

Training Patients on ARC^{EX} for Home Use

This guide does not replace the Instructions for Use (IFU). The IFU contains all the detailed information that must be read and understood.

During rehabilitation sessions in the clinic, you will personalize ARC^{EX} stimulation settings to your Patient's goals. Once tailored, your Patient will have the option to continue ARC^{EX} Therapy at home with their own Personal ARC^{EX} System. This guide covers the training you will provide your Patient and is an excerpt of the Professional IFU (Section 7.2). Note that other steps are required and not included in this guide, such as exporting the stimulation program to the Patient's Personal ARC^{EX} System.

It is your responsibility to set up the stimulation program and instruct the Patient on the use of the Personal ARC^{EX} System at home. Before the Patient uses the ARC^{EX} System at home, go through the following steps to provide comprehensive training and encourage the Patient to read the Personal IFU.

Ensure that the Patient brings their complete Personal ARC^{EX} System to their appointment.

Step 1: General

Inform the Patient to read the "Safety Information" section for safe use of the ARC^{EX} System in the ARC^{EX} Personal IFU.

Step 2: Training

- Physically show the Patient the positioning of the Electrodes based on their program.
- Physically show the Patient the correct connection of Extension Cables to Electrodes and to Splitter Box based on their program.
- Show the Patient the instructional video using this link or QR code: onwd.com/instruction-video



- Remind the Patient that a Rehabilitation Professional should be consulted if any questions arise before, during, or after stimulation.

Step 3: Evaluation

- Ask the Patient to operate the ARC^{EX} System using the **Programmer and the Stimulator**. Use the checklist below (Table 5) as support for evaluating the steps.
- Ask the Patient to operate the ARC^{EX} System using the **Stimulator only**. You or a Person Providing Assistance can help the Patient as needed. Use the checklist below (Table 5) as support for evaluating the steps.
- If any is not performed or not performed correctly, demonstrate the correct way to do it and confirm the Patient's understanding.

Step 4: Completion

- After you are confident that the Patient, with the help of a Person Providing Assistance as needed, can safely use the ARC^{EX} System, the training is complete.

ENSURE PATIENT CAN SUCCESSFULLY COMPLETE ALL OF THE TASKS BELOW**Table 5: Checklist for Patient Training – Evaluation****Task****When operating the ARC^{EX} System with the Stimulator and Programmer:**

- | | |
|--|--------------------------|
| 1. Turn on the Stimulator and the Programmer. | <input type="checkbox"/> |
| 2. Check Programmer and Stimulator battery levels. | <input type="checkbox"/> |
| 3. Unlock Programmer by swiping on the screen and enter PIN. | <input type="checkbox"/> |
| 4. Connect the Programmer to the Stimulator in the myARC ^{EX} app (select the “Device ID” on the Programmer that matches the Serial Number on the back of the Stimulator). | <input type="checkbox"/> |
| 5. Select the program from the “Program List” screen. | <input type="checkbox"/> |
| 6. On your body, identify the areas on where the Active and Return Electrodes will go according to the “Channels” screen. | <input type="checkbox"/> |
| 7. Prepare skin: <ul style="list-style-type: none">◦ Check skin for irritation and integrity before placing Electrodes. Electrodes should not be applied to broken skin. Wait until skin is healed before using the ARC^{EX} System.◦ Clean skin with water or alcohol. Make sure skin is dry before applying Electrodes. | <input type="checkbox"/> |
| 8. Place Electrodes on the prepared skin over the indicated areas according to the “Channels” screen, ensuring they are securely attached to the skin. | <input type="checkbox"/> |
| 9. Connect Extension Cables to Electrodes and Splitter Box according to the setup defined in the “Channels” screen. | <input type="checkbox"/> |
| 10. Connect Splitter Box to Stimulator. Ensure the Stimulator is placed on a flat surface. Do not hold the Stimulator or place it in your lap during the therapy duration. | <input type="checkbox"/> |
| 11. Click “Continue” in the “Channels” screen and confirm the correct Electrode placement. | <input type="checkbox"/> |
| 12. Start stimulation by clicking “Check Ω and start stimulation”. | <input type="checkbox"/> |
| 13. Confirm you are ready to start stimulation by pressing “Yes” in the pop-up window. | <input type="checkbox"/> |
| 14. From the Programmer, increase and decrease Amplitude. | <input type="checkbox"/> |
| 15. Pause stimulation from the Programmer by selecting “Pause Stimulation”. | <input type="checkbox"/> |
| 16. Resume stimulation from the Programmer by pressing “Check Ω and resume stimulation”. | <input type="checkbox"/> |
| 17. Stop stimulation by pressing “Stop stimulation” on the Programmer, then “End session” on the Programmer to complete the session. | <input type="checkbox"/> |

When operating the ARC^{EX} System with the Stimulator only (without the Programmer):

Only use the Stimulator without the Programmer if the Patient can remember where to place the Electrodes and the cabling configuration.

1. Turn on Stimulator and check battery level. ☐
2. Prepare skin:
 - Check skin for irritation and integrity before placing Electrodes. Electrodes should not be applied to broken skin. Wait until skin is healed before using the ARC^{EX} System.
 - Clean skin with water or alcohol. Make sure skin is dry before applying Electrodes.
3. Place Electrodes and connect Extension cables to Splitter Box according to the Program. ☐
4. Plug Splitter Box into Stimulator. ☐
5. Start stimulation by pressing the “Select” button. ☐
6. Increase and decrease Amplitude using the “Increase” and “Decrease” buttons on the Stimulator. ☐
7. Pause stimulation by pressing the “Select” button. ☐
8. Resume stimulation by pressing the “Select” button. ☐
9. Stop stimulation by pressing the “Select” button on the Stimulator once and then press again and hold it for 3 seconds. ☐

After the session ends:

1. Turn off the Stimulator by pressing the “Power” button. If the Programmer was used as well, turn off the Programmer. ☐
2. Unplug Splitter Box from the Stimulator. ☐
3. Remove Electrodes from the skin and disconnect all cables. ☐
4. Check skin for irritation and integrity. Should skin damage or irritation occur, immediately discontinue use of the ARC^{EX} System and wait until skin is healed before using. ☐
5. Charge Stimulator and Programmer if necessary. ☐
6. Return all components to the provided Case. ☐

The ONWARD® Medical ARC^{EX} System is cleared for use in the United States. The ARC^{EX} System is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive). The ARC^{EX} System is intended to be operated in medical centers by Rehabilitation Professionals and at home by Patients and Persons Providing Assistance to the Patient as needed. ARC^{EX}, ARC^{EX} logo, ARC^{EX} PRO™, myARC^{EX}, ONWARD®, ONWARD® Medical logo, and O® logo are proprietary and registered trademarks of ONWARD Medical. Unauthorized use is strictly prohibited. © 2025 ONWARD Medical. All Rights Reserved.