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User Manual
Luna EMG

Rehabilitation robot

Read carefully before use

Technical model: Luna EMG

Gliwice, Poland 2023

CE 2274

1. We are here for you!

Thank you for ordering Luna EMG and welcome to our family!

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

The next steps will empower your therapy with Luna EMG!

To learn more about Luna EMG, visit the following:

Our YouTube page for videos and tutorials!

https://youtube.com/EGZOTech

If you're having unexpected operation or events, issues, medical incidents or any trouble with your Luna EMG, please contact us under the following:

Our Service Desk page:

https://service.egzotech.com

Jira Service Desk

Other direct contact information

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

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

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

2. Quick setup guide

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

Don't like reading? Check out our video tutorials available at http://egzotech.com/manual

2.1 Safety

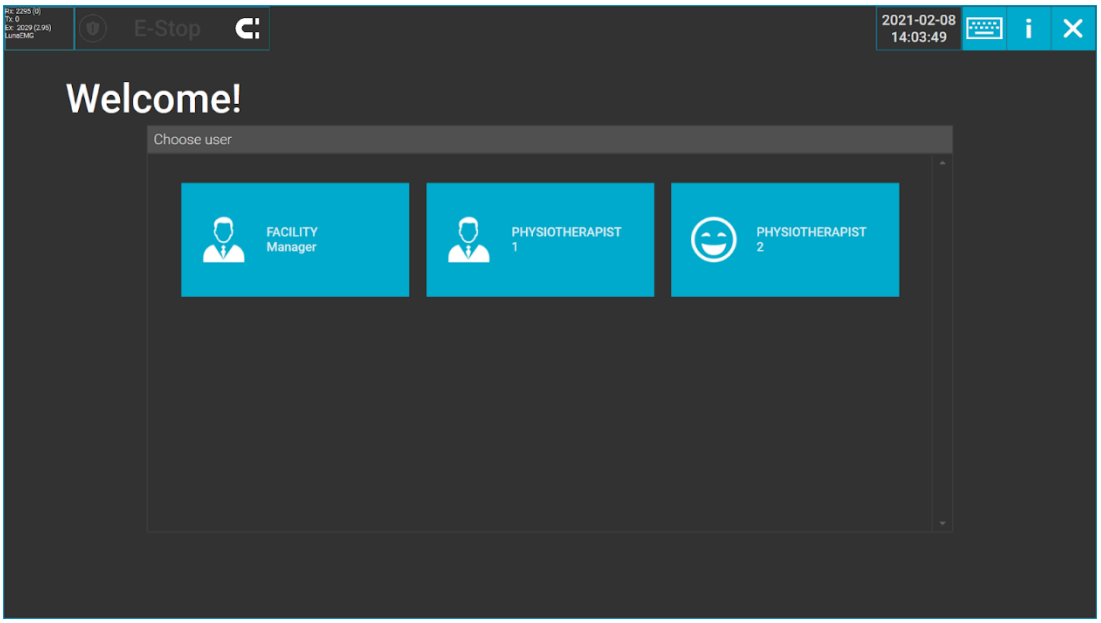
Luna EMG can be dangerous if configured incorrectly!
Do not start using Luna EMG before getting familiar with this User Manual.

2.2 Let's connect everything!

Follow the diagram on the next page for step-by-step electrical connection and basic client assembly of Luna EMG. If You've been visited by one of our product specialists, Luna EMG should be set up and ready for your patients!

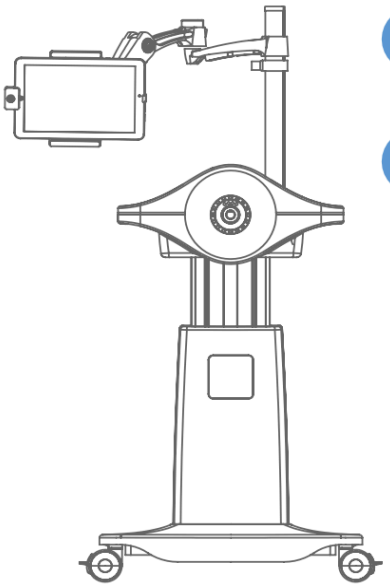
2.3 Let's run the App!

At this point, if everything was connected correctly, Luna EMG's LED Ring front display should indicate "System booting up" state, described in chapter 10.7 LED Ring front display indications. On the Tablet, you should see the Application Login screen shown below (with the users configured by your product specialist).



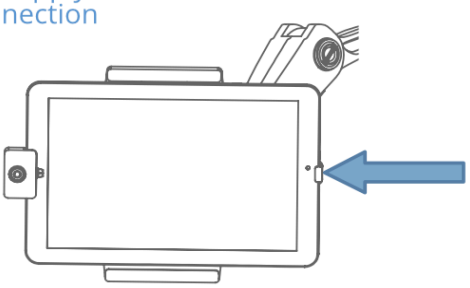
Congratulations! Your Luna EMG is ready for patients! Before you start, we strongly advise you to read the rest of this manual and watch our YouTube videos to learn how to use Luna EMG to best efficiency. Let us know what your experience is on Facebook!

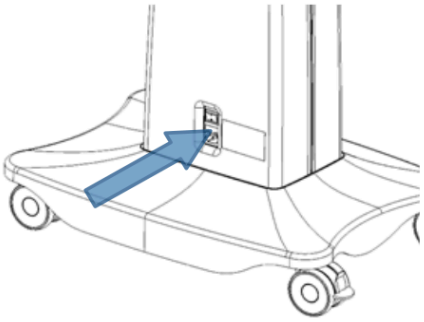
If this is not your first Luna EMG unit, follow the instructions at chapter 19.3 Facility admin configuration.



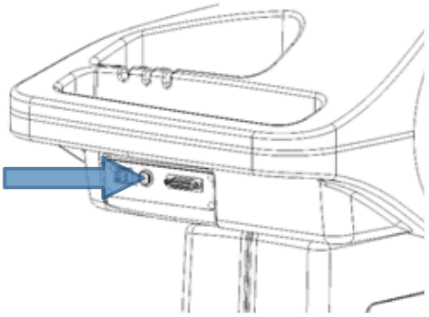
1. Take Luna EMG out of her package, and remove all the transport safety bands.

2. Connect two of the cables located at the back of the tablet holder to the tablet:
   1. DC power supply
   2. USB-A connection

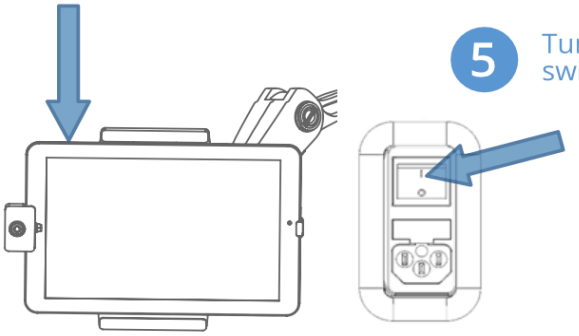




3. Plug the AC cable to the back of Luna EMG and to a grounded electrical socket.

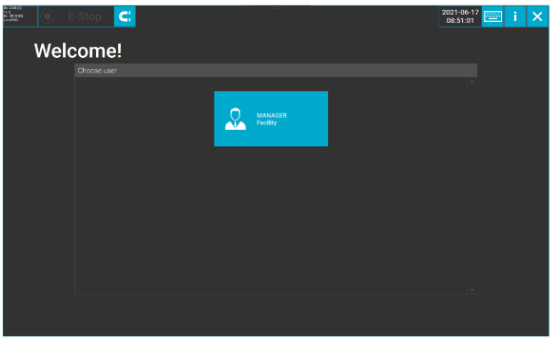


4. Plug in the patient's emergency stop to the socket marked with the symbol below.



5. Turn Luna EMG and the tablet on using both of their switches.

6. Wait for the application to load and start working with Luna EMG.



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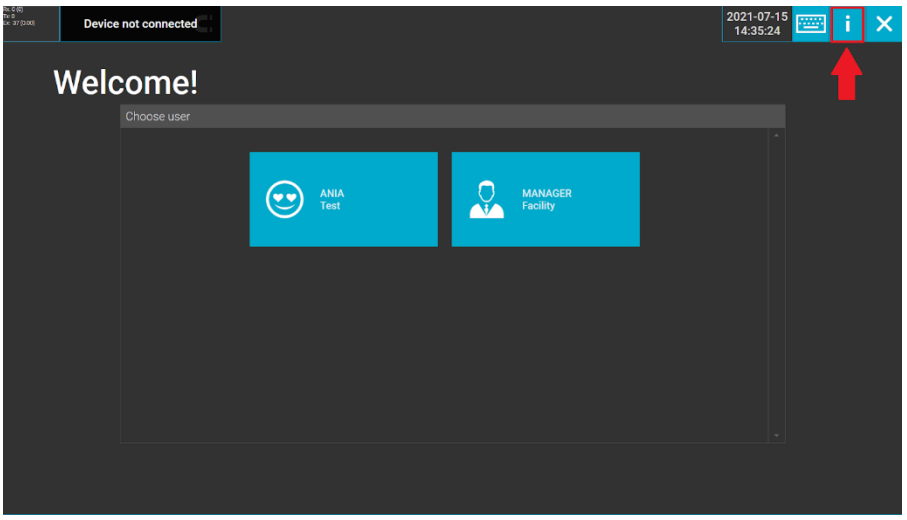
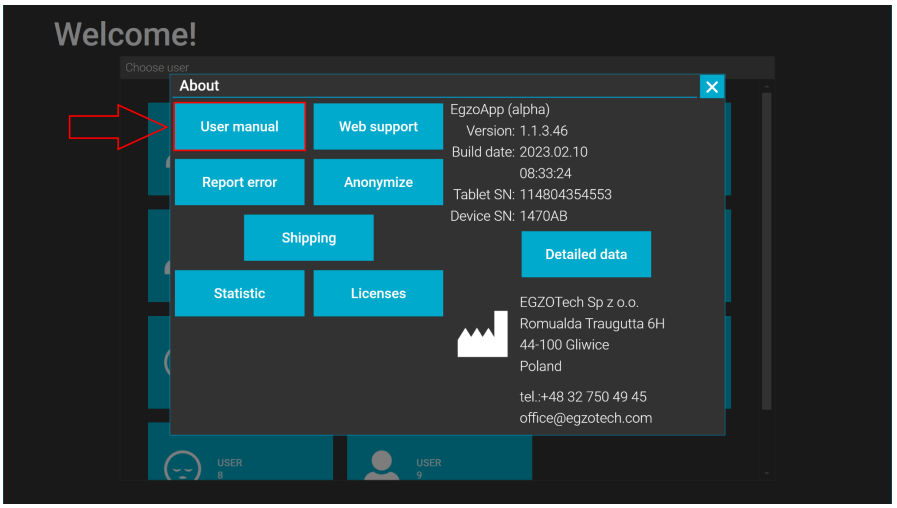
4. Where to get this manual?

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



Also the quick access to User Manual is available through EGZOApp. Users get access by clicking the 'i' icon on the application

After clicking User manual button, user get access to the Luna EMG's Manual.



5. What is Luna EMG

5.1 Device description

The Luna EMG rehabilitation robot with electromyography biofeedback is a medical device used as a tool for automatic motor rehabilitation and assessment of the patient's motor status.
Luna EMG provides methods of rehabilitation assessment, as well as physical and occupational therapy. It is an electrically powered robotic device accessible through software installed in the tablet included with the device. Luna EMG has 6 channels for electromyography and works also with additional equipment as different extensions.
The rehabilitation programs and exercises are conducted by Luna EMG based on force feedback allowing to apply a dynamic resistance and by biofeedback conducted i.e. by means of electromyographic measurements.
Luna EMG is especially intended for motor rehabilitation of patients with orthopaedic and neurological conditions.

Luna EMG should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The device is not suitable for home use.

Luna EMG is an automatic physiotherapy device. Misconfiguration of the training parameters, especially range of motion, maximal applied torque and maximal speed can cause injuries!

6. User responsibilities

6.1 Indications for use

Luna EMG is multi-use rehabilitation robot - rehabilitation exercise device, intended for medical purposes of rehabilitation, physiotherapy and occupational therapy, including both therapy and evaluation of patient's state.

Luna EMG 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;
- Pelvic floor therapy using vaginal or anal probes, to:
  - Improve and evaluate urinary and faecal control;
- Rehabilitation assessment, to:
  - Evaluate muscle innervation by surface electromyography;
  - Evaluate ranges of motion;
  - Evaluate limb rigidity and spasticity;
  - Evaluate maximal muscle strength;
  - Evaluate fatigability.

This list is not meant to be exhaustive.

Patient group

The product is intended to be used by all groups of patients (irrespective of the age, height of weight), giving consideration to the maximal allowable loads provided in the operating manual.

Patient groups should be considered among others:

- Low mobility patients (external use) - patients with possible severely impaired mobility and lack of sensation in their limbs and trunk, 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.
- Pelvic floor patients (internal use) - patients with regions of therapy and diagnosis focused around the pelvis, including the vagina and rectum. It is possible that some of these patients will be classified also as low or non-low mobility patients with pelvic complications arising from other disorders e.g. stroke and spinal cord injuries.

List is not meant to be exhaustive.

6.2 The intended users

Luna EMG is intended for:

MEDICAL PROFESSIONALS - healthcare service providers of one of the following specialities: a physical therapist, an occupational therapist, a rehabilitation doctor, a neurologist, a sexuologist, a nurse or nurse practitioner, an orthopedic doctor and other general practitioners. Luna EMG 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 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, before you start working with your patients with Luna EMG. If you have any doubts, especially the 7. Warnings and basic safety chapter, feel free to reach out to EGZOTech directly and we will do our best to help you.

6.3 Contraindications

When **not to use Luna EMG** (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
- Body or limb weight or dimensions exceeding technical specs
- Deep venous thrombosis
- High-grade fever

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

With the use of vaginal/anal electrode:

- Bladder or vagina infection
- Cervical or anal cancer
- If have or have had epilepsy
- Pregnancy. Pregnant and postpartum period (by about 6 weeks after childbirth)
- Menstruation
- High body temperature
- Allergic reaction in case of oversensitivity for Nickel
- After pelvic surgery within the last 3 months (relative contraindication)
- Advanced dementia, psychosis and severe mental retardation (relative contraindication)
- Children under the age of four

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

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

Before and after every training, check for previously existing wounds and wounds or pressure points caused by training, in particular in bodily areas that contact the device.

- Shoulder-hand syndrome/Subluxation, shoulder instability with uncontrolled shoulder displacement during training
- 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 list above does not claim to be exhaustive.

For patients with relative contraindications, it's possible to use Luna EMG 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 Luna EMG is a device that is intended to help patients, but if used incorrectly, may lead to injuries. There are two fundamental rules that need to be followed at all times.
Luna EMG needs to be operated by a professional user, whether that's a physiotherapist or doctor for patient's therapy. Engineers can operate the device during annual check-ups or service works – engineers are not allowed to work with patients. All supervisors have to be trained beforehand by an authorized EGZOTech product specialist or trainer. A training certificate will be given to all authorized supervisors.
EGZOTech Certified Trainers, engineers, service technicians can perform device training on Luna EMG during product presentation.
For information about the nearest authorized representative or trainer, contact EGZOTech.

Only supervisors with an official EGZOTech training certificate can operate Luna EMG.

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

For patients with relative contraindications, it's possible to use Luna EMG 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.**

6.5 Internet connection

The Internet connection allows you to fully use the potential of Luna EMG. The connection with the Internet is voluntary and largely depends on the safety policy of the health care facility. However, a permanent connection to the Internet will allow you to keep the EgzoApp software updated and some games (Brick Pirates, Burger Mania) are only available with constant Internet connection.
Not connected to the Internet does not affect the basic functions and core operation of the Luna EMG.
If you have Wi-Fi reliable and available at your facility, your product specialist will help to configure connection with Luna EMG.

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

We understand the concerns about data privacy, especially when it comes to sensitive medical data. Therefore, all medical data is stored in your tablet memory. The data is not sent on the cloud or any other external server. You can find more information on how EGZOTech stores your data in chapter 19.2 Facility private password.

7. Warnings and basic safety

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

7.1 General safety consideration and precautions

Luna EMG has been created for specific physiotherapy exercises. Do not use Luna EMG for any other purpose not included in this manual or training videos provided by EGZOTech.

Before starting to treat each patient with Luna EMG you should provide at least the information about the intended treatment, contraindications and safety measures.

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

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

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

In an event that **Luna EMG doesn't behave in an intended manner**, **press either of the 2 stop buttons (emergency stop button or patient safety button)**, notify your product specialist or our customer support immediately.

When you are ready to finish working with Luna EMG, remember to release the extension and store it in the extension box.

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

Use Luna EMG only with authorized accessories! That includes all the package contents listed in chapter What will I find in the package?.

Use only the AC cable supplied. **Do not plug third party sensors, electrodes or other accessories.**

Luna EMG's measurement functions, including electromyography, are susceptible to electromagnetic disturbances. As such, please be aware of other electromagnetic devices or

installations that can affect measurements. Luna EMG meets the electromagnetic compatibility requirements, including immunity to electromagnetic disturbances, providing basic safety. If you encounter any signal artefacts or noise, discard the measurements and don't consider them to the patient evaluation process.

Luna EMG is not intended to be used with needle electrodes.

Do not use Luna EMG outside of its operating environment, including temperature or humidity, specified in the chapter 10.1.2 Technical Specification in this manual.

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

7.2 Electrical safety and electromagnetic compatibility

Luna EMG is running on specific electrical parameters. **Ensure that you have a compatible AC sockets with the requirements specified** in chapter 10.1.2 Technical Specification.

