ONWARD®

ARC EX® System (Professional)

Instructions for Use

English

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These Instructions for Use are valid for the ARC$^{EX®}$ System (Professional)

These Professional Instructions for Use are intended for Rehabilitation Professionals.

This IFU includes important information about setting up the ARC^{EX} System Personal, which is intended for use by patients and/or the Person Providing Assistance (PPA), as needed. For full details, refer to the dedicated ARC^{EX} System Personal Instructions for Use (EXIFU01PEREUEN).

New versions of these Instructions for Use will be made available on the ONWARD® website and can be found at the following link:

www.onwd.com/resources

(Additional languages also available)

A paper version of these Instructions for Use can be requested at no additional cost by contacting ONWARD.

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IFU copyright

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Trademarks

Patents granted and pending

Aspects of this device are covered by several patents and patent applications.

Disclaimer

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Drawings herein are for illustration purposes only.

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ARC EX®
System
(Professional)

Essentials for Setup and Use

English

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ARC EX® Professional System

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Healthcare Professionals Essentials for Setup and Use

Condensed setup and use instructions for the following included in this guide:

For Healthcare Professionals: Using ARC^{EX} System in the rehabilitation center

Refer to the Instructions for Use (IFU) in the rest of this document for comprehensive instructions.

Prior to using the ARC$^{EX®}$ System, refer to IFU section 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS**.

ONWARD® Support Contact:	
Phone	Europe: +31 40 288 2830
Email	support@onwd.com

1. **Unpack** the ARC^{EX} System from the Case.


Professional IFU

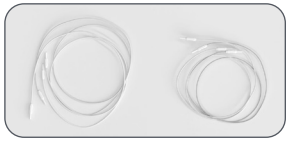
Programmer (ARC^{EX} PRO app)


Programmer Charger


ARC^{EX} Stimulator

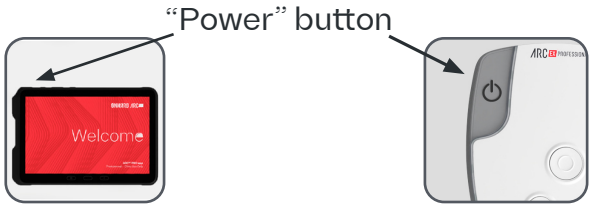

Stimulator Charger


Splitter Box

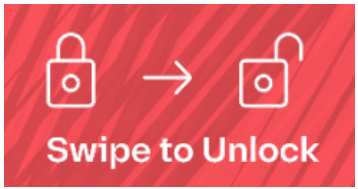
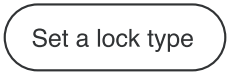

Extension Cables (0.5m/19.7 inches - 1m/39.4 inches)


Active and Return Electrodes

2. Turn **On** the Professional Stimulator and the Programmer by pressing the "Power" button.



3. Confirm Stimulator and Programmer battery levels. Charge them if necessary. Refer to Professional IFU section 6.6.3 for additional details. Battery status shown on Stimulator disappears after 5 seconds. To view it again, turn Stimulator off and back on per Step 2 above.	Stimulator battery status (in notification area of Stimulator screen):  Programmer battery status (top bar): 58%
4. Place the Stimulator on a flat surface with the ARC^{EX} Professional logo readable at the top.	ARC EX PROFESSIONAL

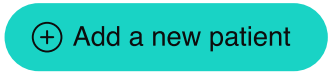
5. **Unlock Programmer** by swiping the screen.	
6. **Enter PIN or**, if this is the first use, **create a PIN.** To create a PIN, press "Set a lock type" to go to the Programmer Settings and set the PIN code. Refer to Professional IFU section 6.1 for additional details.	

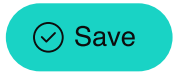
7. Create a new Patient profile in the ARC^{EX} PRO app (installed on the Programmer):

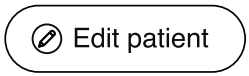
i. Select "Add a new patient" in the "Patient List" screen.
ii. Enter Patient information.
iii. Select "Save".

Or, select an existing Patient profile.

To edit a Patient profile, select the Patient and then select "Edit patient".



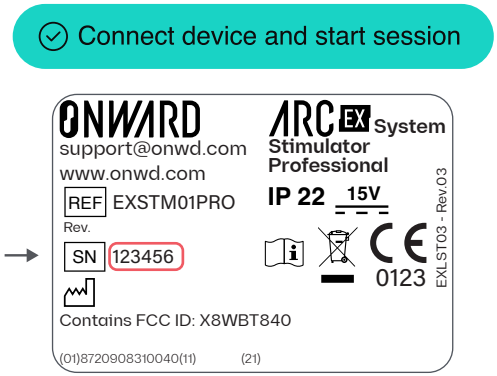




8. Connect the Stimulator to the Programmer by selecting "Connect device and start session" in the "Patient Details" screen. Refer to IFU section 6.3.5 for additional details.

i. Select the "Device ID" on the Programmer screen that matches the Serial Number on the back of the Stimulator.

ii. If the correct Stimulator Serial Number is not listed, select "Search devices".

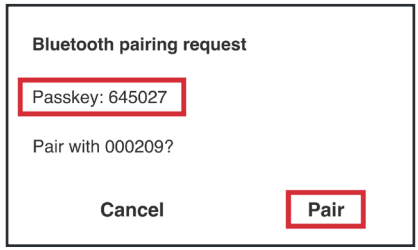


9. If this is the first time you are connecting this Stimulator with this Programmer, **pair the Stimulator with the Programmer:**

i. Visually confirm that the 6-digit passkey on the Programmer screen matches the 6-digit number in the notification area of Stimulator screen.

ii. If they match, press "Pair" in the Programmer AND press the "Select" button on Stimulator (in any order).

Refer to IFU section 6.3.5 for additional details.



10. Create a new program from the "Program List" screen:

i. Select "Create a new program".

ii. Set Program Details:

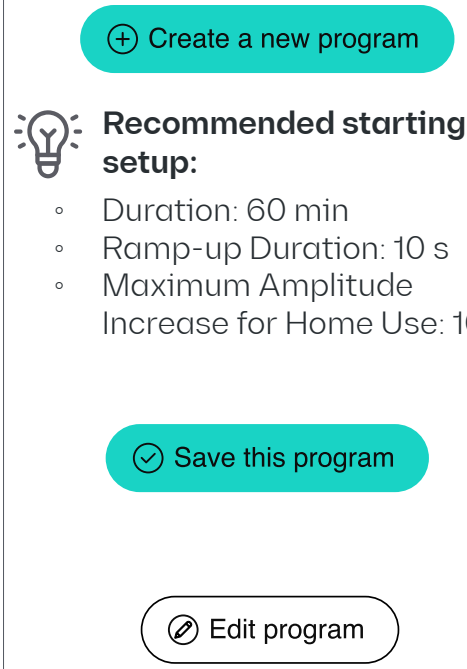
- **Program Name**: Cannot be the same as other names in your "Program List".
- **Program Description**: (optional)
- **Duration**: Maximum program duration [1-180 min]
- **Ramp-Up Duration:** Time to ramp from 0mA to set Amplitude [2-60 s].
- **Maximum Amplitude Increase in Home Use:** Percentage above target Amplitude (intensity) Patient can increase to [0% – 100%].

iii. Select "Save this program".

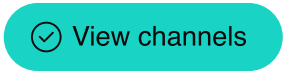
Or, select an existing program.

To edit a program, select the program and then select "Edit program".

Refer to Professional IFU section 6.3.6 for additional details.



11. Select "View channels" to access the "Channels" screen.



12. Determine and set Electrode placement in "Channels" screen:

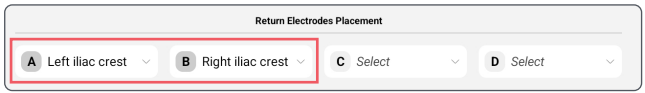
ARC^{EX} Therapy is electrical spinal cord stimulation (SCS). Electrode placement may differ from other stimulation devices. Recommended starting setup is appropriate for upper limb activities.

i. **Set Return Electrode Placement:** In the designated fields labeled A,B,C,D, choose over which bony structures you will place the Return Electrodes (maximum 4). Choose either iliac crests or clavicles.

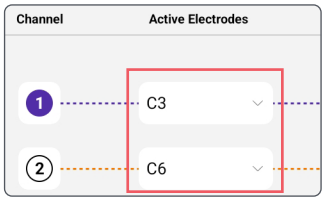
ii. **Set Active Electrode Placement:** In the designated fields labeled 1,2,3,4, choose where on the back of the neck you will place the Active Electrodes (maximum 4).

Recommended starting setup:

Return Electrodes:
A: Left iliac crest
B: Right iliac crest



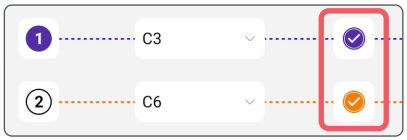
Active Electrodes:
1: C3
2: C6



13. Enable the desired number of channels in the "Channels" screen:

i. **Check the circle** corresponding to the channels you want to use. Once enabled, a checkmark will appear.

Recommended starting setup:
Enable Channels 1 and 2:



14. Select and link the desired Return Electrodes for each enabled channel:

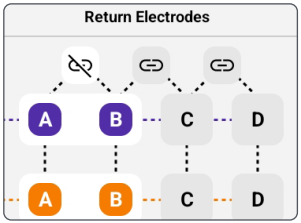
i. Select the field corresponding to the Return Electrode you want to use for a specific channel.

ii. Link the Return Electrodes by clicking the icon.

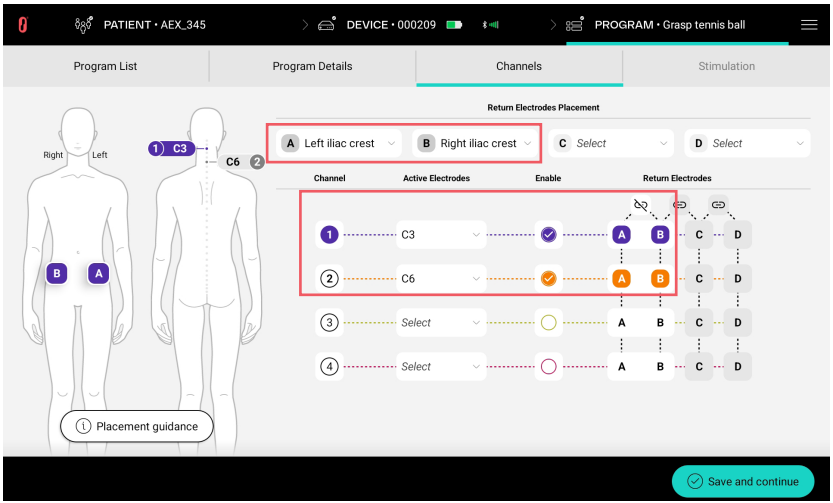
Recommended starting setup:

- Select Return Electrode A for Channels 1 and 2.
- Click the icon between Return Electrodes A and B

They should look like the screenshot below:

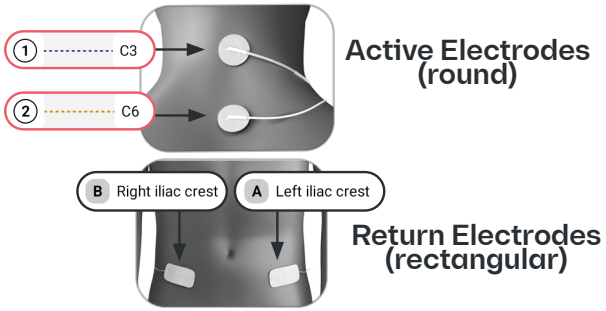


The "Channels" screen should now look like this example:



15. On the Patient's body, locate areas of Electrode placement for both Active and Return Electrodes that you previously inputted in step 12 in the "Channels" screen.

Example of Electrode placement



16. Prepare target areas of skin for Electrode placement for Active and Return Electrodes.

i. 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.

ii. Shave or trim excess hair if needed. Avoid using lotions or oils where the Electrodes will be placed.

iii. Clean skin with water or alcohol. Make sure skin is dry before applying Electrodes.

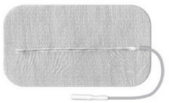
Refer to Professional IFU section 6.4.1.2. for additional details.

17. Place Electrodes on the prepared skin, ensuring they are securely attached to the skin.

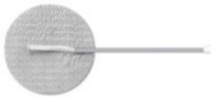
Electrodes should not be removed from their liner or from the skin by the lead wires.

Recommended starting setup:

- Return Electrodes (rectangle) on left and right iliac crests



- Active Electrodes (round) on C3 and C6



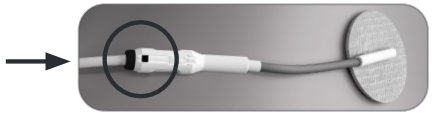
18. Connect Extension Cables:

i. End of Extension Cable(s) with the black ring to the Electrodes.

ii. Other end of Extension Cable(s) without the black ring to the Splitter Box.

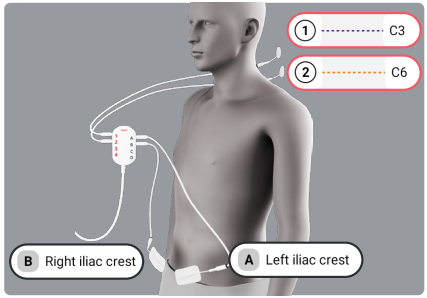
- Round (**Active**) Electrodes to be connected to Active Electrode Sockets of Splitter Box (**red 1-2-3-4**).
- Rectangular (**Return**) Electrodes to be connected to Return Electrode Sockets of Splitter Box (**grey A-B-C-D**).

Replicate configuration in "Channels" screen precisely (e.g., Return Electrode A → left iliac crest, Return Electrode B → right iliac crest).

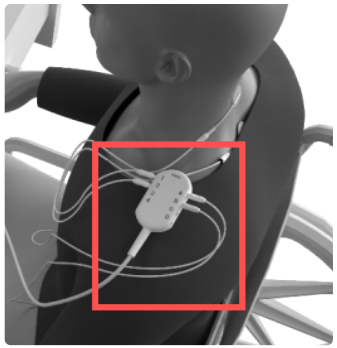


Recommended starting setup:

- Connect Return Electrode on **left iliac crest** to Return Electrode **Socket** A of Splitter Box.
- Connect Return Electrode on **right iliac crest** to Return Electrode **Socket** B of Splitter Box.
- Connect Active Electrode on **C3** to Active Electrode **Socket** 1 of Splitter Box.
- Connect Active Electrode on **C6** to Active Electrode **Socket** 2 of Splitter Box.



19. Clip the Splitter Box (using the built-in clip) to a place, such as on the neck of the Patient's shirt, where Extension Cables can reach the Electrodes without restricting arm movement.



20. Connect the Splitter Box to the Stimulator by inserting grey plug of Splitter Box into grey socket on Stimulator. Use the arrows on the connectors for correct alignment.

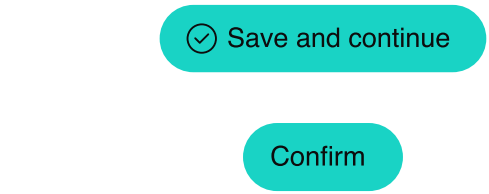
Ensure Stimulator is placed on a flat surface. Do not hold the Stimulator or place it on your lap during the therapy duration.

21. After defining the channel configuration in steps 12-14 above:

i. **Navigate** to "Stimulation" screen:
- Select "Save and continue" in "Channels" screen
- Select "Confirm" after confirming Electrode placement

ii. **Adjust each of the following stimulation parameters to your desired setting** (they will first appear with default settings):
- Waveform: Biphasic or Monophasic
- Amplitude: 0 mA – 250 mA (Biphasic) / 0 mA – 100 mA (Monophasic)
- Pulse Width: 0.1 ms – 5 ms
- Frequency: 0.2 Hz – 100 Hz
- Carrier Frequency: 5 kHz or 10 kHz

Refer to Professional IFU section 6.5.1. for additional details.



Recommended starting setup:
- Waveform: Biphasic
- Pulse Width: 1.0 ms
- Frequency: 30 Hz
- Amplitude: start at 0 mA
- Carrier Frequency: 10kHz

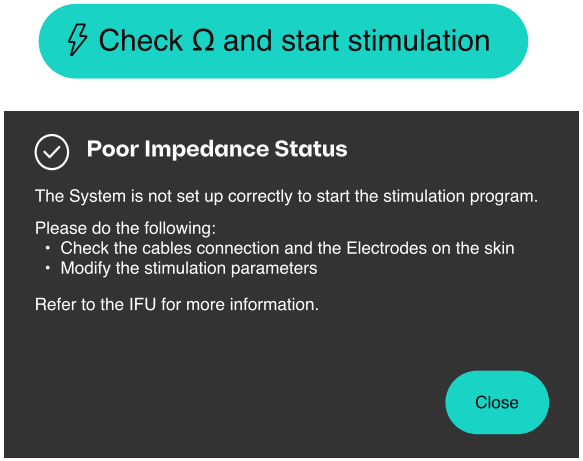
22. Check Impedance Status by selecting "Check Ω and start stimulation".

If you encounter a "Poor Impedance Status" error:

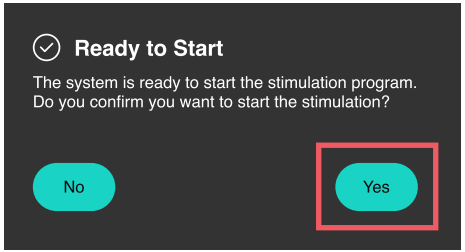
i. Ensure cables are properly connected.

ii. Ensure Electrodes adhere securely to the skin. Use medical tape to secure them or replace with new Electrodes if needed.

Refer to Professional IFU section 6.5.3 for additional details.



23. Confirm you are ready to start stimulation by pressing "Yes" in the pop-up window.



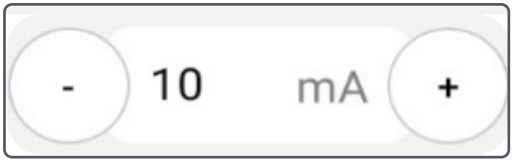
24. Begin task practice.

