NeuRx® Diaphragm Pacing System

Patient/Caregiver Information and Instruction Manual

SYNAPSE
Biomedical Inc.

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1.0. INDICATIONS FOR USE

The NeuRx® Diaphragm Pacing System is intended for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but 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.

Humanitarian Use Device: Authorized by Federal Law for use in the treatment of respiratory insufficiency for high-level spinal cord injured patients. The effectiveness of this device for this use has not been demonstrated.

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

2.0. SYMBOL DESCRIPTIONS

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.

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 packages of devices as an indication of the storage and transit temperature limits. While the symbol appears on actual devices as an indication of the operational 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.

The ***Accompanying Documents*** symbol appears on all packages of devices indicating that instructions for use are available for additional information.

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 ***Warning*** symbol on powered equipment indicates physiological effects not obvious to the user that can cause harm.

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.

IP**24** The ***Ingress Protection (IP) Classification*** symbol appears on powered equipment indicating that the device is protected from splashing water.

MR Unsafe. A device that is known to pose hazards in all MR environments.

3.0. WARNINGS 

- Use only under the direction of a physician. This device is electrically powered and may produce tissue damage or electrical hazard if improperly used. Do NOT attempt to open the external pulse generator (EPG) case or attempt any modifications as this will cause a failure in the EPG functionality; the device has NO patient-accessible controls.

- NeuRx DPS could interfere with some medical equipment. Some medical equipment could interfere with the NeuRx DPS. Call your healthcare provider who is helping you with your NeuRx DPS 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 NeuRx EPG stimulator may interfere with these devices.
    - **Surgery**. Use of high-frequency surgical equipment may cause burns where the electrode wires pass through the skin. It might also damage the NeuRx EPG if connected.
    - **Diathermy treatment.** Diathermy treatment is deep tissue heat treatment. It should not be performed within 30cm of the implanted electrode leads. Unwanted tissue heating through the electrode leads could occur.
    - **External electrical stimulation** such as **transcutaneous electrical nerve stimulation (TENS).** Such stimulation should not be done in the chest area near the electrode wires. Unwanted diaphragm contraction could occur.
    - **Shortwave or microwave therapy.** Operating the NeuRx DPS close to (about 3 feet from) such equipment may interfere with your NeuRx DPS.
    - **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 EPG stimulator and surface electrodes are MR Unsafe. The NeuRx DPS has not been tested with MRI. MRI could cause the electrode wires to move. MRI could also cause unwanted tissue heating through the electrode wires.

- Avoid trans-thoracic stimulation.

- Avoid accidental contact between connected but unused applied parts (cable or leads) and other conductive parts including those connected to protective earth.

- The long-term effects of chronic electrical stimulation are unknown.

WARNINGS (con't) 

- Safety has not been established for the use of the device during pregnancy. It should not be used in patients with suspected heart problems or epilepsy.
- Do not use this device if skin in the area is swollen, infected, or inflamed or if there are skin eruptions such as phlebitis, thrombo phlebitis, or varicose veins.
- **ELECTROMAGNETIC INTERFERENCE WARNING**: Some electrically powered equipment gives off electromagnetic waves which could interfere with your NeuRx EPG. When using your NeuRx EPG around electrical equipment, check the NeuRx EPG screen to make sure the EPG is working.
- Avoid electro-cauterization in the area of the implanted electrodes.
- Disconnect the NeuRx EPG during electrical diagnostic tests such as EMG or ECG.
- Do follow the electromagnetic compatibility (EMC) information provided. The NeuRx EPG needs special precautions regarding EMC. To reduce the possibility of interference on the NeuRx EPG from other electrical equipment or the NeuRx EPG affecting other electrical equipment, do NOT use cables or accessories with your NeuRx EPG other than those specified.
- **RF COMMUNICATION 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 NeuRx EPG stimulator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **FLAMMABILITY WARNING**: Do NOT use the NeuRx EPG in an oxygen enriched environment, such as a hyperbaric oxygen chamber, or near a flammable anesthetic mixture with air, oxygen or nitrous oxide. The NeuRx EPG is not categorized as AP (anesthetic-proof) or APG (anesthetic-proof category G - gas) type of equipment.
- If you use the device full time, then you must always have a back-up means of breathing help (ventilation) available. If you think there is any problem with your NeuRx DPS, then you should use your back-up means right away. When you switch to your back-up means of breathing help, you should turn off the NeuRx DPS.
- Do NOT operate the NeuRx EPG stimulator within 30cm of security systems, metal detectors, or Electronic Article Surveillance (EAS).

WARNINGS (con't) 

- Avoid eating or drinking while conditioning with the NeuRx DPS. There is a risk of food or liquid entering your lungs. **Do NOT have any food or liquid in your mouth when you start conditioning**. If you use the NeuRx DPS full time, talk to your healthcare provider about the ways to reduce the risk of food or liquid entering your lungs.
- To ensure proper operation of the alarm system, verify the following audible and visual indicators prior to use on each patient:
    1. Plug the test plug found in the patient kit into the patient cable connection on the top of the NeuRx EPG.
    2. Turn the EPG ON
    3. Remove the test plug
    4. Verify the High Priority Alarm is active and the display is showing (XXXX)
    5. Replace the test plug. The alarm should stop and the display should show (****)
    6. Remove the battery cover and primary battery
    7. Verify the Low Priority Alarm is active and the display is showing "Low Battery"
    8. Replace the primary battery and battery cover
    9. Turn EPG OFF
    - If proper alarm indicators are not heard and seen, see Section 25.0 Troubleshooting and Use Errors.

4.0. CAUTIONS 

- **This device should be kept out of the reach of children, pets or pests.**
- The NeuRx DPS is a body worn device kept close to the body and the patient cable should NOT be allowed to hang loosely. This is to avoid the potential of any strangulation. The patient cable should be positioned appropriately to not allow any hanging loops.
- Spinal Cord Injury (SCI) patients must have a mechanical ventilator available at all times. If you do not feel that you are receiving adequate ventilation or if any malfunction of the pacing device is suspected, you should be placed on mechanical ventilation immediately and the pacing system turned off.
- Do not expose the pacing device to excessive moisture, heat or severe mechanical shock. If display indicates system failure, pain is felt at the electrode site, or device exposed to excessive moisture, heat or shock, disconnect the cable and contact Synapse Biomedical.
- Do not expose the pacing device to extended sun light or excessive dust or lint. If display indicates system failure, pain is felt at the electrode site, or device exposed to extended sun light, dust or lint, disconnect the cable and contact Synapse Biomedical.
- Precautions should be observed when there is a tendency to hemorrhage following acute trauma or fracture, following recent surgical procedures when muscle contraction may disrupt the healing process, or where sensory nerve damage is present.
- Some patients may feel skin irritation, sensitivity, or have an allergic reaction because of the NeuRx DPS.

  This may be due to:

  - The stimulation
  - The adhesive on the skin bandage.
  - The transparent dressing used over the gauze that covers the electrode wires. (Tegaderm™ and Op-Site™ are examples of transparent dressings).
- Irritation can usually be reduced by changing the settings of the EPG or removing the adhesive. Call your healthcare provider who is helping you with your NeuRx DPS if this occurs.

CAUTIONS (con't) ⚠

- If you think the device is not providing enough stimulation, then call your healthcare provider who is helping you with your NeuRx DPS. This could mean that the NeuRx DPS may not cause your diaphragm to contract.

- To protect the NeuRx EPG against damage due to mechanical shock:
  - **Do NOT drop the NeuRx EPG**. The EPG may break and not be available for use when needed.
  - Use the protective black carrying case provided for transporting the NeuRx EPG when not in use.
- To protect the NeuRx EPG against damage due to moisture, **Do NOT allow the NeuRx EPG to get wet**. The EPG may quit working and not be available for use when needed.
- **Do NOT get the NeuRx EPG wet.** This includes during bathing, showering, swimming, or any other activity in which you could get wet. While the NeuRx EPG is designed to keep moisture out, the EPG is not waterproof. If the location where the electrode wires pass through your skin (the *exit sites*) gets wet, it may affect treatment. You may receive less stimulation. You may also feel the sensation of the stimulation. Take steps to keep the exit sites from getting wet. Protect the exit sites with a gauze pad and transparent dressing (such as Tegaderm™ or Op-Site™). If the exit site gets wet, clean it with an alcohol wipe. Use an individually packaged pad saturated with 70% isopropyl alcohol. Allow the alcohol to air dry before use.

- If the pacing device is not to be used for an extended period or in storage, please remove the primary battery to prevent any possible damage.

- **Choke Hazard:** Patient kit contains small parts. Use caution not to inhale or swallow any small parts. When the small parts are not in use, replace into the designated secured foam insert in the patient kit.

5.0. DEVICE DESCRIPTION

The name of the device is, NeuRx Diaphragm Pacing System (DPS). The NeuRx DPS has implantable parts and external parts. The implantable parts consist of five electrode wires which go through the skin. The tips of four electrode wires are placed into the diaphragm by the surgeon. The diaphragm is the breathing muscle. The tip of the fifth electrode wire is placed under the skin in the chest area to complete the wiring. The other ends of the five electrode wires come out through the skin in the chest area. The outside ends of the electrode wires will be placed in an electrode connector. The electrode connector is attached to the skin with the connector holder. The connector holder has an adhesive patch like a bandage. The electrode connector has a socket to plug in one end of the patient cable. The other end of the patient cable is connected to the NeuRx EPG. The NeuRx External Pulse Generator (EPG) is a stimulator box.

The patient kit contains the external parts. These parts include the NeuRx EPG, patient cables, batteries and connector holders. The patient cable goes between the EPG and the electrode connector.

The stimulator provides repetitive electrical stimulation to the implanted electrodes to cause the patient's diaphragm to contract and cause the patient to draw breath in a manner similar to natural breathing.

Your physician will program the Stimulator so that it produces the right stimulation patterns for you. If the stimulation makes you uncomfortable, tell your physician as he or she can adjust the Stimulator to reduce or eliminate the discomfort.

The user simply connects the device to the implanted electrodes and turns it on for use; no other controls are available or necessary for operation.

During use, the stimulator should be kept close to the patient's body to avoid pulling on the cable and electrodes.

The stimulator can be placed in a pocket of the patient's clothing, a fanny pack or simply placed on a table or other convenient location.

See Figure 1 for a picture of the NeuRx EPG, patient cable, connector holder, electrode connector, and electrode wires. See Figure 2 for a drawing that shows where the electrode wires are implanted in the body.

