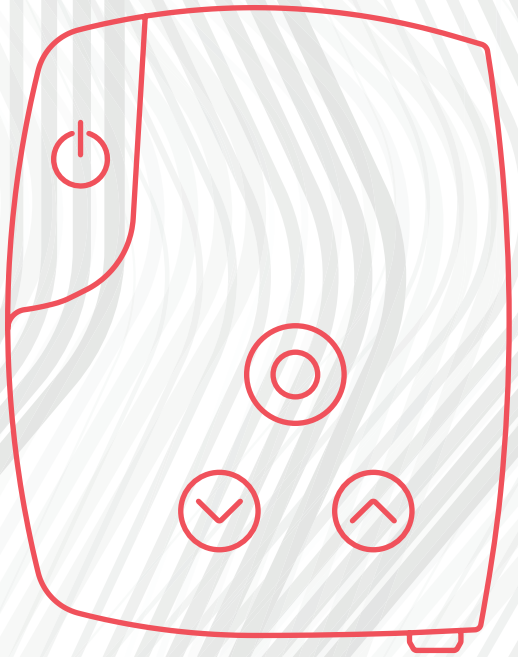
Instructions for Use

English



ARC EX®

System (Personal)

ONWARD®

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These Instructions for Use are valid for the ARC^{EX} System (Personal)

These Personal Instructions for Use are intended for Patients and for the Person Providing Assistance as needed.

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).

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

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IFU copyright

All rights reserved.

Trademarks

Patents granted and pending

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

Disclaimer

ONWARD Medical N.V. and its affiliates do not accept any responsibility for and shall not be liable for any injury suffered by any person or any damage to its products, either directly or indirectly, as a result of improper use, failure to follow operating protocol detailed in the Instructions for Use, or the unauthorized use or repair of the ARC^{EX} System (Personal).

ONWARD reserves the right to improve and amend any information relating to its products at any time, without prior notice, and shall not be responsible for any loss, cost, or damage, including but not limited to consequential damage(s) caused by reliance on the information contained herein.

Drawings herein are for illustration purposes only.

1 Introduction

1.1 How to use these Instructions for Use (IFU)

Read all instructions carefully before using the ARC^{EX} System (Personal) so that you understand its contents. Failure to read and understand the instructions in this document may result in improper use of the ARC^{EX} System, which could compromise your safety and device performance. If you have questions or need clarification concerning anything in these Instructions for Use, please contact your healthcare professional.

The myARC^{EX} 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. Please refer to their original manufacturer instructions provided in the ARC^{EX} System package for more specific information not included in this document.

1.2 Technical support

If you have technical questions or issues regarding the ARC^{EX} System (Personal), please contact your healthcare professional. You may also 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
IPxx	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	US 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
	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 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 waste electrical and electronic equipment is required
	Unique Device Identification number
	FCC Compliance
	Distributor

	Packaging unit
	Single patient multiple use
	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
ONWARD	ONWARD Medical N.V.
RP	Rehabilitation Professional
SCI	Spinal Cord Injury
UDI	Unique Device Identifier
IFU	Instructions For Use

Hz	Hertz. 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.
Impedance	Impedance refers to the resistance of the skin and other body tissues to the flow of current produced by the Stimulator and is measured in ohms (Ω symbol).
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.
mA	Milliampere. A milliampere (also milliamp) is 1/1000 of an Ampere. Ampere is the basic unit for measuring electrical current.
WARNING	Written in all capital letters, this indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
PRECAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury 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 1.5m/5 feet area around the Patient and applies only while stimulation is being delivered
Functional task practice	Functional task practice in the clinic 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).

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

CH REP	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, 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 an instructional video on using your ARC^{EX} System, use the link below or QR code:
onwd.com/instruction-video

For other additional resources, 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 who 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

It is important that you read all warnings and precautions included in these Instructions for Use. They are intended to keep you safe, prevent injury, and avoid situations that could result in damage to the device.

Note	Safety and performance of use during pregnancy have not been established. Limited clinical evidence is available in pregnant women.
Note	The Patient is an intended operator.
Note	You may need assistance to perform some steps with the System such as electrode placement, electrode attaching or removing cable connections, etc. If assistance is needed, provide simple, single-step instructions to your Person Providing Assistance. This IFU includes simple instructions and illustrations to guide both you and your Person Providing Assistance throughout the use of the System.

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 must only be used with the components of the ARC^{EX} System. Using components not part of the ARC^{EX} system will 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. Using damaged components can result in electrical shock. The images below show examples of a damaged Splitter Box. These examples are not exhaustive, other types of damage may also occur either to this component or to other parts of the ARC^{EX} System.

Figure 1. Examples of a damaged Splitter Box. These examples are not exhaustive.

- Contact ONWARD. Never attempt to modify or repair the ARC^{EX} System.

Electrode placement

To prevent further damage to the skin where the Electrodes are placed:

- Electrodes must not be applied over swollen, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.).
- Electrodes must not be applied over, or in proximity to, cancerous lesions.
- Should a skin rash or skin burn occur, immediately discontinue use of the ARC^{EX} System, contact your healthcare professional and wait until skin is healed before using.

Stimulation

- Stimulation must not be applied near or across the chest or upper back because the introduction of electrical current into the heart can cause cardiac arrhythmias or increase the risk of cardiac fibrillation.
- Stimulation must not be applied across or through the head, including directly to the eyes, as it may cause severe neurological effects, seizures or vision problems.
- Stimulation must not be applied over the mouth or the front or side of the neck, especially where the pulse is felt (the carotid sinus nerves). Stimulation in this area may cause closure of the airway, severe muscle spasms of throat muscles, breathing difficulties, and irregularities in heart rate and blood pressure.

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 as it can result in electrical shock.
- Do not hold the Stimulator or place it on your 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.
- If an emergency occurs while charging the Stimulator, unplug the Stimulator Charger from the electrical outlet.

Use and storage environment

- Strangulation hazard: keep power adapter cords, Splitter Box, and Extension Cables away from infants and young children. Never place these items around the neck. Always use the correct length of Extension Cable. If these objects get wrapped around the neck, it can lead to serious injury.
- Do not use ARC^{EX} System adjacent to or stacked with other equipment. This can result in improper operation.
- 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} System in close proximity to such equipment can degrade its performance.
- 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.

3.3 Precautions

General

- The ARC^{EX} System can generate current densities for Electrodes exceeding 2 mA/cm2, which will require special attention of the operator as this may cause skin irritation and redness. If this occurs, pause the therapy session. Refer to section 6.5.1.
- Ensure that the Extension Cables are connected to the Electrodes and the Splitter Box in exactly the same way as defined by your Rehabilitation Professional. Each program has a specific setup. Incorrect setup may increase the chance of muscle spasms, stiffness, tingling or numbness (pins and needles), changes in heart rate, or autonomic dysreflexia.

Electrode placement

- Electrodes not firmly attached to the skin will cause superficial skin burns. "Channels" screen provides guidance on skin preparation before attaching Electrodes.
- Keep Electrodes separated. They must not overlap or touch once attached to the Patient's skin at the target location.

Patient selection cautions

- Caution must be used in Patients with suspected or diagnosed heart problems.
- Caution must be used in Patients with suspected or diagnosed epilepsy.
- Caution must be used in the presence of the following:
  - When there is a tendency to hemorrhage (bleed heavily) 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.
- Keep the ARC^{EX} System out of reach of children, pets, and pests. They can potentially damage the System. See section 6.3.1 for further details.

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

Spinal cord injury can cause episodes of autonomic dysreflexia, which may be triggered by electrical stimulation. Discuss autonomic dysreflexia with your healthcare professional so that you understand how it may impact you and how to:

- Recognize the signs of autonomic dysreflexia.
- React if it occurs, including stopping electrical stimulation.

You can reduce your chances of experiencing autonomic dysreflexia by following these precautions:

- Empty your bladder and bowels before starting a session with the ARC^{EX} System.
- Do not use the ARC^{EX} System if you have an ongoing bladder infection or fever.

Electrical stimulation may lead to:

- Musculoskeletal spasms, stiffness, and pain. If this occurs, contact your Rehabilitation Professional to determine if the stimulation parameters need to be adjusted or if symptoms persist, pause the therapy session.
- Skin irritation, sweating, and redness. If this occurs, move the Electrode(s) to a new location.
- A temporary increase or decrease in heart rate. If this persists, contact your Rehabilitation Professional to determine if the stimulation parameters need to be adjusted or if symptoms persist, pause the therapy session.