Luna EMG is an electrical device with no liquid ingress or solid particle protection (IP30). Protect Luna EMG from any contact with liquids and/or solid particles.

Avoid stretching, riding over, tying up or any activity that could damage the AC cable and/or other cables provided with Luna EMG.

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

While replacing external AC fuses, follow the electrical requirements in the technical specification.

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

Luna EMG is electrically safe, even in an 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 software, take extra caution and contact your product specialist.

Luna EMG has two applied parts (elements that are intended to get in contact with a patient). Applied part B (Extension and extension parts in Luna EMG's Head) is used to transfer mechanical energy to the patient (make the patient limbs move), while the bioelectricity elements (EMG cables, electrodes, and hidden parts in Head) are the applied part BF used to transfer electrical energy from and to the patient. Those parts have extended electrical safety parameters and are labelled according to the symbols table in chapter 8.3 Symbols.

A detailed schematic of AC isolation is provided in chapter 17.5 Electrical isolation information.

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

The Luna EMG complies with the requirements of IEC 60601-1-2:2014 (EMC Collateral Standard) including the E-field susceptibility requirements at a level of 10 volts per meter, at frequencies from 80 MHz to 2.7 GHz. However, even at this level of device immunity, certain transmitting devices (mobile phones, two-way radios, cordless phones, paging transmitters, RFID devices, etc.) emit radio frequencies that could interrupt Luna EMG operation if operated in a range too close to the Luna EMG. Practitioners should be aware of possible radio frequency interference if portable devices are operated in close proximity to the Luna EMG.

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.

Do not connect leads or electrodes to other objects.

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

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

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

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

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

7.3 Mechanical safety

Body weight exceeding technical specs, maximal applied weight per extension is 30 kg

Luna EMG has two trapping zones. The first located between the head and lifting column chassis, and the second between the dynamic extension and static extension or head/lifting column chassis. **Do not put any body parts or other object in any of those trapping zones while Luna EMG is moving. Putting objects in the trapping zones during normal operation may cause injuries.**

Luna EMG has venting holes located on the bottom of the base, and on the top of the tablet's mount. **Do not put any objects or body parts in those holes.**

Before use, always check Luna EMG and extensions for mechanical damages. Do not use Luna EMG or any extension, when a damage was noticed.

Do not make any mechanical modifications to Luna EMG and the extensions. That includes removing the installed screws.

In a rare event of an uncontrolled, unintended movement of Luna EMG, press the emergency stop first, and then proceed with unstrapping your patient from the extension (if needed).

Luna EMG uses her weight and a low center of gravity for stability. **Follow the maximal joint weight and maximal torque stated in the technical specification** to avoid instability and toppling over.

During transport, use the head's handles to ensure maximal stability.

Before starting training, be sure that all of base's wheels are locked in place. Before transportation be sure that all of base's wheels are unlocked.

When riding over obstacles, do not lift the whole robot (it's almost 100kg!). Use the head's handles to lift one part of Luna EMG and right through the obstacle, and then do the same with the other handle.

If you need to lift Luna EMG for transportation (in a situation that all wheels need to be above ground), use the provided transportation case. **The head's handles aren't meant for sustaining extensive weights of Luna EMG.**

During transportation, avoid collisions with other objects.

While using Luna EMG, avoid wet, slippery or uneven surface. Try to avoid those during transportation whenever possible.

Do not step, sit or stand on any part of Luna EMG or extensions. Do not put any unintended objects on Luna EMG.

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

Please report all damages, malfunctions or strange behaviours to your product specialist.

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

7.4 Multiple use precautions and consumables

Before working with patients Luna EMG must perform an auto diagnostic procedure to ensure maximal safety. You will not be able to run any training programs until the results from auto diagnostic tests will comply with intended safety. Follow the software instructions after the quick setup guide to complete these steps.

Luna EMG has been tested to be reliable for multiple use and cleaning with the disinfection products described in the chapter 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 Luna EMG. Luna EMG shouldn't be thrown out, or improperly utilized due to electronic components. Consult your product specialist on how to act best to utilize Luna EMG 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.

Luna EMG accessories and the device itself will experience normal wear and tear over time. Possible degradation of performance over time is possible, especially in electrical connections between the cables and electrodes.

For bioelectric programs (like electromyography) we recommend the use of single-use electrodes. **Remember to use single-use electrodes only once**. If you decide to use different electrodes always consult your product specialist. **With multiple use electrodes remember to clean the electrodes as intended by the manufacturer.**

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

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

For resale, rent, lease or any other form of sharing Luna EMG with a different legal entity consider the EULA (End user license agreement). Because all operations on Luna EMG are linked to a specific user account (facility – therapist – patient). **It's crucial for the safety of the patient that only authorized and trained personnel use Luna EMG.** For sales purposes Luna EMG's database has to be reverted to original state. Contact your product specialist for assistance.

Luna EMG shouldn't be thrown out, or improperly utilized due to electronic components. Consult your product specialist on how to act best to utilize Luna EMG that won't negatively impact the environment.

7.5 Biological safety

Never use Luna EMG with compromised or wounded skin.

Luna EMG is intended and created with biocompatibility of **skin contact**. **Avoid contact with mucosal membranes and breached or compromised surface**, or in any case inside your body.

Luna EMG has been analysed for biocompatibility that includes cytotoxicity, sensitization and irritation or intracutaneous reactivity, however **if you or your patient experience an allergic reaction, irritation, or signs of toxicity, whether from Luna EMG or any other source, cease all training** until the underlying cause has been dealt with.

Luna EMG's materials have been tested with the disinfection products described in the chapter 18. Cleaning. The use of different, especially not intended disinfection products can lead to contamination, surface deterioration, loss of biocompatibility and malfunction.

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 or other Luna EMG accessories etc.

7.6 Environmental safety

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

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

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

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

Luna EMG is intended to be used in the operating temperature and humidity specified in chapter 10.1.2 Technical Specification.

Luna EMG should be used in well lighted rooms.

Luna EMG's Ingress Protection code (IP) is specified in chapter 10.1.2 Technical Specification. The rating is IP30, therefore:

- It is rated 3 for solid particle protection of objects larger than 2.5 mm (0.098 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 0 for liquid ingress protection. This means that the enclosure does not provide liquid ingress protection.

Do not immerse Luna EMG in water or any other liquid substance, including water vapour.

7.7 Software safety and cybersecurity

Luna EMG is equipped with a Windows based tablet with restricted access. Do not install any unapproved applications. **Untested software can interfere with Luna EMG's controls and lead to injuries!**

Do not update the operating system or 3rd party applications without advice from Luna EMG's application.

Luna EMG will update its software automatically, including 3rd party applications. **Do not interrupt the ongoing update process,** because it will have to restart, taking more time.

7.8 Lifetime

Luna EMG, due to moving **mechanical parts, will experience wear and tear**. Due to some safety features being implemented by the use of those mechanical parts, periodical maintenance is required, based on your Luna EMG usage. Due to the implementation of two methods of patient protection for mechanical dangers, Luna EMG's maintenance can be performed after a single fault has occurred. Periodical maintenance carried out to ensure continuous stability and reliability of the device, to prevent single failures, can be carried out by EGZOTech service personnel or partners indicated by EGZOTech.

If your Luna EMG has a stable, unrestricted Internet connection available at all times, your usage will be monitored by EGZOTech and necessary maintenance will be proposed ahead of time, to limit the downtime of your devices.
Periodic maintenance are required at 12-month intervals. This is a precaution to prevent dual, simultaneous failure of methods of patient protection. If your Luna EMG has a stable, unrestricted Internet connection, such tune-up will be proposed by the maintenance team.

7.9 Annual maintenance

As with any medical device, to ensure ongoing safety and viability of Luna EMG, 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 Luna EMG may stop operations if the annual maintenance cycle is skipped. We strongly recommend you avoid skipping the annual tune-up maintenance and in unforeseen events contact your provider immediately. EGZOTech is not liable for any events that happen due to skipping the annual tune-up maintenance.

7.10 Risk and benefits

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

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

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

Luna EMG produces results that are informative, not diagnostic. Qualified individuals must interpret the results.

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

8. How to work safely with Luna EMG?

8.1 Why this user manual is so important

Remember, that Luna EMG is an automatic physiotherapy robot. What that practically means is, it can work as a standalone exerciser for your patients. That also means that **misconfiguration of the training parameters**, especially range of motion, maximal applied torque and maximal speed **can cause injuries!**

Do not start using Luna EMG before getting familiar with this this manual.

8.2 Labelling

On the back on the device the label of Luna EMG is placed. On the label user will find information about owned unit of Luna EMG. Luna EMG 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 Luna EMG.

8.3 Symbols

Luna EMG uses safety symbols on the device itself, as well as inside the software application. Below is an explanation of all the symbols you'll encounter while using Luna EMG.

Symbol	What it means	Symbol	What it means
	Indicates the medical devices manufacturer		Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator

Symbol	What it means	Symbol	What it means
			action in order to avoid undesirable consequences
YYYY-MM-DD	Indicates the date when the medical device was manufactured		Identifies a type B applied part complying with IEC 60601-1
	Applied part type BF, used for electrical connections to and from the patient. Part isolated from all other parts of the device		Refer to User Manual
SN XXXXXX	Indicates the manufacturer's serial number so that a specific medical device can be identified	IP30	Ingress Protection
CE 2274	CE marking indicates that a product complies with applicable European Union regulations. No 2274 is a no of Notification Body	LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
~ 100 -240 VAC 50/60Hz 4A T4AL 250V fuse 100VAC, 1.5A 24VAC, 0.7A	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals	MD	Indicates the item is a medical device
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005		No stepping on surface
	No sitting	Made in Poland	The country of origin must be visibly printed on the product and packaging
	No pushing		Indicates the range of humidity to which the medical device can be safely exposed

Symbol	What it means	Symbol	What it means
	Indicates the temperature limits to which the medical device can be safely exposed		This way up
	Indicates a medical device that needs to be protected from moisture		Do not roll
	Indicates a medical device that can be broken or damaged if not handled carefully		Do not stack

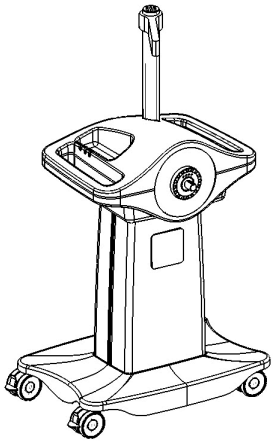
8.4 Additional symbols on accessories

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 needs protection from light sources	PVC	PVC free

9. What will I find in the package?

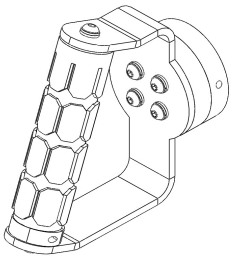
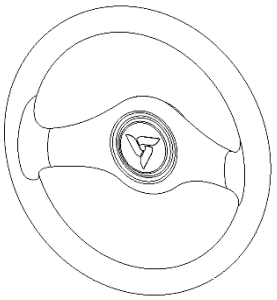
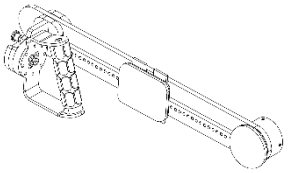
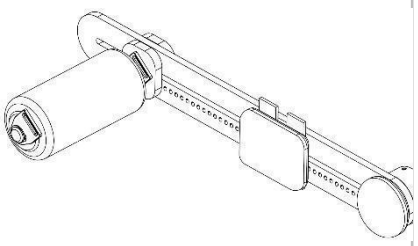
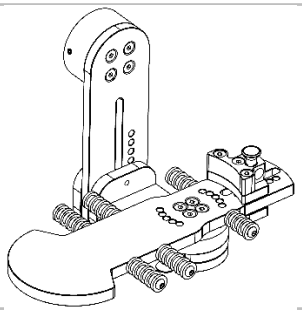
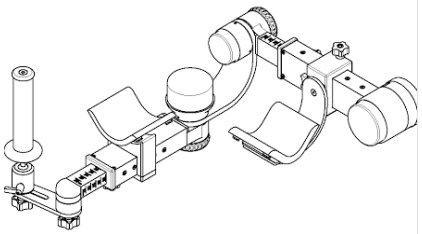
Dependent on your order and configuration, you may find the following products associated with Luna EMG included.

9.1 Luna EMG

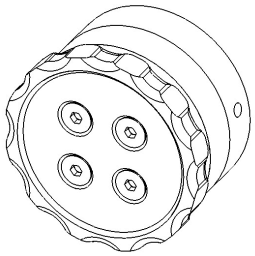
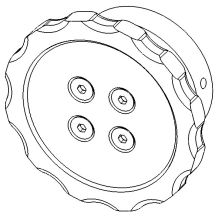
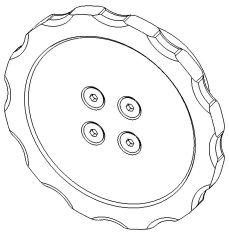
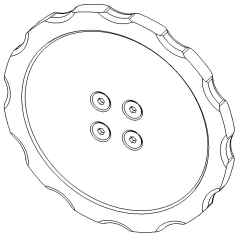
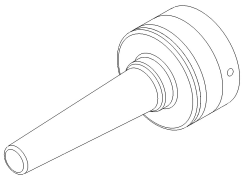
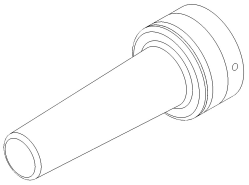
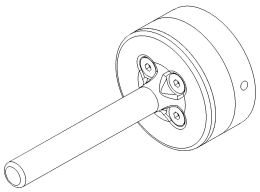
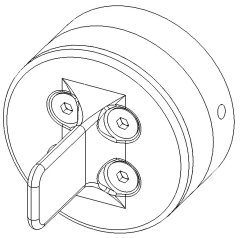
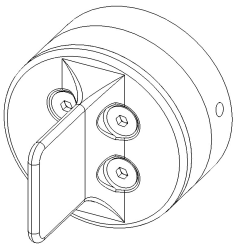
How it looks like	What it is
	Luna EMG robot 1 pcs.

9.2 Extensions

9.2.1 Extensions – Standard extension package

How it looks like	What it is	How it looks like	What it is
	Forearm extension for Luna EMG Code: LE-Ext-01 1 pcs.		Steering wheel extension for Luna EMG Code: LE-Ext-03 1 pcs.
	Upper limb Extension for Luna EMG Code: LE-Ext-02 1 pcs.		Lower limb Extension for Luna EMG Code: LE-Ext-04 1 pcs.
	Ankle extension for Luna EMG Code: LE-Ext-05 1 pcs.		Shoulder extension for Luna EMG Code: LE-Ext-06 1 pcs.

9.2.2 Extensions - Occupational therapy extensions

How it looks like	What it is	How it looks like	What it is
	Disc extension – paediatric for Luna EMG Code: LE-ExtOT-01 1 pcs.		Disc extension - small for Luna EMG Code: LE-ExtOT-02 1 pcs.
	Disc extension – medium for Luna EMG Code: LE-ExtOT-03 1 pcs.		Disc extension – large for Luna EMG Code: LE-ExtOT-04 1 pcs.
	Screwdriver extension – medium for Luna EMG Code: LE-ExtOT-05 1 pcs.		Screwdriver extension – large for Luna EMG Code: LE-ExtOT-06 1 pcs.
	Screwdriver extension – small for Luna EMG Code: LE-ExtOT-07 1 pcs.		Key extension - small for Luna EMG Code: LE-ExtOT-08 1 pcs.
	Key extension - large for Luna EMG Code: LE-ExtOT-09 1 pcs.		

9.3 Tablet Accessories

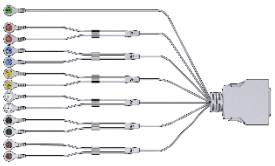
How it looks like	What it is	How it looks like	What it is
	Surface Pro Tablet 1 pcs.		Tablet holder keys 1 pcs.
	USB Hub on tablet holder 1 pcs.		

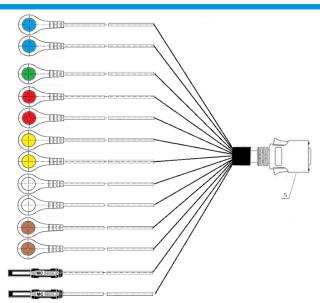
9.4 Main cables

How it looks like	What it is	How it looks like	What it is
	10m AC Cable IEC C13 1 pcs.		Remote controler with safety button for the patient Code: LE-EStop 1 pcs.

AC Cable IEC C13 available in 1.5m and 10m lengths and with the following standards: CEE7 (EU plug), BS1363 (UK plug), Plug K (Denmark, Bangladesh plug).

9.5 Electromyography cables

How it looks like	What it is	How it looks like	What it is
	EMG cable 2 + 0 channels Length : 150 cm 2 channels (4 snaps) to connect the surface electrodes (EMG) only + 1 Reference lead wire (green snap with the REF sign) 1 pcs.		EMG cable 6 + 0 channels Length : 150 cm 6 channels (12 snaps) to connect the surface electrodes (EMG) only + 1 Reference lead wire (green snap with the REF sign) 1 pcs.

How it looks like	What it is	How it looks like	What it is
	EMG cable 5+1 pelvic floor advanced bioelectricity cable 1 pcs. (Optional)		

9.6 Electrodes for surface electromyography

How it looks like	What it is
	EMG surface electrode EGZOTech EE S5540 FWG Electrode area intended to contact the surface of the skin: 3,8 cm^2 55x40 mm 50psc/case For EU only
	EMG surface electrode EGZOTech EE S5540 FWG1 Electrode area intended to contact the surface of the skin: 44x35 mm 3,8 cm^2 50psc/case For EU only

Luna EMG is compliant with any surface ECG/EMG electrodes compliant with IEC 60601-1 requirements.
Follow the information provided with the electrodes by their manufacturer.