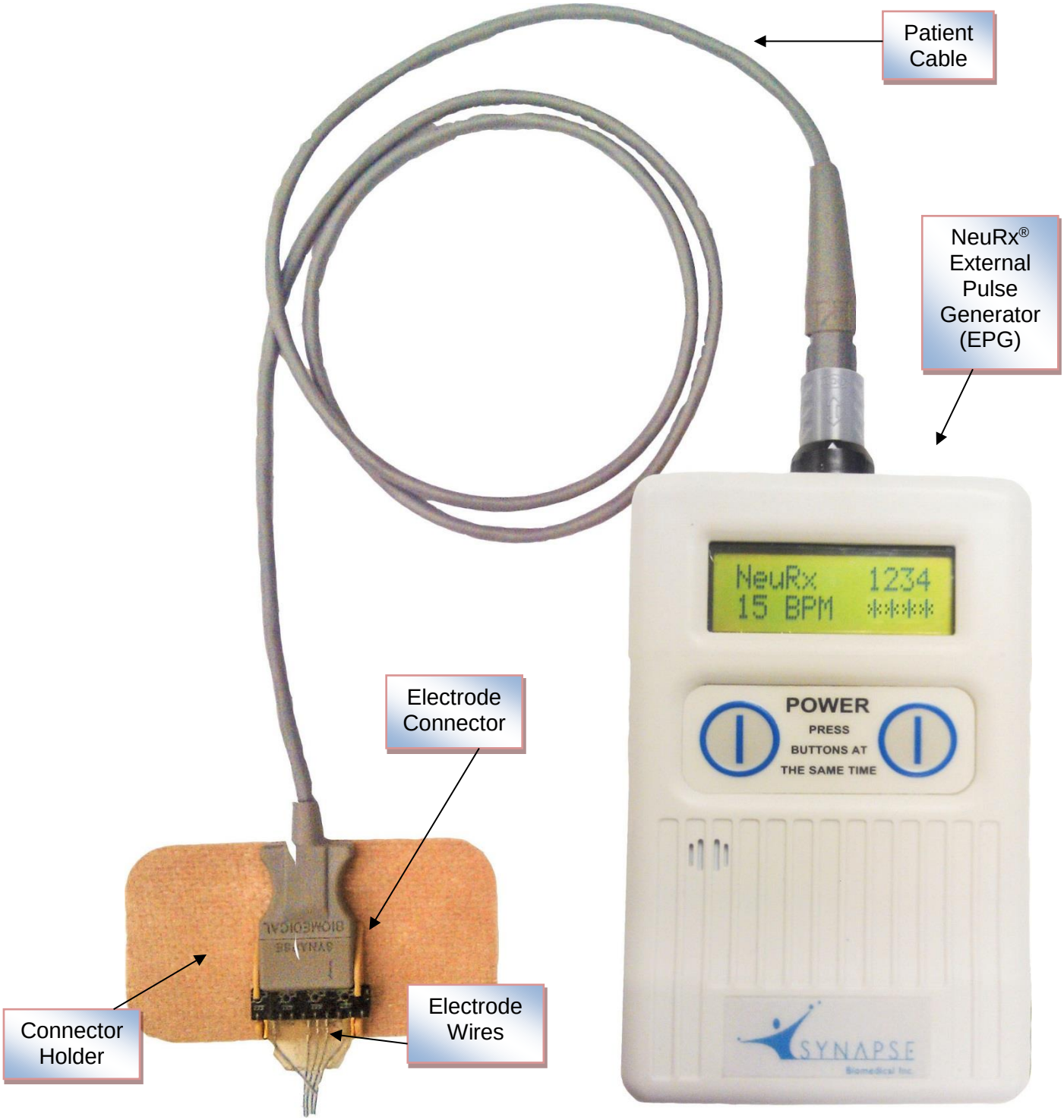


Figure 1. NeuRx External Pulse Generator (EPG), Patient Cable, Connector Holder, Electrode Connector, and Electrode Wires.

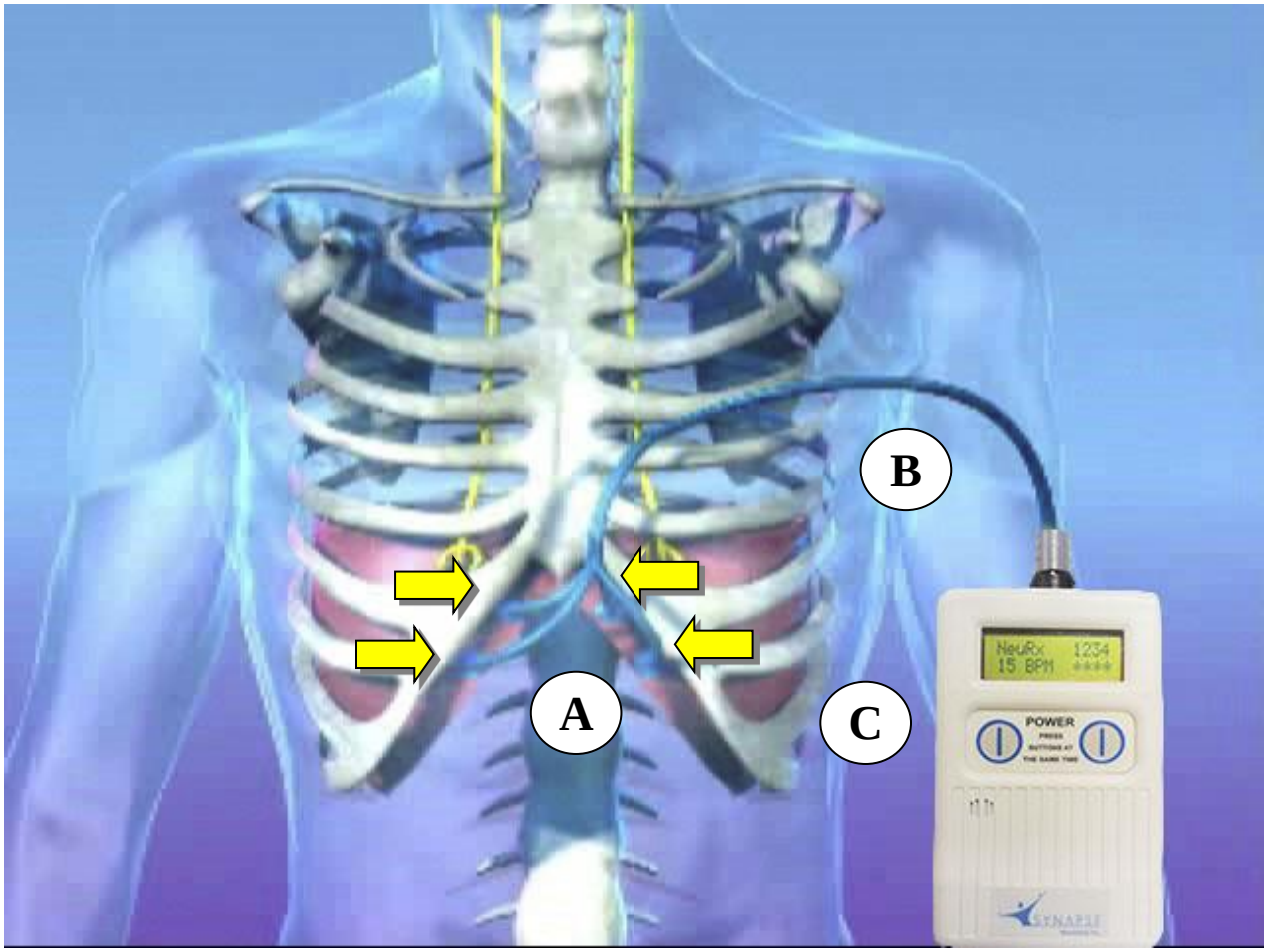


Figure 2. Location in the body where the four NeuRx DPS electrode wires (A) are implanted in the diaphragm. A yellow arrow points to each of the four wire implant locations. The patient cable (B) carries the electrical signal from the EPG (C) to the electrode wires (A) which stimulate the diaphragm to contract.

6.0. BEFORE SURGERY: WHAT TO EXPECT

You must have bilateral intact phrenic nerves below the level of the spinal cord injury for you to benefit from this device. Your healthcare provider may do a phrenic nerve test (PNCS) or a nerve test during an x-ray (fluoroscopy) to check for diaphragm movement. The results of one of these tests may show if you could be a candidate for the NeuRx DPS®.

7.0. SURGERY: WHAT TO EXPECT

The surgeon will make a short cut (incision) in the skin of your abdomen. This incision will give the surgeon access to your diaphragm. The incision will be about half an inch long. A tube will be placed into the incision. Carbon dioxide gas will be pumped through the tube to fill your abdomen. A small tool with a camera on the end (laparoscope) will be inserted into the tube in your abdomen. After the surgeon looks into your abdomen, 3 more incisions will be made. These incisions will also be about half an inch long. A tube will be placed in each incision for the surgeon to work through.

The surgeon will then insert a tool called a probe through one of the tubes. The probe will help the surgeon find the best location to place the electrode wire tips in the diaphragm. The surgeon will use the probe to test several locations on the diaphragm.

Once the surgeon has found the 4 best locations, the surgeon will remove the probe. The surgeon will then insert the tips of 4 electrode wires in these locations. The surgeon will put the other ends of the 4 electrode wires on the outside of your body. These 4 wires will come out through your skin in the same area. A fifth electrode wire is then placed just beneath the skin in the same area to complete the wiring.

After surgery, you will be able to see about 1 to 2 inches of each electrode wire outside of your body.

After surgery you may have an x-ray. This is done to check for abdominal air that may have gone to your chest (capnothorax). If needed, a tube may be placed in your chest to remove the carbon dioxide. After the surgery, your surgeon will decide how long you will have to stay in the hospital.

8.0. AFTER SURGERY: WHAT TO EXPECT

Your NeuRx DPS may be implanted as a same-day surgery. Depending on your condition before and after surgery, you may need to spend the night. If you have a second procedure at the same time as your DPS implant you may need a longer stay in the hospital. You should discuss this with your surgeon prior to the surgery.

While you are recovering from surgery, a healthcare provider will adjust the settings on your NeuRx EPG. The purpose is to give the right amount of stimulation to your diaphragm. If the stimulation makes you uncomfortable, tell your healthcare provider. He or she can change the settings to reduce or eliminate the discomfort.

Before you leave the hospital, the staff will give you detailed instructions on how to use the NeuRx DPS. You will also be given this manual. You will use the NeuRx DPS to condition your diaphragm. In conditioning, the NeuRx EPG sends a small amount of electricity through the wires to your diaphragm. This causes your diaphragm to contract. When your diaphragm is conditioned, it will do a better job of helping your breathing. See Section 14.0 Conditioning Sessions and Section 15.0 Conditioning Warnings for information about conditioning your diaphragm.

You will need to keep the NeuRx EPG dry while using. The NeuRx EPG is splash-proof but not waterproof. For instructions on bathing, showering, swimming, or any activity during which you could get wet refer to Section 20.0 How to Shower or Bathe.

If your NeuRx EPG is properly cared for, the device should keep working for continued use, however, you will need to change the battery in your NeuRx EPG about every 96 hours using alkaline batteries.

The following sections will walk you through the use, care and troubleshooting of the NeuRx EPG.

9.0. PATIENT INFORMATION

Patients with high-level spinal cord injuries typically experience chronic ventilatory insufficiency due to respiratory muscle paralysis. These patients historically have been supported predominantly through positive pressure mechanical ventilation. Alternatively, patients may be ventilated through

activation of the nerves that cause the diaphragm to contract and create an inspiration. A device such as the NeuRx DPS, that is surgically implanted in the diaphragm, does this and has given SCI patients the ventilatory support and freedom to experience a normal breathing pattern with the NeuRx DPS device as long as they have an intact phrenic nerve.

The first step in using the NeuRx DPS device is the process of increasing diaphragm muscle condition. Patients who have long standing and significant respiratory paralysis will require conditioning of the diaphragm muscle in order to sustain ventilation. The more you condition, the stronger your diaphragm will become.

Conditioning can happen every hour. In the beginning, the recommended stimulator usage for SCI patients is 15 to 30 minutes each session. As your diaphragm improves, the length of your sessions should increase and the number of daily sessions should decrease. You should allow 45-60 minutes between sessions to allow your diaphragm to fully recover. Always consult your physician before making any changes to your daily pacing sessions.

10.0. PATIENT KIT CONTENTS

The Patient Kit (20-0024) contains all that is required to begin conditioning and use. The kit will contain the following:

Item	Quantity	Part Number
NeuRx DPS External Stimulator	2	23-0021
Connector Holder Kit	1	22-0004
Patient Cable (1 meter)	2	22-0011
Screwdriver	1	29-0018
Test Plug	1	60-0001
Alkaline Batteries (Included)	6	29-0025
*** (Alternate) Lithium Batteries ***	(6)	29-0007
Surface Electrode, 4 pack with Interconnect	1	22-0034
Patient/Caregiver Instruction Manual	1	77-0090

If any of the items are missing when opened for the first time, contact Synapse Biomedical.

11.0. BATTERY INSTALLATION

WARNING: The NeuRx EPG ships with ALKALINE BATTERIES, but has an Alternative lithium battery. Take care to prevent fire or explosion.