It is normal for electrical stimulation to cause some discomfort, nerve pain, or feeling of tingling, numbness, or "pins and needles." These sensations may become familiar as you use the ARC^{EX} System.

3.5 Incident reporting

If, during use of the ARC^{EX} System (Personal), you have reason to believe that a serious incident has occurred, please report it to your Rehabilitation Professional. They will further report the incident to the manufacturer. 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 Personal** (referred to as Stimulator) (REF: EXSTM01PER) 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 myARC^{EX} app (via the Programmer).

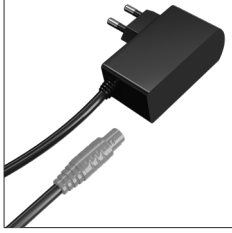
Image	Definition
	**ARC^{EX} Splitter Box** (REF: EXSPT01) The Splitter Box is used to connect the Stimulator to the Electrodes (via the Extension Cables).
	**ARC^{EX} Extension Cables** (REF: EXCBL0105 and EXCBL0110) ◦ 4 short Extension Cables (50 cm/19.7 inches long) ◦ 4 long Extension Cables (100 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 EXCHP01xx) The Stimulator Charger is used to recharge the Stimulator's battery.

Image	Definition
	**ARC^{EX} Programmer** (REF: EXPRG01PERxx) The myARC^{EX} app is proprietary software designed to allow the user to turn on and off a stimulation program predefined by a Rehabilitation Professional and to adjust its Amplitude. This myARC^{EX} 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 myARC^{EX} 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 myARC^{EX} is installed are provided in the ARC^{EX} System package.
	**ARC^{EX} Programmer Charger** (REF: EXPRG01CHGxx) The Programmer Charger is used to recharge the Programmer's battery.
	**ARC^{EX} System (Personal) Instructions for Use (this document)** (REF: EXIFU01PEREUxx) The electronic version of the ARC^{EX} System (Personal) Instructions for Use can also be found on ONWARD's website: www.onwd.com/resources (Additional languages also available)

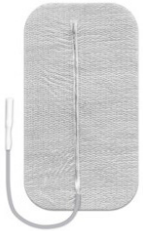
Image	Definition
	**ARC^{EX} System (Personal) Quick Reference Guide** (REF: EXQRG01PERxx) The QRG summarizes the instructions and therapy workflow. All this information can also be found in this document (i.e., ARC^{EX} System Instructions for Use).

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 comprised of an electrode pad and a lead wire. The 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 8.2. Refer to the manufacturer instructions for reuse criteria. **Note: Ensure to check the Electrode size and shape information printed on the Electrode pouch.**

Image	Definition
	**Pack of 4 Return Electrodes** (rectangular, REF 895240) Each Electrode is comprised of an electrode pad and a lead wire. The 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 8.2. 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 turn on and off a stimulation program predefined by a Rehabilitation Professional and to adjust its Amplitude through a software application (myARC^{EX} app). 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**.

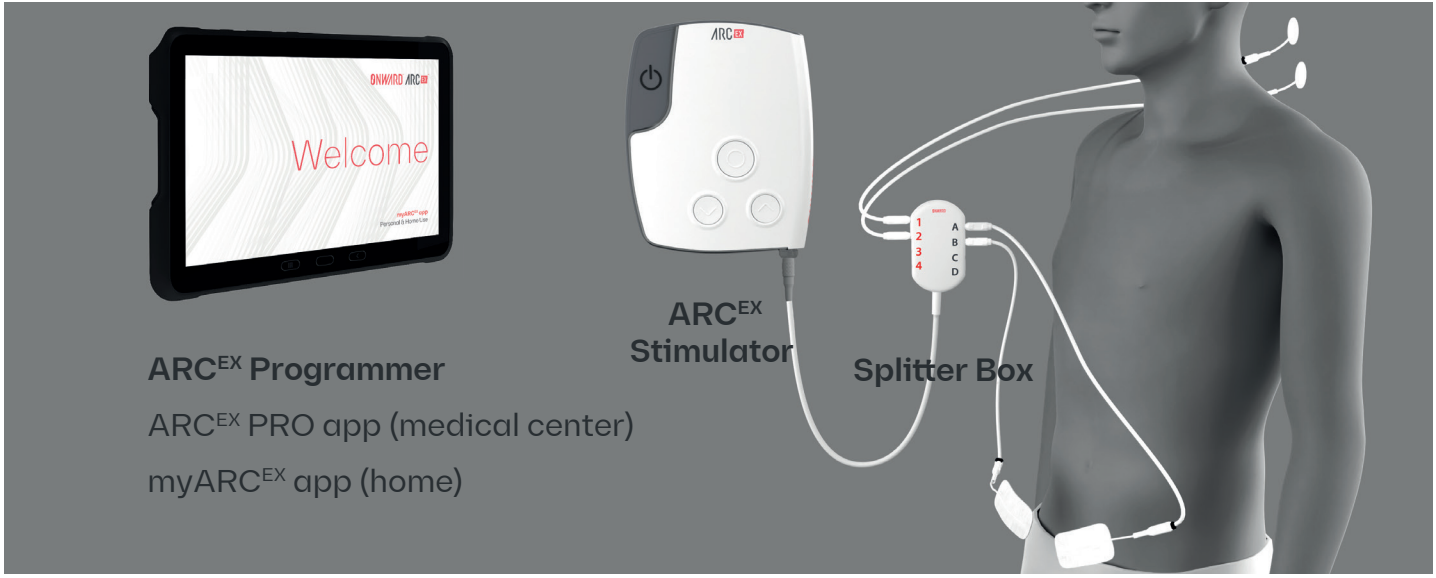


Figure 2. ARC^{EX} System and Electrodes

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 myARC^{EX} app installed on the Programmer. The numbers in the descriptions below correspond to the part of the Stimulator depicted in Figure 3.

1. **Stimulator output port**:
   - To recharge the Stimulator when connected to the Stimulator Charger and then to the MAINS power outlet.
   - To connect to 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.).

Figure 3. ARC^{EX} Stimulator

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

Table 3. Feedback and Corresponding 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	Lightbar: white light around the "Power" button Bluetooth icon is on	No sound	Stimulator is connected to the myARC^{EX} app 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. 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 Bluetooth icon is off	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 aournd 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. 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 myARC^{EX} 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

Message on Stimulator notification area	Light indicator	Sound type	State
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 myARC^{EX} app +[x] or −[x]. (Note: Remember +[x] or −[x] to similarly adjust the Amplitude at next session)
Stopped	Lightbar: white light around the "Power" button	Stimulation off sound	Stimulation has been stopped from the myARC^{EX} app
Error			
Temperature limit	Lightbar: dashed orange	Error sound	The Stimulator reached its warning temperature threshold

Message on Stimulator notification area	Light indicator	Sound type	State
See cables Resume  Stop 3s 	Lightbar: dashed orange, Impedance icon on	Error sound	Impedance is Poor. Refer to Section 6.5.2.
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 10.2.2.

5.3 ARC^{EX} Splitter Box

The Splitter Box manufactured by ONWARD is used to connect the Stimulator to the Extension Cables to distribute electrical current from the Stimulator to the Electrodes. The Splitter Box connects to the Stimulator and to Electrodes.

The Splitter Box contains eight sockets for Extension Cables. Four connect to Active (round) Electrodes (1-4 red numbers) 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 4.

Figure 4. ARC^{EX} Splitter Box

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) 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 developed myARC^{EX} 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.

Note	Do not remove the protective case from the Programmer.

Figure 5. myARC^{EX} 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.

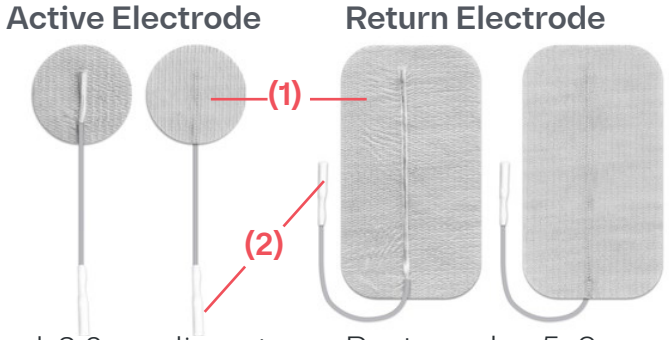


Figure 6. Axelgaard Electrode Types and Parts.

