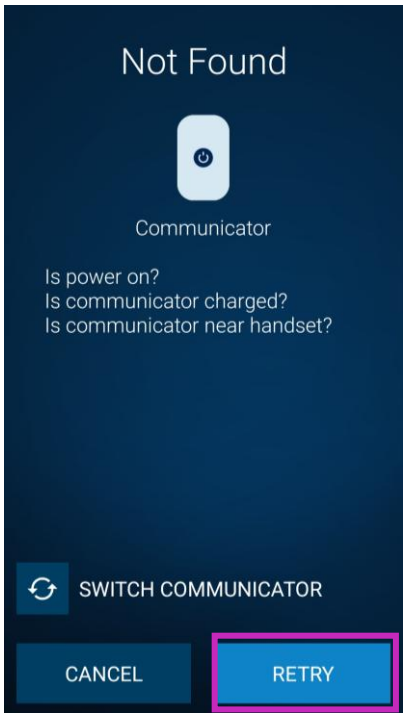
Medtronic

Deep Brain Stimulation – TM91 Percept Communicator

Frequently Asked Questions

This guide provides answers to common questions about your communicator and what the indicator lights mean, so you can confidently use and troubleshoot your device at home. Refer to device user manuals for complete instructions.

"How do I resolve 'Communicator Not Found' message?"



1. Turn on your charged communicator and ensure the battery indicator light is green.
2. Hold the communicator near your patient programmer, then tap **RETRY**. If this does not resolve the issue, follow the steps below to reset your communicator.

Online patient manuals can be found at the link here. Search by your **Percept Model number** (either B35300 Percept RC or B35200 Percept PC).

"How do I reset my TM91 Communicator?"

TM91 Communicator Power Button

Follow these steps:

1. Ensure the Communicator is unplugged from the charging cable.
2. Locate the Communicator power button on your device.
3. Press and hold the Communicator power button firmly.
   - Keep holding the button down for about 30 seconds or longer
   - Watch the lights while holding the button: you may see the indicator lights change colors. The lights may also blink in different patterns – this is expected.
4. Continue holding the button until all lights stop blinking and turn completely off.
5. Once the lights are off, release the button.
6. If you see the "Communicator Not Found" screen tap 'Retry,' and then press and release the Communicator power button.

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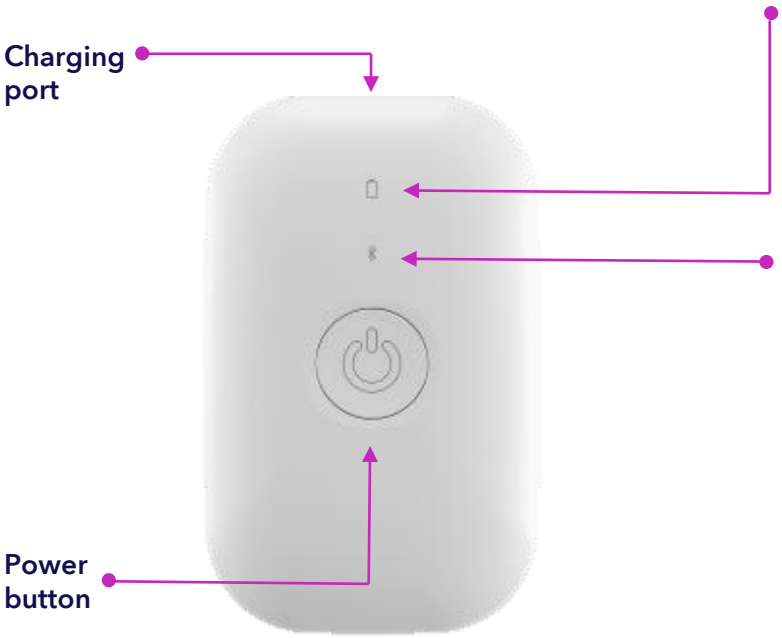
The indicator lights turn off after 3 minutes of inactivity (whether connected to the charging cable or not) and turn back on when the power button is pressed. For more information see A260 Patient User Guide for Model B35200 and B35300 Percept neurostimulators.

"What do the different indicator lights on the Communicator mean?"



Battery Indicator lights:

- **Solid green:** Battery is ready for use
- **Blinks green:** Battery is charging
- **Blinks yellow:** Battery is low
- **Flashes yellow rapidly:** Battery is fully depleted and cannot be used

Bluetooth indicator lights:

- **Blinks blue:** Connecting in progress
- **Solid Blue:** Connected to patient programmer

To turn on: Give the button a short press and release

To turn off: Press and hold button until multiple colors flash simultaneously

Charge your communicator **at least every 6 months**, even if the device is not used.