- **Do NOT short-circuit, recharge, puncture, burn, or crush the battery.**
- **Do NOT immerse the battery in water. Do NOT expose the battery to temperatures above 212ºF (100ºC).**

To install the battery, follow these instructions:

1. When the patient kit is received, install the Primary battery into the NeuRx EPG. This will allow the NeuRx EPG to power ON and charge the secondary battery. To prevent premature discharge of primary and secondary batteries, keep the primary battery installed when not in use.
2. Make sure that the NeuRx EPG is turned OFF prior to installing the battery.
3. Use the provided flat blade screwdriver to loosen the screws on the back bottom of the NeuRx EPG and remove the battery cover.(Figure 3).

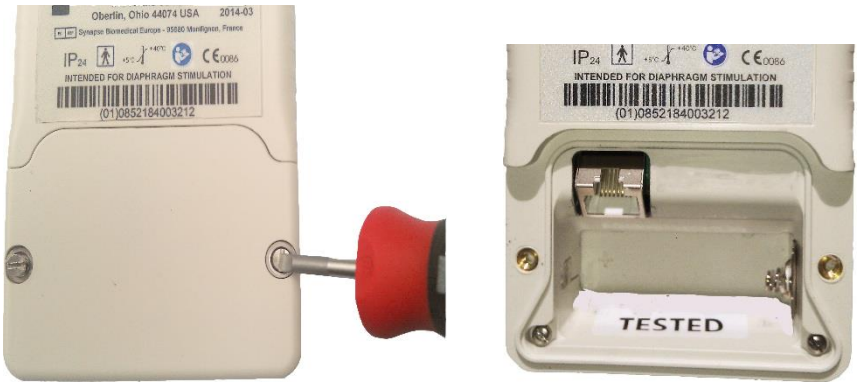


Figure 3.

4. Do NOT touch the battery contacts or communication port while touching the patient.
5. Install the new battery using caution to install with the proper polarity as noted on the device.

    - **IMPORTANT:** Use only the kind of battery specified in this manual.
    - **IMPORTANT:** Put the battery in the correct position. (Figure 4)

Insert (-) negative side of battery in EPG and push battery downward to secure connection

POSITIVE (+) THIS SIDE

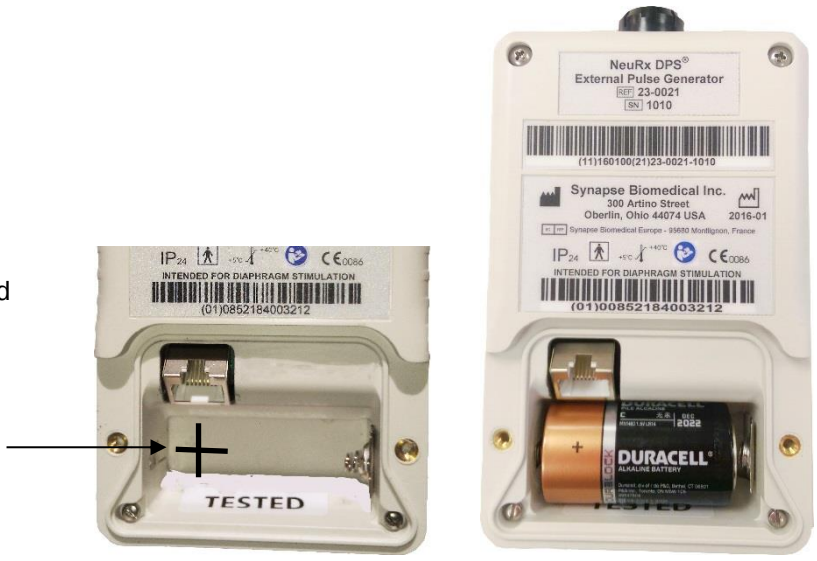


Figure 4.

Replace the battery cover and secure with mounting screws (Figure 4b).

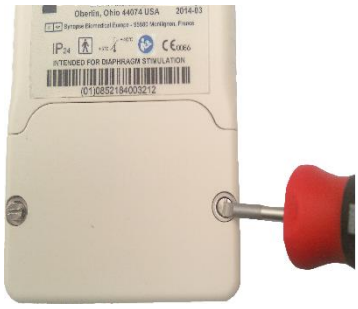


Figure 4b.

12.0. FUNCTIONAL FEATURES

The patient cable should be securely inserted into the exit site connector and the top of the stimulator. The stimulator is programmed with parameter data that satisfies the patient's specific requirements.

To turn the NeuRx EPG ON: Press and release the two buttons on the front of the NeuRx EPG at the same time.

To turn the NeuRx EPG OFF: Press and release the two buttons on the front of the NeuRx EPG at the same time.

The buttons must be pressed at the same time. This is a safety feature to guard against accidentally turning the EPG on or off (Figure 5).

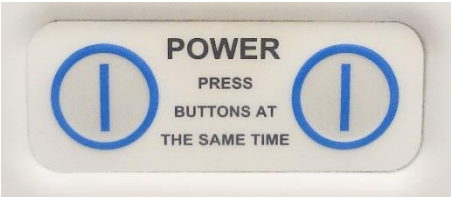


Figure 5. On/Off Buttons.

The NeuRx EPG has a display that shows the current operational status of the NeuRx EPG and if it is working properly.

The NeuRx EPG indicates the Breath-per-Minute (BPM) rate and when the individual electrodes are active.

During the inspiration phase, an asterisk (*) is shown below each output number indicating that the stimulator is working well. (See Figure 6).

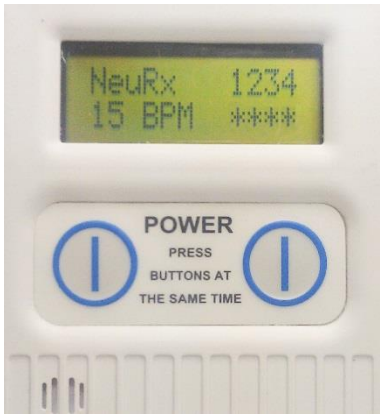


Figure 6. (*) showing that the NeuRx EPG is working properly during inhaling for each electrode wire (number 1, 2, 3, or 4).

During the expiration phase, a '-'character is shown below each output number indicating that the stimulator is not active. (See Figure 7)

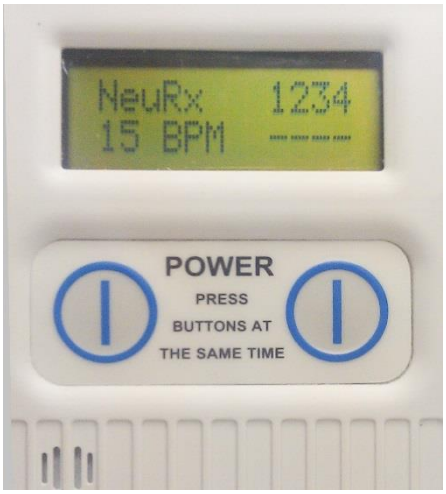


Figure 7. "-"shows that the NeuRx EPG is not active for each wire (number 1, 2, 3, and 4) during exhaling.

In the event that an 'X' appears below an output number, then a problem exists and your physician, center or Synapse Biomedical should be contacted.

The backup Stimulator may be carried with the patient as a spare Stimulator. It can be used at any time and may be helpful when diagnosing Stimulator or patient cable issues. The backup Stimulator should be cleaned and stored just like the Stimulator you use daily. Your physician, center or Synapse Biomedical should be contacted when issues are discovered.

In the event that a "?" appears below an output number, it should be immediately followed by a letter. (See Figure 8) This can occur normally when the pulse modulation parameter is set at a high value or when the pulse width parameter is less than 50 µsec. Your stimulator has been programmed with settings that have been established during your conditioning session. This is considered a normal event.

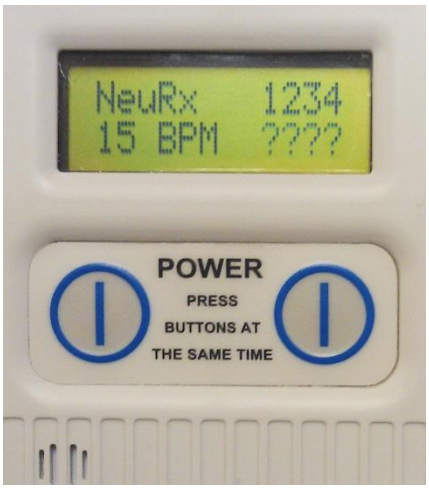


Figure 8. "? "Below an associated electrode wire (number 1, 2, 3, or 4) can occur normally when the EPG's electric signal is at a low level.

The example in Figure 6 shows the NeuRx EPG with (****) on its screen. This means that it is working properly during inhaling. When an (*) appears below the electrode wire numbers 1, 2, 3, and 4, it means that the NeuRx EPG is working.

If 'X' appears below an electrode wire number (Figure 9), possible problem:

- The wire is broken.
- The wire is loose in the electrode connector.
- The patient cable is broken
- The patient cable is not connected properly.
- The NeuRx EPG is broken.

Please follow the troubleshooting guide in Section 25.0 Troubleshooting and Use Errors. If you see that an electrode wire is loose or broken, call your healthcare provider who is helping you with your NeuRx DPS to discuss how to get it repaired.

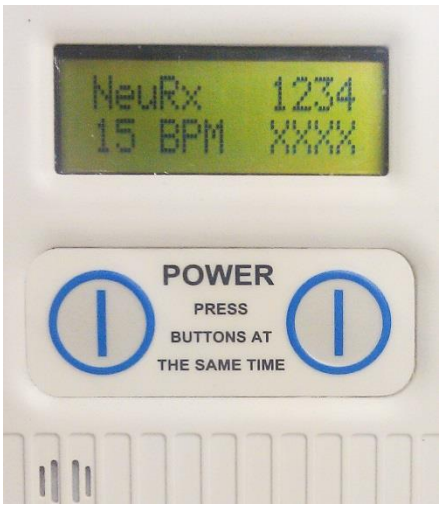
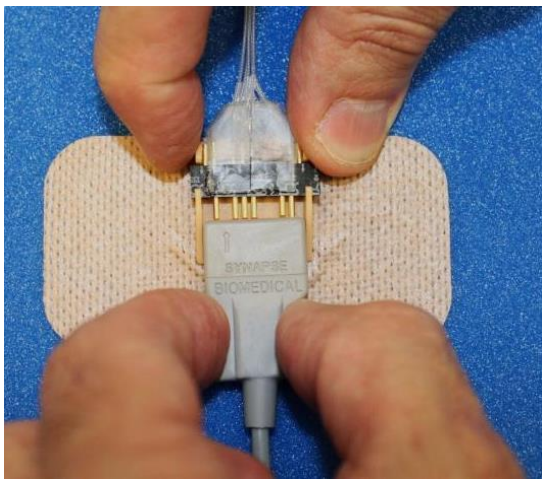


Figure 9. "X" could mean loose or broken electrode wires or patient cable or a broken EPG.

13.0. PATIENT CABLE CONNECTIONS CONDITIONING SESSIONS

The following describes the process for a single conditioning session:

- Wash and dry your hands before starting the conditioning session.
- Clear secretions from your mouth before you condition. Do this again throughout the conditioning session.
- Connect the patient cable to the electrode connector. To do this, hold the electrode connector between two fingers. Slide the patient cable into the connector holder. Secure the patient cable to the electrode connector (Figure 10).



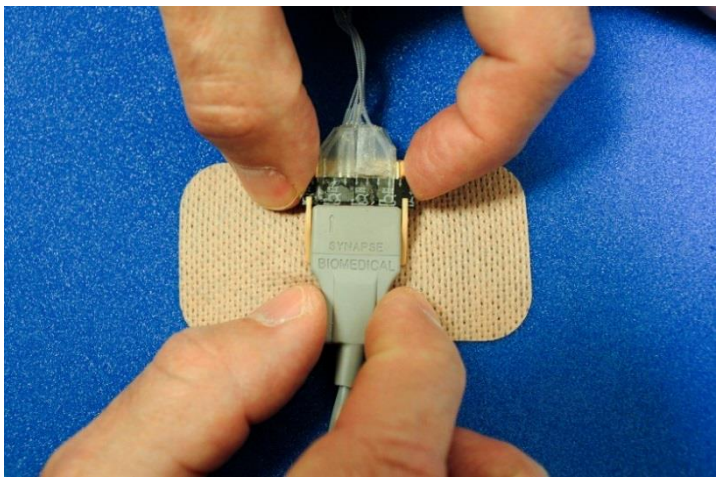


Figure 10. Connecting the patient cable to the electrode connector.