One Axelgaard Electrode consists of the following two parts, as depicted in Figure 6.

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 8.2. Refer to the 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 on how to use the ARC^{EX} System at home.

The ARC^{EX} System can only be used in a home environment after home use program is set up by a Rehabilitation Professional and exported to your personal System.

For an instructional video on using your ARC^{EX} System, use the link below or QR code:

onwd.com/instruction-video

If you have any questions before, during and after using the device, please consult your healthcare professional.

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 will turn on and the charging message will show on the Notification Screen. 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 myARC^{EX} app** (completed via the Programmer):
  - **Turn on the Programmer.**
  - **Confirm or change language:** Language can be changed at any time in the myARC^{EX} 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.
- **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. 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} System delivers electrical spinal cord stimulation called ARC^{EX} Therapy . The Patient may notice buzzing, tingling sensations or mild neck contractions. These are normal and expected.

An ARC^{EX} Therapy session should be completed as follows:	
Prepare	the ARC^{EX} System (Personal) and Patient for the ARC^{EX} Therapy session.
Set up	the Electrodes and stimulation program.
Train	using the ARC^{EX} System.
End	the session.

6.3 Prepare

6.3.1 Collecting the components

Refer to Sections 3.2 and 3.3 for **WARNINGS** and **PRECAUTIONS** related to the ARC^{EX} System components compatibility and integrity

1. **Unpack** the ARC^{EX} System components carefully from the Case.
   Check each part carefully for wear and tear before each 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 7.

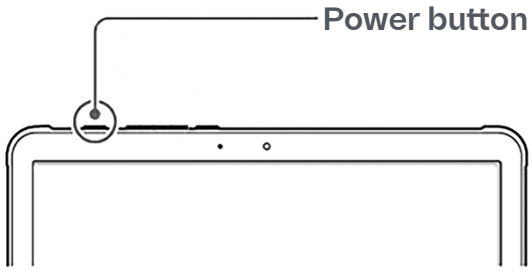
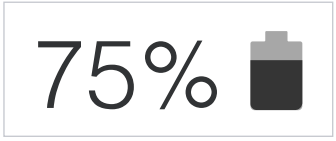


Figure 7. ARC^{EX} Programmer Power Button

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.



4. **Place the Stimulator on a flat surface** with the ARC^{EX} 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 Programmer cannot be used while charging.
Note	If the ARC^{EX} Programmer battery is low, it may disconnect or fail to communicate with the ARC^{EX} Stimulator.
Note	Wait 2.5 hours before using the Stimulator it has been stored below 5°C/41°F or above 40°C/104°F.
Note	Your Rehabilitation Professional will define the appropriate length and number of Extension Cables and number of Electrodes needed for the stimulation program (refer to "Channels" screen, Figure 14).
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 myARC^{EX} app

1. **Unlock the Programmer** by swiping the screen.
2. **Enter PIN** or, if this is the first use, **create a PIN**.
   i. 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 myARC^{EX} app settings

The "SETTINGS" screen lets you access:

- The app and the Stimulator language. Before changing the language, make sure the Stimulator is not connected to the Programmer.
  - To change the app language:
    - Click the language button
    - Select the desired language from the list
    - Click "Apply"
    - Navigate back to the "SETTINGS" screen by clicking the "<" button in the top-left corner.
  - To update the Stimulator language:

    - After changing the app language, connect the Stimulator to the Programmer.
    - Once connected, the selected language is automatically applied to the Stimulator.
- Bluetooth Paired Devices. The app will take you to the Programmer tablet 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.

The "ABOUT" screen provides information about the System and a description of the most recent software changes.

6.3.4 My Details

The "My Details" screen (Figure 8) of the myARC^{EX} app allows you to visualize your profile details. The following information is displayed:

- First name.
- Last name.
- Date of birth.
- Date of spinal cord injury.

