User Manual

Sidra LEG

Lower limb rehabilitation robot

Read carefully before use

Apply to:
Sidra LEG Pro
Sidra LEG Ultra

Gliwice, Poland 2023

CE 2274

1. We are here for you!

Thank you for ordering your Sidra LEG
and welcome to our family!

At EGZOTech, we truly believe that **great user experience isn't just about great products, but reliable support, constant development, and understanding the needs of people using our products** - patients and therapists alike. We truly believe that together, we can change the future of healthcare and physiotherapy!

The next steps will **empower your therapy with Sidra LEG**!

To learn more about Sidra LEG, visit the following:

Our YouTube page for videos and tutorials!

https://youtube.com/EGZOTech

If you're having unexpected operation or events, issues, serious incidents or any trouble with your Sidra LEG, please contact us under the following:

Our Service Desk page:

https://service.egzotech.com

Other direct contact information

support@egzotech.com
https://egzotech.com
+48 32 750 49 45
EGZOTech Sp. z o.o.
Romualda Traugutta 6H
44-100 Gliwice, Poland

We provide additional resources for education, support, maintenance and webinars.
Feel free to check EGZOTech Courses available at https://courses.egzotech.com.

Any serious incident related to Sidra LEG has to be reported to EGZOTech and the competent authorities of the country. Please inform us by sending a message to the address: safety@egzotech.com.

2. Quick Setup Guide

2.1. Safety

Remember, Sidra LEG **can be dangerous if used incorrectly!**
Do not start using Sidra LEG before reading this manual, especially the
7. Warnings and basic safety chapter.

2.2 Unboxing

Sidra LEG is delivered with all ordered accessories in a package. On initial delivery, **please check the contents to confirm that everything you've ordered has been properly delivered.**

Before you start working with your Sidra LEG, let it warm up (or cool down) to its operating temperature (0-40 ℃).

2.3 Starting up your Sidra LEG

Step 1: Plug the device's AC cable to the power source. Push the power button located on the front of the device. Sidra LEG will turn on as well as its tablet which will provide the user with further instructions.

Step 2: Create a new patient profile with an unique ID or choose your already existing profile with a patient ID assigned to you.

Step 3: Mount the desired ankle extension **in the appropriate place (if it is not already mounted).** If it has not been mounted yet, the application will notify you, and guide through the extension.

Step 4: Measure the total length of your **thigh** (from the greater trochanter to the outer knee joint gap) **and calf** (from the knee joint to the foot), **adjust** the chassis lengths according to previously measured lengths of thigh and calf, **place** the leg in the device's chassis (if necessary perform additional adjustments), **insert** the final set lengths of the chassis into the patient's card in the application and **tighten** the clamping straps.
This step is performed only during the patient's first training session, information inserted into the application will be assigned to the patient's ID and saved for the future sessions.

Step 5: Perform the Basing. The Basing consists of two stages:

- Measuring Passive Range of Motion (ROM) performed by Sidra LEG during the maximal passive attachment and flexion of a patient's lower limb using the device's propulsion.
- Measuring Active Range of Motion (ROM) ,speed and torque performed by Sidra LEG during actively flexing the knee up to maximum, and extending the knee to the maximal extension point.

Step 6: The device is ready to use. After performing the basing, the training selection screen will appear.

2.4 Accessing the Application

Step 1: Visit the main page of the application.

Step 2: Create a new patient profile with an unique ID or choose an already existing patient ID assigned to you or your patient.

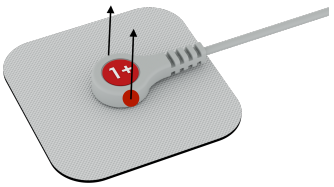
2.5 Finishing your work with Sidra LEG

Step 1: Disable electrical stimulation (if it was used) and end programs within the application first.

Never touch the electrodes during electrical stimulation. Always make sure that the stimulation is disabled first.

Step 2: Turn the Sidra LEG off by switching off the power button.

Step 3: Disconnect all the electrodes and cables from the patient's body (Sidra LEG Ultra only). Grab the cable snap (red mark located on the right and left side) and pull-off from the electrode by giving some force to detach it.



Step 4: Untighten the clamping straps on the patient's lower limb.

Step 5: Disconnect the electrode cables from the cable HUBs.

Step 6: Put everything in the transportation box.

EGZOTech

3. Table of contents

4. Where to get this manual?

Before use, always be sure to check whether this manual corresponds to the version of Sidra LEG you are using. EGZOTech is not responsible for any misuse that may arise due to using an older version of this manual.

Quick access to Sidra LEG's User Manual is available also through the device's software.

5. What is Sidra LEG?

Sidra LEG is a multi-use lower limb rehabilitation robot - rehabilitation exercise device intended for medical purposes of rehabilitation and physiotherapy, including therapy and evaluation of patient's state. It has two main function:

- Continuous passive motion
- Continuous active motion

Sidra LEG Ultra has additionally:

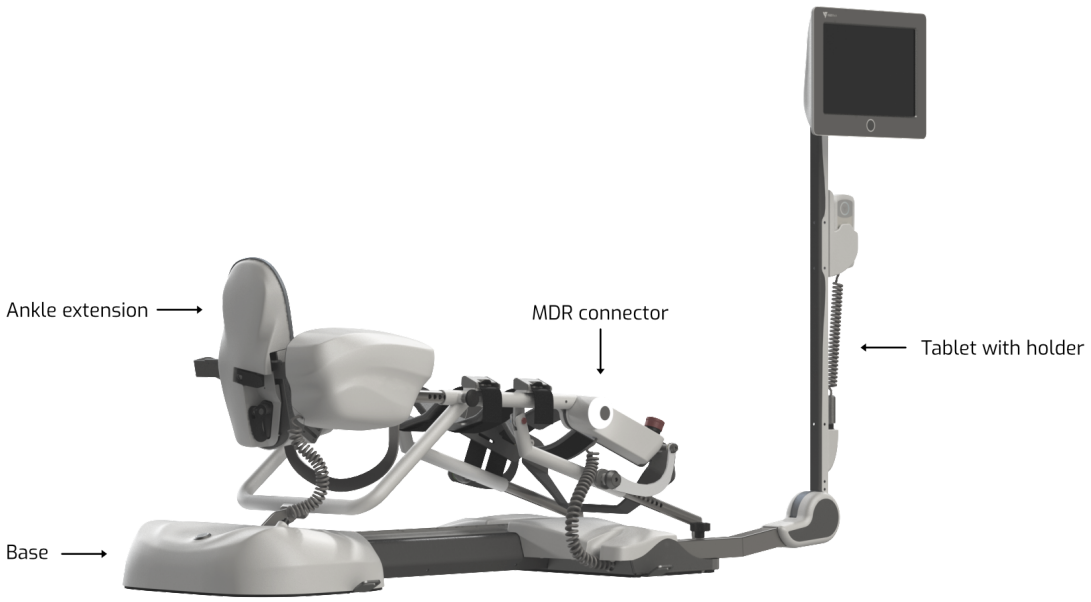
- Electromyography measurement and biofeedback
- Electrical muscle stimulation

The main value proposition are:

- Functional lower limb movement pattern with synchronised electromyography measurement and electrical stimulation in Sidra LEG Ultra only
- Ankle extension enabling active plantar flexion/dorsiflexion driven movement.
- Easy to use with pre-set therapeutic protocols

The Sidra LEG has four main parts:

- Base
- Chassis
- Tablet with holder
- Ankle extension



The therapy is conducted by selection of a proper range of motion and/or locating EMG or EMS electrodes (Sidra LEG Ultra only) and type of evaluation program or exercise. Sidra LEG is intended to conduct rehabilitation procedures in a lying or reclining with trunk support position. The robot is controlled using a touch screen equipped with proper software dedicated for the device.

Software: dedicated for the device, pre installed on tablet, offline.

Environments of use: Clinics, hospital and home environments.

6. User responsibilities

6.1 Indications for use

Sidra LEG is a multi-use lower limb rehabilitation robot - rehabilitation exercise device intended for medical purposes of rehabilitation and physiotherapy, including therapy and evaluation of patient's state. Sidra LEG is intended for the following:

- Physiotherapy, to:
  - Increase muscle strength;
  - Increase the limb range of motion;
  - Increase coordination;
  - Relaxation of muscle spasms;
  - To relearn voluntary motor functions of the extremities;
  - Muscle re-education and relaxation;
  - Relief and management of pain;
- Physiotherapy and occupational therapy using electrical stimulation (Sidra LEG Ultra only), to:
  - Increase the limb range of motion; (using EMS);
  - Relaxation of muscle spasms with EMS;
  - Muscle re-education and relaxation with EMS;
  - To relearn voluntary motor functions of the extremities with EMS;
  - Increasing local blood circulation;
  - Immediate post-surgical stimulation to prevent venous thrombosis;
  - Prevention or retardation of disuse atrophy;
  - Relief and management of pain with using EMS;
- Rehabilitation assessment, to:
  - Evaluate muscle innervation by surface electromyography (Sidra LEG Ultra only);
  - Evaluate ranges of motion;
  - Evaluate limb rigidity and spasticity;
  - Evaluate maximal muscle strength;
  - Evaluate fatigability.

This list is not meant to be exhaustive.

Patient group

The product is intended to be used by all groups of patients (irrespective of the age, height of weight), giving consideration to the maximal allowable values provided in the user manual.
Patient groups should be considered among others:

- Low mobility patients (external use) - patients with possible severely impaired mobility and lack of sensation in their limbs, patients with impairment level 0-2 in the Lovette's scale, even with difficulties of correct definition of their possible muscle strength due to such a huge loss of mobility.
- Non-low mobility patients (external use) - patients with mobility impairment above level 3 in the Lovette' scale.
- Orthopedic patients requiring limb mobilization.

List is not meant to be exhaustive

6.2 Intended users

Sidra LEG is intended for two primary user groups:

PATIENTS - especially suffering from the conditions listed in the **6.1 Indications for use**. **Sidra LEG Pro** is for you, to help you achieve the benefits of using in Continuous Passive Motion (CPM) and Continuous Active Motion (CAM) motorized movement programs with your therapist, as well as, by yourself in a home and home healthcare environment. **Sidra LEG Ultra** is for you, to help you achieve the benefits of

the combination of electromyography and electrical stimulation used in Continuous Passive Motion (CPM) and Continuous Active Motion (CAM) motorized movement programs with your therapist, as well as, by yourself in a home and home healthcare environment. Feel free to use electromyography biofeedback functionalities, as they are considered safe to use in most cases. Remember however to take care while working with Sidra LEG (read the safety instructions!). You need training and consultation from a healthcare professional on how to use electrical stimulation safely before you start using it yourself.

We do expect patients using Sidra LEG themselves to be adults (at least 18 years old) with at least 8 years of education. You have to be conscious and understand the risks and dangers of using Sidra LEG. If you have any doubts about whether you understand this manual and especially the **7. Warnings and basic safety** chapter, please ask your therapist for assistance with Sidra LEG.

