User Manual

Sidra LEG

Lower limb Rehabilitation robot

Read carefully before use

Applies to:
Sidra LEG Pro
Sidra LEG Ultra

Gliwice, Poland 2025

CE 2274

1. We are here for you!

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

At **EGZO**Tech, we truly believe that **great user experience isn't just about having great products, but also 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 as 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 **EGZO**Tech Courses available at https://www.egzotech.com/en/knowledge-base/.

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

2. Quick setup guide

We understand that no one likes long manuals. We want to improve this process. Please check the website with the video tutorial linked below:

Not a fan of reading? Check out our video tutorials available at
https://www.egzotech.com/en/knowledge-base/

2.1. Safety

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

2.2 Unboxing

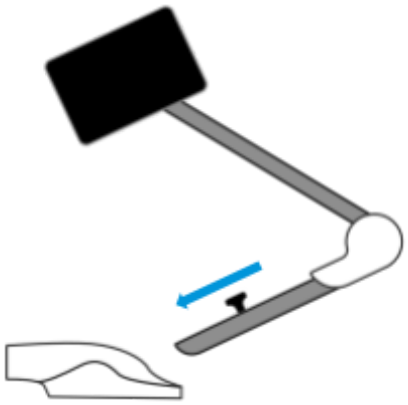
Sidra LEG is delivered with all ordered accessories in a package. On initial delivery, **please check the contents to confirm that everything you've ordered has been properly delivered**.

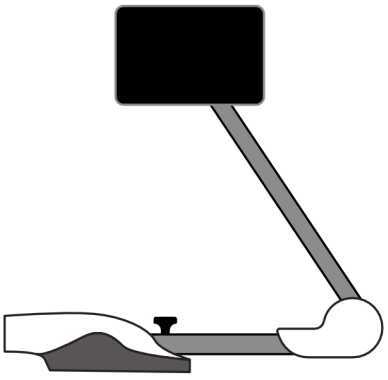
Use your device only in a permissible temperature range (10 - 40 ℃). Before you start working with the Sidra LEG, the device should reach ambient temperature.
Time required for reaching the ambient temperature 20 ℃ from the minimum permissible storage temperature is 1 h.
Time required for reaching the ambient temperature 20 ℃ from the maximum permissible storage temperature is 2 h.

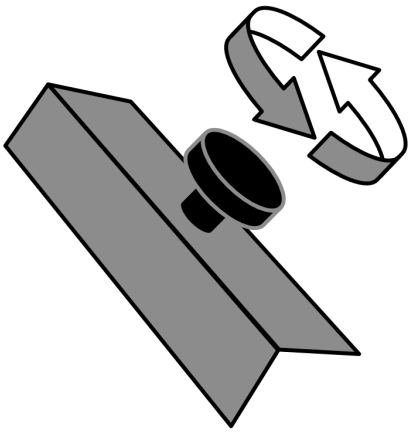
2.3 Starting up your Sidra LEG

Step 1: Place the device in the designated area. Ensure that it is positioned securely and that there is no risk of it shifting during exercise.

Step 2: Attach the device's tablet with holder according to the instructions below:







Step 3: When the device is connected to the AC power network, press the main activation button marked on the picture below. Sidra LEG will automatically turn ON as well as its tablet which will provide the user with further instructions.

The manufacturer recommends that the **Sidra LEG device be connected directly to the mains socket** (not through an extension cord) or directly to the power network. However, if this is not possible, ensure that any **extension cord used is grounded** and **as short as possible** (not applicable in home healthcare environment).

Be aware that Sidra LEG is designed for permanent installation if used in a home healthcare environment; therefore, it is essential to review the information provided in section **6.6 Use in a home healthcare environment**.

Step 4: Create a new clinic by pressing the Sign up text which will redirect to a clinic creating form, and then log in.

Step 5: The device is ready to use. Create a new patient profile or choose an already existing profile from the patients list. After creating a new patient or choosing an existing one, the exercise selection screen will appear.

Congratulations! Your Sidra LEG is ready to perform training! Before you start, we strongly advise you to read the rest of this manual and watch our YouTube videos to learn how to use Sidra LEG to best efficiency. Let us know what your experience is on Facebook!

2.4 Accessing the Application

Step 1: Visit the main page of the application.

Step 2: Create a new patient profile or choose an already existing patient to start performing exercises.

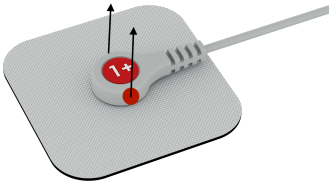
2.5 Finishing your work with Sidra LEG

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

Never grab the electrodes during electrical stimulation. Always ensure that the stimulation is disabled first.

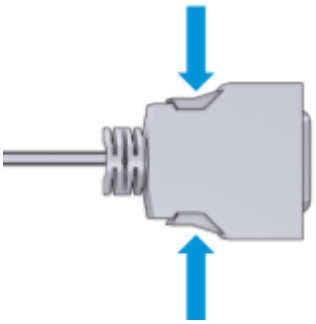
Step 2: Turn off the main power button. Disconnect the Sidra LEG from the power source by unplugging the AC cable or using the installation disconnector.

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 it 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 cable from the device by pressing the latches on both sides of the cable connector and pulling it away from the connector port.



Step 6: Put everything in the transportation box.

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. **EGZO**Tech is not responsible for any misuse that may arise due to using an older version of this manual.

Quick access to the User Manual is available through the device's application. Users can access it by clicking the 'i' icon in the application.

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.
Sidra LEG Pro has two main function:

- Continuous passive motion,
- Continuous active motion.

Sidra LEG Ultra has additionally:

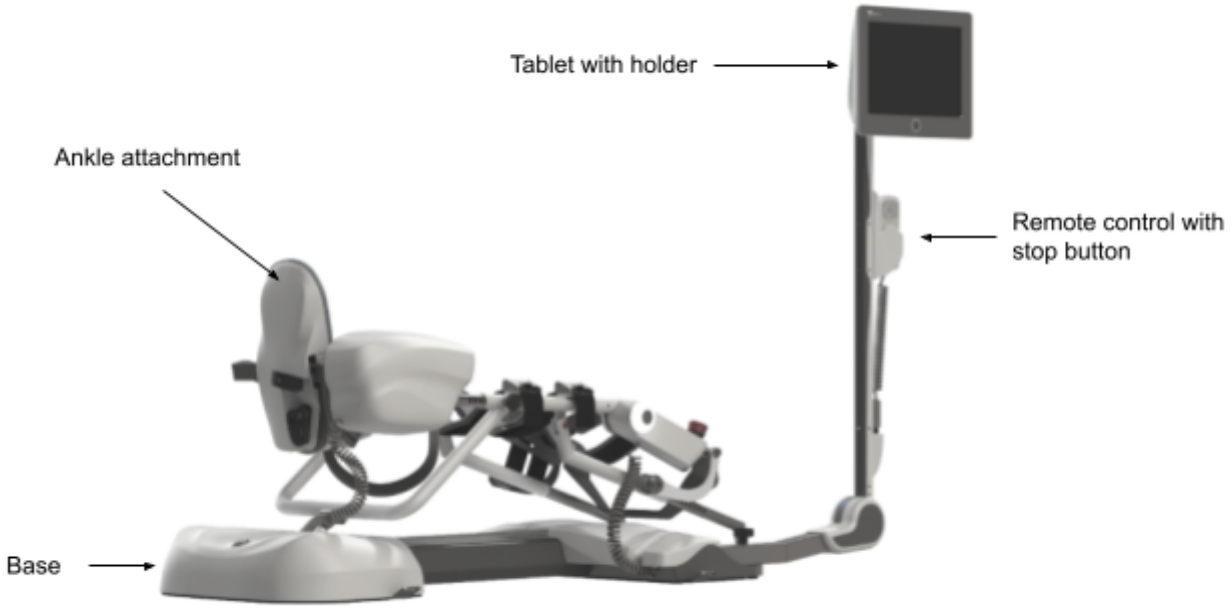
- Electromyography measurement and biofeedback,
- Electrical muscle stimulation.

The main value proposition are:

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

The Sidra LEG has four main parts:

- Base,
- Ankle attachment,
- Tablet with holder,
- Remote control with stop button.



The therapy is conducted by evaluation of a 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.

Sidra LEG is an automatic physiotherapy device. Misconfiguring the training parameters, especially range of motion, maximal applied torque and maximal speed can lead to injuries!

If the document refers to Sidra LEG, it should be understood as applying to both Sidra LEG Pro and Sidra LEG Ultra models.

6. User responsibilities

6.1 Indications for use

Indications:
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 and occupational therapy 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 manufacturer recommends use of the product by all patient groups aged 12 and older. However the product can be successfully and safely used by younger patients if they meet the specified size, height and weight requirements. Remember to always verify the length of the patient's thigh and calf against the limitations specified in the technical specifications included in this User Manual. Always give consideration to the maximal allowable values of the patient height and weight provided in the User Manual.
Patient groups should be considered among others:

- Low mobility patients (external use) - patients with possibly 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 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 clinician, as well as, by yourself in a home and home healthcare environment. Feel free to use electromyography biofeedback functionalities (Sidra LEG Ultra), 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 without supervision** 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 clinician for assistance with Sidra LEG.