- Insert the other end of the patient cable into the top of the NeuRx EPG. To do this, line up the arrows on the patient cable with the top of the EPG. Push the cable into the connection until it is secure (Figure 11).

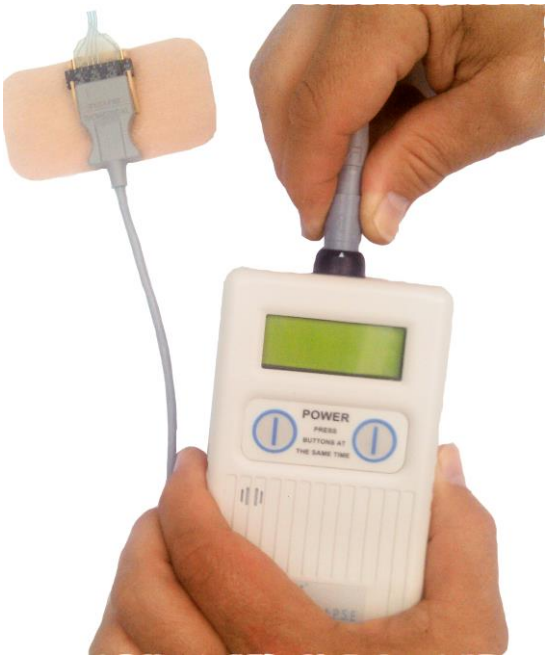


Figure 11. Connecting the patient cable to the NeuRx EPG.

- Press the two buttons at the same time to turn the NeuRx EPG on.
- When the conditioning session is over, press the two buttons at the same time to turn the NeuRx EPG off.
- To disconnect the patient cable from the NeuRx EPG, firmly hold the EPG in one hand. Grasp the cable with two fingers as shown and pull (Figure 12).

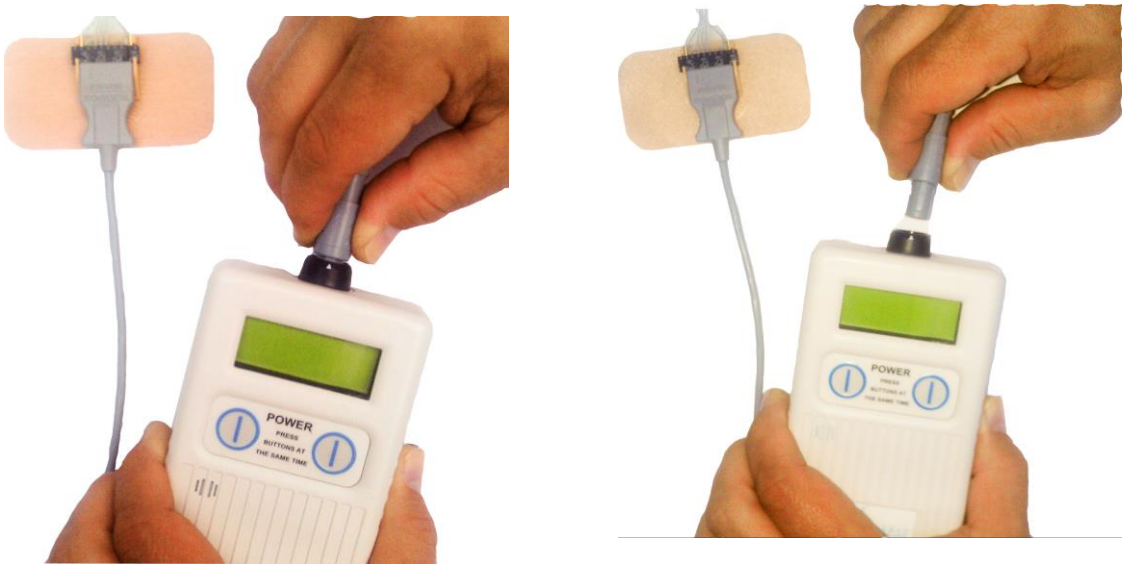


Figure 12. Disconnecting the patient cable.

- Disconnect the patient cable from the electrode connector. To do this, hold the electrode connector between two fingers. Gently pull the patient cable out of the connector holder (Figure 13).

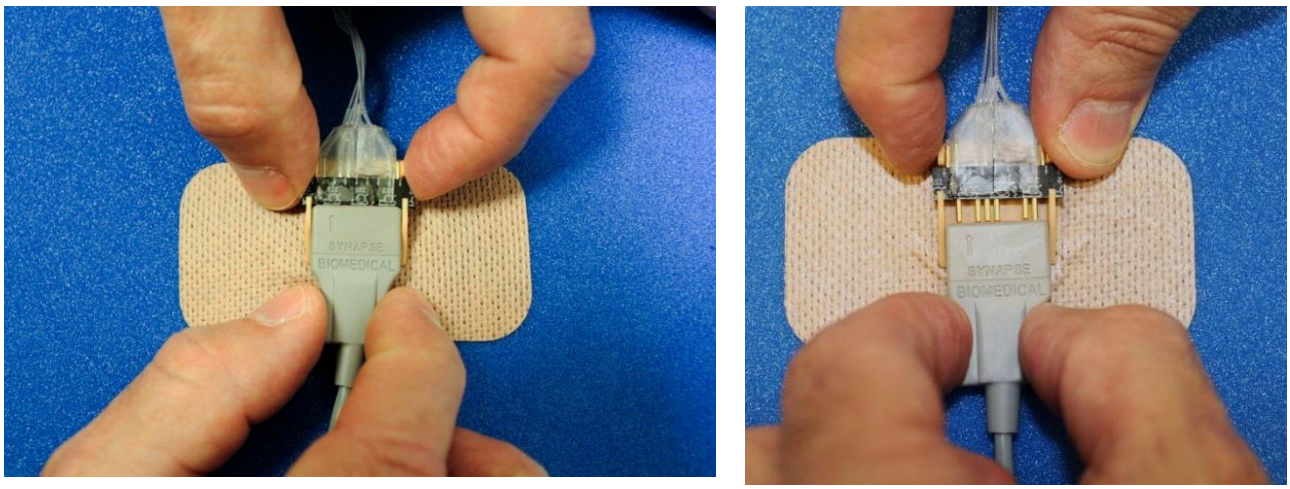


Figure 13. Disconnecting the patient cable from the electrode connector.

- Store all items in the patient kit provided.

14.0. CONDITIONING SESSIONS

You will use the NeuRx DPS to condition your diaphragm. In conditioning, the NeuRx EPG sends a small amount of electricity through the wires to your diaphragm. This causes your diaphragm to contract. When your diaphragm is conditioned, it will do a better job of helping your breathing.

Your healthcare provider will tell you how to use the NeuRx EPG. You should condition your diaphragm with the NeuRx EPG at least 3 times per day. Each session should last at least 30 minutes. You may find it helpful to use the NeuRx EPG for longer periods to help with breathing. The NeuRx EPG may be used at the same time as non-invasive ventilation. You may also sleep with the NeuRx EPG to assist with breathing difficulties at night. Conditioning can happen every hour. In the beginning, the recommended stimulator usage for SCI patients is 15 to 30 minutes each session. As your diaphragm improves, the length of your sessions should increase and the number of daily sessions should decrease. You should allow 45-60 minutes between sessions to allow your diaphragm to fully recover. Always consult your physician before making any changes to your daily pacing sessions

The following describes the process of one conditioning session:

1. Secretions should be cleared prior to conditioning and managed throughout the conditioning session.
2. Connect patient cable to electrode connector in the connector holder and to the stimulator.
3. Place pulse oximeter on patient and continuously monitor throughout conditioning session.
4. Turn stimulator on by pressing the two buttons at the same time. Allow patient to get comfortable on stimulator.
5. Remove from ventilator.
6. Monitor the patient throughout the conditioning session and return to mechanical ventilation:
    - If the effort to breathe on the BORG scale is 4 or greater.
    - If the pulse oximeter reads below 90%.
7. When conditioning session is over, place back on the ventilator and turn the stimulator off by pressing the two buttons at the same time.
8. Allow approximately 45-60 minute rest period between sessions.

15.0. CONDITIONING WARNINGS

- Stop the conditioning session and be placed back on the ventilator if you notice any change in heart rate or feeling of chest discomfort. If you have a cardiac pacemaker it should be evaluated to make sure there is no diaphragm pacemaker to cardiac pacemaker interaction.

- Stop the conditioning session and be placed back on the ventilator:

    - If signs of shortness of breath or any discomfort persists or worsens.
    - If oxygen level remains below 90%.
    - If management of secretions becomes difficult.
    - Your Borg scale is 4 or greater.

      BORG Scale (breathing effort):

      0 = No Breathlessness at all
      1 = Very Slight Breathlessness
      2 = Slight Breathlessness
      3 = Moderate Breathlessness
      4 = Somewhat Severe Breathlessness
      5 = Severe Breathlessness
      7 = Very Severe Breathlessness
      10 = Maximum Breathlessness

- DO wear a Passy- Muir™ valve while sleeping to help prevent obstructive sleep apnea. Contact your physician if you do not already have one.

- DO use caution when eating and drinking while conditioning. Wear a Passy-Muir™ valve during these conditioning sessions to reduce the risk of aspiration.

- DO wear an abdominal binder when you are in your chair as this may improve your tidal (breathing) volumes.

- DO NOT perform external electrical stimulation in the chest area.

- **Do NOT get the NeuRx EPG wet. You may bathe, shower, swim or participate in any other aquatic activities, but the NeuRx EPG must be disconnected from the connector holder**. The NeuRx EPG is splash-proof but not waterproof. If the exit site gets wet, clean it with an alcohol wipe. Use an individually packaged pad saturated with 70% isopropyl alcohol. Allow the alcohol to air dry before use. (See additional information under sections 3.0Warnings and 4.0 Cautions.)

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16.0. CARE OF PATIENT CABLE

- The patient cable is shown in Figure 14. It runs between the electrode connector and the NeuRx EPG (as shown Figure 1 near the front of this manual).
- **Do NOT cut, kink or pull the patient cable.**
- **Do NOT manipulate the metal pins in the end pieces of the patient cable.**
- **Do NOT immerse the patient cable in water.**
- Keep extra patient cables in a dry secure location.
- When in use, the one end of the patient cable should fit securely into the electrode connector. The other end should fit securely into the NeuRx EPG.
- Arrange the patient cable so that it is comfortable. It should allow you to move around without pulling on the exit site connector.
- When in use, keep cable and EPG close to the body to prevent cable snagging on objects.
- Call your healthcare provider if you need replacement cables.

Figure 14. Patient Cable.

17.0. CARE OF THE ELECTRODE WIRES

- **Do NOT pull on the electrode wires coming through the skin.**
- **Do NOT cut the electrode wires.**
- Use extreme caution when shaving the skin around the electrode wire exit site.

18.0. CARE OF EXIT SITES AND CONNECTOR

- Keep the skin at the exit sites clean and dry.
- **Do NOT scratch skin at exit sites.**
- Clean the exit sites with an alcohol wipe. Use an individually packaged pad saturated with 70% isopropyl alcohol. Allow the alcohol to air dry before use. Then place a gauze dressing over the exit site. Be sure to cover all the wire with the gauze. Place a transparent dressing over the gauze. (Tegaderm™ and Op-Site™ are examples of transparent dressings.)
- Change the dressings every 3 days or more often if the dressing becomes wet or soiled.
- If the area becomes red, swollen, painful, or drainage appears, call your healthcare provider.
- Avoid touching the metal pins in the electrode connector.
- The connector holder should lie flat against the surface of the skin.
- Call your healthcare provider if any of the exiting electrode wires are frayed or broken.
- This electrode connector will snap into the connector holder (provided in the patient kit).
- Call your healthcare provider if the electrode connector appears cracked or broken.
- You should change the connector holder weekly or if it becomes soiled.
- Follow the steps on section 19.0 Care of Exit Sites and Replacing Connector Holder.

