NeuRx Diaphragm Pacing System®
Patient/Caregiver Information and Instruction Manual
For Amyotrophic Lateral Sclerosis
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GLOSSARY OF TERMS

- **Alcohol Wipe** – individually packaged pad saturated with 70% isopropyl alcohol. Used to cleanse the skin’s surface. For single use only.
- **ALS (amyotrophic lateral sclerosis)** – See the section of this manual called Information on Condition or Disease.
- **Arrhythmia** – when your heart is beating either very slow, very fast or it feels like it skips a beat. It is also called an irregular heartbeat.
- **Arterial Blood Gas (ABG)** – a blood test that measures the amounts of gases in the blood. The gases measured are oxygen and carbon dioxide.
- **Backup Indifferent Electrode Interconnect** – can be used instead of the “indifferent electrode” if that part fails. (“Indifferent Electrode” is explained further down in this glossary.) The difference is that it goes on the skin instead of under the skin.
- **Capnothorax** – a complication caused by air going through the diaphragm and into your chest during the surgical procedure.
- **Chronic Hypoventilation** – state in which too little air enters the lungs. This causes low levels of oxygen and high levels of carbon dioxide in the blood. This can be due to breathing that is not deep enough or too slow.
- **Conditioning** – use of the NeuRx DPS® to cause the breathing muscle (diaphragm) to contract.
- **Connector Holder** – plastic shell which holds the electrode connector against the skin. Sticks to the skin with an adhesive like a bandage.
- **Covering Bandage** – a bandage that covers the electrode wires where they come out through the skin.
- **Diaphragm** – the main muscle that is used for breathing.
- **Diathermy Treatment** – deep tissue heat treatment using energy from an electrical device.
- **DPS** – See NeuRx DPS®.
- **ECG (electrocardiogram)** – test to check the electrical activity of the heart. The test helps to see if there has been a heart attack, an irregular heartbeat, or other heart problems.
- **Electrode Connector** – a part of the NeuRx DPS® which connects the electrode wires to the patient cable.
- **Electrode Wire** – See Percutaneous Electrode Wire.
- **EPG (NeuRx DPS® External Pulse Generator) (stimulator)** – the part of the NeuRx DPS® System that puts out the electrical signal which stimulates the diaphragm.
runs on batteries. It is outside the body. It is connected (through the electrode connector) to the electrode wires which go into the diaphragm.

- **Exit Site (electrode wire exit site)** – place where an electrode wire passes through your skin.
- **Forced Vital Capacity (FVC)** – the volume of air that one can exhale from the lungs with force.
- **Indifferent Electrode** – the one wire which is placed under the skin in the chest area.
- **Laparoscope** – a small surgeon’s tool with a camera on the end. The surgeon puts it into the abdomen through a half inch long incision. It lets the surgeon look inside the abdomen without the need for a large incision.
- **Maximum Inspiratory Pressure (MIP or Plmax)** – a measure of how well one can breathe in.
- **NeuRx DPS® (Diaphragm Pacing System)** – device which sends a small amount of electricity to the diaphragm muscle. This makes the diaphragm contract. Parts include the electrode wires, the external pulse generator (“EPG”) box, and the patient cable.
- **Non-Invasive Ventilation (NIV)** – breathing help from a small machine that uses a mask that fits over the nose or nose and mouth.
- **Patient Cable** – cable which connects the NeuRx® EPG (external pulse generator box) to the electrode wires. It carries the electrical signal from the NeuRx EPG® to the wires.
- **Percutaneous Electrode Wire** – thin wire which is used to send a small amount of electricity to the diaphragm muscle. One end of the wire is implanted in the diaphragm. The other end is inserted in an electrode connector outside the body over the chest area.
- **Percutaneous Endoscopic Gastrostomy (PEG)** – a tube through which nutrition is given. It is inserted by a surgeon through the skin and into the stomach.
- **Phrenic Nerves** – the nerves which carry the signals that tell your diaphragm to either inhale or exhale.
- **Pulmonary Function Test (PFT)** – breathing tests that show how well your lungs are working (exhaling and inhaling). One such test checks the maximum amount of air you can force out of your lungs (forced vital capacity or FVC). Another test checks how strong your breathing muscles are when you breathe in (maximum inspiratory pressure or MIP).
- **Stimulator** – See EPG (External Pulse Generator).
The name of the device is the 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 your 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 EPG is programmed by your healthcare provider. The EPG sends electrical signals to the diaphragm. The signal causes the muscle to contract in order to condition the muscle.