MEDICAL PROFESSIONALS - healthcare service providers of one of the following specialities: a physical therapist, an occupational therapist, a rehabilitation doctor, a neurologist, a nurse or nurse practitioner, an orthopedic doctor and other general practitioners. Sidra LEG is definitely a tool for you, to use in daily clinical practice (both in-patient and out). If you're a medical professional, you will be in charge of prescribing treatment procedures, including CPM, CAM and, in Sidra LEG Ultra, an electrical stimulation parameters for your patients. Feel free to use this manual and the resources gathered here to expand your knowledge and find a quick guide on how to proceed with your patients.

We do expect medical professionals to have graduated with a higher education degree of at least bachelors and are adults (at least 18 years old). Please make sure that you fully understand the contents of this User Manual and the principles of electromyography and electrical stimulation, before you start working with your patients with Sidra LEG. If you have any doubts, especially the **7. Warnings and basic safety** chapter, feel free to reach out to EGZOTech directly and we will do our best to help you.

6.3 Contraindications

When **not to use Sidra LEG** (contraindications):

- Acute, pronounced, severe or persistent pain symptoms, despite conventional pain therapy in the trained extremity or pain caused or intensified by the training,
- Unable to adjust to the patient position or anatomy,
  Do not carry out training with the system if the adjustment to the patient is not possible, e.g. due to individual physiologic position of the patient, patient's anatomy, limb sizes or lengths, contractures or severe spasticity (joint is fixed/rigid), warped joint surfaces of the trained extremity,
- Severe joint rigidity, spasticity or extremely limited range of motion that can be negatively impacted by low-level passive movement training (risk of injury) (e.g. due to contractures, fixation within the joint, impants, spastic paralysis, arthrodesis etc.),
- Insufficient compliance from the patient, patients with severe psychotic, neurotic disorders or cognitive deficits impeding communication, uncooperative children, neuro-psychological conditions,
- Uncooperative or (self-) aggressive behavior, such as transitory psychotic syndrome,
- High-grade or severe ataxia,
- Fractures, osteosynthesis, advances osteoporosis, fracture risk, osseous instability, non-consolidated fractures, osteopenia, osteogenesis imperfecta, unstable vertebral column, pseudoarthrosis, osteomyelitis, considerably reduced bone density,
  Do not perform training in case of unstable or insufficiently consolidated fractures,
- Unstable vital functions (pulmonary or cardio-circulatory),
- Total or partial loss of sensitivity, e.g. due to lesions,
- Material intolerances, e.g. allergies to washing detergent, adhesive intolerances.
  There might be an allergic reaction to electrodes (Sidla LEG Ultra only),
- Body or limb weight or dimensions exceeding technical specs,

- Deep venous thrombosis,
- High-grade fever,
- Flaccid, spastic phase neurological lesions,
- Lesions in acute phase of evolution,
- Hyperthermia,
- Irritation,
- Bleeding,
- Lesions of the meniscus, with presence of free intra-articular bodies,
- Vascular lesions, vascular disorders of the trained limbs,
- Lesions in conjunctive tissue,
- Severe effusion,
- Joint instability,
- Osteomyelitis,
- Severe joint subluxation of the trained extermity.

Contraindications for Electrical stimulation only (Sidra LEG Ultra only):

- Patients with cardiac demand pacemaker or any implanted defibrillator,
- No stimulation in the proximity of metal implants,
- Pregnancy (Electrical stimulation),
- Feverish or infectious diseases,
- Skin disorders subject to inflammation, as well as thrombosis or phlebitis,
- Body-worn electro mechanical medical devices, i.e. insulin pump,
- Cardiac arrhythmia (do not use on chest),
- Serious arterial circulation problems in lower limbs,
- Abdominal or inguinal hernia,
- Patients with electronic life support equipment, such as respirators,
- Patients with electronic medical devices attached to the body, such as electrocardiographs,
- Patients with other electronic medical devices (device may cause erroneous operation of those devices,
- Placement of electrodes near the head / with current flowing through the carotid sinus or the chest with undiagnosed pain symptoms / disease,

Relative contraindication - The treating physician or therapist evaluates the patient individually and must assess whether training with Sidra LEG is suitable for the patient in case of:

- Apraxia,
- Epilepsy,
- Pacemakers and similar devices, other electrical stimulators, implants, including implanted medication pumps.
  Pacemakers can react differently to external influences. It is, therefore, important to be aware of relevant or possibly dangerous influential factors for the specific pacemaker model. Patients must be informed that there is 5W electromagnet, which enables to attach extensions to the device.
- Infections,
  Including Septic tenosynovitis, until infection is controlled,
  Untreated or uncontrolled infection,
- Joint problems, and degenerative bone diseases, including arthritis, arthrosis, bone cancer
  Joint strain during training can cause pain and irritation in case of diminished load-bearing capacity,
- Neglect,
- Orthostatic circulation problems: increased risk of falling,
- Skin problems, swelling, skin ulcerations, open wounds, decubitus,
  Before and after every training, check for previously existing wounds and wounds or pressure points caused by training, in particular in bodily areas that contact the device,

- Acute strain (musculotendinous unit) or sprain (non-contractile tissue),
- Soft tissue healing constraints (such as immediately after surgery),
- People with difficulties to understand should only use the device under supervision,
- Pregnancy,
- Acute inflammatory processes in the joints, unless on the order of a physician, inflammation, inflammatory diseases,
- Patients with (long-term) infusions,
- Severe postural instability,
- Patients who have been ordered to remain immobile.

The lists above do not claim to be exhaustive.

For patients with relative contraindications, it's possible to use Sidra LEG with successful results, but having the parameters (maximal torque, maximal speed) set for the specific needs of that patient. Take extra caution working with relative contraindications.

6.4 Facility responsibilities

Remember, that Sidra LEG is a device that is intended to help patients, but if used incorrectly, may lead to injuries.

Before working with a patient, the supervisor is required to familiarize the patient with the indications and contraindications above. The decision whether to use Sidra LEG in a specific medical condition remains with the supervisor. All actions done by the supervisors and their consequences remains the facility. View EULA (End User License Agreement) for details.

For information about the nearest authorized representative or trainer, contact EGZOTech.

6.5 Internet connection

The Internet connection allows you to fully use the potential of Sidra LEG. The connection with the Internet is voluntary and largely depends on the safety policy of the health care facility. However, a permanent connection to the Internet allows you to keep the software updated.

Not connected to the Internet does not affect the basic functions and core operation of the Sidra LEG.

A reliable Internet connection is required to ensure the best user experience of Sidra LEG. If your application works less then seamlessly, contact your product specialist.

7. Warnings and basic safety

Sidra LEG Ultra is an electronic medical device incorporating direct electrical connection with the patient's body with the intent of measuring electromyography and providing physiological currents through electrical stimulation as well as motorised movements of patients lower limb such as CPM and CAM. Due to that, **Sidra LEG Ultra can be dangerous if used incorrectly**. Please **read the safety information below and follow the guidelines provided in this manual**.

7.1 General safety considerations and precautions

Sidra LEG has been created for specific physiotherapy treatment and exercises. **Do not use Sidra LEG for any other purpose not included in this manual or training videos provided by EGZOTech**.

Before starting to treat each patient or be an operator of Sidra LEG you should look at least the information about the intended treatment, contraindications and safety measures.

Sidra LEG is intended to be used with touch software running on a provided tablet. The tablet provided with Sidra LEG has been chosen based on numerous parameters and has been configured for best user experience. **Do not exchange the provided tablet for any other device!** Using the software and/or Sidra LEG with any other device is not intended and may lead to injuries.

You should never operate Sidra LEG on yourself, if your motor skills are insufficient to fully operate the device, e.g. to stop it, disconnect the cables or react to any adverse situations. In such cases, seek professional care or assistance.

Keep caution while using Sidra LEG in an event of changes in its performance. If you experience any changes, please contact EGZOTech through one of the channels provided at the end of this manual. Please refrain from using Sidra LEG if you experience any performance changes.

Any serious incident related to Sidra LEG needs to be reported with EGZOTech and the competent authority of the Country in which the user and/or patient is based. Please inform us by sending a message to address: safety@egzotech.com.

Use Sidra LEG only with EGZOTech authorized accessories! That includes all the package contents listed in chapter **9. What will I find in the package?**. **Use only the AC cable supplied**. **Do not plug third party sensors, electrodes or other accessories.**

Sidra LEG's measurement functions, including electromyography (in Sidra LEG Ultra only), are susceptible to electromagnetic disturbances. As such, please be aware of other electromagnetic devices or installations that can affect measurements. Sidra LEG meets the electromagnetic compatibility requirements, including immunity to electromagnetic disturbances, providing basic safety. If you encounter any signal artifacts or noise, discard the measurements and don't consider them diagnostically relevant.

Sidra LEG Ultra is not intended to be used with needle electrodes.

Persistent use of the device in the presence of skin irritation may be injurious and that improper use may result in electrode burns.

Do not use Sidra LEG outside of its operating environment, including temperature or humidity, specified in the chapter **10.2 Technical Specification** in this manual.

Do not use any of Sidra LEG Ultra's electrostimulation programs while sleeping.

Use of Sidra LEG by a child only under the supervision of an adult.

The device should be kept out of the reach of children and pets.

Do not make any modifications to Sidra LEG and the extensions. That includes removing the installed screws. Modifications to the device may affect the safety of the device and its compliance with safety and performance requirements.

Warning: Use of the device with visible damages is forbidden and can lead to injury. In case of any noticeable damages on the device, stop using the device and please contact the service.

Do not make any modifications to Sidra LEG and the extensions. That includes removing the installed screws. Modifications to the device may affect the safety of the device and its compliance with safety and performance requirements.

7.2 Clinical safety

- Warnings while using Sidra LEG:
    - No transcerebral applications,
    - No stimulation in the vicinity of the carotid artery or carotid gland,
    - No contralateral stimulation (i.e. plus and minus pole of the same channel on opposite sides of the body),
    - Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias,
- The patient should consult his/her clinician if there is any change in an existing condition or if any new condition develops.
- Any serious incident related to Sidra LEG needs to be reported with EGZOTech and the competent authority of the Country in which the user and/or patient is based.
- Using the device on patients with demand-type cardiac pacemakers may be hazardous.
- Sidra LEGproduces results that are informative, not diagnostic. Qualified individuals must interpret the results.
- Keep caution while using Sidra LEG for patients with suspected or diagnosed heart problems.
- Keep caution while using Sidra LEG for patients with suspected or diagnosed epilepsy.
- Keep caution while using Sidra LEG for patients with body-worn electromechanical medical devices, i.e. insulin pump, electronic medical devices attached to the body and other medical devices e.i. cochlear implant, electrical or skeletal implants.
- Keep caution while using Sidra LEG with patients with serious arterial circulation problems in the lower limb.
- Keep 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 areas of the skin which lack normal sensation.
- Patients should consult their physicians before using Sidra LEG if they have any of the following:
    - Muscle atrophy,
    - Persistent pain,
    - After trauma or a recent operation (less than 6 months prior),
    - Need for muscle rehabilitation.
- Do not use Sidra LEG with patients or if you're diminished mental capacity or physical competence limiting the use of the device.
- Use of Sidra LEG should be immediately terminated upon any sign of treatment-related distress or discomfort.
- Patient's position during the therapy must be anatomically correct.

