

QUICK START GUIDE



REVOLUTION WIRELESS

QUICK START GUIDE

REVOLUTION WIRELESS.....	4
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INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE	9
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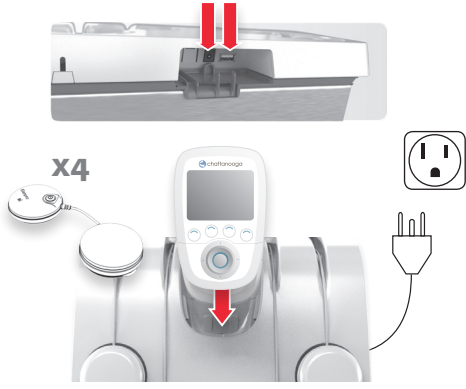
IMPORTANT INFORMATION

IMPORTANT INFORMATION.....	10
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REVOLUTION WIRELESS



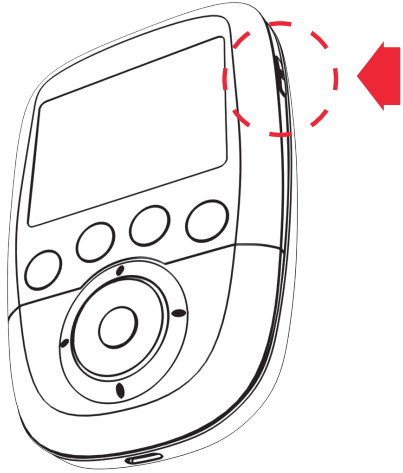
1 CHARGING



2 SYNCHRONIZING



3 POWER ON



4 SELECT LANGUAGE
(FIRST USE ONLY)



START A PROGRAM

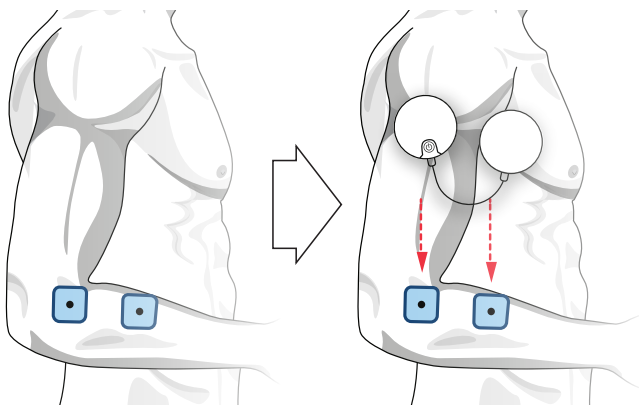
5 CHOOSING A PROGRAM CATEGORY



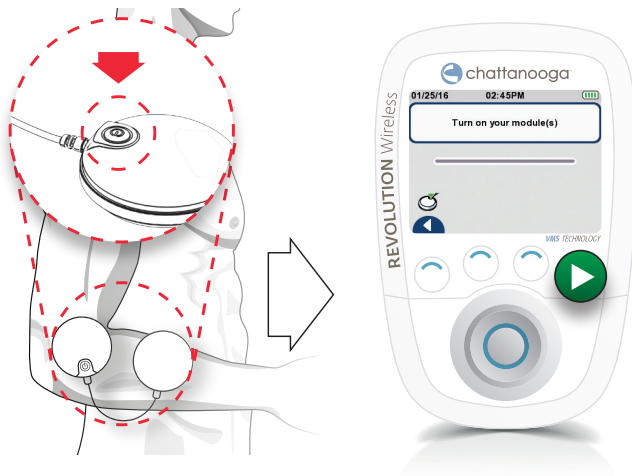
6 CHOOSING A PROGRAM



7 ELECTRODE AND MODULE SETUP



8 TURN ON MODULE (S)



9 INCREASE THE INTENSITY TO START STIMULATION



10 END OF PROGRAM

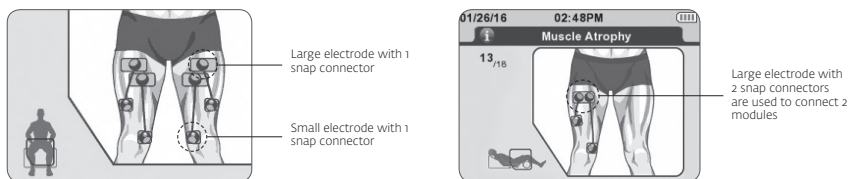


INSTRUCTIONS FOR USE

Do not let the modules come in contact with massage oils or similar products that could damage the device or its accessories.