Be aware that Sidra LEG is designed for permanent installation if used in a home healthcare environment; therefore, it is essential to review the information provided in section **6.6 Use in a home healthcare environment**.

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), as well as to support your patients through telerehabilitation. If you're a medical professional, you will be in charge of prescribing treatment procedures, including CPM, CAM and, in Sidra LEG Ultra, the 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 **EGZO**Tech 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 extremity.

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.
- 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.

Home therapy can be performed if the patient was trained in using the device and is capable of performing training by himself. The device in home use can be used only in the pre-set configuration prepared by a professional user whether that's a physiotherapist or doctor for patient's therapy.

Be aware that Sidra LEG is designed for permanent installation if used in a home healthcare environment; therefore, it is essential to review the information provided in section **6.6 Use in a home healthcare environment**.

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.

Engineers can operate the device during annual check-ups or service works – engineers are not allowed to work with patients.

EGZOTech Certified Trainers, engineers and service technicians can conduct device training on Sidra LEG during product presentation.

For information about the nearest authorized representative or trainer, contact **EGZO**Tech.

6.5 Internet connection

The Internet connection allows you to fully use the potential of Sidra LEG. The connection to 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.

Being disconnected from 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 does not work seamlessly, contact your product specialist.

6.6 Use in a home healthcare environment

Be aware that Sidra LEG is designed to be permanently installed if it is used in the home healthcare environment, which means that the device is connected to the mains by a permanent connection that can only be disconnected using a tool by an authorized service personnel.

The execution of permanent installation must be confirmed by completing the device connection protocol located in chapter 21. Sidra LEG permanent installation protocol - home healthcare environment. Failure to complete this protocol will result in the forfeiture of the device warranty.

The installation, including a correct protective earth connection of Sidra LEG, has to be carried out by qualified service personnel only!

The service personnel has to verify the integrity of the external protective earthing system.

The service personnel has to connect and verify that the protective earth terminal of the permanently installed medical electrical equipment is connected to the external protective earthing system.

Improper connection of the device in a home healthcare environment may result in electric shock, resulting in injury or death.

6.6.1 Guidelines for installing devices in a home environment

The precise requirements for an electrical installation in a home healthcare environment are shown below. Aligned with relevant standards that an authorized service personnel should follow to ensure compliance and safety.

1. Protective Earth (PE) Conductor
   Requirement: A permanently installed protective earth conductor must be provided for all circuits that supply medical equipment. This conductor must be adequately sized to handle fault currents without excessive heating.
   Standard Reference: IEC 60364 and BS 7671 specify the minimum cross-sectional area (CSA) for PE conductors, typically 2.5 mm^2 if mechanically protected or 4 mm^2 if unprotected. (BS 7671)
2. Residual Current Devices (RCDs)
   Requirement: All circuits serving medical equipment in a home healthcare environment must include an RCD with a residual operating current not exceeding 30 mA. RCDs protect against potential electric shock by disconnecting the circuit within 40 milliseconds in the event of a fault.
   Standard Reference: BS 7671 requires the use of RCDs for additional protection, especially in locations where individuals may be vulnerable. (BS 7671, Section 411)
3. Equipotential Bonding
   Requirement: Equipotential bonding must connect all exposed conductive parts (e.g., metal frames of medical devices) and extraneous conductive parts (e.g., metal pipes) within the environment. This minimizes voltage differences, enhancing safety for patients and caregivers.
   Standard Reference: Refer to IEC 60364-4-41 and BS 7671, which outline equipotential bonding requirements to prevent electric shock. (IEC 60364)
4. Socket-Outlets and Plugs

Requirement: Socket outlets must be installed with protective earth connections compatible with the power requirements of the medical equipment used. Ensure the outlet rating (voltage and current) is appropriate for the connected devices, typically 230V, 16A for standard equipment.
Standard Reference: IEC 60601-1-11 requires medical devices for home use to be connected to grounded outlets unless double-insulated. (IEC 60601-1-11)

5. Wiring Systems
   Requirement: Use wiring systems with flame-retardant insulation to reduce fire hazards. Insulation must emit minimal smoke and toxic gasses in the event of a fire. Suitable cable types include LSZH (Low Smoke Zero Halogen) for these environments.
   Standard Reference: BS 7211 specifies low-smoke, halogen-free wiring materials suited for healthcare environments, supporting fire safety regulations. (BS 7211)
6. Emergency Power Supply
   Requirement: For critical medical equipment (e.g., ventilators, oxygen concentrators), an uninterruptible power supply (UPS) or standby generator must be available to maintain continuous operation during outages. Ensure backup power meets the device's rated power requirements.
   Standard Reference: IEC 60364-7-710 provides guidelines on emergency power for medical locations, adapted here for critical home healthcare equipment. (IEC 60364-7-710)
7. Environmental Conditions and Protection Against External Factors
   Requirement: The installation must withstand environmental factors, including temperature and moisture. Electrical outlets and equipment must have ingress protection (IP) ratings suitable for the area—e.g., IP44 in bathrooms or damp environments.
   Standard Reference: IEC 60529 defines IP ratings, and IEC 60601-1-11 provides guidance on moisture resistance for home healthcare devices. (IEC 60529, IEC 60601-1-11)
8. Periodic Testing and Maintenance
   Requirement: Conduct initial verification and periodic inspection/testing of all electrical installations and devices used in the healthcare environment to ensure ongoing compliance and operational safety.
   Standard Reference: BS 7671 and IEC 60364 outline requirements for initial verification and regular testing intervals, especially in environments with vulnerable individuals. (BS 7671)
9. User Training and Documentation
   Requirement: Provide clear operating instructions and user training for caregivers on safe equipment use and maintenance procedures. Maintain accessible documentation for all electrical installations and devices.
   Standard Reference: IEC 60601-1-11 mandates clear user guidance and labeling for devices intended for home healthcare environments. (IEC 60601-1-11)
   These requirements should be strictly followed by electrical engineers and verified during installation to ensure that home healthcare environments are safe, reliable, and compliant with applicable standards.

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 the patient's lower limb such as CPM and CAM. As such, **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 EGZO**Tech.

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

Sidra LEG is intended to be used with 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 replace 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.

Sidra LEG cannot be operated on by a person whose 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, professional care or assistance is necessary.

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

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

In an event that **Sidra LEG does not behave as intended**, **press the emergency stop button** and notify your product specialist or our customer support immediately.

Any serious incident related to Sidra LEG needs to be reported to **EGZO**Tech 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! This includes all the package contents listed in chapter **9. What will I find in the package?** and **11. Extensions**.

Use only the AC cable supplied as specified in chapter 9.2 AC Power Cable. 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 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 programs while sleeping.

Use of Sidra LEG by a child is allowed 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 attachments. 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.

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 their 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 **EGZO**Tech 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 LEG produces 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.

The patient's position during the therapy must be anatomically correct.

Electrodes should be used in accordance with their manuals or the instructions provided on the packaging, if they exist (Sidra LEG Ultra).

7.3 Electrical safety and electromagnetic compatibility

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

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.

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

Sidra LEG is an electrical device with IP21 liquid ingress and solid particle protection. If possible, protect Sidra LEG from contact with liquids and/or solid particles.

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.

To unplug the device from the power supply pull the plug (not the cord) or use the installation disconnector. Never pull cables connected to the device or the installation.

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.

While replacing external AC fuses, follow the electrical requirements specified in chapter **10.2 Technical Specification**.

Use only IEC C13 AC cables that have dual isolation and comply with the electrical requirements in the technical specification.

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 in spite of its detection in the software, take extra caution and contact your product specialist.

Sidra LEG has BF 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 (Sidra 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.

Do not use Sidra LEG Ultra if you are connected to a high-frequency surgical equipment, as this could cause skin irritations or burns under the electrodes.

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

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.

The Sidra LEG complies with the requirements of IEC 60601-1-2 (EMC Collateral Standard) including the E-field susceptibility requirements at a level of 10 V/m, 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.

Warning: Keep RFID readers 30 cm away from the device.

Warning: Operation in close proximity to a shortwave or microwave therapy equipment may produce instability in the applied part.

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 **EGZO**Tech.

The use of accessories and cables other than those specified or provided by **EGZO**Tech for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Avoid using this equipment adjacent to or stacked with other equipment, as this could result in improper operation. If such use is necessary, this equipment and the other equipment should be monitored to ensure 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 healthcare professional**. 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 case of 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.

The 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.

Special attention from 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 been obtained first.

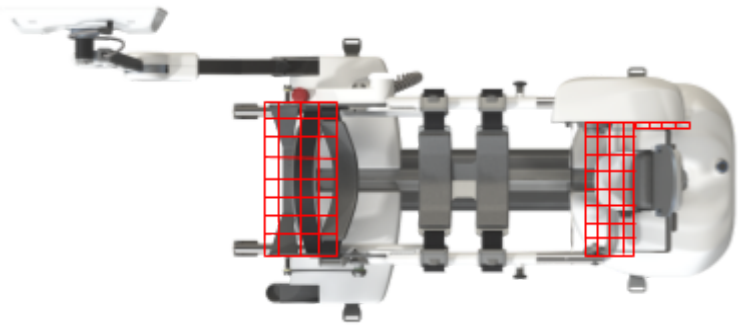
While using electrical stimulation electrodes, make sure that the impedance displayed is correct in the software. The adhesive properties of electrodes do not guarantee good conductivity.

