evomove®

Training Manual

MEDICAL TECHNOLOGY IN MOTION

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1 One System – Many Options

The evomove® is **one system with many options and possibilities**.
A system that is not optimized for one application, but is adapted by you for the individual treatment of the patient and provides optimal support for walking with functional electrical stimulation, whether with or without an orthosis. As with individual orthoses, prior knowledge is necessary here and you become better and safer from screening to screening.

We as a company have the claim to design our products as simple as possible, but to keep possibilities and flexibility. We rely on a fair and transparent calculation and want to achieve a high quality of care with our products.
To achieve this, it is essential to prepare and communicate knowledge and to receive feedback.
This manual should help to convey important contents and serve as a reference book.
The last point goes to you, we look forward to constructive feedback!

"When I founded Evomotion in 2016, I had no idea what to expect. Sure, there was a rough product idea, but I didn't expect to learn so much in such a short time and develop the product so far - even though we are still at the beginning.

The fact that you are reading this shows that you are interested in new technologies and want to push yourself or your company further. You want to get involved with our product and new approaches to delivering Functional Electrical Stimulation and help your patients walk more efficiently and safely through active muscle work and neurological feedback.

Thank you very much!

And now have fun with the evomove®!"

Aljoscha Diercks

2 Basics for Using the evomove®

2.1 Physiology of the Human Voluntary Motor Skills

Our central nervous system, consisting of the brain and spinal cord, has the important function of controlling voluntary movements of the extremities. Movement can only take place when muscles contract. This happens as soon as the electrical voltage on the muscle cell membrane changes to a certain extent (Elsevier GmbH, 2010, p. 47). Such a voltage change is called electrical potential or action potential and is essential for human movement (Elsevier GmbH, 2010, p. 47). The ratio of ions inside and outside the nerve and muscle cells creates certain electrical voltages on the cell membrane. The so-called resting membrane potential is between -100 and -50mV. An incoming action potential initially causes a voltage reversal on the cell membrane by opening ion channels. This depolarization occurs rather slowly at first and when a certain threshold is reached (approx. -50mV) very quickly up to a short-term voltage of 40mV on the cell membrane, so that one speaks of an action potential. Ion pumps and voltage-dependent ion channels restore the original resting membrane potential in the subsequent repolarization phase and the cell cannot briefly absorb any new stimuli (absolute refractory phase). This phenomenon means that the stimulus, the action potential, is typically only passed on in one direction, namely in the direction of the axon or the synapse (Silbernagl, Despopoulos, 1991, p. 26 ff.).

Automatic movement patterns, such as walking, are stored in the brain and are sent to the required skeletal muscles as movement orders in the form of action potentials. This happens via the first and second motor neurons, which are nerve cells that connect the "sender" and the "receiver" with one another. The first motor neuron begins in the motor center of the brain and runs as a single, uninterrupted neuron, through the spinal cord or the pyramidal tract to the anterior horn of a spinal cord segment. There the synaptic interconnection, the transmission of the action potential, takes place on the second motor neuron, which is in the periphery in direct connection with the skeletal muscle. The movement order in the form of an action potential is passed on along the axon of the 1st motor neuron until it is "transferred" to the 2nd motor neuron via the synaptic gap. The previously electrical stimulus is converted into a chemical signal with the help of the release of transmitter substances. These transmitter substances again cause electrical changes in the postsynaptic membrane in the form of a depolarization. This process is repeated at the contact point between the axon of the 2nd motor neuron and the muscle cell (motor end plate), which ultimately responds to this incoming impulse with a contraction (Silbernagl, Despopoulos, 1991, p. 22).

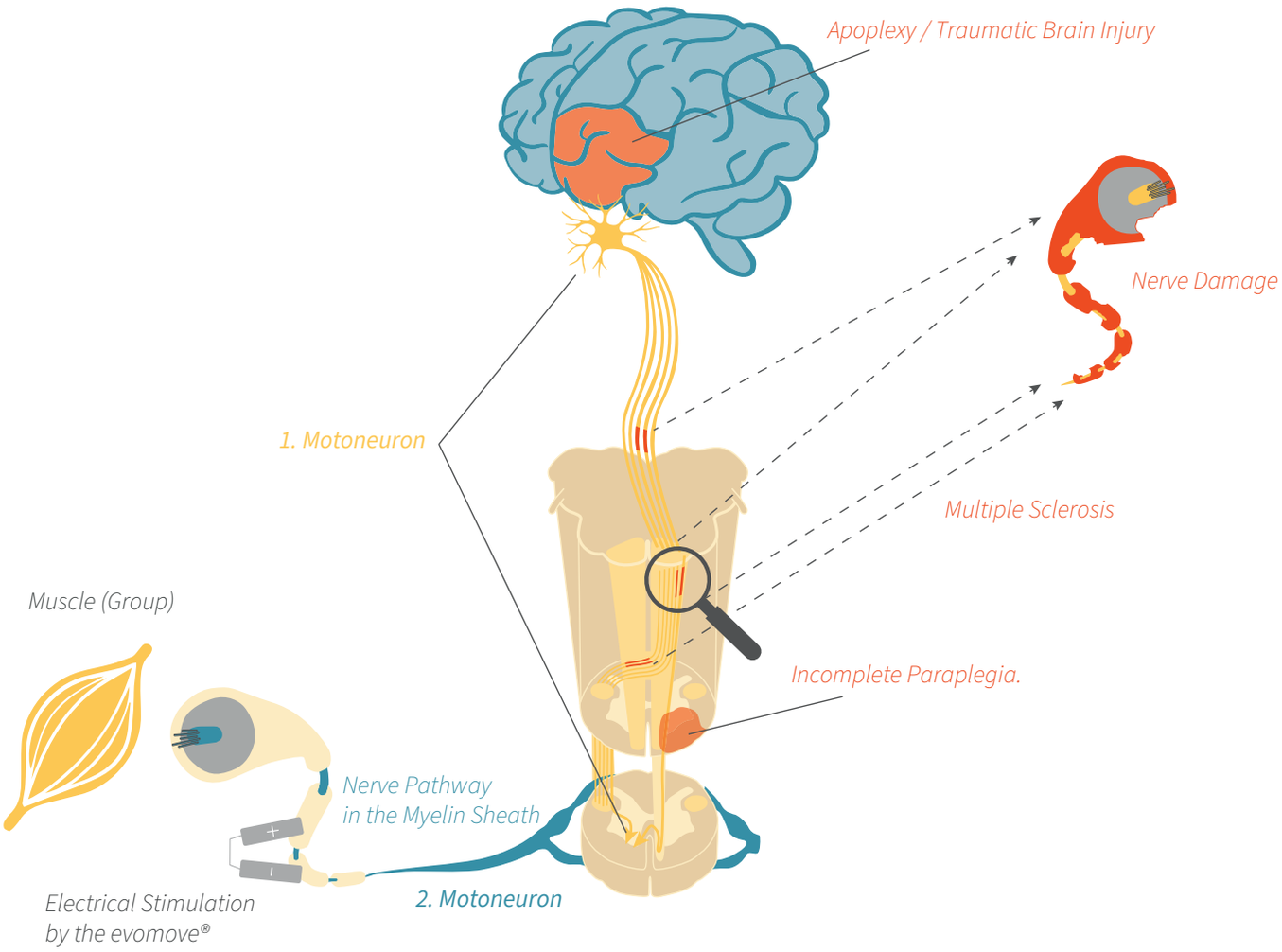


Fig. 1: Schematic Representation of Functional Electrostimulation in Central Nervous Damage

The distinction between the 1st and 2nd motor neuron is so important because if the 1st motor neuron is damaged, the 2nd motor neuron is usually intact. A functioning 2nd motor neuron is a basic requirement for FES. The impulse transmission of the action potentials from the motor center of the brain to initiate movement is disturbed in the case of a lesion of the 1st motor neuron. The FES makes use of the possibility of depolarizing the nerve cell through electrical fields on the skin in the region of the target muscle or the 2nd motor neuron and still triggering an action potential and thus a muscle contraction. Although there is no regulation or dosage of the contraction, which is normally controlled by complex processes in the brain, movement is possible again at all with the help of FES (Faller, Schünke, 2012).

It has been proven that the nervous system is not a rigid structure, but can be restructured and adapted to certain events such as a stroke or a traumatic brain injury. This neuroplasticity takes place either on a structural level through the sprouting of further axons or on a functional level in the form of increased neurotransmitter release. Such changes usually occur in the first weeks and months after the acute event. However, a functional improvement can also be achieved later through compensatory mechanisms of voluntary motor skills and consistent training. Neuroplastic processes are not only observed in the event of damage, but are also favored by increased use of the affected extremity (s). A motor learning process takes place here, which causes plastic changes in the brain and ultimately leads to an improvement in function. (Meier, 2021, p. 10 ff.)

2.2 How the FES Works

Due to the high importance of electrical voltage changes at the cellular level in the human body, as explained above, the relevance of functional electrostimulation becomes clear. The following chapter presents the mode of operation and mechanisms of action of the FES and associated parameters.

2.2.1 Nomenclature

Definition: The aim and purpose of functional electrical stimulation (FES) is the desired and directed release of motor stimuli in the human body.
In the case of irritation via surface electrodes, one speaks of transcutaneous electrical stimulation (TES). A muscle can contract by stimulating the muscle cell (EMS) or the innervating nerve (TENS). If the stimulation is used to induce functional movement, it is called FES.

In FES, the motor parts of a nerve are stimulated - this induces corresponding muscle activities that can be transferred to patient-specific gait patterns.

2.2.2 Electrical Stimulation to a Nerve / Muscle

In TENS, an ion current is generated in human tissue, triggered by a voltage drop between the electrodes. With a sufficiently high current density and / or sufficiently long stimulation, the electric field causes depolarization in the nerve cell (see “Physiology of human voluntary motor skills”). The functional stimulation usually takes place in short pulses. With natural voluntary movement, force regulation takes place through the recruitment of different motor units. First smaller, later larger units are activated; with electrical stimulation this is the other way around. Larger motor neurons are more likely to be stimulated and control can only take place by increasing the ion current and stimulating smaller units or units further away from the electrode. However, different types of muscle fibers can only be stimulated to a limited extent, selectively by adjusting the stimulation parameters. During the natural contraction, the energy metabolism is guaranteed by the asynchronous control of individual fibers. While some fibers are contracting, others can relax. The external force remains the same. This does not happen with external stimulation, but we can extend the regeneration time by carefully selecting the parameters.

The FES uses the principle of neuroplasticity (see “Chapter Physiology of Human Voluntary Motor Skills”) and promotes it. “At FES, there are changes at the neural level at different levels and through a wide variety of aspects. Since the FES pursues an action and exercise-based approach, as with any other therapeutic intervention, active practice by the patient results in a training-induced neuronal plasticity. " (Meier, 2021, p. 21).