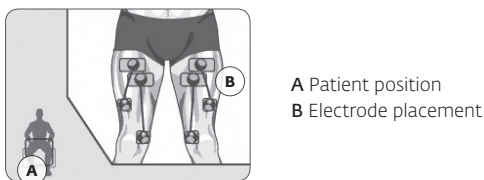
Placement of electrodes

The placement of the electrodes depends on the body area to be treated. Please find detailed recommendations regarding the electrode placement within your Revolution Wireless remote control. Depending on the electrode placement chosen for a desired program, different types and sizes of electrodes may be used. When using two modules, the 2 snap electrode can be utilized in place of two 1 snap electrodes, such that each module is connected to the 2 snap electrode. Refer to the image below illustrating a large electrode with 2 snap connectors used to connect 2 modules.



Patient positioning

To determine the best electrode placement and patient positioning, please refer to the electrode placement guide on the device remote control (see illustration below for example).



Adjusting stimulation intensity

Stimulation intensity settings

Stimulation intensity depends on the treatment objective and patient tolerance. A habituation period may be required to increase patient tolerance and permit the increase of the intensity to the desired level.

For Pain Management treatments, intensity will usually be sensory. Depending on the chosen protocol, the elicited sensation will either be mild-moderate sensory ("tingling") or strong-noxious ("almost painful").

For neuromuscular electrostimulation programs intensity will usually be motor. Depending on the chosen protocol, the elicited response will either be mild-moderate motor (mild contraction, smooth or twitch) or strong motor.

IMPORTANT INFORMATION

Treatment environments

The Revolution Wireless is a stimulator designed for use by healthcare professionals to provide electrical stimulation treatments in pain management (TENS) as well as for neuromuscular stimulation (NMES).

The Revolution Wireless unit is used in medical and therapeutic treatment environments such as hospitals, clinics, general practices and other health care locations by a skilled clinician. This device is not intended to be used in a home environment.

Contraindications

Do NOT use the Revolution Wireless under the following conditions:

- Patients with implanted electronic devices. Do not use the device on patients with a cardiac demand pacemaker, implanted defibrillator or other implanted electronic/electrical device.
- Patients with body worn electro mechanical medical devices, i.e., insulin pump.
- Serious arterial circulation problems in lower limbs
- Abdominal or inguinal hernia
- For symptomatic local pain relief without clearly established etiology.
- Do not use chest stimulation on patients with cardiac arrhythmia.

Additional Precautions

- Use caution for patients with suspected or diagnosed heart problems.
- Use caution for patients with suspected or diagnosed epilepsy.
- Use caution 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.
 - Over areas of the skin that lack normal sensation

Adverse Effects

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- Potential adverse effects with TENS are skin irritation and electrode burns.

IMPORTANT INFORMATION

Safety information

Definitions

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows:



DANGER!

Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.



WARNING!

Text with a "WARNING" indicator explains possible safety infractions that will potentially cause serious injury and equipment damage.



CAUTION!

Text with a "CAUTION" indicator explains possible safety infractions that have potential to cause minor or moderate injury or damage to the equipment.



Dangerous Voltage

Text with a "Dangerous Voltage" indicator serves to inform the user of possible hazards resulting in the electrical charge delivered in certain program configurations of waveforms.



Explosion Hazard

Text with an "Explosion Hazard" indicator will explain possible safety infractions if this equipment is used in the presence of flammable anesthetics.



BioHazardous materials

Text with a "Biohazard" indicator serves to inform the user of possible hazards resulting in improper handling of components and accessories that have come in contact with bodily fluids.

IMPORTANT INFORMATION



Explosion Hazard – Revolution Wireless is not designed for use in areas where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, oxygen-rich environments, skin cleansing agents and disinfectants.



Handle, clean, and dispose of components and accessories that have come in contact with bodily fluids according to National, Local, and Facility rules, regulations and procedures.

Stimulus delivered by the waveforms of this device, in certain configurations, will deliver a charge of 25 microcoulombs (μC) or greater per pulse and may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

Users with an implanted neurostimulation device must not be treated with or be in close proximity to any shortwave diathermy, therapeutic ultrasound diathermy, or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound, and laser) can be transferred through the implanted neurostimulation system, can cause tissue damage, or can result in severe injury or death. Injury, damage, or death can occur during diathermy therapy even if the implanted neurostimulation system is turned off.

