that instructions for use must be consulted for safety.
IP20	The *Ingress Protection (IP) Classification* symbol appears on powered equipment.
	Non-ionizing electromagnetic radiation
	Notice of proper disposal
	ESD sensitive device.
	MR Unsafe. A device that is known to pose hazards in all MR environments.

1.3 General Description

There are three primary aspects of the device implementation that the NeuRx® Clinical Station provides. The station provides intra-operative mapping functionality and electrode characterization, incorporates compatible NeuRx DPS® External Pulse Generator functionality and NeuRx DPS® External Pulse Generator programming capability.

- The first application of the station in the device implementation is to provide intra-operative stimulation and sensing of stimulated response. This surgical mapping mode utilizes surgical components to provide twitch or burst stimulation to record and display the abdominal pressure response through the solid state pressure sensor. A stimulator mode is used to test the channels individually and in combination at the end of the surgery to make sure that all electrodes are intact and providing the anticipated response.
- The station is then used to characterize the response from each electrode utilizing the four stimulus output channels. The amplitude, pulsewidth, frequency, and pulse ramping response are each characterized to optimize the tidal volume and patient comfort on a per breath basis. The inspiration time and respiratory rate are set for appropriate minute ventilation. The stimulator mode can be used to fine tune the settings for the patient.
- Finally, the station sends the desired stimulus and respiratory timing parameters to the NeuRx DPS® External Pulse Generator in the programming mode. The station can also read the currently programmed parameters from a NeuRx DPS® External Pulse Generator to verify the settings.

1.3.1 Safety features

The Clinical Station includes the following safety features:

- Battery charge indicator
- Battery safety interlock – device will not operate while battery is charging
- Electrostatic protection

1.3.2 Operating features

The Clinical Station includes the following operating features:

- Easy-to-view parameter settings
- Low battery indicator – indicates Clinical Station battery charge
- Four-channel operation – independent channels allow independent parameter settings and can be enabled / disabled
- Stimulus parameter settings – allows Frequency, pulsewidth, and amplitude parameters to be programmed.
- Respiratory parameter settings – allows Breaths per minute and inspiration parameters to be programmed.
- Surgical setting – allows mapping of the diaphragm
- Stimulator programming – allows the parameters to be sent or received from the NeuRx Chronic stimulator.
- Printing – allows printing a hard copy of the programmed parameters

1.4 Indications for Use

The NeuRx DPS is intended for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but who lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. For use only in patients 18 years of age or older.

Caution: Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician

1.5 Intended use

1.5.1 The NeuRx DPS Clinical Station is a transient multi-functional medical device used in conjunction with the NeuRx Chronic stimulator system to form the NeuRx DPS. The NeuRx Diaphragm Pacing System (DPS®) is a percutaneous, intramuscular, diaphragm motor point stimulating device intended for use in patients with a dysfunctional diaphragm.

1.5.1.1 The Clinical Station is designed to provide three primary functions to work in conjunction with the Synapse Biomedical NeuRx DPS Chronic stimulator system.

1.5.1.2 The Clinical Station provides intra-operative mapping functionality and electrode characterization.

1.5.1.3 The Clinical Station provides compatible NeuRx DPS® External Pulse Generator functionality.

1.5.1.4 The Clinical Station provides NeuRx DPS® External Pulse Generator programming capability

1.6 Package contents

The Clinical Station kit is supplied with the following items:

- (1) One Clinical Station
- (1) Communication cable
- (1) Test plug
- (1) Battery charger
- (1) Active Sensor module

1.7 Contraindications

- There are no known contraindications.

2 Warnings 

2.1 Use only under the direction of a physician. The Clinical Station is electrically powered and may produce tissue damage or electrical hazard if improperly used. Do NOT attempt to open the Clinical Station case or attempt any unintended modifications as this will cause a failure in the Clinical Station functionality. The device has accessible controls for clinical staff and NO patient-accessible controls.

2.2 Use of Clinical Station could interfere with some medical equipment. Some medical equipment could interfere with the use of Clinical Station. Consult the this User Manual before having any of the following:

- **All active implantable medical devices**. This will include devices such as implanted cardiac pacemakers, implanted cardioverter defibrillators (ICDs), implanted neurostimulators, and body worn medical devices (e.g., insulin pump). Use of the Clinical Station may interfere with these devices.
- **Surgery**. Use of high-frequency surgical equipment may cause burns where the electrode leads pass through the skin. Disconnect the Clinical Station if additional surgical procedures are necessary.
- **Diathermy treatment.** Diathermy treatment is deep tissue heat treatment. Do NOT perform diathermy treatment while implanting electrode leads as unwanted tissue heating through the electrode leads could occur.
- **Use of external electrical stimulation** such as **transcutaneous electrical nerve stimulation (TENS)** should not be done in the chest area near the electrode leads. Unwanted diaphragm contraction could occur.
- **Shortwave or microwave therapy.** Operating the Clinical Station close to (about 3 feet from) such equipment may produce instability in the applied parts.
- **Magnetic Resonance Imaging (MRI) test.** The PermaLoc electrode is MR unsafe. Do not perform a MRI test while implanted with the PermaLoc electrodes.
- **Magnetic Resonance Imaging (MRI) test.** The NeuRx Clinical Station and surface electrodes are MR Unsafe.

2.3 The patient should avoid accidental contact between connected but unused applied parts (cable or leads) and other conductive parts including those connected to earth ground or any device with the ground symbol.

2.4 The patient should avoid trans-thoracic stimulation.

2.5 Safety has not been established for the use of the device during pregnancy.

2.6 It should not be used in patients with epilepsy.

2.7 **ELECTROMAGNETIC INTERFERENCE WARNING**: Some electrically powered equipment gives off electromagnetic waves which could interfere with Clinical Station. When using your Clinical Station around electrical equipment, check the Clinical Station screen to make sure the Clinical Station is working.

2.8 Do follow the electromagnetic compatibility (EMC) information provided. The Clinical Station needs special precautions regarding EMC. To reduce the possibility of interference on the Clinical Station from other electrical equipment or the Clinical Station effecting other electrical equipment, do not use cables or accessories with the Clinical Station other than those specified.

2.9 **RF COMMUNICATION WARNING**: Portable and mobile RF communication equipment may effect medical electrical equipment. Do not use within 30cm of the implanted electrode leads.