7.3 Electrical safety and electromagnetic compatibility

Sidra LEG has met the requirements of ISO 60601-1-2 for electromagnetic compatibility, including immunity, however, **while running Sidra LEG near high frequency/power medical devices, follow the safety manuals of those devices.** Incorrect use of other devices, and non-compliant devices may influence the parameters of Sidra LEG.

In an event that **Sidra LEG doesn't behave in an intended manner, turn the power switch off** and notify your product specialist or our customer support immediately.

Sidra LEG is running on specific electrical parameters. **Ensure that you have a grounded AC socket compatible with the requirements specified** in chapter **10.2 Technical Specification**.

Avoid stretching, riding over, tying up or any activity that could damage the AC cable, remote control cable, tablet's holder or EMG/EMS cables.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

To unplug the device from the power supply, pull it for the plug, not the cord.

Do not disconnect the device from mains power supply during therapy (except emergency).

Do not transport Sidra LEG while it is connected to power supply.

Sidra LEG is electrically safe, even in the event of a single subsystem failure. Nevertheless, if you witness any problems regarding cables, chassis or any safety elements, take extra caution and contact your product specialist.

Sidra LEG Ultra hasBF type applied parts (elements that are intended to get in contact with a patient). Applied parts are used to transfer mechanical energy to the patient (make the patient limbs move), and to transfer electrical energy from and to the patientI (Sdira LEG Ultra only) Those parts have extended electrical safety parameters and are labeled according to the symbols table in chapter **8.3 Symbols**.

Do not connect leads or electrodes to other objects.

Simultaneous connection of the patient to a high-frequency surgical device and to an electromyograph or to a device for recording burst biopotentials, can cause burns at the site of application of the electrical stimulator electrodes or electrodes of the input part for biopotentials and possible damage to the electrical stimulator or biological amplifiers (Sidra LEG Ultra only).

Do not use the Sidra LEG Ultra unit within 1.5 meters of shortwave or microwave devices as this could alter the output generated by the stimulator. If you have any doubts when using the stimulator in close proximity to another medical device, please contact the device manufacturer or your doctor.

Keep caution to avoid accidental contacts between Sidra LEG's Ultra patient lead wires and/ or electrodes with other equipment with conductive parts, including parts connected to the ground.

If you witness any wear and tear problems or damage regarding cables, chassis, or any safety elements, take extra caution and contact EGZOTech.

Use of accessories and cables other than those specified or provided by EGZOTech of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Sidra LEG complies with the requirements of IEC 60601-1-2 (EMC Collateral Standard) including the E-field susceptibility requirements at a level of 9 volts per meter, at frequencies from 80 MHz to 2.7 GHz. However, even at this level of device immunity, certain transmitting devices (mobile phones, two-way radios, cordless phones, paging transmitters, RFID devices, etc.) emit radio frequencies that could interrupt Sidra LEG operation if operated in a range too close to the Sidra LEG. Practitioners should

be aware of possible radio frequency interference if portable devices are operated in close proximity to the Sidra LEG.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Sidra LEG, including cables. Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to or stacked with other equipment should be avoided, because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The electrostimulation treatment needs to be stopped before disconnecting the electrodes (Sidra LEG Ultra only).

7.4 Electrical stimulation safety (including TENS, Sidra LEG Ultra only)

Electrical stimulation should **only be used after training from a therapist**. Always consult your physician before using electrical stimulation, to choose the right output parameters and program for you.

Never touch electrodes directly during electrical stimulation. In distress or unexpected operations of Sidra LEG, immediately push the emergency stop button.

Always check the impedance, distance between the electrodes, and their wear and tear between uses. Using worn or torn electrodes may cause severe burns.

Do not use electrical stimulation wearing clothes lined with, made with or including conductive (especially metal) materials. Do not apply stimulation near metal elements. Remove jewelry, body piercings, belt buckles or any other removable metallic product or device in the area of stimulation. Metals on the body and within worn clothes can conduct electricity during electrical stimulation, causing severe burns. Metal can also impact electromyography measurements.

The long-term effects of chronic electrical stimulation are unknown.

Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

Stimulation should not be applied over the 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 difficulty in breathing.

Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

Stimulation should not be applied transcerebrally.

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 over or in proximity to cancerous lesions.

Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

Stimulation should not be applied in proximity of abdominal or inguinal hernia because the great tension in the abdomen and pelvic floor may worsen this condition.

Stimulation should not be applied in proximity of the abdominal and back for the patients with intestinal clamps.

During a stimulation session, do not disconnect electrodes when stimulation is running. Stop the stimulation first.

For output exceeding 10 mA or 10 V, please make sure to use electrodes meeting those output requirements.

Safety of TENS devices or powered muscle stimulators for use during pregnancy or delivery has not been established.

TENS is a symptomatic treatment and as such may suppress the sensation of pain that would otherwise serve as a protective mechanism on the outcome of a clinical process.

Electrode placement and stimulation settings should be based on the guidance of the prescribing medical practitioner.

The special attention of the operator is required when current density exceeds 2 mA/cm^2. A hazard could exist if excessive current densities are present. Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.

Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

Portable powered muscle stimulators 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.

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. If skin irritation occurs, discontinue use and consult your physician.
If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

TENS is not effective for pain of central origin, as compared to pain of peripheral origin.

TENS is of no known curative value.

The treatment outcome will be influenced by the patient's psychological state and use of drugs.

TENS should be used only under the medical supervision of a physician or under the supervision of a qualified medical practitioner to whom the patient is referred by a physician.

Do not use electrical stimulation with cardiac demand pacemakers, implanted defibrillators or other implanted electronic devices, unless specialist medical opinion has first been obtained.

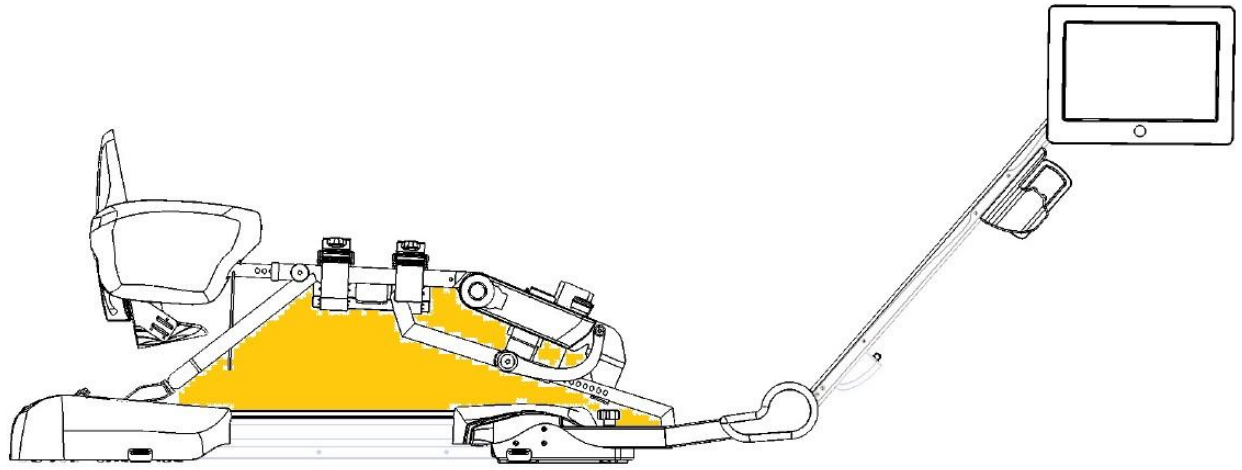
While using electrical stimulation electrodes, make sure that the impedance displayed is correct in the software. The adhesive properties of electrodes do not transfer to good conductivity.

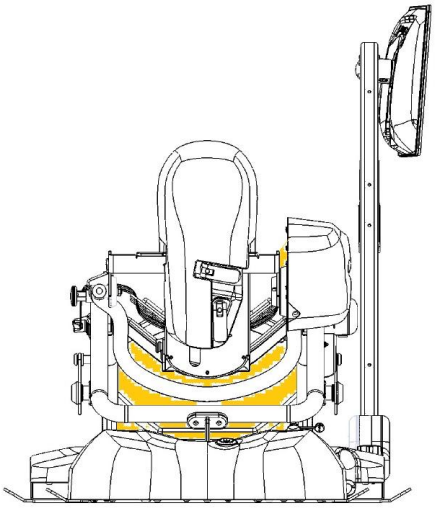
7.5 Mechanical safety

Do not step or stand on any part of Sidra LEG.

Sidra LEG has trapping zones located on both sides between the connectors (connecting the upper and lower part of the frame) and the upper frame part of the device.
Do not put any body parts or other objects in any of those trapping zones while Sidra LEG is moving. Putting objects in the trapping zones during normal operation may cause injuries.

The trapping zones are shown in the picture below.





The device must be fully visible throughout the time of use. Never cover the device (e.g. with bed linen or any other material) during the operation.

During the therapy the remote control must be placed in the patient's hand so that the patient can stop the therapy in case of discomfort, pain, irritation or other danger. Give the remote control to the patient before starting the system. Patients that are not able to use the remote control should not be left without supervision of the operator.

Before use, always check Sidra LEG and accessories for mechanical damages. Do not use Sidra LEG or any accessories, when a damage was noticed.

Do not make any mechanical modifications to Sidra LEG and the accessories. That includes removing the installed screws.

In a rare event of an uncontrolled, unintended movement of Sidra LEG, press the emergency stop first, and then proceed with unstrapping your patient from the device.

Keep small children away and keep caution not to get entangled in the patient lead wires. Strangulation and asphyxiation are possible!

Always plug the least amount of channels, as needed for the training, to limit unnecessary risk.

Keep small children away and keep caution not to inhale or swallow small parts. Choking hazard.

Use the Sidra LEG only on firm, flat, level surfaces.

Simultaneous use of two Exercisers EMG for exercising both legs is not permitted.

7.6 Multiple use precautions and consumables

Sidra LEG has been tested to be reliable for multiple use and cleaning with the disinfection products described in the **19. Cleaning**. The use of different cleaning products can have varying results and can lead to contamination, surface deterioration, loss of biocompatibility and malfunction.

Caution should be used for the disposal of Sidra LEG. Sidra LEG shouldn't be thrown out, or improperly utilized due to electronic components. Consult your product specialist on how to act best to utilize Sidra LEG that won't negatively impact the environment.

Surface electromyography electrodes are designed for single-use. **Using the same electrodes multiple times will lead to signal degradation and possible misuse and incorrect evaluation**.

Sidra LEG is a specialized electrical device and contains dangerous voltages inside, **therefore maintenance is limited only to authorized EGZOTech personnel**. If a malfunction happens, call your product specialist or our customer support immediately. EGZOTech provides the necessary technical information to all maintenance personnel.

Electrical stimulation electrodes are designed for single person use only. Note: The life time of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage and climate (Sidra LEG Ultra).