The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the unit is used.

DO NOT connect the unit to an electrical supply without first verifying that the power supply is the correct voltage. Incorrect voltage may cause unit damage, malfunction, electrical shock, fire, or personal injury. Your unit was constructed to operate only at the electrical voltage specified on the Voltage Rating and Serial Number plate. Contact your DJO dealer if the unit is not properly rated.



Patient hazard –

- U.S.A Federal Law restricts these devices to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.
- Be sure to read all instructions for operation before treating a patient.
- Only authorized individuals are allowed to operate the Revolution Wireless. Individuals are authorized after receiving training in the operation of the unit and reading this operating on manual.
- The long-term effects of chronic electrical stimulation are unknown.
- TENS is not effective for pain of central origin (including headache).
- TENS waveforms have no curative value.

IMPORTANT INFORMATION



Warning!

- TENS is a symptomatic treatment, and as such, suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Before using the therapy unit, the operator must ascertain that it is in correct working order and operating condition. The cables and connectors, in particular, must be checked for signs of damage. Damaged parts must be replaced immediately, before use.
- Stop therapy immediately if you have doubts about the device settings and/or the therapy protocol.
- Patients must be fully conscious while being instructed in the use of the therapy unit and during therapy.
- Do not treat through clothing.
- Stop treatment immediately if patient experiences discomfort or pain.
- The choice of the therapy parameters to program, of the therapy protocols and electrode placement is restricted to the responsible physician or therapist. It is the physician's or therapist's decision whether or not to use the unit on a specific patient.
- The patient must be familiar with the functions of the Revolution Wireless remote control with the modules and the remote control must be within easy reach of the patient, allowing them to stop therapy, if needed. Patients unable to operate the emergency stop function (either by stopping on the remote control or by turning off the modules), e.g. paralytic patients, must never be left unattended during therapy.
- Use of accessories other than those specified in this User Manual may increase electrical emissions, decrease electrical immunity or lead to unsafe conditions.
- The utmost caution is advised under the following conditions. Depending on the judgement of the responsible physician, the unit may only be applied under supervision and with the parameters defined by the responsible physician. Otherwise the exercise may be too strenuous for the patients with:
 1. hypertension (> stage 2), ischemic heart disease and cerebrovascular diseases
 2. cardiovascular diseases
 3. Pregnancy. Safety of powered muscle stimulators for use during pregnancy has not been established.
 4. under 16 years of age

Never apply the electrodes as follows:

- Stimulation should not be applied transcranially, or on the eyes.
- Stimulation should not be applied over the anterior neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficult breathing.
- Counter-laterally, i.e. do not use two poles connected to the same channel on opposite sides of the body.

IMPORTANT INFORMATION

- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmia.
- Stimulation should not be applied over the carotid sinus nerve particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- If the person is pregnant or menstruating do not place electrodes directly on the uterus area or connect pairs of electrodes on either side of the abdomen to avoid any risk for the mother and/or the baby.
- Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.



Warning!

- Extreme caution should be taken when in use around small children and babies! Sufficient distance to the device and its accessories is mandatory for their safety!
- Never leave the device unattended when it is switched on! Switch the device off and disconnect the electrodes from the modules!
- After use, store the device in a safe place to avoid other people not informed to use the device!
- This device is not a toy but a medical device that misunderstanding use can cause damages!



Warning!

Shock hazard — Strictly observe the following warnings. Failure to do so could endanger the lives of the patient, the user and other persons involved.

- **Before use** allow the Revolution Wireless to reach room temperature. If the unit has been transported at temperatures below 0 °C (32°F), leave it to reach at room temperature for about 2 hours, until any condensation has disappeared.
- **Electrosurgical equipment or defibrillators.** Disconnect the electrodes from the device before using electrosurgical equipment, or a defibrillator, to avoid cutaneous burns from the electrodes and destroying the device.
- **Electronic surveillance equipment.** Do not apply stimulation near electronic surveillance equipment (e.g. cardiac monitors, ECG alarms), as there is a risk they may not work properly whilst the electrical stimulation device is being used.
- **Electromagnetic radiation.** Do not use the stimulator in areas in which unprotected devices are used to emit electromagnetic radiation. Portable communications equipment can interfere with the device.