9.7 Pelvic floor electromyography electrodes

How it looks like	What it is
	Adult 2 lead vaginal electrode Everyway PR-02A Pcs or set Electrode area intended to contact the surface of the skin: 7.65cm^2 X2 Optional

How it looks like	What it is
	Small 2 lead vaginal electrode Everyway PR-14A Pcs or set Electrode area intended to contact the surface of the skin: 9.05cm^2 X2 Optional
	Adult 2 lead anal electrode Everyway PR-09A Pcs or set Electrode area intended to contact the surface of the skin: 2,025 cm^2 X2 Optional
	Adult 2 lead anal electrode Neen Anuform Electrode area intended to contact the surface of the skin: 3 cm2 X2 Pcs or set Optional
	Adult 2 lead anal electrode Everyway PR-06A Pcs or set Electrode area intended to contact the surface of the skin: 1.93 cm^2 X2 Optional
	Adult 2 lead anal electrode Everyway PR-13A Pcs or set Electrode area intended to contact the surface of the skin: 3.74 cm2 X2 Optional

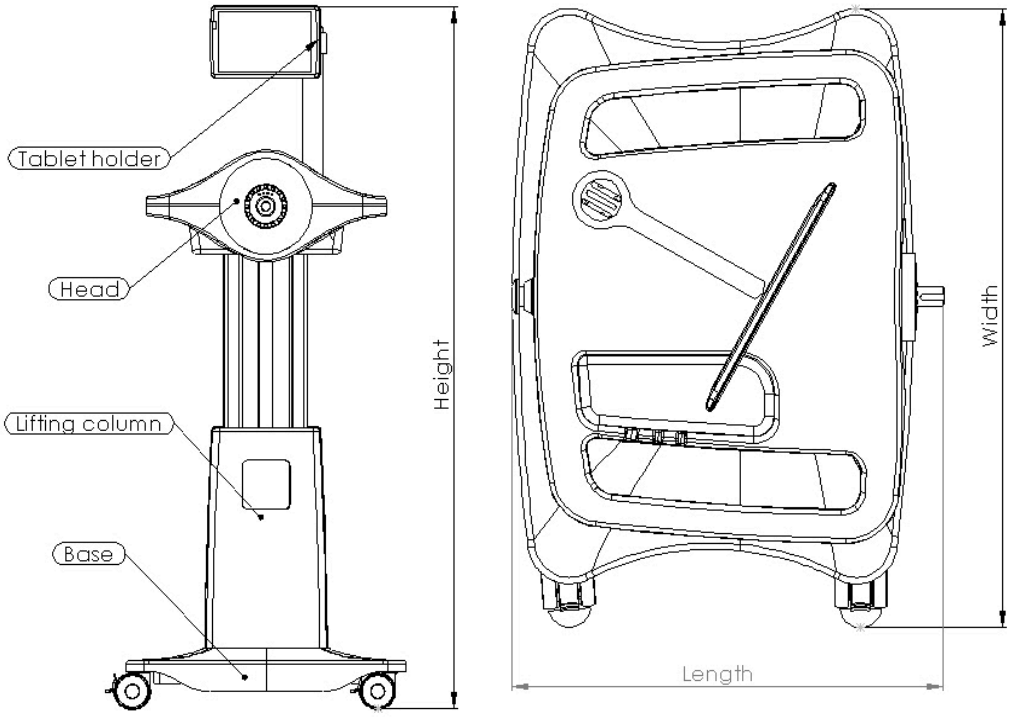
Luna EMG is compliant with any pelvic floor EMG electrodes compliant with IEC 60601-1 requirements.
Follow the information provided with the electrodes by their manufacturer.

10. Basic information about Luna EMG

10.1 How is Luna EMG built

10.1.1 Major components

Luna EMG consists of four major components: Base, Lifting column, Head and Tablet holder. You can see them in the figure below.



10.1.2 Technical Specification

ESTABLISHED AND TRADE NAME:
Luna EMG

DIMENSIONS & WEIGHT (WITHOUT ACCESSORIES):

Total length:	420mm
Total width:	600mm
Total height:	1135-1485mm
Total weight (except extension):	max. 90kg
Maximal applied weight (per extension):	30kg
Base height:	97,5 - 122mm
Lifting column stroke length:	350mm
Wheel diameter:	ø75mm

ENVIRONMENT:

Operating temperature:	10 °C to 40 °C
Maximal temperature variation in 12h:	20 °C
Operating humidity:	5% to 95% RH, not-condensing
Maximum operating altitude:	3 000 m a.s.l.
Cooling: convectional	
Liquid ingress and solid particle protection:	IP30

MECHANICAL PROPERTIES:

Head's rotation axis height:	720-1070mm
Head's rotation limits:	-315° - 315°
Head's rotation position accuracy:	± 2°
Maximal head's rotation torque:	60 Nm
Torque measurement accuracy:	±0,2 Nm
Maximal head's rotation speed (no load):	50°/s
Maximal lifting column's speed (no load):	25 mm/s
Lifting column height position accuracy:	2 mm
Lifting column stroke accuracy:	±2 mm

ELECTROMYOGRAPHY:

Electromyography measurement channels:	Up to 6, simultaneous sampling
Baseline noise:	<0.5 µV RMS

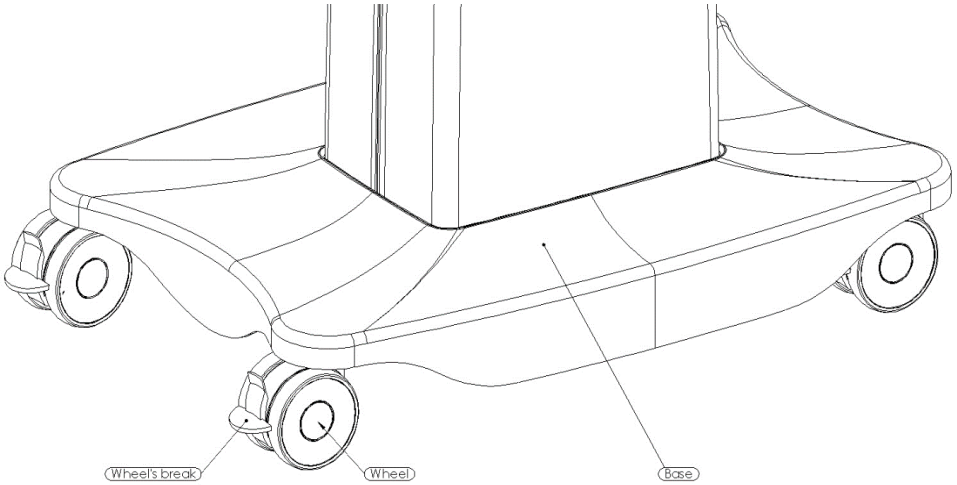
Mobility: under the operating environmental conditions listed above.
Operation type: Continuous, software controlled

OTHERS:
Power supply: 100-240 VAC, ~50/60 Hz grounded
Current required: 100VAC, 1.5A; 240VAC, 0.7A inc. tablet
Applied part type: B, BF
Protection class against electric shock: class I
Fuses used: 4A, T4AL, 250V
Filters:
Band-stop 48-52Hz or 58-62Hz
Band-pass 28-138Hz

Input-referred noise: 10µVpp (10 seconds of raw data)
Measuring Voltage range: -0.6V to 0.6V
Luna EMG's Gain: 1
Sampling frequency:
Up to 1 000 samples per second per channel
Internal resolution: 24-bit
CMRR: -73dB
Input impedance: 10MΩ
Accuracy of electromyography 1µV RMS

10.2 Base

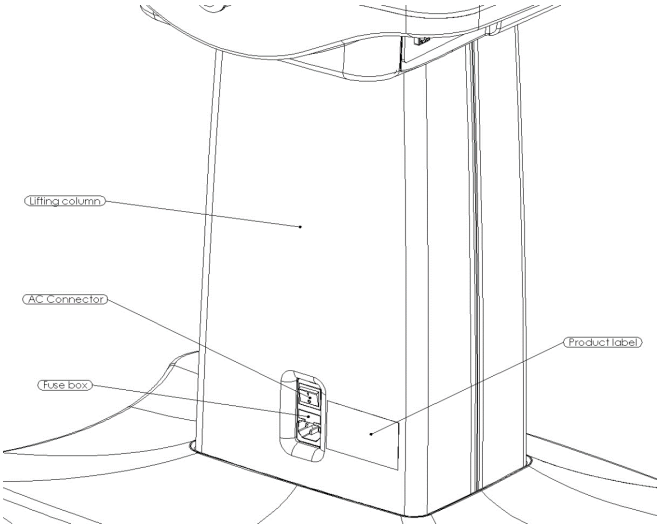
Luna EMG's base allows to transport Luna EMG to any needed location. It's profile is low enough that it can fit under most hospital beds and rehabilitation equipment. With the four wheels it's easy to lock Luna EMG in place with brakes.



Before running any training program, remember to apply the brakes to **all** wheels of Luna EMG's Base.

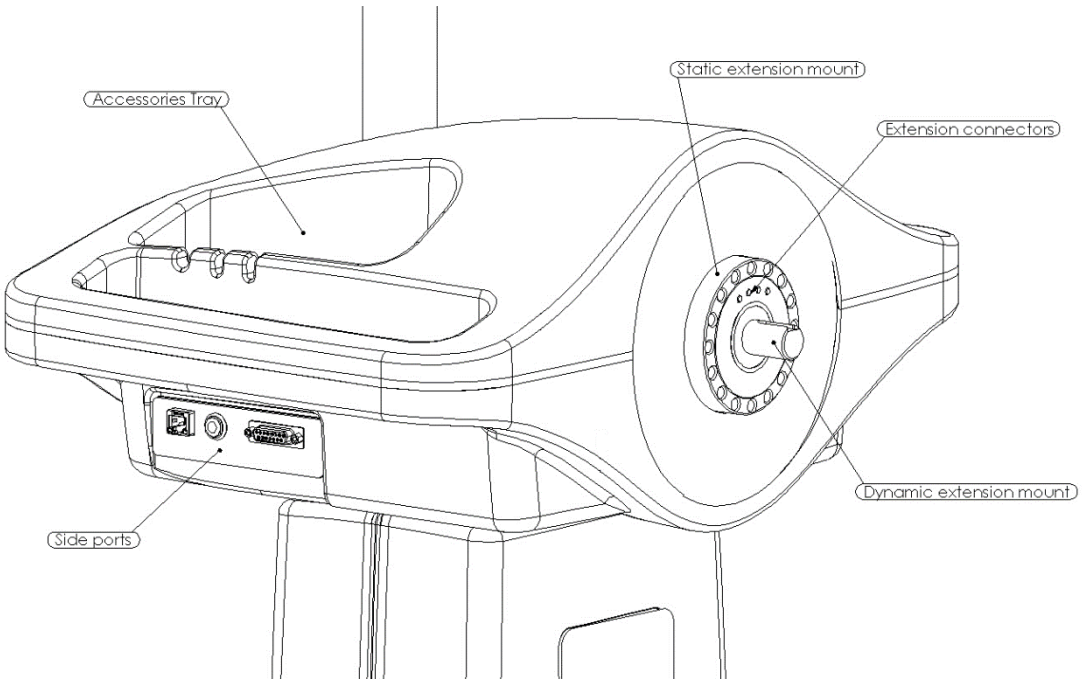
Luna EMG has to be placed on the floor! Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.

10.3 Lifting column



Always use only the compatible AC cables and fuses according to electrical requirements listed in chapter 10.1.2 Technical Specification.

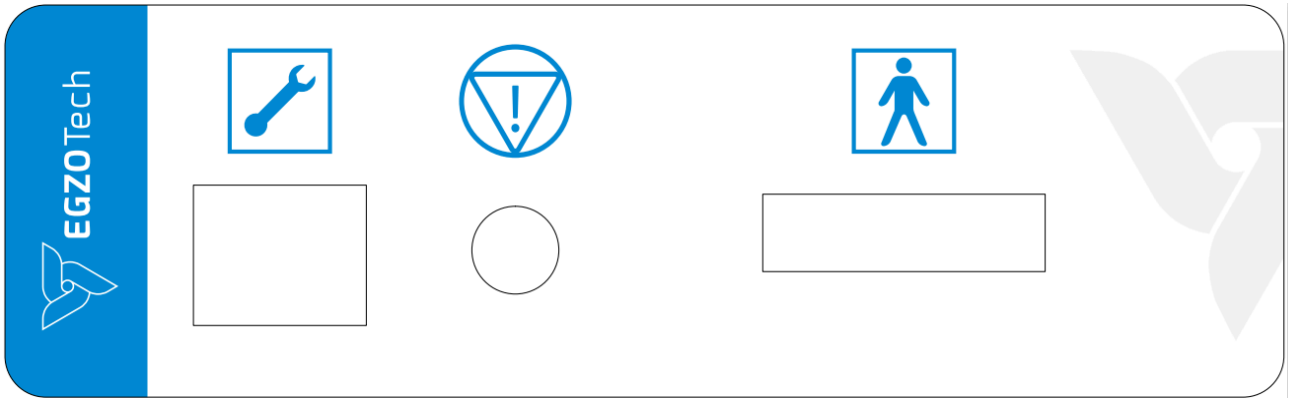
10.4 Head



Luna EMG has handles located on both sides of the Head. They are meant for inside transportation on wheels. Do not lift Luna EMG as a whole on those handles!

Luna EMG has **4 extension connector pins** located on the front of the Head. Those connectors are used to power the extension. While working with Luna EMG **your patient shouldn't touch those connectors**, either directly, or through you (**the patient shouldn't touch the supervisor while he/she is touching those connectors**).

Luna EMG's Head has 3 ports located on the left side.



Port	How to use it and what to connect
	Emergency stop button. Connect only the supplied emergency stop to this port. Luna EMG will only work when this button is connected.
	Maintenance connector. Restricted use for authorized maintenance. Do not connect anything here. It's not an Ethernet socket.
	Applied part type BF, used for electrical connections to and from the patient. Part isolated from all other parts of the device. Connect only a supplied EMG cable to this port.

The connection ports of Luna EMG's Head are intended for specific accessories mentioned above. **Do not connect any other devices to those ports!**

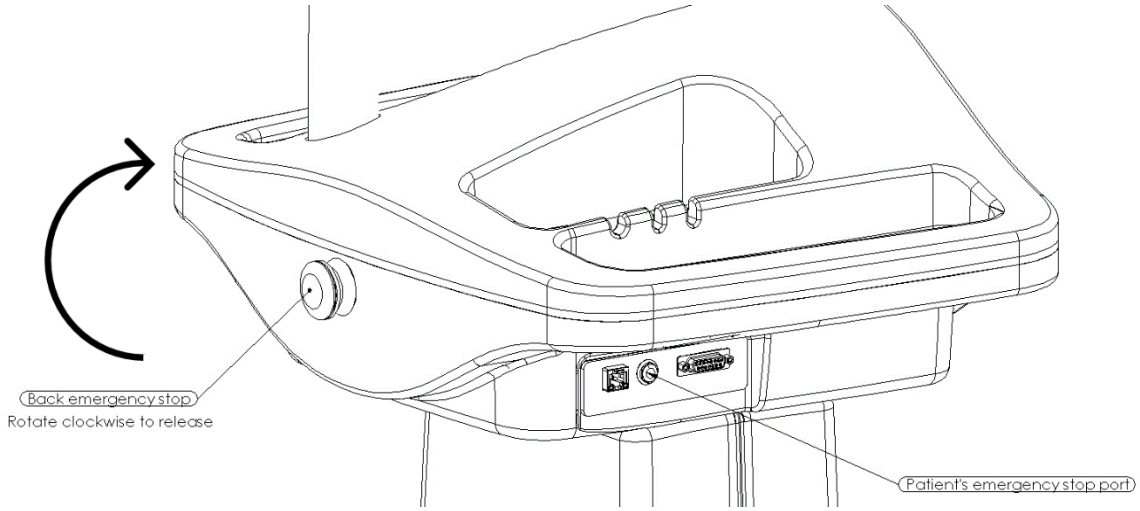
10.5 Tablet holder

The tablet holder has 2 cables integrated: the DC output to the tablet's power adapter and USB cable for data transmission.

The DC and USB cables integrated into the tablet holder are intended for a specific tablet, delivered with Luna EMG. **Do not connect any other devices to those cables!**

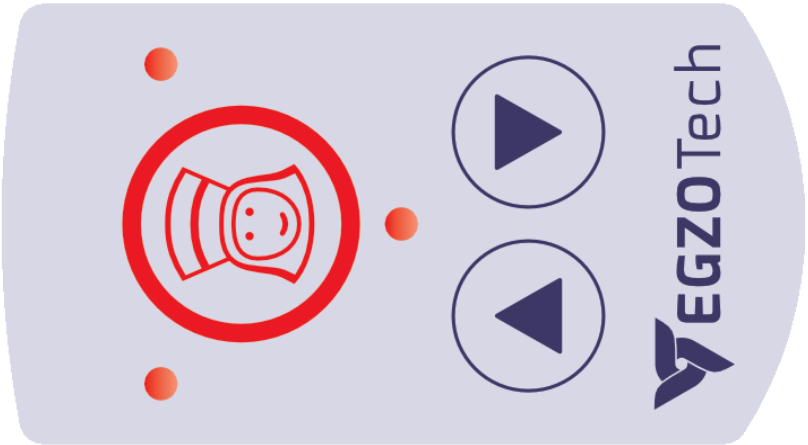
10.6 Emergency stop push button

Luna EMG has emergency stop that will stop all movement of Luna EMG by cutting the motor power supply.