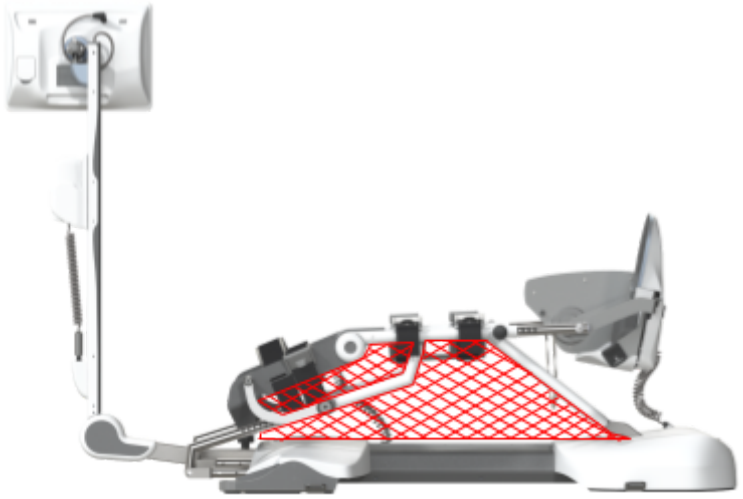
Electrodes should be used in accordance with their user manuals or the instructions provided on the packaging (if available).

7.5 Mechanical safety

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 pictures 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.

If you need to transport Sidra LEG, use the provided transportation box.

During transportation, avoid collisions with other objects.

While using the Sidra LEG, avoid wet, slippery, or uneven surfaces. Try to avoid these during transportation or mounting whenever possible.

Do not step, sit, or stand on any part of Sidra LEG or its accessories. Do not place any unintended objects on the Sidra LEG.

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

Please report all damage, malfunctions, or unusual behaviour to your product specialist.

Always use cables with the minimum number of channels necessary for the training to limit unnecessary risk.

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

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

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

Before therapy, patients need to be instructed on the location of the emergency button and how to stop the device in case of discomfort, pain, irritation or other dangers. Patients who are unable to use the emergency button during therapy should not be left without supervision of the operator.

Before starting therapy with a patient, run several cycles without the patient to test the full range of the device.

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 due to the choking hazard.

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 **18. 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 Ultra only).

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

For bioelectric programs (like electromyography in Sidra LEG Ultra only), we recommend using single-use electrodes. **Remember to use single-use electrodes only once**. If you decide to use different electrodes, always consult your product specialist.

Remember to clean the multiple-use electrodes as intended by the manufacturer.

Electrical stimulation electrodes are designed for single-person use only and can be reused up to 20 times. Note: The lifetime of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage, and climate (Sidra LEG Ultra only).

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. **EGZO**Tech provides the necessary technical information to all maintenance personnel.

Sidra LEG is intended for constant use, however, it is equipped with temperature sensors and early failure detection algorithms. In the rare event that Sidra LEG stops the current operation, it will display a notification about current system status (e.g. overheating, malfunction, etc.). There is no danger in this case, but Sidra LEG will cease all operations until the issue has been resolved, either automatically or by a product specialist or customer support.

7.7 Biological safety

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

Sidra LEG (the device) is intended for surface (intact skin) contact only. **Avoid contact with mucosal membranes, breached or compromised surfaces**, or, in any case, inside your body.

Sidra LEG has been analyzed for biocompatibility, including 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 addressed.

Sidra LEG's materials have been tested with the disinfection products described in chapter **18. Cleaning**. The use of different, especially unintended disinfection, products can lead to contamination, surface deterioration, loss of biocompatibility, and malfunction.

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 and other Sidra LEG accessories.

7.8 Environmental safety

Do not perform service, maintenance and modifications on Sidra LEG by yourself! Use only service providers authorized by **EGZO**Tech.

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 use 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). Be aware that Sidra LEG is designed for permanent installation if used in a home healthcare environment; therefore, it is essential to review the information provided in section **6.6 Use in a home healthcare environment**.

Sidra LEG should be used in well-lit 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 **18. 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 other applications while using Sidra LEG App, as it can disturb normal operations.

Sidra LEG is delivered by **EGZO**Tech with a preconfigured third-party ICT device (tablet) with restricted access. Do not install any unapproved applications. Untested software can interfere with the normal operations of Sidra LEG.

7.10 Lifetime

Sidra LEG, due to its moving **mechanical parts, will experience wear and tear**. Because some safety features are implemented using these mechanical parts, periodic maintenance is required, based on your Sidra LEG usage. With the implementation of two methods of patient protection for mechanical dangers, maintenance of the Sidra LEG can be performed after a single fault has occurred. Official maintenance personnel approved by **EGZO**Tech or its partners can conduct **periodic maintenance to ensure continuous stability and reliability of the device, preventing single fault conditions**. If your Sidra LEG has a stable, unrestricted Internet connection available at all times, your usage will be monitored by **EGZO**Tech and its partners, and necessary maintenance will be proposed ahead of time to limit the downtime of your devices.

7.11 Annual maintenance

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. In order to ensure safety for medical devices, Sidra LEG may stop operations if the annual maintenance cycle is skipped. We strongly recommend that you avoid skipping the annual tune-up maintenance. And in unforeseen events, contact your provider immediately. **EGZO**Tech is not liable for any events that occur 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, the benefits of using Sidra LEG device in both therapeutic and evaluation scope, along with the implemented measures to limit potential risks, indicate that the benefits significantly outweigh the potential risks.

The patient should consult their 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 **EGZO**Tech and the competent authority of the Country in which the user and/or patient is located.

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

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

The 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

Remember that Sidra LEG is an automatic physiotherapy robot. This means it can function as a standalone exerciser for your patients. However, **misconfiguring the training parameters** - especially the range of motion, maximum applied force, and maximum speed - **can cause injuries!**

Do not start using Sidra LEG before being familiar with this user manual.

8.2 Labeling

Sidra LEG's label is placed on the base of the device. This label contains information about the specific unit of the Sidra LEG that you own. Additionally, Sidra LEG uses safety symbols on the device itself, as well as within the software application as well as on packaging of accessories. Below are the Sidra LEG's labels:

Sidra LEG Ultra EU label:

Sidra LEG Pro EU label:

8.3 Symbols

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
	Manufacturer		Medical Device
 YYYY-MM-DD	Manufacturing Date		Serial Number
	The CE marking indicates that a product complies with applicable European Union regulations. No. 2274 is the number of the Notified Body	 courses.egzotech.com	Indicates the need for the user to consult the instructions for use
	FCC mark		Indicates the need for the user to consult the instructions for use

Symbol	What it means	Symbol	What it means
Made in Poland	Indicates Poland as the country of origin.		Caution is necessary when operating the device or control near the location of the symbol, as the current situation may require operator awareness or action to avoid undesirable consequences
IP21	Ingress Protection (IP code)		The product should not be disposed of as unsorted waste but must be sent to separate collection facilities for recovery and recycling
100-240 VAC 50/60 Hz 4A T4AL 250 V fuse 100 VAC, 1.5 A 240 VAC, 0.7 A	Indicates range of permissible power supply parameters and type of fuse used in the device		The device generates radio frequency energy during operation
	Applied part type BF, used for electrical connections to and from the patient. This part is isolated from all other parts of the device		Emergency button
	Indicates the temperature limits to which the medical device can be safely exposed		Indicates the humidity limits to which the medical device can be safely exposed
	No sitting on a device		No stepping on the device
	Medical device packaging and contents should be kept dry		This way up
	Indicates a medical device that can be broken or damaged if not handled carefully		Do not stack
	Do not roll		Warning; Crushing of hands - To warn of a closing motion of mechanical parts of equipment
	General warning sign - To signify a general warning		Warning; Crushing - To warn of moving mechanical parts
 YYYY-MM-DD	The two-letter symbol inside the symbol indicates the country of origin (PL indicates that the product was manufactured in Poland).		Placing of heavy objects on this surface is prohibited.

Symbol	What it means	Symbol	What it means
	YYYY-MM-DD adjacent to the symbol indicates the manufacturing dates		

8.4 Accessories symbols

Symbol	What it means	Symbol	What it means
REF	Indicates the manufacturer's catalogue number so that the medical devices can be identified		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 the date after which the medial device is not to be used		Indicates a medical device that is intended for one single use only
Sensor Ag/AgCl	Silver/silver chloride sensor	LATEX	Latex free
	Indicates a medical device that requires protection from light sources	PVC	PVC free
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified	QTY	Bulk packaging quantity

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 in the package.

For any aspects related to accessories that are not specifically addressed in this section, the general guidelines and procedures outlined in this manual should be followed, particularly regarding cleaning, disinfection, and disposal.

9.1 Sidra LEG

What does it look like?	Description
	Sidra LEG Rehabilitation robot 1 pc.

9.1.1 AC Power Cable

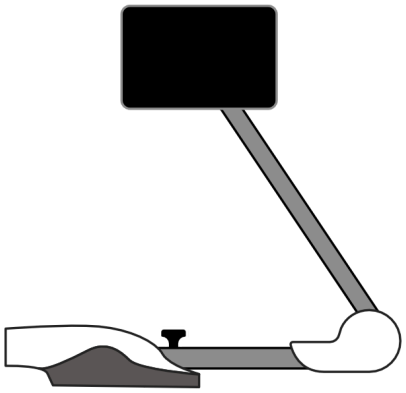
The cable included with the device may vary depending on the order specifications and the environment in which the device will be used.