2.10 **ELECTRO-STATIC DISCHARGE (ESD)**:  After the PermaLoc electrode has been implanted but not connected to the connector block, use caution when handling the electrode leads. Before touching the electrode leads, touch the patient to equalize the electrostatic potential.

2.11 **FLAMMABILITY WARNING**: Do NOT use Clinical Station in an oxygen enriched environment, such as a hyperbaric oxygen chamber, or near a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

2.12 Do NOT connect the Clinical Station Stimulator Outputs to the patient electrodes while in PROGRAMMER Mode.

2.13 Do NOT turn ON the Clinical Station while passing through security systems, metal detectors, or Electronic Article Surveillance (EAS).

3 Precautions

The Clinical Station has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to stresses. To avoid damage to the Clinical Station, observe the following precautions:

3.1 Random failures – The physician should be aware that operational failure of the Clinical Station can occur as the result of battery depletion, mishandling, or random component failure.

Possible operational failures of the Clinical Station can include the following:

- No output or erratic output
- No sensing or erratic sensing (e.g. during self-testing)
- False indicator signals
- Inappropriate variance of rate and output intensity
- Loss of control of rate, output, intensity, or power

If loss of control of rate, output, stimulus, or power occurs, and it is not due to a low battery, disconnect the Clinical Station from the patient, contact Synapse Biomedical Customer Service to return it for evaluation.

3.2 Service condition – Before each use, evaluate the Clinical Station for damage and observable defects. Do not use the Clinical Station if the case is cracked, the controls are not functioning, the displays are not working, or if the controls, displays, or connectors are broken.

3.3 During continuous ECG monitoring, the Clinical Station stimulus artifact may be seen on other monitored bio-potential signals.

3.4 The Clinical Station is designed for clinical use only. Clean the device after each use.

3.5 PermaLoc leads and cables – Improper connection or fracture of leads or cables may result in failure of the Clinical Station. Inspect exiting electrode leads and cables for damage before use.

3.6 The Clinical Station is intended to be used when close to the body and the patient cable should NOT be allowed to hang loosely. The patient cable should be positioned appropriately to not allow any hanging loops.

3.7 If you think the device is not providing enough stimulation, then consult this manual or call Synapse Biomedical customer service. This could mean that the Clinical Station may not cause the patient's diaphragm to contract.

4 Environmental precautions

The Clinical Station has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. To avoid damage to the Clinical Station, observe the following precautions:

4.1 Do not expose the stimulator to excessive moisture, heat or severe mechanical shock. If display indicates system failure or device exposed to excessive moisture, heat or shock, disconnect the Clinical Station and contact Synapse Biomedical customer service.

4.2 To protect the Clinical Station against damage due to mechanical shock. Do NOT drop the Clinical Station. The Clinical Station may break and not be available for use when needed. The Clinical Station should remain in the plastic packaging until needed.

4.3 To protect the Clinical Station against damage due to moisture, Do NOT submerge the Clinical Station in liquid. The Clinical Station may quit working and not able to use when needed.

4.4 Avoid contaminating the patient cable connections with blood or other body fluids.

4.5 Do not attempt to open the Clinical Station. The Clinical Station is sealed at the factory and opening the Clinical Station will damage the device and void the warranty.

Other environmental factors may impact proper performance of the Clinical Station in the hospital setting. Use of appropriate environmental health and safety practices will help prevent environmental damage to the Clinical Station.

5 Adverse effects

- The Clinical Station is used for muscle conditioning and ventilation - possible adverse effects are as follows:
    - None known

6 Preparation for use

6.1 Checks prior to use

6.1.1 Service condition

Visually inspect the Clinical Station before each use for a patient to verify that there are no observable defects. Do not use the Clinical Station if there are any observable defects. Verify that the Clinical Station controls function each time before connecting to a patient.

Caution: Before each use, evaluate the Clinical Station for damage and observable defects. Do not use the Clinical Station if the case is cracked, the controls are not functioning, the display is not working, or if the controls, displays, or connectors are broken.