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

Never leave your patient unattended, and remember to push the emergency button at the back of Luna EMG if any danger occurs. You should provide your patient their patient's remote controler with safetybutton for the time of training. The patient should be instructed beforehand on the use of the patient's emergency stop.



Remote controler with safety button for the patient has three buttons available for you and your patient. They change their operation based on Luna EMG's current state.

Button	During training	Outside of training
	Safety button. Stop all movement of Luna EMG.	Safety button. Stop all movement of Luna EMG.
	While holding, move column up. For better position matching but significant changes are not recommended.	While holding, move column up.
	While holding, move column down. For better position matching but significant changes are not recommended.	While holding, move column down.

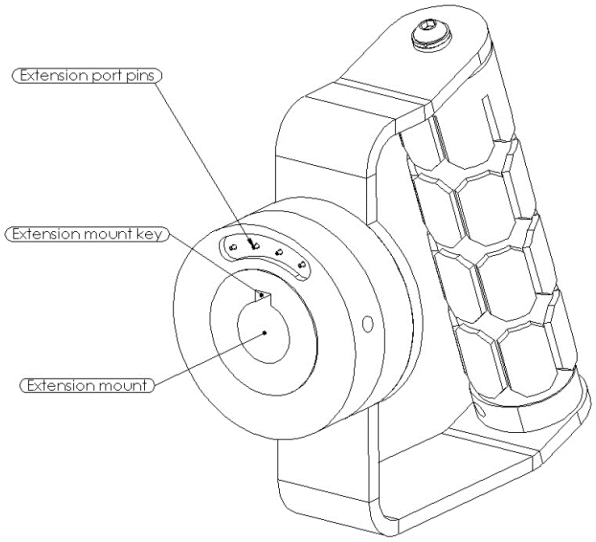
10.7 LED Ring front display indications

The LED Ring front display consists of 80 multicolour (RGB) LED diodes ordered (multiplexed) in a full circle. During standard Luna EMG operations, those diodes will light up to notify the users of dangers, emergencies, as well as current states. The table below is a list of the most important notifications, but different exercises can generate their own notifications.

Notification	What does the LED Ring front display look like
System booting up	Green LEDs fading counter-clockwise
Standard exercise data display	Defined range of motion is lit in green Edges of range of motion are lit in red Current position is lit in blue
All systems ready	All LEDs are either lit, or fading in blue

11. Extensions

Extensions are exchangeable accessories to Luna EMG that mount on the front of Luna EMG's Head and are responsible for performing training exercises.



Extensions are responsible for allowing joint movement with specified force resistance (or assistance). Those are the ones that will in most cases move (or be moved by) your joint. For example, while flexing/extending your elbow joint, you will use a flexion/extension dynamic extension for the elbow, and a static arm extension for holding your shoulder in place.

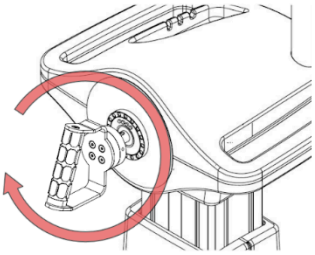
11.1 What kind of extensions do I have?

All the extensions provided with Luna EMG have been listed in chapter 9. What will I find in the package?. The table below shows what kind of exercises are possible using extensions.

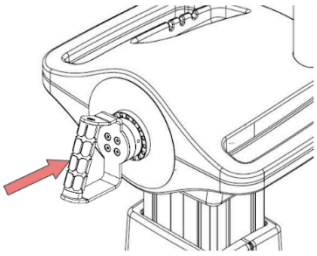
Joint \ Movement	Flexion/Extension	Abduction/Adduction	Rotation
Shoulder	☒	☒	☒
Elbow	☒		☒
Hip	☒	☒	☐
Knee	☒		☐
Ankle	☒		

11.2 Plug in your extension!

Plugging in extensions is so easy, it takes only 2 steps to get it done!
Step 1: Rotate the extension so that the key is oriented upward.
Step 2: Push the extension in the upward position until you reach the extension pins and the electromagnet snaps the extension in place.
The extension is automatically detected in software. All your archived training will be sorted for this particular extension and you are ready to go.
Those steps are presented on the chart below:



1 Rotate the extension so that it's key is oriented upward (you'll feel it slide into a single orientation)



2 Push the extension in the upward position until you reach the extension pins and the electromagnet snaps the extension in place

For isolated training, before mounting the dynamic extension, insert the compatible static extension into the static extension mount. After both of the extensions are mounted, use straps to hold the upper join in place.

12. Warning signals

While using Luna EMG you may encounter visual or sound notifications from Luna EMG's warning signals. Below is a list of the major warning signals notifications that you need to react to.

Warning notification	What does the LED Ring front display look like	What will you hear	What should you do
High	All LEDs are blinking (1,5Hz, 50% cycle) in red	10 rapid impulses (70 dB) separated by a pause	Immediately assist your patient and remove the extension if necessary

The notifications are available for confirmation and cancellation in the tablet software, in all screens in the upper left corner – presented as a warning icon.
You may encounter the following warning signals:

Why it happened	Severity	What should you do
Emergency stop button pressed or patient remote safety button pressed	High	Luna EMG will cease all operations concerning training. Immediately assist your patient and verify the reason for the emergency stop press. When verified, confirm the emergency on the tablet application.

13. Electromyography

13.1 How it works

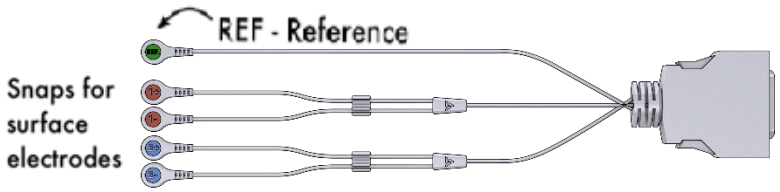
Luna EMG was designed to allow bioelectric measurements, especially for evaluation and reactive electromyography. In Luna EMG's package (described in 9) you will find two EMG cable connector electrode cables: one for surface electromyography and one for pelvic floor and surface electromyography.

13.2 Lead wires and channels for EMG

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

Color	Channel name
Red	Channel 1
Blue	Channel 2
Yellow	Channel 3
White	Channel 4
	Channel 5
Brown	Channel 6
Green	Reference

Each lead wire for the EMG has a coloured snap to connect the EMG electrode. Two snaps of the same colour correspond to one channel. Two colour - coded snaps of each EMG channel, stand for two differential inputs: positive "+" and negative "-". For electromyography it's essential to connect both positive and negative inputs of one channel to the same muscle (the one under assessment).



As you can see, each channel has its positive "+" and negative "-" differential inputs. For electromyography it's essential to connect both positive and negative inputs to the same muscle. You should always have a Reference input for electromyography close to the currently used EMG channels. The closer the reference electrode will be to the measured channel, the less electromagnetic interference there will be. As an example, try to place the reference electrode on the same limb as the measured channels.

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

13.3 Electrodes

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

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

- We recommend the use of single-use clip electrodes compatible with EMG cable.
- For reference electrodes, you are free to use any single use electrode, although we recommend use electrode provide by EGZOTech that you can order from your product specialist or EGZOTech representative.
- To get the best result during work with Luna EMG, we recommend using electrodes with wet gel.
- Do not use any unauthorized electrodes, especially lacking the necessary safety certificates (medical device CE in European Union).
- Never use the single use electrodes more than once, and never on more than one patient.

13.4 Electrode placement and configuration

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

- Electrode specific factors:
    - Area and shape of the electrode detection surfaces, which in turn determines the number of active motor units and innervated muscle fibres – same type of electrodes should be used to compare different results,

- Distance between the electrodes that determines the bandwidth of the differential electrode configuration – should be constant for each measurement,

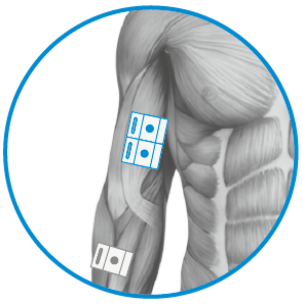
- Location of the electrode with respect to the motor points determines the amplitude and frequency characteristics as well as comparability between a series of measurements. The further from the motor point, the more the amplitude decreases,
- Crosstalk with other muscles due to close proximity of the electrode positions – electrodes should be placed in the middle of the belly and away from the lateral edge. With smaller muscles, crosstalk should be taken into consideration during result interpretation,

Orientation of the bipolar configuration of the electrodes with respect to the muscle fibres – affecting measured conduction velocity, amplitude and frequency of action potentials (depolarisation of muscles).

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

13.4.1 Electrodes application for the surface muscles

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



2. Always use EGZOTech approved electrodes, listed in this User Manual, as electrode properties like gel type, conductivity, snap dimensions can greatly influence measurements.
3. Connect the EMG/ECG 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 colour (i.e. Red channel) 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 fibres, so that the distance between the electrodes can be the same each time.
7. Place **Reference electrode (marked gray)** with the green lead wire ending and REF sign to the skin that is not under evaluation.
8. Place electrodes on to dry and clean skin.

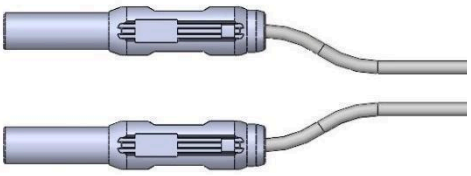
Remember to put the reference electrode on the skin outside of the trained muscle. If you're using more than one channel, remember to select muscles for each channel.

13.4.2 Internal probe application for the Pelvic Floor muscles

For the EMG Biofeedback Programs and EMG Games you will need the Vaginal or Anal electrode and Surface EMG Reference electrode

Vaginal Electrode Anal Electrode

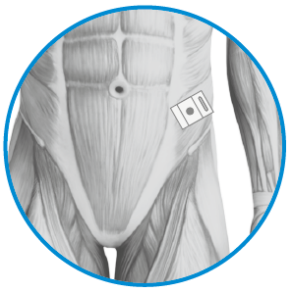
1. Connect the probes to the lead wire (use yellow lead wire colours to connect the probes).



2. Apply some lubricant on the opening part of vagina or anus and then put a probe into your anus or vagina.
3. Always use EGZOTech approved probes listed in this User Manual, as electrode properties like gel type, conductivity, snap dimensions can greatly influence measurements.

Vaginal electrode Application Anal electrode Application

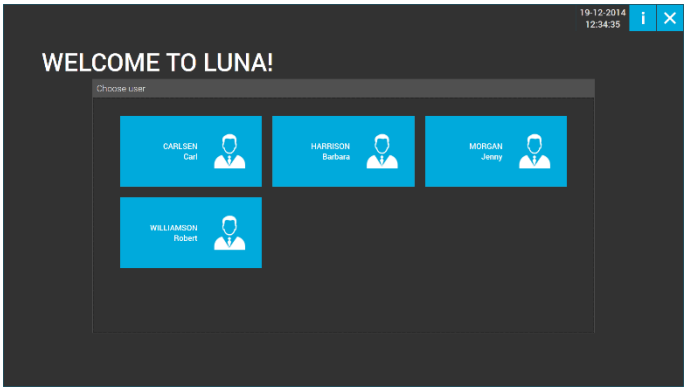
4. Apply additional Reference EMG surface electrode near the bony landmark such as i.e. ASIS (connected to the single green lead wire with the REF sign).



Electrode placement photos are available on https://support.egzotech.com/

14. Software

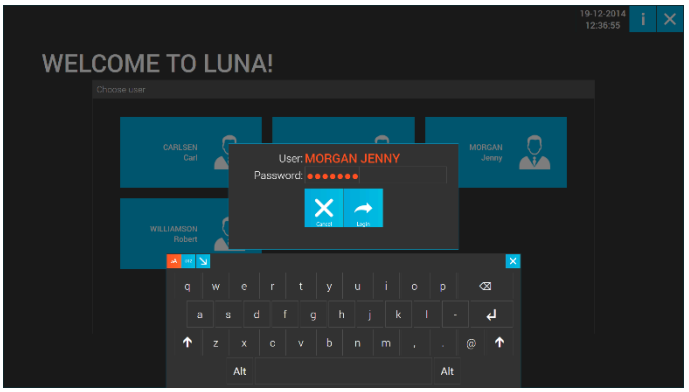
14.1 Logging in



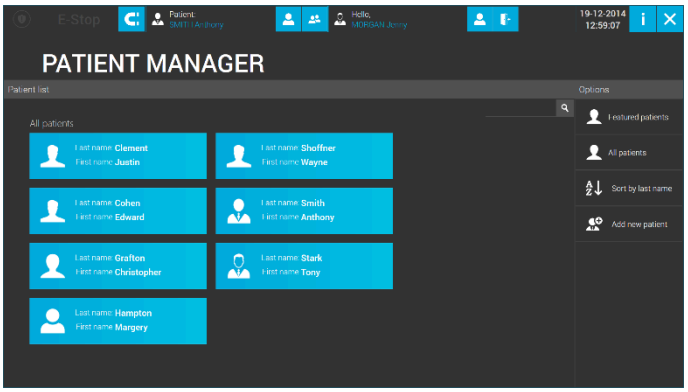
Every time after powering Luna EMG up, You will be greeted by the login screen.

Touch the tile with your Name to begin logging in.

Type your password and confirm with the Enter key (⏎) or login button.



14.2 Managing patients

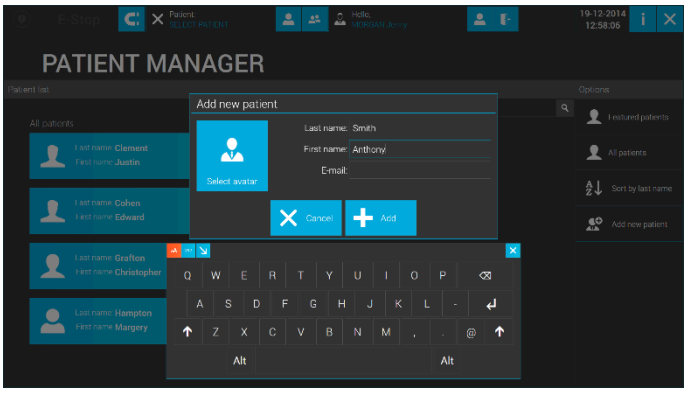


The main screen is the patient manager. You will find your suggested patients ordered by default, as well as the options to sort them in different ways.

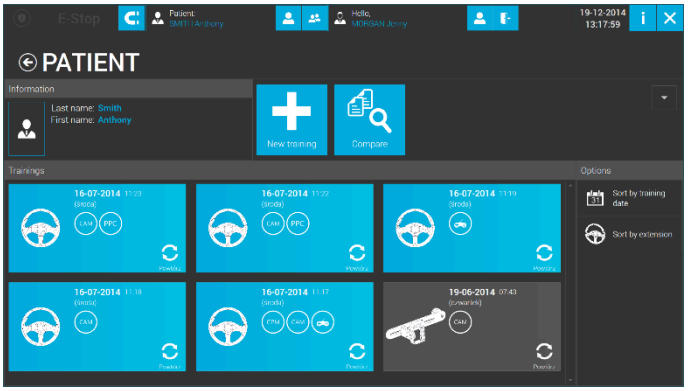
To add new patients click the “Add new patient” button on the right side of the screen.

To add any patient, just type their First Name and Last Name.

You can choose different avatars to help you find patients easier, and specify their e-mail (optional).



14.3 Patient profile



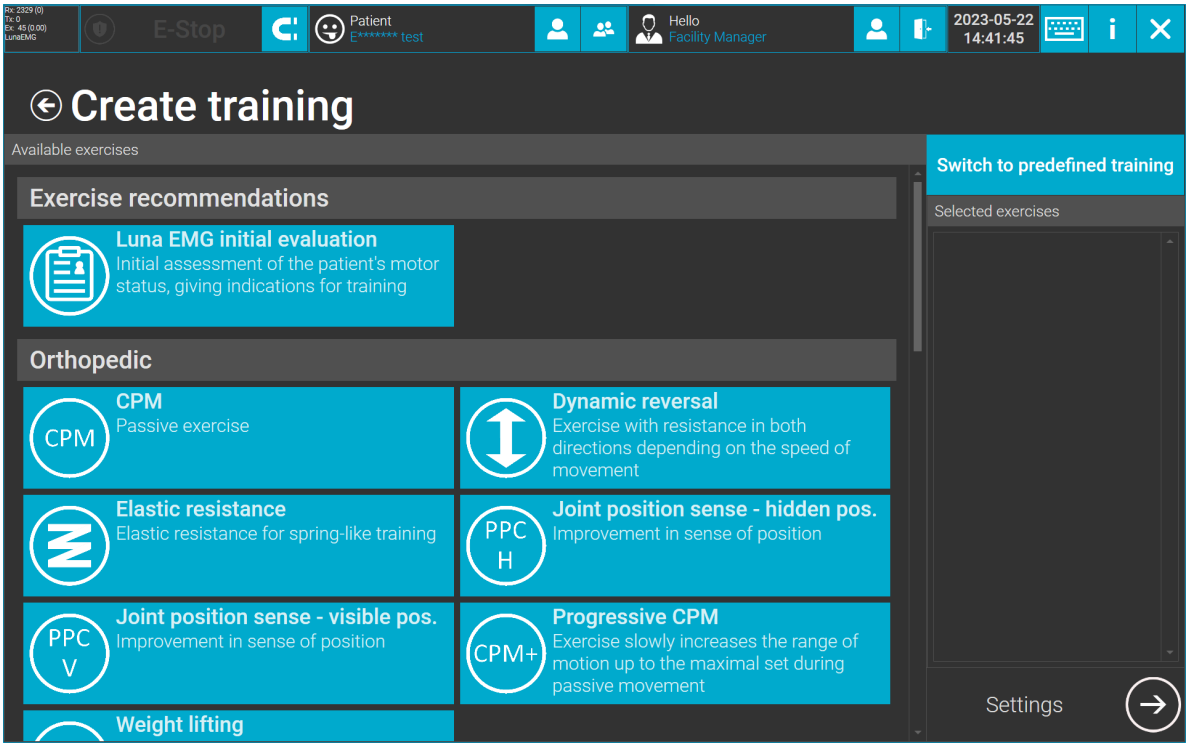
After clicking on a patient tile you can find patient's personal data and training history below.
If an extension is plugged in, you will see the training history sorted for that particular extension.