The FES thus has effects on the premotor cortex, primary and secondary sensory areas of the cortex, on the number of fibers of the corticospinal tract, on neurotrophic factors, axonal growth, myelination of nerve cells and the reinnervation of peripheral nerves.

In addition, the effects on the spinal cord level are increasingly being investigated, as FES has a positive effect on spasticity in clinical practice. One of the explanatory models focuses on promoting reciprocal inhibition by modulating segmental inhibition in the area of the alpha motor neuron (Meier, 2021, p.23 ff.).

2.2.3 Parameter

With FES, the stimulation is done in biphasic pulses (see picture) to avoid charging the skin. First a positive pulse is applied to the active electrode - the ion current flows to the other electrode - then this is reversed, the ion current and thus charge flows back.

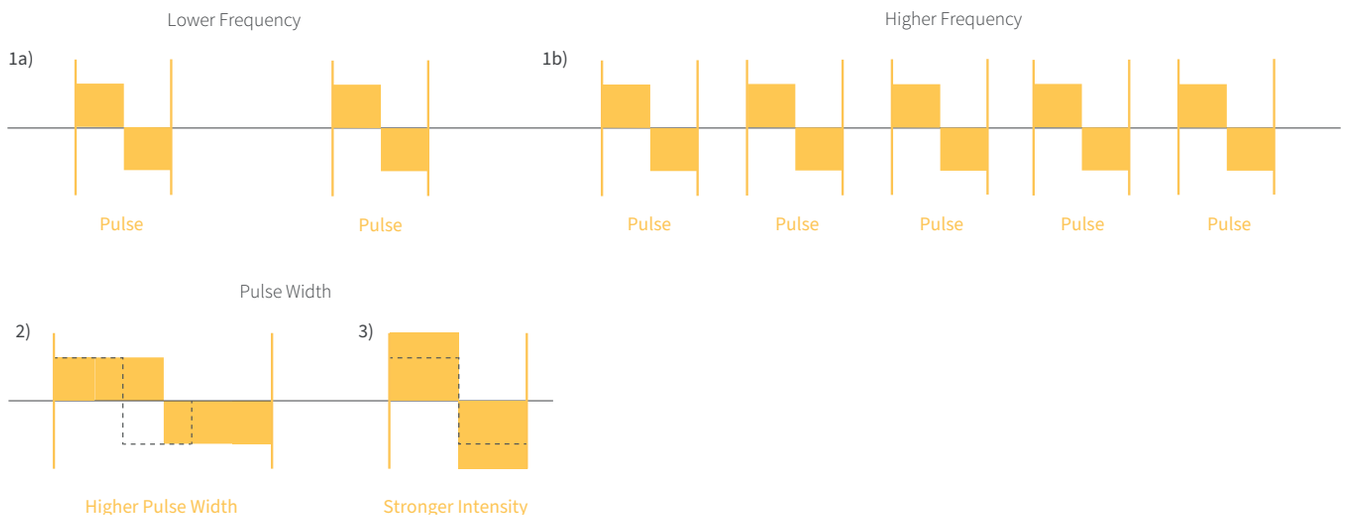


Fig. 2: Changing the Parameters

The strength of a pulse or the energy (yellow area in the picture) depends mainly on the intensity and the pulse width. The pulses can be varied in frequency (frequency (1)), pulse length (width of the yellow field (2)) and pulse intensity (height of the yellow field (3)).
The actual stimulation sensation is very individual from patient to patient. By varying the stimulation parameters, the FES can be adapted to the respective sensation or activation threshold. It should be noted, however, that as soon as one of the parameters (2) or (3) is increased, the result is automatically a larger yellow area and thus a stronger impulse. Therefore, the other parameter should first be reduced accordingly to avoid overstimulation.

- Intensity: Intensity is the key parameter to adjust the strength of stimulation (3). For young patients, about 10mA is sufficient, for adults it is 15 - 35mA depending on the distance and intervening layers. However, depending on the disease, significantly higher values are also possible.
  If the intensity is chosen to be greater than 50mA, care should be taken to ensure good self-evaluation by the patient.

- Pulse width: The pulse width determines the duration of the pulse (2). If the pulse width is increased in the region of the stimulus threshold, the intensity should be reduced significantly for the time being to avoid sudden overstimulation. For lower extremity muscles, pulse widths of 150 - 450µs are typically selected.

- Frequency: frequency affects the frequency of the pulses, the more pulses per unit time, the more action potentials are triggered (1) and the more uniform the contraction, but in this case the muscle has less time to relax. By choosing lower frequencies, which increase the recovery time and tend to target more persistent fibers, the muscle does not fatigue as quickly (this is particularly relevant in multiple sclerosis).

For the muscles of the lower extremity, frequencies of 25 - 60Hz are typically chosen.

Lower extremity muscles consist of different proportions of "fast-twitch fibers" and "slow-twitch fibers" (see chapter "Attachment sites"). The focus of stimulation can thus be placed on specific mucosal fibers via the stimulation parameters. The fast-twitch fibers already respond to short pulses and can be triggered more often in succession. Thus, they can be stimulated preferentially with short and rapidly successive pulses (small pulse widths and high frequency). For slow-twitch fibers, it is exactly the opposite: they generally require longer pulses (longer pulse width) to be activated. However, the contraction then also lasts longer, which is why lower frequencies are necessary. The asymmetric pulse also favors the slower fibers.

2.2.4 Electrodes

To generate the electric fields on the skin, electrodes are needed. We distinguish between two different types of electrodes.

Gel electrodes (Screening)

Gel electrodes (also called TENS electrodes) essentially consist of three layers: an insulating layer, a conductive, usually metallic layer, and a weakly conductive layer for good and uniform skin contact. Surface electrodes are used in screening because they are very flexible in placement and orientation. The electrodes are placed over the nerve or motor end plates of the muscle and connected to the cable of the stimulation unit. Selective stimulation of only one muscle strain is rarely possible because the nerves have similar distances from each other as the nerve to be stimulated has from the skin. Functional units of muscles are often innervated by closely spaced fibers and can thus be stimulated simultaneously with one electrode. The deeper the nerve, the more charge must be applied to the skin and the lower the selectivity. For nerves close to the surface, such as the motoneuron of the gastrocnemius muscle, large-area electrodes can be used. However, for deeper nerves, smaller electrodes should be used. Gel electrodes can be used multiple times and disinfected between patient fittings, but they should be replaced after approximately 2 weeks. Highly oily creams can have a negative effect on the adhesive effect of the electrodes, and stimulus transmission is also disturbed. In such cases, the skin should be cleaned in advance with a damp cloth.

Carbone Electrodes (Permanent Supply)

The carbon electrodes are intended for permanent use and can even be washed in the washing machine. The electrodes are made of a moderately conductive material, which with a little moisture ensures good skin contact and sufficient conductivity. Electrode gel is applied during dressing, and later skin sweat provides sufficient moisture. For patients with very dry skin, electrode gel should be reapplied during use if necessary.

2.3 Indications und Contraindications

In the process of supplying a medical product, in this case specifically the evomove®, it is essential to know the indications and contraindications. The proof of at least one indication or the refutation of contraindications is an important building block for the fulfillment of the supply requirements. In case of uncertainty or doubt, the expertise of medical professionals should always be consulted.

Indications

The indications for the evomove® can generally be summarized under damage to the central nervous system, i.e., the 1st motoneuron, in all persons from 6 years of age. In certain cases, prosthesis patients, spinal disc problems or other peripheral nerve damage can also be treated. Common disorder patterns with their motor symptoms in relation to the lower extremity are explained in the following. Since disorders of the nervous system are very diverse and multifaceted, this list does not claim to be complete, so that in case of doubt, consultation with medical professionals is advisable.

- **Stroke (Apoplexy)**

  Pathophysiology: Cerebral ischemia or cerebral hemorrhage leads to an undersupply (ischemia) of certain brain areas. In 85 percent of cases, a cerebral circulatory disorder is responsible for a stroke. The clinical symptoms result in each case from the affected vascular or brain area (Kolster, Ebelt-Paprotny, 2002, p. 519).

  Motor symptoms: After suffering a stroke, patients often show a contralateral hemiparesis with spastic tonus increase of the musculature. When the cerebral artery is affected, the so-called "Wernicke-Mann gait" is characteristic. This is characterized by extensor spasticity of the contralateral leg and subsequent circular movement (circumduction) of the entire leg during the swing phase (Kolster, Ebelt- Paprotny, 2002, p. 519). Furthermore, impairments in gait triggered by paretic musculature are apparent (see Central spastic paralysis).

- **Traumatic Brain Injury (TBI)**

  Pathophysiology: Craniocerebral trauma is a head injury caused by external force with impaired or lost consciousness. These are graded from Grade I (no changes in brain shape or structure, no permanent dysfunction) to Grade III (severe structural brain injury). Cerebral edema or hematoma associated withTBI, can often occur either between the meninges or directly in the brain substance, resulting in increased intracranial pressure that can cause lasting neurological damage (Kolster, Ebelt-Paprotny, 2002, p. 527).

  Motor symptoms: Cerebral paresis, incoordination, and other motor impairments may also occur with SHT.

- **Infantile Cerebral Palsy (ICP)**

  Pathophysiology: Infantile cerebral palsy refers to any pre-, per- or postnatal damage to the immature brain up to the age of 5. These can be caused, for example, by disturbed regulatory mechanisms of

cerebral blood flow, fluctuations in blood pressure, peri- or postnatal infections or tumors. Since the manifestations are very variable, no uniform clinical picture can be determined. However, permanent postural and movement disorders that change in appearance are often observed.

Motor symptoms: Common motor symptoms include disturbances in postural control, unrythmic and delayed goal-directed movement patterns, and the development of compensations. Apart from the typical neurological leading symptoms and paralysis (see below), cognitive and mental impairments and lower extremity growth deficits may also occur.

- **Encephalomyelitis Disseminata (Multiple Sclerosis)**

Pathophysiology: Autoimmune inflammatory processes in the white matter of the central nervous system, lead to degeneration of the myelin sheaths of the nerve cells. Nerve conduction is thus disturbed. Mostly adults between the ages of 20 - 45 years are affected, with women showing a higher incidence. A genetic link is suspected. Again, the neurological deficits are localization-dependent (Kolster, Ebelt- Paprotny, 2002, p. 526).

Motor symptoms: In addition to a variety of possible symptoms that may also affect autonomic processes, vision, and speech, spastic paralysis of the extremities is common (see below) (Kolster, Ebelt- Paprotny, 2002, p. 526).

