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

All trademarks are the property of their respective holders.

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Additional Information

Refer to the Vercise DBS System Patient Manual, for additional instructions and information about your DBS system.

Product Model Numbers

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<th>Model Number</th>
<th>Product Name</th>
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<tr>
<td>DB-64125-US</td>
<td>Vercise Charging System</td>
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<tr>
<td>DB-6300-C</td>
<td>Vercise Charging Collar Accessories</td>
</tr>
<tr>
<td>DB-6200-C</td>
<td>Vercise Charging Collar, Small</td>
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<tr>
<td>DB-6100-C</td>
<td>Vercise Charging Collar, Medium</td>
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<tr>
<td>NM-6350</td>
<td>Adhesive Kit</td>
</tr>
<tr>
<td>NM-5312</td>
<td>Charger</td>
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<tr>
<td>NM-5305</td>
<td>Base Station</td>
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<td>SC-6300 and NM-6300</td>
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Introduction

The Boston Scientific DBS System is used for deep brain stimulation (DBS), a reversible therapy where structures in the brain are stimulated with small electrical pulses. The Boston Scientific DBS System includes a rechargeable stimulator that will require periodic recharging.

The Charging System allows you to recharge the Stimulator battery as needed. The Charging System for the Stimulator consists of the Charger, a Base Station, and a Power Supply. The Base Station is designed to remain connected to a power outlet at all times. When it is not being used, keep the Charger on the Base Station so that it is always ready to deliver a charge.

This manual provides you with instructions for charging your stimulator. We encourage you to read this and your other Boston Scientific manuals entirely. If you have any questions, or need clarification on anything contained in this manual, please contact Boston Scientific.
Using the Charging System

The Boston Scientific Stimulator is rechargeable. You should expect a daily recharging time of 15 to 30 minutes or a periodic recharging time of 3 to 4 hours every 1 to 2 weeks. Your recharge routine may vary depending on your stimulation parameters. High power users will require more frequent charging. Boston Scientific recommends any recharge routine that fits your schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

Developing a recharge routine involves finding the right balance between four factors:

- How much power is required to experience effective therapy.
- How often you want to recharge.
- How long you want to recharge.
- How you would like to manage your personal schedule.

The Boston Scientific DBS System’s programming software gives your healthcare provider a conservative recommendation for how often to charge. This estimate assumes stimulation is on 24 hours per day, 7 days a week at the programmed energy output level. While you may want to follow these recommendations, you and your physician can also develop an appropriate charge routine that best fits your schedule.

The Remote Control provides an easy-view Stimulator battery meter on the Home screen as well as messages to inform you of the battery’s condition. When the Remote Control indicates a low battery the Stimulator should be recharged as soon as possible. Failure to recharge may lead to loss of stimulation. After stimulation stops, communication with the Stimulator will also cease until a sufficient level of charge has been attained. Refer either to your Vercise DBS Patient Manual or your Remote Control Handbook for more information.
The life of the Stimulator battery is dependent on the stimulation settings and conditions. Over time and with repeated charging, the battery in the Stimulator will lose its ability to recover its full capacity. As a result, over time, the Stimulator may require shorter intervals between charges. The Stimulator will need replacement when stimulation can no longer be maintained with routine charging.
Getting Set Up

Check that you have received all the components below, which are included in your DB-64125-US Vercise Charging System. If any item is missing, please call the Boston Scientific Customer Service department for a replacement.

1. Charging Collar (2)
2. Base Station (1)
3. Power Supply (1) and Adapters
4. Counterweight (1)
5. Charger (1)
6. Charging Spacer (1)

Also, be sure you received your Patient Identification Card from your physician.
Charging the Charger

The Charger contains a rechargeable battery that is used to recharge your Stimulator’s battery.

Cautions:

- Keep the Charging System dry. It should not be exposed to moisture.
- Do not connect the charger to any other device except to the Base Station provided with it.
- Keep the Charging System away from pets, pests and children to avoid damage to the device.