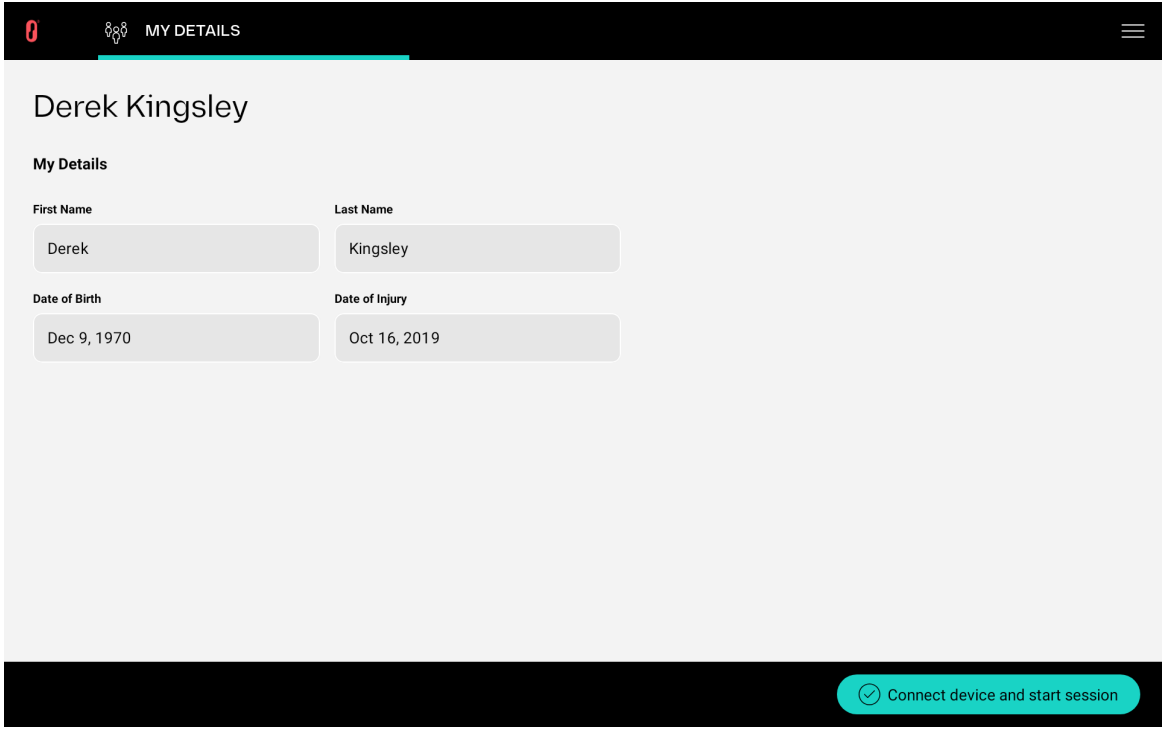


Figure 8. Example of "My Details" Screen

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

6.3.5 Connecting to the ARC^{EX} Stimulator

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

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

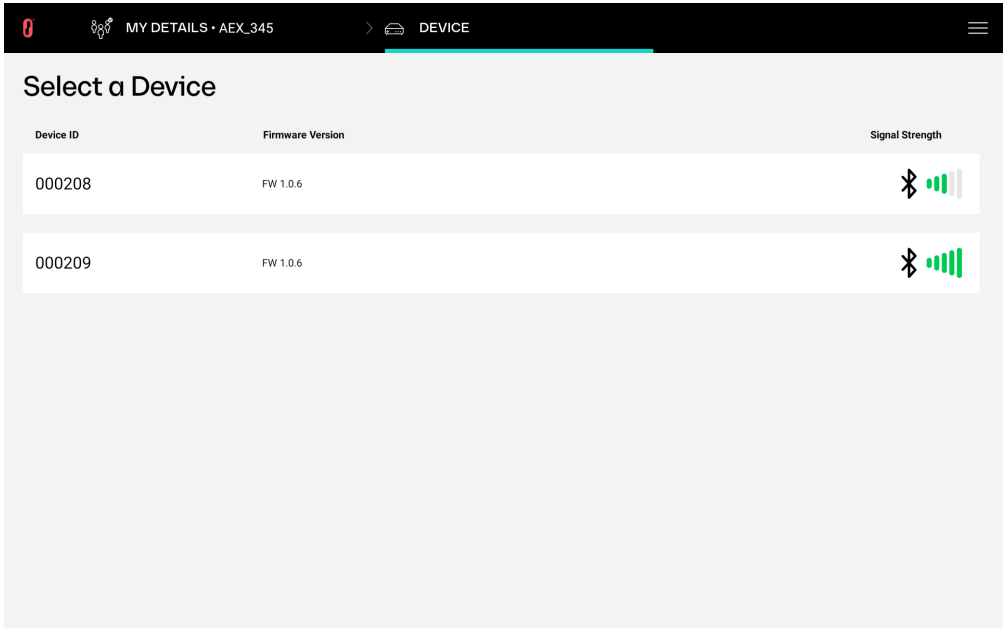


Figure 9. Example of "Select a Device" Screen

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

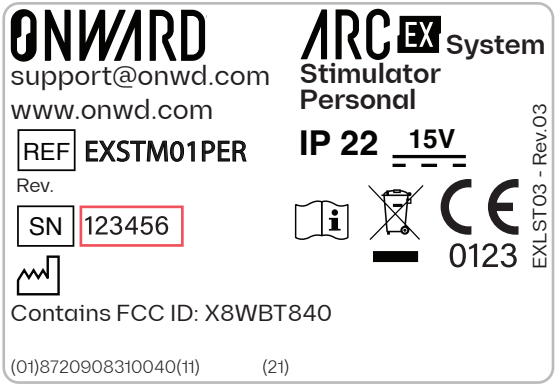
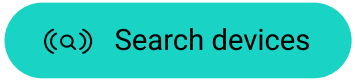


Figure 10. Example of Label on the Back of the ARC^{EX} Stimulator.

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



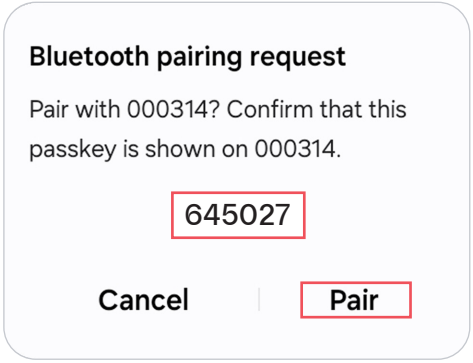
"Signal strength" is an indicator of quality of the Bluetooth signal between the Programmer and the Stimulator, which depends on how close they are.

2. <u>If this is the first time you are connecting this Programmer with this Stimulator</u>, **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.



Once the Stimulator is connected, the following information will appear on the top bar: Device ID, corresponding to the Stimulator SN (1), Battery level of the Stimulator (2), and Bluetooth Signal Strength between the Stimulator and the Programmer (3). See image below.

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.

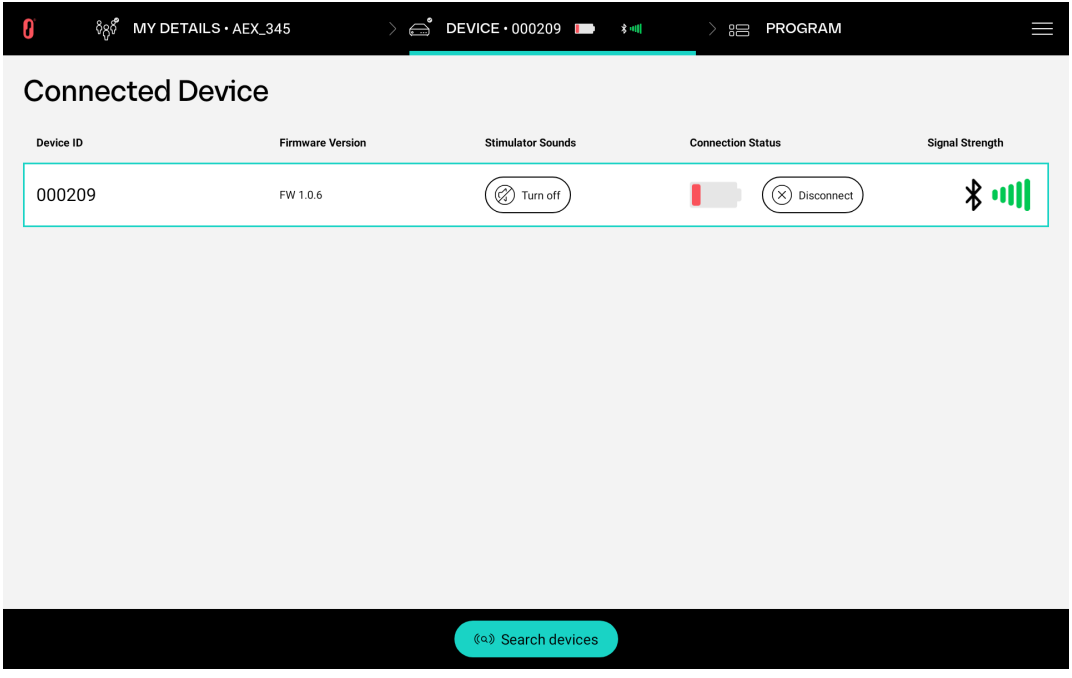


Figure 11. Example of "DEVICE" Tab

6.3.6 Stimulation program management

Access the "Program List" screen (Figure 12) once the Stimulator is connected to the myARC^{EX} app.

1. **Select the program** previously imported by your Rehabilitation Professional from the "Program List" screen (Figure 12).

   i. Click on the desired stimulation program to select it. Once a program is selected, the "Program Details" will be displayed (Figure 13):

   - Name of the program.
   - Description of the program.
   - Stimulation duration in minutes.
   - Ramp-Up Duration in seconds. To make the start of stimulation smoother when starting or resuming stimulation, the Amplitude gradually increases from 0 mA to the set Amplitude during this Ramp-Up Duration.
   - The Maximum Amplitude Increase in Personal ARC-EX is preset and cannot be exceeded.

Note	Only the Rehabilitation Professional can import a program onto your Programmer for home use. If no program is listed, contact your Rehabilitation Professional.

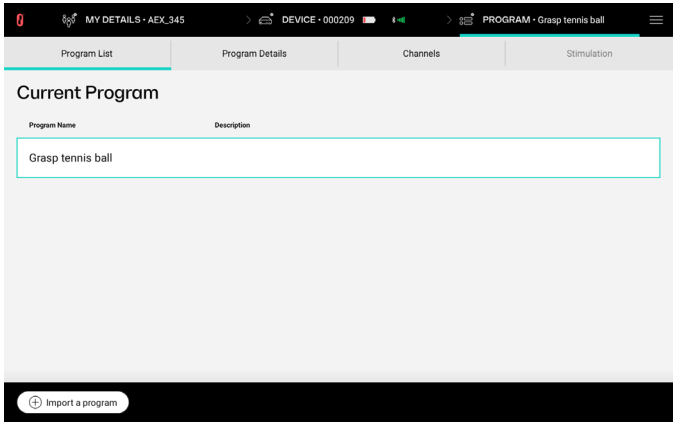


Figure 12. Example of "Program List" Screen

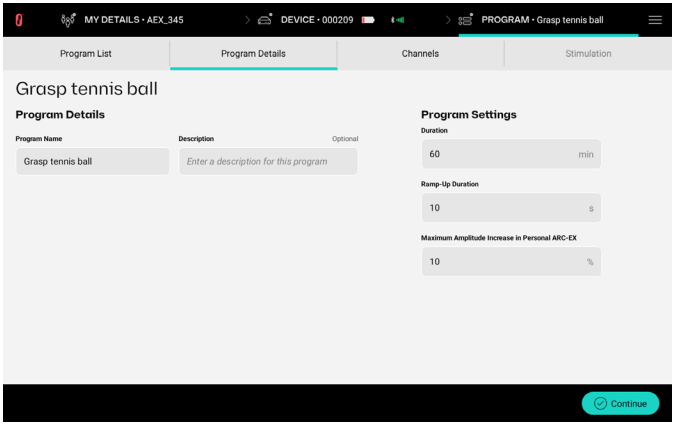
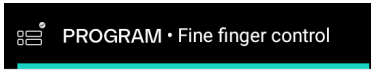


Figure 13. Example of "Program Details" Screen

Once selected, the program name will appear on the top bar.



Note	Stimulation Amplitude cannot be adjusted during the Ramp-Up Duration.
Note	Certain stimulation settings may result in a longer Ramp-Up Duration than what has been set by the Rehabilitation Professional. Exact ramping duration is displayed on the Stimulator.
Note	The ramp-up effect may be limited in case of low frequencies (<2Hz).