See Figure 1 on page 6 for a picture of the NeuRx™ EPG, patient cable, connector holder, electrode connector, and electrode wires. See Figure 2 on page 7 for a drawing showing where the electrode wires are implanted in the body. This drawing also shows the position of the electrode wires, the patient cable, and the NeuRx EPG.
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.
CONTRAINDICATIONS

Are there Any Reasons Why You Should Not Use the NeuRx Diaphragm Pacing System (Contraindications)? None.

INDICATIONS FOR USE

HUMANITARIAN USE DEVICE

Humanitarian Device. Authorized by Federal law for use in the treatment of chronic hypoventilation in ALS 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.

The NeuRx Diaphragm Pacing System (DPS)® is a device. It is meant for patients who have both ALS and diagnosed breathing problems. For the NeuRx DPS® to work, your breathing muscle (diaphragm) must be able to respond to stimulation. This can be shown before surgery by a diaphragm movement test or by a breathing nerve test. You must be able to exhale at least 45% of the air that a typical healthy person could (in an “FVC” test). You must also be 21 years of age or older.

The breathing nerves (phrenic nerves) provide a path from the spinal cord to the diaphragm. It is over this path that your brain sends messages to inhale. Both the right and left phrenic nerves must be at least partially working for the NeuRx DPS® to work. Your phrenic nerves can be tested by your neurologist.

See BEFORE SURGERY: WHAT TO EXPECT for information about these tests.

INFORMATION ON CONDITION OR DISEASE

Amyotrophic lateral sclerosis (ALS) is a disease that affects nerve cells in the brain and the spinal cord. Certain nerve cells called motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. When the motor neurons die because of ALS, the ability of the brain to start and control muscle movement is lost. Patients in the later stages of the disease may become totally paralyzed.

Often ALS affects the motor neurons which reach to the muscles used in breathing. In this way, ALS can cause the breathing problems described in the Indications for Use section above.

For more about ALS see the website of the ALS Association: www.alsa.org/about-als
WARNINGS AND PRECAUTIONS

WARNING: If you use the device full time, then you must always have a back-up means of breathing help (ventilation) available. If you do not feel that you are receiving enough breathing help from the NeuRx DPS®, then you should use your back-up means right away. 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®.

WARNING: If this device is not used properly, it may cause injury or electrical hazard. Follow your healthcare provider’s directions in the use of the NeuRx DPS®.

WARNING: Do NOT use the NeuRx DPS® if you are pregnant. It is unknown if it is safe to use the NeuRx DPS® if you are pregnant. The clinical trial did not involve pregnant women.

WARNING: 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 who is helping you with your NeuRx DPS® about the ways to reduce the risk of food or liquid entering your lungs.

WARNING: 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:

- **Implanted cardiac pacemaker or defibrillator.** The NeuRx DPS® may interfere with these devices. There is not enough information to know for sure whether your NeuRx DPS® can be used safely with these devices. Your healthcare provider should get an opinion from a specialist. Your healthcare provider should also test whether your NeuRx DPS® interferes with devices like these if you need them.

- **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.

- **Magnetic Resonance Imaging (MRI) test.** 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.

- **Diathermy treatment.** Diathermy treatment is deep tissue heat treatment. It should not be done around the implanted electrode wires. Unwanted tissue heating through the electrode wires 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®.

WARNING: Do NOT use this device if the skin around the electrode wires gets swollen, infected, or inflamed. Call your healthcare provider who is helping you with your NeuRx DPS®.

WARNING — FLAMMABILITY: Do NOT use the NeuRx® EPG in rooms or spaces where oxygen is being used. This could cause a fire.

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

CAUTION: 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.

CAUTION: Some patients may feel skin irritation or sensitivity because of the NeuRx DPS®. This may be due to the stimulation. It may also be due to the adhesive on the skin bandage. It could also be due to the transparent dressing used over the gauze that covers the electrode wires. (Tegaderm™ and Op-Site™ are examples of transparent dressings.) Call your healthcare provider who is helping you with your NeuRx DPS® if this occurs. Irritation can usually be reduced by changing the settings of the EPG or removing the adhesive.

CAUTION: Avoid touching the patient cable or electrode wires to other metal objects. Metal objects can conduct electricity. You may accidently get shocked from another metal surface.

CAUTION: To avoid damage to the device, keep this device out of the reach of children.

CAUTION: Do NOT attempt to open the NeuRx® External Pulse Generator (EPG). Doing so can damage the device.