19.0. CARE OF EXIT SITES AND REPLACING CONNECTOR HOLDER

The steps described below will show you how to take care of the “exit sites”. The exit sites are the locations where the electrode wires pass through your skin. These steps will show you how to:

- remove the electrode connector from the old connector holder,
- clean the exit sites, place the electrode connector into a new connector holder,
- apply a new connector holder onto the skin, and
- cover the exiting electrode wires with gauze and transparent dressing.

You should perform these steps every 3 days or more often if the dressing becomes wet or otherwise soiled.

IMPORTANT REMINDER: Do NOT pull the electrode wires. Doing so may pull more electrode wire from under the skin. (See step 6 below.)

1. Wash and dry your hands before caring for the exit sites.
2. Using two fingers, grasp the electrode connector and tilt it down as shown in Figure 15.

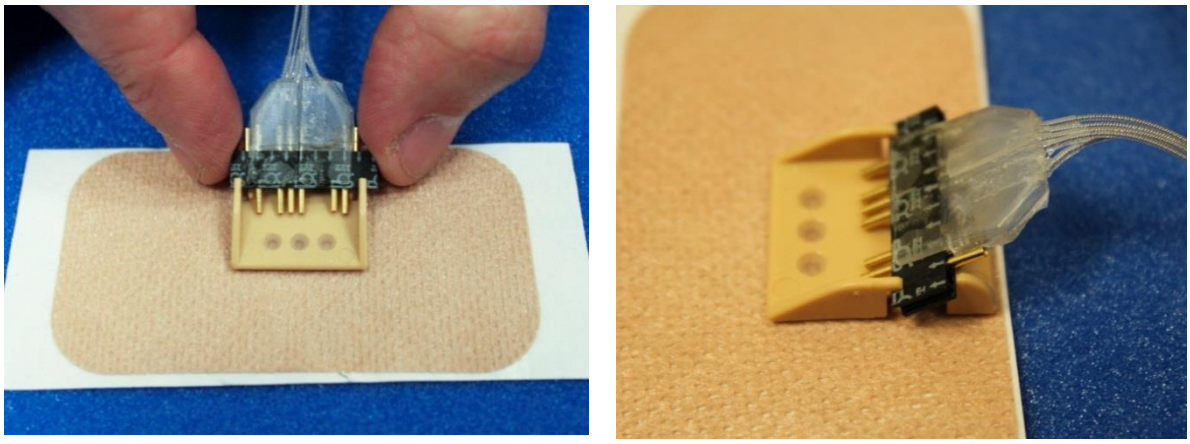


Figure 15.

3. Remove the electrode connector from the connector holder. Now remove the connector holder (Figure 16).

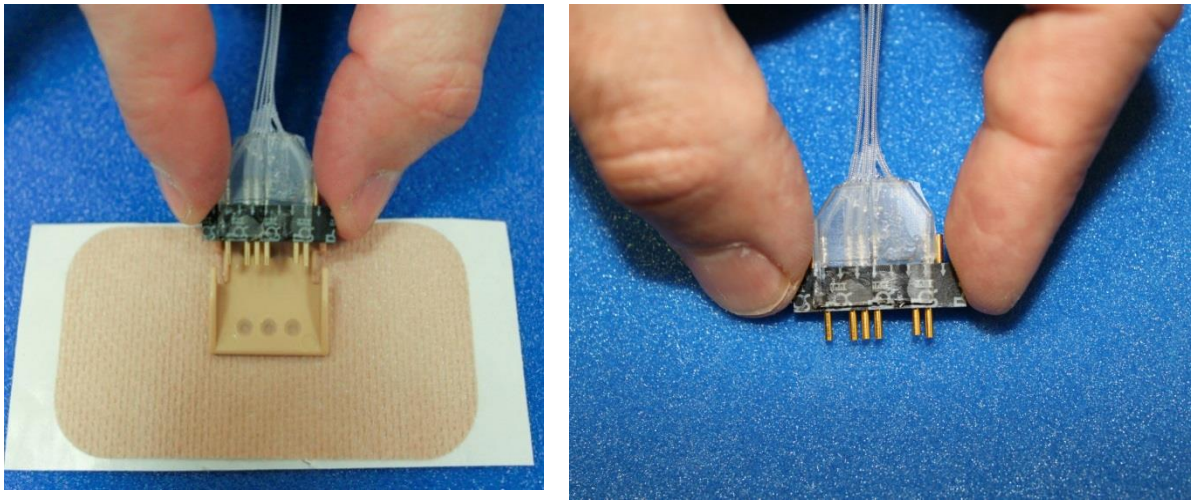


Figure 16

4. Clean the exit sites with an alcohol wipe (with 70% isopropyl alcohol). Always wipe toward the exit site. Allow the alcohol to air dry before use (Figure 17).

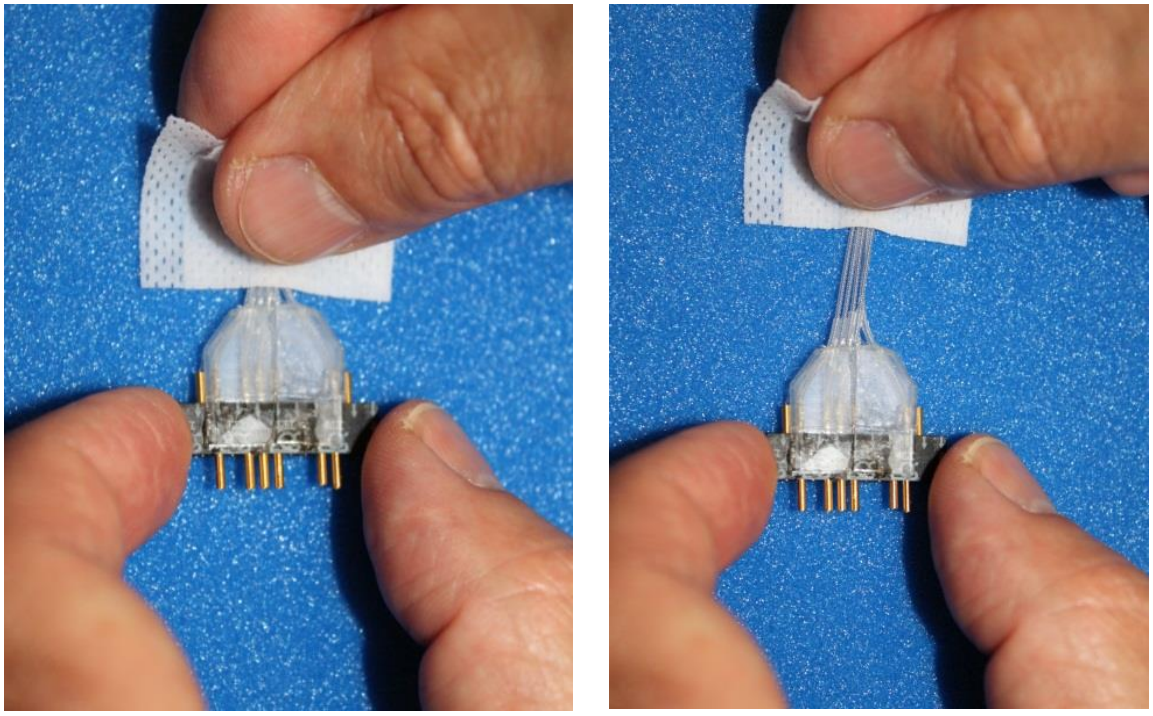


Figure 17

5. Once dry, place the electrode connector into a new connector holder as shown in Figure 18. Snap the electrode connector down into the

connector holder. The gold pins should be facing out for the cable to plug into them.

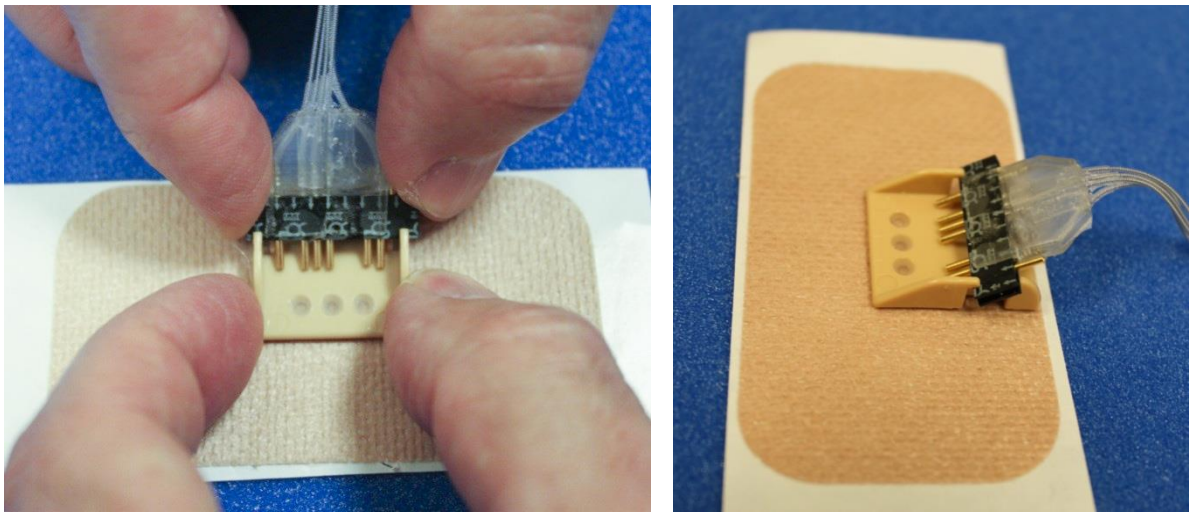


Figure 18

6. Carefully remove the paper backing from a new connector holder. Make sure you **Do NOT pull on the exiting electrode wires** (Figure 19).

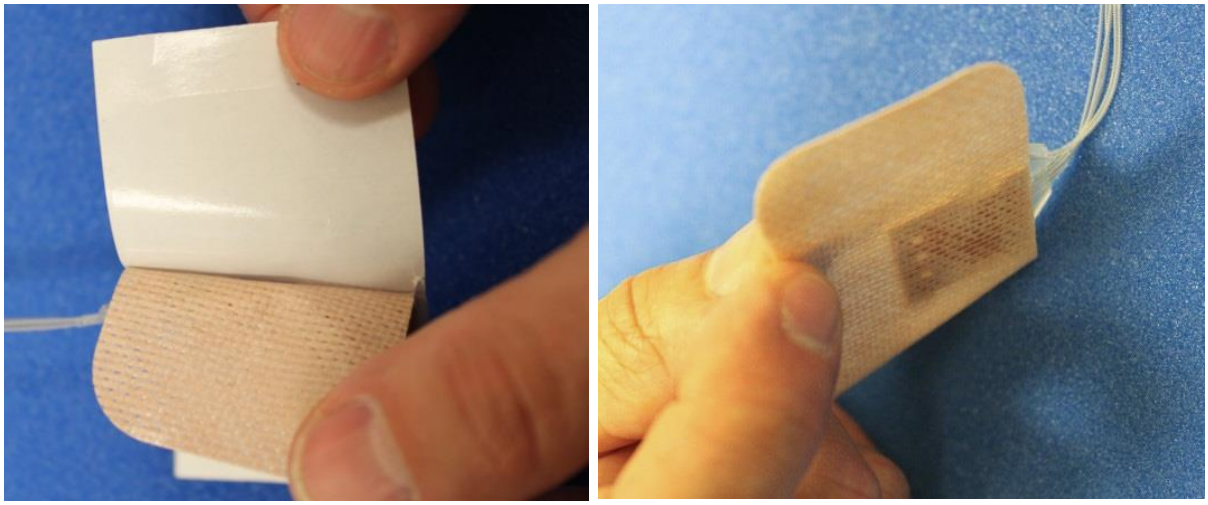


Figure 19.