2. Tap on "Continue" to **review Electrode placement** and channel configuration in the "Channels" screen (Figure 14):

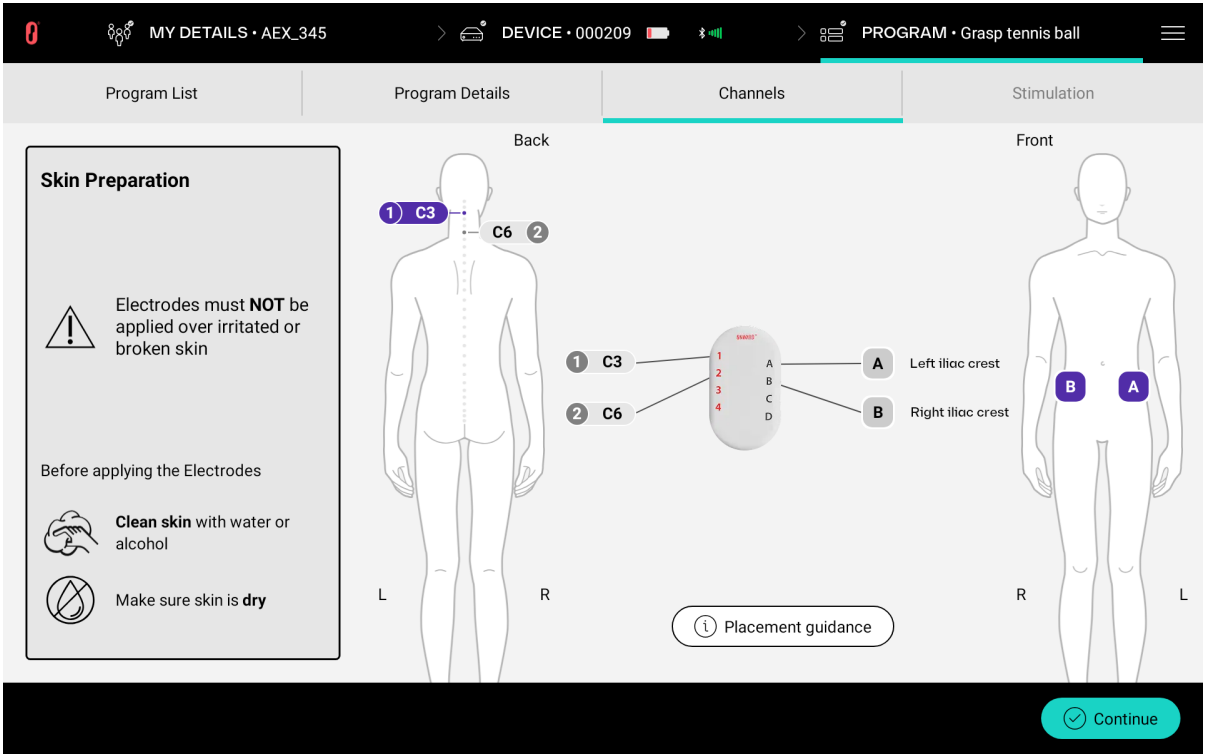


Figure 14. Example of "Channels" Screen

6.4 Set-up

The "Channels" screen (Figure 14) provides all the information to set up the ARC^{EX} System correctly. You will find:

- Skin preparation guidance – steps to prepare your skin before placing the Electrodes
- A personalized setup guide – a visual representation of your setup as defined by your Rehabilitation Professional. This includes:
  - Electrode placement - where to place the Electrodes on your body. Active Electrodes are labeled **1-2-3-4** on the mannequin and Return Electrodes are labeled **A-B-C-D**.
  - Connection guide – guidance on how to connect the Electrodes, using the Extension Cables, to the Splitter Box. In the center of the screen, you will see which Electrode connects to which Splitter Box socket.

6.4.1 Collecting the components

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

1. **On your body, locate the areas** where Active and Return Electrodes will be placed according to the "Channels" screen. See example in Figure 14.
   - Active Electrodes (round) shall be placed on the back of the neck.
   - Return Electrodes (rectangular) shall be placed over bony parts of body (e.g., hip bones or collarbones).

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

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

2. **Prepare target areas of skin for Electrode placement.**
   i. Check skin for irritation and integrity (e.g. change of color, rash, broken skin) before placing the 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.

Note	Do not apply lotion, oils, or ointments over or near the area where Electrodes will be applied.

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

3. **Place Electrodes** on the prepared skin, ensuring they are securely attached to the skin:
   - Place Active Electrodes (round) on the back of the neck.
   - Place Return Electrodes (rectangular) over bony parts of body (e.g., hip bones).

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

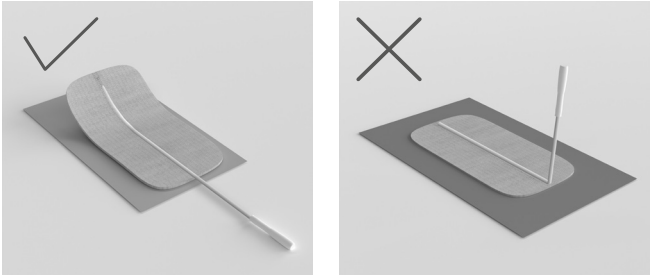


Figure 15. Removing the Electrode from the Liner

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.

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

6.4.2 Setting up the Splitter Box and Stimulator

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

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

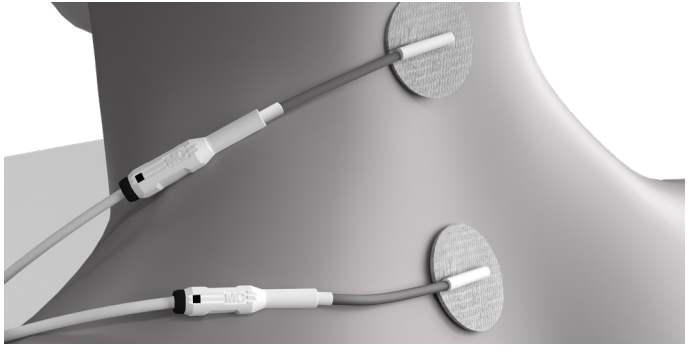


Figure 16. Extension Cables Plugged into Electrodes

- The round **Active Electrodes** to the red **active Sockets** on the Splitter Box. Take care to connect the correct Splitter Box socket (**1**, **2**, **3**, or **4**) to each Active Electrode as specified on the myARC^{EX} app "Channels" screen (Figure 17, highlighted section).

- The rectangular **Return Electrodes** to the gray **Return Sockets** on the Splitter Box. Take care to connect the correct Splitter Box socket (**A**, **B**, **C**, or **D**) to each Return Electrode as specified on the myARC^EX app "Channels" screen (Figure 17, highlighted section).