What does it look like?	Description
	**AC Power Supply Cable** 250 V / 10 A / H05VV-F Class 1 protection acc. to IEC 61140 Device plug: C13 acc. to IEC 60320-1 Socket plug: CEE 7/7 (E & F compatible) standard * Length 5 m - 1 pc. **For professional use only**
	**AC Power Supply Cable** 250 V / 10 A / H05VV-F Class 1 protection acc. to IEC 61140 Device plug: **C13 with LOCK** acc. to IEC 60320-1 VERIFIED PERMANENT CONNECTION to POWER NETWORK is required Length 5 m - 1 pc. **For home healthcare environment dedicated cable** **Be aware that Sidra LEG is designed for permanent installation if used in a home healthcare environment; therefore, it is essential to review the information provided in section 6.6 Use in a home healthcare environment.**

* Other socket plugs available on request. Please contact **EGZO**Tech Sp. z o. o. or your local distributor.

9.1.2 Tablet with holder

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

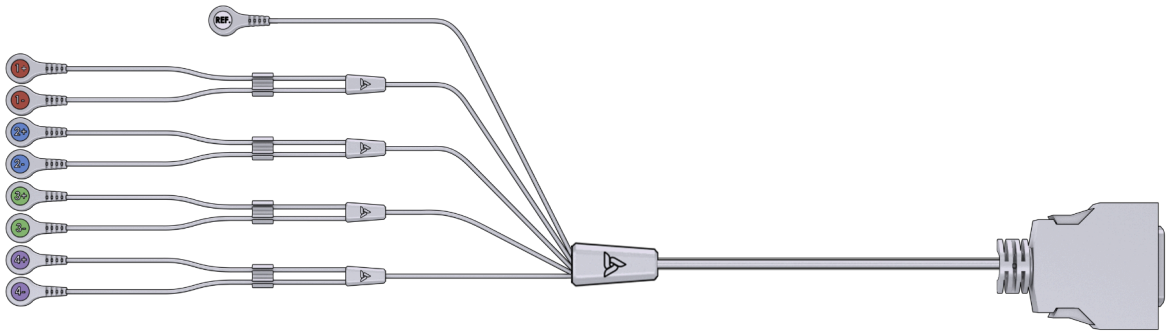


9.1.3 Remote control

- Patient stop button
    - Connected via cable to the device

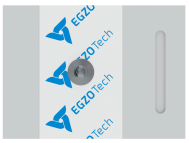
9.2 EMG/EMS cable - 1 pc. (Sidra LEG Ultra only)

- 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 80 cm, reference cable of length 30 cm
- Reference cable is shorter than channel cables



9.3 Electrodes for surface electromyography (Sidra LEG Ultra only)

The table below presents the electrodes that are approved and safe for use with surface electromyography using Sidra LEG Ultra. However the type and quantity of electrodes provided with the device depend on the order specifications and may vary.

What does it look like?	Description
	ECG surface electrode **EGZOTech EE S5540 FWG** Area intended to contact the surface of the skin: 22 cm^2 55 x 40 mm 50 pcs./case
	ECG surface electrode **EGZOTech EE S5540 FWG1** Area intended to contact the surface of the skin: 15.4 cm^2 44 x 35 mm 50 pcs./case

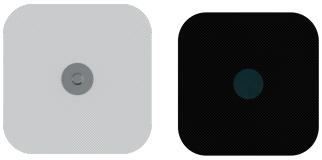
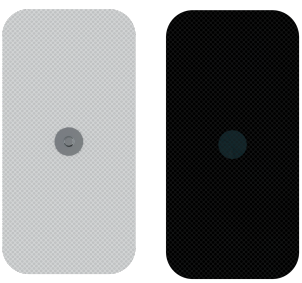
Sidra LEG Ultra is compliant with any surface ECG/EMG electrodes that meet IEC 60601-1 requirements. The device is designed for use with snap electrodes; using other types of electrodes requires an adapter.

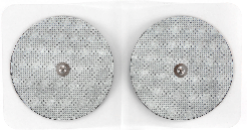
Before use, always check and follow the information provided by the electrode manufacturer.

Always **confirm the use of electrodes** not listed above **with the manufacturer or the local distributor**. The use of electrodes not listed in the table above or not confirmed by the manufacturer or local distributor may result in device malfunction, failure to operate, or **pose a burn risk to the patient**.

9.4 Electrodes for electrostimulation (Sidra LEG Ultra only)

The table below presents the electrodes that are approved and safe for use with electrostimulation using Sidra LEG Ultra. However the type and quantity of electrodes provided with the device depend on the order specifications and may vary.

What does it look like?	Description
	Small electrical stimulation electrode **UltraStim Snap SN2020** Area intended to contact the surface of the skin: 25 cm^2 50 x 50 mm 4 pcs./case Manufactured by: Axelgaard Manufacturing Co.,Ltd. 520 Industrial Way Fallbrook, CA 92028, USA
	Large electrical stimulation electrode **UltraStim Snap SN2040** Area intended to contact the surface of the skin: 50 cm^2 50 x 100 mm 4 pcs./case Manufactured by: Axelgaard Manufacturing Co.,Ltd. 520 Industrial Way Fallbrook, Axelgaard 92028, USA

	Small electrical stimulation electrode **HRTC32BP** Area intended to contact the surface of the skin: 8 cm^2 dia 32 mm 4 pcs./pack Manufactured by: HUREV Co., Ltd. 107-3 Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea

Sidra LEG Ultra is compliant with any surface self-adhesive EMS electrodes that meet IEC 60601-1 requirements (carbon electrodes are not recommended). **Using electrodes smaller than 32 mm in diameter (with a surface area less than 8 cm^2)** may lead to burns due to the concentration of current over a smaller area. The device is designed for use with snap electrodes; using other types of electrodes requires an adapter.

Before use, always check and follow the information provided by the electrode manufacturer, paying particular attention to the maximum allowable current for electrical stimulation.

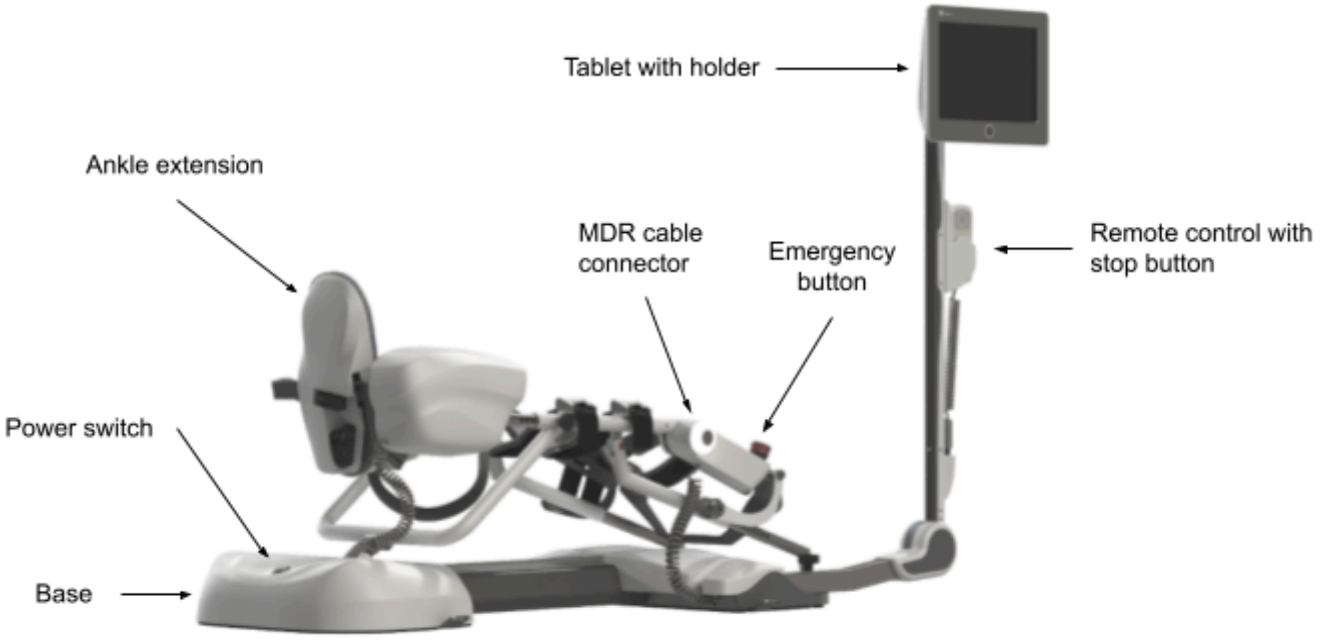
Always **confirm the use of electrodes** not listed above **with the manufacturer or the local distributor**. The use of electrodes not listed in the table above or not confirmed by the manufacturer or local distributor may result in device malfunction, failure to operate, or **pose a burn risk to the patient**.

9.5 Transport box

- Box where operator can put and storage device.
- Provides protection for the device during delivery and storage.
- Designed for transport from manufacturer to the client.
- Reusable.
- Optional.