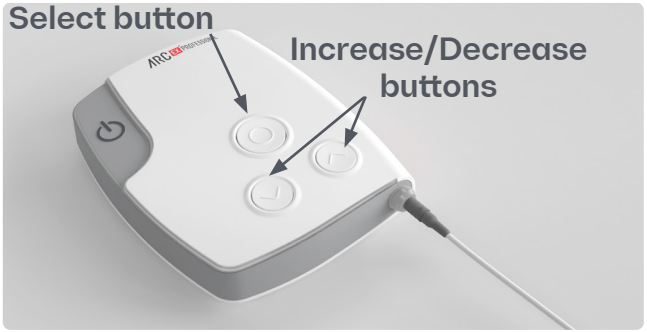
Once the stimulation starts, the current ramps up from 0 mA to the set Amplitude for each channel.

i. **Adjust Amplitude** from the Programmer to change the stimulation intensity. Start at 0mA and gradually increase until task performance is improved. If stimulation creates discomfort, consider reducing Amplitude.

Note:

If the connection to the Programmer is lost, you can increase/decrease Amplitude from the Stimulator buttons.



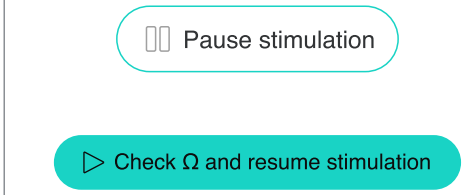


25. You may pause stimulation at any time from the Programmer by selecting "Pause stimulation" or from the Stimulator by pressing the "Select" button.

To **resume stimulation**, press "Check Ω and resume stimulation" on the Programmer.

Note:

If the connection to the Programmer is lost, you can resume stimulation by pressing the Stimulator "Select" button.



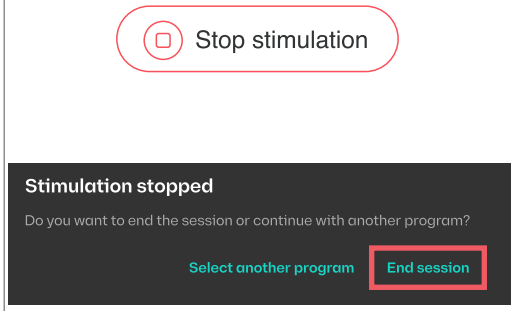
26. Stop stimulation:

i. Press "Stop stimulation" on the Programmer, or

ii. Wait for the program to end based on the set "Duration", or

iii. Press the "Select" button on the Stimulator once and then press it again and hold it for 3 seconds. If stimulation is already paused, press and hold the "Select" button for 3 seconds.

Then, press "End session".



27. After the session ends or you stop stimulation:

i. **Turn off the Stimulator** by pressing the "Power" button.

ii. **Unplug Splitter Box** from the Stimulator.

iii. **Remove Electrodes** from the skin and **disconnect all cables.**

iv.  **Check skin** for integrity and irritation. Should a skin rash or skin burn occur, immediately discontinue use and wait until skin is healed before using the ARC^{EX} System.

v. **Return** all components to the provided Case.

vi. **Clean and charge** Stimulator and Programmer if necessary. Refer to Professional IFU sections 6.6.2 and 6.6.3 for additional details.

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ONWARD®

ARC EX®
System
(Professional)

Instructions for Use

English

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1 Introduction

1.1 How to use these Instructions for Use (IFU)

Read all instructions carefully before using the ARC^{EX} System (Professional). Failure to read and understand the instructions in this document may result in improper use of the ARC^{EX} System, which could compromise patient safety and device performance.

The ARC^{EX} PRO app is a medical device and is installed on a commercially available tablet. The tablet itself is not a medical device. The Electrodes are distributed by ONWARD Medical. For information regarding their safe use, refer to the original manufacturer's instructions provided with the ARC^{EX} System package.

1.2 Technical support

If you have technical questions or issues regarding the ARC^{EX} System (Professional), please contact ONWARD using the following contact details.

Phone	Europe: +31 40 288 2830
Email	support@onwd.com

1.3 Explanation of symbols in package labeling and System markings

MD	Medical device
QTY	Quantity
REF	Reference Number
IP xx	Ingress Protection. The first numeral refers to the protection against solid objects and is rated on a scale from 0 (no protection) to 6 (no ingress of dust). The second numeral rates the enclosure's protection against liquids and uses a scale from 0 (no protection) to 9 (high-pressure hot water from different angles).
EC REP	European Authorized Representative
EU REP	European Authorized Representative
XX REP	Country Authorized Representative. The XX text of the symbol represented the two letters country code.

	Bluetooth®
CE	European CE marking – Indicates compliance with Regulation (EU) 2017/745. The number identifies the Notified Body.
Rx ONLY	USA federal law restricts this device to sale by or on the order of a healthcare professional
	Caution is necessary when operating the device. Consult accompanying documents for specific warnings or precautions associated with the device.
	Consult Instructions for Use
	Read Instruction for Use
	Manufacturer
CC	Country of manufacture

	Date of manufacture
	Use-by date
	Serial number
	Batch code
	Fragile. Handle with care to avoid damage to the contents of the package
	Do not use if package is damaged
	Keep dry and protected from moisture
	Temperature limitation for storage, handling, and transport, where x = minimal value, y = maximum value. Temperatures outside of the stated range for each device can cause damage

	Humidity limitation for storage, handling, and transport, where x = minimal value, y = maximum value. Store in an area that it is not exposed to liquids or excessive moisture
	Atmospheric pressure limitation for storage, where x = minimal value, y = maximum value. Pressure outside of the stated range per device can cause damage
	Type BF (body floating) applied part (not suitable for direct cardiac application)
	15 Volt direct current
	Separate collection for electrical and electronic equipment waste is required
	Unique Device Identification number

	FCC Compliance
	Distributor
	Packaging unit
	Underwriters Laboratories (UL) is an independent, globally recognized agency that certifies, validates, tests, inspects and audits corporations and products.
	Importer

1.4 Abbreviations and definitions

Abbreviation	Description
EMI	Electromagnetic Interference
IFU	Instructions for Use
LED	Light Emitting Diode LED is a type of diode that produces light. A diode is a device that controls an electric current so that it can only flow in one direction.
ONWARD	ONWARD Medical N.V.
RP	Rehabilitation Professional
SCI	Spinal Cord Injury
UDI	Unique Device Identifier
Hz	Hertz is a unit derived from time which measures Frequency in the International System of Units (SI). Frequency is how often something happens. A Frequency of 1 hertz means that something happens once a second.
Iliac crest	This is the curved superior border of the ilium, the largest of the three bones that merge to form the hip bone. It is located on the superior and lateral edge of the ilium very close to the surface of the skin in the hip region.

mA	Milliampere A milliampere (also milliamp) is 1/1000 of an Ampere. Ampere is the basic unit for measuring electrical current.
WARNING	This indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
PRECAUTION	This indicates a potentially hazardous situation which, if not avoided, may result in minor or damage to the device or other property.
NOTE	This indicates additional information to clarify/ elaborate upon adjacent instruction.
Patient environment	The Patient environment is defined as the 1.5 m/5 feet area around the Patient and applies only while stimulation is being delivered.
Functional task practice	Functional task practice in the medical center setting includes the practice of customizable tasks as defined by the Rehabilitation Professional and based on each Patient's individual goals.
Take-home exercises	Take-home exercises include a wide range of simple tasks and activities of daily living recommended for the home setting at the discretion of the Rehabilitation Professional. Exercises may include tasks such as grasping large objects or manipulating small items (e.g. inserting a key in a padlock, grasping a cup, twisting nuts and bolts, tying knots).
QRG	Quick Reference Guide – available only for patient's ARC^{EX} System (Personal).

1.5 Manufactured by and ONWARD customer contact

Company name	ONWARD Medical N.V.
Address	Schimmelt 2, 5611ZX Eindhoven, The Netherlands
Phone	Europe: +31 40 288 2830
Email	support@onwd.com
Website	www.onwd.com

1.6 Contact information for authorized representatives and importers

	Authorized representatives and importers for Switzerland:	ONWARD Medical SA
	Address:	Pont Bessières 3 1005 Lausanne, Switzerland

1.7 Warranty

The ARC^{EX} System warranty is described in the Warranty Statement outlined in the ARC^{EX} System sales documentation.

Note	If the Warranty seal on the back of the ARC^{EX} Stimulator is damaged or removed, please note that the integrity of the device is potentially compromised, and the warranty is void.

1.8 End User License Agreement

The ARC^{EX} System End User License Agreement (EULA) is outlined in the EULA documentation included in the ARC^{EX} System sales documentation.

1.9 Additional supporting material

For additional resources, please visit

www.onwd.com/resources

2 ARC^{EX} Intended Use

2.1 Intended use and indications for use

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 (>1 year post-injury), 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.

2.2 Intended purpose

The ARC^{EX} System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in individuals with an incomplete spinal cord injury (SCI) between 18 and 75 years old.

2.3 Intended population

The ARC^{EX} System is intended for individuals between 18 and 75 years old with chronic, non-progressive, incomplete (Grade B, C or D on the American Spinal Injury Association (ASIA) Impairment Scale (AIS)) cervical spinal cord injury (C2-C8 inclusive).

2.4 Intended users

2.4.1 Rehabilitation Professional (RP)

The Rehabilitation Professional is a licensed clinician or therapist who defines and/or supervises rehabilitation training sessions and/or guides the rehabilitation process for a Patient.

2.4.2 Patient

The Patient is the recipient of ARC^{EX} Therapy who may request assistance from the Person Providing Assistance.

2.4.3 Person Providing Assistance

The Person Providing Assistance is a family member, friend, or caregiver who supports the

Patient as needed in using the System. They are individuals with normal upper extremity mobility who are able to communicate with the Patient.

2.5 Clinical benefits

The ARC^{EX} System, used in conjunction with the practice of functional tasks, is effective for the improvement of hand sensation and strength.

3 Safety Information

The decision as to whether a Patient is suitable for treatment always lies within the competence of the healthcare professional in charge, who has sole medical responsibility for the treatment.
It is important to read all warnings and precautions included in these Instructions for Use to prevent injury and avoid situations that could result in damage to the device.
Prior to therapy, inform the Patient about contraindications, warnings, and precautions of the ARC^{EX} System.

Note	Safety and performance of use during pregnancy have not been established. Limited clinical evidence is available in pregnant women.

3.1 Contraindications

The ARC^{EX} System should not be used on patients with active implantable devices or wearable defibrillators.

3.2 Warnings

Compatibility with other components

- The ARC^{EX} System should only be used with the components of the ARC^{EX} System package (section 4.1) and the recommended Electrodes (section 4.2).
- Do not use accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment . This could **result in increased electromagnetic emissions** or decreased electromagnetic immunity of this equipment and result in improper operation.

In case of damage

- Do not use the ARC^{EX} System if any components are **damaged**. Refer to Section 6.3.1 for more details.
- Never attempt to **modify or repair** the ARC^{EX} System. Contact ONWARD for any technical support.

Electrode placement

- Stimulation should not be applied near the **thorax or trans-thoracically** because the introduction of electrical current into the heart may cause cardiac arrhythmias or increase the risk of cardiac fibrillation.
- Stimulation should not be applied **across or through the head**, including directly to the eyes or mouth because severe spasm of the laryngeal and pharyngeal muscles may occur, resulting in closure of the airway or difficulty with breathing.
- Stimulation should not be applied to the **front or side of the neck** (especially over the carotid sinus nerves).
- Electrodes should not be applied over **swollen, infected, or inflamed areas or skin** eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Electrodes should not be applied over, or in proximity to, **cancerous lesions**.
- Do not apply Electrodes to **broken skin**. Should a skin rash or skin burn occur, immediately discontinue use.

Interaction with the ARC^{EX} System during use and charging

- **Do not touch both** the Active and Return Electrodes at the same time during stimulation (signaled by the yellow light above the Stimulator Output Port).
- Do not hold the Stimulator or place it on **one's lap during the therapy** duration. The temperature of the Stimulator can rise to 60˚C/140˚F when operating at an ambient temperature of 40˚C/104˚F, increasing the likelihood of burns.
- Simultaneous connection of a Patient to high frequency surgical electrical equipment and to the Stimulator may result in burns at the site of the Electrodes and possible damage to the Stimulator.

Emergency handling

- If an **emergency occurs while charging** the Stimulator, unplug the Stimulator Charger from the MAINS supply.

Use and storage environment

- Do not use within 1 m/40 inches of **shortwave** or **microwave** therapy equipment. Using the ARC^{EX} System in close proximity to such equipment may produce instability in the output of the Stimulator.
- The ARC^{EX} System should not be used **adjacent to or stacked** with other equipment. This could result in improper operation. If such use is necessary, the ARC^{EX} System and the other equipment should be observed to verify that they are operating normally.
- Do not use within 30 cm/12 inches of portable radio frequency communications equipment (such as **antenna cables** and **external antennas**). Using the ARC^{EX} in close proximity to such equipment could degrade its performance.
- Avoid wet areas: Never use, charge, or store the ARC^{EX} System in **wet or damp areas** such as bathrooms or other areas that could increase the risk of contact with moisture.

Cleaning

- **Failure to follow cleaning instructions** or using cleaning agents other than as described in section 6.6.2 can affect the safety and performance of the System.

3.3 Precautions

General

- The ARC^{EX} System can generate current densities for Electrodes exceeding 2 mA/cm2, which may require special attention of the operator as this may cause skin irritation and redness. If this occurs, pause the therapy session. Refer to section 3.4.

Electrode placement

- Electrodes **not firmly attached** to the skin may cause superficial skin burns.
- **Keep Electrodes separated**. They must

not overlap or touch once attached to the Patient's skin at the target location.

Patient selection precautions

- Caution should be used in Patients with suspected or diagnosed **heart problems.**
- Caution should be used in Patients with suspected or diagnosed **epilepsy**.
- Caution should be used in the presence of the following:
  - When there is a tendency to **hemorrhage** following acute trauma or fracture;
  - Following **recent surgical procedures** when muscle contraction may disrupt the healing process;
  - Over a **menstruating or pregnant uterus**; and
  - Over areas of the **skin which lack normal sensation**.

Use and storage environment

- **Store the Electrodes** at room temperature as recommended by the original manufacturer instructions.

Compatibility with other activities

- The ARC^{EX} System should not be used **while driving, operating machinery, or during any activity** in which involuntary muscle contractions may put the user at undue risk of injury.

3.4 Potential side effects

Autonomic dysreflexia may be triggered by electrical stimulation. The chances of experiencing autonomic dysreflexia can be reduced by following these precautions:

- Ensure Patient has emptied their bladder and bowels before starting a session with the ARC^{EX} System.
- Do not use the ARC^{EX} System if there is an ongoing bladder infection or fever.

Electrical stimulation may lead to **musculoskeletal spasms, stiffness, and pain**. If this occurs, consider adapting the stimulation parameters (e.g. reduce Amplitude) or if symptoms persist, pause the therapy session. For more details on how to adjust stimulation parameters, refer to section 6.5.1.

Electrical stimulation may lead to **skin irritation, sweating and redness**. If this occurs, move the Electrode(s) to a new location.

Electrical stimulation may lead to a temporary **increase or decrease in heart rate**. If this persists, adapt the stimulation parameters (e.g. reduce Amplitude) or if symptoms persist, pause the therapy session. For more details on how to adjust stimulation parameters, refer to section 6.5.1.

It is normal for electrical stimulation to cause some **discomfort, paresthesia, or neuralgia**. This sensation may become familiar as the Patient uses the ARC^{EX} System.

3.5 Incident reporting

If, during use of the ARC^{EX} System, you have reason to believe that a serious incident has occurred, report it to the manufacturer (refer to section 1.2).

For customers in the European Union, report the serious incident to your national competent authority as well. For customers in the UK, report to the MHRA Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4 Components

The shipping box contains the ARC^{EX} Case and the Electrodes.

4.1 ARC^{EX} System package

The ARC^{EX} System is packed in a Case and consists of the ARC^{EX} Stimulator, Splitter Box, Extension Cables, Stimulator Charger, Programmer, and Programmer Charger.

Table 1. ARC^{EX} System Package

Image	Definition
	**ARC^{EX} Case** (REF: EXCAS01) The ARC^{EX} Case is intended for transportation and storage of the ARC^{EX} System.
	**ARC^{EX} Stimulator Professional** (referred to as Stimulator) (REF: EXSTM01PRO) The Stimulator is intended to generate and deliver electrical stimulation to the Electrodes, through the Splitter Box and Extension Cables, based on commands received from the ARC^{EX} PRO app (via the ARC^{EX} Programmer).
	**ARC^{EX} Splitter Box** (REF: EXSPT01) The Splitter Box is used to connect the Stimulator to the Electrodes (via the Extension Cables).

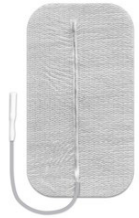
Image	Definition
	**ARC^{EX} Extension Cables** (REF: EXCBL0105 and EXCBL0110) ◦ 4 short Extension Cables (50 cm / 19.7 inches long) ◦ 4 long Extension Cables (100 cm / 39.4 inches long) The Extension Cables are used to connect the Splitter Box to the Electrodes. Either cable length may be used.
	**ARC^{EX} Stimulator Charger** (REF: EXSTM01CHG and EXCHP01UK) The Stimulator Charger is used to recharge the Stimulator's battery.
	**ARC^{EX} Programmer** (REF: EXPRG01PROEU) The ARC^{EX} PRO app is proprietary software designed to allow Rehabilitation Professionals to configure stimulation parameters and customize therapy programs for individual patients. This ARC^{EX} PRO app is installed on off-the-shelf Android-based tablet and communicates wirelessly with the ARC^{EX} Stimulator using Bluetooth® Low Energy (BLE) technology. For the purposes of this document, the ARC^{EX} PRO app installed on the off-the-shelf tablet will be referred to as the "Programmer." The original tablet manufacturer instructions for the tablet on which ARC^{EX} PRO app is installed are provided in the ARC^{EX} System package.