You can choose different sort parameters at all times.
Trainings are explained in detail in chapter 15. How to set up a training program.

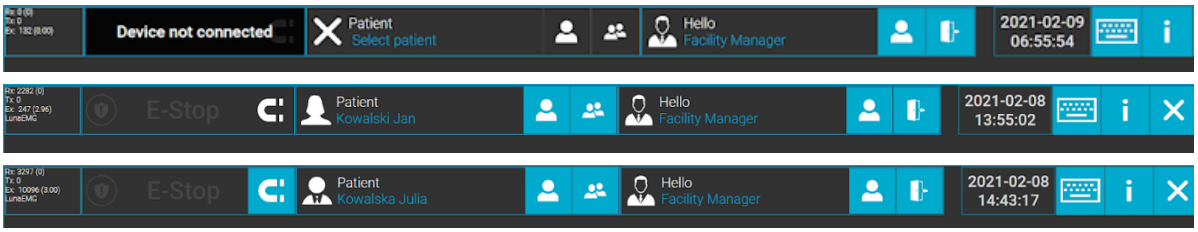
EGZOTech does not have access to the personal date from patient profile.

According to the chapter 16. Operation Mode available trainings are divided into few groups - neurologic, game, evaluation and other. Once you connect the extension to the device an additional orthopaedic group of training sessions appears and additional training sessions appear in previous groups as well.
Depending on the chosen type of training - only with EMG, only with extension or with extension and EMG, there are different options to choose before performing the training.

Some trainings are available only with an extension connected.
An example of the exercises seen when the extension is connected below.



14.4 Top bar



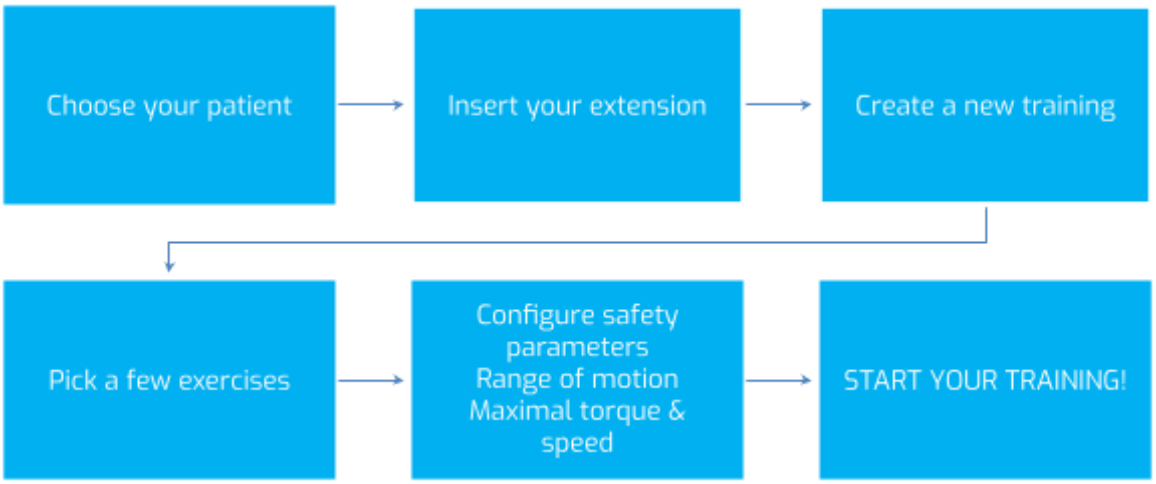
Besides the icons above, next to the electromagnet state icon on the main bar there is also information if the device is connected to the software or not.
On the top of the application, you can see the following icons and controls:

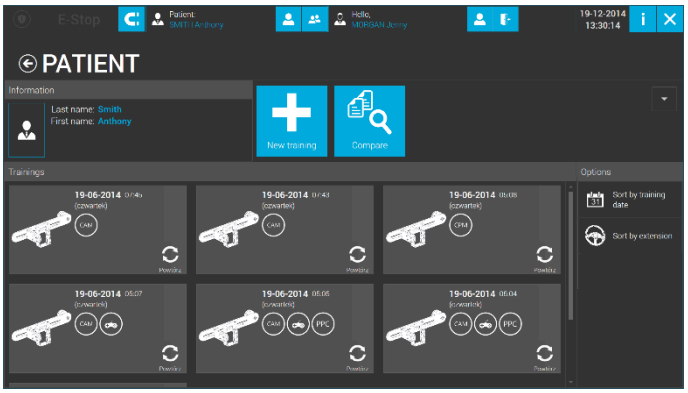
Control	What it means
	Emergency stop notification icon. If this icon is flashing red it's indicating emergency stop state. Displays current emergency notifications when pressed.
	Warning notification icon. Displays current warning notifications when pressed.
	Electromagnet state icon. If the background is blue that means that an extension is plugged in and the electromagnet is holding it in place. Disables the electromagnet when pressed.

	Patient or Supervisor profile icon. Enters the patient's or supervisor's profile when pressed.
	Patient manager icon. Enters patient manager when pressed.
	Logout icon. Logs the current user out when pressed.
	On screen keyboard. Turn on and off the on screen keyboard.
	Information icon. Shows the device specific information as well as tutorials for Luna EMG when pressed.
	Close the application button. Closes the application when pressed (confirmation required).

15. How to set up a training program

Trainings on Luna EMG are organized around patients, extensions and exercises. Follow the simple steps below to easily configure your first training program.

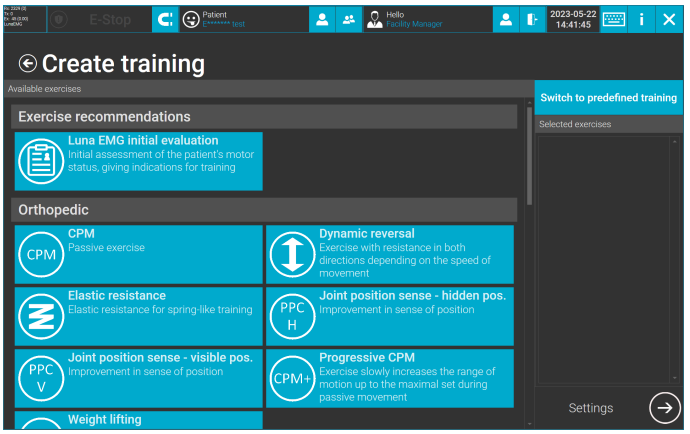


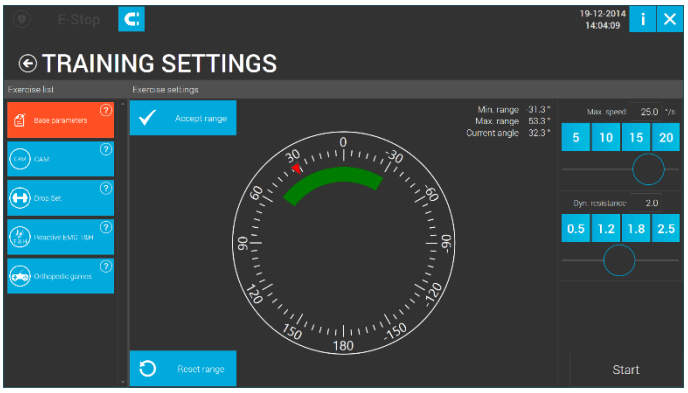


While in the patient profile, click the "New training" icon.

You can have the extension plugged in, or plug it in after pressing the icon.

Choose the exercises you'd like to perform from the left panel. They will automatically be added to your training (listed on the right).
When satisfied, click the right arrow button to follow to safety setting.



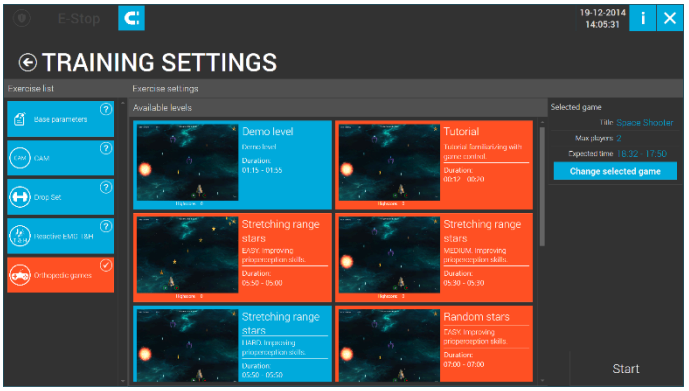


At the safety configuration screen, move the extension with the patient to declare the range of motion. Press the reset button to start over.
You can specify the maximal torque and speed for the whole training at this screen.

Be sure to go through the range of motion with your patient strapped in. **Range of motion** is extremely important, and **if set incorrectly may result in injuries**.

All the exercises except games have default values set up, that you can change when needed.
If you have chosen games or specific training that require additional safety configuration, they will need setting up (every one likes different games).

When everything is set up, press the Start button to begin training.



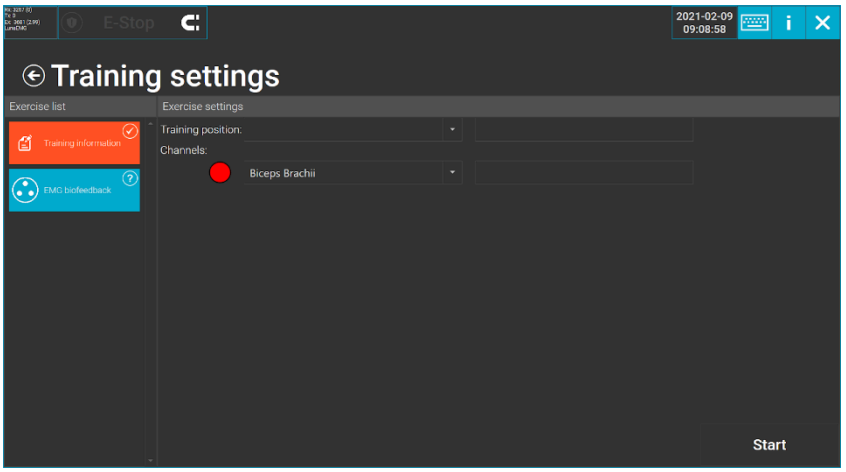
15.1 What exercises can I perform?

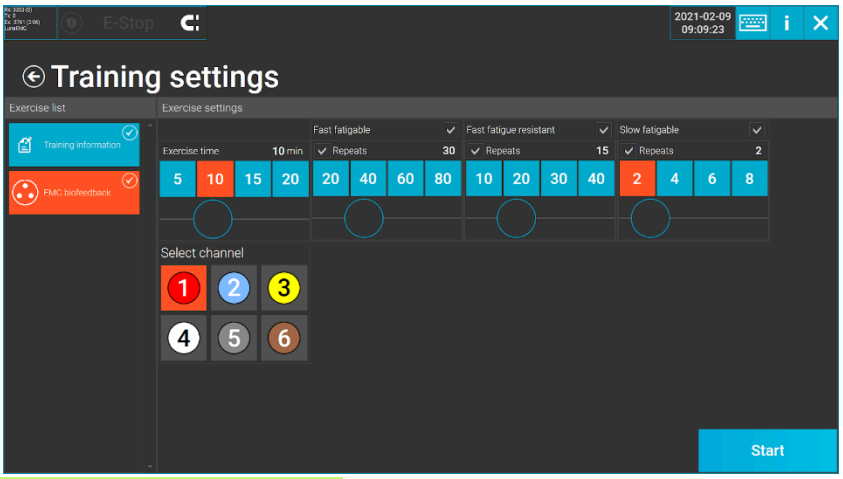
All training modes are described in chapter 16. Operation Mode.

Luna EMG is constantly changing, therefore, we've provided you with the most recent exercise manual in the package. However, be sure to check our website and the application notifications after each update, to find out the newest exercises added to your machine at http://courses.egzotech.com.

15.1.1 Training with electromyography

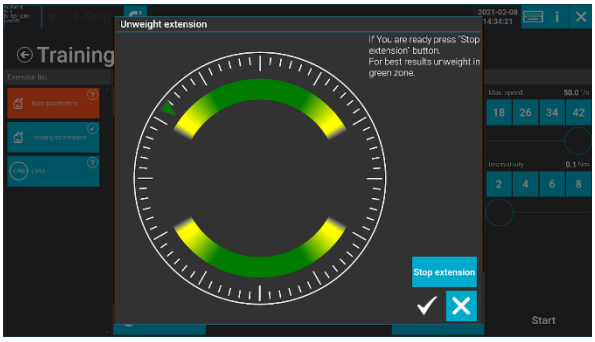
For training only with EMG it is necessary to select a used EMG channel (see chapter EMG Cables).
It is also possible to choose the muscle location of electrodes from each used cable channel.

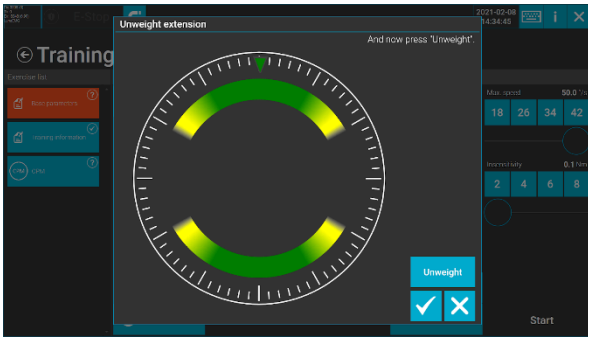


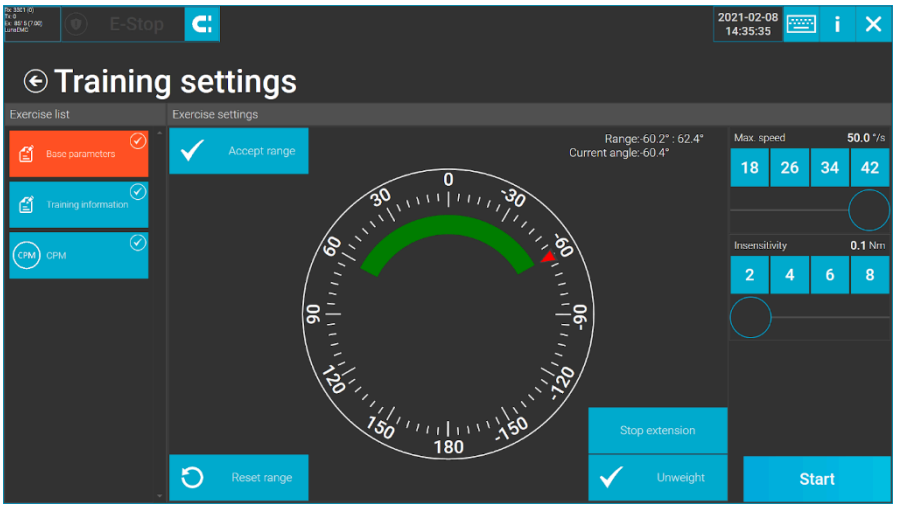


15.1.2 Training with extension

Before performing the training with the extension it is necessary to follow a few steps to calibrate the device and the extension - unweight the extension and select the range of motion of the extension.

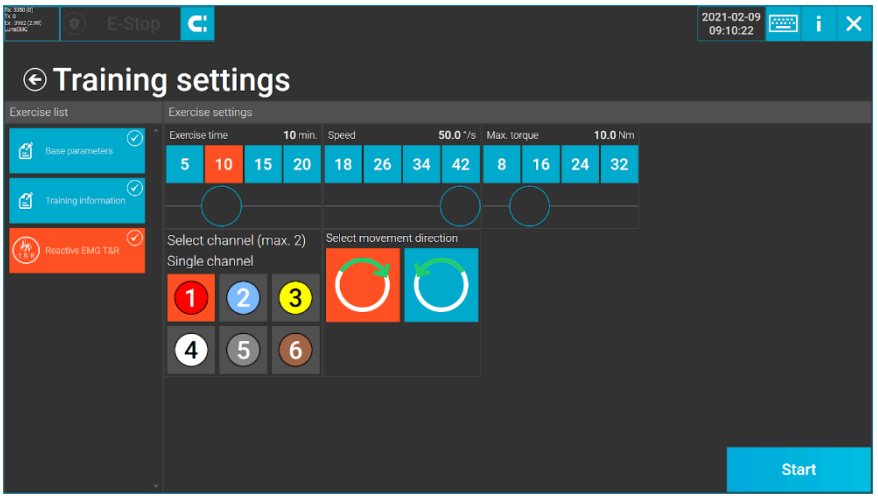




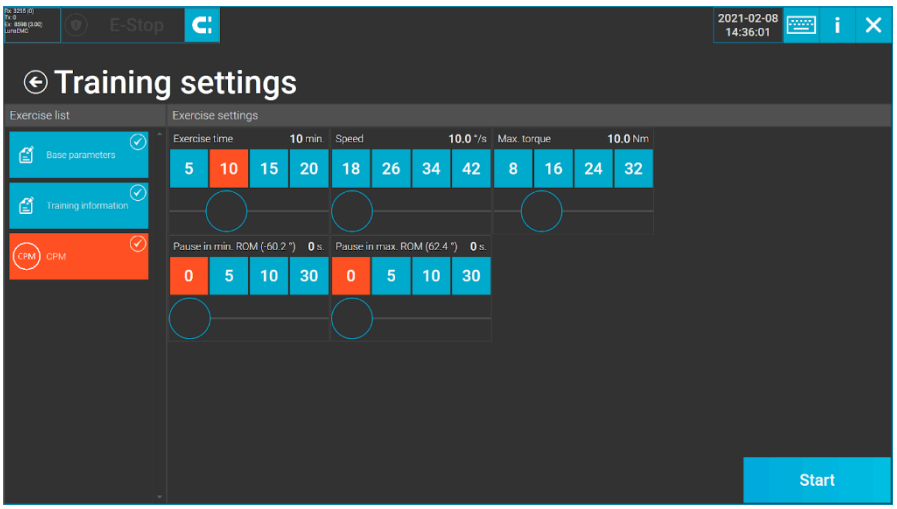


15.1.3 Training with electromyography and extension

If there is a training provided with extension and EMG except the previous selection it is necessary to select the direction of extension movement (clockwise, counterclockwise).