IMPORTANT INFORMATION



Warning!

- **Cancer.** Do not apply stimulation if you have progressive cancer or near any cancerous tumour. The increased metabolism, caused by certain modes of stimulation, is likely to encourage cancer cells to spread.
- **Muscle shortening.** During the muscular contraction phase it is recommended to hold the extremities of the stimulated limbs to avoid any shortening of the muscle during contraction, which could cause cramps.
- **Contralateral stimulation.** Do not use two terminals connected to the same channel on opposite segments of the body (for example, a positive terminal on the left arm and a negative terminal on the right arm).
- **Loss of sensation.** Proceed with caution if stimulation is applied to areas of the skin whose level of sensation is lower than normal. Do not apply stimulation to a person who cannot express themselves.
- **Battery leakage.** If there is leak from a component, take steps to ensure the liquid does not come into contact with skin or eyes. Should this occur, wash the affected area with water and consult a doctor.
- **Strangulation.** Do not wind cables around the neck. Tangled cables can cause strangulation.
- **Post-surgery.** Proceed with caution after recent surgery.
- **Accessibility of the power adaptor.** The plug socket must be close to the power adaptor and be easily accessible.
- **Internal bleeding.** Proceed with caution if you are prone to internal bleeding; for example, after an injury or a fracture.

The Revolution Wireless must only be operated in dry rooms.

- **Do not use** the Revolution Wireless in water or in a humid atmosphere (sauna, Bath, Shower etc.) that would cause electronic failure.
- **Water protection.** The unit is not protected from the ingress of water.
- When connecting the unit to other equipment or when creating a medical system, check that the sum of leakage currents will not cause any hazard. Please contact DJO GLOBAL if you have questions regarding this matter.
- No modification of this equipment is allowed.
- Do not open the product and its accessories as there is risk of electrocution.
- Before cleaning and service interventions, **turn the remote control and the modules off and disconnect the tablet from the power line** by removing the power cord from the wall outlet.
- **Liquids and foreign material (such as dust, metal etc.) must not be allowed** to enter the remote control, the modules, the charging tablet or the power supply. If such material has entered into the units, it must be immediately checked by a service technician, before it can be reused.

IMPORTANT INFORMATION



- **Electricity supply.** Never connect the stimulation cables to an external power supply, as there is a risk of electrocution.
- Do not apply stimulation near the area of an implant, such as cochlear implants, pacemakers, skeletal anchorage or electric implants. This could cause an electrical shock, burns, electrical interference or death.
- Never use the Revolution Wireless or the AC adaptor if it is damaged or open. There is a risk of electric shock.
- Disconnect the AC adaptor immediately if there is abnormal heating or smell, or if smoke comes from the AC adaptor or the device.
- Do not place the docking station in a confined space (carrying case, drawer etc.) when charging the device. There is a risk of electrocution.

Equipment malfunction — these warnings refer to potential equipment malfunctions that could result in patient hazards.

- Magnetic and electrical fields are capable of interfering with the proper performance of the unit. For this reason make sure that all external devices operated in the vicinity of the unit comply with the relevant EMC requirements. → Devices that intentionally radiate electromagnetic energy, such as X-ray equipment, MRI devices, –radio systems and cell phones are possible sources of interference, as well as RFID equipment (e.g. electromagnetic security systems).
- Keep the unit away from such equipment and verify its performance before use. For additional information, refer to the EMC section of this Manual.
- Do not use the Revolution Wireless within 3 feet of short wave or microwave devices as this could alter the currents generated by the stimulator. If you are in any doubt as to the use of the stimulator in close proximity to another medical device, seek advice from the manufacturer of the latter or from your doctor.
- Exercise caution when using electrotherapy while the patient is connected to monitoring equipment with electrodes attached to the body. Stimulation could disrupt the signals sent to the monitoring equipment.
- Refer **repair and maintenance** to authorized persons. Persons are authorized after training by a specialist trained and commissioned by the manufacturer.
- Do not disassemble or modify the Revolution Wireless or its accessories. This may cause damage, malfunction, electrical shock, fire, or personal injury.
- Inspect the **Revolution Wireless** and its accessories for damage and loose connections at least **once a year**. Damaged and worn parts must be immediately replaced with original spare parts by authorized staff.
- Do not use the device if you are connected to a high-frequency surgical instrument as this could cause skin irritation or burns under the electrodes.