Sidra LEG accessories and the device itself will experience normal wear and tear over time. Possible degradation of performance over time is possible, especially in electrical connections between the cables and electrodes as well as between snaps and electrical stimulation electrodes themselves.

7.7 Biological safety

Never use Sidra LEG **with compromised or wounded skin**.

Sidra LEG (the device) is intended for surface - **skin contact only. Avoid contact with mucosal membranes and breached or compromised surface**, or in any case inside your body. Sidra LEG has been analyzed for biocompatibility that includes cytotoxicity, sensitization, and irritation or intracutaneous reactivity, however **if you or your patient experience an allergic reaction, irritation, or signs of toxicity, whether from Sidra LEG or any other source, cease all training** until the underlying cause has been dealt with.

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 (Sidra LEG Ultra).

Clean and disinfect Sidra LEG after every patient to avoid transmission of infectious diseases.

The user or the medical service provider must contact its local authorities to determine the proper method of disposal of potentially biohazardous materials, including but not limited to: surface electrodes, straps or other Sidra LEG accessories etc.

7.8 Environmental safety

Do not perform service, maintenance and modifications of Sidra LEG by yourself! Use only service providers authorized by EGZOTech.

Always use and store Sidra LEG, the accessories and electrodes according to their storage instructions. Please consult the accompanying documents for electrode storage instructions.

Do not use Sidra LEG in an oxygen-rich atmosphere.

Do not use Sidra LEG in a dangerous environment (includes explosion risk, gas risk, etc.).

Sidra LEG is intended for usage in a moisture-free environment. Keep away from water, including generated by other devices, e.g. kettles, nebulisers, showers etc.

Sidra LEG is intended to be used in the operating temperature, humidity and air pressure specified in **10.2 Technical specification**.

Sidra LEG is intended to be used in a home environment, a home healthcare environment (e.g. retirement homes) and a healthcare environment (e.g. hospital, clinic).

Sidra LEG should be used in well lighted rooms.

Sidra LEG is intended for indoor use only.

Dust, water, lint or other pollutants can interfere with electronics, especially if they are located near the cable connectors. Please clean Sidra LEG periodically, according to the **19. Cleaning**.

Due to Sidra LEG's sensitivity and risk of damage during improper handling, please keep away from kids, pets and pests.

Sidra LEG's Ingress Protection code (IP) is specified in the **10.2 Technical specification**. The rating is IP21, therefore:

- It is rated 2 for solid particle protection of objects larger than 12.5 mm (0.49 in). This means that the enclosure provides protection against hazardous parts, especially electrical conductors and the ingress of solid foreign objects of the mentioned size.
- It is rated 1 for liquid ingress protection of dripping water. This means that the enclosure provides protection against harmful ingress of water, to the extent of vertically dripping water.

Do not immerse Sidra LEG in water or any other liquid substance, including water vapor.

7.9 Software safety and cybersecurity

Do not use different applications while using Sidra LEG App, as it can disturb normal operations.
Do not install any unapproved applications. **Untested software can interfere with Sidra LEG's normal operations!**

7.10 Lifetime

Do not perform service, maintenance and modifications of Sidra LEG by yourself! Use only service providers authorized by EGZOTech.

Do not open Sidra LEG or perform any service and maintenance activities while the Sidra LEG is in use.

Keep Sidra LEG and accessories clean. Follow the **19. Cleaning** provided.

Sidra LEG, due to moving **mechanical parts, will experience wear and tear**. Due to some safety features being implemented by the use of those mechanical parts, periodical maintenance is required, based on your Sidra LEG usage. Sidra LEG's maintenance can be performed after a single fault has occurred. Official maintenance personnel approved by EGZOTech or its partners can perform **periodic maintenance to ensure continuous stability and reliability of the device to prevent single fault conditions**. **There is a mid-life (every 2 years) major tune-up required**.

7.11 Annual maintenance

As with any medical device, to ensure ongoing safety and viability of Sidra LEG an **annual tune-up maintenance is required**. Your product specialist will schedule these maintenance visits with you. We strongly recommend you avoid skipping the annual tune-up maintenance and in unforeseen events contact your provider immediately. EGZOTech is not liable for any events that happen due to skipping the annual tune-up maintenance.

7.12 Risks and Benefits

As a medical device, Sidra LEG was developed for therapeutic application of lower limbs. Sidra LEG is intended for motor rehabilitation of lower limbs. You can find a complete list of indications in chapter **6.1 Indications for use**.

Sidra LEG Pro has safety features to provide complex treatment based CPM and CAM motorized movements of lower limb muscles. Sidra LEG Ultra has safety features to provide complex treatment based on electromyography biofeedback and electrical stimulation used in CPM and CAM motorized movements of lower limb muscles. The positive treatment results were confirmed and a concept of the device is well described in literature, based on the clinical trials. Relying on the clinical literature research, clinical evaluation and the similar devices introduced on the market the effectiveness of the treatment concept is confirmed.

Available information for similar devices and risk analysis conducted by manufacturer indicated that likelihood and severity of risk for Sidra LEG is low. Sidra LEG fulfills safety requirements included in standards.

Based on clinical evaluation benefits from device use in the therapeutic and evaluation scope as well as owing to the presented measures limiting the possible risk, one can state that the benefits significantly exceed the potential risk.

The patient should consult his/her clinician if there is any change in an existing condition or if any new condition develops.

Any serious incident related to Sidra LEG needs to be reported with EGZOTech and the competent authority of the Country in which the user and/or patient is based.

Sidra LEG produces results that are informative, not diagnostic. Qualified individuals must interpret the results.

Use of Sidra LEG should be immediately terminated upon any sign of treatment-related distress or discomfort.

Manufacturer provides appropriate warnings and labeling which limits the possible risk.

8. How to work safely with Sidra LEG?

8.1 Why this user manual is so important

Sidra LEG is an electrical medical device incorporating direct electrical connection with the patient's body with the intent of measuring electromyography and providing physiological currents through electrical stimulation. As such, **Sidra LEG can be dangerous if used incorrectly**. Please **read the safety information below and follow the guidelines provided in this manual**.

8.2 Labeling

Sidra LEG's label is placed on the base of the device. On the label user will find information on the owned unit of Sidra LEG. Sidra LEG uses safety symbols on the device itself, inside of the software application as well as on accessories packages. The following points contain an explanation of all the symbols you'll encounter while using Sidra LEG.

Sidra LEG Pro EU label

Sidra LEG Ultra EU label

8.3 Symbols

Sidra LEG labels are on the bottom of the device.

Sidra LEG uses safety symbols on the device itself, as well as inside the software application and on packages with accessories. Below is an explanation of all the symbols you'll encounter while using Sidra LEG.

Symbol	What it means	Symbol	What it means
	Indicates the medical devices manufacturer		Indicates the date when the medical device was manufactured

Symbol	What it means	Symbol	What it means
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	SN	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Applied part type BF, used for electrical connections to and from the patient. Part isolated from all other parts of the device		Emergency switch
CE 2274	CE marking indicates that a product complies with applicable European Union regulations. No 2274 is a no of Notification Body	Made in Poland	The country of origin must be visibly printed on the product and packaging
 courses.egzotech.com	Indicates the need for the user to consult the instructions for use	~ 100 -240 VAC 50/60Hz 2.2A 245 W (T 4AL, 250V fuse)	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005	MD	Indicates the item is a medical device
	FCC mark		Indicates the temperature limits to which the medical device can be safely exposed
	The device generates radio frequency energy during operation		Indicates a medical device that needs to be protected from moisture
	Indicates the range of humidity to which the medical device can be safely exposed		Indicates a medical device that can be broken or damaged if not handled carefully

Symbol	What it means	Symbol	What it means
	This way up		Do not roll
	Do not stack		No sitting
	No stepping on surface		Refer to the operating instructions
IP21	Ingress Protection		

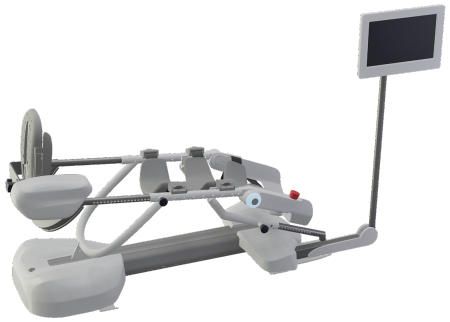
8.4 Accessories symbols

Symbol	What it means	Symbol	What it means
	Indicates the manufacturer's catalog number so that the medical devices can be identified		Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates the date after which the medial device is not to be used		Indicates a medical devices that is intended for one single use only
	Indicates that a medical device that should not be used if the package has been damaged or opened and that the users should consult the instruction for use for additional information		Indicates a medical device that needs protection from light sources
	PVC free		Latex free
	Ag/AgCl Sensor		

9. What will I find in the package?

Depending on your order and configuration, you may find the following products associated with Sidra LEG included.

9.1 Sidra LEG

What does it look like?	Description
	Sidra LEG robot 1 pcs. Ankle extension Code: SL-Ext-02 1 pcs.

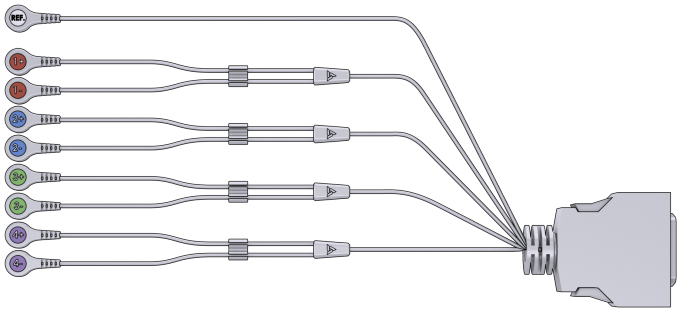
9.2 AC Cables

What does it look like?	Description
	AC Cable Length: 3m Plug types: B, E, F, G 1 pcs.

AC Cable IEC C13 available with the following standards: CEE7 (EU plug), BS1363 (UK plug), Plug K (Denmark, Bangladesh plug).

9.3 EMG/EMS cable (Sidra LEG Ultra only)

- All channel cables and reference cable are combined into one connector (MDR connector)
- Each channel cable has 2 separate wires coming out of the splitter
- Wire has snap connector to the electrode
- Channel cables of length 80cm, reference cable of length 30cm
- Reference cable is shorter than channel cable

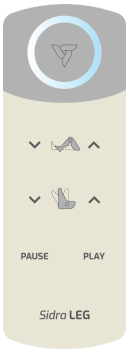


9.4 Tablet with holder

- Tablet - computer and screen is on holder
- Communication with device via CAN
- Has USB connection for special use under the cover
- Option to change placing due to exercised leg (left or right)
- One manual button
- 10.1" screen size
- One hand operated
- Without changing orientation of screen

9.5 Remote control

- Patient pause button
    - Connected via cable to the device

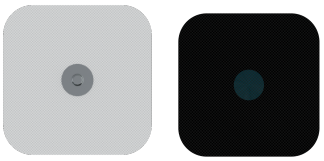
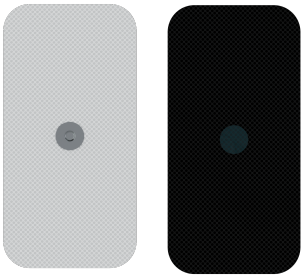


9.6 Electrodes for surface electromyography

What does it look like?	Description
	EMG surface electrode EGZOTech EE S5540 FWG Electrode area intended to contact the surface of the skin: 3,8 cm^2 55x40 mm 50psc/case For EU only Manufactured by: Sorimex Sp. z o.o. Sp. k. ul. Równinna 25 87-100 Toruń, Poland
	EMG surface electrode EGZOTech EE S5540 FWG1 Electrode area intended to contact the surface of the skin: 44x35 mm 3,8 cm^2 50psc/case For EU only Manufactured by: Sorimex Sp. z o.o. Sp. k. ul. Równinna 25 87-100 Toruń, Poland

9.7 Electrodes for electrostimulation

Follow the information provided with the electrodes by their manufacturer.