Image	Definition
	**ARC^{EX} Programmer Charger** (REF: EXPRG01CHGUK) The Programmer Charger is used to recharge the Programmer's battery.
	**ARC^{EX} System (Professional) Instructions for Use (this document)** (REF: EXIFU01PROEUEN) Intended for Rehabilitation Professionals, it covers the use of the ARC^{EX} System, including the Stimulator and the ARC^{EX} PRO app as well as the set up of the myARC^{EX} app to support Patient home use. The electronic version of the ARC^{EX} System (Professional) Instructions for Use can also be found on the ONWARD website: **www.onwd.com/resources.** (Additional languages available)

4.2 Electrodes

Electrodes are accessories to the ARC^{EX} System and are provided together with their original manufacturer instructions.

Table 2. Electrodes

Image	Definition
	**Pack of 4 Active Electrodes** (round, REF 879100) Each Electrode is composed of an Electrode pad and a lead wire. The Electrodes are intended for use by one person only. They are reusable but need to be replaced when they expire or begin to lose adhesion a described in section 9.2. Refer to the manufacturer instructions for reuse criteria.
	**Pack of 4 Return Electrodes** (rectangular, REF 895240) Each Electrode is composed of an Electrode pad and a lead wire. The Electrodes are intended for use by one person only. They are reusable but need to be replaced when they expire or begin to lose adhesion a described in section 9.2. Refer to the manufacturer instructions for reuse criteria.

Note	Ensure to check the Electrode size and shape information printed on the Electrode pouch.

5 ARC^{EX} System Description

5.1 ARC^{EX} System Overview

The ARC^{EX} System consists of a **Programmer** that allows the user to define or control stimulation programs through dedicated clinician and personal software applications.

The Programmer communicates with the **Stimulator** that generates and delivers electrical stimulation to the **Electrodes** (Active and Return) via the **Splitter Box** and **Extension Cables**.

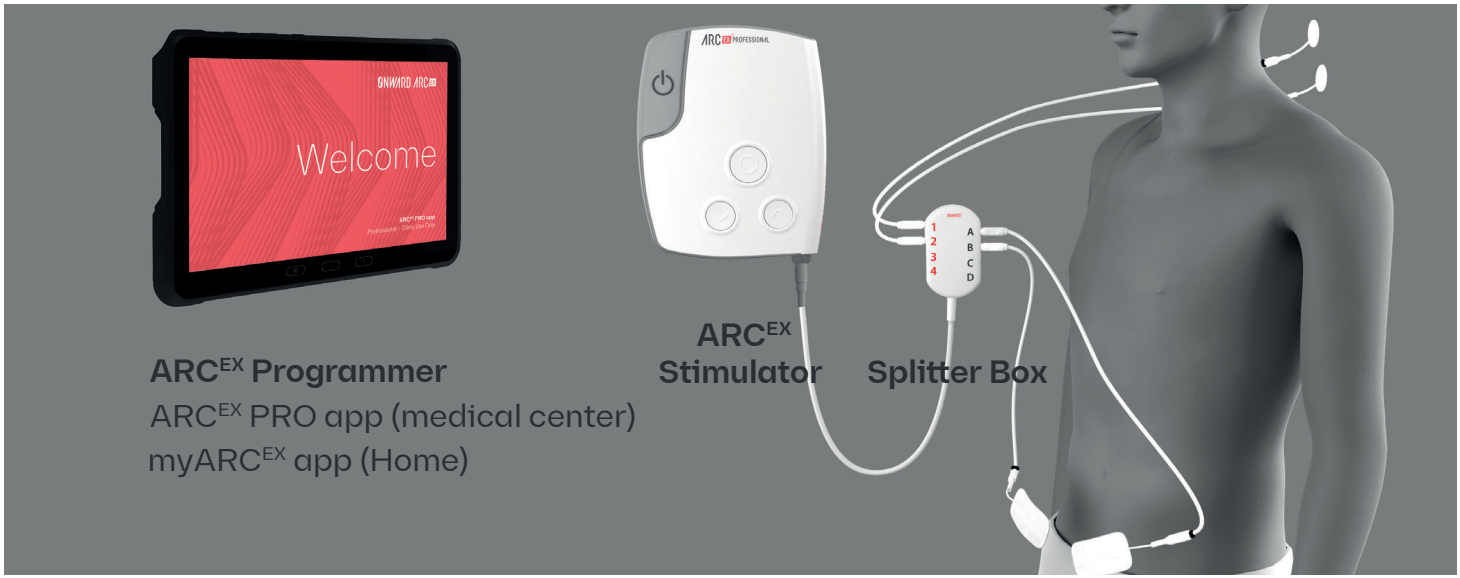


Figure 1: ARC^{EX} System and Electrodes

5.2 ARC^EX Stimulator

The Stimulator is an internally powered device equipped with a rechargeable battery. It generates and delivers electrical stimulation to the Electrodes, based on commands received from the ARC^EX PRO app (via the ARC^EX Programmer).

Figure 2. ARC^EX Stimulator

The numbers in the descriptions below correspond to the part of the Stimulator depicted in Figure 2.

1. **Stimulator output port**:
   - To connect to the Stimulator Charger and then to the MAINS power outlet.
   - To connect the Splitter Box.
2. **"Power" button** to turn the Stimulator on and off.
3. **"Decrease" button** to decrease stimulation Amplitude.
4. **"Increase" button** to increase stimulation Amplitude.
5. **"Select" button** to start/stop/pause the stimulation.
6. **Notification area (screen)** to display instructions and status of the stimulation session.

7. **LED status indicators** to indicate the status of battery level, Bluetooth® connection to the Programmer, and electrode impedance status:
   Battery Bluetooth® Impedance Status
   
8. **Lightbar** to display device states (e.g., stimulation on, error, etc.).

Indicators, sounds, the lightbar, and the notification area (screen) on the Stimulator help users determine ARC^{EX} System state and Table 3 summarizes the feedback provided by the Stimulator.

Table 3. Feedback and Corresponding ARC^{EX} Stimulator State

Message on Stimulator notification area	Light indicator	Sound type	State
Stimulator turns on:			
Welcome	Lightbar: white light around the "Power" button	Turn on sound	Stimulator is booting

Message on Stimulator notification area	Light indicator	Sound type	State
Battery: [value]%	Lightbar: white light around the "Power" button	No sound	Battery check
Control from app	Bluetooth icon is on lightbar: white light around the "Power" button	No sound	Stimulator is connected to the ARC^{EX} PRO and ready to start stimulation
Program ready Start 	Lightbar: white light around the "Power" button	No sound	Stimulator is ready to start stimulation
Stimulator turns off:			
Goodbye	All lights are turned off	Turn off sound	Stimulator is turning off
Battery status while Stimulator is in use:			
-	Battery icon is blinking	Warning sound	Battery is getting low (but the Stimulator can still be used)
Charge device	Battery icon is blinking, lightbar: dashed orange	Error sound	Battery is too low to use the Stimulator

Message on Stimulator notification area	Light indicator	Sound type	State
Charging:			
Charging: [value]%	Battery icon on	No sound	Charging in progress. Please note that this message is only shown for 30s when starting charging and upon pressing the Select button
Charging: 100%	Battery icon on	No sound	Battery is full
Connection to the ARC^{EX} Programmer:			
Pairing [numeric code] Accept 	Lightbar: white light around the "Power" button	No sound	Pairing process at first connection with new Stimulator
Connect to app	Lightbar: white light around the "Power" button	No sound	Stimulator is ready to start but connection with Programmer is not established

Message on Stimulator notification area	Light indicator	Sound type	State
Stimulation:			
Program ready Start 	Lightbar: white light around the "Power" button and yellow light above the Stimulator output port	No sound	Stimulator is performing a pre-stimulation check and stimulation will start in a few seconds. Please note that during this time, no other commands can be executed
Ramp [xx]s, Pause 	Lightbar: blue light all along the bar up to the ending above the Stimulator output port where light is yellow	Stimulation on sound	Stimulation started and is ramping up for [xx]s
[Time elapsed] Pause 	Lightbar: blue light all along the bar up to the ending above the Stimulator output port where light is yellow	No sound	Stimulation ongoing while controlling stimulation from ARC^{EX} PRO app (*Note*: instructions are displayed only periodically while stimulation ongoing)

Message on Stimulator notification area	Light indicator	Sound type	State
[Time elapsed] Adjust  Pause 	Lightbar: blue light all along the bar up to the ending above the Stimulator output port where light is yellow	No sound	Stimulation ongoing while controlling stimulation from Stimulator (*Note*: instructions are displayed only periodically while stimulation ongoing)
Paused Resume  Stop 3s 	Lightbar: dashed white	Stimulation paused sound	Stimulation is paused
Stopped Final Amp: +[x] or –[x]	Lightbar: white light around the "Power" button	Stimulation off sound	Stimulation has been stopped from the Stimulator, the latest used stimulation Amplitude was the one sent by ARC^{EX} PRO app +[x] or –[x]. (*Note*: Remember +[x] –[x] to similarly adjust the Amplitude at next session)

Message on Stimulator notification area	Light indicator	Sound type	State
Stopped	Lightbar: white light around the “Power” button	Stimulation off sound	Stimulation has been stopped from the ARC^{EX} PRO app
Error:			
Temperature limit	Lightbar: dashed orange	Error sound	The Stimulator has reached its warning temperature threshold
See cables Resume  Stop 3s 	Lightbar: dashed orange, Impedance icon on	Error sound	Impedance Status is Poor

Message on Stimulator notification area	Light indicator	Sound type	State
System error [error code]	Lightbar: dashed orange	Error sound	A system error has occurred. Note the error code displayed. Turn the Stimulator off and on again. If problem persists, please contact ONWARD and be prepared to share the error code. For more details on the error codes, refer to section 11.2.2.

5.3 ARC^{EX} Splitter Box

The Splitter Box manufactured by ONWARD is used to connect the Stimulator to the Extension Cables. The Splitter Box connects to the Stimulator via its Cable. Its aim is to distribute the electrical stimulation sent by the Stimulator to the connected Extension Cables and, in turn, to the Electrodes.

Figure 3. ARC^{EX} Splitter Box

The Splitter Box contains eight sockets for Extension Cables. Four connect to Active (round) Electrodes (1-4 red number) and four connect to Return (rectangular) Electrodes (A-D grey letters).

The numbers in the description below correspond to the parts of the Splitter Box depicted in Figure 3.

1. Sockets for Active Electrodes (1, 2, 3, 4)
2. Sockets for Return Electrodes (A, B, C, D)
3. Plug to connect Splitter Box to the Stimulator
4. Clip

5.4 ARC^{EX} Extension Cables

The Extension Cables are used to connect the Splitter Box to the Electrodes. A black ring indicates which side of the Extension Cable should be connected to the Electrode.

Two different Extension Cable lengths (50 cm and 100 cm/19.7 inches and 39.4 inches) manufactured by ONWARD are provided. Either may be used. Choose the appropriate cable length as needed.

5.5 ARC^{EX} Programmer

The manufacturer of the Programmer tablet is Samsung. The ONWARD ARC^{EX} PRO app is delivered pre-installed on the tablet. Refer to the tablet manufacturer's user manual for details such as handling, charging, and cleaning in case of exposure to water or pollutants. The ARC^{EX} PRO app is used by the Rehabilitation Professional, in a medical center setting, to program and control ARC^{EX} Therapy.

Note	Do not remove the protective case from the Programmer.

Figure 4. ARC^{EX} PRO app

5.6 Electrodes

The Electrodes are PALS Electrodes manufactured by Axelgaard and distributed by ONWARD. Placed directly on the skin, they deliver transcutaneous electrical stimulation via the Stimulator.

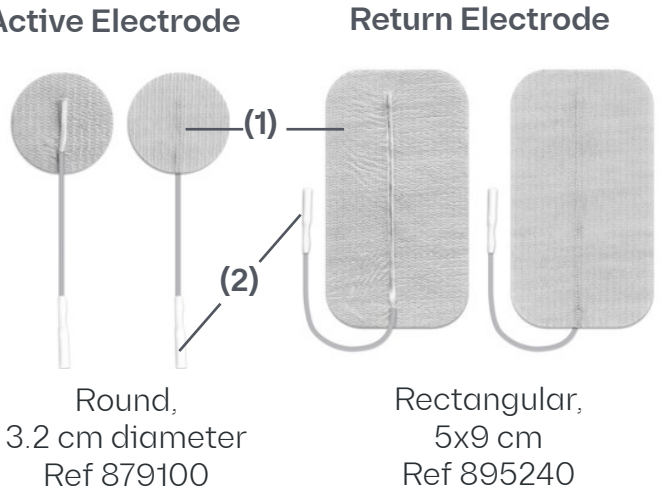


Figure 5. Axelgaard Electrode Types and Parts.

One Axelgaard Electrode consists of the following two parts, as depicted in Figure 5:

1. Electrode pad – placed on the skin.
2. Lead wire – connected to the Extension Cable (end with the black ring).

These Electrodes are intended for use by one Patient only. They are reusable but need to be replaced when they expire or begin to lose adhesion as described in section 9.2. Refer to the Electrode manufacturer instructions for reuse criteria.

Refer to the Electrode manufacturer's IFU for additional details and instructions.

6 ARC^{EX} System Instructions

This section provides instructions for use of the ARC^{EX} System in a medical center environment by Rehabilitation Professionals. Refer to the ARC^{EX} System (Personal) IFU and Quick Reference Guide (QRG) for details on how to use the ARC^{EX} System in a home use environment by Patients and Persons Providing Assistance, if needed. The ARC^{EX} System (Personal) IFU and QRG are found in the Case containing the Patient's ARC^{EX} System and online at

www.onwd.com/resources.

6.1 Setting up the System prior to first use

The ARC^{EX} System requires the following actions:

- **Charge**: It is recommended to charge the Stimulator before first use. This takes about 3 hours. To charge, connect the Stimulator Charger to the Stimulator Output Port and then to the MAINS power outlet. The battery LED indicator on the Stimulator will turn on and the charging message will appear on the notification area of the Stimulator. It is also recommended that you charge the Programmer before first use. Refer to original manufacturer instructions included in the ARC^{EX} System package for information on charging the Programmer.
- **Setting up the ARC^{EX} PRO app** (completed via the Programmer):
  - **Confirm or change language**: App language can be changed at any time in the ARC^{EX} PRO app settings. Refer to section 6.3.3 for more details.
  - **Bluetooth access**: The app needs Bluetooth to function properly and may prompt to provide permission.
  - **Data Privacy information**: you will get Information on collection of anonymized data.
  - **Concealment of the Patient's personal information (optional)**: If you activate this toggle, the Patient List will not show Patient names; only Patient IDs will appear. Concealment of a Patient's personal information can be changed at any time in the ARC^{EX} PRO app settings.

- **Set a lock type**: To prevent unauthorized access to the ARC^{EX} System, set up a PIN code (at least 8 digits) or a password (min. 6 characters). Tap "Set a lock type" to go to the Programmer Settings and set the PIN code. Repeating or consecutive digits are not allowed (E.g. 11111111 or 12345678). Remember the PIN and store it safely for retrieval by authorized personnel. If the PIN code is lost, the Programmer will not be accessible anymore and you will need to contact an ONWARD representative for assistance.
- **Add a fingerprint:** It is recommended to also add fingerprint identification for the Programmer. To do so, access the Settings screen and tap on the "Add fingerprint" button. You can register up to three fingerprints during this setup. All fingerprints must be added at the same time. Once fingerprints are registered, you will not be able to add additional fingerprints later. Ensure all desired fingerprints are registered during the initial setup.

6.2 ARC^{EX} Therapy session

The ARC^{EX} Therapy session can be summarized in the following workflow:

1. **Prepare** the ARC^{EX} System and Patient for the rehabilitation session.
2. **Set up** the Electrodes and stimulation program.
3. **Train** with the Patient using the ARC^{EX} System.
4. **End** the rehabilitation session.

6.3 Prepare

6.3.1 Collecting the components

⚠	Refer to section 3.2 for **WARNINGS** related to the ARC^{EX} System components compatibility and integrity.

1. **Unpack** the ARC^{EX} System components carefully from the Case.
   Check each component carefully for wear

and tear prior to every use. If you notice any damage — such as cracks, breaks or loose connections, stop using the ARC^{EX} System and contact ONWARD.

Collect all necessary components:

- Programmer;
- Stimulator;
- Splitter Box;
- Appropriate length and number of Extension Cables for the intended channel configuration;
- Appropriate number of Active Electrodes for the intended channel configuration;
- Appropriate number of Return Electrodes for the intended channel configuration.

2. Turn **On** the Stimulator **and** the Programmer. The Power button of the Programmer is the left-most button on the side of the Programmer when Programmer is oriented per Figure 6.

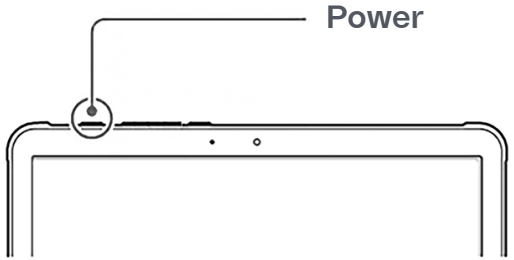


Figure 6: ARC^{EX} Programmer Power Button

3. **Confirm Stimulator and Programmer battery level** and charge them if necessary. The Stimulator battery status is shown in the notification area of the Stimulator screen after it is powered on and disappears after 5 seconds. To view it again, turn Stimulator off and back on. The Programmer battery status appears on the top bar.

58%

4. **Place the Stimulator on a flat surface** with the ARC^{EX} Professional logo readable at the top.

Note	It is recommended to charge the Stimulator and the Programmer prior to first use.
Note	Check the Stimulator and Programmer battery levels before the session.
Note	The Stimulator cannot be used while charging.
Note	Wait 2.5 hours before using the Stimulator if stored below 5°C/41°F or above 40°C/104°F.
Note	If the ARC^{EX} Programmer battery is low, it may disconnect or fail to communicate with the ARC^{EX} Stimulator.
Note	Do not use expired Electrodes because they might not adhere properly to the skin. Check the expiration date on the package.