To charge the Charger:

1. Find a convenient electrical outlet that meets the following criteria:
   - will not expose the Charging System to water or direct heat
   - next to a flat, clear surface for the Base Station.
2. Plug the Power Supply into a standard AC wall outlet.
3. Connect the Power Supply to the Base Station.
4. Place the Charger in the Base Station with the power button facing up.
The Charger is ready to fully charge your Stimulator when the indicator light is green. If the light is yellow, the Charger can only partially charge the Stimulator. It may be used, but it may not be able to return your Stimulator to a full charge (and you may need to charge sooner than usual).

<table>
<thead>
<tr>
<th>Indicator Light</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>The Charger is fully charged and ready to charge the Stimulator.</td>
</tr>
<tr>
<td>Yellow</td>
<td>The Charger is partially charged. The Charger may still be used, but it may not be able to fully charge the Stimulator. To fully charge the Charger, place it in the Base Station.</td>
</tr>
<tr>
<td>Off</td>
<td>The Charger is off –or– the Charger battery is empty. If pressing the Power Button does not turn on the Charger, place the Charger in the Base Station to charge.</td>
</tr>
</tbody>
</table>

**Charger Battery Service Life:** The Charger battery has a typical service life of 500 charging cycles.
Understanding the Charger Sound Alerts

The Charger emits different sounds to alert you of specific situations. Before you begin charging your Stimulator, it is important to understand these sounds. The following chart describes what each sound means.

<table>
<thead>
<tr>
<th>Sound</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeated Single Beep</td>
<td>The Charger is searching for your Stimulator and is not properly aligned with the Stimulator. Align the Charger as shown in the section <em>Properly Aligning the Charger</em>.</td>
</tr>
<tr>
<td>Repeated Double Beep</td>
<td>The Charger has fully charged the Stimulator battery. Turn off the Charger and return it to the Base Station.</td>
</tr>
</tbody>
</table>
Charging Your Stimulator

When charging, you must use the Charger with either the Charging Collar or an Adhesive Patch to hold the Charger over the Stimulator. The Adhesive Patches are made of non-reactive and natural Latex-free material suitable for most sensitive skin types.

⚠️ WARNINGS:

- Do not charge while sleeping. This may result in a burn.
- While charging, the Charger may become warm. It should be handled with care.
- Failure to use either the Charging Collar or an Adhesive Patch while charging may result in a burn. If pain or discomfort is felt, cease charging and contact your physician.

Using the Charging Collar

1. When the indicator light is green, remove the Charger from the Base Station. (The indicator light will go off, regardless of the ready status of the Charger.)
2. If instructed to do so by your physician, place the Charging Spacer at the back of the pocket.
3 Place the Charger into the appropriate pocket on the Charging Collar with the power button facing out, as shown. If your Stimulator is on the right side of your chest, place the Charger in the right pocket. If the Stimulator is on the left side of your chest, place the Charger in the left pocket.

4 If instructed to use the Charging Spacer, make sure it is between the Charger and the back of the pocket.

5 Place the Counterweight in the pocket opposite of the Charger.

6 Put the Charging Collar over your neck, with the pockets facing out, as shown.

7 For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See sections Properly Aligning the Charger and Tips for Properly Aligning the Charger to ensure you center the Charger over the Stimulator. It is recommended that you follow the instructions in both sections the first time you charge your Stimulator.

8 If the Charger is not centered over the Stimulator, you may need to adjust the length of the Charging Collar using the straps. Occasionally checking that the Charger is aligned over the Stimulator during your charging session is recommended.

**Note:** The Charging Collar can be placed under or over clothing. You should not wear tight fitting or heavy clothing over the Charger while charging to allow air flow around the Charger.

**Note:** Do not use the Charging Collar when it is wet or damp.
Using the Adhesive Patch

1. When the indicator light is green, remove the Charger from the Base Station. (The indicator light will go off, regardless of the ready status of the Charger.)

2. Apply the Adhesive Patch to the backside of the Charger by peeling the clear liner from the patch and applying the white side with the blue stripe to the rear of the Charger, as shown.