7. Carefully press the new connector holder onto the skin (Figure 20).

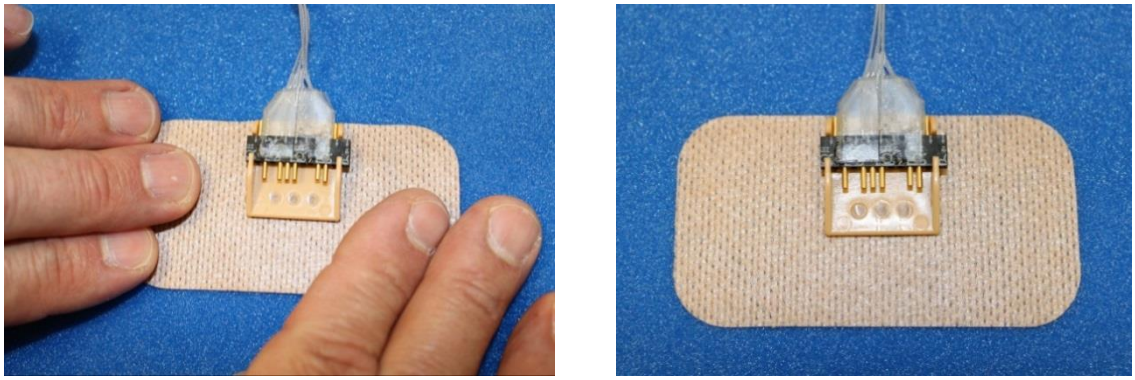


Figure 20

8. Place a 2” X 2” gauze pad over the exiting electrode wires (Figure 21).

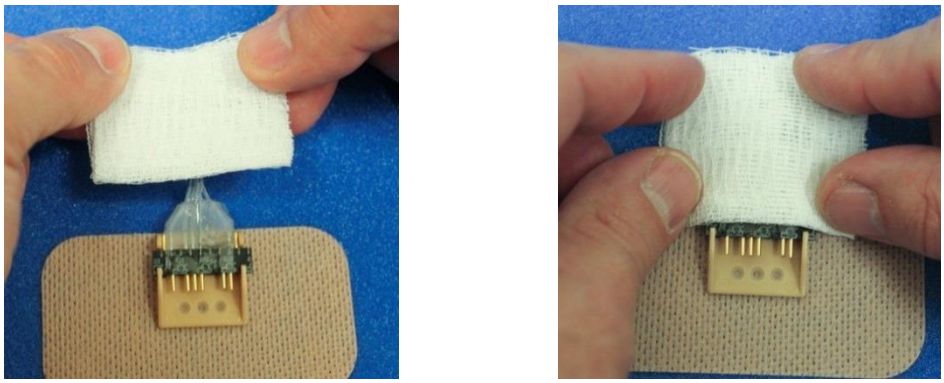


Figure 21.

9. Place a transparent dressing over the gauze. (Tegaderm™ and Op-Site™ are examples of transparent dressings) **Do NOT cover the gold pins with the transparent dressing. (Figure 22).**

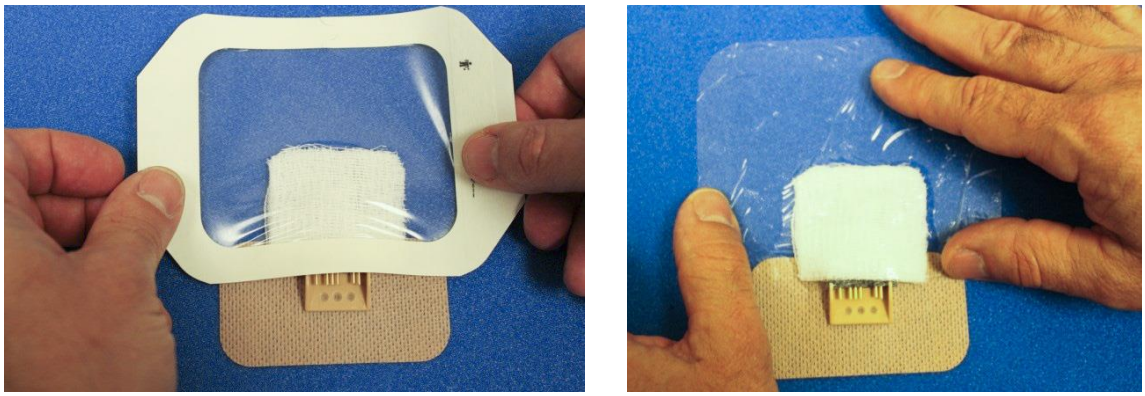


Figure 22

20.0. HOW TO SHOWER OR BATHE

CAUTION: Do NOT get the NeuRx EPG wet while using. You may bathe, shower, or swim, but the NeuRx EPG must be disconnected from the connector holder. The NeuRx EPG is splash proof but not waterproof. If the exit site gets wet, clean it with an alcohol wipe. Use an individually packaged pad saturated with 70% isopropyl alcohol. Allow it to air dry before use. (See more information under sections 3.0Warnings and 4.0 Cautions.)

The following instructions are written for “bathing”. However, these instructions should be followed for any activity in which you would get wet.

1. Before bathing, disconnect the patient cable from the electrode connector (Figure 23).

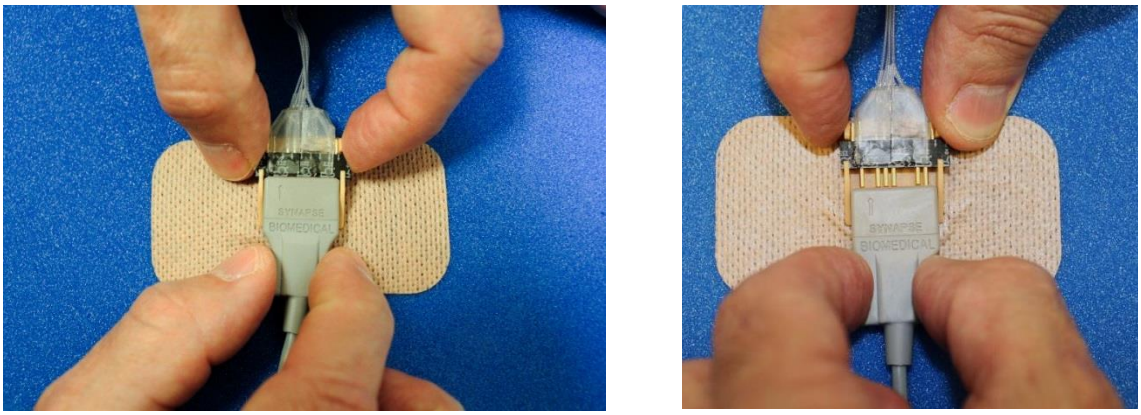


Figure 23

2. Before bathing, cover the wires and the connector holder with a waterproof dressing (Figure 24).

Figure 24

3. When you are done bathing, carefully uncover the wires and the connector holder.

4. If you notice moisture on the electrode connector, wipe it with an alcohol wipe. Use a wipe with 70% isopropyl alcohol. Allow the alcohol to air dry before use.

21.0. CLEANING OF COMPONENTS

CAUTION: Do NOT soak the NeuRx EPG or the patient cable in liquid.

- Clean the NeuRx EPG and the patient cable as needed. The surfaces of the Stimulator may be cleaned and disinfected with a less than 6% bleach solution or a less than 10% isopropanol solution. Typical cleaners such as glass or multi-surface spray cleaners are adequate.

- The surfaces of the patient cables may be cleaned with a mild anti-bacterial hand soap solution.

22.0. ALARMS

The NeuRx DPS has prioritized alarms, uniquely sounding an alarm for a HIGH, MEDIUM, and LOW priority alarm. The alarms are both audible and visual.

ALARM Priority	Reason	Cause	Audible ALARM	Visual ALARM
HIGH	Microprocessor not operational	Microprocessor not programmed or faulty	Alarm burst 10 times every 8 seconds	LCD displays nothing (blank)
HIGH	High impedance on the indifferent electrode	Broken or disconnected indifferent electrode	Alarm burst 10 times every breath rate	LCD displays "XXXX" under "1234"
MEDIUM	High impedance on 1 or more electrodes	Broken or disconnected electrode	Alarm burst 3 times every breath rate.	LCD displays an "X" under corresponding electrode
MEDIUM	Secondary battery charge is low	Low secondary battery	Alarm burst 3 times every 30 seconds	LCD displays "LOW BATTERY!"
LOW	Primary battery charge low	Low Primary battery	Alarm burst 2 times every 30 minutes	LCD displays "Low Battery"

All alarms are important and MUST be addressed in a timely manner for the NeuRx DPS to continue to function correctly. The higher the priority, the sooner the alarm must be addressed.

All Alarm limits are pre-set by Synapse Biomedical and CANNOT be changed.

23.0. BATTERY INSTALLATION WARNINGS

- If the NeuRx DPS displays “LOW BATTERY!” then replace the battery immediately!
- Ensure that the NeuRx DPS is turned OFF prior to battery replacement. For more information look at Section 12.0 Functional Features.
- The device contains lithium-ion battery. Replacement by inadequately trained personnel could result in an explosion.

24.0. BATTERY REPLACEMENT

Replace the Alkaline battery every 96 hours of NeuRx EPG use. This is about every 4 days if you are using NeuRx DPS full time. The NeuRx EPG screen will initially show “Low Battery”. It will alarm 2 times every 30 minutes when your battery needs to be replaced. When the primary battery is depleted, there will be an additional 8 hours of run time on the secondary battery. Replace the battery immediately if the NeuRx DPS screen shows “LOW BATTERY!” and if the NeuRx EPG alarms 3 times every 30 seconds. This will indicate the secondary battery is approaching its 8 hours of additional run time.

WARNING: The NeuRx EPG ships with ALKALINE BATTERIES, but has an alternative lithium battery. Take care to prevent fire or explosion.

- **Do NOT short-circuit, recharge, puncture, burn, or crush the battery.**
- **Do NOT immerse the battery in water. Do NOT expose the battery to temperatures above 212ºF (100ºC).**

Alternative battery options include the Airline Travel Battery (See Section 28.0 Traveling with the NeuRx DPS).

NOTE: Alkaline and travel batteries have a shorter run time than lithium batteries.

To change the battery, follow these instructions:

1. Make sure that the NeuRx EPG is turned OFF prior to replacing the battery.

2. Use the provided flat blade screwdriver to loosen the screws on the back bottom of the NeuRx EPG. Remove the battery cover located on the back bottom of the NeuRx EPG (Figure 25).

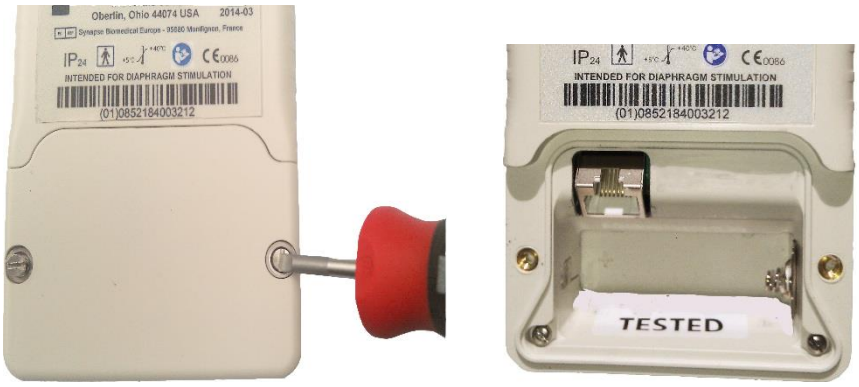


Figure 25.