6.3.2 Starting the ARC^{EX} PRO app

1. **Unlock the Programmer** by swiping the screen.

2. **Enter PIN, or**, if this is the first use, **create a PIN**.
   - To create a PIN, press "Set a lock type" to go to the Programmer Settings and set the PIN code. Refer to section 6.1 for instructions on creating a PIN.

6.3.3 ARC^{EX} PRO app settings

Tap on the hamburger menu (three horizontal lines) on the right of the navigation top bar to access settings and device information:

The **"SETTINGS"** screen lets you access the following:

- **The app language.** The app will redirect you to the Programmer settings to change the language. It is recommended to avoid changing the language settings while stimulation is on.
- **Bluetooth Paired Devices.** The app will redirect you to the Programmer settings to unpair the Stimulator if needed.
- **ONWARD Privacy Policy** available in the provided link.
- **Extract logs.** A button to extract the logs recorded by the ARC^{EX} System. These logs may be useful for technical troubleshooting and can be retrieved by ONWARD representatives if needed.
- **Add Fingerprint.** The app will redirect you to add fingerprint identification for the Programmer. You can register up to three fingerprints. All fingerprints must be added at the same time. Once fingerprints are registered, you will not be able to add additional fingerprints later.
- **Display only the patient's anonymous identifier:** to protect patient privacy, you can enable the option to display only anonymous identifiers on the Patient List screen. Activate the toggle to conceal patient names and show only their anonymous identifiers.

The **"ABOUT"** screen provides information about the System.

6.3.4 Patient profile management

Patient profiles are displayed and can be managed in the "Patient List" screen below (Figure 7).

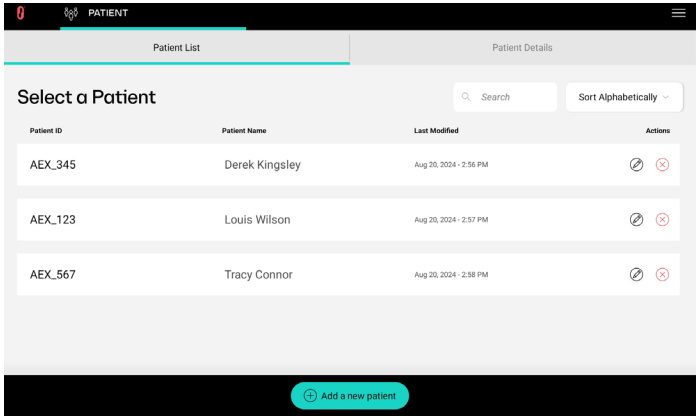


Figure 7. Example of "Patient List" Screen

The ARC^EX PRO app allows you to create a new Patient profile or select an existing Patient profile to start therapy.

All existing Patient profiles can also be edited or deleted. Details on how to perform these actions are described in the following sections.

The ARC^EX PRO app allows you to manage multiple Patient profiles.

You can choose to sort the Patient profiles either alphabetically or chronologically (the last profile used will appear at the top of the list). Select the desired option in the drop-down menu in the top right of the "Patient List" screen. You can also search for a specific Patient profile by typing their ID or name (when the name is visible on the list).

6.3.4.1 Select or create Patient profile

Select the desired Patient profile by clicking on the corresponding line of the list. Once a Patient profile is selected, the "Patient Details" screen is displayed (Figure 8 below).

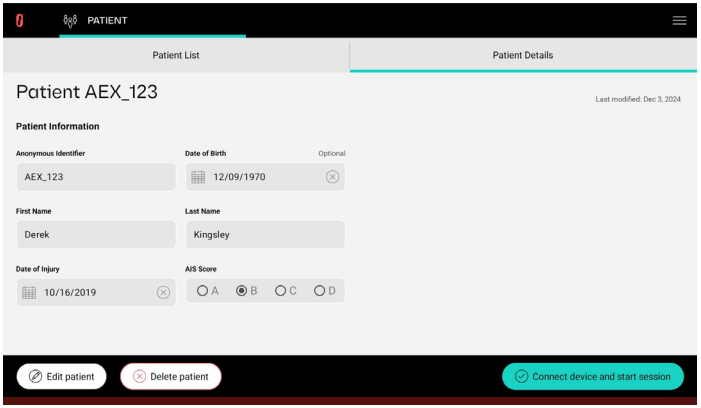


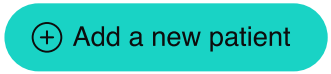
Figure 8. Example of "Patient Details" Screen

Note	The names and dates shown in the above example are for demonstration purposes only and do not represent actual persons, living or deceased. Any resemblance is purely coincidental.

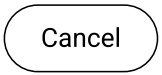
If the desired Patient profile is not in the Patient List, create the Patient profile to be able to proceed with the session.

To **create a Patient profile**, perform the following steps:

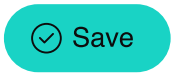
1. Tap on "Add a new Patient" on the bottom bar to add a new Patient profile:



2. Fill in the requested information about the Patient:
   - Anonymous identifier: should be unique for identifying the Patient. Do not use Patient's first or last name.
   - Date of birth (optional).
   - First name.
   - Last name.
   - Date of spinal cord injury.
   - AIS score.
3. You can always cancel the profile creation by tapping on "Cancel" on the left of the bottom bar:



4. Save the Patient profile by tapping "Save" on the right of the bottom bar. You need to fill in all the required information to be able to save the profile:



5. Once saved, you will be able to revise the Patient details and edit, delete the recently created Patient profile, or "Connect to a device and start the session" with the Patient.

Note	As soon as the new Patient profile is saved, it will be visible in the "Patient List" screen.

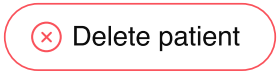
6.3.4.2 Edit or delete patient profile

All Patient profiles can be:

1. Edited, by tapping on the edit icon in the "Patient List" screen or by tapping on "Edit patient" in the "Patient Details" Screen:

Save or cancel your changes by tapping on the corresponding button on the bottom bar.

2. Deleted, by tapping on the delete icon in the "Patient List" screen or by tapping on "Delete patient" in the "Patient Details" Screen:



A pop-up message will ask you to confirm the deletion action. If you confirm the action, the data will not be accessible from the app. If you cancel there will be no change to the Patient List.

6.3.5 Connecting to the ARC^{EX} Stimulator

1. **Connect the Stimulator to the Programmer** by selecting "Connect device and start session".

At this point, the Patient's anonymous ID will appear on the top bar. Ensure that the correct Patient profile has been selected.

The "Select a device" screen shows a list of all detected Stimulators within range (Figure 9).

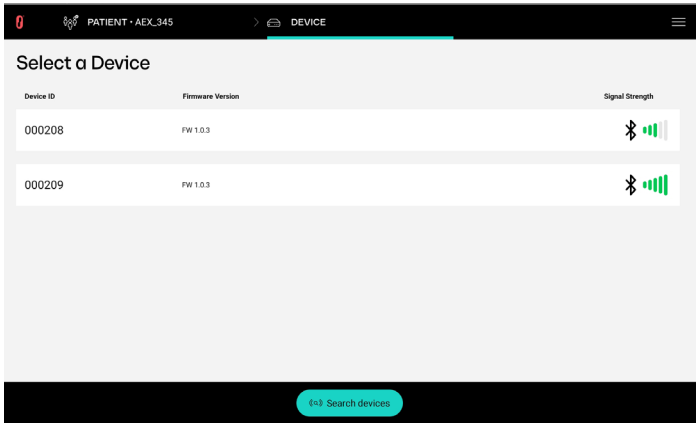


Figure 9. Example of "Device" Screen

i. Select the "Device ID" on the Programmer screen that matches the Serial Number on the back of the Stimulator.

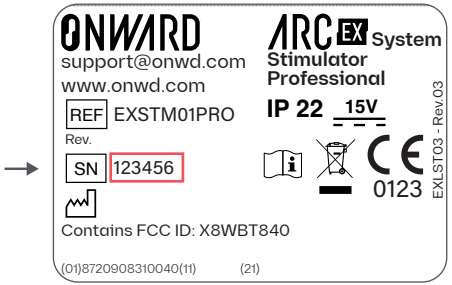
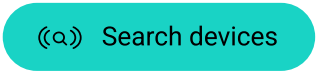


Figure 10. Example of Label on the Back of the ARC^{EX} Stimulator.

ii. If the correct Stimulator Serial Number is not listed, select "Search devices".



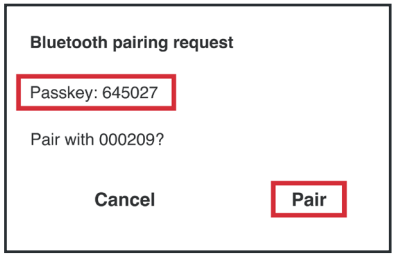
"Signal strength" is an indicator of quality of the Bluetooth signal between the Programmer and the Stimulator, and depends on how close they are.

2. If this is the first time you are connecting this Stimulator with this Programmer, **pair the Stimulator with the Programmer**:

   i. Visually confirm that the 6-digit passkey on the Programmer screen matches the 6-digit number in the notification area of the Stimulator screen.

   ii. If they match, accept the pairing in the Programmer by pressing "Pair" and press the "Select" button on the Stimulator (in any order). Note that the 6-digit pairing number appears for 30 seconds in the Stimulator before it times out and you must start this process over.

Select button



Once the Stimulator is connected, the following information will appear on the top bar.

1. Device ID, corresponding to the Stimulator SN
2. Battery level of the Stimulator
3. Bluetooth Signal Strength between the Stimulator and the Programmer

For more details on the connected Stimulator, navigate to the "DEVICE" tab where the following information are displayed (Figure 11):

- The Device ID, which corresponds to the Stimulator SN.
- The Firmware version installed on the Stimulator.
- The option to turn off the sound of the Stimulator.

- The Battery level of the Stimulator and the option to disconnect from the Stimulator.
- The Bluetooth Signal Strength between the Stimulator and the Programmer.

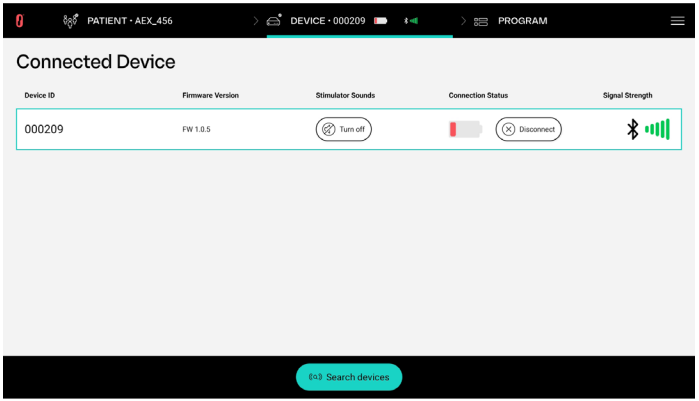


Figure 11. Example of "Device" Tab

6.3.6 Stimulation program management

Access the "Program List" for the Patient once the Stimulator is connected to the ARC^{EX} PRO app (Figure 12) to create a new program or select an existing program to start therapy.

To edit or delete programs, follow the instructions in the following sections.

The ARC^{EX} PRO app allows you to manage up to 10 customized programs per Patient profile.

You can choose to sort programs either alphabetically or chronologically (the last used program will appear at the top of the list). Select the desired option in the drop-down menu.

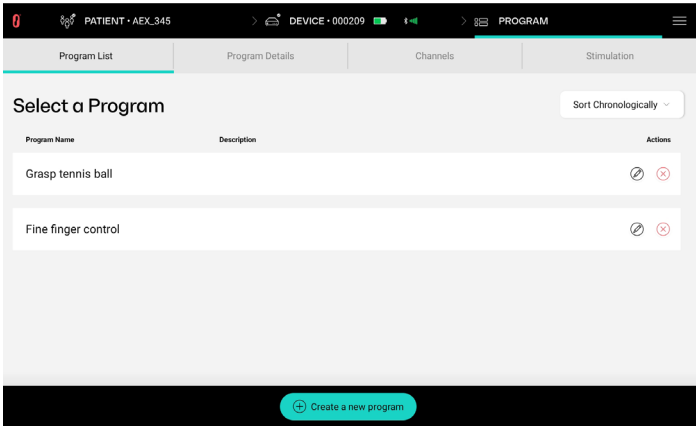


Figure 12. Example of "Program List" Screen

6.3.6.1 Select or create a stimulation program

1. **Select the program** by clicking on it. Once a program is selected, the "Program Details" screen is displayed (Figure 13) and the program name will appear on the top bar. Ensure the correct program is selected.

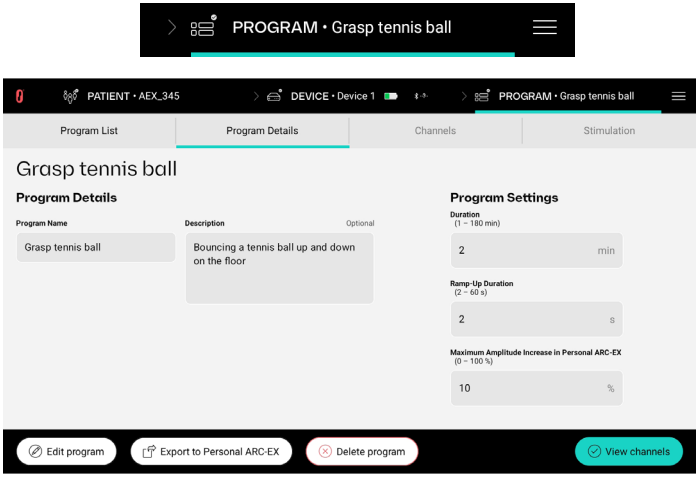


Figure 13. Example of "Program Details" Screen

If the desired stimulation program is not in the "Program List", create a new one as described below.

> **Recommended starting setup**
> - Stimulation Duration: 60 min
> - Ramp-up Duration: 10 s

2. **To create a program**, perform the following steps:

   i. Tap on "Create a new program" from the "Program List" screen:

   ii. Set program details:

- Program Name: Cannot be the same as other names in your "Program List".
- Program Description (optional).
- Duration [*1min – 180min*]: maximum program duration
- Ramp-Up Duration [*2 s – 60 s*]: Time to ramp from 0mA to set Amplitude.

To make the start of the stimulation less abrupt when starting or resuming stimulation:

- A longer Ramp-Up Duration means a slower build-up to the set Amplitude, which can

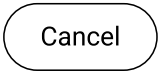
be more comfortable for the Patient when setting higher Amplitudes.

- A shorter Ramp-Up Duration means a faster build-up to the set Amplitude, thus allowing adjustments to be made soon after starting stimulation.

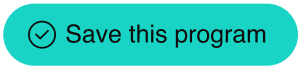
Note	Stimulation Amplitudes cannot be adjusted during the Ramp-Up Duration.
Note	Specific stimulation settings may cause the Ramp-Up Duration to be automatically adapted to be longer than the value set by the user. This ensures a smooth start-up of stimulation with the Patient. Exact ramping duration is displayed on the Stimulator.
Note	The ramp-up effect may be limited in case of low frequencies (<2Hz).

- Maximum Amplitude Increase in Home Use [0% – 100%]: this is the percentage above the target Amplitude (intensity) that the Patient is allowed to increase during use at home. For example, if you set the Amplitude at 20mA on the "Stimulation" screen and the "Maximum Amplitude Increase in Home Use" at 10%, then they will only be allowed to increase Amplitude to a maximum of 22mA at home.

iii. You can always cancel program creation by tapping on "Cancel" on the left of the bottom bar:

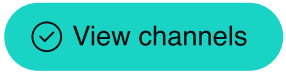


iv. Save the stimulation program general details by tapping on "Save this program" on the right of the bottom bar. You need to fill in all the required information within the range limits to be able to save the program:



Note	As soon as the program general details are saved, the program will be visible in the "Program List".

3. **Tap on the "View channels" button** to define or visualize Electrode placement and channel configuration:



The selected stimulation program can be exported for home use. For more details, refer to section 7.

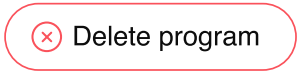
6.3.6.2 Edit or delete a stimulation program

All Programs can be:

- Edited, by tapping on the edit icon in the "Program List" screen or by tapping on "Edit program" in the "Program Details" Screen:

Save or cancel your changes by tapping on the corresponding button on the bottom bar.

- Deleted, by tapping on the delete icon in the "Program List" screen or by tapping on "Delete program" in the "Program Details" Screen:



A pop-up message will ask you to confirm the deletion action. If you confirm the action the stimulation program data will not be accessible from the app, if you cancel there will be no change to the "Program List".

Note	A program cannot be deleted once it has been used in a session. It can, however, be updated with new stimulation parameters as needed.

You can choose to sort programs either alphabetically or chronologically (the last used program will appear at the top of the list). Select the desired option in the drop-down menu.

6.4 Set up

6.4.1 Channel configuration, skin preparation and Electrode placement

ARC^{EX} Therapy is electrical spinal cord stimulation (SCS). Electrode placement may differ from other stimulation devices, such as Functional Electrical Stimulation (FES) and Neuromuscular Electrical Stimulation (NMES). The recommended starting setup will allow you to stimulate the spinal cord to support upper limb activities (e.g. grasping a ball, pinching, fine finger movement).

The ARC^{EX} System uses Active Electrodes and Return Electrodes. Active Electrodes are positioned along the spine, while Return Electrodes are positioned over bony landmarks such as the iliac crests or the clavicles.

Note	Refer to the Electrode manufacturer's IFU for further details on handling and care instructions.

6.4.1.1 Channel configuration

Once you have selected a stimulation program (as described in section 6.3.6, the "Channels" screen is displayed (Figure 14). In this screen you need to define the Channels and Electrode configuration.