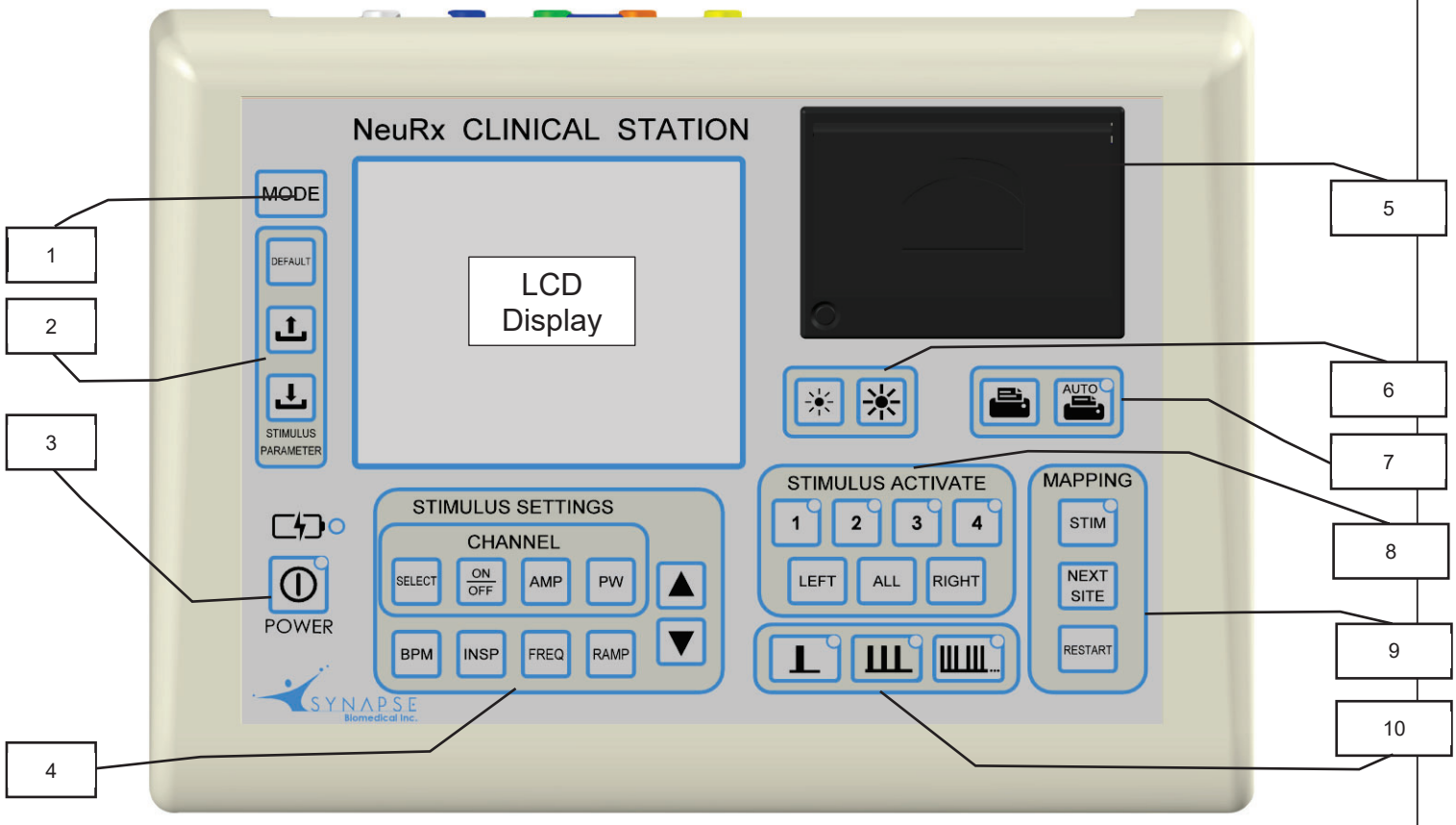
7 Controls

7.1 Control Buttons

The buttons used to control the functions and parameter settings of the Clinical Station are described in this section.

7.1.1 Clinical Station controls

The Clinical Station control buttons are easy to use and conveniently located to program the parameters for each patient's requirements.



1	MODE Button	6	Display Control
2	Operation Control	7	Printer Control
3	Power Button	8	Stimulus Activation Control
4	Stimulus Setting Control	9	Surgical Mapping Control
5	Printer	10	Stimulation Pattern Control

7.1.3 Power Control Buttons

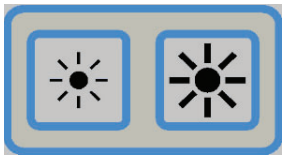
7.1.3.1 Power Button

- To turn ON the device, Press and hold the *POWER* button for 1 second. The indicator **LED** illuminates **GREEN**.
- To turn OFF the device, Press and hold the *POWER* button for 1 second and then release the button.

7.1.3.2 Charging Indicator

- The Charging indicator **LED** is **RED** while the internal battery is recharging, it changes to **GREEN** when the battery is fully charged.

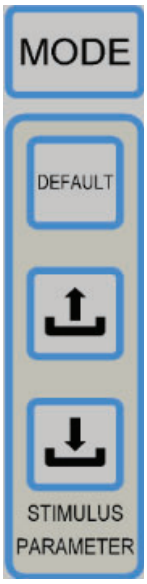
7.1.4 Display Control Buttons



7.1.4.1 Display Contrast

- Display contrast can be adjusted for optimal viewing angle. These buttons can be pressed as necessary.

7.1.5 Operation Control Buttons



7.1.5.1 Operating Mode Button

- The *MODE* button allows the selection for the current operating mode of the device.

- Pressing the button scrolls through the following modes:
  1. STIMULATOR
  2. PROGRAMMER
  3. SURGICAL

7.1.5.2 Default Button

- The *DEFAULT* button resets the displayed stimulus parameter settings to default values.

- This button may be selected during **STIMULATOR** Mode

7.1.5.3 Send Stimulus Settings Button 

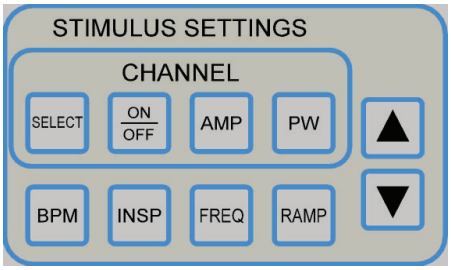
- The *SEND STIMULUS SETTINGS* button sends stimulus settings, as they are displayed, to an attached NeuRx DPS® External Pulse Generator.
- This button may be selected during **STIMULATOR** Modes

7.1.5.4 Retrieve Stimulus Setting Button 

- The *RETRIEVE STIMULUS SETTINGS* button retrieves stimulus settings from an attached NeuRx DPS® External Pulse Generator. The stimulus settings are then displayed.

- This button may be selected during PROGRAMMER Mode

7.1.6 **Stimulus Control Settings Buttons**



7.1.6.1 Channel specific parameters are modifiable by using the following buttons:

SELECT Selects the channel number for modification with the up/down arrows. The selected channel number is indicated by a '>' symbol on the LCD display.

ON:OFF Toggles channel enable status.

AMP Selects amplitude to modify with the up/down arrows.

PW Selects pulsewidth to modify with the up/down arrows.

General timing parameters modifiable by using the following buttons:

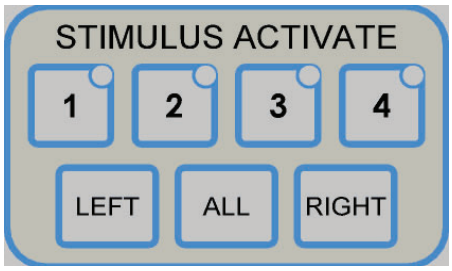
BPM Selects breaths-per-minute to modify with the up/down arrows.

INSP Selects inspiration time to modify with the up/down arrows.

FREQ Selects pulse frequency to modify with the up/down arrows.

RAMP Selects pulse ramp modulation to modify with the up/down arrows.

7.1.7 **Stimulus Activation Control Buttons**



7.1.7.1 The *STIMULUS ACTIVATE* buttons allows for individual outputs or combination of outputs to be activated. Indicator LEDs illuminate while outputs are active

Channel 1 Activates Output 1.

Channel 2 Activates Output 2.

Channel 3 Activates Output 3.

Channel 4 Activates Output 4.