CAUTION: 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.
CAUTION: 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.

CAUTION: Do NOT get wet while using the NeuRx® EPG. This includes 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.

CAUTION: Do NOT have the EPG connected during any type of electrical diagnostic test such as an electromyogram (EMG) or electrocardiogram (ECG). The use of the EPG during such tests could interfere with those tests.

CAUTION — ELECTROMAGNETIC INTERFERENCE: 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.
- To reduce the possibility of interference from other electrical equipment, do NOT use cables or accessories with your NeuRx® EPG other than those specified.
RISKS AND PROBABLE BENEFITS

INTRODUCTION
The NeuRx DPS® System was evaluated in a clinical study. The study involved 106 patients at 9 hospitals (8 in the U.S. and 1 in France). From the 106 patients in the study, 86 would have met the indications for the NeuRx DPS®. The results discussed here are from those 86 patients. The results show that the benefits of using the NeuRx DPS® System outweigh the health risks. Risks and probable benefits of the NeuRx DPS® are described below. The results of the clinical study are also described.

SURGICAL PROCEDURE RISKS
There are risks of the surgery to implant the electrode wires. These serious adverse effects were seen in the study:

- Breathing failure occurred in one of the 86 patients in the study after surgery. This patient also had a feeding tube inserted during the DPS surgery. The feeding tube moved out of place and caused problems. Those problems led to the patient needing breathing support, through a tube in their throat, from a breathing machine.

- Problems caused by the abdominal air getting through the diaphragm and going into the chest cavity during the surgery (capnothorax). This happened in 15 out of 86 patients in the study (in about 1 out of every 6 patients). Two of these patients (in about 1 out of every 43 patients) needed special treatment for this problem. In one case, a small tube was placed in the chest for a short time. In one case, the patient had to stay in the hospital longer than normal. In the other 13 patients (in about 1 out of every 7 patients), the problem went away on its own.

- Reaction to anesthesia. One patient had a serious reaction to anesthesia. After starting anesthesia in the operating room the patient had a low heart rate and low blood pressure. The surgery was then cancelled before any incision was made.
Table 1. Serious adverse events from the study which related to the device or the surgery.

<table>
<thead>
<tr>
<th>Serious Adverse Event</th>
<th>Reported Occurrence (Likelihood) of Serious Adverse Event</th>
<th>Adverse Effect</th>
<th>Reported Occurrence (Likelihood) of Adverse Effect</th>
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<tbody>
<tr>
<td>capnothorax</td>
<td>2 out of 86 patients (1 out of every 43 patients) (2.3%)</td>
<td>catheter placement</td>
<td>1 out of 2 patients who had serious capnothorax</td>
</tr>
<tr>
<td></td>
<td></td>
<td>extended hospitalization</td>
<td>1 out of 2 patients who had serious capnothorax</td>
</tr>
<tr>
<td>respiratory failure</td>
<td>1 out of 86 patients (1.2%)</td>
<td>tracheostomy, mechanical ventilation</td>
<td>1 out of 1 patient who had respiratory failure related to the surgery</td>
</tr>
<tr>
<td>anesthesia reaction</td>
<td>1 out of 87* patients (1.1%)</td>
<td>low heart rate (bradycardia), low blood pressure (hypotension), and cancellation of surgery</td>
<td>1 out of 1 patient who had serious anesthesia reaction</td>
</tr>
</tbody>
</table>

*87 patients = the 86 patients who were implanted and the 1 patient who was not implanted because of anesthesia reaction

There are other surgical risks which were not seen in the clinical study. These include:

- Nerve, tissue or organ damage as a result of the procedure.
- Irregular heartbeat (cardiac arrhythmia) when the electrode wires are implanted in the chest.
DEVICE RISKS

Once the surgery is over and you have recovered, there are risks associated with having the NeuRx DPS® System. The following adverse effects were seen in the study but none were considered serious:

**Table 2.** Adverse events related to the device (other than due to surgery). All were non-serious.

<table>
<thead>
<tr>
<th>Device Adverse Event</th>
<th>Reported Occurrence (Likelihood) of Device Adverse Event</th>
<th>Notes (About Adverse Effects, Resolution, etc.)</th>
</tr>
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| infection where electrode wire passes through skin (exit site) | 8 out of 86 patients (1 out of every 11 patients) | • 7 resolved with antibiotics.  
• 1 resolved after the wires were adjusted in the healthcare provider’s office.  
• None required removal of the wires. |
| discomfort from stimulation | 22 out of 86 patients (1 out of every 4 patients) | • Resolved in 20 patients.  
• Unresolved in 2 patients but tolerable (the patients continued using the NeuRx DPS®). |
| wire leading to diaphragm – break outside the body | 28 out of 86 patients (about 1 out of every 3 patients) | • Affected wire does not deliver therapy until repaired.  
• Requires healthcare provider appointment to repair.  
• No patients had to return to surgery to fix. |
| wire under skin in chest area (indifferent electrode) – break outside the body | 18 out of 86 patients (about 1 out of every 5 patients) | • The NeuRx DPS system does not deliver therapy until repair.  
• Requires healthcare provider appointment to repair.  
• No patients had to return to surgery to fix. |
<table>
<thead>
<tr>
<th>Device Adverse Event</th>
<th>Reported Occurrence (Likelihood) of Device Adverse Event</th>
<th>Notes (About Adverse Effects, Resolution, etc.)</th>
</tr>
</thead>
</table>
| wire under skin in chest area (indifferent electrode) came out of the body | 6 out of 86 patients (in about 1 out of every 14 patients) | • No patients had to return to surgery to fix.  
• Fix involves reinserting the wire under the skin in the healthcare provider’s office under topical anesthetic.  
• Patient may temporarily use an alternate part (the backup indifferent electrode interconnect) until an appointment can be made for the healthcare provider to reinsert the wire under the skin. |
| broken NeuRx® EPG (stimulator) | 6 out of 86 patients (in about 1 out of every 14 patients) | No NeuRx DPS® therapy can occur without a working NeuRx® EPG. A replacement NeuRx® EPG can be shipped to the patient. |
| broken patient cables | 4 out of 86 patients (in about 1 out of every 22 patients) | No NeuRx DPS® therapy can occur without a working patient cable. Two cables are provided with each kit. The patient cables are meant to be disposable. More replacement cables can be shipped to patient. |
| pain where electrode wire passes through skin (exit site) | 3 out of 86 patients (about 1 out of every 29 patients) | • All 3 cases were “mild” pain.  
• One case resolved in 12 days. One case resolved in 5 days.  
• One case did not resolve. The healthcare provider’s report described said that pain was “really mild and occurs rarely”. |
| skin irritation or inflammation | 5 out of 86 patients (about 1 out of every 17 patients) | • All 5 cases were “mild” in severity.  
• All cases resolved within a month and a half (except one case in which the time to resolve was unknown). The average time to resolve was 18 days. The longest known time to resolve was 43 days. |
There are some device risks which were not seen in the study but are considered possible. These device risks include:

- Food or liquid entering your lungs while using the device.
- Bleeding where the electrode wire tip is attached to the diaphragm muscle.
- Electrode wire breaks inside the body. This could lead to a loss of therapy or less therapy. It could require another surgical procedure to correct.
- Allergic reaction to the materials which are used in the electrode wires.
- Use of the NeuRx DPS® causing problems with devices such as heart pacemakers and defibrillators. (See the warning about this under Warnings and Precautions in this manual.)
- Problem interactions with some medical equipment:
  - High-frequency surgical equipment may cause burns where the electrode wires pass through the skin. It might also damage the NeuRx® EPG if connected.
  - MRI could cause the electrode wires to move. MRI could also cause unwanted tissue heating through the electrode wires.
  - Diathermy treatment equipment used for deep tissue heat treatment. Unwanted tissue heating through the electrode wires could occur.
  - External electrical stimulation such as transcutaneous electrical nerve stimulation (TENS). If this is performed 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®.
  - Electrical diagnostic test equipment such as an electromyogram (EMG) or electrocardiogram (ECG). The use of the EPG during such tests could interfere with those tests.
- Impeding treatment if the location where the electrode wires pass through your skin (the exit sites) gets wet.
- Electromagnetic interference: Some electrically powered equipment gives off electromagnetic waves which could interfere with your NeuRx® EPG.
- Accidentally getting shocked from another metal surface if the patient cable or electrode wires touch other metal objects.
PROBABLE BENEFITS

You may get help from the NeuRx DPS® because in a study:

- The patients who used the NeuRx DPS® plus non-invasive ventilation (NIV) survived 16 months longer (on average) than patients who just used NIV. This 16 month time frame is from the time of diagnosis. Survival time was measured until death or the need for a full time ventilator and a tube in the throat (tracheostomy). The patients who just used NIV were similar patients in a different study.