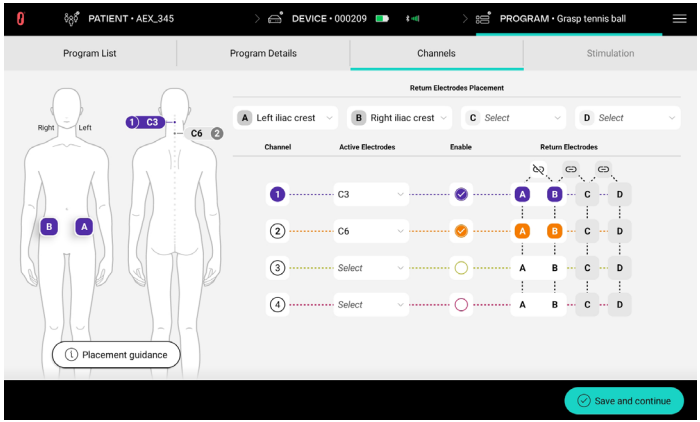
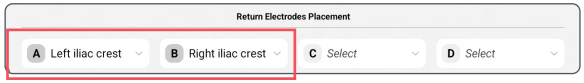


Figure 14. Example of "Channels" Screen with recommended initial Configuration.

Recommended starting setup

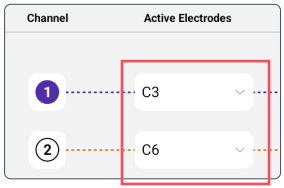
- **Return Electrodes:**

A: Left iliac crest
B: Right iliac crest

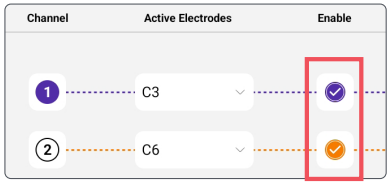


- **Active Electrodes:**

1: C3
2:C6

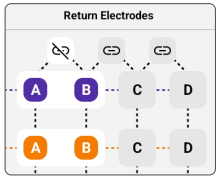


- **Enable Channels 1 and 2**



- Select Return Electrode A for Channels 1 and 2.
- Click the icon between Return Electrodes A and B

When Return Electrodes A and B are linked, they should look like the screenshot below:



Refer to Figure 14 for the recommended initial configuration.

Determine and set Electrode placement:

1. **Set "Return Electrodes" placement:** in the designated fields labeled A,B,C,D, choose over which bony structures you will place the Return Electrodes (maximum 4). Choose either iliac crests or clavicle.

   At least 1 Return Electrode must be set.

2. **Set "Active Electrode" placement:** in the designated fields labeled 1,2,3,4, choose where on the back of the neck you will place the Active Electrodes (maximum 4).

   At least 1 Active Electrode must be set.

3. **Enable the desired number of channels** (maximum 4). A channel configuration consists of 1 Active Electrode associated with 1 to 4 Return Electrode(s).

   Check the circle  corresponding to the channels you want to use. Once enabled, a checkmark will appear  .

   At least 1 Channel must be enabled.

4. **Select and link the desired Return Electrodes** for each enabled channel:

- Select the field corresponding to the Return Electrode you want to use for a specific channel.
- Link the Return Electrode by clinking the  icon This option connects multiple Return Electrodes so that the current flows from the Active Electrode to all the linked Return Electrodes.
- Return Electrodes can be unlinked by clicking the  icon.

Once Electrode placement is defined, it will appear on the digital representation of a mannequin at the left of the screen for visualization. When tapping on a specific channel, the corresponding Electrode is highlighted on the digital representation of the mannequin.

6.4.1.2 Skin preparation and Electrode Placement

⚠	Refer to sections 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS** related to the Electrode placement.

1. **On the Patient's body, locate areas of Electrode placement** for both Active and Return Electrodes that you previously inputted in the "Channels" screen.
   - Active Electrodes (round) shall be placed over designated cervical spinous processes.
   - Return Electrodes (rectangular) shall be placed over designated bony landmarks, namely over the iliac crests and/or clavicles.

You can tap on the "Placement guidance" button for more instructions on how to identify anatomical landmarks.

Note	Please note that the frontal view of the digital representation of a mannequin shows Return Electrodes, while the back view shows the Active Electrodes.

2. **Prepare target areas of skin** for Electrode placement for both Active and Return Electrodes:

i. Check skin for irritation and integrity before placing the Electrodes. Wait until skin is healed before using the ARC^{EX} System. Refer to sections 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS** related to the Electrode placement.

ii. Shave or trim excess hair if needed. Avoid using lotions or oils where the Electrodes will be placed.

iii. Thoroughly clean the skin with water or alcohol. Make sure skin is dry before applying Electrodes.

For further guidance on skin preparation, you can refer to the manufacturer instructions.

3. **Place Electrodes** on prepared skin, ensuring they are securely attached to the skin.

	Recommended starting setup ◦ Return Electrodes (rectangle) on left and right iliac crests. ◦ Active Electrodes (round) on C3 and C6.

i. Remove the Electrode from the protective liner by lifting the edge. Save the liner for potential reuse.

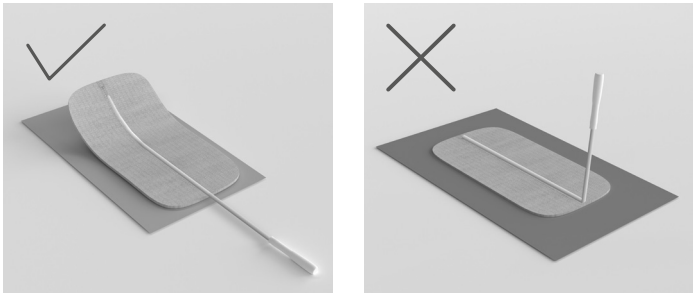


Figure 15: Removing the Electrode from the Liner

Note	Do not remove the Electrode pad from the protective liner by pulling the lead wire.

ii. Apply Electrode pad center to skin first, then smooth down Electrode pad edges.

iii. Ensure Electrodes are securely attached to skin.

6.4.2 Setting up the Splitter Box and Stimulator

⚠	Refer to sections 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS** related to to the interaction with the ARC^{EX} System during a therapy session.
💡	**Recommended starting setup** ◦ Connect Return Electrode on **left iliac crest** to Return Electrode **Socket A** of Splitter Box. ◦ Connect Return Electrode on **right iliac crest** to Return Electrode **Socket B** of Splitter Box. ◦ Connect Active Electrode on **C3** to Active Electrode **Socket 1** of Splitter Box. ◦ Connect Active Electrode on **C6** to Active Electrode **Socket 2** of Splitter Box. .

1. Connect Extension Cables

i. End of Extension Cable(s) with the black ring to the Electrodes (Figure 16).

ii. End of Extension Cable(s) without the black ring to the Splitter Box.

- Round Electrodes are Active Electrodes and should be connected to the Active Electrodes Sockets of the Splitter Box (red 1, 2, 3, 4).
- Rectangular Electrodes are Return Electrodes and should be connected to the Return Electrodes Sockets of the Splitter Box (grey A, B, C, D).

Replicate configuration in "Channels" screen precisely (e.g. Return Electrode A ⟶ left iliac crest, Return Electrode B ⟶ right iliac crest).

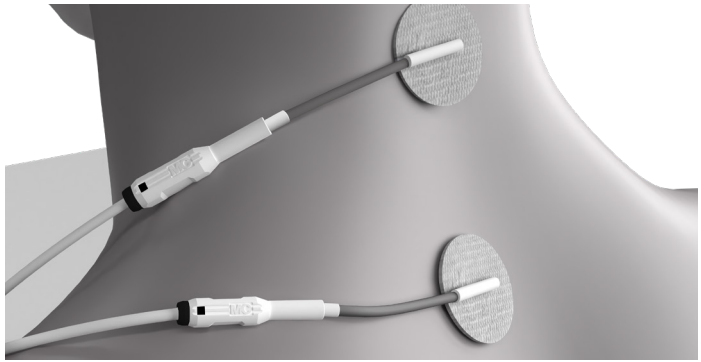


Figure 16. Extension Cables plugged into Electrodes

2. **Clip the Splitter Box** (using the built-in clip) to a place, such as on the neck of the Patient's shirt, where the Extension Cables can reach the Electrodes without restricting arm movement (Figure 17).

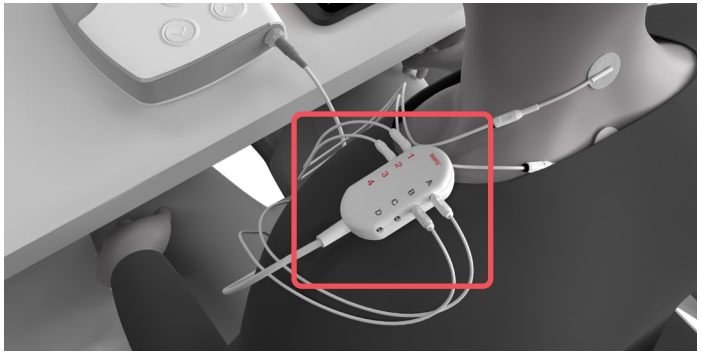


Figure 17. Example of Splitter Box Placement

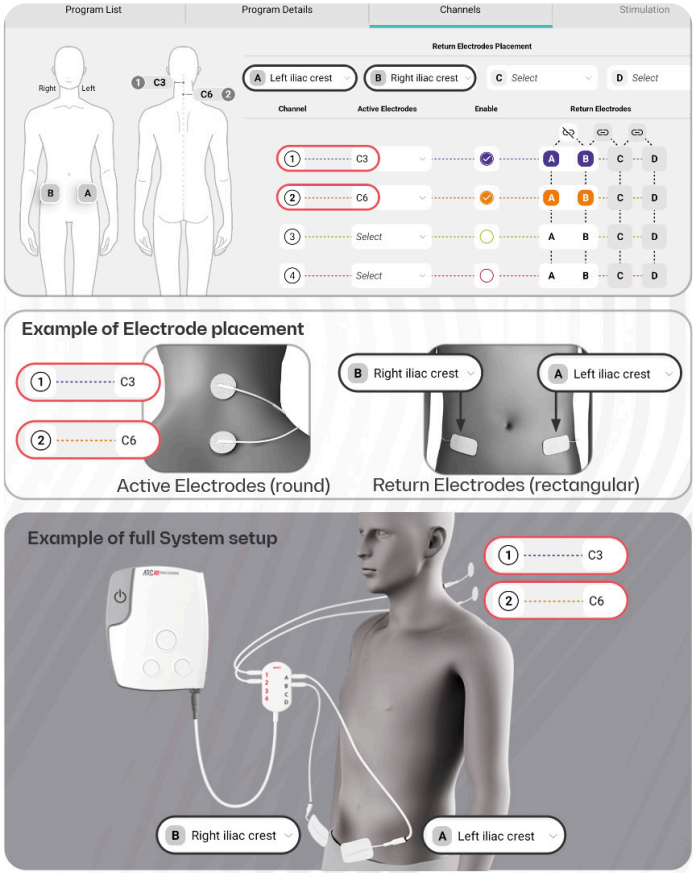


Figure 18: Example of Splitter Box and Electrode Setup

Note	Two different Extension Cable lengths are available (1m and 0.5 m/39.4 inches and 19.7 inches). Choose the most convenient length to reach each Electrode's placement without restricting the Patient's arm movement.
Note	Ensure secure connection of: ◦ The Active Electrodes placed over the spine to the correct socket on the Splitter Box (marked with 1, 2, 3, 4). ◦ The Return Electrodes placed on bony landmarks to the correct socket on the Splitter Box (marked with A, B, C, D).

3. **Connect the Splitter Box to the Stimulator** by inserting the grey plug of the Splitter Box into the grey socket on the Stimulator. Use the arrows on the connectors for correct alignment (Figure 19).

   Ensure Stimulator is placed on a flat surface. Do not hold the Stimulator or place it on your lap during the therapy duration.

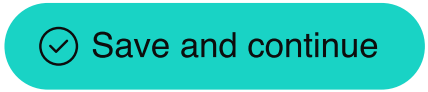
Figure 19: Connecting the Splitter Box to the Stimulator

An example of the final set-up is shown in the picture below (Figure 20):

Figure 20: Example of ARC^{EX} Setup

4. **Navigate to "Stimulation" screen** by:

i. Selecting "Save and continue" in the "Channels" screen



ii. Selecting "Confirm" after confirming Electrode placement

Note	You need to have at least one enabled channel to be able to continue.

6.5 Train

⚠	Refer to sections 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS** related to to the interaction with the ARC^{EX} System during a therapy session.

6.5.1 Stimulation Waveform configuration

1. **Adjust the stimulation parameters** in the "Stimulation" screen (Figure 21).

💡	**Recommended starting setup** Waveform: Biphasic Pulse Width: 1.0 ms Frequency: 30 Hz Amplitude: start at 0 mA Carrier Frequency: 10kHz

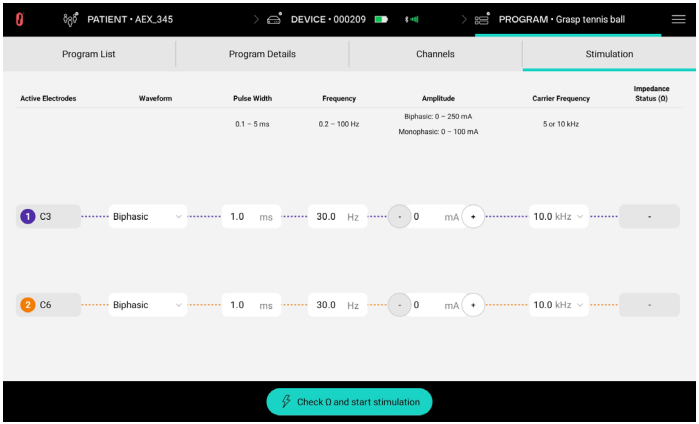


Figure 21. Example of "Stimulation" screen with standard configuration.

Each previously defined channel (as defined in section 6.4.1.1) will deliver electrical current with the features described in Figure 22 (note: the figure is only for conceptual understanding, not to scale).

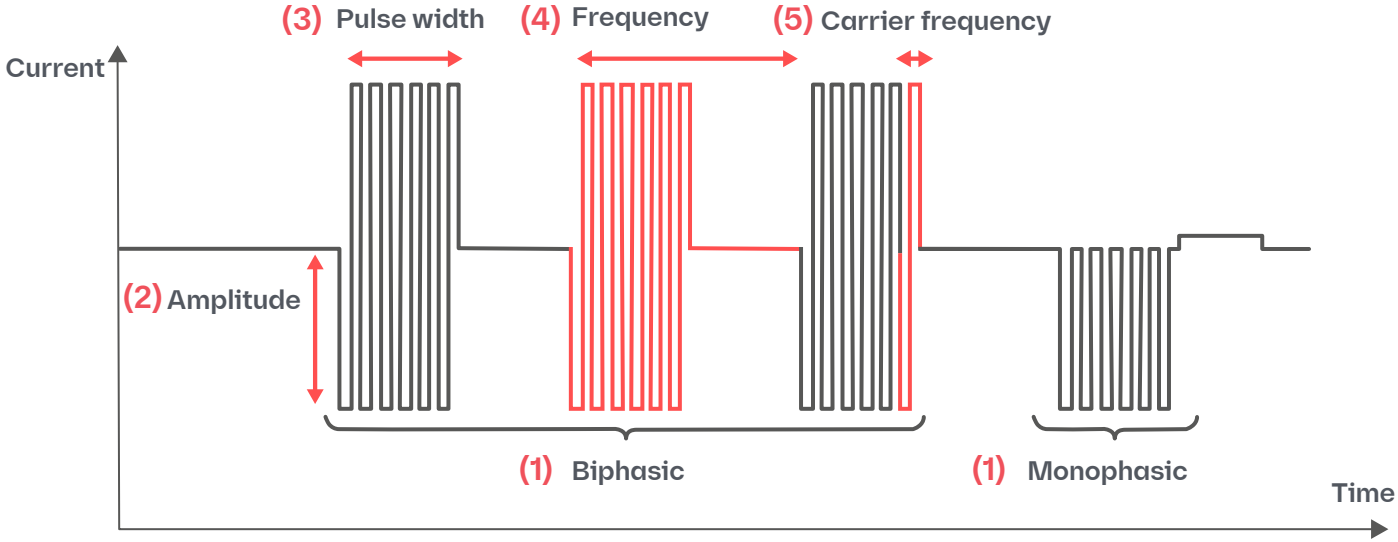


Figure 22. Definition of Stimulation Parameters

For each channel, you can program the following stimulation parameters (Figure 22):

(1) **Waveform** (*Biphasic/Monophasic*):

In Biphasic Waveform, alternating positive and negative currents occur within the pulse. The charge is balanced with constant alternation of polarity.
In Monophasic Waveform, only negative current is delivered within the pulse. The charge is balanced with a subsequent "charge-balance pulse" of current of the opposite polarity, to avoid buildup of charge.

Changing the Waveform may impact the perception of stimulation intensity.

(2) **Amplitude** (mA):

[*Biphasic 0 mA – 250 mA; Monophasic 0 mA – 100 mA*]

Amplitude refers to the greatest absolute value of the negative phase of the pulse, also known as the intensity. Typical effective Amplitude range for the Biphasic Waveform is 30 to 65 mA. Typical effective Amplitude range for the Monophasic Waveform is 20 to 55 mA.

Increasing Amplitude will increase stimulation intensity.

(3) **Pulse Width** (ms): [*0.1 ms – 5 ms*]

Pulse Width refers to the duration of time of a pulse. How long the pulse lasts or the width of the pulse.

Increasing Pulse Width will increase stimulation intensity.

(4) **Frequency** (Hz): [*0.2 Hz – 100 Hz*]

Frequency refers to how many times the pulse repeats itself per second.

Increasing Frequency will increase stimulation intensity.

(5) **Carrier Frequency** (kHz):

[*5 kHz or 10 kHz*]

Carrier Frequency refers to the frequency of oscillation within a pulse. In case of a Monophasic waveform, the Carrier Frequency does not apply to the charge balance pulse.

Increasing the Carrier Frequency is expected to improve Impedance Status. Refer to section 6.5.3.