- **Incomplete Paraplegia**

Pathophysiology: As a result of traumatic damage to the spinal cord, a space-occupying tumor, a herniated disc, a circulatory disturbance of the vessels supplying the spinal cord, or inflammatory processes, incomplete paraplegia develops. Its severity depends on the height of the affected spinal segment and the associated nerve roots. These nerve roots are responsible for supplying certain muscular areas of the body (myotomes) and for processing sensitive information (dermatomes). Because the spinal cord is not completely severed in this condition, residual sensory and/or motor functions can still be expected below the damaged segment.

Motor symptoms: At the level of the spinal cord injury and below, motor impairments are expected in addition to vegetative and sensory deficits. These manifest as central paralysis symptoms. In the first phase immediately after the injury ("spinal shock"), flaccid paralysis always occurs initially. After about six to eight weeks, spinal spasticity develops and tends to increase. This can lead to the superimposition of remaining voluntary motor functions, but can also be helpful for supporting functions (Hüter- Becker, Dölken, 2004, p. 266 ff., Kolster, Ebelt- Paprotny, 2002, p. 513).

Leading Symptoms

All the neurological diseases listed above result from damage to the central nervous system in the brain or spinal cord. Due to this, they often result in the same sensorimotor impairments, which are also called leading symptoms:

- **Central (Spastic) Paralysis**

Central paralysis can take on different dimensions. In the case of incomplete or complete hemiplegia, the term hemiparesis or hemiplegia is used. Tetraparesis or tetraplegia refers to paralysis of all four extremities, while paraparesis or paraplegia affects only the arms or only the legs. As soon as the musculature of the lower extremities can no longer be controlled voluntarily, coordination disorders, balance problems, insufficient stance stability and consequently increased risk of falls in gait result. In the course of time, these flaccid forms of paralysis can develop into spasticity, i.e. involuntary increases in muscle tension. This is accompanied by increased muscle reflexes, decreased reciprocal inhibition and clonus (repetitive activation of the muscles). The surrounding joints are thus usually no longer freely movable and become contracted (Kolster, Ebelt- Paprotny, 2002, p. 503, Hüter- Becker, Dölken, 2004, p. 204).

- **Contractures**

  Joint contractures often form as a result of spasticity, but also due to muscle imbalances caused by paralysis. As a rule, these are flexion contractures that are evident in the lower extremity in the hip joint, knee joint, and ankle joint (pointed foot position) (Hüter-Becker, Dölken, 2004, p. 278). These limitations are an important factor in the application of FES in order to be able to assess how much range of motion can be expected at all and which muscles need to be detonated or toned.

- **Sensory Disturbances**

  In addition to motor impairments, the sensitive sensation of those affected is often also disturbed, since the signals picked up in the periphery are not appropriately transmitted to the processing center in the central nervous system. On the one hand, this can affect surface sensitivity, i.e. the ability to feel touch, temperature or pain. On the other hand, there are often also difficulties with regard to position sensation, movement sensation and force sensation, which are summarized under the term depth sensibility. This leading symptom should be considered accordingly when using FES, especially in screening. Patients may have difficulty providing feedback on current sensation or perceiving changed gait motor function.

Contraindications

Contraindications, i.e. factors for which a fitting with the evomove® is not recommended, can be divided into absolute and relative contraindications. If an absolute contraindication applies, an evomove® fitting is not advisable or even harmful. Absolute contraindications usually result from diseases that affect the immediate area of the electrode application or the cuff or radius. Relative contraindications must be clarified in advance (before screening) by a physician and certified by a declaration of no objection. In addition, the vessels should be insensitive to compression.

Note: If you deactivate the app connection (see Chapter 3 "Finish"), it must be ensured that the patient is physically and cognitively capable of releasing the plug-in connection between evomove® and electrodes. If this is not the case, there is a contraindication!

Absolute contraindications:

- Thromboses
- Varices

- Thrombophlebitis
- Malignant Processes (Cancer)
- Fractures
- Skin Lesions

Relative Contraindications (Medical consultation required):

- Epilepsy
- Active Implants (Pacemaker or Similar)
- Pregnancy (Risk of Falling)
- Artificial Joint Replacement

2.4 The Natural Human Gait

A certain degree of mobility is one of the "basic human needs" (Schwarze et al., 2020, p. 238) and thus contributes to maintaining quality of life. Gait as a form of locomotion is thus of high importance in order to be able to perform activities of daily living (Bartz, 2015, p. 12). In persons with central nervous disorders, motor effects often also influence gait, so that all requirements for a physiological, strength-saving gait pattern are no longer met (Götz- Neumann, 2011, p. 5). Such gait deviations in diseases of the central nervous system can be very diverse. An exact analysis of these is therefore essential in order to be able to select and implement effective gait support measures, such as a fitting with the evomove®.

For this purpose, it makes sense to orient oneself to a standard that reveals deviations and simplifies communication in the interdisciplinary team. Nevertheless, such a norm must always be considered in light of a large variability of normal walking resulting from different factors (Götz- Neumann, 2011, p. 9). Dr. Jaquelin Perry, an American physician, coined gait analysis at the end of the 20th century and published a widely used instrument in her book Gait Analysis: Normal and Pathological Function (1992). Physiotherapist Kirsten Götz-Neumann has translated and expanded this concept into German (Götz-Neumann, 2011). These elaborations allow to divide the complexity of gait into functional phases and sections without resorting to special instruments. The complex interaction of movements of the joints, selectively controlled activity of the muscles and position perception thus becomes transparent and can be interpreted accordingly.

Gait Cycle, Stance and Swing Leg Phase

In the gait analysis according to Perry, one leg, the so-called "reference leg", is always considered during a double step (Perry J., 1992). This means that the period from the beginning of the stance phase, through the swing phase, until shortly before the renewed beginning of the stance phase is taken into account. This sequence can also be called "Gait Cycle (GC)" and lasts approximately one second (see Fig. 4).
The stance phase accounts for about 60 percent and the swing phase for 40 percent. The stance phase describes the process from touchdown of the reference leg to lift-off. The swing phase is limited to the subsequent period until the next touchdown. The stance phase begins with the double-supported phase. Both legs are in contact with the ground. The body weight is then shifted to the reference leg. This is followed by the monopedal stance phase, i.e. the single-leg stance phase. The entire weight of the body is applied to the reference leg while the contralateral leg is swung forward and the contralateral foot touches down. At this point, both legs are again on the ground. In the terminal bipedal stance phase, the detachment of the reference leg is prepared by shifting weight onto the contralateral leg (Götz-Neumann, 2011, p. 9 ff.).

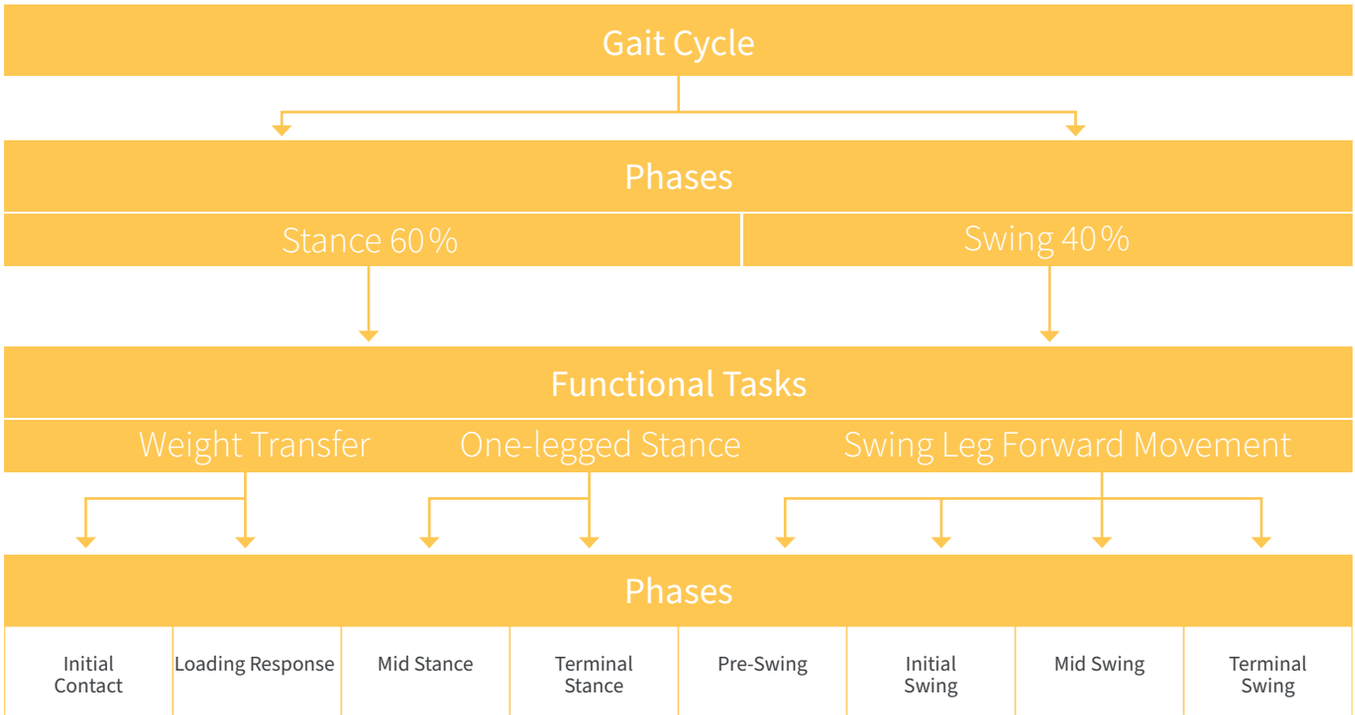


Fig. 3: Gait Cycle

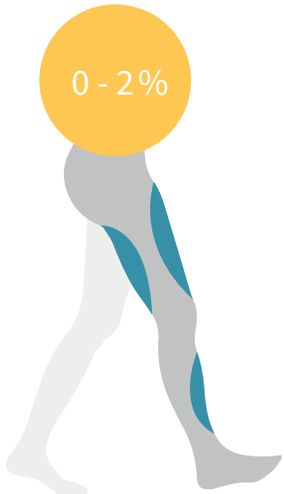
Gait Cycle

Perry (1992) made a further subdivision of the stance and swing leg phases into eight functional gait phases. This approach allows a precise analysis of the individual events in the gait and includes both the goal of each phase and the interaction of the required musculature.

Phases							
1. Initial Contact	2. Loading Response	3. Mid Stance	4. Terminal Stance	5. Pre-Swing	6. Initial Swing	7. Mid Swing	8. Terminal Swing
							
0 - 2 %	2 - 12 %	12-31 %	31 - 50 %	50-62 %	62 - 75 %	75 - 87 %	87 - 100 %

Fig. 4: Gait Phases

1. Initial Contact – IC



- **Function:** Making heel contact with the ground.
- **Time period:** From touching until the heel of the reference leg is in contact with the ground (0 - 2 percent of GC).
- **Joint positions:** Hip joint: 20 degrees of flexion | Knee joint: 0-5 degrees of flexion | Ankle: 0 degrees.
- **Muscles involved:** M. quadriceps femoris, M. tibialis anterior, M. gluteus medius and maximus and the hamstring muscles.