- The patients who used the NeuRx DPS® plus NIV survived 9 months longer (on average) than patients who just used NIV. This is from the time they started using NIV.

- Some patients had a feeding tube placed with the NeuRx DPS®. All of these patients survived past 30 days. Normally, 2 to 25 patients out of 100 (up to a fourth of all patients) would not survive this long.

- Some patients could not get used to or were unable to use NIV but used the NeuRx DPS®. They survived an average of 16 months after getting the NeuRx DPS®.

- Some patients had their sleep tested after using the NeuRx DPS® for 4 months. They tended to have better sleep than before they received NeuRx DPS®.

ALTERNATIVE PROCEDURES AND TREATMENTS

Other breathing treatments exist for patients with ALS. These include non-invasive ventilation through a mask or invasive ventilation with a tube through the throat.

**Non-invasive ventilation (NIV).** The common device used for NIV is a bilevel or continuous positive airway pressure machine. These supply air to the mouth or nose. The choice of mask depends on fit, air leaks, looks, and claustrophobic concerns. A number of current papers show NIV may help patients with ALS. Current treatment advice is that all patients with ALS and respiratory symptoms, or an FVC less than 50%, should be offered NIV. In general, NIV may be used with the NeuRx DPS®.

**Mechanical ventilation.** At some point, ALS reduces the ability to breathe so much that invasive ventilation becomes the only choice for survival. Invasive ventilation uses a tube placed through the throat connected to a ventilator. This can prolong life for several years.
BEFORE SURGERY: WHAT TO EXPECT

Your healthcare provider will need to do breathing tests to see if your breathing problems can be treated using the NeuRx DPS®. These tests include checking how well your lungs are working (breathing out and breathing in). One test checks the maximum amount of air you can force out of your lungs (forced vital capacity or FVC). Another test checks how strong your breathing muscles are when you breathe in. A blood test may be done to see how much oxygen and carbon dioxide are in your blood. In another test, a small monitor is placed over your finger during sleep. The monitor measures the level of oxygen in your blood. The results of any one of these tests can show if you could be a candidate for the NeuRx DPS®.

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 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.
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 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 the sections on Conditioning Sessions and Conditioning Warnings for information about conditioning your diaphragm.

You will need to keep dry while using the NeuRx® EPG. The NeuRx® EPG is not waterproof. Refer to the section “HOW TO SHOWER OR BATHE” on page 34 for instructions on bathing, showering, swimming, or any activity during which you could get wet.

If your NeuRx® EPG is properly cared for, the device should keep working for years. However, you will need to change the battery in your NeuRx® EPG about every 500 hours of use. The following sections will walk you through the use, care and troubleshooting of the NeuRx® EPG.
FUNCTIONAL FEATURES

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 3).

![Figure 3. On/Off Buttons.](image)

The NeuRx® EPG has a screen that shows what the NeuRx® EPG is currently doing and if it is working properly.

The NeuRx® EPG screen shows the breaths-per-minute (BPM) and when the individual electrode wires are active. When the EPG sends electricity to the diaphragm to trigger inhaling, a letter “A”, “B” or “C” is shown below each of the electrode wire numbers (1, 2, 3, and 4). This shows that the NeuRx® EPG is working properly. The example in Figure 4 below shows the NeuRx® EPG with “AAAA” on its screen. This means that it is working properly during inhaling. When any letter “A”, “B” or “C” appears below the electrode wire numbers 1, 2, 3, and 4, it means that the NeuRx® EPG is working. Other examples could be “AABB”, “BABA”, “BACC”, “BBBB”, “BBCC”, “CCCC”, etc., just as long “A”, “B” or “C” appears below each of the four electrode wire numbers.

![Figure 4. “A”, “B” or “C” showing that the NeuRx® EPG is working properly during inhaling for each electrode wire (number 1, 2, 3, or 4).](image)
During exhaling, a ‘-’ character is shown below each electrode number (1, 2, 3, and 4) on the screen (Figure 5). This means that the NeuRx® EPG is not active. It is not sending electrical stimulation.

![Image of NeuRx® EPG during exhaling]

**Figure 5.** “-” shows that the NeuRx® EPG is not active for each wire (number 1, 2, 3, and 4) during exhaling.

Your NeuRx® EPG has been programmed with settings that your healthcare provider determines are right for you. A “?” appearing below an electrode number (1, 2, 3, or 4) on the screen can occur normally when the EPG’s electric signal is at a low level (Figure 6). Later the “?” should switch to a letter (A, B, or C) when the EPG’s electric signal level gets high enough.