How does it look like	Description
	Small electrical stimulation electrode (5cm x 5cm) UltraStim Snap SN2020 4psc/case Area intended to contact the surface of the skin: 25 cm^2 *Optional* Manufactured by: Axelgaard Manufacturing Co.,Ltd. 520 Industrial Way Fallbrook, CA 92028, USA
	Large electrical stimulation electrode (5cm x 10cm) UltraStim Snap SN2040 4psc/case Area intended to contact the surface of the skin: 50 cm^2 *Optional* Manufactured by: Axelgaard Manufacturing Co.,Ltd. 520 Industrial Way Fallbrook, Axelgaard 92028, USA

9.8 Positioning cushion

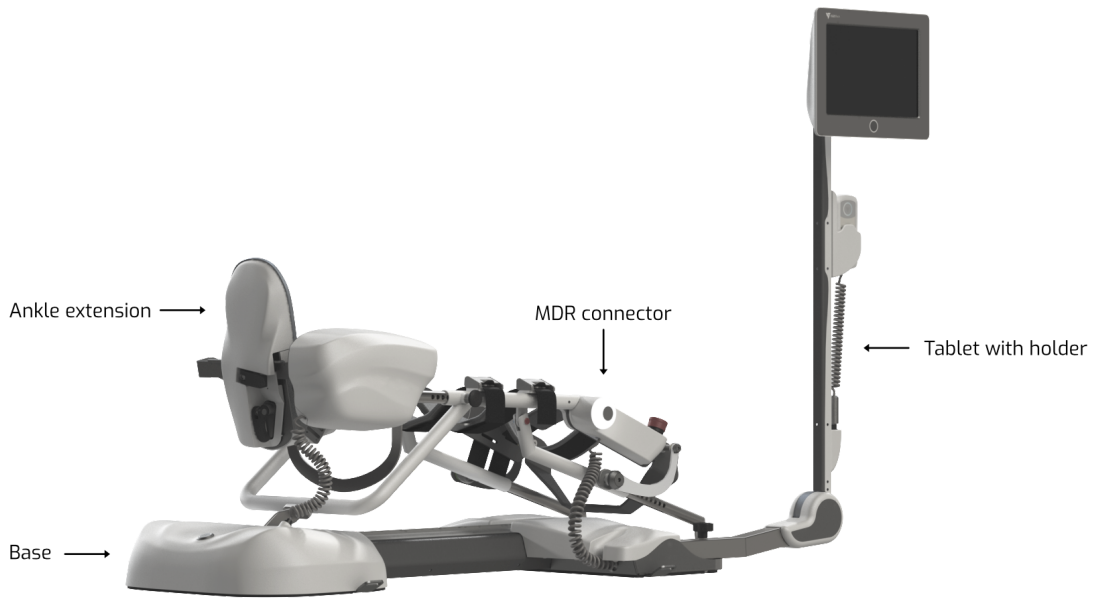
- To better positioning patient in lying position
- To better stabilization of the device during active exercisers

9.9 Transport box

- Box where operator can put and storage device
- For transport from manufacturer to the client
- Reusable
- Protection the device during deliver

10. Basic information about Sidra LEG

10.1 How is Sidra LEG built



10.2 Technical Specification

DIMENSIONS & WEIGHT:
Total length: 875mm (without screen holder) - 1155 - 1890mm (with screen holder)
Total width: 530 mm
Total height: 530 - 905 (max. holder) mm
Total weight (with ankle extension): <20 kg

ENVIRONMENT:
Operating temperature: 10 °C to 40 °C
Operating humidity: 5 % to 95 % RH, not-condensing
Maximum operating altitude: 3 000 m a.s.l.
Cooling: convectional
Liquid ingress and solid particle protection: IP21
Mobility: Portable
Operation type: Continuous, software controlled

OTHERS:
Power supply: 100-240V ~ 50/60 Hz grounded with PE, interial
Current required: max. 2,2A at 240VAC
Protection class against electric current: class I
Fuses used: 4A (T4AL250V)
Applied part type: BF

MECHANICAL PARAMETERS:
HIP ROM: from 0° to 115°
Knee ROM: from -10° to 125° (for rotation 120°)
Flexion/Extension Ankle ROM: from -25° to 45°
Rotation Ankle ROM: from -40° to 40°
Knee/hip speed: 0.2 - 20°/s
Ankle speed: 0.2 - 60°/s
Knee/hipforce: 1 - 65 kg (Autorewers)
Ankle torque: 20 Nm
Ankle torque measurement accuracy: ± 0,1 Nm
Thigh force measurement: ± 0.5 kg
Goniometer measurement accuracy: ± 2°

ELECTROMYOGRAPHY (Sidra LEG Ultra only):
Electromyography measurement channels:
Up to 4, simultaneous sampling
Baseline noise: <0.5 µV RMS
Input-referred noise: 10µVpp (10 seconds of raw data)
Measuring Voltage range: -0.6V to 0.6V
Sidra LEG's Gain: 1
Sampling frequency:
Up to 1 000 samples per second per channel
Internal resolution: 24-bit

Communication: Wired and Wireless (WiFi, Bluetooth), USB

PATIENT SIZES:
Thigh length (from the greater trochanter to the outer knee joint gap) : 30 - 49 cm
Calf length (from the knee joint to the foot): 42 - 61 cm
Passive ankle extension calf length: 23 - 59 cm
Weight of leg: max. 30 kg

CMRR: -73dB
Input impedance: 10MΩ
Electromyography accuracy: ± 0.5 % full scale

ELECTRICAL STIMULATION (Sidra LEG Ultra only):
Electrical stimulation channels: Up to 4, sequential
Waveforms and types:
Low-frequency, dual-phase, and direct current free rectangular, triangular, and trapezoidal pulses, electromyography-triggered
Maximum output voltage and current:
50 V / 100 mA at 500 Ω
Waveform generation accuracy: ± 0.5 % full scale
Output Resolution: 16-bit
Sampling frequency: Up to 1 000 000 samples per second
Load impedance: 500 - 2000 Ω

10.3 LED Ring display indications

During usage of Sidra LEG, it is important to monitor the activity of the device based on LED Ring communication, located on the device's chassis near the patient's knee.

The LED Ring display consists of multicolour (RGB) LED diodes ordered (multiplexed) in a full circle. During standard Sidra LEG operations, those diodes will light up to notify the users of dangers, emergencies, as well as current states. The table below is a list of the most important notifications, but different exercises can generate their own notifications.

Description	Tablet Display	Operators Activity	Status
The LED ring lights up slowly in white, then flashes slightly	Tablet displays Sidra LEG's home screen	After plugging the device's AC cable and/or switching the power switch on	**Turning on**
The white LED ring pulses slowly in white.	Tablet displays home screen / training choice screen	-	**Standby mode**
The LED ring performs a flow animation	Tablet displays appropriate training screen	-	**Ongoing training session**
The LED ring flashes slightly and then slowly begins to dim until it stops glowing.	Tablet display shuts down	After switching off Sidra LEG through the application or by switching the power switch off	**Turning off**

Description	Tablet Display	Operators Activity	Status
The whole LED ring flashes yellow	Tablet displays appropriate warning notification	Check the notification in the app and follow the instructions in the app. e.g. check the cable connection	**Warning**
The whole LED ring flashes red	Tablet displays appropriate error notification	Check the error notifications in the application and follow the instructions in the app. If there is a problem, a service request form is available at: https://service.egzotech.com	**Error**

10.4 Typical issues

Anyone who attempts to repair and/or modify the Sidra LEG and/or its accessories risks damaging the Sidra LEG and/or accessories. Therefore, any steps not described in the troubleshooting guide are prohibited. Improper use voids all warranty claims.

Problem	Possible Cause	Solution
Sidra LEG does not turn on	AC cable plugged incorrectly AC cable not plugged Power switch turned off	Replug the AC cable Plug in the AC cable Turn the power switch on
Sidra LEG does not detect the extension	Attachment cable plugged incorrectly Attachment cable not plugged to the device's chassis	Replug the attachment cable Plug in the attachment cable to the device's chassis
Weak electrostimulation	Dried out or damaged electrodes Incorrect electrode placement Worn or damaged lead wires	Replace and re-connect electrodes. Replace and re-connect electrodes. Replace leads.
Intermittent EMG signal	Electrode lead set is loose or disconnected. Electrodes dried out or damaged or were not in contact with bare skin.	Check the lead set connections in both the Sidra LEG and electrodes. Change the electrode to a new one.
The EMG signal cannot be controlled	Electrode cable is not connected properly.	Check and improve connection cable and reference.

Problem	Possible Cause	Solution
	Reference cable is not connected properly. Electrode lead set is loose or disconnected. Electrodes dried out or damaged or were not in contact with bare skin.	Check the lead set connections in both the Sidra LEG and electrodes. Change the electrode to a new one.
Sidra LEG does not move	Device's drive malfunction	Contact with EGZOTech. service request form is available at: https://service.egzotech.com

10.5 Emergency stop

Main emergency stop

- Located on device housing

Sidra LEG has one emergency stop that will stop all movement of Sidra LEG by cutting the motor power supply. The emergency stop button on the Sidra LEG is located near the thigh, on the chassis, pointed upwards, and can be pushed both by the therapist and the patient in case any danger occurs.
Emergency stop does not switch off the power of Sidra LEG entirely. In case of a fire, water spill or any other non-mechanical malfunction, step away from Sidra LEG as soon as possible.

11. Extensions

11.1 What kind of extensions do I have?

The following table contains information on what kind of movements are possible using the provided ankle extension.

Joint	Motorized Movement	Flexion Extension
Hip	Flexion/Extension	**Yes**
	Abduction/Adduction	No
	External/Internal Rotation	No
Knee	Flexion/Extension	**Yes**
	External/Internal Rotation	No
Foot	Flexion/Extension	**Yes**

12. Electromyography (Sidra LEG Ultra only)

12.1 Basics of electromyography

Electromyography is an electrodiagnostic medicine technique for evaluating and recording the electrical activity produced by skeletal muscles. The signal originates from the depolarisation of the motor units and muscle fibers by the action potentials (signals generated in our motor cortex, going through the spinal cord and into skeletal muscles). The more motor units get activated simultaneously during muscle contraction, the higher the amplitude of EMG RMS signal.