10. Basic information about Sidra LEG

10.1 How is Sidra LEG built



10.2 Technical Specification

ESTABLISHED AND TRADE NAME

Sidra LEG

DIMENSIONS & WEIGHT

Total length	875 mm (without screen holder) 1155 - 1890 mm (with screen holder)
Total width	530 mm
Total height	530 - 905 mm (max. holder)
Total weight (with ankle attachement)	max 19.9 kg

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 (autoreverse)
Ankle torque	20 Nm
Ankle torque measurement accuracy	± 0.1 Nm
Thigh force measurement	± 0.5 kg
Goniometer measurement accuracy	± 2°

ENVIRONMENT

Operating temperature	10 °C to 40 °C
Operating humidity	10 % to 95 % RH non-condensing
Maximum operating altitude	3 000 m a.s.l.
Cooling	convectional
Ingress protection IP (code)	IP21
Mobility	portable
Operation type	continuous, software controlled

ELECTROMYOGRAPHY (Sidra LEG Ultra only)

Electromyography measurement channels	up to 4 simultaneous sampling
Baseline noise	< 0.5 µV RMS
Input-referred noise	10 µVpp (10 s of raw data)
Measuring Voltage range	-0.6 V to 0.6 V
Sidra LEG's Gain	1
Sampling frequency	up to 1 000 samples/s per channel
Internal resolution	24-bit
CMRR	-73 dB
Input impedance	10 MΩ
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

PULSES PARAMETERS

Pulse frequency	5 - 100 Hz
Pulse width	50 - 500 µs
Rise time	0 - 4 s
Plateau time	1 - 20 s
Fall time	0 - 4 s
Waveform generation accuracy	± 0.5 % full scale
Output resolution	16-bit
Sampling frequency	up to 1 000 000 samples/s
Load impedance	500 - 2000 Ω

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
Patient age	at least 12 y. o.*

OTHERS

Power supply	100-240 V AC, 50/60 Hz
Protection against electric shock	class I grounded/earthed connection required
Current required	max 0.7 A at 240 V max 1.5 A at 100 V
Fuses type used	4 A (T4AL250V type)
Applied part type	BF
Communication interfaces	wired (USB) and wireless (Wi-Fi, Bluetooth)

* Please refer to **6.1 Indications for use** for detailed information.

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 the current state including dangers and emergencies. 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 in green and blue	Tablet displays Sidra LEG's home screen	After plugging the device's AC cable and/or switching the power switch on	**Turned on**
The LED ring stops glowing.	Tablet display shut down	After switching off Sidra LEG through the application or by switching the power switch off	**Turned off**
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: service.egzotech.com	**Pressed Emergency Button**

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 (table below) are prohibited. Improper use voids all warranty claims.

Problem	Possible Cause	Solution
Sidra LEG does not turn on	AC cable plugged incorrectly	Replug the AC cable
	AC cable not plugged	Plug in the AC cable
	Power switch turned off	Turn the power switch on
Sidra LEG does not detect the attachment	Attachment cable plugged incorrectly	Replug the attachment cable
	Attachment cable not plugged to the device's chassis	Plug in the attachment cable to the device's chassis
Weak electrostimulation	Dried out or damaged electrodes	Replace and re-connect electrodes
	Incorrect electrode placement	Replace and re-connect electrodes
	Worn or damaged lead wires	Replace leads
Intermittent EMG signal	The electrode lead set is loose or disconnected	Check the lead set connections in both the Sidra LEG and electrodes
	Electrodes dried out or damaged or were not in contact with bare skin	Change the electrode to a new one
The EMG signal cannot be controlled	The electrode or reference cable is not connected properly	Check and improve connection of electrode or reference cable
	The electrode lead set is loose or disconnected	Check the lead set connections in both the Sidra LEG and electrodes
	Electrodes dried out or damaged or were not in contact with bare skin	Change the electrode to a new one. Ensure if the skin is properly prepared
Sidra LEG does not move	Device's drive malfunction	Contact with **EGZO**Tech service request form is available at: https://service.egzotech.com

10.5 Emergency stop

The emergency stop button is located near the thigh, on the goniometer module housing, near the MDR cable connector. It is pointed upwards, and can be pushed both by the therapist and the patient in case any danger occurs.

Sidra LEG has one emergency stop that will stop all movement of Sidra LEG by cutting off the motor power supply.

Emergency stop does not switch off the power of Sidra LEG entirely. In the event of a fire, water spill, or any other non-mechanical malfunction, step away from Sidra LEG as soon as possible.

11. Attachments

11.1 What kind of attachments do I have?

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

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.

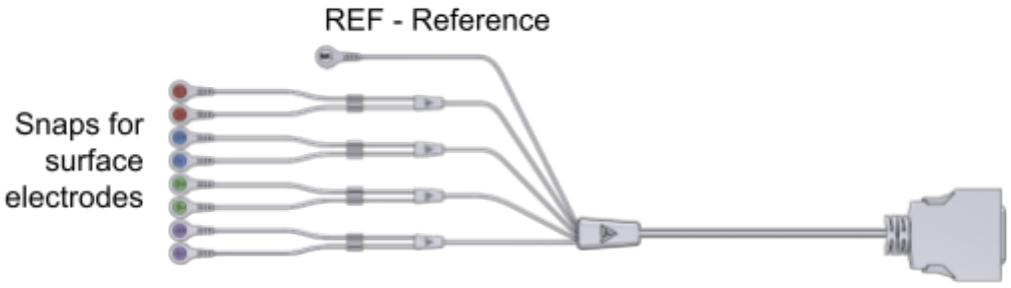
Sidra LEG Ultra was designed to allow bioelectric measurements, particularly for diagnostic and reactive electromyography. In the Sidra LEG Ultra's package (described in chapter **9. What will I find in the package?**), you will find an EMG/EMS cable and electrodes for surface electromyography.

12.2 Lead wires and channels for EMG

The cables have color-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

Each lead wire for the EMG has a colored snap to connect the EMG electrode. Two snaps of the same color correspond to one channel. The two color-coded snaps of each EMG channel represent two differential inputs: positive "+" and negative "-". **For electromyography, it is essential to connect both positive and negative inputs of one channel to the same muscle** (the one being assessed).



You should always have a reference input for electromyography close to the currently used EMG channels. The closer the reference electrode is to the measured channel, the less electromagnetic interference there will be. For example, try to place the reference electrode on the same limb as the measured channels.

For each EMG program (whether for data collection for diagnostic purposes or therapeutic use), you will need at least three connected electrodes: two of the same color connected to one channel and one white reference electrode.

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

There's more! Visit our website for the latest available courses!
https://support.egzotech.com

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. 2 cm).

Do not use any unauthorized electrodes, especially lacking the necessary safety certificates.

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

- We recommend using single-use snap electrodes compatible with the EMG cable.
- For reference electrodes, you are free to use any single-use electrode, although the manufacturer recommends using electrodes provided by **EGZO**Tech, which can be ordered from your product specialist or **EGZO**Tech representative.
- To achieve the best results when working with the Sidra LEG Ultra, we recommend using electrodes with wet gel.
- Do not use any unauthorized electrodes, especially those lacking the necessary safety certificates (medical device CE in the European Union).
- Never use single-use electrodes more than once, and never on more than one patient.

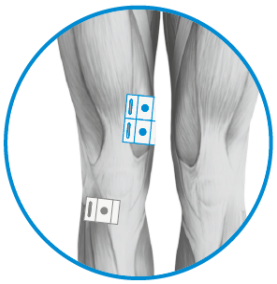
12.4 EMG Electrode placement and configuration

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 determine the number of active motor units and innervated muscle fibers. The same type of electrodes should be used to compare different results.
    - Distance between the electrodes, which determines the bandwidth of the differential electrode configuration. This distance 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 the electrode is 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 considered during result interpretation,
- Orientation of the bipolar configuration of the electrodes with respect to the muscle fibers, which affects the measured conduction velocity, amplitude and frequency of action potentials (depolarisation of muscles).

Follow the steps below 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 **EGZO**Tech 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 the **reference electrode (marked gray)** with the white lead wire ending and REF sign to the skin that is not under evaluation.
8. Ensure that electrodes are placed on 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. Electric stimulation (Sidra LEG Ultra only)

13.1 Basics of electrical stimulation

Electrical stimulation should **only be used after receiving training from a healthcare professional.**
Always consult your physician before using electrical stimulation, to ensure the correct output parameters and program are selected for you.

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

The electrical stimulation programs in Sidra LEG Ultra include:

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

13.2 Lead wires and channels for EMS

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

13.3 EMS Electrode arrangement and configurations

In Sidra LEG Ultra, a two-electrode electrical stimulation method is used. This technique involves placing two electrodes of equal size on the skin, positioned where the muscle transitions to the tendon. This method is typically used for electrostimulation of denervated muscles. However, the two-electrode method can also yield good results when used to stimulate healthy or mildly damaged muscles to contract.

Use only electrodes authorized by **EGZO**Tech described in chapter **9.7 Electrodes for electrostimulation. Using electrodes of inadequate size or not suited for the application could lead to skin reactions or burns.** Electrode properties like dimensions, conductivity, impedance and connector types can greatly impact safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

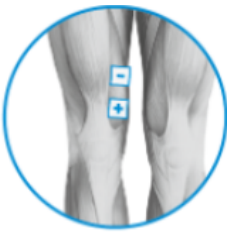
In bipolar electrode placement, two stimulation electrodes are positioned to target the specific area. This method helps limit the current flow primarily to the excitable tissue of interest.