IMPORTANT INFORMATION



Read, understand, and practice the precautionary and operating instructions found in this manual. Know the limitations and hazards associated with using electrical stimulation. Observe any precautionary and operational decals placed on the unit.

Patient hazard — these cautions need to be observed to avoid the risk of electrical shock or other negative effects to the patient.

- The device is designed to comply with electromagnetic safety standards. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference by using one or more of the following:
 - Reorient or relocate the receiving device.
 - Increase the separation between the equipment (refer to the EMC section in this manual for recommended separation distances).
 - Connect the equipment to an outlet on a different circuit.
 - Consult your DJO dealer for assistance.
- Do not apply stimulation close to metal. Remove jewelry, piercings, belt buckles or any other metallic product or device in the area of stimulation.
- Be careful if the patient has sensitivity problems or is not able to communicate that he or she feels discomfort, however light.
- Never begin an initial stimulation session on a person who is standing. The first five minutes of stimulation must always be performed on a person who is sitting or lying down. In rare instances, people of a nervous disposition may experience a vasovagal reaction. This is of psychological origin and is connected with a fear of the muscle stimulation as well as surprise at seeing one of their muscles contract without having intentionally contracted it themselves. A vasovagal reaction causes heart to slow down and blood pressure to drop, which produces a feeling weakness and a tendency towards fainting. If this does occur, all that is required is to stop the stimulation and for the person to lie down with the legs raised until the feeling of weakness disappears (5 to 10 minutes).
- Never allow muscular contraction during a stimulation session to result in movement. You should always stimulate isometrically; this means that the extremities of the limb in which a muscle is being stimulated must be firmly fixed, so as to prevent any movement that results from contraction.
- Do not disconnect any module that is switched on during the stimulation session. They must be switched off first.

IMPORTANT INFORMATION



Caution!

- Do not use the stimulator while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury. Do not apply stimulation during sleep.
- Do not use the stimulator at altitudes of over 9,800 feet.
- Always turn off the stimulator before moving or removing any electrodes during a session, to avoid electrical shock to the patient.
- Do not try to place electrodes on a body part not directly visible without assistance.
- Attach the electrodes in such a way that their entire surface is in contact with the skin.
- For reasons of hygiene, each patient must have their own set of electrodes. Do not use the same electrodes on different patients.
- Contaminated electrodes or gel can lead to infection.
- Use of electrodes with degraded hydrogel can result in burns to the skin.
- **Size of electrodes.** Do not use electrodes with an active area of less than 16 cm² due to the risk of associated burning. Proceed systematically with caution when the density of the current is over 2 mA/cm².
- Do not place the electrodes in water.
- Do not apply solvents of any kind to the electrodes.
- **Skin irritation.** Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement. If redness of the skin is observed under the electrode, do not start another stimulation session on the same area if the redness is still visible.
- **Instructions for electrodes.** See the usage and storage instructions displayed on the bag of electrodes.

Equipment damage —

- **Do not let the modules get in contact with massage oils or any other products of the same type that could damaged the device or its accessories.**
- Check that the voltage and frequency ratings of your local power line are those indicated on the type plate of the power supply.
- Do not expose the **Revolution Wireless** to direct sunlight, because some of the components may reach unacceptably high temperatures.
- The unit is not protected from the ingress of water droplets from rain if used outside the carrying case.
- The presence of children, pets and vermin does not normally affect the proper functioning. However, make sure that these sources do not contaminate the physiotherapy unit and keep them away from it. Also, keep the unit clean and protect it from dust and lint. The safety rules and regulations set forth apply in any case.

IMPORTANT INFORMATION



Caution!

- It is recommended to use the transport bag that comes with the unit, for transport of the device, and to use a proper transport box to ship it.
- Always use the AC adaptor (power supply) provided by the manufacturer to recharge the unit.
- Do not store the modules and remote control for a long time with uncharged batteries.
- Only use electrodes supplied by the manufacturer. Other electrodes may have electrical properties that are unsuitable for or may damage the Revolution Wireless.

Note

- For best results and device safety, wash and clean the skin of any oil and dry it before attaching the electrodes.
- For more information on use and storage please consult the user manual.

Contact:

We would be happy to answer any questions you may have about our products and services. Please contact your local dealer, or your corresponding DJO Global site.

For technical service from DJO Global, please contact:

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MOTION IS MEDICINE⁺