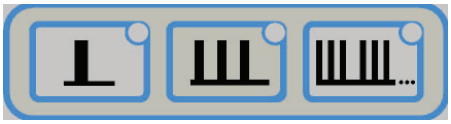
LEFT Activates Outputs 1 & 2.
Corresponds to **LEFT** Outputs **1** & **2**

ALL Activates all 4 Outputs.

RIGHT Activates Outputs 3 & 4.
Corresponds to **RIGHT** Outputs **1** & **2**

Note: All buttons temporarily over-ride the displayed enable status.

7.1.8 Stimulus Pattern Control Buttons



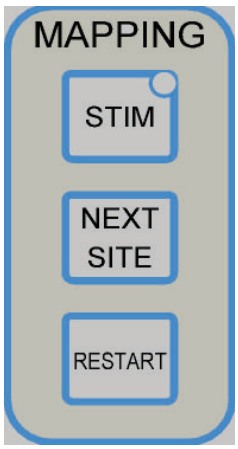
7.1.8.1 The *STIMULATION PATTERN* buttons allow the selection of  or  for the SURGICAL MAPPING mode, and allow the selection of  or  for the STIMULATOR mode

- PULSE 
  - A single stimulus pulse will be sent to the mapping probe.

- INSPIRATION INTERVAL 
  - A train of stimulus pulses will be sent to the mapping probe or the activated output(s), for the **INSP** interval.

- BREATHS PER MINUTE 
  - A continuous stream of stimulus trains will be sent to the activated output(s) at the set **BPM** rate.

7.1.9 Surgical Mapping Control Buttons



- **STIM**

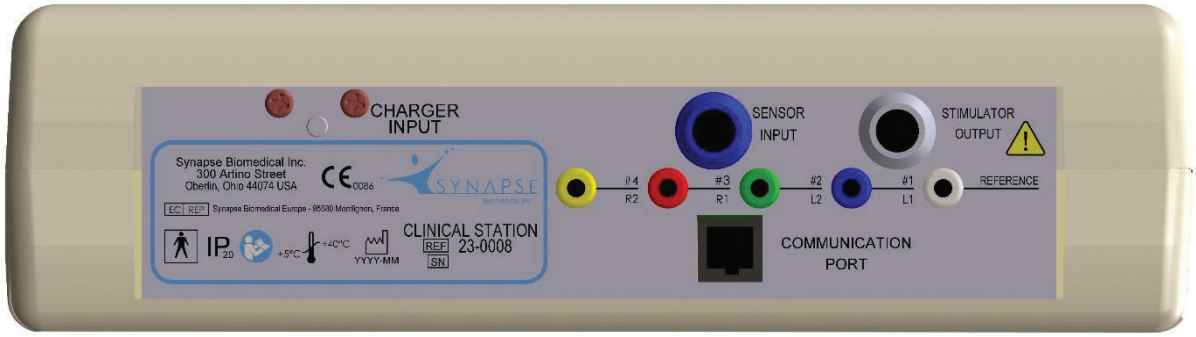
The stimulus can either be a single pulse or an inspiration train as determined by the STIMULUS PATTERN CONTROL. The stimulus parameter settings are determined by Channel 1 settings as displayed while in STIMULATOR mode.

- **NEXT SITE**

Prints out the maximum value of the current site, then increments the mapped site counter.

- **RESTART**

The *RESTART* button resets displayed mapping site counters. This button is active during SURGICAL Mode



NeuRx® CLINICAL STATION REAR PANEL

8 Rear Panel Description

8.1 STIMULUS OUTPUT

8.1.1 STIMULATOR OUTPUT CONNECTOR

The STIMULATOR OUTPUT connector directly connects to the patient cable. This connection is used during electrode characterization.

8.1.2 INDIVIDUAL OUTPUT CONNECTORS

The INDIVIDUAL OUTPUT connectors are used during Surgical Mapping. The REFERENCE connector is attached to the temporary surface Anode and the #1 output connector is attached to the Mapping Probe

WHITE	REFERENCE
BLUE	Channel #1 or LEFT 1
GREEN	Channel #2 or LEFT 2
ORANGE	Channel #3 or RIGHT 1
YELLOW	Channel #4 or RIGHT 2

8.1.3 DURATION OF CONTACT

Connection of the colored cables to the electrode leads may result in a maximum temperature of 41.2 ° C. The conditions of safe contact remain greater than 10 minutes for the applied parts.

8.2 SENSOR INPUT

8.2.1 SENSOR INPUT CONNECTOR

The SENSOR INPUT connector connects to the ACTIVE SENSOR MODULE cable. The Module senses the abdominal pressure during Surgical Mapping stimulation. The pressure waveform is processed by the NeuRx® Clinical Station and graphically displayed on the LCD.

8.3 PROGRAMMER PORT

8.3.1 PROGRAMMER PORT CONNECTOR

- The PROGRAMMER PORT must not be used and remain covered when the Clinical Station Stimulator Outputs are connected to the patient electrodes.
- The PROGRAMMER PORT connector provides a serial communication port for a NeuRx DPS® External Pulse Generator. The NeuRx® Clinical Station provides NeuRx DPS® External Pulse Generator programming capability while in PROGRAMMER Mode.

8.4 BATTERY CHARGING 

8.4.1 CHARGER INPUT

- ONLY the supplied charger is permitted to be connected to the CHARGER INPUT. The MEDICAL POWER SUPPLY is rated for 9 VDC & 1.33A.
- The Clinical Station will not power ON while the battery charger is plugged in and charging the internal battery.

THE CHARGER MUST NOT BE USED DURING NORMAL OPERATION!