There are also additional settings available to each training.



15.2 Important training parameters

Luna EMG will estimate most parameters in real time to provide the best training experience and result for your patient. There are however important parameters that require consideration for specific patient needs.

Be sure to go through the range of motion with your patient strapped in. Range of motion is extremely important, and if set incorrectly may result in injuries.

Maximal torque is a safety precaution. Set the maximal torque just above the maximal torque generated by the patient during normal use.
With maximal torque set incorrectly, Luna EMG will not detect spasticity, malfunctions or incorrect range of motion, and may cause injuries.

Maximal speed is a safety precaution. For patients that need restricted maximal speed, e.g. with spasticity, set the maximal speed accordingly.

15.3 Training summary

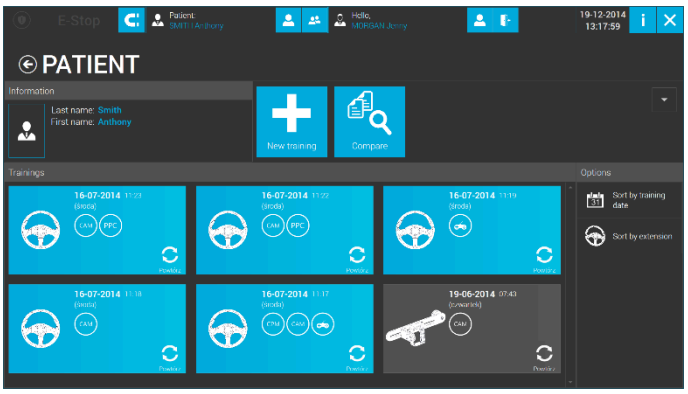
After every training and for any training in patient history, Luna EMG provides a summary and detailed information about all performed exercises. That information come as in-app charts on the tablet, and in a PDF printer-ready reports.

In-App reports allow you to circle through all exercises, analyze data, zoom in and move through charts.

Printed reports are generated after pressing the “Generate PDF report” button in the training summary. They are opened in application.

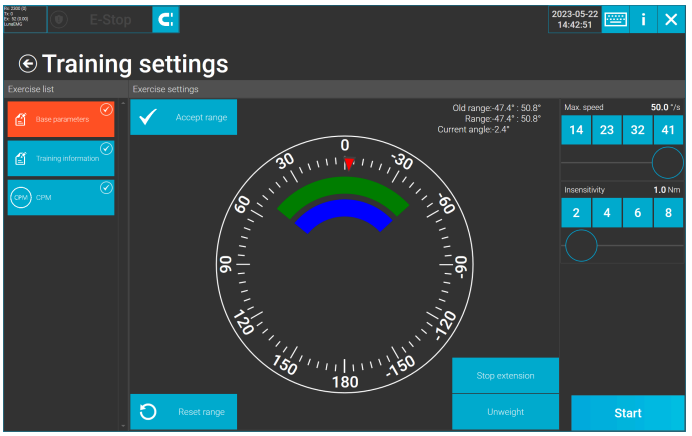
15.4 Repeating trainings

Because we value both your and your patient’s time, we have implemented an easy and efficient way to repeat trainings once performed by your patients.



In the patient profile, click the repeat training icon located at the bottom right corner of every training tile. When the right extension is plugged in, Luna EMG will ask your permission to position the extension and lifting column to the last locations used in the selected training session.

With repeat training feature, the range of motion, maximal speed and maximal torque parameters will already be set.



For patients with restricted range of motion it's safer to reset and adjust the range of motion with each training. Only accept the range of motion in repeated training when you have absolute certainty that your patient doesn't have pain points within the set range of motion. Not validating the set range of motion may cause injuries.

16. Operation Modes

Luna's EMG main functions are:

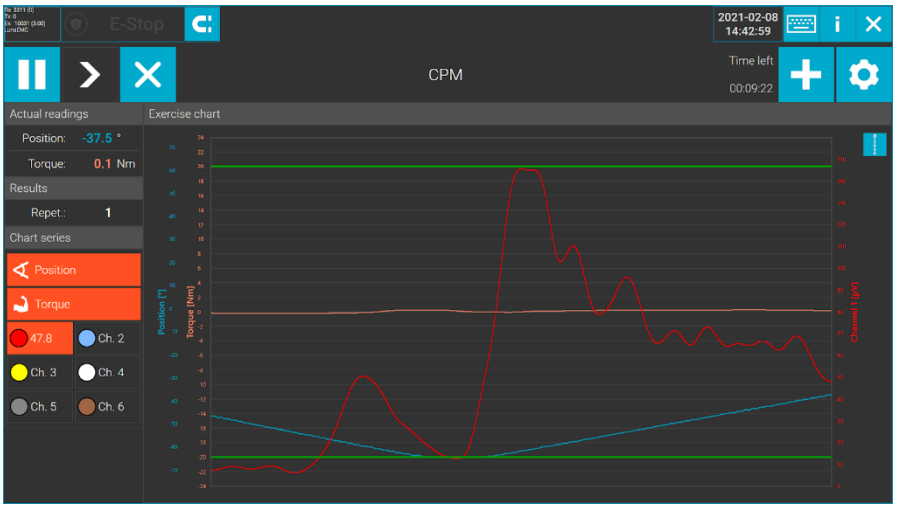
- Physical and electromyography performance testing and measurements, including isokinetic, isometric and isotonic muscle tests, range of motion, limb rigidity, spasticity, fatigability and maximal muscle strength, functional capacity;
- Biofeedback training for any modality, including surface electromyography biofeedback, Pelvic floor electromyography for perineal muscles, anorectal or urethral sphincter;
- EMG-Triggered assistive movement.

EGZOTech constantly meets the needs of users. We have created a website http://courses.egzotech.com where we publish courses related to the manual and functions of Luna EMG.

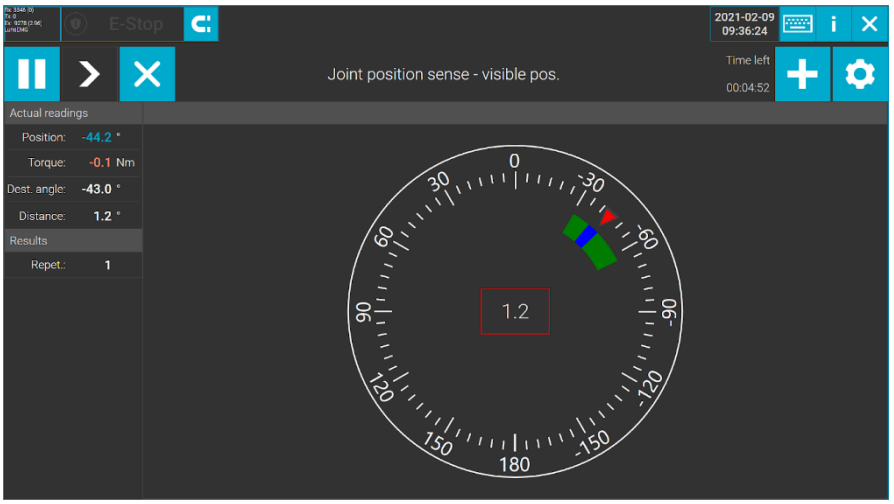
16.1 Physical and electromyography performance testing measurement

Testing and measurements are most typically performed training with patients to check and improve its muscles activity and range of joint motion. Passive, active and active assistive exercises are three solutions that Specialist utilise when dealing with various injuries. It is also common to arrange isokinetic exercises which are resistance-based exercises that involve the use of the equipment which provides variable resistance to a movement and allows muscles to contract at constant speeds. Luna EMG device allows us to perform all of the mentioned exercises with or without EMG to control the activity of appropriate and additional muscles.

Below there is an additional red chart showing the EMG activity of chosen muscles except the range of joint motion (picture above) so except visible joint movement it is also possible to check the appropriate and additional muscles activity during the exercise.



Except mentioned training Luna EMG gives an opportunity to perform proprioception training. It is a training focused on somatosensory signals such as proprioceptive or tactile afferents in the absence of information from other modalities such as vision.



16.2 EMG biofeedback trainings

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

16.3 EMG-triggered trainings

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

16.4 Training groups

Based on technological possibilities Luna EMG has trainings divided into few groups:

- Orthopaedic
- Neurologic
- Games
- Evaluation
- Other

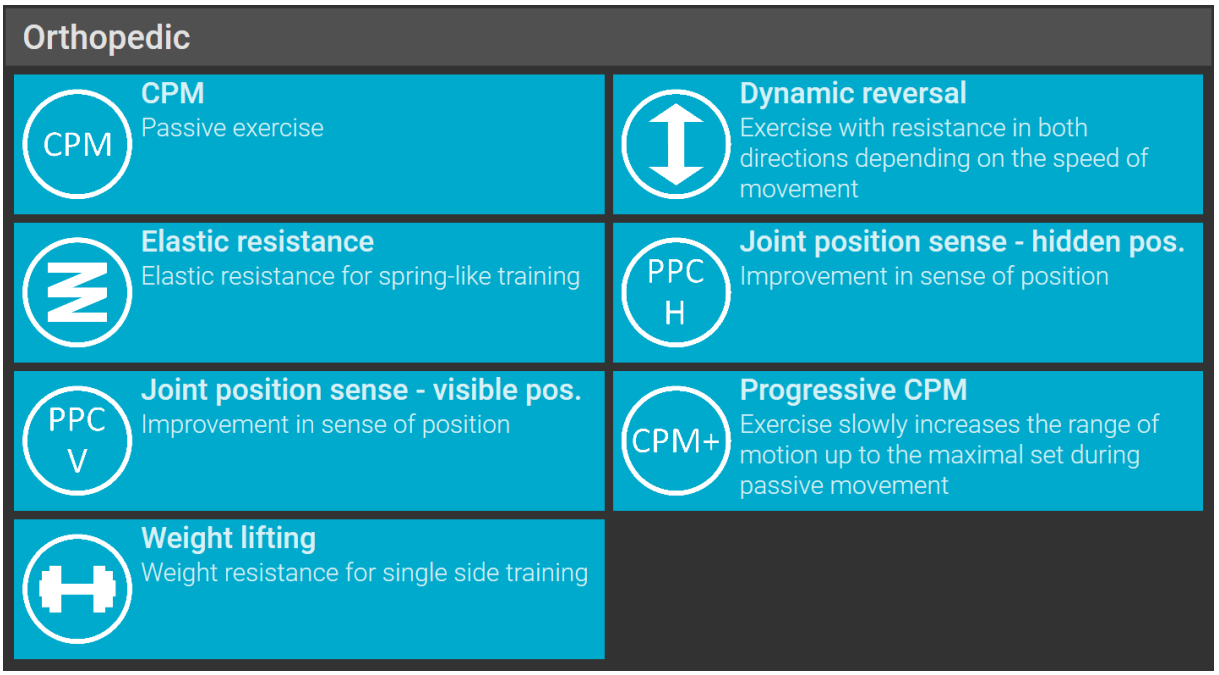
16.4.1 Orthopaedic

Orthopaedic exercises possible to provide on Luna EMG are continuous passive motion (CPM), progressive continuous passive motion, dynamic reversal exercises, elastic resistance exercises, weight lifting and joint position sense exercises with visible and hidden position.

- **Continuous passive motion (CPM)** - exercise is a standard therapy where Luna EMG applies a set torque, moving a static patient through the set range of motion with a set maximal speed. When a maximal value of range of motion is reached, CPM will switch the

direction of the applied torque and guide the patient's limb to another direction. During the CPM the patient is to remain static.

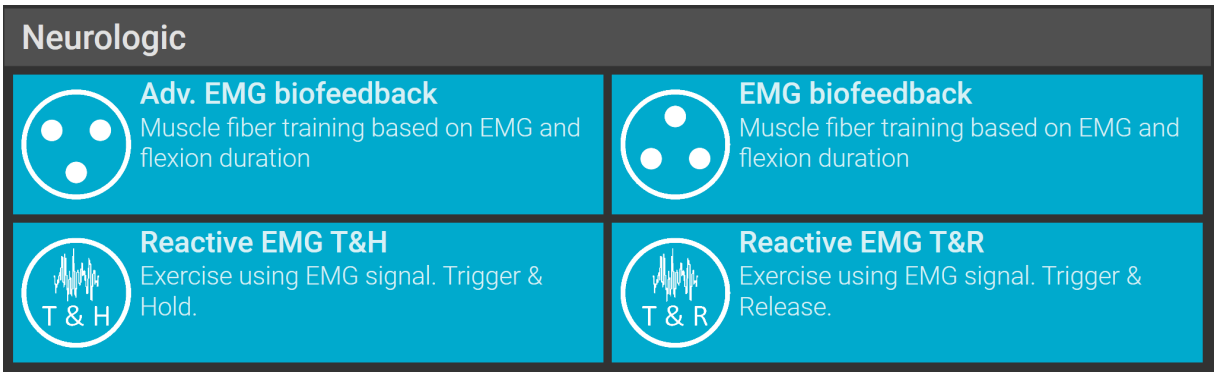
- **Progressive continuous passive motion (Progressive CPM)** - similar to (CPM) exercise. It also applies a set torque, moving a static patient with a set maximal speed but the range of motion starts off at a specific point and is extended gradually. The therapist can set the increments of the range of motion as well as the starting position of the movement. As in CPM, when a maximal value of range of motion is reached, Progressive CPM will switch the direction of the applied torque and guide the patient's limb to another direction. During the Progressive CPM the patient is to remain static.
- **Dynamic reversal exercises** - also known as: continuous active motion (CAM) are exercises where Luna EMG provides dynamic resistance (based on the applied torque) and allows the patient to move freely throughout the range of motion. Dynamic reversal is achieved when the patient voluntarily participates in dynamically and rapidly changing the direction of movement when an end of the range of motion is reached. With such exercises an evaluation of the maximal muscle strength can be performed.
- **Elastic resistance exercises** - Luna EMG provides a gradually increasing torque, starting from the starting point and until the torque multiplier reaches the maximal torque specified during configuration.
- **Weight lifting** - Luna EMG provides the possibility to provide isotonic exercises with a fixed torque at specific direction (towards the center of gravity point).
- **Joint position sense (Proprioception) – Visible Position** - aimed at training limb position coordination. During proprioception exercises Luna EMG acts as in dynamic reversal exercises. The patient is encouraged to move their limb towards the randomized goal position. During proprioception – visible position, the current position of the limb is visible at all times.
- **Joint position sense (Proprioception) – Hidden Position** - aimed at training limb position coordination. Proprioception – hidden position, differs from proprioception – visible position exercises in a way that the current position of the limb is hidden at all times.



16.4.2 Neurologic

As a neurologic exercises possible to provide on Luna EMG can be mentioned EMG Biofeedback, Reactive Electromyography Trigger and Hold, Reactive Electromyography Trigger and Release and Advanced EMG Biofeedback.

- **EMG Biofeedback** exercises are aimed at training muscle flexion and relaxation of any selected muscle group, while monitoring the flexion and relaxation of other muscle groups. EMG Biofeedback allows the training of all motor units: fast fatigable, fast fatigue-resistant and slow motor units.
- **Reactive Electromyography *Trigger and Hold*** - type of exercise, where the patient controls the movement of the extension through contraction of single or multiple muscles (described for each extension in the Extension Information Cards). Trigger is a level set during EMG calibration, corresponding to a fraction of the maximal detected muscle strength (through EMG). During training, when the trigger level is reached (either by a single muscle, resulting differential relative antagonist muscle strength, or multiple muscles) Luna EMG will start to move similarly to concentric exercises (but with EMG as the primary input signal), while the resulting EMG signal remains above the trigger level (hold). Relaxing the muscle/muscles will allow the extension to return to its starting position.
- **Reactive Electromyography *Trigger and Release*** - a type of exercise, where the patient controls the movement of the extension through contraction of single or multiple muscles. Trigger is a level set during EMG calibration, corresponding to a fraction of the maximal detected muscle strength (through EMG). During training, when the trigger level is reached (either by a single muscle, resulting differential relative antagonist muscle strength, or multiple muscles) Luna EMG will start to move throughout the whole range of motion. After reaching the limit of the range of motion, Luna EMG will await the resulting EMG signal to drop below the trigger level (release) and after that will start to move throughout the whole range of motion until she reaches the starting point.
- **Advanced EMG Biofeedback** - a group of exercises aimed at training the contraction and relaxation of any selected muscle group, with the possibility of monitoring the work of other muscle groups. It was divided into two modules: evaluation and exercises. The "Evaluation" module contains tests on the strength and activity of various types of muscle fibers. It has also been enriched with a study in the field of urogynecology. The "Exercises" module enables training of all motor units: fast twitch fibers, fatigue resistant fast twitch fibers, slow twitch fibers and endurance training. There is also the option of individual training planning.