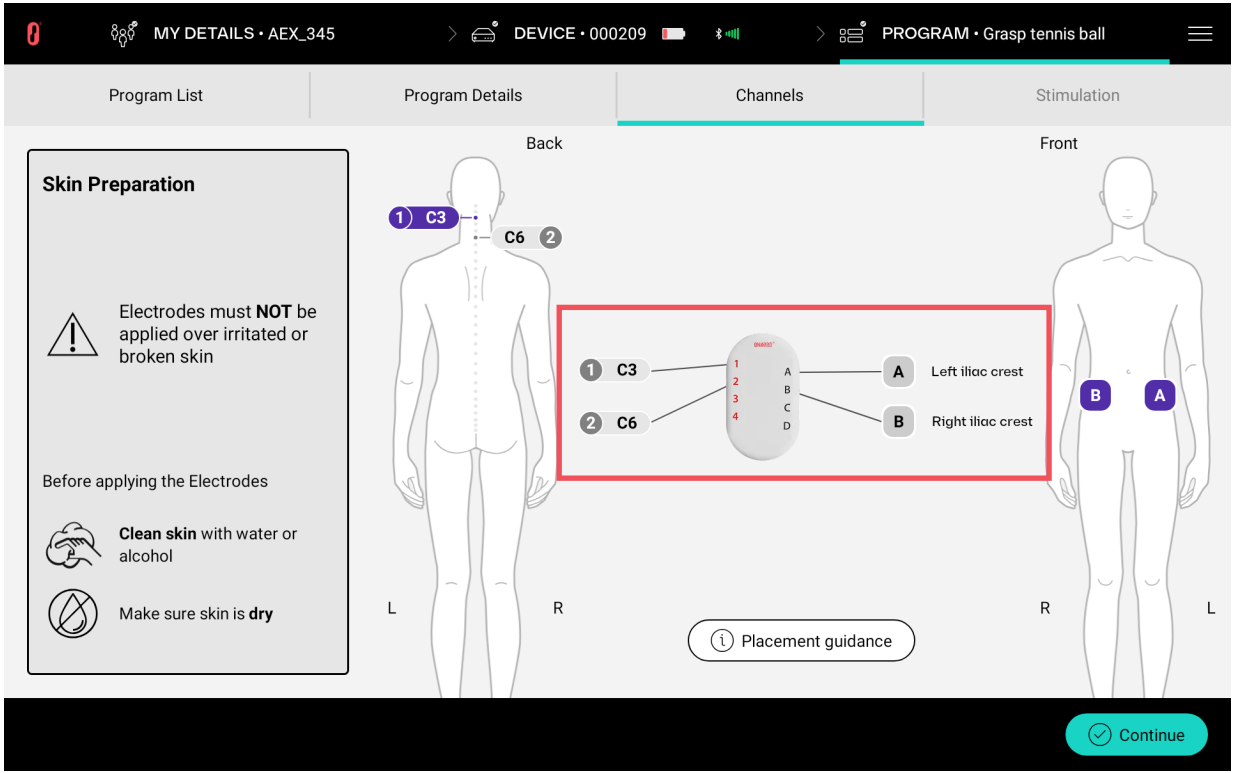


Figure 17. "Channels" Screen – highlight on Splitter Box Setup

Note	Two different Extension Cable lengths are available (1m/39.4 inches and 0.5 m/ 19.7 inches). Choose the most convenient length to reach each placed Electrode without restricting 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 area to the correct socket on the Splitter Box (marked with **A, B, C, D**).

2. **Clip the Splitter Box** (using the built-in clip) to a place, such as the neck of your shirt, where cables can reach the Electrodes without restricting your arm movement (Figure 18).

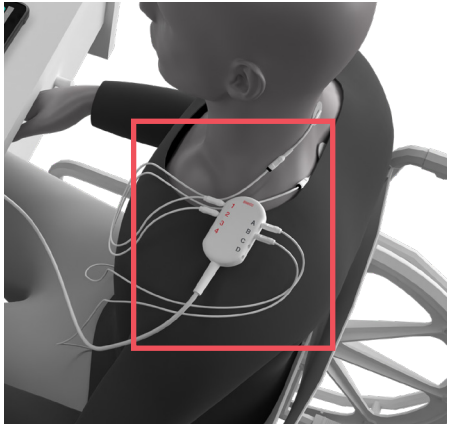


Figure 18. Example of Splitter Box Placement

3. **Connect the Splitter Box to the Stimulator** by inserting grey plug of Splitter Box into grey socket on Stimulator (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.

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

Figure 19. Connecting the Splitter Box to the Stimulator

Figure 20. Example of ARC^{EX} Setup

4. **Navigate to "Stimulation" screen:**
   i. Select "Continue" in the "Channels" screen
   ii. Select "Confirm" after confirming Electrodes placement

6.5 Train

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

6.5.1 Stimulation control

6.5.1.1 Controlling ARC^{EX} Therapy from the Programmer (myARC^{EX} app)

In the "Stimulation" screen (Figure 21), you can view the stimulation settings and control the stimulation.

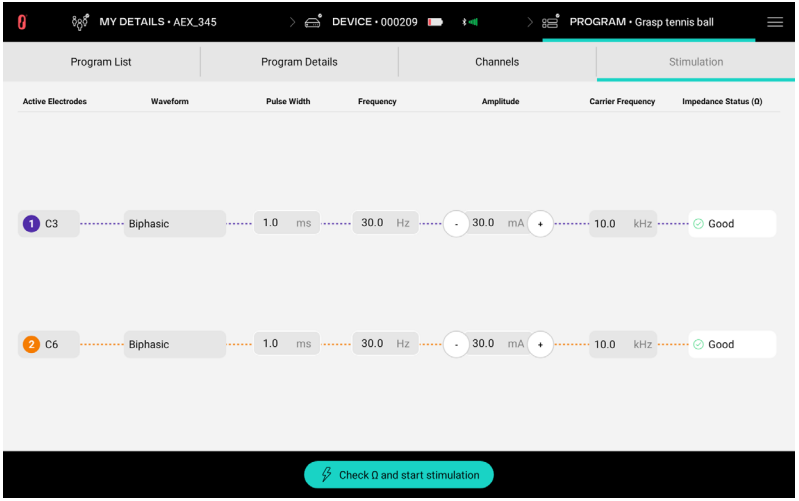
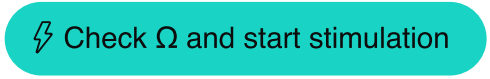


Figure 21. Example of "Stimulation" Screen

1. **Check impedance** by tapping on "Check Ω and start stimulation" (more information on Impedance Status in section 6.5.2). Note that this step may take a few seconds.

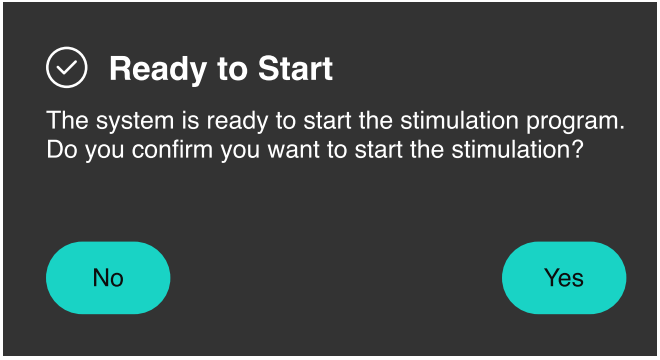


If you encounter a Poor Impedance Status error, improve the Impedance Status by:

- 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 6.5.2 for more details.

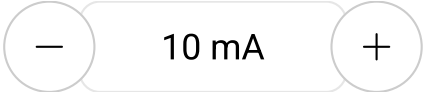
2. **Confirm you are ready to start stimulation** by tapping "Yes" in the pop-up window.



3. **Begin exercises** assigned by your Rehabilitation Professional.

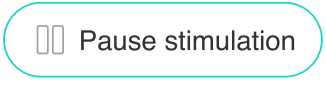
   Once the stimulation starts, the current ramps up from 0 mA to the set Amplitude for each channel. The stimulation status bar will appear on the bottom of the screen.

   During session, from the Programmer, you can **increase or decrease Amplitude** (stimulation intensity) by pressing the "+" and "-" buttons.



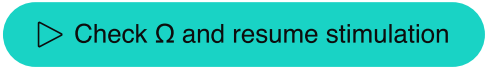
- If stimulation does not improve your performance on your assigned exercises, consider increasing Amplitude.
- If stimulation creates discomfort, consider reducing Amplitude.

4. You may **pause stimulation** from the Programmer by tapping on "Pause stimulation"



To resume stimulation

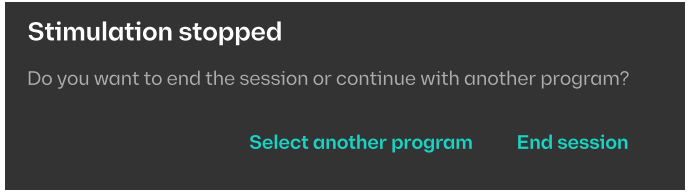
i. Press "Check Ω and resume stimulation". When resuming, the stimulation will restart where it paused. The current will ramp up again from 0 mA to the set Amplitude for each channel.



5. **Stop stimulation:**

i. Press “Stop stimulation”. This will stop stimulation entirely. You will have to restart the stimulation program from the beginning.

When the stimulation is stopped or the program is completed, the myARC^{EX} app will ask if you want to end the session or continue it. Selecting “End session” returns to the first screen (“My Details”). Otherwise, it goes back to the “Program List” to restart a stimulation program.



Note	When stimulation is stopped, the stimulation parameters will be reset to the default values provided by the Rehabilitation Professional.
Note	Stimulation parameters can only be adjusted within the ranges specified by the Rehabilitation Professional.
Note	If connected to the myARC^{EX} app, stimulation parameters cannot be adjusted via the “Increase”/ “Decrease” buttons on the Stimulator.