- *The physiological joint position is immensely important for optimal absorption as well as forthe energy managment in the subsequent phase*

2. Loading Response -LR

- **Function:** Shock absorption in the knee and ankle joint; Load acceptance and stability in the hip joint; Directed forward movement through the first rocker (1st rocker).
- **Time period:** from the IC to the lifting of the contralateral leg (2 - 12 percent of the GC).
- **Joint positions:** Hip joint: 20 degrees of flexion | Knee joint: 20 degrees of flexion | Ankle: 5 - 10 degrees of plantar flexion.
- **Muscles involved:** M. quadriceps femoris, M. tibialis anterior, M. gluteus medius and maximus, M. adductor magnus, M. tensor fascia latae, M. tibialis posterior and M. peroneus longus.

- *The abrupt shift in weight with the IC creates a large plantar flexion torque on the heel.*
- *In order to maintain the forward movement, roll over the heel or the heel hump.*
- *Through the plantar flexion of the ankle joint (5 - 10 °) and the associated flexion of the knee (20 °), the entire load is dampened.*
- *The reference leg moves further forward in relation to the floor reaction force vector.*
- *The forces resulting from weight shifting are largely cushioned by the thigh muscles.*

3. Mid Stance – Mst

- **Function:** Controlled forward movement of the tibia; Shift the center of gravity forwards with the second rocker (2nd rocker).
- **Time period:** From the lifting of the contralateral foot to just before the heel of the reference leg is detached (12 - 31 percent of the GC).
- **Joint positions:** Hip joint: 0 degrees | Knee joint: 0-5 degrees of flexion | Ankle: 5 degrees of dorsiflexion.
- **Muscles involved:** Gastrocnemius and soleus muscles.

- *In the course of movement, the body vector is shifted from posterior to anterior and thus a forward movement is maintained.*

4. Terminal Stance – Tst

- **Function:** The controlled dorsiflexion in the ankle joint with the heel detaching from the floor.
- **Period:** From the end of the MSt to the touchdown of the contralateral foot (31 - 50 percent of the GC).
- **Joint positions:** Hip joint: - 20 degrees hyperextension | Knee joint: 0-5 degrees of flexion | Ankle: 10 degrees of dorsiflexion.
- **Muscles involved:** M. soleus, M. gastrocnemius, M. flexor digitorum longus, M. flexor hallucis longus, M. tibialis posterior, M. peroneus longus and M. peroneus brevis.

- *By continuing the rolling movement in the direction of the forefoot, the body's center of gravity shifts over the front edge of the support surface.*
- *The weight shift to the forefoot causes the heel to lift off the ground.*

5. Pre-Swing – Psw

- **Function:** Passive knee joint flexion of 40 °; Plantar flexion of the ankle.
- **Period:** From the end of the TSt to the preparation of the push-off (50-62 percent of the GC).
- **Joint positions:** Hip joint: - 10 degrees hyperextension | Knee joint: 40 degrees of flexion | Ankle: 15 degrees of plantar flexion.
- **Involved muscles:** M. soleus, M. gastrocnemius, M. rectus femoris and M. adductor longus.

- *The reference leg is relieved by shifting weight to the other leg and by the continuous forward transport.*
- *The so-called "push-off" is characterized by further lifting of the heel and the middle foot from the ground as well as a knee flexion and represents the end of this gait phase.*
- *The doubly supported terminal stance phase is functionally part of the swing phase.*

6. Initial Swing – Isw

- **Function:** Ensuring knee flexion of at least 55 ° in order to achieve sufficient ground clearance, on which the step length depends in direct proportion.
- **Time period:** From detaching the toes to crossing the tibia of both legs in the sagittal plane (62 - 75 percent of GC).
- **Joint positions:** Hip joint: 15 degrees of flexion | Knee joint: 60-70 degrees of flexion | Ankle: 5 degrees of plantar flexion.
- **Muscles involved:** M. extensor hallucis longus, M. flexor hallucis longus, M. sartorius, M. iliacus and M. tibialis anterior.

- *The reference leg is lifted by the flexion in the knee and hip joint and moved forward dynamically.*

7. Mid Swing – Msw

- **Function:** Increasing hip flexion to 25 °; Dorsiflexion of the ankle to the neutral position.
- **Time period:** From crossing the tibiae until the tibia of the reference leg is perpendicular to the floor and the foot is approximately one centimeter above the floor (75 - 87 percent of the GC).
- **Joint positions:** Hip joint: 25 degrees of flexion | Knee joint: 25 degrees of flexion | Ankle: 0 degrees.
- **Muscles involved:** M. semimembranosus, M. semitendinosus, M. biceps femoris and M. tibialis anterior.

- *The hip joint is flexed further so that at the end the greatest hip joint flexion occurs in the GC at 25°.*
- *The knee is thus extended from strong flexion (60 °) to only slight flexion (25 °).*

8. Terminal Swing – Tsw

- **Function:** Knee joint extension to neutral position; Preparation for the subsequent stance phase.
- **Time period:** From “free fall” to the heel is directly off the ground (87-100 percent of GC).
- **Joint positions:** Hip joint: 20 degrees of flexion | Knee joint: 0-5 degrees of flexion | Ankle: 0 degrees.
- **Muscles involved:** M. quadriceps femoris, M. semitendinosus, M. semimembranosus, M. biceps femoris and M. tibialis anterior.

- *The foot of the reference leg is placed far in front of the body's center of gravity, and the muscles are prepared for the IC and the associated weight absorption or shifting.*

The human gait can be assessed on the one hand using qualitative criteria (gait phases) and on the other hand using quantitative observation criteria. However, these must always be adapted to the target group, as children meet different gait criteria than older people. A selection of those relating to the lower extremity are described below (after Götz-Neumann, 2011, p. 18 ff.).

Stride length: The stride length is not a uniformly defined parameter, but results from individual proportions. However, it should be the same for both legs.

Stride length: This specification stands for the length of two steps and provides information about the functionality of the locomotive or the relationship between the stance and swing phases. The normal average stride length is around 1.4m.

Walking speed: This measures the distance covered per unit of time. The average value is 1.4 m/s or 84 m/min.

Step frequency: This parameter stands for the number of steps per minute. 120 steps / min are usual, although this information varies between 100-130 steps / min depending on the physical conditions.

2.5 Pathological Gait – Deviations, Causes and Effects

Pathological changes in the natural human gait pattern in qualitative and/or quantitative form usually show typical disadvantages for the patient. Often a reduced stability can be observed, so that the feeling of security suffers. In addition, the walking speed and the walking endurance are reduced. An increased expenditure of energy also leads to faster exhaustion. The following table shows the individual gait phases with typical deviations, their causes, effects and compensations (according to Götz-Neumann, 2011, p. 124 ff.).

	Gait Phase	Deviation / Joint Position	Causes	Effects	Compensations
Stance	Initial Contact	Excessive plantar flexion: • low heel (flat heel contact) • foot-flat-contact • forefoot contact	Pretibial muscle weakness, plantar flexion contractures, spasticity of the soleus and gastrocnemius muscles	• Reduced heel-rocker function • IC with the entire sole of the foot • IC with forefoot at knee and plantarflex of 20 degrees	Hyperextension in the knee joint
	Loading response	Foot slap	Too weak pretibial muscles	Reduced to canceled shock absorption, reduced knee flexion	–
		Forefoot contact	see above	Heel falls to the ground / heel remains off / sudden hyperextension of the knee → reduced forward tibia transport	–

		Excessive dorsiflexion	Weakness of the triceps surae muscle, fixation of the ankle joint in neutral-zero position	Excessive heel rocker function with increased knee flexion, increased demands on the quadriceps femoris muscle → Accelerated tibial advancement	Increased knee flexion
		Limited knee flexion	Quadriceps femoris muscle weakness, knee joint pain	Reduced shock absorption, reduced forward swing of the tibia	–
		Excessive knee flexion	Flexion contracture in the knee joint, hypertension of the knee joint flexors, pain in the knee joint	Increased demands on M. triceps surae, M. quadriceps femoris and hip joint extensors, reduced stability of the standing legs	–
	Mid stance	Premature heel-off	Pretibial muscle weakness, plantar flexion contractures, spasticity of the soleus and gastrocnemius muscles	No ankle-rocker function, hyperextension of the knee joint, shortened contralateral stride length	Forward trunk lean
		Persistent knee flexion	Quariceps femoris muscle weakness, knee pain, contractures	Shortened stance phase	Excessive dorsiflexion in the ankle joint
		Hyperextension of the knee joint	Intentionally to improve standing leg stability, weak quadriceps femoris muscle	Potential risk of injury to all posterior knee joint structures, reduced forward movement of the tibia	–
	Terminal stance	Hyperextension of the knee joint	see above	see above	–
		No heel-off	Plantar flexor weakness	Reduced forward transport due to lack of push-off	Excessive hip joint flexion
Swing leg phase	Pre-swing	Extended heel contact	Weakness of the triceps surae muscle, fixation of the ankle joint in neutral-zero	Tibia is advanced far beyond normal range of motion	Increased demands on the quadriceps femoris muscle
		Limited knee flexion	Hypertension plantar flexors and / or knee joint extensors	Prolonged heel contact, increased knee and hip joint requirements	Excessive dorsiflexion in the SPG
		Excessive contralateral knee flexion	Intentionally to keep swing leg closer to the ground	Indirect lengthening of the reference leg, disruption of the foot detachment of the reference leg, disrupted forward movement of the reference leg	–
	Initial Swing	Limited knee flexion	Hypertension plantar flexors and / or knee joint extensors, knee joint extension contracture, weakness of the hip joint flexors	Toes drag across the floor	Excessive hip flexion, circumduction, lateral trunk tilt, contralateral vaulting

The table continues on the next page →

		Limited hip flexion	Weakness of the hip joint flexors, range of motion in RL <40 degrees of flexion, hypertension of the hip joint extensors, pain in the hip joint	Shortened stride length, disturbed detachment of the foot from the ground, reduced forward movement of the swing leg	Posterior pelvic tilt, lifting of the pelvis, excessive forward rotation of the pelvis, abduction in the hip joint, circumduction, excessive knee joint flexion, contralateral vaulting, trunk tilting laterally
	Mid Swing	Limited knee flexion	see above	Dragging your toes over the ground, risk of falling	Exaggerated hip flexion, circumduction, lateral trunk tilt, contralateral vaulting
	Terminal Swing	Excessive knee flexion	Flexion contracture in the knee joint, inability to extend the knee joint with simultaneous hip joint flexion, weak quadriceps muscle, ischiocrurales muscle hypertension	Shortened stride length, reduced hip joint flexion → reduced flexion torque in the hip joint, reduced requirements for hip joint extensors, unfavorable alignment of the foot for IC	–

Certain deviations in the **hip joint** affect all gait phases and are shown below (according to Götz-Neumann, 2011, p. 158 ff.).