Do not exceed an intensity of 0.1 W/cm^2.
Follow these steps to maximize reliability, safety and accuracy of output parameters for your electrical stimulation.

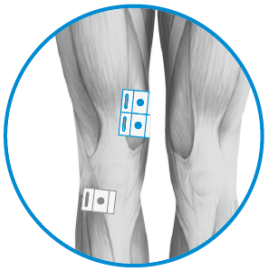
13.3.1 EMS Programs - Electrode Arrangement

1. Ensure the electrical stimulation is turned 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 muscle being stimulated. 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 and save it for later use. Electrodes for electrostimulation are typically intended for multiple uses, so the liner will be needed to protect them between uses.
5. The skin must always be clean, dry and free from lotion. Do not apply electrodes to injured skin.
6. Place the negative ("-") electrode on the proximal end of the muscle, securing it firmly to the skin. Apply the center first, then smooth down the edges of the electrode.
7. Place the positive ("+") electrode on the distal end of the same muscle. The distance between the electrodes should be at least 1 cm. Apply the center first, then smooth down the edges of the electrode.



13.3.2 EMG - Electrode Arrangement for EMG-Triggered EMS Program



Follow **13.3.1 EMS Programs - Electrode Arrangement** to connect surface EMS electrodes (marked blue) to a single 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 modes

This type of mode enables electrical stimulation based on pre-set programs. Details of the programs are described below.

Parameter	Description	Clinical relevance
Type of current	Direct current is, at most basic level, continuous and flows in only one direction. Alternating current passes first in one direction and then another. Pulse current refers to either direct or alternating current in which there is a gap between successive pulses.	Direct current is used for iontophoresis. The alternating current is used mainly for innervated muscle contraction and sensory stimulation, with the pulses being continuous and combined. However, from the perspective of nerve excitation, the distinction between direct and alternating current is irrelevant. The pulse current differs from the alternating current because the pulses are separated. This separation means less energy may be delivered to the tissue when using this type of current.
Current amplitude	The magnitude of current is defined with reference to the	Increasing current amplitude will increase the energy delivered to the tissues under the electrode. This

Parameter	Description	Clinical relevance
	zero-current baseline at a given moment. It can be referred to as the intensity of stimulation.	contributes to the sensory or motor response that the electrical current produces. The current amplitude is one of the determinants of torque production when using neuromuscular electrical stimulation. Increasing the current amplitude activates a higher percentage of muscle fibers; this 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 polarized, 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, while 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, It is often incorrectly labeled "pulse width" on a clinical stimulator.	The greater the pulse duration, the greater the skin impedance and the greater the patient's discomfort. Increasing pulse duration has been shown to enhance the charge of the pulse and increase motor unit recruitment. Alternating the pulse duration depends on the patient's comfort and the 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.	The 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 it also accelerates muscle fatigue.
Waveform shape (rectangular)	The geometric shape of the pulse is represented on the graph of current (or voltage) versus time.	Limited clinical research has examined the effects of using different pulse shapes. Previous studies showed that there were individual differences in preferences for three different waveforms: sinusoidal, sawtooth, and square symmetric biphasic waveforms. There was no particular waveform identified as either the least or most comfortable to the patient during neuromuscular electrical stimulation.
Stimulation mode (when more than one channel)	Reciprocal, asynchronous, or sequential.	Channels operate in a simultaneous or alternating fashion, according to a set duty cycle. In sequential stimulation, multiple stimulation channels are used (usually, to activate multiple synergist muscles separately), allowing motor units to rest when the corresponding stimulation channel is not active. Asynchronous stimulation also utilizes 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	The 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 reducing skin impedance, the discomfort typically associated with traditional low-frequency current is minimized.
Burst	The generation of two or more consecutive pulse or cycles separated by a 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	The frequency at which bursts are generated.	This parameter influences the fatigue potential of muscles, particularly if the frequency is high (>50 or 60 Hz). At low frequencies (between 20 and 50 Hz), there is effective recruitment of nervous fibers, while at very low frequencies (2 to 10 Hz) the nervous fibers promote relaxation of the muscle fibers.
Burst duty cycle	The 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.	The burst duty cycle, similarly to burst duration, affects torque production, discomfort, and fatigue.

14. Software

14.1 How to launch the application?

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

14.2 Registration

The user creates a new clinic profile by filling out the registration form. Information such as the email address, clinic name, user's name and surname is required. After registering the clinic, a password field will appear.

If your clinic profile already exists, refer to chapter **14.3 Signing in**.

14.3 Signing in

The user can sign in by entering their clinic's email address and password on the application's home screen.

14.4 Clinic's profile

After logging in, the user will see a list of their patients.

14.5 Patient's profile

After clicking on the selected patient's tile, the therapist will see their patient's card, which includes 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 completing all the activities described in the chapter **2.3 Starting up your Sidra LEG**

Step 1: After selecting the patient, the user chooses an exercise they wish to perform from the training selection screen. The detailed training list is available in chapter **16. Programs Overview**. The training options are displayed in three categories: "Suggested," "Filters," and "All."

Step 2: Follow the instructions on the screen to continue with the Basing procedure.

Step 2.1: Choose the exercise parameters that suit the patient's needs, ensuring their safety and preventing any potential hazards.

Step 2.2: Select the trained side - left or right.

Step 2.3: Enter the thigh length of the trained lower limb. Information about the distance to set the thigh part of the rail will appear at the bottom of the screen.

Step 2.4: Apply the Range of Motion (ROM) recommended by the healthcare professional. Position the device, so it is in the middle of the patient's Range of Motion.

Step 2.5: Position patients lower limb in the device following the instructions shown on the screen and tighten it with the clamping straps. **Ensure proper patient position during exercise.** It is recommended to perform the exercises in the anatomical position.

Step 2.6: Set the passive Range of Motion.

Step 2.7: Position the rail in the middle of the set passive Range of Motion and perform lower limb taring.

Step 3: (EMG/EMS in Sidra LEG Ultra only) After choosing the training involving EMG or EMS, the user must perform the additional actions described below.

Step 3.1: (EMG/EMS in Sidra LEG Ultra only) Connect the EMG cable using the MDR socket located on the side of the chassis. The cable is correctly attached if you hear two "click" sounds, and it cannot be pulled off.

Step 3.2: (EMG/EMS in Sidra LEG Ultra only) Select the patient's target muscles that need to be monitored or stimulated. The number of muscles that can be selected depends on the number of channels in the cable.
The channel colors in the software correspond to the lead wire colors.

Step 3.3: (EMG/EMS in Sidra LEG Ultra only)

Choose what function the channels will perform. In the EMG exercise, it can be a Triggering function. While in the EMS exercise, it can be Electrostimulation or Biomyography. In the EMS+EMG exercise, both functions are possible.

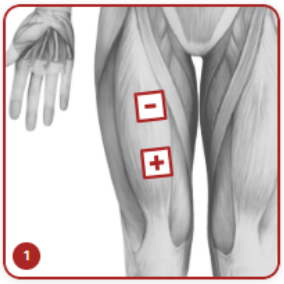
Step 3.4: (EMG/EMS in Sidra LEG Ultra only)

Connect the electrodes to the appropriate lead wire channels before applying them to the patient's skin.
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.

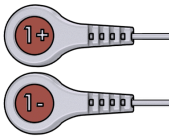
Choose the appropriate electrodes for the intended application - EMG electrodes for EMG Biofeedback and EMS electrodes for EMS program.

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

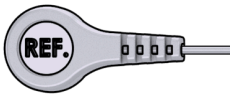
Place Electrodes connected to the snaps with a "+" and "-" sign in the appropriate place as shown on the icon.



Quadriceps femoris



If an exercise with elements of Electromyography was chosen, don't forget to connect the reference electrode to the white single lead wire (reference channel) marked with the REF sign if there is a gray electrode on the software icon.



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

The channel colors in the software correspond to the lead wire colors.

When all electrodes are successfully connected, you can proceed.

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 **EGZO**Tech described in chapter **9.6 Electrodes for surface electromyography** and **9.7 Electrodes for electrostimulation**. **Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns**. Electrode properties such as dimensions, conductivity, impedance and connector types can greatly influence safety. **Never use ECG/EMG electrodes for the purpose of electrical stimulation.**

Step 3.5: (EMG/EMS in Sidra

In the EMG-triggered programs, it is necessary to calibrate the measurement range. To do this, generate a Maximal Voluntary Contraction (MVC) with the muscle(s) on which the

LEG Ultra only)

electrodes are located, then set the threshold for the triggering channel. You can also change the threshold during the exercise later.

In programs that use electrostimulation, it is also necessary to calibrate the intensity of the flowing current according to the individual patient's comfort level before starting the workout. Press "+1" to increase the intensity and "-1" to decrease the intensity by 1 mA. This can be recalibrated later during the exercise.

In the EMG+EMS exercise, both steps need to be completed.

Once the setup is done, press the "Next" button.