If you are trying to use your communicator and do not see any lights, try these steps:

- **Press the Power Button**
  Press the power button once to make sure the Communicator is turned on.
- **Check the Battery Indicator**
  Look at the battery indicator to confirm whether the device has power or needs to be charged.
- **Check the Cable Connection**
  Ensure the power cable is securely connected to both the Communicator and the power adapter.
- **Try Another Outlet**
  Plug the power adapter into a different wall outlet to rule out an issue with the original outlet.

If you need further assistance, contact **Medtronic Patient Services** at **1-800-510-6735**.

Brief Statement: Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, Obsessive-Compulsive Disorder, and Epilepsy. Patients should always discuss the potential risks and benefits with a physician.

Medtronic DBS Therapy for Parkinson's Disease: Deep brain stimulation (DBS) helps control the movement symptoms of Parkinson's disease, including tremor, slowed movement, and stiffness. You may be a candidate for this therapy if you have had levodopa-responsive Parkinson's for at least 4 years and at least 4 months of movement symptoms not well controlled by medications or medication side effect such as unintended movements (dyskinesia).

Medtronic DBS Therapy for Tremor: Deep brain stimulation (DBS) delivers electrical stimulation to an area in the brain to help treat essential tremor. Electrical stimulation is only delivered to one side of the body and is used to treat tremor in one arm of the body. You may be a candidate for this therapy if you have essential tremor not adequately controlled by medications and the tremor is disabling.

Medtronic DBS Therapy for Dystonia: Deep brain stimulation (DBS) Therapy for Dystonia is indicated for bilateral stimulation of the internal globus pallidus (GPi) as an aid in the management of chronic, intractable (oral and/or injectable medication refractory) primary dystonia, including:

- generalized dystonia, segmental dystonia of the head and neck, and cervical dystonia (torticollis) in adult patients.
- generalized dystonia in pediatric patients twelve years of age or above.

Medtronic Reclaim™ DBS Therapy for Obsessive-Compulsive Disorder*: The Medtronic Reclaim™ DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

Medtronic DBS Therapy for Epilepsy: Deep Brain Stimulation (DBS) Therapy for Epilepsy is an adjunctive therapy (used along with medications) that delivers electrical stimulation to an area in your brain to reduce the frequency of seizures. You may be a candidate for this therapy if you are 18 years of age or older and diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are not adequately controlled by three or more antiepileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

Warning for Obsessive-Compulsive Disorder:

Electroconvulsive Therapy (ECT) – The safety of ECT in patients who have an implanted deep brain stimulation (DBS) system has not been established. Induced electrical currents may interfere with the intended stimulation or damage the neurostimulation system components resulting in loss of therapeutic effect, clinically significant undesirable stimulation effects, additional surgery for system explantation and replacement, or neurological injury.

Placing the DBS system requires brain surgery, which can have serious and sometimes fatal complications including bleeding inside the brain, stroke, seizures, and infection. Once implanted, infection may occur, parts may wear through your skin, and the lead and/or extension connector may move. Medtronic DBS Therapy could stop suddenly because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return, worsen or become life-threatening as with status dystonicus, which requires immediate medical treatment. Pediatric patients may have increased risk of infections, device-related complications, revisions, and explants compared to adults. Medtronic DBS Therapy may cause new or worsening neurological or psychiatric symptoms. For Epilepsy: cessation, reduction, or initiation of stimulation may potentially lead to an increase in seizure frequency, severity, and new types of seizures. Symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. Memory impairment has been reported, although no direct cause-and-effect relationship has been established.

In patients receiving Medtronic DBS Therapy for Parkinson's disease or essential tremor, new onset or worsening depression, suicidal thoughts, suicide attempts, and suicide have been reported. In patients receiving Medtronic DBS Therapy for Dystonia or Epilepsy, depression, suicidal thoughts, and suicide have been reported although no direct cause-and-effect relationship has been established. In patients receiving Medtronic DBS Therapy for Obsessive-Compulsive Disorder, depression, suicidal thoughts, and suicide have been reported.

This therapy is not for everyone. Implantation of a DBS system is contraindicated (not allowed) for patients who will be exposed to diathermy (deep heat treatment) or transcranial magnetic stimulation. Magnetic Resonance Imaging (MRI) should only be performed as described in the product labeling. The DBS system may interact with other medical devices and other sources of electromagnetic interference which may result in serious patient injury or death, system damage or changes to the neurostimulator or to stimulation. The impact of DBS on overall brain development and behavioral changes in pediatric patients is unknown.

A prescription is required. Not everyone who receives DBS Therapy will receive the same results.

*Humanitarian Device: Authorized by Federal law for use as an adjunct to medications and as alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The effectiveness of the devices for this use has not been demonstrated.

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