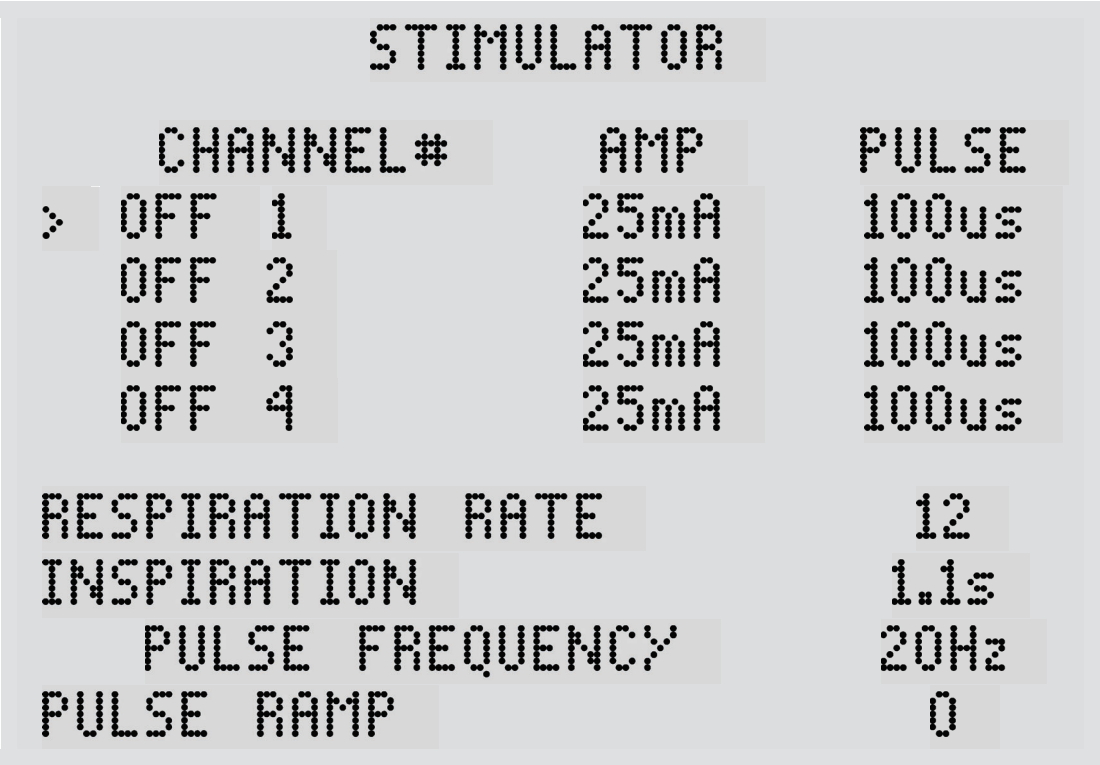
- The Low Battery indicator will light YELLOW to indicate a low battery. The unit is automatically powered OFF while charging. The battery charging time is approximately 4 hours.
- In the event that the internal rechargeable battery fails to hold an adequate charge, the device should be returned to Synapse Biomedical Inc. for battery replacement and proper disposal of depleted battery.

8.4.2 CLINICAL STATION USE LOCATION

- Position the Clinical Station for easy accessibility to remove the battery charger before use.

9 Modes of Operation

9.1 **STIMULATOR MODE**



9.1.1 STIMULATOR DISPLAY

- The start-up screen displays default parameters for all stimulator values. The four outputs have individual values for Amplitude and Pulsewidth, and share parameter values for Respiration Rate, Inspiration Interval, Pulse Frequency and Pulse Ramp. Parameter values can be modified by using the STIMULUS SETTINGS Control buttons.

PARAMETER	RANGE	DELTA
AMPLITUDE	5mA – 25mA	1mA
PULSEWIDTH	20µsec – 200µsec	10µsec
RESPIRATION RATE	8 - 18	1
INSPIRATION INTERVAL	0.8sec – 1.5sec	0.1sec
PULSE FREQUENCY	5,10,11,12,13,14,15,16, 17,18,19,20 Hz	NA
PULSE RAMP	0 - 10	1

STIMULUS PARAMETER RANGES

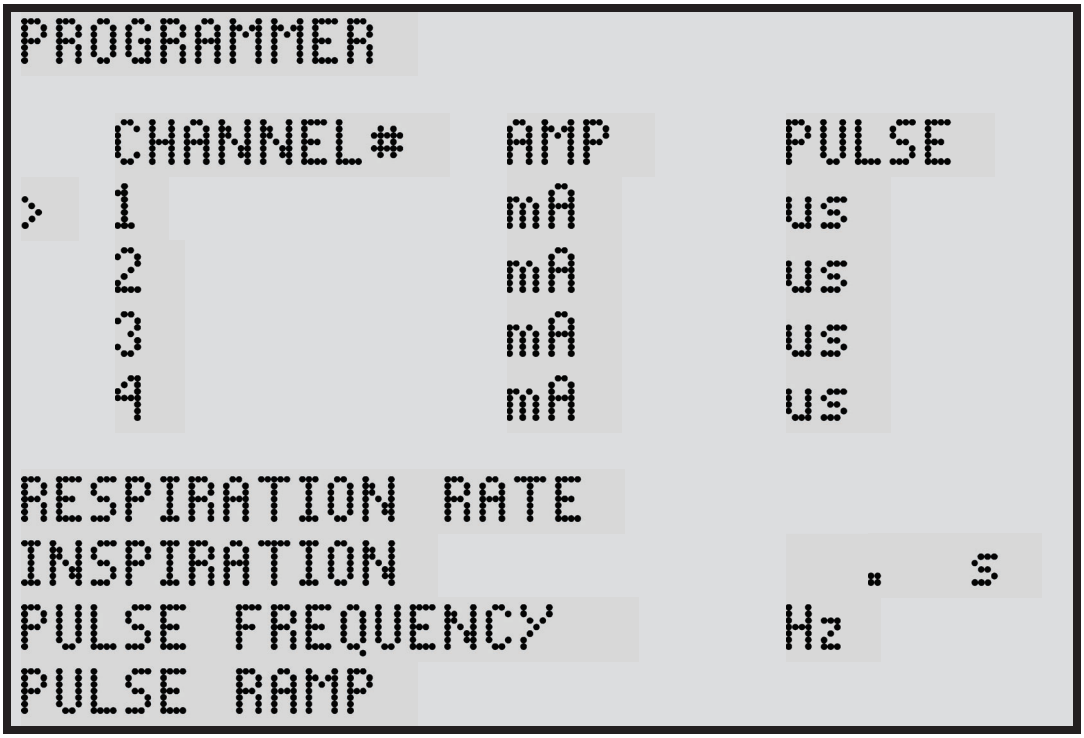
- Stimulus outputs may be activated by pressing any of the **ACTIVATE STIMULUS** buttons.

  > ON 1 * 25mA 100us

- As an Output is activated, an indication of relative electrode lead impedance is displayed on each line of the corresponding output's parameters. Impedance levels are displayed as follows: '*' and 'X', with 'X' indicating a likely open circuit.