16.4.3 Games

Luna EMG has three primary game categories:

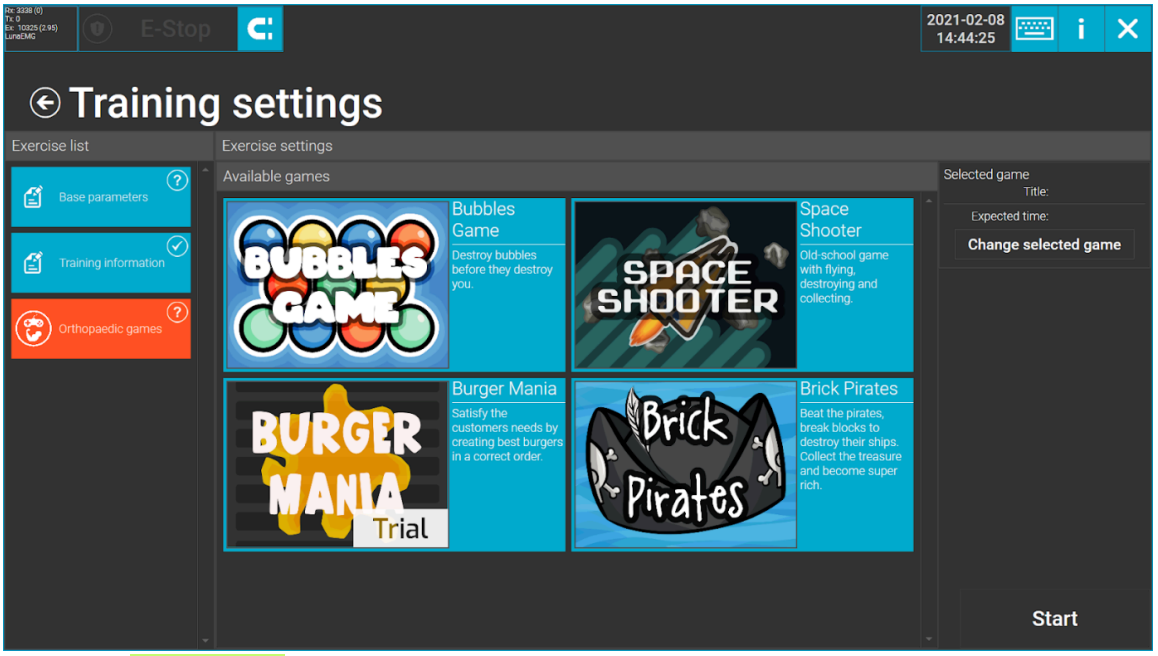
- Orthopaedic games – acting like Concentric exercises
- Reactive EMG games– acting like Reactive Electromyography *Trigger and Hold*

- Isometric EMG games – acting like EMG Biofeedback exercise

All parameters, indications and monitored parameters are consistent with the above exercises. Furthermore, all games are for single player which means that the patient trains on Luna EMG alone.

Available games:

1. **Space Shooter** is a game where the patient controls the movement of a spaceship. Levels consist of challenges like gathering stars, dodging asteroids, shooting enemies and even fighting bosses.
2. **Bubbles game** is a logic game, similar to PC Bubbles Game. The patients control the position of a bubble gun, launching different colour bubbles to form patterns. When a bubble hits 3 or more connected bubbles they break and disappear.
3. **Brick Pirates** is a game where the patient controls the movement of a base and a flying ball can bounce from it to break a wall and collect gold.
4. **Burger Mania** is a game where the patient controls the movement of the playing character to catch all of the necessary products to create a perfect burger.



16.4.4 Evaluation

Evaluation is a group of tests which consist of EMG evaluation, joint position sense evaluation (proprioception assessment), range of motion measurement, force isometric test, patient initial evaluation, muscle spasticity test and MVIC EMG test.

- **EMG evaluation** is a part of the evaluation group. The patient doesn't need to be connected to any extension for this exercise. Luna EMG will monitor all EMG channels and the electrical activity within. If an extension is connected, the channels will automatically correspond to the muscles indicated in the Extension Information Card.
- **Joint position sense evaluation** is a part of the evaluation group. The patient needs to be connected to an extension for this test. The goal of the test is to assess the proprioception of the patient. The therapist is setting the desired position of the limb. Luna EMG is bringing the limb to that position and keeping it in that position for an applied time (Learning Stage). The patient needs to learn the position and repeat it in the next attempt.
  The test can be perform in two modes: passive mode , when Luna EMG passively move the limb throughout the whole range of motion (Reaching Position Stage) and the patient needs to inform the therapist, when it reaches the right angle; active mode, when patient

needs to actively move the limb to achieve the learned position. The therapist is accepting the reached position in the software and Luna EMG is counting the difference between applied position and reached position. The test can be performed with eyes open and eyes closed.

- **ROM measurement** - the goal of the test is to assess the range of motion of chosen joint. Patient attached to the extension moves the limb while Luna EMG measures the angle of the movement.
- **Force isometric test** - belongs to the group of evaluation tests. To perform this test, it is necessary to attach a long extension (elbow or knee extension). The test is designed to assess muscle strength based on static (isometric) muscle contraction without visible movement. The patient should be relaxed at the beginning of the test. Then, after hearing the command "Contract", he must push in the right direction and maintain it throughout the activity phase (represented by the grey box visible on the screen). On the "Relax" signal, the patient relaxes the tested muscle.
- **Patient initial evaluation** - evaluation test providing basic information on the patient's motor status. To perform the test connect one out of 5 extensions (shoulder, knee, foot, forearm or elbow extension) and then connect the EMG to the selected muscles.. Luna EMG will monitor all EMG channels and their electrical activity as well as muscle strength. At the beginning, we determine the range of motion and activity of which muscles will be subjected to EMG examination. The patient's task is to make a movement in a given direction and maintain muscle activity until the end of the active phase (gray field visible on the screen). The training summary provides information on the activity and strength of the muscles tested, as well as a list of recommended exercises for the patient.
- **Muscle spasticity test** - the aim of the test is to assess muscle stiffness during passive movements of various speeds. Connect one out of 6 extensions to perform the test. The Luna EMG can also monitor all EMG channels and the electrical activity present, although the EMG signal is not necessary to be able to perform the test. At the beginning, we define the range of motion and optionally the EMG channel of the tested muscle. During the test, the limb moves in the indicated range with the certain speed mode (10, 50, 100°/s). The rest between sets is 30 seconds. The patient should be instructed to remain relaxed throughout the entire test.
- **MVIC EMG test** - belongs to the group of evaluation tests. Luna EMG will monitor all EMG channels and the electrical activity occurring in them. To perform this test, it is necessary to attach a long extension (elbow or knee extension). The test is designed to evaluate muscle activity based on static (isometric) muscle contraction without visible movement. The patient should be relaxed at the beginning of the test. Then, after hearing the command "Contract", he must tense the tested muscle and maintain this tension throughout the entire activity phase (grey box visible on the screen). After receiving the "Relax" signal, the patient should relax the tested muscle.

Evaluation

EMG evaluation
Evaluation exercise displaying EMG signal

Force isometric test
Strength test involving static contraction of a muscle with no visible movement in the joint angle.

Joint position sense evaluation
Evaluation of position sensing in patient

Muscle spasticity test
Assessment of muscles in passive movement at different speeds.

MVIC EMG test
An electromyographic test consisting of muscle contraction with no visible movement in the joint angle.

Patient initial evaluation
Initial assessment of the patient's motor status, giving indications for training

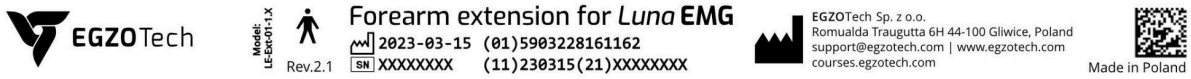
ROM measurement
Passive and active ROM measurement

17. Miscellaneous

17.1 How to identify your Luna EMG or extensions

During trouble shooting and consulting with your product specialist and or customer support, there may come a time, you will be asked to read your Luna EMG Serial Number or the Serial Number of one or more of your extensions.
Luna EMG has a label located at the back of the lifting column that looks like this:

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 extensions have similar labels as the example presented below. Always look at the serial number (SN).
Label of Luna EMG extension:



The serial number (SN) is on the right side of DataMatrix.

17.2 Behaviour of Luna EMG

During usage of Luna EMG, it is important to monitor the activity of the device based on LED Ring communication.

Status	Action to do by operator	Description
Power off	Power off Luna EMG	All leds are off
Power on	Power on tablet and start EgzoApp	The LEDRing is displaying green spin animation
Preparation for calibration	Disconnect extension and don't touch shaft	The LEDRing is slowly pulsating green
Calibration	Disconnect extension and don't touch shaft	The LEDRing is slowly pulsating green
Stand by	Can start exercising	The LEDRing is displaying blue spin animation
Training	Exercise according to manual or information displayed on tablet screen	According to exercise type, LEDRing is displaying blue spin animation or green range of exercise
High severity signal	Please assist patient and follow on-screen instructions	The LEDRing is blinking red
Medium severity signal	Please assist patient and follow on-screen instructions	The LEDRing is blinking yellow
Low severity signal	Please assist patient and follow on-screen instructions	The LEDRing is glowing yellow

17.3 Description of user maintenance responsibility

The consumable items for use with your Luna EMG:

- EMG electrodes are designed for single-use.
- Report the need for annual inspections

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

17.4 Auto diagnostics

Luna EMG will occasionally want to perform software auto updates (both for the tablet application, as well as for electronic modules). You will be notified of those updates by a popup

window. Software updates ensure that Luna EMG stays safe and may include updates in exercises, games, manuals etc.

Because software updates include safety enhancements, allow Luna EMG to update as notifications arrive.

After each update, Luna EMG will need to perform an auto diagnostic procedure. The goal of this procedure is to check all Luna EMG's systems for intended operations. During auto diagnostics, Luna EMG will require you to insert a specific dynamic and/or static extension. Follow the in-app instructions specified and LunaEMG will be ready for patients in no time.

Be sure that Luna EMG's space for raising and lowering the lifting column, as well as moving the extension freely is not restricted by any external objects and/or yourself or your patients. **During auto diagnostics Luna EMG will perform stress tests that may result in injury.**

Based on the auto diagnostic data, Luna EMG will schedule maintenance visits, that 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 Luna EMG.

- Luna EMG is equipped with a permanently mounted AC power inlet/switch described in chapter 10.3 Lifting column. By detaching the AC cable or turning the switch OFF, you are disconnecting both poles of the AC voltage (compatible with IEC 61058-1 standard),
- Emergency stop push buttons described in chapter 10.6 Emergency stop push buttons do not disconnect the AC voltage, only the 24 internal voltage,
- The AC voltage is connected to Luna EMG by a flexible cable specified in chapter 9. What will I find in the package?,
- All voltages above 60V DC or 42,4V AC inside Luna EMG's chassis that cannot be disabled by the AC power switch are additionally protected and isolated. There is a warning symbol located on the product label described in chapter 17.1 How to identify your Luna EMG or extensions?.

17.6 Expected product service life

Expected product service life of Luna EMG is 5 years, under normal operations and proper maintenance and handling. Luna EMG's accessories and detachable parts **will experience normal wear and tear**, which will decrease the product service life.

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

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

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

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

times, your usage will be monitored by EGZOTech and its partners, and necessary maintenance will be proposed ahead of time, to limit the downtime of your devices. Periodic inspections are required every 12 months. This is a precaution to prevent dual, simultaneous failure of methods of patient protection. If your Luna EMG has a stable, unrestricted Internet connection, such tune-up will be proposed by the maintenance team.
In order to obtain information about the nearest authorized service contact EGZOTech.

17.7 Storage and transportation instructions

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

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

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

17.8 How to safely dispose of the device

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

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

The equipment has to be given to a suitable collection point for the treatment by this way, you contribute to the safeguarding of the natural resources and human health protection.
Electrodes should be disposed of according to their manual on the package.

17.9 Warranty

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

- Within the warranty period, the manufacturer will replace your faulty Luna EMG or accessories at no charge (except shipping & 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 regulated in details in the EULA. Before accepting the terms, one should carefully read the content available at website: https://support.egzotech.com/terms-and-conditions.

18. Cleaning

There is a video tutorial available for this chapter at: https://support.egzotech.com/

For long life and excellent quality, remember to clean Luna EMG and extensions on a regular basis. Follow the rules below:

Part of Luna EMG	How to clean it
Case and cables (plastics, polyesters, metal, labels) Cloth based accessories (strap, belts)	Use moist cloth with **70 % isopropyl alcohol** for cleaning and disinfection of the device and lead wires. **STEP 1 :** Turn the device off and disconnect the lead wire from the unit. **STEP 2 :** Any excess of the soil can be removed by wiping the device with the cloth/paper towel moistened with 70% isopropyl alcohol and left to dry for 5 min. **STEP 3:** Spray the 70% isopropyl alcohol directly on the device and lead wires and leave for a period of time indicated in the instructions attached to the cleaning agent. (until dry). **STEP 4:** Wipe the device and lead wires with a dry cloth/paper towel.
Extensions, EMG cables	Use moist cloth with **70 % isopropyl alcohol** for cleaning and disinfection of extension. **STEP 1 :** Disconnect the extension/cable from Luna EMG. **STEP 2 :** Any excess of the soil can be removed by wiping the extension with the cloth/paper towel moistened with 70% isopropyl alcohol and left to dry for 5 min. **STEP 3:** Spray the 70% isopropyl alcohol directly on extension and leave for a period of time indicated in the instructions attached to the cleaning agent. (until dry). **STEP 4:** Wipe the extension/cable with a dry cloth/paper towel.

Never clean Luna EMG while the AC cable is connected. This may result in electric shock or short circuit the electronics inside. Never use running water or other fluids for cleaning. Do not sterilize.

Never use cleaning detergent that have active oxygen or chlorine, due to possible surface damage.

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

While using high level disinfectant always follow the guidelines for safety. Especially if you are using the solution on elastomer materials like Luna EMG's grips, straps etc. always wash them

under running water to prevent the product from staying on Luna EMG for too long. Always follow the instruction provide by disinfectant's manufacturer.

Luna EMG is used for multiple patients, please:

1. Clean Luna EMG, the cables and accessories after every use and before first use that day, according to the instructions above.
2. Consider using multiple extensions, to limit exposure between patient-to-patient.
3. Luna EMG and its accessories should be dried before storage or re-use.
4. Store according to 17.7 Storage and transportation instructions.

19. End user license agreement (EULA)

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

19.1 Data retention

EGZOTech reserves the right to retain the collected data for the period of no less than 10 years from the cessation of manufacturing of the last Luna EMG, based on the requirements of EU MDR 2017/745.

19.2 Facility private password

During the first run of Luna EMG you be given a private password generated specifically for you. It will be stored on the local tablet and can be printed out for safety. This password will encrypt and decrypt your users' (patients' and therapists') private and sensitive data in your Luna' EMG's Tablet memory.

Your facility's private password is only stored on your tablet and/or printed out by you. EGZOTech does not have a copy of this password, nor is it sent out to the cloud for processing.

If this password is lost, EGZOTech cannot recover your users' personal data!

19.3 Facility admin configuration

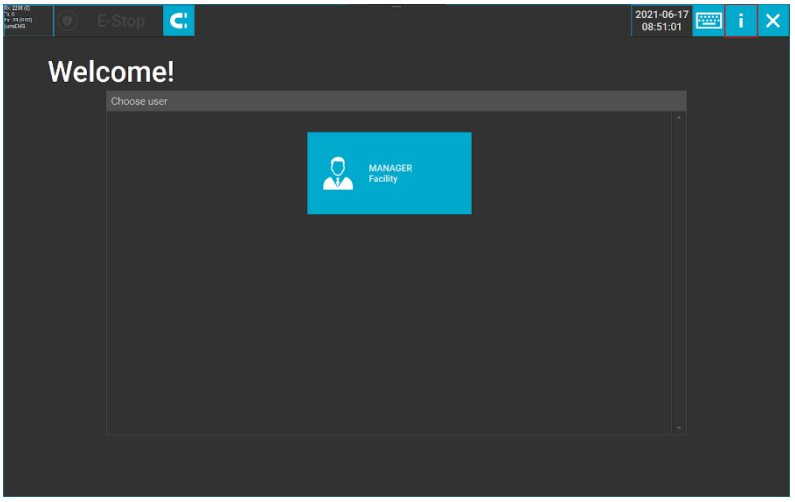
If Luna EMG has arrived to you as a replacement unit, or it's not a first one at your facility, only with **the explicit instructions** from your product specialist you can configure Luna EMG to work with your existing infrastructure.