Step 3.6: (EMG/EMS in Sidra LEG Ultra only)

If the exercises CAM Isokinetic, CAM Torque or CAM Game were chosen, the Maximum Force needs to be measured and the threshold should be set. You can also change the threshold during the exercise later.
In the above exercises, apart from games, it is also possible to change the threshold during basing and during training.

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

Step 5: To begin the training, press the "Play" button. Treatment display views vary for the different exercises.

Step 6: After training is complete, an autogenerated report can be viewed. If electrodes were used during training, they should now be disconnected from the patient.

Step 7: Check and follow the instructions in chapters **2.5 Finishing your work with Sidra LEG** and **18. Cleaning**.

15.1 What exercises can I perform?

All training modes are described in chapter **16. Programs Overview**.

Sidra LEG is constantly evolving. Therefore, we've provided you with the most recent exercise manual in the package. However, be sure to check our website https://www.egzotech.com/en/knowledge-base/ and the application notifications after each update to find out the newest exercises added to your machine.

16. Programs Overview

16.1 Continuous Passive Motion (CPM)

16.1.1 Regular

Regular Continuous Passive Motion (CPM) is a standard therapy exercise where Sidra LEG applies a set torque, moving a static patient through the specified range of motion at a set maximum speed. When a maximum 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 CPM + EMS (Sidra LEG Ultra only)

Continuous Passive Movement with synchronized electrostimulation of the selected muscle involves moving the patient's limb from one end of the range of motion to the other at a set maximum speed. The electrostimulation is activated during one of the selected movement phases. The patient remains passive during the exercise. The electrostimulation supports muscle activation and re-education.

16.1.3 CPM + EMG (Sidra LEG Ultra only)

Continuous Passive Movement triggered by the patient's muscle activity by EMG. During calibration, the activity of the selected muscle using EMG is collected and the threshold is selected. Then, after starting the exercise, the patient must, depending on the selected mode (trigger & release or trigger & hold), generate muscle activity above the threshold or generate and maintain it throughout the entire range of movement performed by the robot.

16.1.4 CPM + EMG + EMS (Sidra LEG Ultra only)

Continuous Passive Movement with electrostimulation triggered by the patient's muscle activity. During calibration, the activity of the selected muscle using EMG is collected and the threshold is selected. Then, after starting the exercise, the patient must, depending on the selected mode (trigger & release or trigger & hold), generate muscle activity above the threshold or generate and maintain it throughout the entire range of movement performed by the robot. Electrostimulation is triggered simultaneously with the selected direction of movement.

16.2 Continuous Active Motion (CAM)

16.2.1 Classic CAM Isokinetic

Continuous active motion (CAM) consists of exercises where Sidra LEG provides dynamic resistance (based on the applied torque) and allows the patient to move freely throughout the range of motion. The movement speed is constant during the whole movement (after exceeding the threshold). Dynamic reversal is achieved when the patient voluntarily participates in dynamically and rapidly changing the direction of movement upon reaching the end of the range of motion. With such exercises, an evaluation of the maximal muscle strength can be performed.

16.2.2 CAM Torque

CAM Torque consists of exercises where Sidra LEG provides dynamic resistance based on the applied torque, allowing the patient to move freely throughout the range of motion. The movement speed is proportional to the applied force — after exceeding the threshold, the device moves slowly at first and accelerates as the force increases. Dynamic reversal is achieved when the patient voluntarily and rapidly changes the direction of movement upon reaching the end of the range of motion. With such exercises, an evaluation of maximal muscle strength can be performed.

16.2.3 CAM Game “Space Mission”

A game in which the patient's task is to move the extension along a designated path within the range of motion selected during configuration (turning to the right raises the ship, while turning to the left lowers it). The game offers two types of exercises: Strength and Coordination. In the "Strength" module, the patient works on the strength of the lower limb muscles by moving along a track of a regular shape. In the "Coordination" module, the patient must dynamically change the direction of movement by navigating along a more complicated track. Each module is divided into several difficulty levels. The extension moves as it does in the Isokinetic CAM Classic exercise.

16.2.4 CAM Game “Dream Drive”

A game in which the player controls a car using a special adapter. The goal is to cover the longest possible distance within a set time. The car moves faster when it stays on the road, but if it goes off-track, it slows down. Obstacles appear along the route, which must be avoided to maintain speed.

The game offers two gameplay modes: strength and coordination. The strength mode involves navigating a track with many turns, requiring intense muscle work and increased endurance. The player must maintain stable control of the vehicle despite dynamic direction changes. The coordination mode focuses on precise vehicle control. The track is designed to develop movement control and the ability to react quickly to changing conditions.

The player can adjust the difficulty level by modifying the vehicle's speed and the frequency of obstacles. This allows the game to be tailored to the user's individual needs.

Each mode is divided into several difficulty levels. The adapter moves according to the principles of the Isokinetic CAM Classic exercise.

16.2.5 CAM Game “Ocean Paradise”

The player controls a sea turtle in a simulated aquatic environment, tasked with collecting a specified number of coins within a set time limit. During gameplay, they must avoid interactions with a paparazzi diver, which hinders movement and optimization of the movement trajectory.

The game mechanics feature a power-up system that allows temporary modulation of control parameters. The player can access bonuses such as a protective shield against the diver's negative influence, a x2 multiplier for collected coins, a magnet that automatically attracts coins, and an extra life.

Gameplay is divided into two modes: strength and coordination. The strength mode emphasizes movement intensity and frequency, requiring increased activation of muscle groups. The coin layout is designed to enforce repetitive, controlled movements that support endurance development and motor stabilization. The coordination mode focuses on precise control and adaptation to dynamic environmental changes. The coin positions are arranged to require high accuracy in movement trajectory, aiding in proprioception and manual control development.

The player can adjust the difficulty level by selecting parameters that affect the game's dynamics. The adapter operates according to the biomechanical principles of the Isokinetic CAM Classic system, ensuring realistic motion replication in a controlled environment.

16.3 EMS Programs settings (Sidra LEG Ultra only)

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**.

16.3.1 EMS programs details

EMS programs details	
Type of current	Biphasic symmetric
Shape	Rectangular
Repetitions	5 - 100
ROM max (deg)	Max passive ROM
ROM min (deg)	Min passive ROM
Starting point	Flexion - min, extension - max
Movement direction	Flexion / extension
Pause time in ROM max (s)	0 - 60
Pause time in ROM min (s)	0 - 60
Channels min	1
Channels max	4
Frequency (Hz)	5/10/15/20/25/30/35/40/45/50/60/70/80/90/100
Pulse duration (µs)	50/100/150/.../500
Pulse rise time (s)	0/1/2/3/4
Pulse plateau time (s)	1/2/3/.../20
Pulse fall time (s)	0/1/2/3/4

Sidra LEG Ultra provides the following programs involving electrostimulation:

- Continuous Passive Motion (CPM) + EMS,
- Continuous Passive Motion (CPM) + EMG + 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.

16.3.2 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)	1/2/5/10/15/20/25/30/45/60
Duration (repetitions)	5/10/15/20/50/100
Intensity (mA)	0 - 99
Pulse duration (µs)	50/100/150/... /500
Frequency (Hz)	5/10/15/20/25/30/35/40/45/50/60/70/80/90/100
Rise time (s)	0/1/2/3/4
Fall time (s)	0/1/2/3/4
Plateau time (s)	1/2/3/.../20

16.4 Typical use cases

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

Use by a Professional User:

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. The 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.

Use by a Lay Person:

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

17. Miscellaneous

17.1 How to identify your Sidra LEG or accessories

When troubleshooting and consulting with your product specialist and or customer support, you may be asked to provide your Sidra LEG Serial Number or the Serial Number of your accessories (inc. attachment).

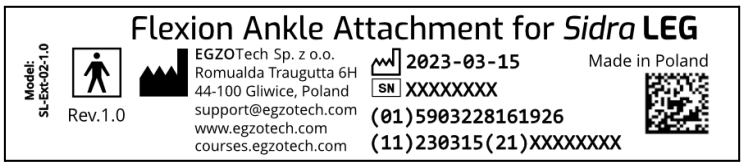
The Sidra LEG serial number can be found on a label located on the side of the basis, which looks like this:

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).

All attachments have similar labels as shown in the example below. Always check the serial number (SN) when referencing accessories.



17.2 Behavior of Sidra LEG

During the usage of Sidra LEG, it is crucial to monitor the activity of the device through the LED Ring communication. The LED Ring provides visual feedback regarding the device's status and operational state. Each color can indicate different functions or information, assisting the operator in understanding the current status of the device at a glance.

Status	Action by Operator	Description
Power OFF	Power OFF Sidra LEG	All LEDs are off.
Power ON	Power ON Sidra LEG	The LED Ring lights up in dark blue, with a green area indicating the extension's position.

17.3 Description of user maintenance responsibilities

The consumable items for Sidra LEG:

- EMG electrodes - Designed for single-use (Sidra LEG Ultra only).

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

The user is obliged to report the need for annual inspections.

It is suggested to regularly restock your supply to ensure availability when needed.

17.4 Software auto updates

Sidra LEG will occasionally want to perform software auto updates for both the tablet application and electronic modules. You will be notified of these updates through a popup window. Software updates ensure that Sidra LEG remains safe and may include enhancements in exercises, games, manuals etc.

Because software updates include safety enhancements, allow Sidra LEG to update as notifications arrive.