12.2 Lead wires and channels for EMG

The cable have colour coded snaps for each of the differential EMG channels:

Color	Channel name
Red	Channel 1
Blue	Channel 2
Green	Channel 3
Purple	Channel 4
White	Reference

For electromyography it's essential to connect both positive and negative inputs of one channel to the same muscle.

For each EMG program (whether evaluative or therapeutic) you will need at least 3 connected electrodes (2 of the same color, connected to one channel and one white Reference electrode).

The reference electrode can be connected to any part of the skin surface that is not under evaluation or is not a part of the training routine, near the bony landmark.
The closer the reference electrode will be to the measured channel, the less electromagnetic interference there will be.

Electromyography and electromyography biofeedback can be safely used by any user - patient or therapist alike.

12.3 Electrodes

For differential channels (positive "+" and negative "-") to ensure the reliable training-to-training comparison of results we advise the use of electrodes with a fixed distance between the electrode snaps (e.g. 2cm). Do not use any unauthorized electrodes, especially lacking the necessary safety certificates.

Use only EMG electrodes approved by the EGZOTech.
Never use the single use electrodes more than once, and never on more than one patient.

Never use the single use electrodes more than once, and never on more than one patient.

12.4 EMG Electrode arrangement and configurations

Because electromyography is connected to motor unit action potentials and the depolarisation of muscle fibers, there are multiple factors that influence the reliability of the EMG signal acquisition, including:

- Electrode specific factors:

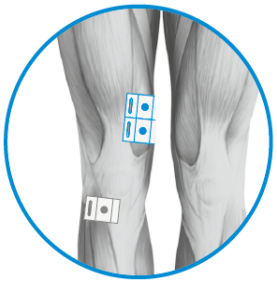
  - Area and shape of the electrode detection surfaces, which in turn determines the number of active motor units and innervated muscle fibers – same type of electrodes should be used to compare different results,
  - Distance between the electrodes that determines the bandwidth of the differential electrode configuration – should be constant for each measurement,
- Location of the electrode with respect to the motor points determines the amplitude and frequency characteristics as well as comparability between a series of measurements. The further from the motor point, the more the amplitude decreases,
- Crosstalk with other muscles due to close proximity of the electrode positions – electrodes should be placed in the middle of the belly and away from the lateral edge. With smaller muscles, crosstalk should be taken into consideration during result interpretation,
- Orientation of the bipolar configuration of the electrodes with respect to the muscle fibers – affecting measured conduction velocity, amplitude and frequency of action potentials (depolarisation of muscles).

Follow these steps to maximize reliability, sensitivity and accuracy of your electromyography measurements.

1. Remove hair from the patient's skin in the application area, when necessary. Clean with appropriate cleaning and disinfecting agents.

2. Always use EGZOTech approved electrodes, listed in this User Manual, as electrode properties like gel type, conductivity, snap dimensions can greatly influence measurements.

3. Connect the surface electrodes to the lead wires before you connect them to the patient's skin. Connect the electrodes marked blue to the snaps of the same color and the electrode marked Gray to the Reference lead wire (with the REF sign).



4. Select a muscle you want to measure.

5. Place the first electrode on the center of the muscle.

6. Place the second electrode adjacent to the first electrode, along the muscle fibers, so that the distance between the electrodes can be the same each time.

7. Place Reference electrode (marked gray) with the white lead wire ending and REF sign to the skin that is not under evaluation.

8. Place electrodes on to dry and clean skin.

Remember to put the reference electrode on the skin outside of the trained muscle. If you're using more than one channel, remember to select muscles for each channel.

13. Electrical stimulation (Sidra LEG Ultra only)

13.1 Basics of electrical stimulation

Electrical stimulation should **only be used after training from a therapist. Always consult your physician** before using electrical stimulation, to choose the right output parameters and program for you.

Electrical stimulation provides muscle contraction by conducting an electric current through the muscle fibers of the targeted muscle. It mimics the action of signals coming from the nervous system.

Electrical stimulation programs in Sidra LEG are:

- **EMS programs** - programs enable electrical stimulation of the motor neurons.
- **EMG - triggered EMS** - involves initiating a voluntary contraction for a specific movement until the muscle activity reaches a pre-set threshold level, and then an assisting electrical stimulus begins.

13.2 Lead wires and channels for EMS

For electrical stimulation you should use two outputs from one channel positive "+" and negative "-" corresponding to 2 lead wire snaps of the same color.

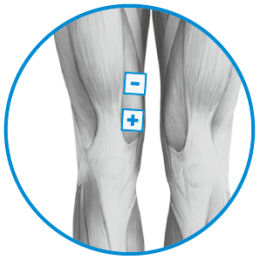
13.3 EMS Electrode arrangement and configurations

In Sidra LEG, a two-electrode electrical stimulation is used. The method involves placing two, equal-size electrodes on the skin in places corresponding to the transition of the muscle to the tendon. This method is usually used in the case of electrostimulation of denervated muscles. The two-electrode electrical stimulation method can also be used with good results in stimulating healthy or slightly damaged muscles to contract.

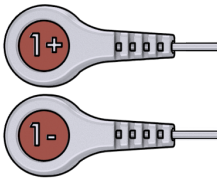
Use only electrodes authorized by EGZOTech described in chapter **9. What will I find in the package?. Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.** Electrode properties like dimensions, conductivity, impedance and connector types can greatly influence safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

Bipolar electrode placement, two stimulation electrodes are placed to affect the target area. In this way, the current flow through tissue is more limited to the excitable tissue of interest. **Do not exceed an intensity of 0.1 Watt/cm^2.**
Follow these steps to maximize reliability, safety and accuracy of output parameters for your electrical stimulation.

13.3.1 EMS Programs - Electrode Arrangement

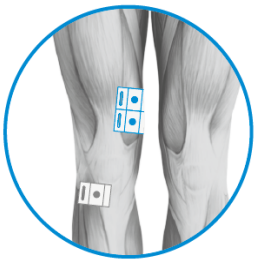


1. Make sure the electrical stimulation is off and Sidra LEG LEDs do not indicate any abnormalities or program operation. before proceeding.
2. Select the size of the electrical stimulation electrode according to the width of the stimulated muscle. Use larger electrodes for wider muscles and smaller electrodes for thinner muscles.
3. Connect the self-adhesive electrodes to the lead wires snaps of the same color.
4. Remove the protective liner from the electrode. Save the liner.



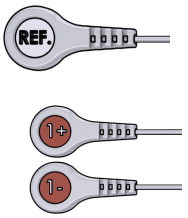
5. Skin must always be clean, dry and free from lotion. Do not apply to injured skin.
6. Place the negative (-) electrode on the proximal end of the muscle. Apply the electrode securely to the skin. Apply center first, then smooth down to electrode edges.
7. Place the positive (+) electrode on the distal end of the same muscle. The distance between the electrodes should be minimum 1 cm.

13.3.2 EMG - Electrode Arrangement for EMG-Triggered EMS Program



Follow **13.3 EMS electrode arrangement and configuration** to connect surface EMS electrodes (marked blue) to one channel.

Place third, Reference EMS electrode (marked gray) connected to the white lead wire snap with REF sign. The reference electrode must also be attached to the extremity that is the object of therapy, near the bony landmark.



13.4 Electrical stimulation mode

This type of mode enables electrical stimulation based on preset programmes.

Parameter	Description	Clinical relevance
Type of current	Direct current is at most basic level continuous and flows in only one direction. Alternating is a current that passes in one direction and then another. Pulse current is the current (direct or alternating) in which	Direct current is used for iontophoresis. The alternating current is used mainly for innervated muscle contraction and sensory stimulation, and the pulses are joined and continuous. However from the point of view of nerve excitation, the direct/alternating current is irrelevant.

Parameter	Description	Clinical relevance
	there is a gap between successive pulses.	The pulse current is distinguished from the alternating current because the pulses are separated. This means less energy may be delivered to the tissue when using this type of current.
Current amplitude	Magnitude of current with reference to the zero-current baseline at any one moment. It can be referred to as the intensity of stimulation.	Increasing current amplitude will increase the amount of one delivered to the tissues under the electrode. It contributes to the sensory or motor response the electrical current produces. The current amplitude is one of the determinants of torque production when using neuromuscular electrical stimulation. Increasing the current amplitude increases the percentage of muscle activated; increasing the current amplitude results in a proportional increase in the torque produced and the size of the activated cross-sectional area of stimulated muscle.
Current polarity	Biphasic pulse: charged particles move in one direction and then in the opposite direction.	If the current is polar, physiological effects will include alterations in the cell membrane permeability, causing different responses under positive (anode) and negative (cathode) electrodes. For example, a marked hyperemia is usually expected under the cathode and a decreased nerve excitability is expected under the anode.
Pulse duration	The elapsed time between the beginning and end of all phases in a single pulse; on a clinical stimulator is often incorrectly labeled "pulse width".	The greater the pulse duration, the greater the skin impedance and the greater the patient's discomfort. Increasing pulse duration has been shown to increase the charge of the pulse and motor unit recruitment. Alternating the pulse duration is dependent on the patient's comfort and desired therapeutic effect. However, pulses with too short duration are inefficient.
Pulse frequency (F)	The number of pulse cycles generated per unit of time for pulse current.	Frequency of the pulses has been studied extensively because of its important role in determining the torque development and controlling muscle fatigue. Increasing frequency results in a sigmoidal increase in torque production but concurrently accelerates muscle fatigue.
Waveform shape (rectangular, triangular and trapezoidal shape)	Geometric shape of the pulse as it appears on the graph of current (or voltage) versus time	Little clinical research has examined the clinical effect of using different pulse shapes. Previous studies showed that there were individual differences in preferences for three different waveforms of sinusoidal, sawtooth and square symmetric biphasic waveform and no particular waveform that was either the least or most comfortable to the patient during neuromuscular electrical stimulation.

Parameter	Description	Clinical relevance
Stimulation mode (when more than one channel)	Reciprocal, asynchronous or sequential	Channels operate in a simultaneous or alternating fashion, per set duty cycle. In sequential stimulation, multiple stimulation channels are used (usually, to separately activate multiple synergist muscles), thereby allowing motor units to rest when the corresponding stimulation channel is not active. Asynchronous stimulation also uses multiple stimulation channels. However, the stimulus pulses are delivered in an interleaved manner so that lower stimulation frequencies are achieved at each stimulation frequency is achieved at each stimulation channel while retaining a high composite stimulation frequency.