![Image of NeuRx® EPG with “?”]

**Figure 6.** “?” 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.

If ‘X’ appears below an electrode wire number (Figure 7), it could mean one of these things:
- 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 provided in this manual. 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 7. "X" could mean loose or broken electrode wires or patient cable or a broken EPG.

**CONDITIONING SESSION**

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.

At visits to your ALS healthcare provider, the settings of your NeuRx® EPG may be adjusted as needed. The number of “breaths” or stimulations you receive per minute may be changed. The “power” or charge of each stimulation may also be changed.
The following describes the process for a single conditioning session:
1. Wash and dry your hands before starting the conditioning session.
2. Clear secretions from your mouth before you condition. Do this again throughout the conditioning session.
3. 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 8).

![Figure 8. Connecting the patient cable to the electrode connector.]

4. 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 9).

![Figure 9. Connecting the patient cable to the NeuRx® EPG.]
5. Press the two buttons at the same time to turn the NeuRx® EPG on.
6. When the conditioning session is over, press the two buttons at the same time to turn the NeuRx® EPG off.
7. 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 10).

![Figure 10. Disconnecting the patient cable.](image)

8. 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 11).

![Figure 11. Disconnecting the patient cable from the electrode connector.](image)

9. Store all items in the patient kit provided.
CONDITIONING WARNINGS

STOP the conditioning session if:
- You notice any change in heart rate or a feeling of chest discomfort.
- You have shortness of breath or if any discomfort persists or worsens.
- You want to eat or drink.
- You cannot manage secretions.

WARNING: 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 who is helping you with your NeuRx DPS® about the ways to reduce the risk of food or liquid entering your lungs.

CAUTION: Do NOT bathe, shower, swim or participate in any other aquatic activities while using the NeuRx® EPG. The NeuRx® EPG is 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 the Warnings and Precautions section.)

BATTERY INSTALLATION

Replace the battery every 500 hours of NeuRx DPS® use. This is about every 20 days if you are using NeuRx DPS® full time. The NeuRx® EPG screen will initially show “REPLACE BATT”. It will alarm for 10 seconds every hour when your battery needs to be replaced. Replace the battery immediately if the NeuRx® EPG screen shows “LOW BATTERY” and if the NeuRx® EPG alarms for 20 seconds every minute.

WARNING: The NeuRx® EPG has a 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 302°F (150 C).

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 12).

3. Remove the old battery. Replace it with a new battery (Figure 13).
• **IMPORTANT:** Use only the kind of battery specified in this manual. **Do NOT use a standard alkaline battery in the NeuRx® EPG.**

• **IMPORTANT:** Put the battery in the correct position (see Figure 13 on page 27).

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

5. Follow the local regulations when you dispose of old batteries.

![Image of battery cover with arrows pointing to screws](image.png)

**Figure 12.** Loosen these screws on the battery cover to replace battery.
Figure 13. Replacing the disposable battery.
ALARMS

The NeuRx® EPG sounds an alarm if it detects any of the following problems:

- A beep lasting the duration of each inhaled breath will sound:
  - if the patient cable gets disconnected from the NeuRx® EPG or if the connection is loose.
  - if the patient cable gets disconnected from the electrode connector or if the connection is loose.
  - if an exiting electrode wire is broken at the electrode connector.

The alarm will repeat until the problem is resolved.

- A beep lasting 10 seconds may sound and “REPLACE BATT” appears on the screen. The 10 second alarm repeats once every hour. This means the NeuRx® EPG has switched to the internal backup battery. It means that it is time to replace the main battery.

- A beep lasting 20 seconds may sound and “LOW BATTERY” appears on the screen. The 20 second alarm repeats once every minute. This means the internal backup battery is low. It means that it is time to replace the main battery immediately.

CARE OF PATIENT CABLE

- The patient cable is shown in Figure 14. It runs between the electrode connector and the NeuRx® EPG (as shown in 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.
- Call your healthcare provider if you need replacement cables.
CARE OF THE EXITING 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.

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 beginning on the next page under “Care of Exit Sites”.

Figure 14. Patient Cable.
CARE OF EXIT SITES

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).

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).
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](image18.jpg)

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](image19.jpg)
7. Carefully press the new connector holder onto the skin (Figure 20).