3. Remove the skin side beige liner from the adhesive (only good for one fixation).

4. For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See sections Properly Aligning the Charger and Tips for Properly Aligning the Charger to ensure you center the Charger over the Stimulator. It is recommended that you follow the instructions in both sections the first time you charge your Stimulator.

**Note:** Do not put the Charger directly on the skin (e.g., without an Adhesive Patch).
Properly Aligning the Charger

1. Press the power button. The indicator light will come on again, and the Charger will begin beeping repeatedly to signal that it is searching for the Stimulator.

2. Position the Charger over the Stimulator.

   The beeping will stop when the Charger is partially aligned with the Stimulator. For optimal charging, make sure the Charger is centered over the Stimulator.

   Charging time may increase if the Charger is not fully aligned with the Stimulator. To fully align the Charger over the Stimulator, position the bottom curve of the Charger approximately 1 cm lower than the bottom curve of the Stimulator, as shown.

   If you are having trouble properly aligning the Charger or experiencing longer than normal charging times, see section Tips for Properly Aligning the Charger.

3. Secure the Charger over the Stimulator either by pressing the adhesive to the skin over the Stimulator, or letting go of the Charging Collar.

   **Note:** If the Adhesive Patch is accidentally located in the wrong place, or if the Charging Collar moves out of alignment, the Charger will start beeping again. Use a new Adhesive Patch or readjust the Charging Collar to place the Charger back into the fully aligned position.
Note: Moving around while charging is acceptable, but be aware that the Charger must stay centered over the Stimulator for proper charging. Excessive movement may cause the Charger and Stimulator to become misaligned.

4 When the Charger emits a distinct double beep, press the power button to turn off the Charger and check the Stimulator’s battery with the Remote Control.

5 If the Stimulator is fully charged, remove the Charging Collar or Adhesive Patch from your body.

6 Separate the Charger from the Charging Collar or Adhesive Patch. Set aside the Charging Collar or discard the Adhesive Patch.

7 Return the Charger to the Base Station.

Note: Do not confuse the end of charge signal (a distinct double beep) with repeated beeping indicating misalignment.

Tips for Properly Aligning the Charger

If you are having trouble properly aligning the charger or are experiencing longer than normal charging times, you can use the following procedure to help you properly align the Charger.

1 Lightly press on your skin until you find the implanted Stimulator.

2 Press the Power Button on the Charger. The Charger will begin beeping repeatedly to signal that it is searching for the Stimulator.
3. Place the Charger to the left of the Stimulator.
4. Slowly move the Charger to the right, towards the Stimulator.
5. Stop moving the Charger when it stops beeping.
6. Make a mark on your skin with a soft-tipped marker at the right edge of the Charger, as shown.
7. Place the Charger to the right of the Stimulator.
8. Slowly move the Charger to the left, towards the Stimulator.
9. Stop moving the Charger when it stops beeping.
10. Make a mark on your skin at the left edge of the Charger, as shown.
11. Place the Charger above the Stimulator.
12. Slowly move the Charger down, towards the Stimulator.
13. Stop moving the Charger when it stops beeping.
14. Make a mark on your skin at the bottom edge of the Charger, as shown.
15  Place the Charger below the Stimulator.

16  Slowly move the Charger up, towards the Stimulator.

17  Stop moving the Charger when it stops beeping.

18  Make a mark on your skin at the top edge of the Charger, as shown.
    The marks on your skin should create a square or crosshair. The center of this crosshair indicates the center of the Stimulator.

19  Now that you have located the center of the Stimulator, properly align the Charger over the Stimulator as shown.

Cleaning Instructions

Cleaning the Charger, Base Station, and Power Supply. The components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning. Do not clean the Charger, Base Station, or Power Supply while they are connected to a power outlet.

Cleaning the Charging Collar. Hand wash the Charging Collar with mild soap and warm water. Do not machine wash the charging collar. Let the Charging Collar air dry. Be sure to remove the Charger and Counterweight from the Charging Collar before washing the Charging Collar.
Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your healthcare professional. If you need to contact Boston Scientific for any other reason, please call (833) DBS-INFO or (833) 327-4636.