Once the stimulation parameters have been set, the ARC^{EX} PRO app provides the following feedback in case the stimulation cannot be started due to simultaneous pulses across channels or safety limits:

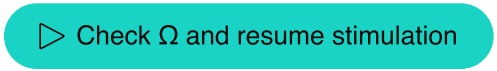
- When ARC^{EX} PRO app detects a Waveform with simultaneous pulses across multiple enabled channels:
  - The ARC^{EX} PRO app automatically adjusts the parameters to avoid simultaneous pulses and highlights the parameters that were changed.
  - If the ARC^{EX} PRO app is unable to automatically adjust, the app indicates which set of parameters can be changed to achieve a Waveform without simultaneous pulses. You can tap on the ⓘ button to gather more information.
- When the ARC^{EX} PRO app detects a Waveform that exceeds the safety limits, the app indicates which set of parameters can be changed to achieve a Waveform within the limit. You can tap on the ⓘ button to gather more information.

Stimulation start will not be available until the parameters are adapted to resolve the above feedback (simultaneous pulses across channels and safe stimulation limits).

6.5.2 Stimulation control

6.5.2.1 From the ARC^{EX} PRO app

1. **Check Impedance Status** by selecting "Check Ω and start stimulation" (more information on Impedance Status in section 6.5.3). Please note that this step may take a few seconds.

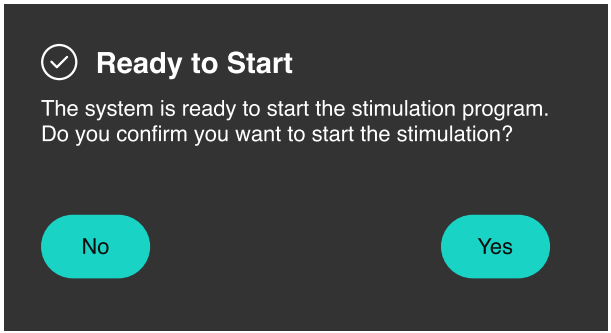


If you encounter a Poor Impedance Status error, improve the Impedance Status by:

- Ensuring cables are properly connected.
- Ensuring Electrodes adhere securely to the skin. Use medical tape to secure them or replace with new Electrodes if needed.

Refer to section 6.5.3 for more details.

2. **Confirm you are ready to start stimulation** by pressing "Yes" in the pop-up window.



3. **Begin task practice.**

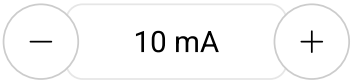
Once the stimulation begins the stimulation starts ramping the current up from 0 mA to the set Amplitude for each channel. The stimulation status bar will appear on the bottom of the screen.

Once the stimulation program is started, the program is sent by Bluetooth to the Stimulator which starts delivery of the therapy. Control ongoing stimulation through the app (i.e., start, stop, pause, resume, adjust stimulation Amplitude).

- Adjust the stimulation Amplitude from the Programmer by pressing the "+" and "-" buttons for each channel to change the stimulation intensity.

Tips

- During stimulation, start at 0mA and gradually increase Amplitude until task performance is improved by clicking on the "+" button. If stimulation creates discomfort, consider reducing Amplitude by clicking on the "-" button.



- Allow the Patient to train at a comfortable Amplitude with the other default recommended parameters over several therapy sessions. Note that higher Amplitudes may be tolerated as the user becomes familiar with the therapy.
- If simple Amplitude adjustments do not result in improved performance

after several therapy sessions, consider making the following parameter adjustments, in order as needed until effective parameters are identified:

i. Change Waveform to Monophasic

ii. Shift Active Electrode locations within the cervical area

iii. Move Return Electrodes to the clavicles

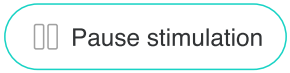
iv. Increase Frequency

v. Increase Pulse Width

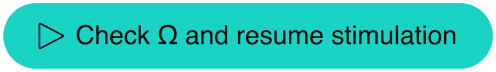
Each new program configuration should be assessed over several therapy sessions before moving to the next parameter adjustment.

- Each time another parameter is adjusted, ensure to restart Amplitude at 0 mA and gradually increase until a comfortable and effective value is found.

- **You may pause the stimulation** from the Programmer by pressing "Pause stimulation" or by pressing the "Select" button on the Stimulator.



- **To resume the stimulation** tap on "Check Ω and resume stimulation" on the bottom bar when stimulation is paused. When resuming stimulation after pausing, the stimulation will restart where it stopped, and the stimulation current will ramp up again from 0 mA to the set Amplitude for each channel.



4. **Stop the stimulation** by:

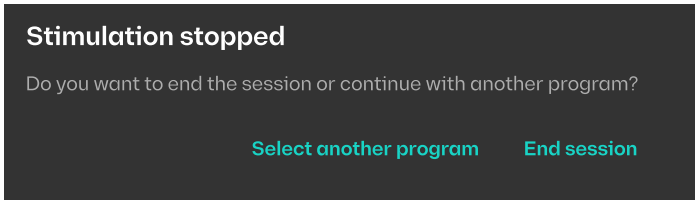
i. Pressing "Stop stimulation" on the Programmer, or

ii. Waiting for the program to end based on the set "Duration", or

iii. Pressing the "Select" button on the Stimulator once and then pressing it again and holding it for 3 seconds. If stimulation is already paused, press and hold the "Select" button for 3 seconds.

Then, press "End session".

- If you want to end the session with the current Patient, then press "End session" and the System will redirect you to the "Patient List" where you will be able to select the next Patient. Ensure you have finished the session with the current Patient before choosing this option.
- If you want to stop the current ongoing program and choose a different program for the Patient, press "Select another program" and the System will redirect you to the "Program List" for the current Patient to select the next program.



Stopping the stimulation will stop it entirely and you will have to restart a stimulation program from the beginning.

Note	If connected to the ARC^{EX} PRO app, stimulation parameters cannot be adjusted via the "Increase"/"Decrease" buttons on the Stimulator.
Note	Stimulation parameters, except for the Amplitude, cannot be changed while the stimulation is running. Pause the stimulation to change them.

6.5.2.2 Controlling ARC^{EX} Therapy from the ARC^{EX} Stimulator

When the Stimulator is connected with the ARC^{EX} PRO app (on the Programmer), you can only pause or stop the stimulation from the Stimulator (by pressing the "Select" button).

However, if the stimulation is ongoing and the ARC^{EX} PRO app disconnects from the Stimulator, the current program will continue and it will be possible to control it with the three Stimulator buttons, until the end of the stimulation program. In this case, the functions below are possible from the Stimulator buttons (see Figure 23):

- **Pause** stimulation by pressing the "Select" button once while the stimulation is ongoing.
- **Resume** stimulation by pressing the "Select" button once while the stimulation is in pause.
- **Stop** stimulation by pressing the "Select" button once and then pressing it again and holding it for 3 seconds. If stimulation is already paused, press and hold the "Select" button for 3 seconds.
- **Increase / Decrease** the Amplitude using the two-buttons with arrows signifying "Increase" and "Decrease".
  - Each press changes the stimulation Amplitude by 1 mA across all the enabled channels of the stimulation program. Stimulation Amplitudes can only be adjusted while stimulation is ongoing.
  - With each button press, the Stimulator will briefly display how far the Amplitudes have deviated from the Amplitude set before the Stimulator was disconnected from the ARC^{EX} PRO app. For example, if the Increase buttton was pressed 5 times in a row, then "Amplitude: +5" would briefly appear on the display.
  - If a channel reaches its maximum (or minimum) Amplitude limit, it is not possible to further increase (or decrease) the Amplitude for the enabled channels and the message "Amplitude: Max" (or "Amplitude: Min") would briefly appear on the display.

Figure 23. Controlling Stimulation from the ARC^{EX} Stimulator

Note	To start a new stimulation program you need to reconnect to the ARC^{EX} PRO app.

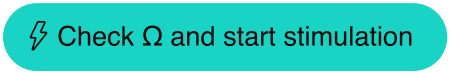
6.5.3 Impedance Status

Impedance Status refers to the resistance of the skin and other body tissues to the flow of current produced by the Stimulator. The Impedance Status shown on the ARC^{EX} PRO app indicates the following:

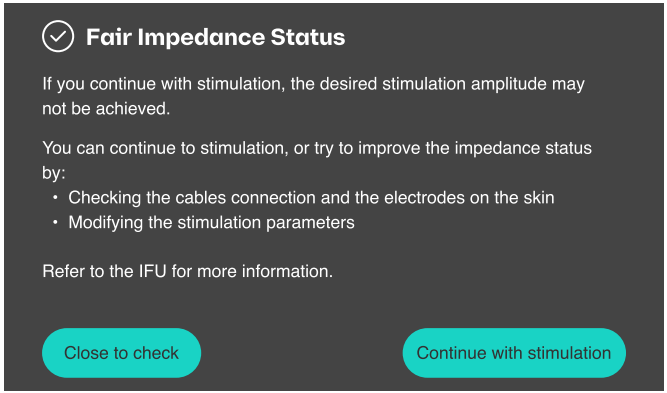
- **"Good"**: the System is well set up and the stimulation can start.
- **"Fair"**: the stimulation can start but the level of impedance of the System may limit the stimulation output. If the desired Amplitude cannot be reached, it is recommended that the user check the attachment of the Electrodes to the skin and/or the connections of the cables to improve the System Impedance Status.
- **"Poor"**: the Impedance Status of the System is inefficient and stimulation cannot start. Check that Electrodes are securely attached to the skin and that all cable connections are properly set up to the System before starting the stimulation (see "Factors that could improve Impedance Status" below).

- **“-”**: the Impedance Status of the System is not measurable as the stimulation Amplitude is set to 0 mA. This means the channel is currently not delivering any current and the Impedance Status is not relevant.

After defining the desired stimulation parameters and tapping the “Check Ω and start stimulation” button, an impedance check is performed. Please note that this step may take a few seconds.



The stimulation can only start if this check of Impedance Status detects impedance values that would allow the target Amplitude (i.e., “Good” and “Fair” impedance check results) to be reached. If the detected Impedance Status is “Fair,” you can either continue with stimulation (by tapping “Continue with stimulation” button) or try to improve Impedance and repeat the impedance check by tapping the “Close to check” button.



Once the stimulation session has started, if a channel is set to an Amplitude of 0 mA, the Impedance Status cannot be measured and will be displayed as “-”. This does not affect the ongoing stimulation.

Whenever the Impedance Status changes during the session, the ARC^{EX} System will compensate to maintain the desired current Amplitude output; if impedance is too high ("Poor" status), then the Stimulator will automatically stop stimulation.

Impedance Status variations may be observed during a stimulation session and are prevalent between individuals based on various factors, including external humidity, use of lotion or oil, temperature, sweat, and skin integrity.

Suggestions to improve Impedance Status:

- Ensure cables are properly connected.
- Ensure Electrodes adhere securely to the skin. Use medical tape to secure them and replace with new Electrodes if needed.
- Ensure skin is prepared as indicated in section 6.4.1.2:
  - Check skin for irritation and integrity before placing the Electrodes
  - Thoroughly clean the skin with water or alcohol. Make sure skin is dry before applying Electrodes.

If Impedance Status still does not improve:

- Add drops of water to the gel surface of the Electrodes.
- Avoid using lotions or oils where the Electrodes will be placed.
- Higher Carrier Frequencies generally reduce skin impedance.
- Advise Patients to avoid rapid head movements.

6.5.4 Prompt interruption of stimulation

If you need to promptly interrupt the stimulation, press "Pause stimulation" or "Stop stimulation" on the ARC^{EX} PRO app:

If the device does not respond accordingly, press the "Power" or the "Select" button on the Stimulator:

Figure 24. Prompt interruption of Stimulation with Power or Select Buttons.

If the device does not respond to these attempts, unplug the Splitter Box from the Stimulator. This can be achieved by quickly pulling on the connector:

Figure 25. Prompt interruption of Stimulation by Unplugging Splitter Box,

Issues with pausing or stopping stimulation should be reported to ONWARD.

6.6 End session

6.6.1 Turning off the System

1. **Turn off the Stimulator** by pressing the "Power" button (Figure 2).
2. **Unplug the Splitter Box** from the Stimulator.
3. **Remove the Electrodes** from the skin and **disconnect all cables**.
   i. Place the Electrodes back on the protective liner. Be sure to place the Electrode gel surface against the "ON" side of the liner.
   ii. Reseal the Electrodes in their original packaging (refer to the Electrode manufacturer's IFU for additional details and instructions).

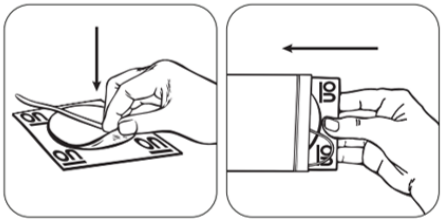


Figure 26. Placing Electrodes on Liner

4. **Check skin** for integrity and irritation. Should a skin rash or skin burn occur, immediately discontinue use and wait until skin is healed before using of ARC^{EX} System.

6.6.2 Cleaning

	Refer to section 3.2 for **WARNINGS** related to the ARC^{EX} System cleaning

All components of the ARC^{EX} System can be cleaned by carefully wiping them with a damp cloth. The Stimulator, the Splitter Box and the Extension Cables may also be cleaned using wipes or cloths saturated (but not dripping) with 70% isopropyl alcohol per the instructions below. The electrical components are not waterproof. Do not immerse any component in water and follow the instructions below.

1. Ensure the ARC^{EX} Stimulator is off.
2. Disconnect the Splitter Box and the Extension Cables.
3. Gently wipe all the surfaces with the damp cloth or cleaning product containing 70% isopropyl alcohol.
4. Wait until all surfaces are dry.

Using cleaning techniques and agents other than as described above can affect safety and performance of the System.

6.6.3 Charging and battery levels

Regularly charge the Stimulator and the Programmer to ensure sufficient battery capacity for the next session.

To preserve the battery when not in use, it is recommended to turn off the Programmer.

6.6.3.1 ARC^{EX} Programmer

Charging the Programmer: Charge the Programmer according to the tablet manufacturer's user manual.

Battery level of the Programmer: To check the battery level of the Programmer, look at the notification bar at the top of the screen. A battery icon will be displayed, and a percentage may be shown.

Refer to the tablet manufacturer's user manual for the details.

6.6.3.2 ARC^{EX} Stimulator

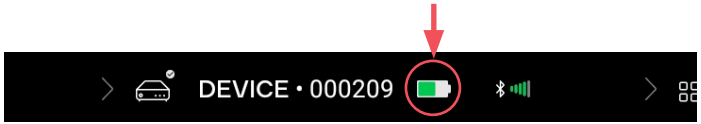
Charging:

1. Plug the Stimulator Charger into a MAINS power outlet.
2. Connect the charging cable to the ARC^{EX} Stimulator. Recharging will start automatically: The Stimulator's battery icon will light up and the charging level will be displayed on the Stimulator's screen.
3. Charging can take up to 8 hours depending on the initial charge level of the battery. When charging session is complete, the Stimulator's sceen will display "Charging: 100%".
4. Unplug the Charger from the power outlet (MAINS).
5. Disconnect the charging cable from the Stimulator.

Note	Charge the Stimulator at least once every 6 months to preserve its battery

Battery level

This can be checked on the top bar of the Programmer screen, in the ARC^{EX} PRO app or every time the Stimulator is turned on.



When the Stimulator battery level is low, the Stimulator will emit a warning sound and the battery LED status icon will start blinking.

Charging is recommended at this time.

Note, however, that the Stimulator will continue to run until the battery is too low to prevent further use, which will be signaled on the Stimulator by an error sound, the dashed orange lightbar, and the blinking battery icon.

6.6.4 Storing the ARC^{EX} System

⚠	Refer to sections 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS** related to the ARC^{EX} System use and storage environment.

Return components to the provided Case and store it in a safe location.

7 Preparation for home use

During rehabilitation sessions in the medical center, you will personalize ARC^{EX} stimulation settings to your Patient's goals. Once tailored, your Patient will have the option to continue use at home with their own personal ARC^{EX} System.

At the back of this IFU, you also find an "Essentials Guide" for the Preparation of Home Use.

To prepare the Patient's Personal ARC^{EX} System for home use:

- Ensure that the Patient brings their complete Personal ARC^{EX} System to their appointment.
- A program must be created on the Professional ARC^{EX} System and used with the Patient at least once before you can export it to the Patient's Personal ARC^{EX} System for home use.
- The Patient must be adequately instructed on the use of the ARC^{EX} System, see section 7.2.
  - Instruct the Patient by demonstrating use with the Patient's ARC^{EX} System they will use at home (there are differences between the Professional and Personal Systems and IFUs).

Refer to the sections below to:

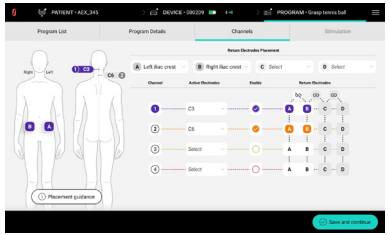
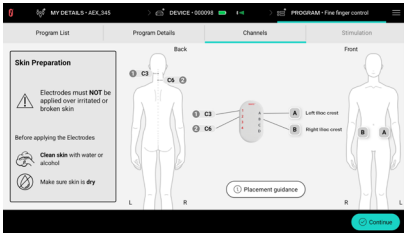
- Export a program for home use.
- Adequately instruct Patients on the use of the ARC^{EX} System (section 7.2).

The ARC^{EX} System Personal differs from the ARC^{EX} System Professional as summarized in Table 4. Please note that:

- The Stimulators and Programmers are specific for each System.
- The Personal Stimulator shall only be used with the Personal Programmer.
- The Professional Stimulator shall only be used with the Professional Programmer.
- Each System has its own IFU.
- The Personal System includes a Quick Reference Guide.