Deviation	Causes	Impacts	Compensations
Excessive internal rotation	Muscular hypertension or internal rotational contracture, Femoral Antetorsion, Intentionally to improve knee joint stability	Functional lengthening of the leg through toe-in position → disturbed forward movement and detachment of the foot, loading of the lateral knee joint structures	–
Excessive external rotation	External rotation contracture, limited mobility in dorsiflexion, intentional for the functional shortening of the leg in the swing leg phase and to compensate for weak hip joint flexors	Toe-out position creates an enlarged support area and disrupts the foot rocker function	–
Excessive adduction	Adductor hypertension, often associated with increased internal rotation	Reduced support area, reduced standing leg stability, the swinging of the leg may be disturbed → scissor gait, differentiation from pseudo adduction important!	Ipsilateral pelvic depression
Excessive abduction	Abductor hypertension, functional elongation of the reference leg	Enlargement of the support area, reduction of the relative leg length	–

3 The evomove®

Fig. 5: evomove® control unit

The following chapter contains all information about our product, the evomove®. Among other things, you will find information worth knowing about its functionality, the components, attachment points, different variants and, above all, the operation in this section.

The evomove® is a care concept for adults and children from 6 years with disorders of the central nervous system. It is to be regarded as an aid suitable for everyday use and can be worn indoors and outdoors. With the help of functional electrical stimulation (FES), the motor parts of nerves are stimulated and the muscle activity is transferred to a patient-specific gait pattern. As a result, the evomove® not only contributes to improving walking movement, but also ensures increased blood flow in the application area, trains the muscles and prevents atrophy. Through repetitive movements as physiological as possible, joint mobility is maintained and contractures are counteracted.

The basic principle of the FES is used by placing electrodes over the gait-relevant muscles on the lower and / or thigh with the help of a cuff and / or cycling shorts. The evomove® control unit, which is worn on the leg and records the gait, provides individually adjustable electrical impulses and thus muscle contractions in the corresponding gait phases. The mobility in the joints involved is increased and the gait pattern visibly improves, so that an increase in individual performance occurs. The evomove® can be combined with an orthotic fitting or used on its own (see chapter "Ordering, variants and calculation").

So that the evomove® can be used safely, it is important that the patient is generally able to walk and stand. Even if their muscles could improve through regular use, a certain muscle status is needed right from the start. In a preliminary talk, you will find out whether your patients are currently sufficiently confident in their stance. In addition, people respond differently to electrical stimulation. This means that the same electrical impulse will cause muscle contraction in some people and not in some. In addition, the different levels of tolerance for pain should be taken into account. The evomove® is basically suitable for anyone who responds well to electrical stimulation. In addition, motor and cognitive skills must be available to operate the evomove® as well as a certain level of compliance.

Benefits

The evomove® has several advantages and sets it apart from previously known medical devices for functional electrical stimulation:

- **Can be combined with orthotic fitting (evomove®orthokit):** The evomove® can be used in combination with an orthosis. As a result, the stabilizing function of the orthosis is used when walking and, at the same time, the muscles involved are activated by the electrical stimulation.

- **Can be used on its own (evomove®solokit):** With sufficient stability, the evomove® can also be used as a stand-alone support system for walking. If necessary, this can be upgraded afterwards and thus offers flexibility for users and providers.

- **Gait detection:** As soon as the evomove® has been set for a movement, it automatically detects the right time to stimulate the muscles that are needed for walking. This is done via an integrated sensor. This ensures that the evomove® provides ideal support.

- **Training mode:** In addition to a supporting function while walking, the evomove® can also be used to stimulate the muscles in the form of training during rest periods and less active days.

- **App control:** The evomove® is operated with the evomove® app on a control device (smartphone, tablet, etc.) with an iOS or Android operating system. All the necessary settings and device information are displayed directly on the control device and no additional device has to be taken with you in everyday life. In order to set the stimulation individually, an initial adjustment by experts is necessary, which is carried out in a so-called screening (procedure see chapter Screening: App operation). Users can then change the stimulation in a defined range in order to adapt the evomove® to their daily shape.

- **Influence on trunk stability:** The muscles around the hip joint can be stimulated with the thigh system. In conjunction with our cycling shorts, which offer additional compression thanks to their fit, the pelvis is supported in its holding function while walking.

- **Safer and more economical walking:** The use of the evomove® (alone or in combination with an orthotic) ensures the development of a more natural and safe gait pattern and thus a reduction in the risk of falling. In addition, an extension of the walking distance and mobility is generated.

- **Stimulate two muscle groups independently of one another:** Two-channel FES system - two muscle groups can be stimulated in parallel and the timing for each individual muscle group can be precisely set in the app.

- **Stimulation with individual precision:** All parameters at a glance - In the screening, the stimulation is adapted to the individual needs of the user based on the values for intensity, timing, pulse width and frequency.

- **Discrete:** Small device, simple design, almost no cable.

- **Suitable for children from 6 years of age:** Supports child-friendly activities.

3.1 The Components

The evomove® as a medical product consists of several components, which are shown in the following chapter.

3.1.1 Control Unit, Device Status

The control unit (p. 26 Fig. 5) is the heart of the evomove®. It does everything from gait recognition to generating electrical impulses. The 6D inertial sensor (IMU) integrated in the evomove® records the angular velocity and linear acceleration of the system. Both serve to reconstruct walking movements. Learning / adaptable algorithms recognize stimulation-relevant gait phases that can be controlled patient-specifically. At the previously configured points in time within the gait phase, the evomove® triggers electrical stimulation or muscle contraction, which improves the gait pattern. The built-in battery charges via a new reverse polarity protected USB-C technology and guarantees running performance for the whole day.

Fig. 6: Casting dummy

Practical: With our casting dummy and the bracket, you can build the control unit directly into the orthosis.

3.1.2 Cuff or Shorts

We manufacture the cuff or cyclist individually for each user in order to be able to offer a perfect fit on the leg and a high level of comfort. Only one cuff is available for the lower leg, while a cuff or a Radler can be made for the thigh. A special built-in band in the Radler also stabilizes the patient's torso. The electrode position is determined patient-specifically in the screening, so that the stimulation electrodes can then be sewn or glued firmly in a cuff / radler made of skin-friendly softshell material. This ensures that the electrodes are permanently held in the correct position. Since central nervous damage is often unilateral, the product is designed to be put on with one hand in the case of a moderate disorder. The optimal fit can also be checked and, if necessary, corrected using optical marking aids. The cuff / Radler or the electrodes and the stimulation unit are connected to one another via a fabric cable. There is also the option of integrating a pocket for stowing the evomove® and / or the control unit in the cuff / Radler. Due to the simple design, the cuff / Radler can be worn alone and with any common orthotic system and is washable including electrodes and cables.

Fig. 7: User cuff for the shank

Fig. 8: User shorts

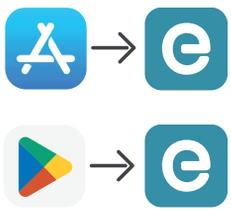
3.1.3 Electrodes and Cable

Self-adhesive electrodes are used for screening and determining the optimal electrode position. These can thus be freely positioned and can be used several times after disinfection. The long-lasting stimulation electrodes, which are firmly sewn or glued to the cuff / Radler, are made of silicone and carbon. The electrodes or the cuff and the stimulation unit are connected to one another via a flat, flexible and sewn / glued-in fabric cable.

Fig. 9: Adhesive electrodes for the screening

Fig. 10: Fabric cable forthe screening

3.1.4 Control Devices (Smartphone)



The evomove® is operated very easily and intuitively via an app that can be installed on the control unit free of charge. The expert area of the app, through which you set the configuration, is only available for the iOS operating system. Users can use the app with both iOS and Android-powered smartphones, iPad, iPod or Apple Watch to set the daytime-dependent stimulation. During use, the evomove® establishes a Bluetooth connection to the control unit, which serves as a remote control. In this way, you can make settings for the individual stimulation of different muscle groups in the so-called expert area (intensity, frequency, pulse width and timing). Up to two channels and thus up to two different muscle groups per segment can be configured independently of one another with one device. In a protected area, the users have the option of switching the stimulation you have preset on and off or adapting the intensity to the current form of the day. The area also has a built-in pedometer.

The following advantages result from using the evomove® app:

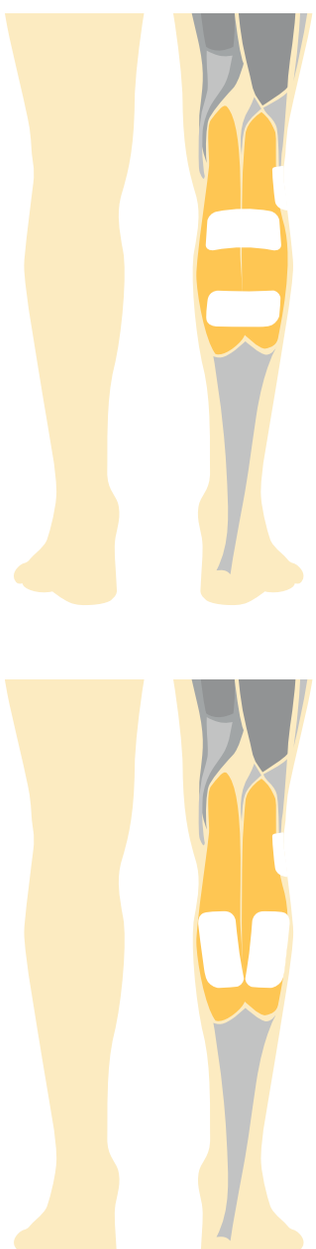
- **Be mobile** in every way.
- **No additional remote control** necessary.
- User modes for you and your patient **in one app.**
- Complete **control and configuration** of the evomove® via **one control unit.**
- **Simple operation** and intuitive user guidance enable use for **many age groups.**
- Stimulation can be **configured by you** in basic steps.
- All steps are explained in an **easy-to-understand** way and, if necessary, with help from info screens.
- **Fast and stable** bluetooth connection.
- No storage of any data related to the user.
- **Integrated pedometer** can be used for statistical purposes and as motivation.