19.4 Protection of personal data on the Luna EMG

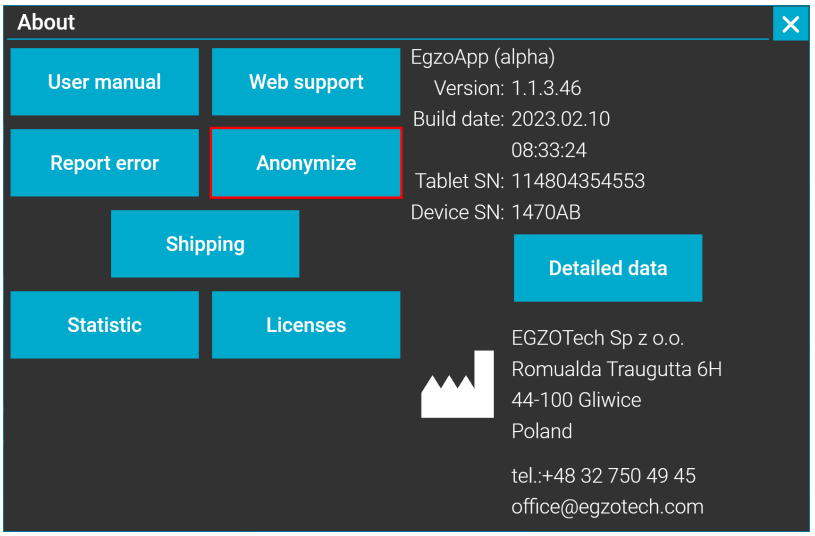
Remember that you are responsible for entering personal data into the Luna EMG device.

If you hand over the robot outside the facility or give access to it to an unauthorized person, then: make personal data anonymous as is presented below:

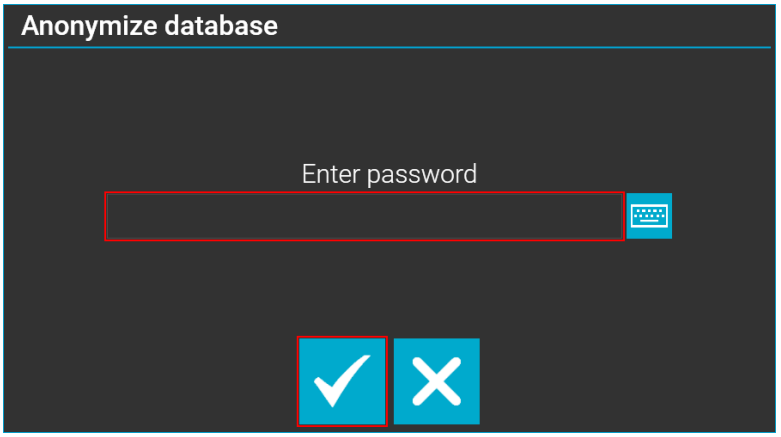
1. Click the 'i' button.



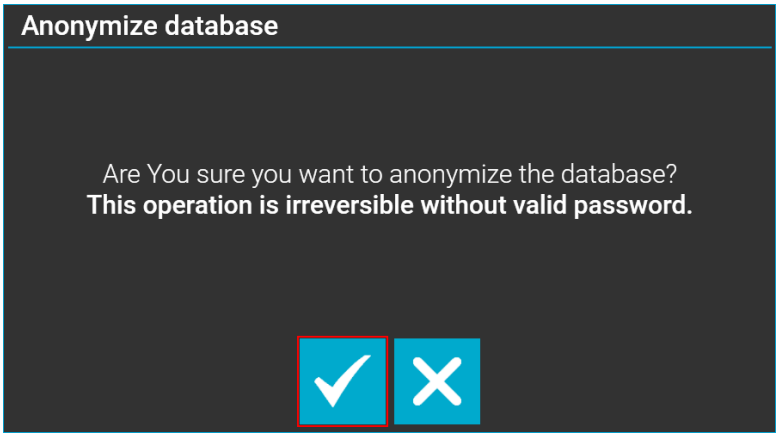
2. Click Anonymize



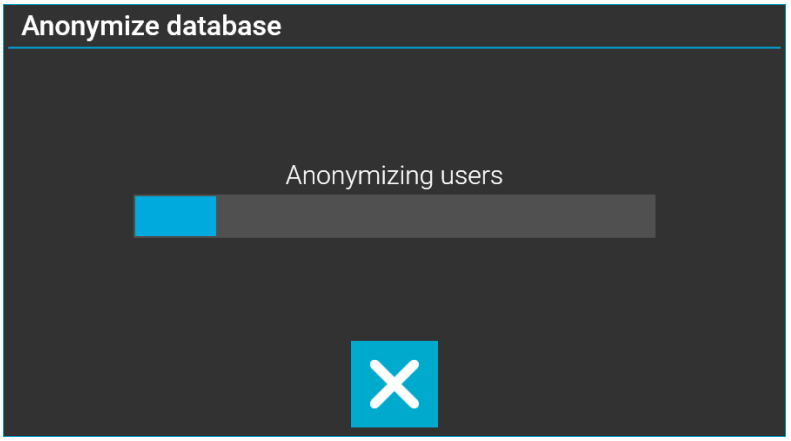
3. Enter any password to protect the database against de-anonymization. **Remember not to give this password to people who should not have access to patients' personal data.** Write your password in an area with a red bracket and confirm by clicking the checkbox.



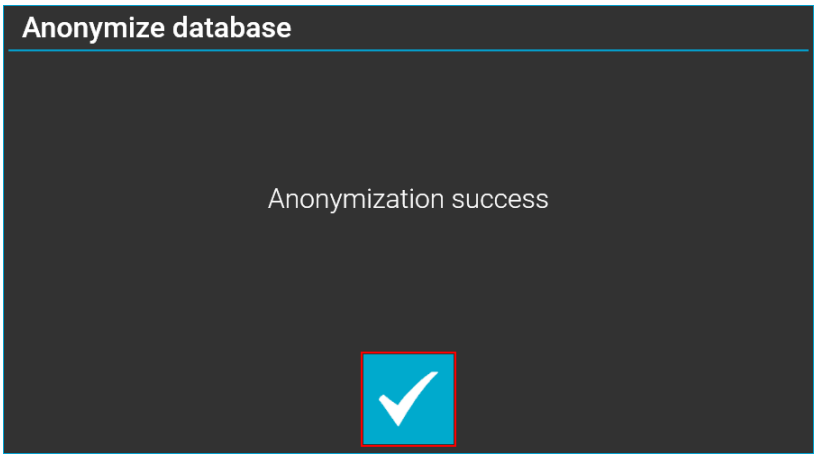
4. Confirm that you want to anonymize. Remember that the database cannot be denominated without a password.



5. Anonymization continues

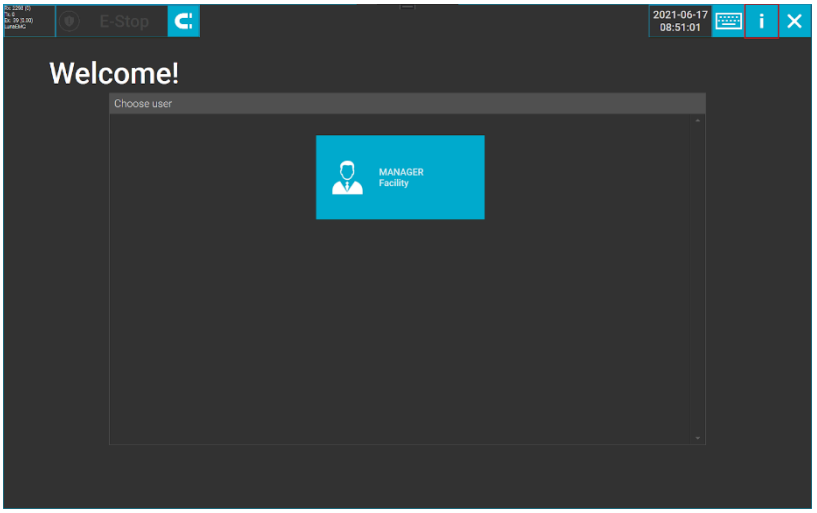


6. The anonymization was successful. Click the checkbox button to leave anonymize database screen.

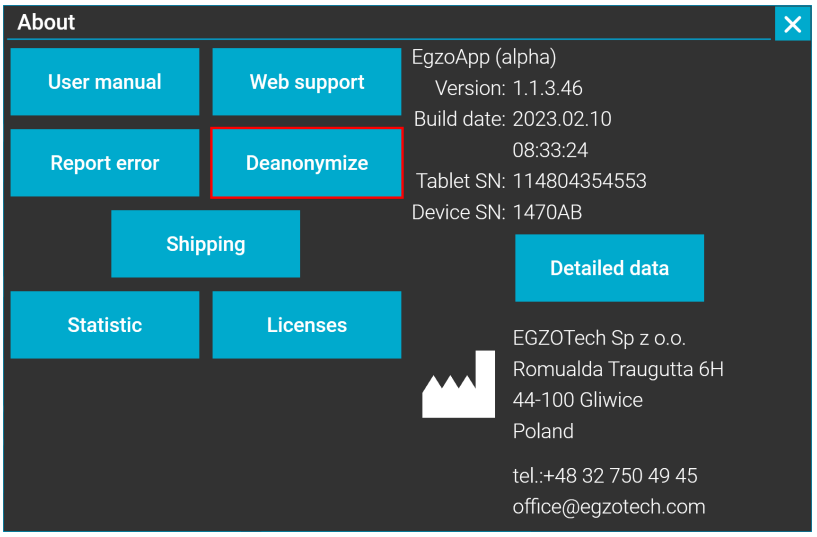


Anonymization of personal data is a reversible process. The user may have access to personal data again using a password. The function was introduced to protect personal data, the administrator of which is their owner (the healthcare facilities or the person who entered this data into the robot).

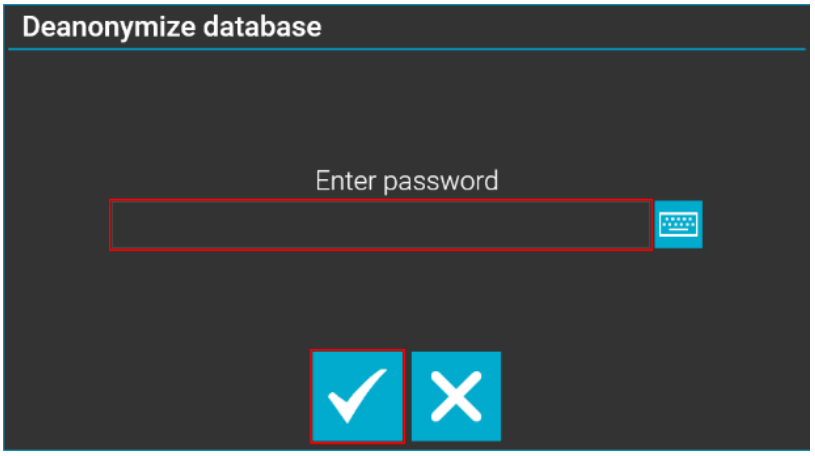
1. Click the 'i' button.



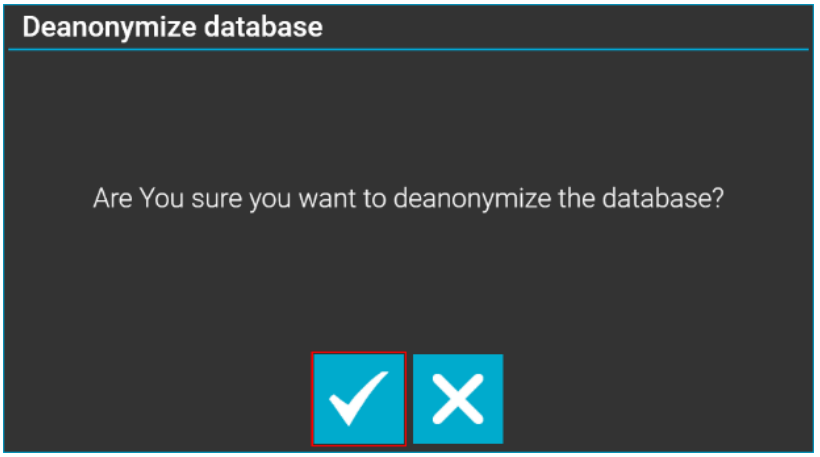
2. Click deanonymize.



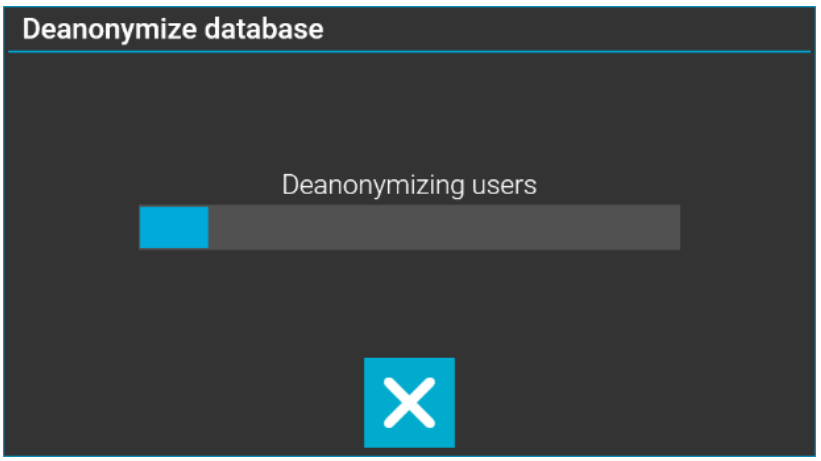
3. Enter the password provided during the anonymization. Write your password in an area with a red bracket and confirm by clicking the checkbox.



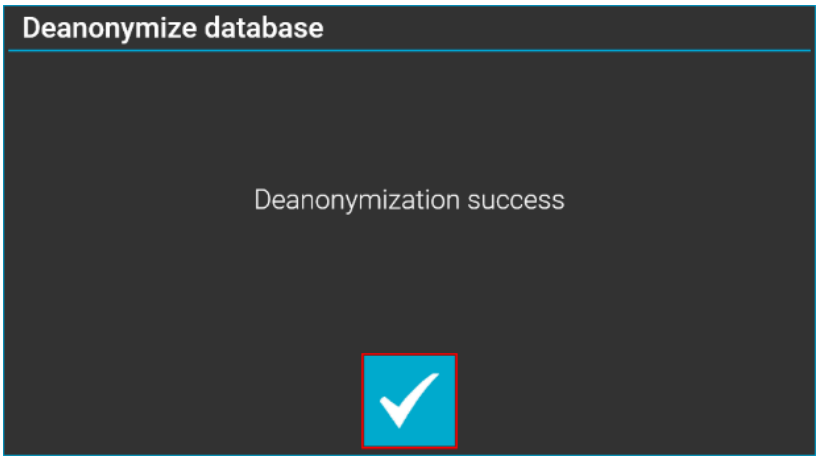
4. Confirm that you want to deanonymize the database by clicking the checkbox.



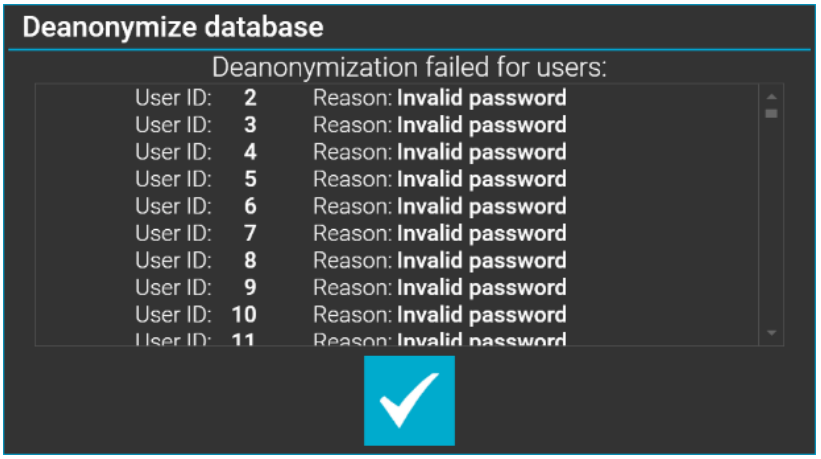
5. Deanonymization continues.



6. De-anonymization was successful.



7. Incorrect password entered during deanonymization



20. Declaration of conformity and compliance statements

20.1 Declaration of conformity

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

20.2 Manufacturer's declaration – electromagnetic emissions

Luna EMG is intended for use in the electromagnetic environment specified below. The customer or the user of Luna EMG should assure that it is used in such an environment.
Luna EMG complies with the electromagnetic compatibility requirements for emissions and immunity, specified in the tables below. Users must adhere to the electromagnetic environment guidance and any deviations from collateral standards specified. For necessary instructions for maintaining basic safety and essential performance in relation to electromagnetic disturbances and expected service life, please refer to general warnings, described in this manual.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Luna EMG 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 A	Luna EMG is suitable for use in professional healthcare – hospitals, clinics
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

20.3 Manufacturer's declaration – electromagnetic immunity

Luna EMG is intended for use in the electromagnetic environment specified below. The customer or the user of Luna EMG should assure that it is used in such an environment.
Luna EMG complies with the electromagnetic compatibility requirements for emissions and immunity, specified in the tables below. Users must adhere to the electromagnetic environment guidance and any deviations from collateral standards specified. For necessary instructions for maintaining basic safety and essential performance in relation to electromagnetic disturbances and expected service life, please refer to general warnings, described in this manual.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of Luna EMG requires continued operation during power mains interruptions, it is recommended that Luna EMG be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2,5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of Luna EMG, 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 electromagnetic site surveys, should be less than the compliance level in each frequency range. [B] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the (ME EQUIPMENT or ME SYSTEM) is used exceeds the applicable RF compliance level above, the (ME EQUIPMENT or ME SYSTEM) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the (ME EQUIPMENT or ME SYSTEM). [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

20.4 Recommended separation distances between portable and mobile RF communications equipment and Luna EMG

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

Thank you for taking your time to read this manual!

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

The service request form is available at:

HTTPS://SERVICE.EGZOTECH.COM

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