DBS Patient Application and TM90 Communicator

FOR ACTIVA™ DEVICES

Medtronic Further, Together
# TABLE OF CONTENTS

- Patient Programmer Compatibility ......................................... 1
- Communicator, Pairing and Linking ......................................... 2
- Connecting to Your Neurostimulator ........................................ 4
- Main Screens Overview ................................................ 6
- Charging and Cleaning TM90 Communicator (Activa) ....................... 8
- Battery Status Explanations ............................................. 9
- Communication, Updates, Wifi ............................................. 11
# DBS Patient Programmer

## Patient Programmer Compatibility

<table>
<thead>
<tr>
<th>Implant/Programmer Compatibility</th>
<th>Legacy Patient Programmer (37642)</th>
<th>Intercept™ Patient Programmer (37441)</th>
<th>DBS Patient Application + TM90 Communicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTiva™ PC</td>
<td><img src="image1" alt="Legacy Patient Programmer" /></td>
<td><img src="image2" alt="Intercept™ Patient Programmer" /></td>
<td><img src="image3" alt="DBS Patient Application + TM90 Communicator" /></td>
</tr>
<tr>
<td>ACTiva™ SC</td>
<td><img src="image1" alt="Legacy Patient Programmer" /></td>
<td><img src="image2" alt="Intercept™ Patient Programmer" /></td>
<td><img src="image3" alt="DBS Patient Application + TM90 Communicator" /></td>
</tr>
<tr>
<td>ACTiva™ RC</td>
<td><img src="image1" alt="Legacy Patient Programmer" /></td>
<td><img src="image2" alt="Intercept™ Patient Programmer" /></td>
<td><img src="image3" alt="DBS Patient Application + TM90 Communicator" /></td>
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</tbody>
</table>

*Epilepsy features such as the seizure key are available ONLY with the Intercept Patient Programmer (37441)*
PAIRING

Pairing is an activity performed upon device setup, and creates an association between the handset and communicator. The process will require the user to confirm that the intended communicator is being paired by entering the last two digits of the Serial Number, which can be found on the communicator’s back.
Linking is a similar process to pairing, during which the handset will become associated with a patient’s INS(s). If a new INS is introduced to the system, whether it be a replacement or the addition of a second laterality, all existing links must first be removed in the My Links tab of the Main Menu. The new INS and existing INS (if applicable) can then be linked to the handset.

Note: You will need your communicator held over your neurostimulator for this.
PAIRING
Every time you connect to your neurostimulator, you must use two devices:

- **Handset** – the device with a screen that has the DBS application.
- **Communicator** – the smaller, blue and white device.

To view your therapy, follow the steps in the order listed:

1. Turn on the communicator and handset. Check that they are charged.

2. Tap the OPEN button of the DBS Therapy Application on the handset.

3. Place the communicator directly over the neurostimulator you want to connect to.
4. Keep the communicator over the neurostimulator and tap the CONNECT button on the handset.

5. When the DBS Therapy app is open and connected to the neurostimulator, the HOME screen will be visible. Keep the communicator over the neurostimulator for any further interactions during the session.
*In order to change therapy or otherwise communicate with the implant, the communicator must be held over the implant*

**HOME SCREEN**

1. Menu button (≡) – Tap to access additional app features.

2. **OTHER DEVICE** button – Tap to switch neurostimulators (only shows if you have two neurostimulators).

3. **My Battery** icon – Your neurostimulator battery status.

4. **My Therapy OFF** button – Tap to turn your therapy off. *You will need to hold your communicator over your neurostimulator*

5. **BATTERY** button – Tap to view your detailed battery status.

6. **THERAPY** button – Tap to view or adjust your therapy.
BATTERY SCREEN
The **BATTERY** screen shows the status of three different batteries:

- **My Battery** – the battery level of the neurostimulator, the device implanted in your body.
- If you have two neurostimulators implanted, you can view the battery level of the other device by switching to the other device (Choose the **Other Device** button from either the Home screen or Therapy screen).
- **Communicator Battery** – the battery level of the communicator, the device that you hold over your neurostimulator.
- **Handset Battery** – the battery level of the handset, the device that runs the DBS app.