Ensure that the Sidra LEG's range of motion is not restricted by any external objects, yourself, or your patients.

The maintenance visits for Sidra LEG should be performed not less frequently than once a year.

17.5 Electrical isolation information

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

- Sidra LEG is equipped with an integrated fuse AC power supply socket type C14 according to IEC 60320, to connect power cord described in chapter **9.2 AC Power Cable**
- To permanently disconnect the device from external electric circuits, it is necessary to detach the AC cable, use the installation disconnector or turn the switch OFF.
- By detaching the AC cable or turning the switch OFF, you are disconnecting both poles of the AC voltage according to IEC 61058-1
- Use of emergency stop push buttons described in chapter **10.5 Emergency stop** disconnect only 24 V internal power supply circuits. AC power supply circuits remain connected after use of emergency stop push buttons.
- All voltages above 60 V DC or 42,4 V AC inside Sidra LEG's chassis that cannot be disabled by the AC power switch are additionally protected and isolated. A BF applied symbol (a patient inside the square) located on the product label described in chapter **17.1 How to identify your Sidra LEG or accessories**.

17.6 Expected product service life

The expected product service life of Sidra LEG is 2 years, under normal operating conditions and receives proper maintenance and handling. The accessories and detachable parts of Sidra LEG **will experience normal wear and tear**, which will decrease the product service life.

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

If you notice any decline in performance of the Sidra LEG's parts, particularly the chassis, the or any of the accessories, please consider replacing them.

Due to the moving mechanical parts, Sidra LEG will experience wear and tear. Given that some safety features rely on these mechanical components, periodic maintenance is required, based on your Sidra LEG usage. With the implementation of two patient protection methods for mechanical hazards, maintenance can be

performed after a single fault occurs. Official maintenance personnel approved by **EGZO**Tech or its partners can conduct periodic maintenance to ensure the device's continuous stability and reliability and to prevent single fault conditions. If your Sidra LEG has a stable, unrestricted Internet connection available at all times, your usage will be monitored by **EGZO**Tech and its partners.

17.7 Storage and transportation instructions

The device and accessories should be stored and transported in its case.

They must be kept in a dry environment and should not be immersed in water or any liquid.

The storage and transportation conditions for Sidra LEG should be:

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

Do not expose Sidra LEG and its accessories to temperatures exceeding the specified range. To prevent short circuits, which can pose burn hazard or lead to gas release, do not store metal jewelry, metal-covered tables, or metal belts alongside the device.

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

17.8 How to safely dispose of the device

The Sidra LEG contains electrical and electronic components that may include materials harmful to the environment if disposed of with general waste. Residents of the European Union must follow specific disposal or recycling instructions for this product. While residents outside the EU must dispose or recycle it in accordance with local laws or regulations.

The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling according to local regulations.

The equipment must be delivered to a suitable collection point for the treatment. By doing so, you contribute to the conservation of natural resources and the protection of human health.

Electrodes should be disposed of according to the instructions provided in their package.

17.9 Warranty

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

During 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.

Warranty conditions are detailed in the EULA. Before accepting the terms, please carefully read the content available at the website: https://support.egzotech.com/terms-and-conditions.

17.10 Manufacturer's service obligation

EGZOTech Sp. z o.o. provides the possibility of sharing on demand electrical schematic, bill of materials, descriptions, calibration manuals, and other information useful for authorized service personnel necessary for the repair serviceable parts permitted by the manufacturer.

18. Cleaning

For long life and excellent quality, remember to clean Sidra LEG and accessories regularly. Follow the guidelines below:

Component of Sidra LEG	Cleaning Instructions
Case, chassis and cables (plastics, polyesters, metal, labels) Cloth-based accessories (strap, belts)	Use a moist cloth with **70% isopropyl alcohol** for cleaning and disinfecting the device and lead wires. **STEP 1:** Turn the device off. Disconnect power supply cable or use an installation disconnector. **STEP 2:** Remove any excess soil by wiping the device with a cloth or paper towel moistened with 70% isopropyl alcohol, and allow it to dry for 5 minutes. **STEP 3:** Spray the 70% isopropyl alcohol directly on the device and lead wires, and leave for the duration indicated in the instructions attached to the cleaning agent (until dry). **STEP 4:** Wipe the device and lead wires with a dry cloth or paper towel.
EMG cables	Use a moist cloth with **70% isopropyl alcohol** for cleaning and disinfecting the EMG cables. **STEP 1:** Disconnect the cable from Sidra LEG. **STEP 2:** Remove any excess soil by wiping the cable with a cloth or paper towel moistened with 70% isopropyl alcohol, and allow it to dry for 5 minutes. **STEP 3:** Spray the 70% isopropyl alcohol directly on cable and leave it for the duration indicated in the instructions attached to the cleaning agent (until dry). **STEP 4:** Wipe the cable with a dry cloth or paper towel.

Never clean Sidra LEG with mains power ON! This may result in electric shock or short circuit the electronics inside.

Never use running water or other fluids for cleaning, except for elastomer components such as grips or straps, which may require rinsing under running water if disinfected with high-level disinfectants, according to their guidelines.

Do not sterilize.

Never use cleaning detergents that contain active oxygen or chlorine, as they may cause surface damage.

For the best cleaning experience, the manufacturer advises using a high-level disinfectant that can handle both bacterial and viral contaminations. An example can be Amity International's Virusolve+ products, available in both spray form (excellent for extension grips) and wipes (ideal for chassis and metal parts).

While using high level disinfectants, always follow the guidelines. If applying the solution to elastomer materials such as Sidra LEG's grips, straps etc. always wash them under running water to prevent the product from remaining on Sidra LEG for too long. Always read and follow the information provided with the substance.

If Sidra LEG is used for multiple patients. Therefore, please follow these guidelines:

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

3. Store according to the instructions provided in chapter **17.7 Storage and transportation instructions**.

No substances emitted by the device were detected in any material during its operational life, including the disinfection and cleaning processes.

19. Data protection

19.1 End user license agreement (EULA)

To provide services using the Sidra LEG device, the user will be asked to sign an End User License Agreement (EULA) with **EGZO**Tech to regulate legal obligations between **EGZO**Tech and the user. The EULA can be found here https://support.egzotech.com/terms-and-conditions.

19.2 Data retention

EGZOTech reserves the right to retain the collected data for a minimum period of 10 years from the cessation of manufacturing of the last Sidra LEG device, in accordance with the requirements of Regulation (EU) 2017/745.

20. Declaration of Conformity and compliance statements

20.1 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 on medical devices.

Classification: Class IIa, rule 9, according to Annex VIII of MDR Regulation.

This product complies with all relevant European and international standards. All applicable requirements are listed in the Declaration of Conformity of the device.

Sidra LEG is intended for use in the electromagnetic environment specified below. The customer or the user of Sidra LEG should ensure it is used in such an environment.

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 on maintaining basic safety and essential performance in relation to electromagnetic disturbances and expected service life, please refer to general warnings described in this manual.

20.2 Manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

20.3 Manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity test	**IEC 60601-1-2 test level - the device is tested to compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	The floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply line repetition frequency: 100 kHz	Mains power quality should be that of a home, typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a home, typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° & 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a home, typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity test	**IEC 60601-1-2 test level - the device is tested to compliance level**	**Electromagnetic environment - guidance**
	0 % U_T: 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz (Professional Healthcare) 10 V/m 80 MHz to 2.7 GHz (Home Healthcare)	
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/SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT/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/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 wave	2	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	9
745 780 810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	28
1 720 1 845 1 970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, IMTS	Pulse modulation 217 Hz	2	28
2 450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	28
5 240 5 500 5 785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	9
The Manufacturer is Compliant with all the above listed specifications.					

GUIDELINES:

(a) For best performance of Sidra LEG's wireless communication use Wi-Fi channels that are less populated by other Wi-Fi 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 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

20.4 Recommended separation distances between portable and mobile RF communications equipment and Sidra LEG

Sidra LEG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sidra LEG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 (m)		
	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 metres (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.

20.5 RF 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. Sidra LEG permanent installation protocol - home healthcare environment only

Service Location:

Address: _____

Date of Service: _____

Client details:

Name: _____

Address: _____

Phone Number: _____

Authorized service personnel (electrician) details:

Name: _____

Electrician qualification (e.g., SEP): _____

Phone Number: _____

Installation Confirmation

I, the undersigned electrician, confirm that the installation of the medical electrical equipment Sidra LEG, serial number: _____, was completed in compliance with current regulations, safety standards and requirements specified in chapter **6.6 Use in home healthcare environment**. The client has been informed about the correct usage of the device.

Installation Details (according to IEC 60364)

Cable Type and Cross-Section: _____

Residual Current Device (RCD): Yes / No

Grounding Verification: Yes / No

Supply Voltage: _____

Type of Protection (Rated Current): _____

Does the installation meet manufacturer requirements and comply with relevant standards: Yes / No

Control and Measuring Instrument Used for Verification

Manufacturer: _____

Model: _____

Serial Number: _____

Additional Notes

_____
_____
_____
_____
_____
_____
_____

Electrician's Signature: _____

Date: _____

Client's Signature: _____

Date: _____

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

EGZOTech Sp. z o. o.
Romualda Traugutta 6H
44-100 Gliwice, POLAND
office@egzotech.com
+48 32 750 49 45