Medium-frequency alternating current parameters		
Carrier frequency	Frequency of underlying alternating current waveform in the burst	Medium frequencies are used to diminish the impedance offered by the skin and subcutaneous tissues, turning the current more comfortable to the patient. Thus, by diminishing skin impedance, the discomfort normally incurred by traditional low-frequency current is reduced.
Burst	The generation of 2 or more consecutive pulse or cycles separated (by burst interval) from the next series of consecutive pulse or cycles	The burst duration has a role in torque production, discomfort and fatigue.
Burst frequency or modulation	Frequency at which bursts are generated.	This parameter focuses on the fatigue possibilities of muscles if the frequency is high (>50 or 60 Hz). In low frequencies we have good recruitment of nervous fibers (between 20 and 50 Hz), and in very low frequencies (2-10Hz) the nervous fiber relaxes the muscle fibers.
Burst duty cycle	Burst duty cycle of medium-frequency alternating current, expressed as a percentage, can be defined as the ratio of the burst duration to the total time of the cycle.	Burst duty cycle, similarly to burst duration, has an impact on torque production, discomfort, and fatigue.

14. Software

14.1 How to launch the application?

Sidra LEG's application is launched automatically on its tablet after plugging in the device's AC cable to the power source and switching the power button on.

The application through which Sidra LEG is controlled works in kiosk mode - Operation Mode of the application for Sidra LEG on a device configured by the EGZOTech team.

14.2 Registration

User creates a new patient profile by generating a new profile ID. No additional information such as password or patient's name/surname is required.

14.3 Signing in

The user can sign in by clicking the profile tile with their unique Patient ID in the application's home screen.

14.4 Patient's profile

After logging in, the user will see their patient's card with the history of training sessions and training sessions prescribed by the therapist.

15. How to set up a training program

The following sequence of steps can be executed only after performing all of the activities described in the point **2.3 Starting up your Sidra LEG**

Step 1: After the user successfully performs Basing, the training selection screen is displayed allowing the user to choose between three options: "Suggested", "Filters" and "All".

Step 2: The user chooses an exercise they want to perform. The detailed training list is available in chapter **16. Programs Overview**.

Step 3.1: (EMG/EMS - Sidra LEG Ultra only) After choosing the training involving EMG or EMS the user has to connect electrodes to appropriate lead wire channels before applying them to the patient's skin.

Next to the channel icon is a marker indicating the quality of the connection between the electrode and the skin.

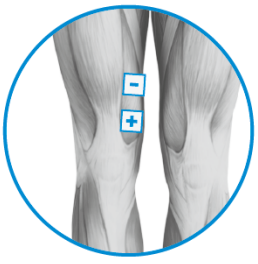
Channel colors in the software correspond to the lead wire colors.

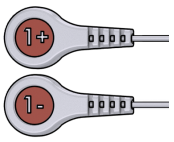
Step 3.2: (EMG/EMS - Sidra LEG Ultra only) The user applies the Electrodes to the patient's skin based on Electrode placement for the selected muscle or body part, displayed in the software.

For EMG Biofeedback programs and EMG Games use EMG electrodes. For EMS programs use EMS electrodes.
The program will show what electrode to use for each exercise.

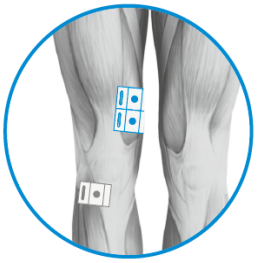
The user will see the electrode placement to guide you on how to correctly place the electrodes for that muscle.

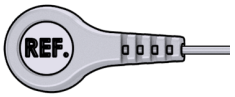
Place Electrodes connected to the snaps with a "+" and "-" sign in the appropriate place as shown on the icon.





(EMG) You should connect the Reference electrode to the white single lead wire with the REF sign if there is a gray electrode on the software icon.





For more detailed instructions on electrode choice and electrode placement see chapter **13.3 EMS Electrode arrangement and configurations** and chapter **12.4 EMG Electrode arrangement and configurations**.

Use only electrodes authorized by EGZOTech described in chapter **9. What will I find in the package?**. **Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.** Electrode properties like dimensions, conductivity, impedance and connector types can greatly influence safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

Step 4: The user confirms being ready to start the training.

Step 4.1: (EMG/EMS - Sidra LEG Ultra only) In the EMG triggered Electrostimulation programs, EMG Biofeedback and EMG Games, it is necessary to calibrate the measurement range. In order to do this, generate a Maximal Voluntary Contraction (MVC) with the muscle(s) on which the electrodes are located.

Once the setup is done, press the "Finish Calibration" button.

Step 4.2: (EMS - Sidra LEG Ultra only) In programs that use electrostimulation, it is also necessary to calibrate the intensity of the flowing current according to the individual patient's feelings before starting the workout. Press +1 to increase the intensity and -1 to decrease the intensity by 1mA.

See chapter **17. EMS Programs settings** to see the complete list of parameters and list of adjustable parameters.

Once the setup is done, press the "Finish Calibration" button.

Step 5: Conducting the training.

Press the “Play” button to begin your training. Treatment display views vary for the exercises. If you want to see the training windows for different programs, go to Chapter **16. Programs Overview** for more detailed information.

Step 6: After training is done, disconnect the electrodes.

Step 7: See chapter **2.5 Finishing your work with Sidra LEG** and chapter **19. Cleaning**.

16. Programs Overview

16.1 Continuous Passive Motion (CPM)

16.1.1 Classic

Classic Continuous Passive Motion (CPM) is a standard therapy exercise where Sidra LEG applies appropriate torque, moving a static patient with a constant speed through the set range of motion. When a maximal value of range of motion is reached, CPM will switch the direction of the applied torque and guide the patient's limb to another direction. During the CPM the patient is to remain static.

16.1.2 Progressive

Similarly to the regular CPM exercise, progressive CPM also applies a set torque, moving a static patient with a set maximal speed but the range of motion starts off at a specific point and is extended gradually. The therapist can set the increments of the range of motion as well as the starting position of the movement. As in regular CPM, when a maximal value of range of motion is reached, Progressive CPM will switch the direction of the applied torque and guide the patient's limb to another direction. During the Progressive CPM the patient is meant to remain static.

16.2 Continuous Active Motion (CAM)

16.2.1 Dynamic Reversal

Continuous active motion (CAM) are exercises where Sidra LEG provides dynamic resistance (based on the applied torque) and allows the patient to move freely throughout the range of motion. Dynamic reversal is achieved when the patient voluntarily participates in dynamically and rapidly changing the direction of movement when an end of the range of motion is reached. With such exercises an evaluation of the maximal muscle strength can be performed.

16.2.2 Weightlifting

Sidra LEG provides the possibility to perform isotonic exercises with a fixed torque at specific direction (towards the center of gravity point).

16.2.3 Elastic Resistance

Sidra LEG provides a gradually increasing torque, starting from the starting point and until the torque multiplier reaches the maximal torque specified during configuration.

16.3 Proprioception

Proprioception is a sense that allows us to determine the positioning and sensation of movement of parts of our own body without visual control. Deep sensing, although unconsciously, is also essential in performing daily life activities. It is an integral part of the process of managing perception.

The sense of proprioception has a very important role in human functioning - it is a component of the process of sensing joint movement (kinesthesia) and sensing joint position during passive and active movement.

The sense of proprioception can be presented as the ability of central nervous systems (CNS) to manage the process of collecting and processing of sensory ascending-afferent information collected in the periphery by receptors called proprioceptors.

16.3.1 TTDPM (Threshold to Detect Passive Motion)

Angular velocity sensing threshold for passive motion detection - determining the sensitivity of the motion system by finding the lowest perceptible angular velocity of motion interpretable as the sensation of motion

16.3.2 JPR (Joint Position Reproduction)

Recreating the joint angular alignment position previously set as a test - also known as joint position adjustment:

A- passive or active conditions (passively or actively)

B- ipsilateral or contralateral

16.3.3 AMEDA (Active Movement Extent Discrimination Assessment)

Ability to distinguish the position of the angular range of motion (ROM) in a joint between different settings.

16.3.4 Reproduction of angular velocity of motion

The exercise involves reproducing the angular velocity of movement of the lower limb by the patient.

16.3.5 Repetition of achieved muscle forces/moments of muscle forces

Exercise involves repetition of the achieved muscle forces or moments of muscle forces by the patient's limb

16.4 EMG biofeedback - Sidra LEG Ultra only

EMG enables operators to assess EMG activity of the surface muscles and allows patients to perform simple exercises with EMG biofeedback. EMG biofeedback mode also enables biofeedback games controlled by EMG signals. For EMG Biofeedback Games the patient has to control the game via muscle contractions. There are different levels of difficulty and tutorials to guide the patient through the game. Each EMG channel has two differential inputs: positive “+” and negative “-“. For each EMG program the user will need at least 3 connected electrodes. One of those electrodes is the Reference Electrode. The reference electrode can be connected to any part of the skin surface that is not under diagnosis or is not a part of the training routine. The closer the reference electrode will be to the measured channel, the less electromagnetic interference there will be. The placement of the positive “+” and negative “-“ leads of the same channel should be in the same distance from each other for every training and should be placed in the middle of the monitored muscle’s head with each electrode lead pointing towards the opposite tendons.

16.5 EMG - triggered movement - Sidra LEG Ultra only

EMG-triggered training is a training using a technology to detect the extremely small electrical EMG signals still measurable to initiate the exercise with the attachment. This group of training helps patients after stroke and other neurological difficulties whose muscle activity is not enough to generate a joint movement but the muscle is not degenerated with a possibility to rebuild its activity.

16.6 Typical use cases

Basic schemes of device use were defined on the basis of a device usability analysis.

Clinical Use:

1. Therapist performs all of the steps described in chapter **2.3 Starting up your Sidra LEG**
2. Therapist chooses an exercise program for the patient.
3. The operator connects electrodes to the patient (For EMG/EMS only - Sidra LEG Ultra).
4. Therapist launches the training session.
5. Patient performs the training.
6. Therapist unfastens the patient from the device.
7. After finishing the training, the therapist turns off the device and cleans it.

Home use:

1. Patient performs all of the steps described in chapter **2.3 Starting up your Sidra LEG**
2. Patient chooses an exercise program prescribed to them by the therapist.
3. Patient connects the electrodes to themself (For EMG/EMS only - Sidra LEG Ultra).
4. Patient launches the training session.
5. Patient performs the training.
6. Patient unfastens themself from the device.
7. After finishing the training, the patient turns off the device.

17. EMS Programs settings (Sidra LEG Ultra)

In the following subchapters you will find possible settings for typical electrical stimulation procedures. They are valid for the load impedances specified in section **10.2 Technical specifications**.

17.1 EMS programs details

EMS programs details	
Type of current	Biphasic symmetric
Shape	Rectangular, triangular, trapezoidal
Repetitions	1-60
Extension type	flexion
ROM max (deg)	Max passive ROM
ROM min (deg)	Min passive ROM
Starting point	Max / middle / min
Pause time in ROM max (s)	0 - 60
Pause time in ROM min (s)	0 - 60
Time to return after max torque (s)	0 - 5
Channels min	1
Channels max	4

Sidra LEG provides the following programs involving electrostimulation:

- Continuous Passive Motion (CPM) + EMS
- Isokinetic CAM + EMS
- Isometric Training + EMS

Depending on the desired effect of electrostimulation on a patient's muscles, one of the following four frequency ranges can be chosen for each type of program involving EMS offered by Sidra LEG medical device.