- Do NOT connect the Clinical Station Stimulator Outputs to the patient electrodes while in PROGRAMMER Mode.

9.2 **PROGRAMMER MODE**



9.2.1 PROGRAMMER DISPLAY

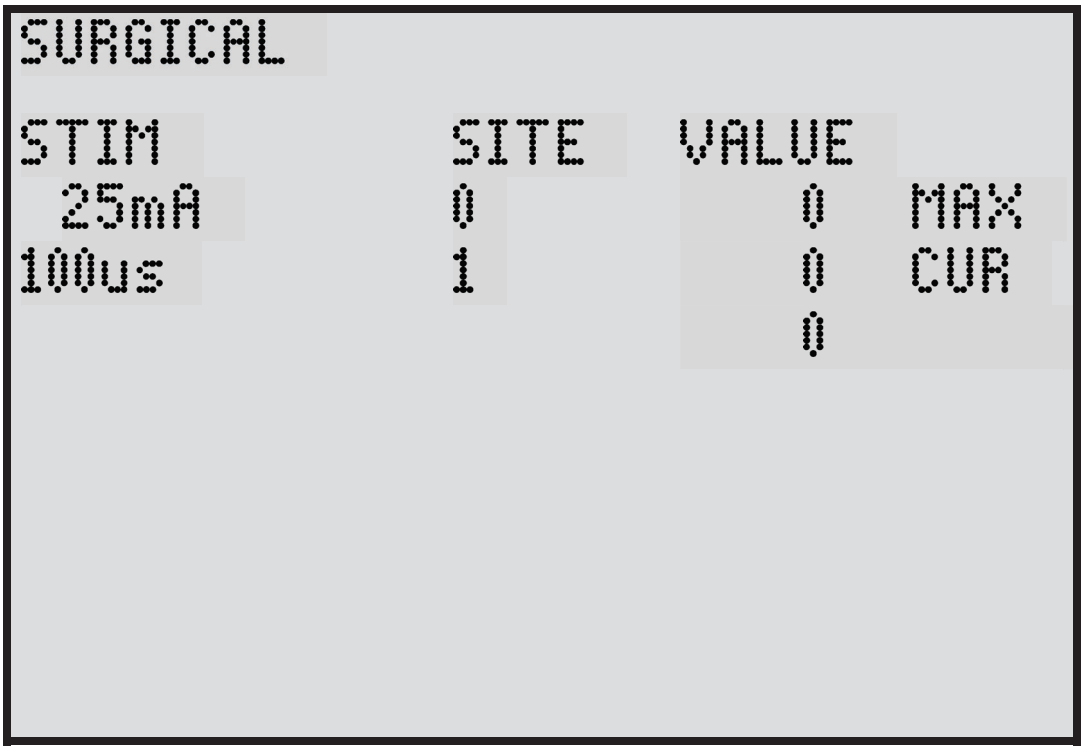
- The Clinical Station Stimulator Outputs must not be used when the Clinical Station PROGRAMMER PORT is connected.

- The start-up screen displays blanks for all parameter values. Stimulus parameter data must first be retrieved from an externally connected NeuRx DPS® External Pulse Generator.

- Connect the NeuRx DPS® External Pulse Generator to the PROGRAMMER PORT on the rear panel of the NeuRx® Clinical Station using the Communication Cable. If the NeuRx DPS® External Pulse Generator is not connected to a patient, than connect a Test-Load plug to the Patient Output connector on the top of the NeuRx DPS® External Pulse Generator.

- While the NeuRx DPS® External Pulse Generator is powered ON, press the **RETREIVE STIMULUS SETTINGS**. The NeuRx DPS® External Pulse Generator parameter settings will be displayed. Parameter values can be modified by using the STIMULUS SETTINGS Control buttons.

9.3 **SURGICAL MAPPING MODE**



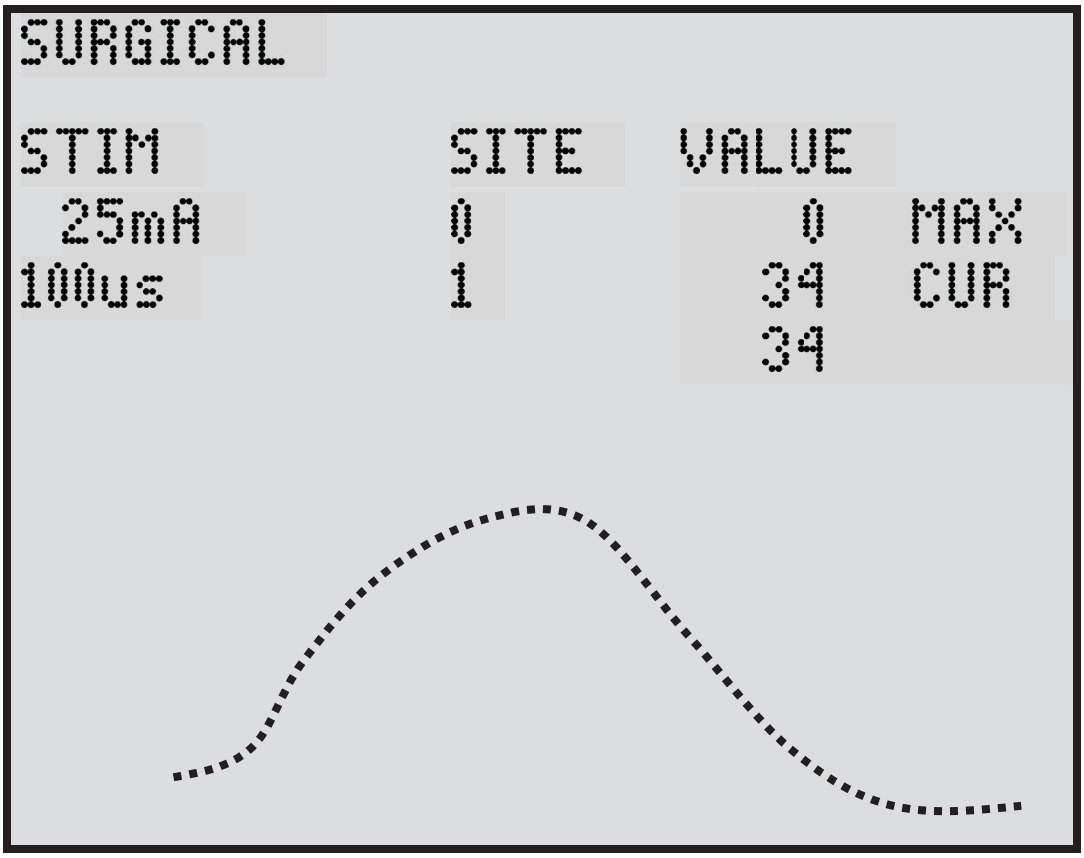
9.3.1 SURGICAL MAPPING DISPLAY

- When ready to initiate Surgical Mapping, press the ENABLE AUTO PRINT button, the indicator LED will illuminate and a header for patient information will be printed.