Table 4. Difference Between ARC^{EX} Professional and ARC^{EX} Personal Systems

	ARC^{EX} System - Professional	ARC^{EX} System - Personal
Logo on Stimulator	ARC^{EX} Professional logo	ARC^{EX} logo
Stimulator power button and side color	Light grey 	Dark grey 
App on Programmer	ARC^{EX} PRO app (red screensaver) 	myARC^{EX} app (white screensaver) 
Features	◦ Multiple Patient profiles ◦ Each Patient profile, up to 10 stimulation programs ◦ Full freedom in tailoring therapy programs (Amplitude, Pulse Width, Frequency, Waveform, Carrier Frequency) ◦ Controlling stimulation from the Stimulator: pause and stop always possible. Resume and adjust Amplitude only if connection to Programmer is lost during a stimulation program	◦ 1 Patient profile ◦ 1 stimulation program, pre-defined by the Rehabilitation Professional ◦ Possibility to adjust only Amplitude, within set-range by clinician ◦ Controlling stimulation from Stimulator: start/pause/stop/ change of Amplitude always possible

	ARC^{EX} System - Professional	ARC^{EX} System - Personal
"Channels" screen	Fully customizable "Channels" screen to tailor therapy to each patient. 	"Channels" screen represents the patient-specific setup as defined by the Rehabilitation Professional. 
Documentation	IFU Professional (red background) 	IFU Personal (white background) Quick Reference Guide  

7.1 Exporting a program for home use

To set up a Patient for home use, gather both the Professional and Personal ARC^{EX} Systems and follow the steps below.

In the ARC^{EX} Professional System (ARC^{EX} PRO app)

1. Turn on the Professional Stimulator and Programmer
2. Select Patient and connect the Stimulator in the ARC^{EX} PRO app. Refer to section 6.3.5).

Note	To export a program, the program must be fully created (general details, stimulation channels configuration, stimulation parameters) and must have been used with the Patient at least once.

3. Select the program to export from the "Program List" (if the program is not in the list, refer to section 6.3.6.1 for following the program creating process). Select "Export to Personal ARC-EX" button (Figure 27) to generate a QR code, which will be scanned by the Patient's Personal Programmer (in the myARC^{EX} app). Refer to Figure 28.
   - Verify stimulation settings that appear next to the QR code.
   - If you make any modifications to the program, you must use the program with the Patient at least once before exporting it.

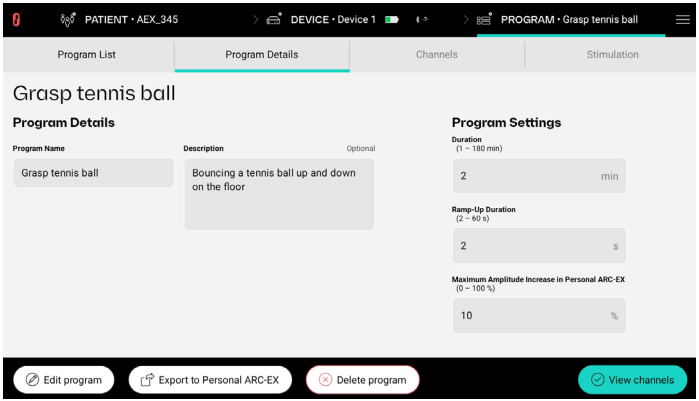


Figure 27. Example of Preparation of Program for Home Use

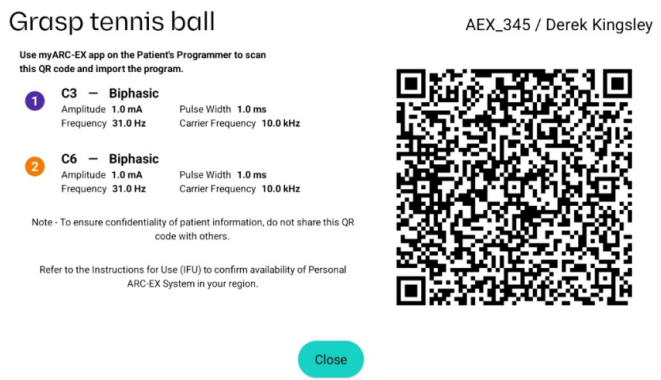


Figure 28. Example of Pop-Up Window Generated for Exporting a Program for Home Use.

Note	The pop-up contains all the information to ensure the correct program is being transferred to the Patient's myARC^{EX} app (i.e., Patient ID and complete name, program name, enabled channels with Active Electrode position, Waveform type and stimulation program parameters).
Note	Only one program can be imported onto the Patient's personal ARC^{EX} System (i.e., myARC^{EX} app and Stimulator).
Note	Any previous data in myARC^{EX} app will be overwritten when importing a new program.

In the Patient's Personal ARC^{EX} System (myARC^{EX} app)

1. Turn on the Patient's Personal Stimulator and Patient's Personal Programmer
2. Connect the Patient's Personal Programmer to the Patient's Personal Stimulator by selecting "Connect device and start session". Refer to section 6.3.5 for additional details.
   i. Select the "Device ID" that matches the Serial Number on the back of the Patient's Personal Stimulator.
   ii. If the correct Stimulator Serial Number is not listed, select "Search devices".
3. If this is the first time you are connecting this Stimulator with this Programmer, pair Patient's Personal Programmer with Patient's Personal Stimulator. Refer to section 6.3.5 for additional details.
   i. Visually confirm that the 6-digit passkey on the Patient's Personal Programmer screen matches the 6-digit number on the notification area of the Patient's Personal Stimulator screen.
   ii. If they match, press "Pair" in the Patient's Personal Programmer and press the "Select" button on the Patient's Personal Stimulator (in any order).

Note	If the myARC^{EX} app is not yet set up, permissions will be requested similarly to the ARC^{EX} PRO app, and you need to tap on "Set up device" before being able to connect to the desired Stimulator and import the program.

4. Select "Import a program" in the "Program List" screen, which will activate the camera of the Patient's Personal Programmer.

Note	The QR code also contains Patient data that will be imported in the app together with the stimulation program settings.

5. Scan the QR code displayed in the ARC^{EX} PRO app of the Professional Programmer with the Patient's Personal Programmer camera by pointing the Patient's Personal Programmer camera at the QR code on the Professional Programmer screen.
6. Verify the Patient and program details are correct and confirm the import by pressing "Yes" in the pop-up window.

7.2 Training Patients on home use

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.

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.	☐
2.	Check Programmer and Stimulator battery levels.	☐

	Task	
3.	Unlock Programmer by swiping on the screen and enter PIN.	☐
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)	☐
5.	Select the program from the "Program List" screen.	☐
6.	On your body, identify the areas on where the Active and Return Electrodes will go according to the "Channels" screen.	☐
7.	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.	☐
8.	Place Electrodes on the prepared skin over the indicated areas according to the "Channels" screen, ensuring they are securely attached to the skin.	☐
9.	Connect Extension Cables to Electrodes and Splitter Box according to the setup defined in the "Channels" screen.	☐
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.	☐
11.	Click "Continue" in the "Channels" screen and confirm the correct Electrode placement.	☐

Task		
12.	Start stimulation by clicking "Check Ω and start stimulation".	☐
13.	Confirm you are ready to start stimulation by pressing "Yes" in the pop-up window.	☐
14.	From the Programmer, increase and decrease Amplitude.	☐
15.	Pause stimulation from the Programmer by selecting "Pause Stimulation".	☐
16.	Resume stimulation from the Programmer by pressing "Check Ω and resume stimulation".	☐
17.	Stop stimulation by pressing "Stop stimulation" on the Programmer, then "End session" on the Programmer to complete the session.	☐
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.	☐

8 Cybersecurity

8.1 Protecting access to the Programmer

To prevent unauthorized access to your device, set up a PIN code.
To do this, when starting the app for the first time, a security message will appear if no lock type has been set up on the Programmer. You cannot continue to use the Programmer unless you set a PIN code. To do so, tap "Set a lock type" and you will be redirected to the Programmer Settings to set the PIN code. Note that the PIN needs to be considered strong enough – this means that repeating or consecutive digits are not allowed (E.g. 11111111 or 12345678). Ensure to remember the PIN and to store it in a safe location for retrieval by authorized personnel. Note that if the PIN code is lost, the Programmer will not be accessible anymore and you will need to contact an ONWARD representative for assistance.

8.2 Wireless security measures

Wireless signals are secured through ARC^{EX} System design that includes the following features:

- Encrypted wireless communication.
- Wireless network (Wi-Fi) is disabled.
- Only one Programmer may communicate with the Stimulator at the same time.
- A unique key for each unit is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth Smart wireless technology, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the Stimulator.

8.3 Guidelines for secure use

To ensure secure and effective use of the ARC^{EX} System, follow the guidelines below. Residual cybersecurity risks remain and are indicated where relevant.

8.3.1 Protection of paired devices

- Do not use the ARC^{EX} PRO app if the Programmer is displaying an operating system error (other than related to the Stimulator) .
- Do not share your Programmer password or PIN code.
- Do not allow unauthorized individuals to access or operate the Programmer.
- Ensure the Programmer is locked when not in active use.

Unauthorized access may result in manipulation of therapy parameters or exposure of personal data.

8.3.2 Management of Bluetooth connections

- Disconnect the Programmer from the Stimulator when not in active use.
- Do not pair or connect the Programmer with unknown or untrusted Bluetooth Low Energy (BLE) devices.

Unauthorized or unintended connections may lead to data interception, therapy disruption, or alteration of device functionality.

8.3.3 Compliance with security controls

- Do not attempt to disable or bypass the ProKiosk mode on the Programmer.
- Do not try to install any applications on the Programmer.

Unauthorized modification of the device's security settings may compromise system integrity, reduce cybersecurity protections, and void the device warranty.

8.3.4 Use of USB ports

- Do not connect the Programmer to any third-party devices via USB ports.

USB connections to unknown devices may introduce security risks such as malware, allow

unauthorized data access, or corrupt system software.

8.3.5 Software and security updates

- Do not attempt to manually install or alter system updates or security patches.
- All updates are managed exclusively by authorized ONWARD representatives during scheduled visits.

Regular updates are essential to maintain device security and ensure compliance with applicable cybersecurity standards.

8.3.6 Reporting security concerns

- If you suspect any security-related issue or abnormal system behavior, please immediately contact an ONWARD representative.

Prompt reporting helps mitigate cybersecurity threats and ensures continued safe operation.

8.4 Log files

The ARC^{EX} System generates protected logs. Only ONWARD representatives have access to the log files. If access to the logs is required, please contact an ONWARD representative.

8.5 Cybersecurity End of Support

Notification of the discontinuation of support will be provided six months prior to the end-of-support date.

8.6 Software Bill of Materials

On request, a copy of a machine-readable Software Bill of Material can be obtained by contacting an ONWARD representative.

9 Maintenance and Service

The ARC^{EX} System does not require any maintenance or servicing during use. For device support or to request replacement parts, please contact an ONWARD representative.

Nonetheless, all components of the System must be visually inspected for damage before each use, as described in Section 6.3.1.

9.1 ARC^{EX} System updates

New versions of the software and firmware, including those to implement new features, may be released by ONWARD.
Only ONWARD representatives are allowed to perform ARC^{EX} System updates, over-the-air, requiring on-site presence.
Please contact an ONWARD representative for additional information.

9.2 Electrode purchase and replacement

To ensure correct delivery of stimulation, ensure that Electrodes:

- Have not passed their expiration date (please check the date on the package of the Electrodes).
- Have sufficient adhesion i.e., the entire surface must adhere to the skin. Per the manufacturer, gently rubbing one or two drops of water onto the gel surface may increase Electrode adhesion. In case of doubt, discard the Electrode and use a new one.

To purchase new Electrodes, contact ONWARD.

10 Technical Information

10.1 Specifications

Table 6. Specifications

Characteristic	Values
Expected service life	3 years
Mode of operation	Continuous operation mode
Wall adapter input voltage	100 - 240 V (AC)
Wall adapter input frequency	50/60 Hz
Wall adapter output voltage	15 V (DC)
Wall adapter input current	1.5 - 0.8 A
Wall adapter output current	4A
Wall adapter output power	60 W
Wall adapter classification	Class II
Available socket type	A (US), C (Europe), G (UK)
Electromagnetic Compatibility Classification	Class B
Battery capacity	3.2 Ah / 37 Wh

Characteristic	Values
Dimensions	235 x 190 x 55 mm
Memory Flash	32 MB
Wireless cpability and performances	Technology: BLE (adaptive frequency hopping) Transmit Power: +8.7 dBm (max) Operating Frequencies: 2.40 - 2.48 GHz Receiver Sensitivity: -95 dBm Recommended maximum operational distance: 3 m Latency/throughput: 100 bytes of data within 0.5 s
Effective Radiofrequency Radiated Power Output	+8dBm to -20dBm
Channel status	Enabled / Disabled
Waveform	Monophasic / Biphasic
Monopasic Stimulation Pulse Amplitude range	0 mA- 100 mA (1 mA steps) For load impedance range from 150 Ohms to 500 Ohms Note: At higher load condition the output capability may be reduced.

Characteristic	Values
Monopasic Balance Pulse Amplitude range	0 mA - 12.5 mA Note: the Amplitude is configured automatically for charge balancing.
Biphasic Stimulation Pusle Amplitude range	0 mA- 250 mA (1 mA steps) For load impedance range from 150 Ohms to 500 Ohms Note: At higher load condition the output capability may be reduced.
Intra-burst Pulse Repetition Frequency	10000 Hz or 20000 Hz
Intra-burst Pulse Width	100us for Intra-burst Pulse Repetition Frequency = 10000Hz 50us for Intra-burst Pulse Repetition Frequency = 20000Hz
Carrier Frequency	5 000 Hz or 10 000 Hz
Frequency	0.2 Hz - 100 Hz
Pulse Width	0.1 ms - 5 ms
Ramp-up Duration	2 s - 60s Note: For specific stimulation settings the Ramp-Up Duration can be automatically lenghtened up to 125s.
Applied parts	Splitter Box, Extension Cables and Electrodes Applied parts are type BF

Characteristic	Values
IP rating	Stimulator, Stimulator Charger and Splitter Box are IP22. Protected from access by fingers or objects >12.5mm. Protected from dripping water (15° tilted).
Length of Splitter Box cable	150 cm / 59.1 inches
Length of the Extension Cables	50 cm/19.7 inches and 100 cm/39.4 inches
Environmental ranges	**Temperature:** Usage: +5 to +40°C Storage (Within Case): -25 to +70°C Transport (Within Case): -25 to +70°C **Humidity**: Usage: 10 to 90% humidity (non-condensing) Transport & Storage: up to 90% humidity (non- condensing) **Pressure**: 700 to 1060 hPa
Parts suitable for use within patient environment	Stimulator, Splitter Box, Extension Cables, Programmer and Electrodes are suitable for use within 1.5m/5feet area of the Patient while stimulation is in progress.

10.2 Exposure

10.2.1 Electromagnetic interference

Take precautions against the risks of electromagnetic interference (EMI) between the ARC^{EX} System and other electronic devices that may be reasonably foreseen to be present during specific diagnostic investigations, evaluations, therapeutic treatments, and other procedures where EMI from the ARC^{EX} System could affect other equipment. Table 7 provides ARC^{EX} System electromagnetic emission test results.

Table 7. Electromagnetic Emissions

Type of Test	EMC Basic standard and Test Level(s)	Electromagnetic Environment - Guidance
Conducted	IEC 60601-1-2 (CISPR 11 Class B)	Professional healthcare facility Home healthcare
RF Radiated emissions	IEC 60601-1-2 (CISPR 11 Class B)	Professional healthcare facility Home healthcare
Harmonic emissions	IEC 60601-1-2 (IEC 61000-3-2)	Professional healthcare facility Home healthcare
Voltage fluctuations	IEC 60601-1-2 (IEC 61000-3-3)	Professional healthcare facility Home healthcare

The ARC^{EX} System was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2 standards. Table 8 describes the electromagnetic environment for which the device has been tested and is safe to use.

Table 8. Electromagnetic Immunity

Immunity Test	IEC 60601 Compliance Test Level (s)	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2 ± 8 kV (contact) ± 15 kV (air)	Professional healthcare Home healthcare
RF Radiated Field	IEC 61000-4-3 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Professional healthcare Home healthcare

Immunity Test	IEC 60601 Compliance Test Level (s)	Electromagnetic Environment – Guidance
Electrical fast transient/burst	IEC 61000-4-4 ± 2 kV (100kHz rep.)	Professional healthcare Home healthcare Applicable to charging mode only, while AC/DC adapter connected to the MAINS supply.
Surge (Line-Line)	IEC 61000-4-5 ± 0,5 kV, ± 1 kV	
RF Conducted disturbances	IEC 61000-4-6 3 Vrms 150kHz to 80 MHz 6 V 150 kHz to 80 MHz (in ISM bands)	
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11	
Power Frequency Magnetic Fields	IEC 61000-4-8 30 A/m 50Hz , 60 Hz	Professional healthcare Home healthcare
Proximity fields from RF wireless communications	IEC 61000-4-3, Table 9 IEC 60601-1-2	Professional healthcare Home healthcare
Proximity magnetic fields in range 9kHz to 13,56 MHz	IEC 61000-4-39, Table 11 IEC 60601-1-2	Professional healthcare Home healthcare

There are currently no known devices or other sources that can potentially cause interference problems.

Note	This ARC^{EX} System complies with part 15 of the FCC Rules. Operations is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

10.2.2 Radio frequency interference

The ARC^{EX} System is intended for use in an electromagnetic environment in which radiated radio frequency (RF) disturbances are controlled. Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARC^{EX} System as recommended below, according to the maximum output power of the communications equipment.

Table 9. Recommended Distances Between RF Communications Equipment and the ARC^{EX} System

	Separation Distance According to Frequency of Transmitter			
Rated Maximum Output Power of Transmitter (W)	150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.4\sqrt{P}$	800 MHz to 1000 MHz $d = 0.7\sqrt{P}$	1000 MHz to 2.5 GHz $d = 2.3\sqrt{P}$

11 Troubleshooting

11.1 ONWARD Support

For additional support, contact an ONWARD representative:

Phone	Europe: +31 40 288 2830
Email	support@onwd.com
Website	www.onwd.com

11.2 ARC^{EX} Stimulator troubleshooting

11.2.1 Stimulator does not turn on

The battery of the ARC^{EX} Stimulator may be empty. Please attempt to charge it using the charger (refer to section 6.6.3). If it still does not turn on after charging, please contact an ONWARD representative for assistance.

11.2.2 Stimulator shows an error code

If the Stimulator encounters an event that requests your attention, the lightbar will illuminate in dashed orange, an error tone will sound and the stimulation will be interrupted if in progress Check the Stimulator display and/or ARC^{EX} PRO app to confirm error details and follow suggested instructions. If the problem persists, contact an ONWARD representative for assistance.