Frequency (Hz)	Effect on muscle
1-10	Generation of a single contraction. Activation of slow-contracting fatigue-resistant muscle fibers.
10-20	Partial muscle contraction. Increasing the muscle's endurance.
20-50	Tetanic contraction. Activation of fast muscle fibers. Increase in muscle strength.
69-90	Increasingly stronger tetanic contraction. Increase in muscle strength and muscle mass.

17.2 Custom EMS Program settings

All of the possible input parameters and ranges for custom electrostimulation program have been listed below:

Input parameters of Custom EMS program	
Duration (min)	5/10/15/.../60
Intensity (mA)	0-100
Pulse duration (µs)	50/100/150/.../500
Frequency (Hz)	20/25/40/50/80
Rise time (s)	(0/1/2/3/4)
Fall time (s)	0/1/2/3/4
Plateau time (s)	1/2/3/.../20
Pause time (s)	1/2/3/.../20

18. Miscellaneous

18.1 How to identify your Sidra LEG

During troubleshooting and consulting with your product specialist and or customer support, there may come a time, you will be asked to read your Sidra LEG Serial Number or the Serial Number of one or more of your attachments.

Sidra LEG has a label located at the base of the device that looks like this:

Sidra LEG Pro EU label

Sidra LEG Ultra EU label

In the white box on the lower part of the label on the left side of DataMatrix you can find the serial number SN.

18.2 Description of user maintenance responsibilities

The consumable items for use with your Sidra LEG:

- EMG electrodes are designed for single-use.
- Electrical stimulation electrodes are designed for single person use only. Note: The life time of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage and climate.

It is suggested to regularly restock your supply to have available products when needed.

Routine user's maintenance recommended for the Sidra LEG is cleaning the device's case, cable and fastening straps after each patient or periodically (see **19. Cleaning**).

18.3 Electrical isolation information

This chapter gives you basic information on how AC voltage is isolated in Sidra LEG.

- Sidra LEG is equipped with a permanently mounted AC power inlet/switch. By detaching the AC cable or turning the switch OFF, you are disconnecting both poles of the AC voltage (compatible with IEC 61058-1 standard),
- Emergency stop push buttons do not disconnect the AC voltage, only the 24 internal voltage supplying the motor drives,

- The AC voltage is connected to Sidra LEG by a flexible cable specified in chapter **9. What will I find in the package?**.
- All voltages above 60V DC or 42,4V AC inside Sidra LEG's chassis that cannot be disabled by the AC power switch are additionally protected and isolated. There is a warning symbol located on the product label described in chapter **18.1 How to identify your Sidra LEG?**.

18.4 Expected product service life

Expected product service life of Sidra LEG is 2 years, under normal operations and proper maintenance and handling. Sidra LEG's accessories and detachable parts will experience normal wear and tear, which will decrease the product service life.

Expected shelf life and product service life for accessories, including surface may differ. Please refer to their associated documents and packaging for more information.

If you see any of Sidra LEG's parts declining in performance, especially the chassis, the or any of the accessories, please consider replacement.

Detectable device failures are signalized by the Led Ring and in the software.

Sidra LEG, due to moving mechanical parts, will experience wear and tear. Due to some safety features being implemented by the use of those mechanical parts, periodical maintenance is required, based on your Sidra LEG usage. Due to the implementation of two methods of patient protection for mechanical dangers, Sidra LEG's maintenance can be performed after a single fault has occurred. Official maintenance personnel approved by EGZOTech or its partners can perform periodic maintenance to ensure continuous stability and reliability of the device to prevent single fault conditions.

18.5 Storage and transportation instructions

The device and accessories should be stored and transported in its case.
The device and accessories should be stored in a dry environment. Do not immerse them in water or liquid.
Storage and transportation conditions for Sidra LEG should be:

- Temperature: 10°C to 40°C,
- Relative humidity: 5% to 95% RH, non-condensing.

Do not expose Sidra LEG and accessories to high temperatures, above specified. Since short circuits can cause burn hazard or gas release, do not store metal jewelry, metal covered tables, or metal belts.

The operator should check with the carrier to confirm how the device can be carried on the airplane.

18.6 How to safely dispose of the device

Sidra LEG contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.

The pictogram wheeled bin barred means that the equipment can't be thrown with the household refuse, but that it makes the object of a selective collection.

The equipment has to be given to a suitable collection point for the treatment by this way, you contribute to the safeguarding of the natural resources and human health protection.

Electrodes should be disposed of according to their manual on the package.

18.7 Warranty

EGZOTech Sp. z o.o. provides a warranty to the original purchaser that this product will provide for a period of 1 years from the date of purchase.

Within the warranty period, the manufacturer will replace your faulty Sidra LEG or accessories at no charge (except shipping and handling fees in some cases), provided that the product:

- Has been used for the intended purpose and in the manner described in this manual.
- Has not been connected to an unsuitable power source.
- Has not been subjected to misuse or neglect.
- Has not been modified or repaired.
- Has not been damaged further by shock.

Legal rights are not affected by this warranty.

19. Cleaning

For long life and excellent quality, remember to clean Sidra LEG and accessories on a regular basis - after each patient. Where are two types of materials used for Sidra LEG, that have specific cleaning requirements.

Material type	How to clean it
Case, chassis and cables	Use wet cloth with non-allergic alcohol (disinfection) based detergent and wipe the surface.
Fastening straps	Hand wash

- For the best cleaning experience we advise the use of a specialized medical equipment disinfection product that can handle both bacterial and viral contaminations. An example can be Amity International's Virusolve+ products, both in the form of spray and wipes.
- While using high level disinfectants, always follow the guidelines for safety. Especially if you are using the solution on elastomer materials like Sidra LEG's grips, straps etc. always wash them under running water to prevent the product from staying on Sidra LEG for too long. Always read and follow the information provided with the substance.
- Do not immerse Sidra LEG in any water or liquid during cleaning.

If Sidra LEG is used for multiple patients, please:

1. Clean Sidra LEG, the cables and accessories after every use and before first use that day, according to the instructions above.
2. Sidra LEG and its accessories should be dried before storage or re-use.

Store according to **18.5 Storage and transportation instructions**.

20. Data protection

20.1 End user license agreement (EULA)

In order to provide services by EGZOTech using the Sidra LEG device the user will be asked to sign an End User License Agreement with EGZOTech, in order to regulate legal obligations of EGZOTech towards the user. The EULA is available here **https://support.egzotech.com/terms-and-conditions**.

20.2 Data retention

EGZOTech reserves the right to retain the collected data for the period of no less than 10 years from the cessation of manufacturing of the last Sidra LEG, based on the requirements of Regulation (EU) 2017/745.

21. Declarations of conformity and compliance statements

21.1 Declaration of conformity

We hereby declare that Sidra LEG, complies with the transposing Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 concerning medical devices, annex II. Classification: Class IIa, rule 9, according to Annex VIII of the Regulation (EU) 2017/745

This product conforms to international standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 60601-2-10.

21.2 Radio Regulatory Statement

FCC Statement

This device 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. Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device contains an RF modules

FCC ID: 2AC7Z-ESP32WROVERE

FCC ID: TFB-1004

21.3 Recommendations on separation distance from other devices

Recommended separation distance between portable and mobile RF communications equipment and the Sidra LEG

Sidra LEG is intended for use in an electromagnetic environment in which radiated RF disturbances are in reasonable ranges. To limit or prevent electromagnetic interference, maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and Sidra LEG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0,12	0,12	0,24
0.1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,69	3,69	7,38
100	11,67	11,67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according

to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

21.4 Electromagnetic compatibility information

Sidra LEG complies with the electromagnetic compatibility requirements for emissions and immunity, specified in the tables below. Users must adhere to the electromagnetic environment guidance and any deviations from collateral standards specified. For necessary instructions for maintaining basic safety and essential performance in relation to electromagnetic disturbances and expected service life, please refer to general warnings, described in this manual.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic emissions and immunity</th></tr>
<tr><th>Phenomenon and basic EMC standard or test method</th><th colspan="2">Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td colspan="2">Group 1</td><td>Sidra LEG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The Sidra LEG is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td><td></td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td><td></td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td><td>Complies</td><td></td></tr>
</table>

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><th>Phenomenon and basic EMC standard or test method</th><th>Test levels</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Electrostatic discharge (ESD)

IEC 61000-4-2</td><td>± 8 kV contact
± 15 kV air</td><td>± 8 kV contact
± 15 kV air</td><td>-</td></tr>
</table>

Electrical fast transient/burst IEC 61000-4-4	A.C. Power Ports, D.C. Power Ports: ± 2 kV 100 kHz repetition frequency Signal I/O Ports: ± 1 kV 100 kHz repetition frequency	A.C. Power Ports, D.C. Power Ports: ± 2 kV 100 kHz repetition frequency Signal I/O Ports: ± 1 kV 100 kHz repetition frequency	-
Surge IEC 61000-4-5	A.C. Power Ports Line-to-line ± 1 kV Line-to-ground ±2 kV D.C. Power Ports Line-to-line ± 1 kV Line-to-ground ±2 kV Signal I/O Ports Line-to-ground ±2 kV	A.C. Power Ports Line-to-line ± 1 kV Line-to-ground ±2 kV D.C. Power Ports Line-to-line ± 1 kV Line-to-ground ±2 kV Signal I/O Ports Line-to-ground ±2 kV	Mains power quality should be that of a typical home, commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % U_T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles Single phase: at 0°	0 % U_T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles Single phase: at 0°	
Electrical transient conduction along supply lines	Not applicable	Not applicable.	-
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See guidance and manufacturer's declaration - immunity to RF wireless communications equipment		
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			
Conducted disturbances included	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur	Portable and mobile RF communications equipment should be

induced by RF fields IEC 61000-4-6 Radiated RF fields IEC 61000-4-3	radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	used no closer to any part of Sidra LEG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ For 80 MHz to 800 MHz: $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ For 800 MHz to 2,5 GHz: $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d in the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal

performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

[a]Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Guidance and manufacturer's declaration - immunity to RF wireless communications equipment					
Test F (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max power (W)**	**Immunity test level (V/m)**
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	9
745	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation18 Hz	2	28
780					
810					
870					
930					
1 720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, IMTS	Pulse modulation 217 Hz	2	28
1 845					
1 970					
2 450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	28
5 240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	9
5 500					

5 785					

The Manufacturer is Compliant with all the above listed specifications.

GUIDELINES:

(a) For best performance of Sidra LEG's wireless communication use WiFi channels that are less populated by other WiFi networks,
(b) Other wireless communication may impact Sidra LEG's essential performance, but not basic safety.
(c) Please consider cybersecurity guidelines in this manual to prevent hacking.

NOTE:

(a) For some services, only the uplink frequencies are included.
(b) The carrier shall be modulated using a 50% duty cycle square wave signal
(c) As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it does not represent actual modulation, it would be the worst case.

Thank you for taking your time to read this manual!

Feel free to contact us at any time. We are here for you!

The service request form is available at:

HTTPS://SERVICE.EGZOTECH.COM

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