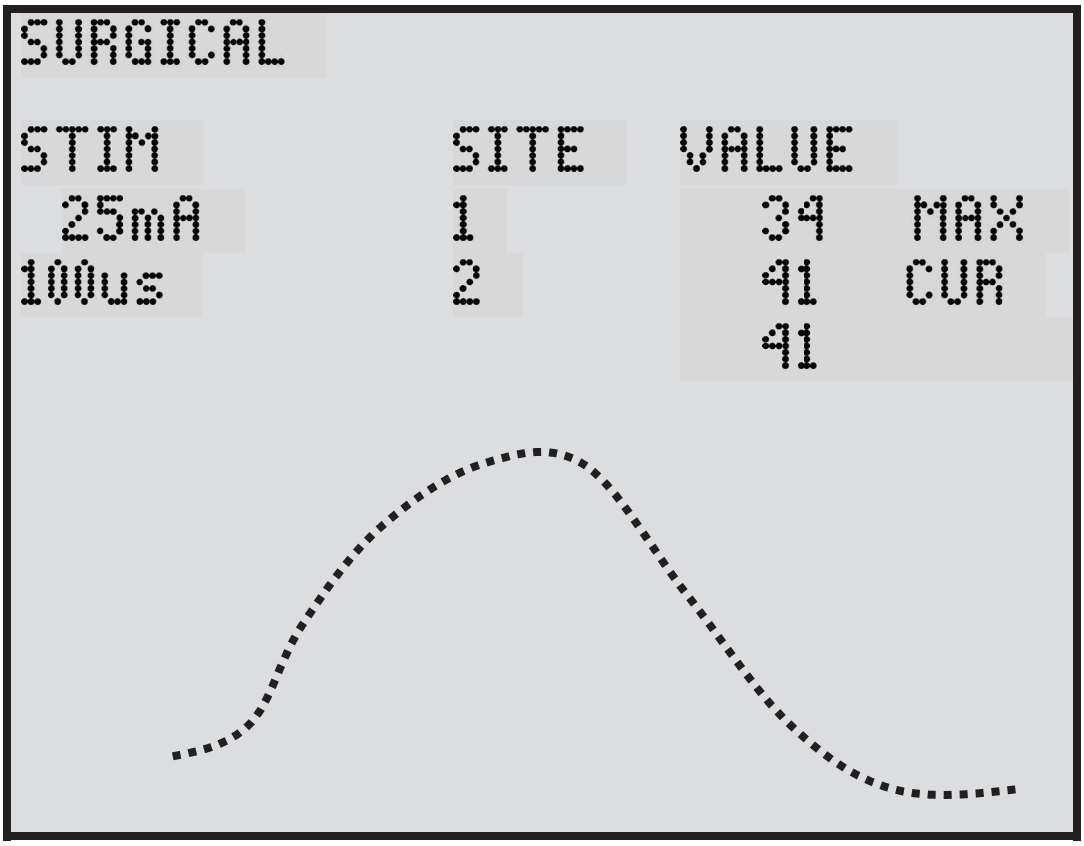
DATE: _____
PATIENT: _____
LOCATION:_____

The LOCATION refers to the Left or Right hemi-diaphragm.

- A stimulus pulse is triggered to the Mapping Probe by pressing the STIM button. The indicator LED illuminates briefly when the stimulus pulse is sent. The SENSOR MODULE detects the abdominal pressure change that results from the stimulus pulse. The pressure waveform is displayed and an analysis is made to determine the pressure change. The CURrent pressure change is displayed in arbitrary units and is used as a relative measurement to confirm best stimulus response.



- Successive stimulus pulses may be sent to the same SITE by repeatedly pressing the STIM button. The MAXimum value from all successive pulses is remembered and will be printed when the NEXT SITE button is pressed.



- Additional SITES are mapped until it is determined where the maximum response is attained.

- When starting mapping on the other hemi-diaphragm, press the RESET SURGICAL MAPPING button to clear all data and SITE counters.

10 Maintenance and Service

- The surfaces of the NeuRx® Clinical Station and the Active Sensor Module may be cleaned per Hospital facility procedures.

- The surfaces of the Patient and Communication cables may be cleaned with disinfectant wipes ONLY per Hospital facility procedures.

- The NeuRx® Clinical Station has no user serviceable parts and therefore should not be opened. It is recommended that if the unit becomes inoperable it is returned to Synapse Biomedical Inc. for repair.

- The Active Sensor Module requires no routine maintenance and if it becomes inoperable it can be returned to Synapse Biomedical Inc. for replacement.

- In the event that the internal rechargeable battery fails to hold an adequate charge, the device should be returned to Synapse Biomedical Inc. for battery replacement and proper disposal of depleted battery.

- Any further questions may be answered by contacting Synapse Biomedical Inc.

11 Specifications

Power Source	Internal rechargeable battery, non-replaceable 7.2v Li-ion
Operating Temperature	+5 to +40 C
Storage Temperature	-20 to +54 C
Relative Humidity	15% to 93%, non-condensing
Pulse Waveform-type	Regulated-current biphasic
Pulse Amplitude	5mA to 25mA
Pulsewidth	20µsec to 200µsec
Pulse Period	50msec to 200msec
Inspiration Interval	0.8sec to 1.5sec
Inspiration Rate	8 to 18 Breaths per Minute
Load Resistance	100 ohms to 1500 ohms

12 Placement during use

When the Clinical Station is in use, place it in an area that reduces the potential of damage due to dropping or pulling the cables.