8. Place a 2” X 2” gauze pad over the exiting electrode wires (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).
HOW TO SHOWER OR BATHE

CAUTION: Do NOT get wet while using the NeuRx® EPG. This includes bathing, showering, or swimming. The NeuRx® EPG is 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 the Warnings and Precautions section.)

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).

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

**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. Wipe the outside of the NeuRx® EPG and the patient cable using a clean, damp cloth with an anti-bacterial cleaning solution. Be sure to wipe away any leftover cleaner.

**TROUBLESHOOTING – NeuRx® EPG**

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 “AAAA” when activated.

   b. If “AAAA” does not appear on the screen or if there is still a problem, call Synapse Biomedical.

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:

<table>
<thead>
<tr>
<th>Problem</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacing of the diaphragm stops.</td>
<td>• Check the connection of the patient cable to the electrode connector.</td>
</tr>
<tr>
<td></td>
<td>• Check the connection of the patient cable to the NeuRx® EPG.</td>
</tr>
<tr>
<td></td>
<td>• Try a different patient cable.</td>
</tr>
<tr>
<td></td>
<td>• Inspect the connections of the electrode wires to the electrode connector for breakage.</td>
</tr>
<tr>
<td>Discomfort while pacing.</td>
<td>STOP use of the NeuRx® EPG and call your healthcare provider who is helping you with your NeuRx DPS®. The EPG settings may need adjustment.</td>
</tr>
<tr>
<td>_bleeding, bruising, or infection where the electrode wires pass through the skin.</td>
<td>Call your healthcare provider who is helping you with your NeuRx DPS®.</td>
</tr>
<tr>
<td>Pain at the electrode wire exit site.</td>
<td>STOP use of the NeuRx® EPG and call your healthcare provider who is helping you with your NeuRx DPS®.</td>
</tr>
<tr>
<td>Skin irritation or hypersensitivity to stimulation.</td>
<td>Call your healthcare provider who is helping you with your NeuRx DPS®.</td>
</tr>
<tr>
<td>Multiple “X”s appear on the NeuRx® EPG screen.</td>
<td>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®.</td>
</tr>
<tr>
<td>The NeuRx® EPG is exposed to substantial amount of water or fluid.</td>
<td>STOP use of the NeuRx® EPG. Call your healthcare provider who is helping you with your NeuRx DPS®.</td>
</tr>
<tr>
<td>Alarm sounds during each stimulation.</td>
<td>• Check the connection of the patient cable to the electrode connector.</td>
</tr>
<tr>
<td></td>
<td>• Check the connection of the patient cable to the NeuRx® EPG.</td>
</tr>
<tr>
<td></td>
<td>• Try a different patient cable.</td>
</tr>
<tr>
<td></td>
<td>• Inspect the connections of the electrode wires to the electrode connector for breakage.</td>
</tr>
<tr>
<td>The NeuRx® EPG beeps for 10 seconds every hour. (This means the NeuRx® EPG is running on its backup battery.)</td>
<td>Replace the main battery as described in this manual. See the Battery Installation section of this manual for the steps.</td>
</tr>
<tr>
<td>Problem</td>
<td>Action</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The NeuRx® EPG beeps for 20 seconds every minute. (This means the NeuRx® EPG is running on its backup battery and the backup battery is getting low.)</td>
<td>Replace the main battery right away. See the Battery Installation section of this manual for the steps.</td>
</tr>
</tbody>
</table>
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” (see Figure 25 below) but the patient cable and EPG still work correctly.

Figure 25. EPG displaying “XXXX”.

Follow these steps to use the backup connector:

1. Disconnect the patient cable from the electrode connector (Figure 26).

Figure 26
2. Remove the backup connector (Figure 27) and the surface anode (Figure 28) from the kit.

![Figure 27. Backup Indifferent Electrode Interconnect](image1)

![Figure 28. Surface Anode Packet](image2)

3. Remove one surface anode (Figure 29) from the packet. Connect the brown cable to the white cable (Figure 30).

![Figure 29](image3)

![Figure 30](image4)
4. Plug the backup connector into the electrode connector that is secured in the connector holder (Figure 31 and Figure 32).

![Figure 31](image1)

![Figure 32](image2)

5. 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 33).

![Figure 33](image3)
If steps 1 through 5 were successful, then during conditioning the NeuRx® EPG screen will show four letters in a row. An example (“AAAA”) is shown Figure 34. Other examples of correct operation are described under “FUNCTIONAL FEATURES” on page 20. If the system does not seem to be working correctly, refer to “TROUBLESHOOTING – NeuRx® EPG” on page 35.