THERAPY SCREEN

**NOTE:** Your **THERAPY** screen may not look exactly as shown. It depends on your settings, and does not mean anything is wrong.
CHARGING
The USB charging cable and AC adaptor are included in the handset package. Use this cable or another USB 2.0 compliant cable to charge the device (5V 1.0A)

- For best results, charge the communicator overnight, so it is fully charged and ready for use at the beginning of the day.
- Charge the communicator at least every 6 months, even if it is not in use, to ensure the battery maintains power.
- The communicator will not connect to the implanted device while it is charging.
- Note that the communicator will turn off after 3 minutes if not communicating with the handset.

A yellow battery indicator light means that it is time to charge the communicator.

The battery indicator turns orange when the battery is charging.

The battery indicator turns green when fully charged. It remains green until the communicator is removed from the power source.

CLEANING
- Clean the communicator with a damp cloth or sponge. Mild household or medical cleaners will not damage the device.
- The communicator is not waterproof. Do not allow moisture to get inside of the device.
### NON-RECHARGEABLE INS

<table>
<thead>
<tr>
<th>Battery State</th>
<th>Description And Required Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OK</strong></td>
<td>The neurostimulator battery is good and no action is needed.</td>
</tr>
</tbody>
</table>
| **ERI (elective replacement indicator)** | The neurostimulator is nearing the end of its service life and needs to be replaced.*  
For patients who use high levels of stimulation, end of service could occur in as little as 10 weeks after the neurostimulator reaches ERI. Patients who use lower levels of stimulation will have more time before reaching end of service.  
ERI will be displayed until the neurostimulator reaches EOS.  
* This notification appears when battery voltage reaches 2.58 V for Activa SC and 2.60 V for Activa PC |
| **End of Service (EOS)**            | The neurostimulator needs to be replaced.  
The neurostimulator has reached the end of its service life and is no longer delivering stimulation.                                                                                           |

### RECHARGEABLE INS END-OF-LIFE NOIFICATIONS:

<table>
<thead>
<tr>
<th>Battery State</th>
<th>Description And Required Action</th>
</tr>
</thead>
</table>
| **ERI (elective replacement indicator)** | The neurostimulator is nearing the end of its service life and needs to be replaced.  
Replace the neurostimulator within 12 months.  
Note: Before replacement, ensure the neurostimulator has provided the updated service life of 15 years. |
| **End of Service (EOS)**            | The neurostimulator needs to be replaced.  
The neurostimulator has reached the end of its service life and is no longer delivering stimulation.                                                                                           |
### Battery level

<table>
<thead>
<tr>
<th>Battery level</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Full Battery" /></td>
<td>The battery is OK. You do not need to do anything now.</td>
</tr>
<tr>
<td><img src="image" alt="75% Battery" /></td>
<td>The battery is about 75% full. You do not need to do anything now.</td>
</tr>
<tr>
<td><img src="image" alt="Half Battery" /></td>
<td>The battery is about half full. Consider recharging the handset, communicator or rechargeable INS.</td>
</tr>
<tr>
<td><img src="image" alt="25% Battery" /></td>
<td>The battery is about 25% full. <strong>Recharge the handset or Communicator, or rechargeable INS.</strong></td>
</tr>
<tr>
<td><img src="image" alt="Empty Battery" /></td>
<td>The battery is nearly empty. <strong>Recharge the handset, communicator, or rechargeable INS immediately.</strong> If it does not recharge, call your clinician. If this indicator appears for rechargeable INS, you may not be receiving therapy.</td>
</tr>
</tbody>
</table>
COMMUNICATION

Data is transmitted to the Model TM90 Communicator via the Mobile Platform’s Bluetooth radio. The Communicator then transfers the data to the Activa neurostimulator using Medtronic proprietary Telemetry-N technology.

UPDATES

Software and System updates are managed by the Mobile Device Management System (AirWatch™) but must be installed locally by an end user. Updates are not automatically installed behind the scenes so that the system will not interrupt a user who is actively using the system. Notifications will be made when system updates are available and the patient, caregiver or clinician can install application and system updates at the earliest convenient opportunity.
**CONNECTING TO WIFI**

Connecting the Handset to local wifi allows the user to receive important updates and access helpful online content. The wifi will be turned on by default. Step 2 in the process below will only be necessary if the wifi has previously been turned off.

**Step 1**

Tap the Settings icon.

**Step 2**

Toggle the WiFi switch on.

**Step 3**

Tap on your network of choice.

**Step 4**

Enter the appropriate password to join the network. Tap “Connect” to join the chosen Wi-Fi network. Press the Home button to return to the Home screen.
See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.