3.2 Application Points

The electrodes of the evomove® can be placed on the lower leg as well as on the thigh. The muscle groups located there have different muscle fiber types. Depending on the type of muscle fiber, there are different contraction properties that must be taken into account in the FES (see chapter Functionality of the FES, parameters). So-called “Fast Twitch Fibers” (FTF) or “Type I Fibers” react sensitively and vigorously to stimulation but fatigue again just as quickly. “Slow-Twitch-Fibers” (STF) or “Type II-Fibers”, on the other hand, respond more slowly to muscle stimulation, but show sustained activity.

Anatomical and functional information about the muscle groups can be read at any time via the info button next to the muscle name within the app.

Lower Leg System:



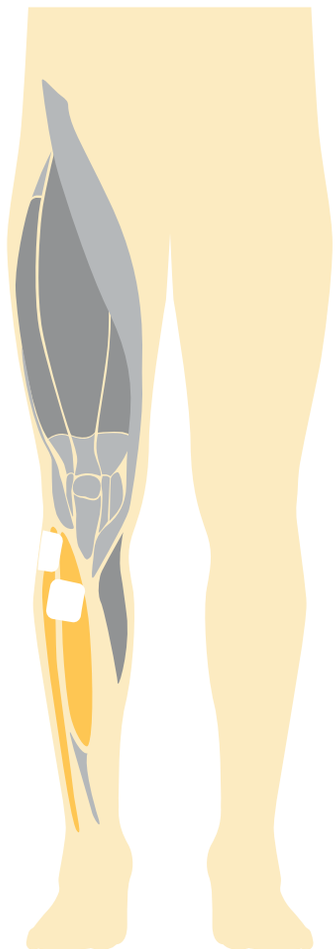
M. triceps surae

- Anatomy:
  The triceps surae muscle, located dorsally on the lower leg, consists of three parts. The two-headed gastrocnemius muscle (FTF) and the underlying soleus muscle (STF) are important for FES. The two heads of the gastrocnemius muscle arise from the lateral and medial caput of the femoral condyles and unite in the Achilles tendon. The soleus muscle extends from the upper third of the tibia and fibula and also ends in the Achilles tendon. The tricpes surae muscle is innervated by a branch of the sacral plexus, the tibial nerve.

- Gait Specific Function:
  The two-headed and two-jointed gastrocnemius muscle, as part of the triceps surae muscle, causes flexion in the knee joint on the one hand. Together with the deep-lying soleus muscle, it is also responsible for plantar flexion in the upper ankle. This enables the heel to lift off while walking and controlled forward movement of the tibia. In addition, the gastrocnemius muscle can counteract hyperextension in the knee joint during gait through eccentric activity.

- Electrode Position:
  The electrodes are placed dorsally on the lower leg, horizontally and parallel about 3 cm below the popliteal. The further distal the lower electrode is placed, the more activity the M. soleus is to be expected. Alternatively, the electrodes can be placed as a “V” along the two heads of the gastrocnemius muscle.

M. tibialis anterior and fibularisloge
(M. fibularis peroneus longus and brevis)

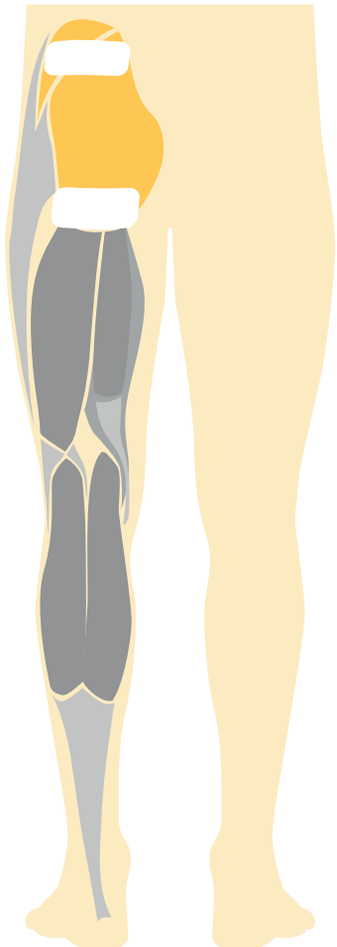


- Anatomy:
  The M. tibialis anterior (FTF) is located on the ventral side of the lower leg and is one of the dorsiflexors of the upper ankle. Together with the fibular islet (STF), which is located more laterally on the lower leg, it forms a functional unit. While the M. tibialis anterior runs more diagonally from the condyle lateralis of the tibia over the malleolus medialis to the plantar surface of the foot, the M. fibularis peroneus longus and brevis are found along the fibula over the malleolus lateralis to the plantar side of the foot. The M. tibialis anterior are innervated by the Nervus fibularis profundus and the M. peronei by the Nervus peroneus superficialis, which can usually be electrically stimulated at the fibular head.

- Gait Specific Function:
  The tibialis anterior muscle is primarily responsible for dorsiflexion in the ankle joint and also ensures supination and inversion. Its antagonist is the fibular islet, which causes pronatoric twisting of the forefoot in gait and an eversion in the lower ankle. Both muscle groups together form a so-called "stirrup" through agonistic and antagonistic activity, which is responsible for the stability of the ankle.

- Electrode Position:
  The upper third of one of the electrodes is placed laterally on the fibular head to stimulate the superficial fibular muscle. From there, the second electrode is placed about 3 - 5 cm anteriorly and 3 - 5 cm distal on the motor endplate of the M. tibialis anterior.

Thigh System:



Mm. glutei

- Anatomy:
  As a muscle group located dorsally on the pelvis, the Mm. glutei to the muscles surrounding the hip joint. Its largest part, the gluteus maximus muscle (STF / FTF), has a wide range of origins in the sacrum and coccyx and a strong attachment tendon that radiates into the iliotibial tract and the gluteal tuberosity on the thigh. The gluteus medius muscle (rather STF) arises at the edge of the iliac blade and attaches to the greater trochanter of the thigh. The gluteus minimus (STF) muscle also runs from the surface of the iliac bone to the greater trochanter. Except for the gluteus maximus muscle, which is innervated by the inferior gluteus nerve, the other two parts of the Mm. glutei controlled by the superior gluteus nerve.

- Gait Specific Function:
  The gluteal muscles play a crucial role both in straightening and in the stability of the pelvis and thus of the trunk when standing and walking. The gluteus maximus muscle is mainly responsible for stretching the hip joint. During the stance phase, its stabilizing function prevents the pelvis from tilting forward. The M. gluteus medius and the M. gluteus minimus form a functional unit and, thanks to their lateral fibers, have the function of stabilizing the pelvis in the sagittal plane. During the stance phase or the one-legged stance, the pelvis is held in an abductor position thanks to its activity.

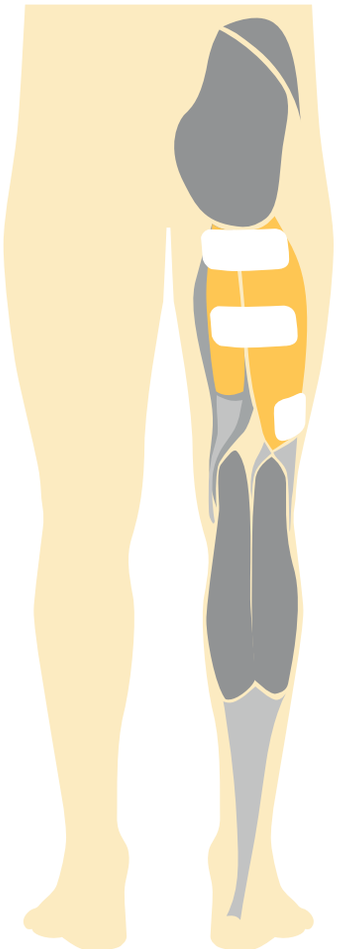
- Electrode Position:
  The electrodes are placed dorsally on the buttocks, parallel over the glutes. The further lateral these are positioned, the more the gluteus medius and gluteus minimus are addressed.

Mm. ischiocrurales (STF/FTF)

- Anatomy:
  The hamstring muscles located dorsally on the thigh include the biceps femoris, the semitendinosus, and the semimembranosus. The course of the muscle group can be derived from the name: All parts originate on the ischium and insert either medially (M. semitendinosus and M. seimimembranosus) or laterally (M. biceps femoris) on the distal lower leg.

- Gait Specific Function:
  The predominantly two-jointed muscles cause extension in the hip joint and flexion in the knee joint. In the swing phase, eccentric activity enables a regulated forward movement of the thigh and a controlled extension of the knee joint. Only the short part of the biceps femoris muscle, the caput breve, only has an effect on the flexor activity of the knee joint and supports the forward movement of the swinging leg by means of concentric activity. Together with the quadriceps femoris muscle, the hamstring muscles also ensure stability in the sagittal plane.

- Electrode Position:
  The active electrode is placed on the dorsal side of the thigh approx. Three fingers above the hollow of the knee and the second with a little space above it. In order to stimulate the head of the biceps femoris muscle with its knee flexion function, the electrodes are placed further laterally above the knee.

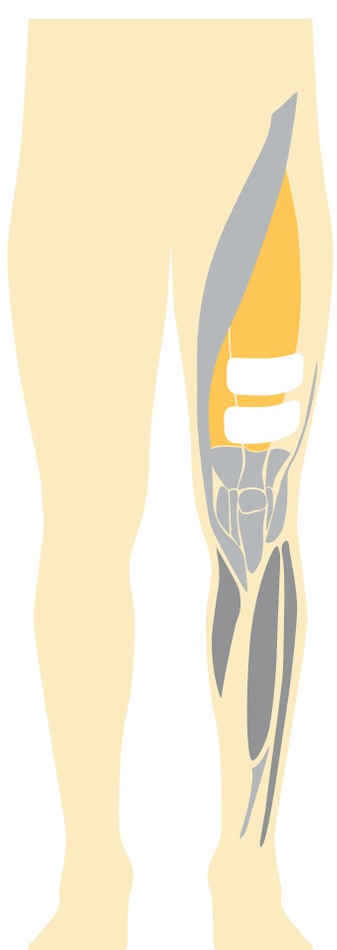


M. quadriceps femoris

- Anatomy:
  The quadriceps femoris muscle is located on the ventral side of the thigh and consists of four parts: the two-jointed rectus femoris muscle (FTF), the vastus intermedius muscle (STF), the vastus medialis (STF) and the vastus muscle lateralis (STF). The three mm. vasti arise lying profoundly from the thigh bone, while the rectus femoris muscle originates from the anterior inferior iliac spine of the pelvic bone. All four muscles have the same insertion and converge in the patellar tendon. Innervation takes place via the femoral nerve of the lumbar plexus.

- Gait Specific Function:
  The quadriceps femoris muscle primarily takes on the function of knee extension and is therefore responsible for ensuring that the load is taken on in the stance phase, thus ensuring stability of the standing leg when walking. The hip joint flexing function of the rectus femoris muscle can contribute to the forward movement of the swinging leg.