If the Stimulator error contains an error code, please take note of the error code. If the error code is E004, ensure the Splitter Box is securely plugged into the Stimulator. For other error codes, try turning the Stimulator off and on again. If the problem and error code persist, contact an ONWARD representative with the error code at hand to resolve the issue. Refer to Table 10 for more details on the error codes.

Table 10. Stimulator Error Codes

Error code	Error Description
E001, E003	Error during check of supply voltage
E002	Error in charging
E004	Error in Splitter Box, Cable detection. Ensure the Splitter Box is securely plugged into the Stimulator
E005, E011, E012	Error in stimulation delivery
E006	Lightbar error
E007	Error in temperatur detection
E008	Audio file unretrievable
E009, E010	Versions compatibility error
E013	Error in monitoring circuit

11.2.3 Stimulator shows a "See cables" error

A "See cables" error on the Stimulator means that the Impedance Status is poor. To improve the Impedance Status:

i. Ensure cables are properly connected.
ii. Ensure Electrodes adhere securely to the skin. Use medical tape to secure them or replace with new Electrodes if needed.

Refer to section 6.5.3 for additional details.

11.2.4 Stimulator screen or buttons are unresponsive

If the Stimulator or the buttons become unresponsive, restart the Stimulator. If the Stimulator is unresponsive while stimulation is paused, press the Select button on the Stimulator for 3 seconds. If the issue persists, contact an ONWARD representative.

11.2.5 The Stimulator is either not responding or is delaying its response to the Programmer

If you experience frequent delays in the

response of the Stimulator, either when pairing with the Programmer or when controlling stimulation, make sure the Stimulator and Programmer are within 3 meters/10 feet of each other to improve connectivity. If the problem persists, turn off or remove Wi-Fi routers, cell phones, laptops and Bluetooth devices from the vicinity of the Stimulator and Programmer.

11.2.6 The Stimulator shuts down unexpectedly

This usually occurs when the battery of the Stimulator is too low.
Charge it using the Stimulator Charger (refer to section 6.6.3). If it still does not turn on after charging, contact an ONWARD representative.

11.2.7 Stimulation does not start

If connection between the Stimulator and the ARC^{EX} PRO app is lost and stimulation cannot be resumed from the Stimulator, reconnect to the ARC^{EX} PRO app to confirm if an error occurred. If so, take note of the error message displayed on the ARC^{EX} PRO app and try turning the Stimulator off and on again. If the problem and error message persist, contact an ONWARD representative with the error message at hand.

11.2.8 How do I factory reset a Stimulator?

Make sure the Stimulator is turned off. Press and hold the "Increase" and "Decrease" buttons at the same time for 1 second and then, without releasing the buttons, press the "Power" button in addition and hold the three buttons until the message "Factory Reset" is displayed on the Stimulator notification area.
All connection data, Patient data, and stimulation programs saved on the Stimulator will be erased.

11.2.9 How do I change the language of the Stimulator?

Turn off the Stimulator. Change the language in ARC^{EX} PRO app following the instructions in section 11.3.14. Turn on the Stimulator and connect it to ARC^{EX} PRO app via the app.

11.3 ARC^{EX} Programmer troubleshooting

11.3.1 Programmer becomes unresponsive to touch

Power down and restart the Programmer. Refer to the tablet manufacturer's user manual for further details.

11.3.2 Programmer loses connection with Stimulator

You will be notified of lost connection between the Stimulator and Programmer through feedback on the Stimulator and on the Programmer. If the connection is lost while stimulation is ongoing, the current program will continue to be delivered, but it can only be controlled using the three buttons on the face of the Stimulator. When the stimulation program ends or connection is lost while stimulation is not ongoing, the connection with the ARC^{EX} PRO app must be reestablished, as described in section 6.3.5.

11.3.3 I cannot see the Stimulator in the Device List

If you cannot see the Stimulator you wish to connect in the Device List, this means that the ARC^{EX} PRO app could not find it.

- Ensure that the Stimulator is turned on.
- Ensure you have waited a couple of minutes after turning the Stimulator on before you let the app search and connect to it, as described in section 6.3.5.
- If this still does not solve the issue, try turning the Stimulator off and back on.

If the problem persists, contact an ONWARD representative for assistance.

11.3.4 I cannot connect to the Stimulator

If you cannot connect to the Stimulator, you may see the message "Could not connect to the Stimulator" or "Could not pair with the Stimulator". In this case:

- Retry connecting to the Stimulator by clicking on the "Device ID" from the "Device List" that corresponds to the Serial Number (SN) on the back of the Stimulator (refer to section 6.3.5).
- If this does not solve the issue, turn the Stimulator off and back on.
- If this still does not solve the issue, perform a Factory Reset of the Stimulator as described in section 11.2.8 and unpair the Stimulator on the ARC^{EX} PRO app as described in section 11.3.13.

If the problem persists, contact an ONWARD representative for assistance.

11.3.5 "Poor Impedance Status" on Programmer

If "Poor Impedance Status" error is shown on the Programmer, improve the Impedance Status:

i. Ensure cables are properly connected.
ii. Ensure Electrodes adhere securely to the skin. Use medical tape to secure them or replace with new Electrodes if needed.
iii. Ensure Patient skin is prepared as indicated in section 6.4.1.2:
    a. Check skin for irritation and integrity before placing the Electrodes
    b. Thoroughly clean the skin with water or alcohol. Make sure skin is dry before applying Electrodes. Refer to section 6.5.3 for additional details.

11.3.6 The screen stays off when I try to turn on the Programmer

Ensure that the tablet's battery is not depleted by plugging it into a wall socket using the provided Charger (please refer to section 6.6.3) and wait a few minutes before turning it on. For more details, refer to the tablet manufacturer's user manual. If the problem persists, please contact an ONWARD representative.

11.3.7 The battery of the Programmer depletes within a few hours

In normal use, the Programmer should be usable for several hours after it is fully charged. Be aware that the screen consumes the most power. If you feel that battery longevity has significantly degraded since you first started using the Programmer, please contact an ONWARD representative.

11.3.8 Non-functioning stimulation program

If a program is nonfunctioning (e.g. cannot be started or accessed via the ARC^{EX} PRO app), the program will have to be re-created. If a program is nonfunctioning on the Patient's myARC^{EX} app, it can be re-imported or the Patient can start it from the Stimulator.

Note	Unless the error is related to a failure or corruption of the program configuration, the program will be intact once you recover from the error. If the program has been corrupted, you will not be able to choose the program and you will need to use the ARC^{EX} PRO app to reconfigure the program.

11.3.9 Can I change or customize the settings of the ARC^{EX} PRO app?

Some settings cannot be modified using the app screens. However, an ONWARD representative can customize or change such values for you. Please contact an ONWARD representative for more information on settings you would like to have changed.
Note that once an ONWARD representative changed these settings for you, they will apply to all future sessions. Settings cannot be changed "per Patient" and/or "per user".

11.3.10 How can I unlock the Programmer if I lost my PIN code?

Please contact an ONWARD representative for assistance.

11.3.11 Can I install other apps on the Programmer?

No. Please be aware that the Programmer is only meant to be used for running the ARC^{EX} PRO or the myARC^{EX} apps. The Programmer does not allow installation of other apps.

11.3.12 Can I use the Programmer while charging it?

You can use the Programmer while charging it, however, during delivery of therapy, the Programmer shall be charged only at a distance of 1.5m/5 feet from the Patient.

11.3.13 How do I unpair a Stimulator?

In the ARC^{EX} PRO app, go to the ‘’SETTINGS’’ menu (three horizontal lines in the top-right navigation bar) and select the Bluetooth option. In the Bluetooth settings, identify the Stimulator you wish to unpair and click on “Forget”. Please note that once you have unpaired a Stimulator, you will need to perform a Factory Reset to be able to pair with that specific Stimulator again. Refer to section 11.2.8 for instructions on how to perform a Factory Reset.

11.3.14 How do I change the language of the app?

The language of the app can be changed in the “SETTINGS” menu within the ARC^{EX} PRO app (three horizontal lines in the top-right navigation bar). Refer to section 6.3.3.

12 Disposal

Before disposing of the ARC^{EX} System, contact an ONWARD representative to delete the ARC^{EX} PRO app from the Programmer and to permanently remove data beyond recovery.

Electrical devices are recyclable material and should not be disposed of with household waste.
Dispose of components and packaging at the appropriate collection points, in accordance with hospital, administrative, and/or local government policy.

Please contact the organization which is responsible for waste disposal in you area if you have any questions.

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ONWARD®

ARC EX®
System
(Professional)

Essentials for Home Use Preparation

English

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ARC EX® Professional System

ONWARD®

For Healthcare Professionals: Setting up a Patient for ARC^{EX} home use

During in-clinic rehabilitation sessions, you will personalize ARC^{EX} stimulation settings to your Patient's goals. Once set, **your Patient will have the option to continue use at home with their own personal ARC^{EX} System.**

To set up a Patient for home use, gather both the Professional and Personal ARC^{EX} Systems and follow the steps below. Refer to Professional Instructions for Use (IFU) before this guide for comprehensive instructions.

There are two parts to the preparation for home use:

Exporting a program from the Professional ARC^{EX} System to the Patient's Personal ARC^{EX} System for home use.

Training Patients on the use of the ARC^{EX} System.

Exporting a program for home use

The Patient's Personal ARC^{EX} System differs from your Professional ARC^{EX} System:

i. The Stimulators and Programmers are specific to each System.

ii. The Personal Stimulator should be used only with the Personal Programmer.

iii. The Professional Stimulator should be used only with the Professional Programmer.

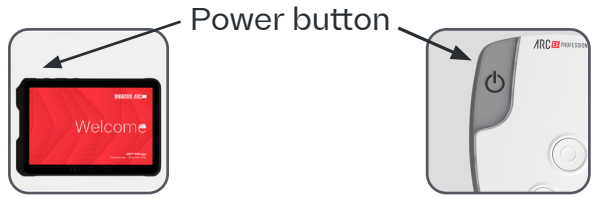
iv. Each System has its own IFU.

v. The Personal System also has a Quick Reference Guide.

Patient's Personal ARC^{EX} System

Professional ARC^{EX} System

Use the ARC^{EX} Professional System for the following steps

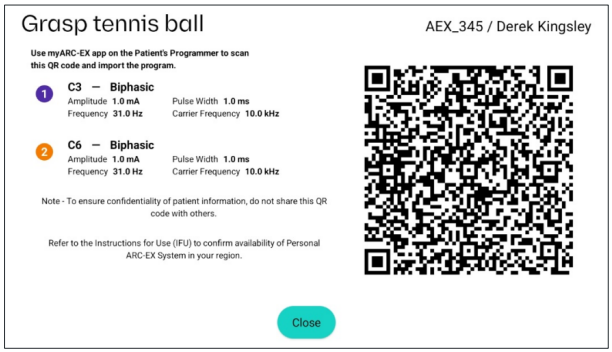
1. Turn **On** the Professional Stimulator and Programmer by pressing the "Power" button.	 Programmer ARC^{EX} PRO app ARC^{EX} Stimulator
2. Prepare to export a program to your Patient for home use: i. **Swipe** to unlock. ii. **Select the Patient** in the "Patient List" screen. iii. **Connect the Professional Stimulator to the Professional Programmer** by selecting "Connect device and start session" in the "Patient Details" screen. *Note:* Refer to Professional IFU section 6.3.5. A program must be created on the Professional ARC^{EX} System and used with the Patient at least once before you can export it to the Patient's Personal ARC^{EX} System for home use.	

3. Select the program to export from the "Program List" screen.

4. Select **"Export to Personal ARC-EX"** to generate a QR code, which will be scanned by the Patient's Personal Programmer (in the myARC^{EX} app).

i. Verify the stimulation settings that appear next to the QR code.

If you need to make any modifications to the program, you must use the program with the Patient at least once before exporting it.

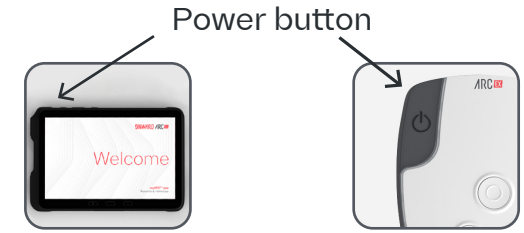


Use the ARC^{EX} Personal System for the following steps

1. Turn **On** the Patient's Personal Stimulator and Patient's Personal Programmer by pressing the "Power" button. During the first use, the Patient's ARC^{EX} System will require to:

- Confirm or change language
- Grant Bluetooth access
- View the data privacy information
- Set a lock type

For more information, refer to section 6.2 of the Patient's Personal ARC^{EX} IFU.



Programmer myARC^{EX} app

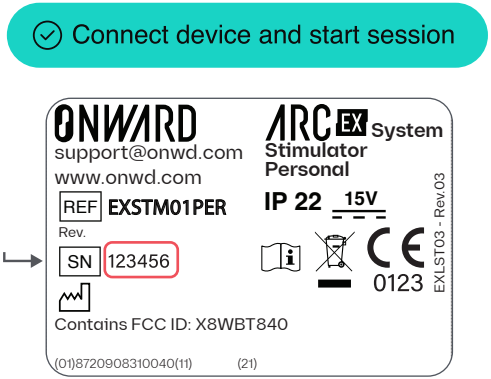
ARC^{EX} Stimulator

2. **Connect the Patient's Personal Programmer** in the myARC^{EX} app **to the Patient's Personal Stimulator** by selecting "Connect device and start session".

i. Select the "Device ID" that matches the Serial Number on the back of the Patient's Personal Stimulator.

ii. If the correct Stimulator Serial Number is not listed, select "Search devices".

Refer to Professional IFU section 6.3.5. for additional details.

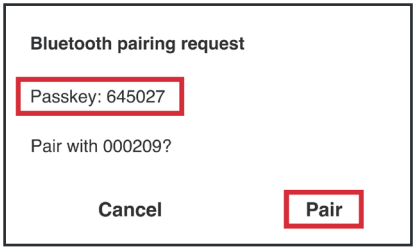


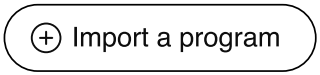
3. If this is the first use, **pair Patient's Personal Stimulator with Patient's Personal Programmer:**

i. Visually confirm that the 6-digit passkey on the Patient's Personal Programmer screen matches the 6-digit number in the notification area of the Patient's Personal Stimulator screen.

ii. If they match, press "Pair" in the Patient's Personal Programmer AND press the "Select" button on the Patient's Personal Stimulator (in any order).

Refer to Professional IFU section 6.3.5 for additional details.



4. Select "Import a program" in the "Program List" screen of the Patient's Personal Programmer, which will activate the camera of the Patient's Personal Programmer.	
5. Scan the QR code displayed in the ARC^{EX} PRO app of the Professional Programmer with the Patient's Personal Programmer camera by pointing the Patient's Personal Programmer camera **at the QR code on the Professional Programmer** screen.	
6. Verify that patient and program details are correct in the Patient's Personal Programmer and confirm the import by pressing "Yes" in the pop-up window. Only one program can be imported onto the Patient's Personal ARC^{EX} System.	

7. Confirmation of Program Upload:

i. Confirm the program has been imported by starting the imported stimulation program on the Patient's Personal ARC^{EX} System.

ii. After stimulation starts, stop the stimulation and press "End session".

iii. The Patient's Personal Stimulator screen should now display "Program ready Start" in the notification area.

iv. At this point, the Patient's home use program has been successfully uploaded and is ready for use by the patient with or without the Programmer.

Training patients on home use

Use the ARC^{EX} Professional System for the following steps

Instruct the Patient how to use their Personal ARC^{EX} System. More details in section 7.2 of this IFU:

1. Inform the Patient to read the "Safety Information" section for safe use of the ARC^{EX} System in the ARC^{EX} Personal IFU.
2. Physically show the Patient the positioning of the Electrodes based on their program
3. Physically show the Patient the correct connection of Extension Cables to Electrodes and to Splitter Box based on their program
4. Show the Patient the instructional video using the link or QR code on the right
5. Ask the Patient to operate the ARC^{EX} System using the Programmer and the Stimulator. Use the checklist in section 7.2 (Table 5) and below as support for evaluating the steps.
6. 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 in section 7.2 (Table 5) and below as support for evaluating the steps.
7. If any is not performed or not performed correctly, demonstrate the correct way to do it and confirm the Patient's understanding

Instructional video for patient:

onwd.com/instruction-video

Use this checklist to evaluate the Patient's ability to use the ARC^{EX} System.

ENSURE PATIENT CAN SUCCESSFULLY COMPLETE ALL OF THE TASKS BELOW

	Task	
	When operating the ARC^{EX} System with the Stimulator and Programmer:	
1.	Turn on the Stimulator and the Programmer.	☐
2.	Check Programmer and Stimulator battery levels.	☐
3.	Unlock Programmer by swiping on the screen and enter PIN.	☐
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)	☐
5.	Select the program from the "Program List" screen.	☐
6.	On your body, identify the areas on where the Active and Return Electrodes will go according to the "Channels" screen.	☐
7.	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.	☐

	Task	
8.	Place Electrodes on the prepared skin over the indicated areas according to the "Channels" screen, ensuring they are securely attached to the skin.	☐
9.	Connect Extension Cables to Electrodes and Splitter Box according to the setup defined in the "Channels" screen.	☐
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.	☐
11.	Click "Continue" in the "Channels" screen and confirm the correct Electrode placement.	☐
12.	Start stimulation by clicking "Check Ω and start stimulation".	☐
13.	Confirm you are ready to start stimulation by pressing "Yes" in the pop-up window.	☐
14.	From the Programmer, increase and decrease Amplitude.	☐
15.	Pause stimulation from the Programmer by selecting "Pause Stimulation".	☐
16.	Resume stimulation from the Programmer by pressing "Check Ω and resume stimulation".	☐
17.	Stop stimulation by pressing "Stop stimulation" on the Programmer, then "End session" on the Programmer to complete the session.	☐

Task		
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.	☐

Task		
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.	☐

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