3. Do NOT touch the battery contacts or communication port while touching the patient.

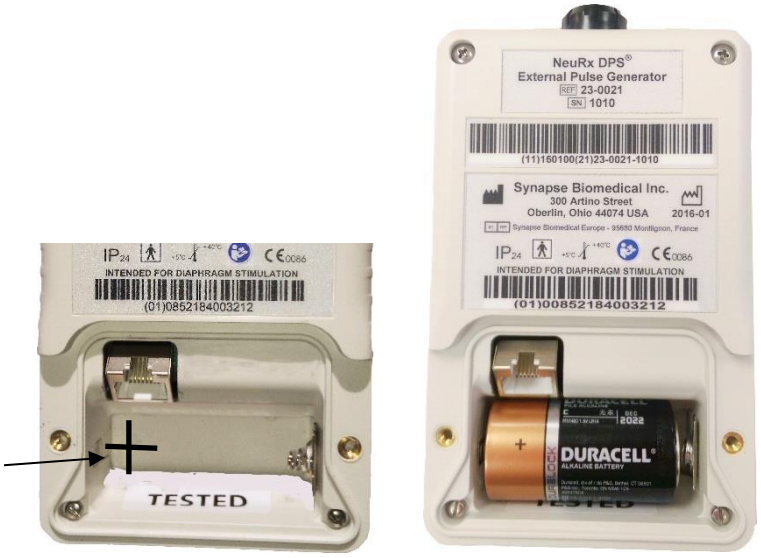
4. Remove the old battery. Replace it with a new battery.

   - **IMPORTANT:** Use only the kind of battery specified in this manual.

   - **IMPORTANT:** Put the battery in the correct position.

Insert (-) negative side of battery in EPG and push battery downward to secure connection

POSITIVE (+) THIS SIDE



5. Replace the battery cover and secure with mounting screws.

6. Turn the NeuRx EPG ON to continue operation.

7. The used discharged lithium batteries are required to be disposed of properly. Follow the local regulations when you dispose of old batteries. Shipping MUST NOT be air freight. Ground ship only.

   - **Disposal in the United States:**

     Can send to: Battery Center
     1520-B Broadmoor Boulevard
     Buford, Georgia 30518
     https://www.call2recycle.org

     Including on the label:

     Shipping Container MUST meet: DOT Packaging Group II requirements
     Maximum Shipping Weight: 66 pounds
     PROPER SHIPPING NAME: Waste lithium Batteries
     DOT Shipping Description: UN3480
     Lithium Ion Battery: Class 9, PG II, UN3090
     Lithium Metal Battery: Class 9, PGII
     Mark on Container: LITHIUM BATTERIES – FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.

   - **Disposal in Europe:**

     - The return has to be advised prior to shipment to the sales department of Tadiran Germany:
       Phone: +49(0)6042/954-122
       Fax: +49(0)6042/954-190
     - Batteries have to be returned properly packed, if possible in the original package; minimum demand: protection against short circuit.
     - Shipment has to be free warehouse Tadiran. Key word on dispatch papers: "Disposal". Batteries for disposal should not be transported by air. For road transport of dangerous goods ADR special provision 636 and packing instruction 903a apply.

25.0. TROUBLESHOOTING AND USE ERRORS

If you think that the NeuRx EPG is not working properly or multiple “X”s appear on the screen, please follow the steps below:

1. Check the connection between the patient cable and the NeuRx EPG. Check the connection between the patient cable and the electrode connector. Make sure these connections are secure.
2. Replace the patient cable with the spare cable in the patient kit.
3. Disconnect the patient cable from the NeuRx EPG.
4. Insert the test plug.
    a. When the test plug is inserted into the NeuRx EPG, the screen should show (****) when activated.
    b. If (****) does not appear on the screen or if there is still a problem, call Synapse Biomedical.
5. Replace the test plug back into the foam insert on the patient kit.

A onetime patient/caregiver training session is supplied by a Synapse Biomedical trained Clinician. The training consists of “Hands on” training and demonstrations from the information in this Manual (77-0090). The training session can range from 1 to 2 hours. Customer Service is always available to help answer any questions that may arise.

For help with your NeuRx DPS device, first call your healthcare provider who is helping you with your NeuRx DPS. As a back-up you may also call:

Synapse Biomedical Customer Service
U.S. Toll Free: 1-888-767-3770
From outside the U.S.: 001-440-774-2488

Use the following troubleshooting guide to help solve problems with your NeuRx EPG:

Problem	Action
Pacing of the diaphragm stops.	• **Connect patient to their mechanical ventilator.** • Check the connection of the patient cable to the electrode connector. • Check the connection of the patient cable to the NeuRx EPG. • Try a different patient cable. • Inspect the connections of the electrode wires to the electrode connector for breakage. • If the problem continues, call your healthcare provider who is helping you with your NeuRx DPS.
Patient is not receiving adequate ventilation.	• **Connect patient to their mechanical ventilator.** • Disconnect the Stimulator and return the patient to a ventilator.
Discomfort while pacing.	• **Connect patient to their mechanical ventilator.** • The EPG settings may need adjustment. • STOP use of the NeuRx EPG. • Call your healthcare provider who is helping you with your NeuRx DPS.
Bleeding, bruising, or infection where the electrode wires pass through the skin.	• Call your healthcare provider who is helping you with your NeuRx DPS.
Pain at the electrode wire exit site.	• **Connect patient to their mechanical ventilator.** • STOP use of the NeuRx EPG. • Call your healthcare provider who is helping you with your NeuRx DPS.
Skin irritation or hypersensitivity to stimulation.	• **Connect patient to their mechanical ventilator.** • Call your healthcare provider who is helping you with your NeuRx DPS.

Problem	Action
Multiple "**X**"s appear on the NeuRx EPG screen.	• **Connect patient to their mechanical ventilator.** • Try a different patient cable. • If the problem continues, disconnect the patient cable from the NeuRx EPG and insert the test plug (found in the patient kit). • If the EPG is working properly, use the Backup Indifferent Electrode Interconnect. • If the problem continues, call your healthcare provider who is helping you with your NeuRx DPS.
The NeuRx EPG is exposed to excessive amount of water or fluid.	• **Connect patient to their mechanical ventilator.** • STOP use of the NeuRx EPG. • Call your healthcare provider who is helping you with your NeuRx DPS.
The NeuRx EPG is exposed to extended sun light or excessive amount of dust or lint.	• **Connect patient to their mechanical ventilator.** • STOP use of the NeuRx EPG. Call your healthcare provider who is helping you with your NeuRx DPS.
The NeuRx EPG is exposed to excessive heat.	• **Connect patient to their mechanical ventilator.** • STOP use of the NeuRx EPG. • Call your healthcare provider who is helping you with your NeuRx DPS.
Alarm sounds 10 times every 12 seconds	• **Connect patient to their mechanical ventilator.** • Confirm the display is blank • Call your healthcare provider who is helping you with your NeuRx DPS.

Problem	Action
Alarm sounds 10 times during each breath.	• **Connect patient to their mechanical ventilator.** • Confirm on the display “XXXX” under “1234” • Check the connection of the patient cable to the electrode connector. • Check the connection of the patient cable to the NeuRx EPG. • Try a different patient cable. • Inspect the indifferent electrode for breakage • If the problem continues, call your healthcare provider who is helping you with your NeuRx DPS.
Alarm sounds 3 times every 4th breath.	• **Connect patient to their mechanical ventilator.** • Confirm on display “X” under 1 or more “1234” • Check the connection of the patient cable to the electrode connector. • Check the connection of the patient cable to the NeuRx EPG. • Try a different patient cable. • Inspect the connections of the electrode wires to the electrode connector for breakage. • If the problem continues, call your healthcare provider who is helping you with your NeuRx DPS.
Alarm sounds 3 times every 30 seconds.	• **Connect patient to their mechanical ventilator.** • Confirm on display “LOW BATTERY!” • Replace Primary battery IMMEDIATELY • See section 24.0 Battery Replacement for the steps. • If the problem continues, call your healthcare provider who is helping you with your NeuRx DPS.

Problem	Action
Alarm sounds 2 times every 30 minutes.	• **Connect patient to their mechanical ventilator.** • Confirm on display “Low Battery” • Replace Primary battery • See section 24.0 Battery Replacement for the steps. • If the problem continues, call your healthcare provider who is helping you with your NeuRx DPS.

USE Error	Action
Incorrect installation of battery	- Polarity is clearly displayed - See section 24.0 Battery Replacement - Clinician trains caregiver/user
Installation of wrong battery type	- See section 24.0 Battery Replacement - Clinician trains caregiver/user
Dropping	- EPG should be kept close to the body or in a pocket to prevent dropping - See sections 4.0 Cautions and 16.0 Care of Patient Cable - Clinician trains caregiver/user
Mechanical stress (stepping on or running over with wheelchair)	- EPG should be kept close to the body or in a pocket to prevent damage or pulling on electrodes - See sections 4.0 Cautions and 16.0 Care of Patient Cable - Clinician trains caregiver/user
Ignoring ALARMS and letting the battery completely discharge	- Must respond to all ALARMS both audible and on display - See section 22.0 Alarms - Clinician trains caregiver/user

USE Error	Action
Exposed to high humidity for extended periods	- EPG must not be exposed to high humidity for extended periods - See section 4.0 Cautions - Clinician trains caregiver/user
Exposed to shower or bath	- Bathing or showering must be done per procedure - See section 20.0 How to Shower or Bathe - Clinician trains caregiver/user
Incorrect cleaning of patient cable, EPG or exit site	- Cleaning of components and exit site must be done per procedure - See section 21.0 Cleaning of Components - Clinician trains caregiver/user

26.0. BACKUP INDIFFERENT ELECTRODE INTERCONNECT

The troubleshooting section of this manual may tell you to use the *backup indifferent electrode interconnect.* This is called the *backup connector* for short. It is part number 22-0026 of the patient kit. The backup connector may be useful when the indifferent electrode under the skin has failed. This is when the NeuRx EPG displays “XXXX” (Figure 26) but the patient cable and EPG still work correctly.

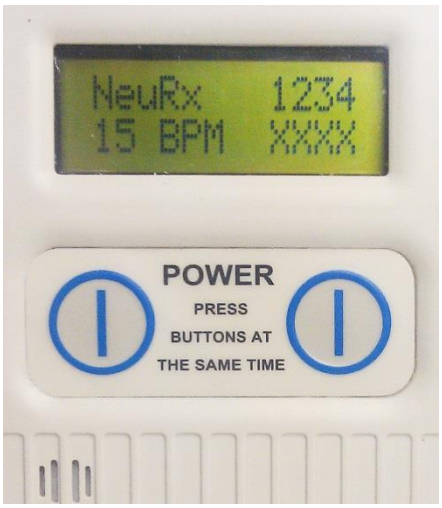


Figure 26. EPG displaying “XXXX”.

