SETPOINT SYSTEM SET-UP

CONFIRM CHARGER FIT

- Prior to the implant procedure, either place the Charger, or instruct the patient to place the Charger around their neck while they are seated upright.

- Verify that the magnetic latch closes and remains latched without discomfort.

- Remove the Charger or instruct the patient to remove the Charger.

See section **Charger Fit Confirmation** for more details.

UNPACK AND ISSUE THE CHARGER

- Unpack the Charger and Docking Station and plug the Docking Station into power.

- Place the Charger briefly on the Docking Station to wake up the Charger. No charging is required.

- Train the patient on how to use their SetPoint System and provide them with the Patient IFU QR code.
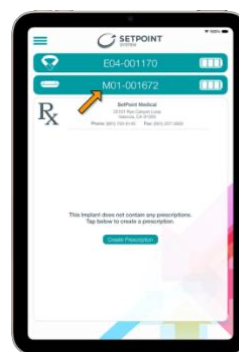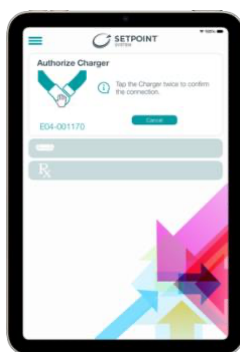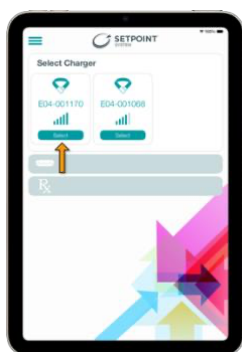
See sections **Unpacking and Issuing the Charger** and **Patient Quick Reference Guide** for more details.

CONNECTING PROGRAMMER, CHARGER, AND IMPLANT

1. Place and close the Charger around the patient's neck.
2. Confirm the connection with the Implant; indicated by two beeps that go up in tone and green or orange LED on the Charger.
3. Launch and sign in to Programmer.
4. Press "Select" under the patient's Charger in Programmer.
5. Tap twice on the Charger's magnetic latch to authorize connection; confirmation is indicated by one single long beep.
6. Confirm the Implant serial number matches the patient's record.

See section **Connecting Programmer to Charger and Implant** for more details.

PRESCRIPTION MANAGEMENT

CREATING A PRESCRIPTION

- Connect Programmer, Charger, and Implant.
- Press **Create Prescription** in the Prescription Panel.

See section **Creating the Prescription** for more details.

EDITING A PRESCRIPTION

- Press **Edit** to the right of **Strength**.
- Adjust the prescription in 50-250 µA increments to determine a comfortable stimulation strength.
- Test the dose for 15 seconds by pressing **Test Dose Strength**.
- If the test dose is uncomfortable, let discomfort resolve, then decrease the dose strength by 50 µA and retest. Repeat until stimulation is comfortable.
- Accept or reject the dose by pressing **Accept** or **Reject**.
- Save prescription by pressing **Accept** and **Save**.

See section **Adjusting Dose Strength** for more details.

SUSPENDING THERAPY

- Press the Implant Panel.
- Press **Suspend Therapy** and then **Suspend**.
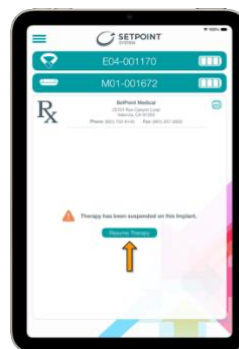- Ensure the Charger LED shows solid pink.

See section **Suspending Therapy** for more details.

RESUMING THERAPY

- Press the Implant Panel or Prescription Panel and then press **Resume Therapy**.
- When prompted, press **Resume** to confirm.
- Ensure the Charger LED shows green or orange.

See section **Resuming Therapy** for more details.

It is important to read and understand the entire contents of the Prescriber IFU prior to use of the SetPoint System. It is also important to provide the patient with the Patient IFU and to train them on how to use their SetPoint System using section **Patient Quick Reference Guide**. Once training is complete, ask the patient to demonstrate their understanding and provide further training on areas that need reinforcement. Make sure to brief the patient on contraindications and warnings using section **Important Safety Information**.

MKT-104.A