- Electrode Position:
  The electrodes are placed parallel to each other about a hand's breadth over the patella. By varying the position to the left and right, the vastus medialis and vastus lateralis muscles are more included.

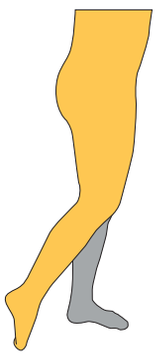


(Schuenke M., Schulte E., Schumacher U., Voll M., Wesker K. (2013); Prometheus, Learning Cards of the Movement System, Thieme Verlag).

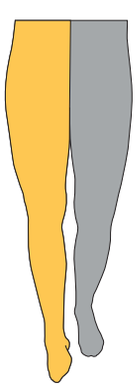
3.3 Supply Groups

If the ability to stand and walk is required, the following target groups result in which the evomove® can be used either as an evomove®solokit or as an evomove®orthokit. The explanations relate to unilateral treatments, but can also be transferred to bilateral treatments. Whether a lower leg and / or thigh system is prescribed must be decided on a case-by-case basis. Contraindications must be checked for all care groups.

Muscle group M. tibialis anterior

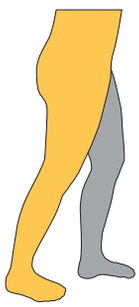


1 Decreased Foot Lift Swing Phase	
Orthosis	Is held passively in neutral 0.
FES	The foot is raised in dorsiflexion by stimulating the tibialis anterior and the fibularis loge.
Advantage through additional FES	The foot is better centered in the orthosis and actively raised further in dorsiflexion.
Advantage through additional orthosis	Orthosis supports up to neutral 0.
Combination *Possible optimization*	-

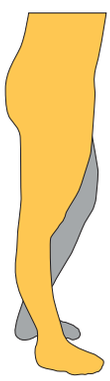


2 Ankle Instability	
Orthosis	Three-dimensional and / or cross-joint guidance with footbed.
FES	The activation of the stapes (M. tibialis anterior and Fibularis Loge) ensures pronation and supination stability and prepares the foot to take on the load.
Advantage through additional FES	FES ensures supination and pronation stability, especially when taking on a load. Avoidance of shear forces and pressure points.
Advantage through additional orthosis	Orthosis can provide stability on uneven surfaces and when standing.
Combination *Possible optimization*	The foot section can be made slimmer.

Muscle group M. triceps surae

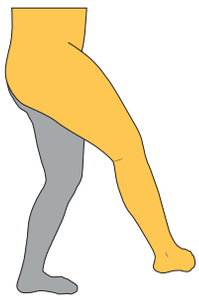


3 Decreased Heel Detachment / Decreased Knee Flexion	
Orthosis	Dorsiflexion stop for heel detachment or force return by spring.
FES	Active push off, initiation of knee flexion.
Advantage through additional FES	Active push off through FES, initiation of knee flexion.
Advantage through additional orthosis	Pre-positioning of the lower leg with a plantar and / or dorsal stop in order to achieve the optimal position for activating the gastrocnemius muscle.
Combination *Possible optimization*	With sufficient activation possible saving of the dorsiflexion stop.

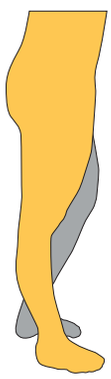


4 Genurecurvatum	
Orthosis	The lower leg is held passively forward, as well as a plantar stop or Knee Ankle Foot Orthosis (KAFO).
FES	Is prevented by activating the M. gastrocnemius.
Advantage through additional FES	Is reduced / prevented by activating M. gastrocnemius.
Advantage through additional orthosis	Ankel Foot Orthosis (AFO) can hold the lower leg forward to provide an optimal position for innervation of the gastrocnemius muscle. Frontal installation can be offered as security in order to be accepted as a stable alternative.
Combination *Possible optimization*	KAFO can be prevented. Plantar stop can be saved.

Muscle group hamstrings

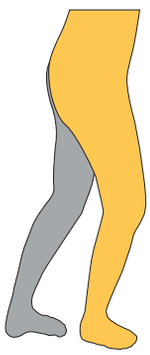


5 Unrestrained Swing Leg Forward Movement *(Lower leg thrust)*	
Orthosis	-
FES	Braking of the lower leg by activating the sciocrural muscle group at the end of the swing phase. If necessary, a combination with M. quadriceps femoris.
Advantage through additional FES	-
Advantage through additional orthosis	-
Combination *Possible optimization*	-



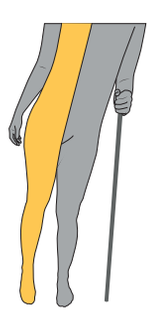
6 Genurecurvatum	
Orthosis	KAFO with extension stop.
FES	Active knee stability through activation of the sciocrural muscle group.
Advantage through additional FES	Active knee stability.
Advantage through additional orthosis	-
Combination *Possible optimization*	KAFO can be prevented.

Muscle group M. quadriceps femoris



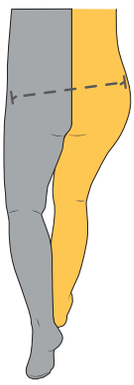
7 Increased Knee Flex When Taking on a Load	
Orthosis	Frontal contact and dorsal stop or KAFO.
FES	Active knee extension, possibly in combination with hamstrings
Advantage through additional FES	Active knee extension in preparation for and when taking on the load.
Advantage through additional orthosis	Frontal contact and dorsiflexion stop for safe standing.
Combination *Possible optimization*	KAFO can be prevented.

8 Flexed Gait Pattern	
Orthosis	Frontal contact and dorsal stop or KAFO with extension spring.
FES	Active knee extension in preparation for and when taking on the load and also in the pre-swing phase.
Advantage through additional FES	Active knee extension in preparation for and when taking on the load and in the pre-swing phase.
Advantage through additional orthosis	AFO with frontal contact and dorsal stop for securing while standing.
Combination *Possible optimization*	KAFO can be prevented.



9 Lack of Knee Flex Swing Phase	
Orthosis	-
FES	Knee flexion by activating the sciocrural muscle group.
Advantage through additional FES	-
Advantage through additional orthosis	-
Combination *Possible optimization*	-

Muscle group M. glutues maximus



10 Pelvic Instability	*• Shortened stance phase* *• Internally rotated / adducted gait pattern* *• Trendelenburg sign / Duchenne gait*
Orthosis	Rotation reins / pants with wedges or hip brace with joints.
FES	Activation of the hip joints / abductors and extensors in order to be able to hold swing leg weight and provide rotational stability.
Advantage through additional FES	-
Advantage through additional orthosis	-
Combination *Possible optimization*	-

Indefinite

11 High Muscle Tone Due to Spasticity	
Orthosis	Orthosis with dynamic spring joints / construction of footbeds and other tonus-inhibiting orthotic elements.
FES	The tone is regulated by direct inhibition (PIR) or indirect inhibition (antagonist inhibition).
Advantage through additional FES	The tone is regulated by direct inhibition (PIR) or indirect inhibition (antagonist inhibition).
Advantage through additional orthosis	The leg axis can also be kept in a starting position that is as spastic as possible.
Combination *Possible optimization*	-

3.4 Screening: App Operation

Before using the evomove® for the first time, you must carry out an initial adjustment, a so-called screening. This screening can and may only be carried out by you, trained partners. During the application, users can only change some settings within a defined framework.

In the screening, the correct electrode position is first determined using self-adhesive electrodes in order to achieve the best possible result. This is followed by the configuration, the setting of the stimulation parameters / times, based on the patient-specific gait patterns.

Then the configuration sheet (see chapter Ordering, Variants and Calculation) is filled out. On the basis of this configuration sheet, which contains, among other things, dimensions and the individual electrode position, we will manufacture a tailor-made cuff or radler.

The evomove® stimulation unit, as the central element, is placed with the holder on the screening cuff during the screening and then placed on the affected leg. Thanks to the Velcro surface, you have all the freedom to find the best position. The electrodes are then connected to the control unit by cables.
Of course, the system can be worn with or without an orthosis.

The screening kit includes an Evomotion partner card with which you can activate the expert area in the evomove® app.

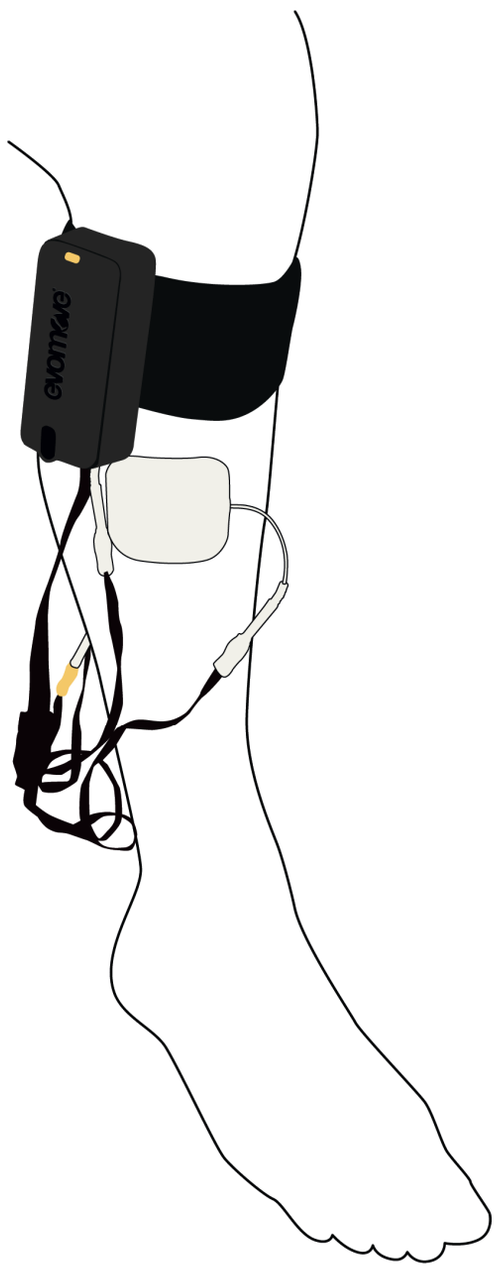
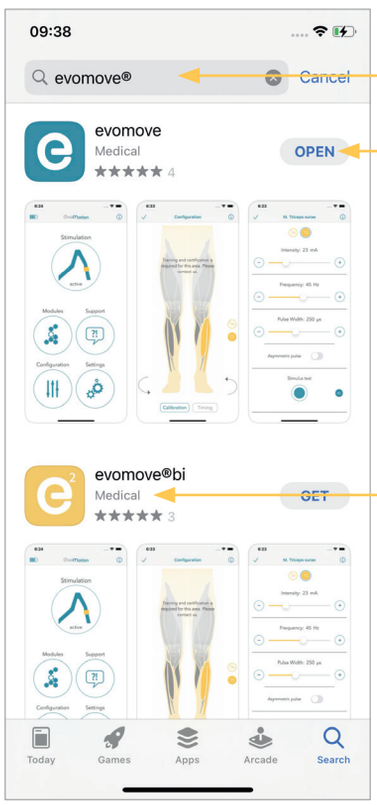


Fig. 11: evomove® on the screening cuff

Installation

For the screening you need the evomove® app on a device with an iOS operating system. To do this, you have to carry out the following steps.