- Verify that the stimulator is directly observable by medical staff.

12.1.1 **Cleaning prior to use**

During normal use, the Clinical Station stimulator and cables may become soiled with blood or body fluids. Verify that the Clinical Station stays clean during use.

13 Default Settings

The Clinical Station Stimulator will have a default setting from the factory. Please adjust the setting per patient requirements.

- Amplitude 25mA (all channels)
- Pulsewidth 100 uSec (all channels)
- Respiration Rate 12 BPM
- Inspiration 1.1 Sec
- Pulse Frequency 20Hz
- Channels Enabled All 4 channels OFF
- Pulse Ramp 0

NOTE: IF adjustments are made, the DEFAULT button will return the device to default settings.

14 Errors During Normal USE

14.1 Error Indicator 

- Low Battery - This error displays a low battery error during operation. The yellow LED will stay lit until the device has been re-charged.

15 Cleaning

15.1 Cleaning the Clinical Station Stimulator

Cautions:

- Clean the Clinical Station stimulator when required.
- ONLY clean with disinfectant wipes.
- Do not immerse the Clinical Station stimulator in water or cleaning agents. Severe damage to the device may occur.

Cleaning – Follow Hospital facility procedures for all cleaning of the Clinical Station.

Note: Do not expose the Clinical Station to ethers, acetone, or chlorinated solvents. These solvents may damage the case, labels, or metal components.

15.2 Safety checks

Perform safety checks on the Clinical Station if the device has been dropped or damage is suspected.

15.2.1 Visual inspection

Perform the following visual inspections each time the Clinical Station is used:

- Check that there is no mechanical or physical damage to the device.
- Confirm that the device will power up and all controls buttons function.

15.2.2 Functional inspection

Perform the following functional inspections each time the Clinical Station is used:

- Power on the device and confirm the LCD display is displaying operational status
- Verify that the control buttons and displays function and work properly.
- Inspect all connections and cables.

Caution: Do not attempt to open the Clinical Station. The Clinical Station is sealed at the factory and opening the Clinical Station will damage the device.

16 Replacement Parts

The following replacement parts may be ordered from an authorized supplier.

ITEM	PART NUMBER	ORDER QUANTITY
Patient Cable (1m)	22-0011	1 Each
Active Sensor Module (2m)	23-0007	1 Each
Communication Cable	29-0008	1 Each
Thermal Paper Roll	29-0009	1 Each
Battery Charger (Wall; WMMPU12A9V-SB)	29-0010	1 Each

Storage of Replacement Parts:

1. Store in a dry location within the specified temperature range

Storage of Clinical Station

1. Store in a dry location within the specified temperature range
2. Store in the protective case as received

DISPOSAL of Replacement Parts:

1. Clinical Station disposal – return to Synapse Biomedical
2. All other replacement parts with potentially bio-hazardous contamination – please follow hospital policies for proper method of disposal.

17 Customer Service

For questions concerning the Clinical Station, please contact the Synapse Biomedical Customer Service at 1-888-767-3770 Ext. 137.

For Technical questions and training concerns, please contact:
1-888-767-3770 Ext. 137.

18 Troubleshooting

Use the following troubleshooting guide to help solve problems with your Clinical Station:

	Problem	Action
1	Clinical Station powers off during use.	• Check the battery indicator. • Plug in the battery charger and the red LED should light up on the battery indicator • Use the backup Clinical station • If the problem continues, call Synapse Biomedical customer service for assistance.
2	The Clinical Station does not power up.	• Inspect for mechanical failures on the case due to being dropped. • Check the battery indicator. • Plug in the battery charger and the red LED should light up on the battery indicator • Call Synapse Biomedical customer service for assistance.
3	Patient is not receiving adequate stimulation for the evaluation.	• Qualified hospital staff modify the settings of the stimulator.
4	Discomfort while pacing.	• Qualified hospital staff to evaluate. • Reduce stimulus
5	Bleeding, bruising, or infection where the electrode leads pass through the skin.	• Qualified hospital staff to evaluate.
6	Skin irritation from surface electrode	• Qualified hospital staff to evaluate.

	Problem	Action
7	One or multiple “X”s appear on the Clinical Station stimulator display.	• Inspect the connections of the electrode leads to the surgical cable set or connector block for non-connection or breakage of the electrode. • If the problem continues, call Synapse Biomedical customer service for assistance.
8	The Clinical Station stimulator is submerged in water or fluid.	• STOP use of the Clinical Station. • Replace with new Clinical Station.
9	The Clinical Station is dropped.	• Visually inspect the Clinical Station for physical damage. • Confirm the device power, controls buttons and display are functioning. • If device is broken, STOP use of the device and replace with new Clinical Station.

19 Electro-Magnetic Compatibility

(Applicable when the Clinical Station stimulator is powered by battery.)

The Clinical Station stimulator requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

Essential Performance

1. Stimulus LCD display parameters remain unchanged during continuous operation
2. Stimulus output is evident on display with electrode continuity or test plug.
3. Delivery of stimulation to the Patient cable at the LCD display settings.

- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Clinical Station stimulator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Clinical Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinical Station should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Clinical Station uses RF energy only for its internal function. Therefore, its RF emissions are very low and are no likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Clinical Station is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Clinical Station or shielding the location.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Clinical Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinical Station should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	The Clinical Station is battery operated equipment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration – electromagnetic immunity

The Clinical Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinical Station should assure that it is used in such an environment..

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Clinical Station, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/3] √P 80 MHz to 800 MHz d = [7/3] √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clinical Station stimulator is used exceeds the applicable RF compliance level above, the Clinical Station should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Clinical Station stimulator.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Clinical Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinical Station should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Clinical Station, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the Clinical Station

The Clinical Station is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Clinical Station stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Clinical Station as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz $d = [3.5/3]\sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 d = [6/9] √P	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 d = [6/28] √P
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

300 Artino Street
Oberlin, Ohio 44074
U.S.A.
www.synapsebiomedical.com

Tel: 1-888-767-3770 extension 137
1-440-774-2488 extension 137
Fax: 1-440-774-2572

EC REP Synapse Biomedical - Europe
7 Rue de la Liberation
95880 Enghien Les Bains, France
France +33 (0) 9 60 12 44 98
Other European Countries +33 (0) 1 64 95 23 99

CE 2797

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