Follow these steps to use the backup connector:

1. Disconnect the patient cable from the electrode connector (Figure 27).

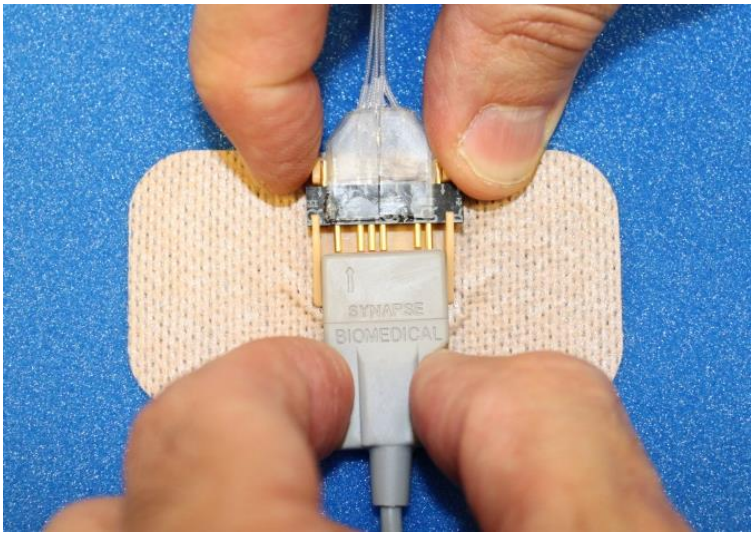


Figure 27

2. Remove the backup connector (Figure 28) and the surface anode (Figure 29) from the kit.

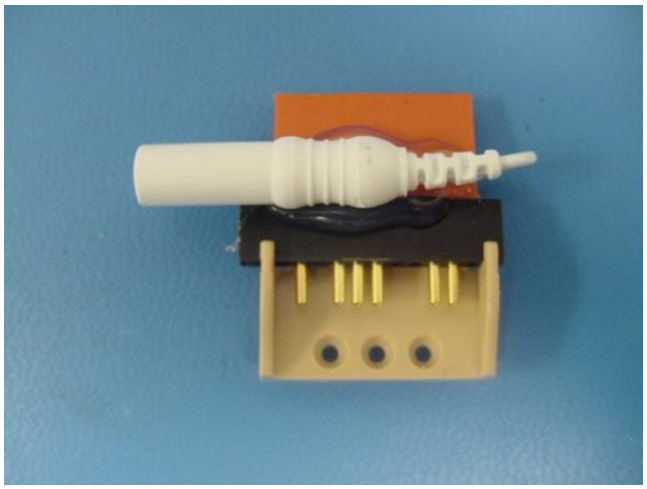


Figure 28. Backup Indifferent Electrode Interconnect

Figure 29. Surface Anode Packet

3. Remove one surface anode (Figure 30) from the packet. Connect the brown cable to the white cable (Figure 31).

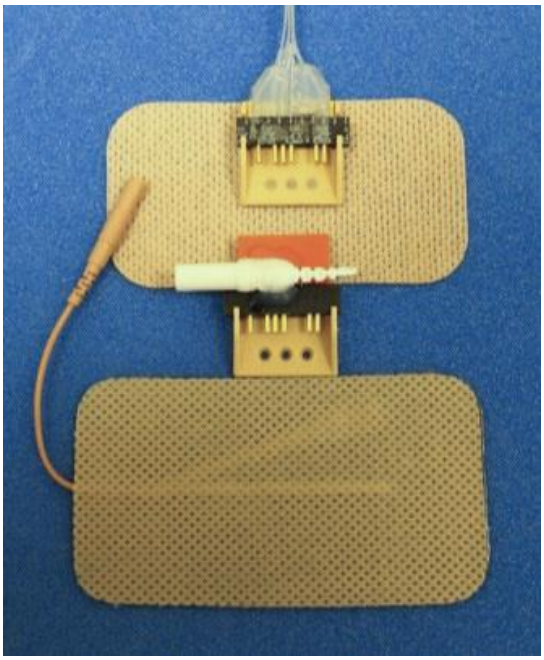


Figure 30

Figure 31

Plug the backup connector into the electrode connector that is secured in the connector holder (Figure 32 and Figure 33).

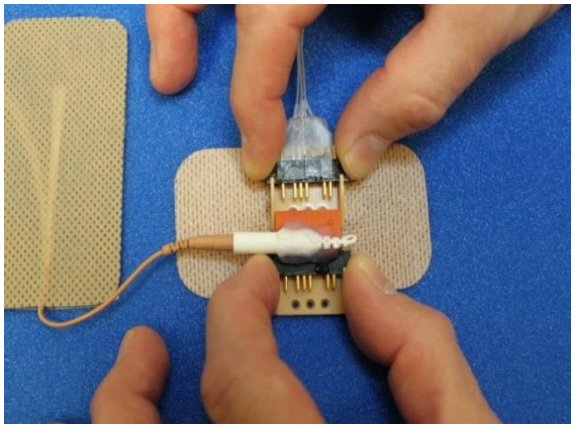


Figure 32

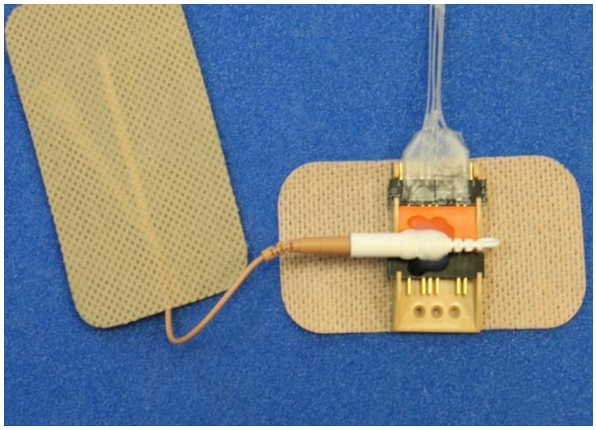


Figure 33

4. Remove the plastic backing from the surface anode. Place the surface anode on the patient near the electrode connector holder. Plug the patient cable into the backup connector (Figure 34).

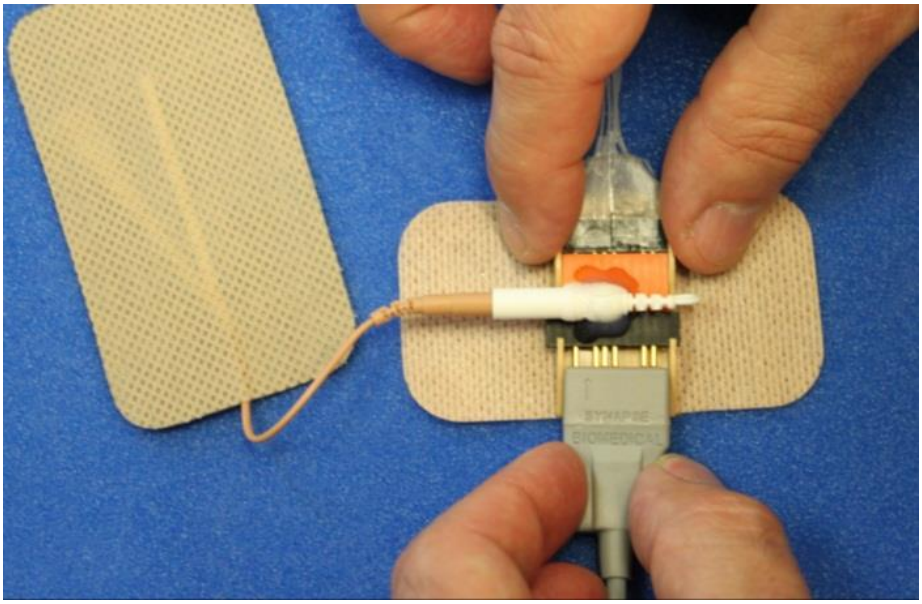


Figure 34

If steps 1 through 4 were successful, then during conditioning the NeuRx EPG screen will show four letters in a row. An example (****) is shown Figure 35. Other examples of correct operation are described under Section 12.0 Functional Features. If the system does not seem to be working correctly, refer to Section 25.0 Troubleshooting and Use Errors.

Figure 35. (*) showing that the NeuRx EPG is working properly during inhaling for each electrode wire (number 1, 2, 3, or 4).

27.0. WARRANTY STATEMENT

The NeuRx EPG has a one year unconditional warranty from the date of installation.
The patient cable has a 90-day unconditional warranty from the date of installation.

28.0. TRAVELING WITH THE NEURX DPS

The government puts out information for travelers with disabilities and medical conditions. You should check the Transportation Security Administration website for the latest advice.

The address for the U.S. is:
http://www.tsa.gov/travelers/airtravel/specialneeds/index.shtm.

The address for Europe is:
https://www.aci-europe.org/policy/position-papers.html?view=group&group=1&id=5

Compatible replacement battery can be found in Section 30.0 Replacement Parts.

29.0. SERVICE

You should not try to fix the NeuRx EPG on your own. Units needing service should be returned to Synapse Biomedical, Inc. Service personnel will have access to the required documentation to repair the device for safe and correct operation.

WARNING: No modifications of this equipment are allowed.

30.0. REPLACEMENT PARTS

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

ITEM	PART NUMBER	SERVICE LIFE	ORDER QUANTITY
Patient Cable	22-0011	90 days	1 Each
Battery, 1.5v Alkaline C	29-0025	96 Hours	1 pack
Lithium Batteries (3 per pack)	22-0020	500 Hours	1 Each
Connector Holder (30 per pack)	22-0004	3 days*	1 pack
Surface Electrodes (4 per pack)	22-0034	7 days*	1 pack
Airline Travel Batteries (3 per pack)	22-0021	Single Use	1 pack

*As needed

DISPOSAL of Replacement Parts:

1. Battery disposal - see Section 24.0 Battery Replacement
2. All other replacement parts with potentially bio-hazardous contamination – please contact local authorities to determine proper method of disposal.

31.0. STORAGE AND DISPOSAL OF PARTS

Store all parts at a temperature between -4ºF to +131ºF, -20ºC to 55ºC.

Secure parts in the patient kit provided when not in use.

Dispose of all used connector holders and broken patient cables in the trash.

For used discharged lithium batteries, dispose per section 24.0 Battery Replacement.

32.0. SPECIFICATIONS (DETAILS OF DEVICE OPERATION)

This section is included to comply with safety standards.

Primary Power Source	1.5 volt Alkaline battery (Alternative 3.6v Lithium battery)
Primary Battery Life	96 hours (alkaline battery) 500 hours (lithium battery)
Secondary Battery Life	500 recharge cycles
Operating Temperature	+41ºF to +104ºF, +5ºC to 40ºC
Storage / Transport Temperature	-4ºF to +131ºF, -20ºC to 55ºC
Relative Humidity	15% to 93%, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Pulse Waveform type	regulated-current biphasic
Pulse Amplitude	5mA to 25mA
Pulse Width	10usec to 200usec
Pulse Period	50msec to 200msec
Inspiration Interval	0.8sec to 1.5sec
Inspiration Rate	8 to 18 breaths per minute
Alarm Volume:	
High Priority	50 dB
Medium Priority	50 dB
Low Priority	50 dB
Intended Environment	Clinical and Home
Essential Performance	1. Stimulus data array 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 stimulus data array settings.

33.0. ELECTROMAGNETIC COMPATIBILITY

- **ELECTROMAGNETIC INTERFERENCE (EMI) WARNING**: Some electrically powered equipment gives off electromagnetic waves which could interfere with your NeuRx EPG. When using your NeuRx EPG around electrical equipment, check the NeuRx EPG screen to make sure the EPG is working.

- Do follow the EMC information provided to maintain essential performance and basic safety. In the event of an EMI disturbance, please see Section 22.0 Alarms of this manual for alarm fault conditions. The NeuRx External Pulse Generator (EPG) needs special precautions regarding electromagnetic compatibility (EMC). To reduce the possibility of interference on the NeuRx EPG from other electrical equipment or the NeuRx EPG effecting other electrical equipment, do NOT use cables or accessories with your NeuRx EPG other than those specified.

- **RF COMMUNICATION 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 NeuRx EPG stimulator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- The NeuRx EPG should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the NeuRx EPG should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The NeuRx External Pulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuRx External Pulse Generator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The NeuRx External Pulse Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NeuRx External Pulse Generator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 NeuRx External Pulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuRx External Pulse Generator 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 NeuRx External Pulse Generator 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.			

Guidance and manufacturer's declaration – electromagnetic immunity

The NeuRx External Pulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuRx External Pulse Generator should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the NeuRx External Pulse Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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	Recommended separation distance $d = [3.5/3] \sqrt{P}$ 80 MHz to 800 MHz $d = [7/3] \sqrt{P}$ 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 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.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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 NeuRx External Pulse Generator is used exceeds the applicable RF compliance level above, the NeuRx External Pulse Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NeuRx External Pulse Generator.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity			
The NeuRx EPG stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the NeuRx EPG stimulator 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 NeuRx EPG stimulator , 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 NeuRx EPG stimulator

The NeuRx EPG stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NeuRx EPG stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NeuRx EPG stimulator 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 $d = [6/9] \sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 $d = [6/28] \sqrt{P}$
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.

34.0. USER ASSISTANCE

For assistance with your NeuRx DPS device including troubleshooting, first call your healthcare provider who is helping you with your NeuRx DPS. Below are spaces to write down your healthcare provider's name and phone number:

Healthcare Provider Name:

_____

Healthcare Provider Phone Number:

_____

If you cannot reach your healthcare provider, you may also call Synapse Biomedical Customer Service:

Synapse Biomedical Customer Service
U.S. Toll Free: 1-888-767-3770
From outside the U.S.: 001-440-774-2488

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

Tel: 1-888-767-3770
1-440-774-2488
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

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