6.5.1.2 Controlling ARC^{EX} Therapy without the Programmer

The stimulation can also be started and adjusted without the Programmer by using only the Stimulator buttons (Figure 22).

Using the Stimulator without the Programmer is recommended only if you are confident that you remember where your Rehabilitation Professional instructed you to place both the Active Electrodes and the Return Electrodes on your body and can recall the configuration for connecting the Extension Cables to the Splitter Box.

Below are actions that can be performed directly on the Stimulator:

- **Start** stimulation by pressing the "Select" button once.
- **Pause** stimulation by pressing the "Select" button once while the stimulation is in progress.
- **Resume** stimulation by pressing the "Select" button once while the stimulation is paused.
- **Stop** stimulation by 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.
- **Increase/decrease** the Amplitude by pressing the "Increase" button (up arrow) or the "Decrease" button (down arrow). 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 much the Amplitudes have changed from the default. For example, if the Increase button 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.

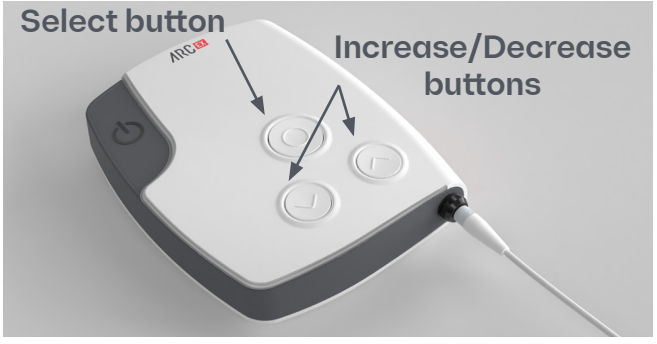


Figure 22. Controlling Stimulation without the Programmer

Note	At the end of a stimulation program, Amplitudes will be reset to the values provided by the Rehabilitation Professional.
Note	Every time a stimulation program is started from the myARC^{EX} app, the stimulation parameters predefined by your Rehabilitation Professional will be sent to the Stimulator.

6.5.2 Impedance Status

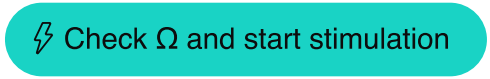
Impedance Status indicates the resistance of the skin and other body tissues to the flow of current produced by the Stimulator. During a stimulation session, Impedance Status may change due to factors such as external humidity, temperature and sweat.

Impedance Status on the myARC^{EX} app:

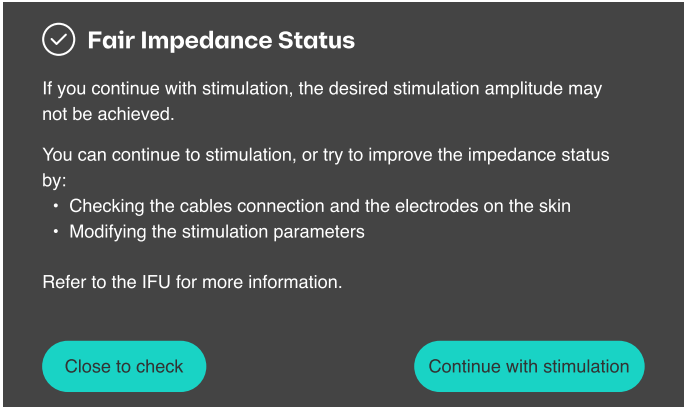
The Impedance Status shown on the myARC^{EX} app indicates the following:

- "Good": the System is well set up and the stimulation can start.
- "Fair": the stimulation can start, but the impedance level of the System may limit the stimulation output. If the desired Amplitude cannot be achieved, it is recommended to check the attachment of the Electrodes to the skin and/or the connections of the wires to improve the System Impedance Status (see "Suggestions to improve Impedance Status" below).
- "Poor": the stimulation cannot start. Check that the Electrodes are securely attached to the skin and that all wires connections are properly set up to the System before starting the stimulation (see "Suggestions to improve Impedance Status" below).
- "-": the Impedance Status is not measurable because the stimulation Amplitude is set to 0 mA. This means the channel is not delivering any current, so the Impedance Status is not applicable.

From the "Stimulation" screen of the myARC^{EX} app, tap the "Check Ω and start stimulation" button to perform an impedance check. Note that this step may take a few seconds.



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



During stimulation, if a channel’s Amplitude is set to 0 mA, the Impedance Status will be displayed as “-” and cannot be measured. This does not affect the ongoing stimulation.

If the Impedance Status changes during the session, the ARC^{EX} System will adjust to maintain the desired current Amplitude output. However, if impedance is too high (“Poor” status), then the Stimulator will automatically stop stimulation. The Stimulator will display the “Ω” LED indicator, the message “See cables” and the lightbar will turn dashed orange.

Suggestions to improve Impedance Status:

- Ensure cables are properly connected (including Splitter Box, Extension Cables and Electrodes).
- Ensure Electrodes are securely adhered 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:
  - Check skin for irritation and integrity before placing Electrodes.
  - Shave or trim excess hair if needed. Avoid using lotions or oils where the Electrodes will be placed.
  - 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.
- Avoid rapid head movements, which may displace the Electrodes.

6.5.3 Prompt interruption of stimulation

To stop the stimulation immediately, press "Pause stimulation" or "Stop stimulation" on the myARC^{EX} app:

- If the device does not respond as expected, press the "Power" or the "Select" button on the Stimulator (Figure 22).
- If the device does not respond to these actions, unplug the Splitter Box from the Stimulator (Figure 23). This can be done by quickly pulling on the connector.

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

Figure 23. Prompt Interruption of Stimulation with "Power" or "Select" Buttons

Figure 24. Prompt Interruption by Unplugging Splitter Box.

6.6 End session

6.6.1 Turning off the System

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

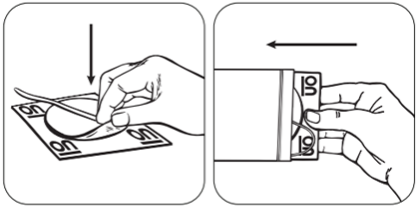


Figure 25. Placing Electrodes on Liner

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

6.6.2 Cleaning

All components of the ARC^{EX} System can be cleaned by carefully wiping them with a damp cloth. 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.
4. Wait until all surfaces are dry.

Using cleaning techniques and agents other than those as 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

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

Battery level

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 75%
Refer to the tablet manufacturer's user manual for details.

6.6.3.2 ARC^{EX} Stimulator

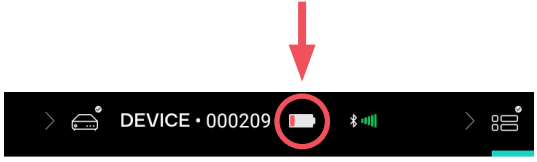
Charging

1. Plug the Stimulator Charger into a MAINS power outlet.
2. Connect the charging cable to the Stimulator. Recharging will start automatically: the Stimulator's battery icon will light up and the charging level will show on the Stimulator's screen.
3. Charging can take up to 8 hours depending on the starting level of the battery. When charging is complete, the Stimulator screen 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 myARC^{EX} app or every time the Stimulator is turned on.



When the Stimulator battery is low, a warning will sound from the Stimulator and the battery LED status icon will start blinking. Charging is recommended at this time. However, the Stimulator can continue to be used until the battery is too low for further use. This will be indicated on the Stimulator by an error sound, the dashed orange lightbar, and a blinking battery icon on the Stimulator.

6.6.4 Storing the ARC^{EX} System

⚠	Check Sections 3.2 and 3.3 **WARNINGS** and **PRECAUTIONS** section related to the ARC^{EX} use and storage environment

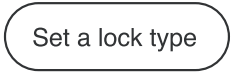
Return components to the provided Case and store it in a safe location.

7 Cybersecurity

7.1 Protecting access to the Programmer

To prevent unauthorized access to your device, set up a PIN code.

To do this, when starting the app, 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). Take care to remember the PIN and ensure it is recorded in a safe location. 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.



7.2 Wireless security measures

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

- Encrypted wireless communication.
- Wireless network (Wi-Fi) is disabled.
- Only one Programmer may communicate with the Stimulator at a time.
- A unique key for each unit that 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.

