Diaphragm Pacing System
A Diaphragmatic Pacing System (DPS) is a battery operated neurostimulation product for respiratory insufficiency disorders. It is believed that current ventilation methods cause atrophy and accelerate respiratory compromise. The DPS with its minimally invasive approach is both scientifically and clinically proven to preserve muscle strength and maintain vital capacity. The device electrically stimulates the diaphragm to contract and expand; bringing back breathing to some of those that would otherwise remain on a ventilator. The DPS can provide part-time or full-time respiratory support those who normally need to be on a mechanical ventilator. Though children still require a tracheostomy when they have diaphragm pacing, the pacing procedure offers an alternative to traditional mechanical ventilation in children whose breathing depends 24 hours per day on a ventilator.

Diaphragm pacing relies on implanted phrenic nerve electrodes and receivers. An external transmitter communicates a battery-generated train of impulses to antennae that lie over the subcutaneously implanted receivers. The antennae convert the electrical impulse into a radiofrequency signal, and that signal is detected by the implanted receivers. The receivers, connected to the phrenic nerve electrodes, generate a signal that will be detected by the phrenic nerve, and the intact phrenic nerve-diaphragm results in the patient generating a breath.

Although the technology of diaphragm pacing has been around since the 1970s, Dr. Ray Onders didn’t start doing implants until 2000. He developed a method of laparoscopically implanting the electrodes used for pacing on the diaphragm itself instead placing them on the phrenic nerve as had previously been done. (Christopher Reeves was the 3rd person to have a DPS implanted).

An estimated 6,000 U.S. ventilator dependent Spinal Cord Injury patients spend over $100,000/year on ventilatory support and still their life expectancy is reduced by 40 – 70%. To date, the DPS has been implemented in over 50 SCI patients worldwide with long term beneficial results, freeing 98% of patients from mechanical ventilation.

Components of a DPS Unit
Below are several pictures of different manufacturer’s units. Please note that there is more than one manufacturer and instructions will be provided in the User Manual.

Example #1

(Photo Courtesy of Synapse Biomedical, Inc.)

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Example #2

(Photo courtesy of NeuRx Clinical Simulators)

What are the benefits of DPS better than being on a ventilator?
• It decreases secretions
• It decreases pulmonary infections
• It decreases lifetime costs (only need 1 ventilator instead of 2)
• It decreases morbidity
• It increases quality of life

What are the risks or side effects of DPS?
• Pain and spasm at the surgical site
• Mild nausea after the anesthesia
• Damage to internal organ less than 1 in 5000
• The expected risks with any general anesthesia

Not all risks and side effects can be predicted

Implant Procedure
• The surgeon will create four to five dime size holes in the abdominal region
• A laparoscope will be inserted, so that the diaphragm muscle can be seen
• The electrodes are attached to the diaphragm muscle and wires (leads) are tunneled under the skin to exit at the lateral chest.

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• The wires (leads) will be tunneled under and out of the skin through the chest, and be attached to the connector pins that will secure the wires (leads).
• The connector will snap into the bandage connector port
• Connector should lie flat against the skin.
• The electrodes are attached to the EPG that stimulates and causes a contraction of the diaphragm.

General Care of the Skin Exit Sites and Connector
The MD will order the skin exit site care. Below is a sample of that care based on one individual manufacturer’s recommendations. Follow the instructions provided on the POT.
• A skin bandage with connection port (clip) will be provided
• The bandage has a connection port that will anchor the orange exit connector

• Keep the skin at the exit sites clean and dry
• Do not scratch skin at exit sites or try to remove glue residue
• Clean the exit sites as instructed.
• Change the dressings as ordered, typically every 3 days or more often if the dressing becomes wet or otherwise soiled
• Beige skin bandage with connection port (clip) will be placed on chest near nipple line or bra line, observe pins.
• Clean 4x4 gauze pad, taped down on the 3 sides of the pad, bottom section of pad untapped for accessible connection to the simulator cable.
• Do Not place tape on the skin clip bandage
• Caught tape should be trimmed around the edge of the tape bandage instead of tearing the tape off causing disruption of clip bandage.
Connection to the Stimulator
The User Manual will provide instructions on how to connect the lead wires to the cable and to the simulator. It will also provide general On/Off instructions.

General instructions include:
- Do not cut, kink or pull the cable
- Do not manipulate the metal pins in the end pieces of the cable
- Keep extra cables in a dry secure location
- When in use, the cable should fit securely into the exit site connector and the stimulator
- The length of the cable should be long enough to provide comfort and allow range of motion without pulling on the exit site connector.
- Stimulator can be placed in a pocket of the patients clothing, a fanny pack or a table or any other convenient location.
- The cable should be securely inserted into the exit site connector and the top of the stimulator.

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• Do not drop, hit, or throw stimulator
• Do not immerse in water
• Do not attempt to open the box
• Do not expose to long periods of heat or cold
• Keep in a dry and secure location
• When in use, keep close to the patient’s body to avoid pulling on the cable and wires
• Do not pull or cut the wires
• Use extreme caution when shaving skin area around wire site
• Do not manipulate the metal pins in the connector

Cleaning of Stimulator and Cable
The User Manual will discuss Cleaning Instructions. Please be sure that the cleaners used on the device do not have contact with the skin.

Stimulator Alarms and Battery
The User Manual will discuss Alarm situations based on the device in use. They may include:
• Will alarm if it detects a problem with itself, wires or the connections. If the cable or wires become loose/disconnected a BEEPING sound will go off until the cable or wire is reconnected.
• A long beep will alarm when the stimulator switches to the internal backup battery. This alarm may repeat once every hour.
• A longer beep may alarm when the internal backup battery is low. This may repeat once every minute.
• Will alarm when battery power begins to run low
• If the stimulator displays “LOW BATTERY” or “REPLACE BATT” then replace the battery immediately!

Battery Replacement
The User Manual will provide instructions for battery replacement. Typically only Lithium batteries (not Alkaline) are used. Additional information will be provided regarding frequency of batter replacement which may be every 500 hrs. (3 weeks of full time pacing). Stimulator must be TURNED OFF before replacing battery.

Testimonial
Heather Johnson (Barnhart, Missouri)
I was excited when I found out that I was getting the diaphragm pacer, but I didn’t think it was going to change my life. I was wrong! It has given me back some of the peace of mind and confidence that I lost in my car accident. When I’m out in public, I feel that I look more normal without the ventilator hooked up to me, or hanging off the back of my wheelchair. I also used to fear popping off in public because of the attention that the loud ventilator alarm would attract. It’s so much easier to go out now, too, since we don’t have bulky ventilator batteries to carry along. The pacer has allowed me to do many things that I never thought I would be able to do again. I’ve taken several road trips, and have even started
taking college classes again – things I wouldn’t have felt comfortable doing while I was on the ventilator. It’s true that the diaphragm pacer doesn’t change the fact that I’m paralyzed.

References:
http://alsworldwide.org/diaphragm.htm  Accessed 2/21/12
https://www.myvitalconnections.org/webmanuals.nsf/ae05066a27d4960485256afb0069d063/c08a4b6497322a6985257585004cc146lOpenDocument  Accessed 2/21/12