![Figure 34](image)

**Figure 34.** “A”, “B” or “C” showing that the NeuRx® EPG is working properly during inhaling for each electrode wire (number 1, 2, 3, or 4).

### CLINICAL STUDIES

The NeuRx DPS® System was evaluated in a clinical study. The study was done at 9 clinical centers (8 in the U.S. and 1 in France). There were 106 patients with ALS who received the device. Eighty-six patients had breathing problems like those described in the NeuRx DPS® Indications for Use. The risks and benefits of the NeuRx DPS® are based on the results of these 86 patients. See the Risks and Probable Benefits section of this manual for the study results.

### 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.
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 is:
http://www.tsa.gov/travelers/airtravel/specialneeds/index.shtm

SERVICE

You should not try to fix the NeuRx® EPG on your own. Units needing service should be returned to Synapse Biomedical, Inc.

REPLACEMENT PARTS

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

<table>
<thead>
<tr>
<th>ITEM</th>
<th>PART NUMBER</th>
<th>ORDER QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Cable</td>
<td>22-0011</td>
<td>1 Each</td>
</tr>
<tr>
<td>Lithium Batteries (3 per pack)</td>
<td>22-0020</td>
<td>1 pack</td>
</tr>
<tr>
<td>Connector Holder (30 per pack)</td>
<td>22-0004</td>
<td>1 pack</td>
</tr>
<tr>
<td>Surface Electrodes (4 per pack)</td>
<td>22-0034</td>
<td>1 pack</td>
</tr>
<tr>
<td>Airline Travel Batteries (3 per pack)</td>
<td>22-0021</td>
<td>1 pack</td>
</tr>
</tbody>
</table>

STORAGE AND DISPOSAL OF PARTS

Store all parts at a temperature between +20°F and +140°F.

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

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

Follow the local regulations when you dispose of old batteries. Take care to prevent fire or explosion. **Do NOT burn the batteries.**
**SPECIFICATIONS** *(DETAILS OF DEVICE OPERATION)*

This section is included to comply with safety standards.

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Source</td>
<td>3.6-volt lithium battery</td>
</tr>
<tr>
<td>Battery Life</td>
<td>500 hours</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>+41 to +100°F</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>+20 to +140°F</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>10% to 85%</td>
</tr>
<tr>
<td>Pulse Waveform type</td>
<td>regulated-current biphasic</td>
</tr>
<tr>
<td>Pulse Amplitude</td>
<td>5mA to 25mA</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>10usec to 200usec</td>
</tr>
<tr>
<td>Pulse Period</td>
<td>20msec to 250msec</td>
</tr>
<tr>
<td>Inspiration Interval</td>
<td>0.8sec to 1.5sec</td>
</tr>
<tr>
<td>Inspiration Rate</td>
<td>8 to 18 breaths per minute</td>
</tr>
</tbody>
</table>
### LABEL SYMBOLS

Below is an explanation of the symbols used on this product and its packaging.

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Symbol 1" /></td>
<td>This symbol appears on the back of your EPG. It is just a reminder to look into this manual first when you have questions.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Symbol 2" /></td>
<td>This symbol appears on the back of your EPG. It means that the EPG has been tested to protect you from electrical shock. This is because the EPG is battery powered. IEC 60601-1, Type BF Equipment.</td>
</tr>
<tr>
<td><img src="image3.png" alt="Symbol 3" /></td>
<td>This symbol appears on the back of your EPG. It means that the EPG has met standards in Europe. The device meets Medical Device Directive 93/42/EEC. This has been certified by notified body number 0086.</td>
</tr>
<tr>
<td><img src="image4.png" alt="Symbol 4" /></td>
<td>This symbol appears on the back of your EPG. It means that it is protected against splashing water.</td>
</tr>
<tr>
<td><img src="image5.png" alt="Symbol 5" /></td>
<td>This symbol appears on the top of your EPG near the output connector. It warns that output voltages may approach 50 volt D.C. while you are using the EPG.</td>
</tr>
<tr>
<td><img src="image6.png" alt="Symbol 6" /></td>
<td>This symbol appears on the back of your EPG. It shows the serial number of your specific device.</td>
</tr>
<tr>
<td><img src="image7.png" alt="Symbol 7" /></td>
<td>This is the company address outside the U.S.: Moustapha Diop 156 Place des Aubépines 95680 Montlignon France</td>
</tr>
</tbody>
</table>
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, 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