7.3 Guidelines for secure use

To help keep the ARC^{EX} System safe and working properly, please follow these simple security steps. Even when you follow all instructions, some low risks may still remain. They are indicated where relevant.

7.3.1 Keep your Programmer secure

- Do not use myARC^{EX} app if the Programmer shows a system error.
- Never share your password or PIN code.
- Do not allow unauthorized people to access the Programmer.
- Lock the screen when you are not using it.

If someone else gets access, they could change your therapy or see your personal data.

7.3.2 Use Bluetooth safely

- Turn off the Bluetooth connection to the Stimulator when you're not using the system.
- Don't pair or connect to devices you don't know or trust.

Untrusted connections could lead to data being seen by others or therapy being disrupted.

7.3.3 Follow device rules

- Don't try to turn off the locked settings (ProKiosk mode).
- Don't try to install any apps on the Programmer.

Changing settings may harm the system or prevent it from working as it should.

7.3.4 Do not use USB ports

- Don't plug the Programmer into any other devices using USB.

This could bring in harmful software or allow others to access your data.

7.3.5 Let ONWARD handle updates

- Don't try to install updates or change anything on the system.
- ONWARD representatives will take care of updates during visits.

Updates keep the System secure and working as expected.

7.3.6 Report any security concerns

- If you think something may be wrong or unsafe, please contact an ONWARD representative right away.

Telling us early helps keep your System working as expected.

7.4 Log files

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

7.5 Cybersecurity End of Support

You will be notified to the discontinuation of support six months prior to the end-of-support date.

7.6 Software Bill of Material

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

8 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

8.1 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. For additional information, please contact an ONWARD representative.

8.2 Electrode purchase and replacement

To ensure correct delivery of stimulation, ensure that Electrodes:

- Have not passed their expiration date (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.

9 Technical information

9.1 Specifications

Table 4. 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	4 A
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

Characteristic	Values
Battery capacity	3.2 Ah / 37 Wh
Dimensions	235 x 190 x 55 mm
Memory Flash	32 MB
Wireless capability 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 Pulse 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 - 60 s Note: For specific stimulation settings the Ramp-Up Duration can be automatically lengthened 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 IP 22. 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 / 41°F to 104°F Storage (Within Case): -25 to +70°C / -13°F to 158°F Transport (Within Case): -25 to +70°C / -13°F to 158°F **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.

9.2 Exposure

9.2.1 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 5 provides ARC^{EX} System electromagnetic emission test results.

Table 5. Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment - Guidance
Conducted emissions	IEC 60601-1-2 (CISPR 11)	Professional healthcare Home healthcare
Radiated RF emissions	IEC 60601-1-2 (CISPR 11)	Professional healthcare Home healthcare
Harmonic distortion	IEC 60601-1-2 (IEC 61000-3-2)	Professional healthcare Home healthcare
Voltage fluctuations and flicker	IEC 60601-1-2 (IEC 61000-3-3)	Professional healthcare Home healthcare

The ARC^{EX} System (Personal) was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2 standard. Table 6 describes the electromagnetic environments for which the device has been tested and is safe to use.

Table 6. 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 80MHz - 2,7 GHz 80% AM at 1kHz	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.
Surges (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	The ARC^{EX} System complies with part 15 of the FCC Rules. Operation 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.

9.2.2 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, e.g. wi-fi routers, laptops, home appliances, etc.) and the ARC^{EX} System as recommended below, according to the maximum output power of the communications equipment.

Table 7. Recommended Distances Between RF Communications Equipment and the ARC^{EX} System (Personal)

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter			
	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 $d = 2.3\sqrt{P}$

10 Troubleshooting

10.1 ONWARD® Support

For additional support, contact an ONWARD representative:

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

For an instructional video on using your ARC^{EX} System, use the link below or QR code:
onwd.com/instruction-video

10.2 ARC^{EX} Stimulator troubleshooting

10.2.1 Stimulator does not turn on

The battery of the Stimulator may be empty. Attempt to charge it using the Stimulator Charger (refer to Section 6.6.3.2). If it still does not turn on after charging, please contact an ONWARD representative for assistance.

10.2.2 Stimulator shows an error code

If the Stimulator encounters an event that requires 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 the myARC^{EX} app to confirm the error details and follow the suggested instructions. If the problem persists, contact an ONWARD representative for assistance. If the Stimulator error contains an error code, 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 8 for more details on the error codes.

Table 8. 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 temperature detection
E008	Audio file unretrievable
E009, E010	Versions compatibility error
E013	Error in monitoring circuit

10.2.3 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:

- Ensure cables are properly connected.
- Ensure Electrodes adhere securely to the skin. Use medical tape to secure them or replace with new Electrodes if needed.
- Ensure skin is prepared as indicated in section 6.4.1:
  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 6.5.2 for additional details

10.2.4 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.

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

If the Stimulator takes a long time to respond when you are pairing it with the Programmer or controlling stimulation, make sure they are within 3 meters/10 feet of each other to improve the connection. If the problem continues, turn off or move any Wi-Fi routers, mobile phones, laptops, and Bluetooth devices away from the Stimulator and Programmer.

10.2.6 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 6.6.3.2). If it still does not turn on after charging, contact an ONWARD representative.

10.2.7 Stimulation does not start

When attempting to start the stimulation from the Stimulator (without the Programmer), if stimulation does not start, connect to the myARC^{EX} app to confirm if an error occurred. If this is the case, the myARC^{EX} app will display an error message.

Take note of the error message 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.

10.2.8 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 the stimulation program saved on the Stimulator will be erased.

10.2.9 How do I change the language of the Stimulator?

Turn off the Stimulator. Change the language in the myARC^{EX} app following instructions in Section 10.3.14. Turn on the Stimulator and connect it to the myARC^{EX} app.

10.3 ARC^{EX} Programmer troubleshooting

10.3.1 Programmer becomes unresponsive to touch

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

10.3.2 The 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, stimulation will pause. Refer to Section 6.5.1.2 for further details controlling stimulation without the Programmer. To reestablish connection with the Stimulator, complete the actions listed in Section 6.3.5. When the stimulation program ends or connection is lost while stimulation is not ongoing, the connection with the myARC^{EX} app must be reestablished.

10.3.3 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 myARC^{EX} 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, please contact an ONWARD representative for assistance.

10.3.4 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" 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, try turning 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 10.2.8 and unpair the Stimulator on the myARC^{EX} app as described in Section 10.3.1.

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

10.3.5 I cannot start the Stimulation

If you cannot start the stimulation and you see the message "Could not transfer the stimulation, due to: InvalidParameter", this may be due to a compatibility issue between the Programmer and the Stimulator. Please contact an ONWARD representative for assistance.

10.3.6 "Poor Impedance Status" on Programmer

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

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

- Ensure skin is prepared as indicated in section 6.4.1:
  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 6.5.2 for additional details.

10.3.7 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 (refer to Section 6.6.3.1) 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.

10.3.8 The battery of the Programmer depletes within a few hours

In normal use, the Programmer will 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.

10.3.9 Non-functioning stimulation program

If a stimulation program is not functioning (e.g. cannot be started or accessed via the myARC^{EX} app), please contact your Rehabilitation Professional. You can continue to use the stimulation program by starting it from the Stimulator.

Note	Unless the error is related to a failure or corruption of the program configuration, the stimulation 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 contact your Rehabilitation Professional.

10.3.10 Can I change or customize the settings of the myARC^{EX} 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.

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

Please contact an ONWARD representative for assistance.

10.3.12 Can I install other apps on the Programmer?

No. The Programmer is only meant to be used for running the myARC^{EX} app and does not allow installation of other apps.

10.3.13 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.

10.3.14 How do I unpair a Stimulator?

In the myARC^{EX} 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 "Unpair". 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 10.2.8 for instructions on how to perform a Factory Reset.

10.3.15 How do I change the language of the app?

The language of the app can be changed in the "SETTINGS" menu within the myARC^{EX} app (three horizontal lines in the top-right navigation bar), refer to Section 6.3.3.

10.3.16 Update of the Stimulator is required

If you cannot connect to the Stimulator and you see the message "Update Required" on the programmer, the Stimulator may need to be updated. Please contact an ONWARD representative.

11 Disposal

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

Electrical devices are recyclable material and should not be disposed of with houshehold 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 your area or your Rehabilitation Professional for any further disposal instructions of any of the device components.

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