1. Open the app store of your control device.



2. Enter the search term "evomove".
3. Load and install the evomove® app.

Note: *The evomove®bi app is an additional app to the evomove® app and only for bilateral aids. With it, you and your patients can operate a second control unit and thus control even more muscles.*

Authentication

1. Make sure that your Screening evomove® and your control device are sufficiently charged, are within range of each other and that the evomove® has been "woken up" from standby mode.
2. After opening the app, tap on "Start".
3. To establish a connection, Bluetooth must be switched on and all authorizations granted. An internet connection is also required for the first scan.
4. Scan the QR code of the personal partner card to activate the expert mode.
5. Scan the QR code of the evomove® to establish the connection.

Note: *If the authentication was forgotten when the app was started for the first time, authentication can also be carried out afterwards via settings "Change / add device".*

Introduction

Before you can start with the configuration, you will receive a brief introduction to the app. Important symbols, the meaning of colors and buttons, such as the back or audio button, are explained, and you receive general important information. You can get more detailed information on individual topics via the info buttons on the respective screens. When you have read everything, you can "Start" and you will be directed to the main menu. Screening and configuration begin there.

The introduction can be repeated at any time in the support area.

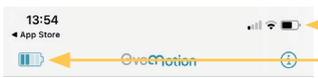
LED Signals

Before you continue with the screening and start the configuration, you should know what you can read from the LED and sound signals on the control unit. The following table gives you an overview.

Fig. 12: LED on the evomove®

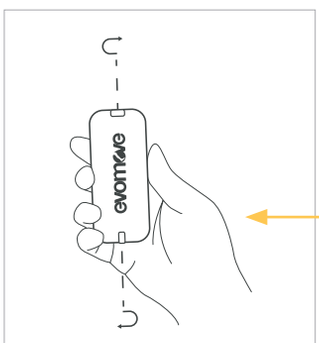
What do the LED signals on the evomove® control unit mean?	**The LED shows you the status of the evomove®.**
No signal	The evomove® is not connected to any control device. Activate Bluetooth on your control unit, make sure that the evomove® is "awake" and open the evomove® app. The connection is established automatically if both devices have already been connected to one another.
Flashes **BLUE** once and emits an acoustic signal	The evomove® was woken up from standby mode by rotating it around its longitudinal axis and can now be connected to a control device (Fig. 12: LED on the evomove®)
Flashes **BLUE**	The evomove® is successfully connected to the control unit and can be controlled via the evomove® app.
Flashes **YELLOW**	The evomove® is connected to a control unit and the stimulation has been switched on.
Lights up **YELLOW** and emits an acoustic signal (with every stimulation)	The evomove® stimulates (a) muscle group(s) and each stimulation is indicated by the LED. In addition, a sound signal sounds with each stimulation, which is of different pitch for several muscle groups.
Flashes **GREEN**	Der evomove® wurde mit dem Ladegerät an eine Steckdose angeschlossen. Wenn Du den evomove® verwenden möchtest, entferne das Ladegerät.
Lights up **GREEN** (steady)	The evomove® battery is fully charged. Please remove the charger.
Flashes **RED** (once) and emits an acoustic signal	The error diagnosis of the evomove® has identified an error that requires a check. Please note the app notifications. The stimulation is no longer active.
Flashes **RED** (steadily)	The error diagnosis of the evomove® has identified an error that requires a check. The stimulation is no longer active. Check the app notifications, follow the instructions and, if necessary, contact Evomotion GmbH to have the evomove® checked.
Flashes **TURQUOISE** and flashes **GREEN** once	The evomove® carries out a calibration. Please note the information in the app.

Configuration

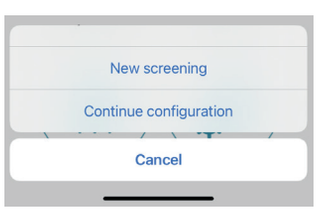


At the beginning you should always make sure that the evomove® and the control unit are loaded. You can see the battery level here. For more information, tap the battery icon.

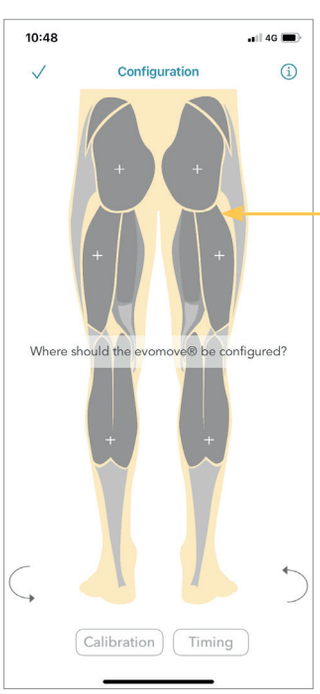
Note: *If the battery is discharged for a longer period of time (deep discharge: flashes white once when you wake up), it may take a while before the LED starts flashing green, indicating that it is charged.*

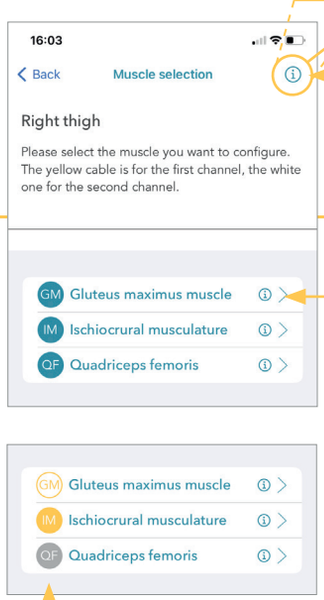


If there is no connection and the evomove® is not moved for a long time, it switches to standby mode. The evomove® is reactivated by turning around the longitudinal axis. The blue LED and a beep indicate that you have switched to active mode.



1. Tap the "Configuration" button in the main menu and start a new screening straight away. If you have already saved a configuration, you can continue or change it.



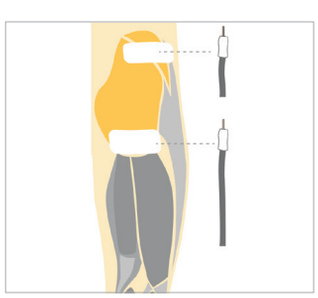


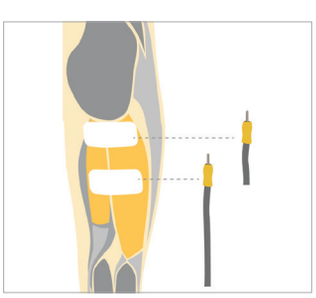
You can find such an info button on almost all screens. Here you can get helpful information on the respective topic.

2. Tap on the part of the leg where you want to configure the evomove®. You can then choose which muscle you want to start with.

Here you can read information about the respective muscle, such as the electrode position.

3. If you have set the stimulus parameters for both muscles (see next point), the colors of the icons in front of the muscle names will change. These show you which cable color you need to connect to the corresponding electrodes.

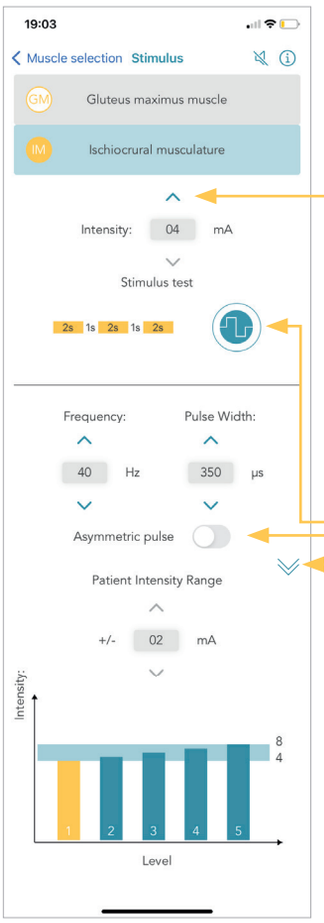




Example: *The yellow cable must be used for the triceps surae muscle and the white cable for the tibialis anterior muscle.*

Note: I colori dei cavi devono essere osservati solo durante la schermatura.

Stimulus



1. During the stimulation, the stimulus parameters are adapted to the needs of the patient.

   The intensity, frequency and pulse width are adjusted either via the arrows or by tapping and selecting the number.

   Note: *Make sure that patients do not injure themselves on the highest intensity level. Values cannot fall below or below 0 mA*
   Do not exceed 80 mA.

2. Switch between symmetrical and asymmetrical stimulation.

3. When all values are set, test your settings by double-tapping the blue button. The button is yellow while electricity is flowing. Only the intensity can be changed during the test. A simple tap stops the stimulation.

   Note: *The stimulation test is only active from 4 mA.*

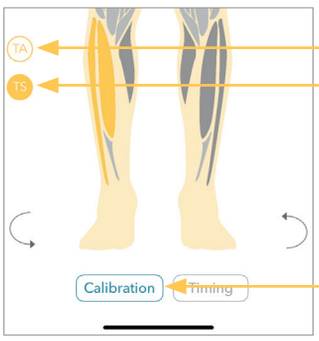
4. If you tap on the double arrow, another settings area will open.
   If you tap on it again, the area closes again.

   The adjustment of the intensity range is used to determine the intensity levels that can be regulated by the patient. In this way, the stimulation strength can be adjusted depending on the type of day, while the sensitive tolerance range is still taken into account. When configuring several muscles, it is therefore possible to increase individual muscle activities or functions in percentage terms more than others by increasing the level.

   Level 3 includes the intensities (mA) configured in the screening. You can use the arrows to determine the maximum percentage by which the intensity increases (level 5) or decreases (level 1).

   Example:
   M. triceps surae:
   Configured intensity: 9 mA
   Intensity range: +/- 30%
   Patient level 1: 6 mA
   Patient level 5: 12 mA

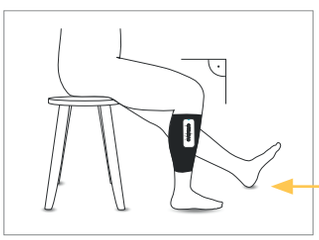
5. Exit the stimulus area using the back button. The set values are saved automatically. The settings are only valid if the intensity is not equal to 0 mA.



6. Now you will find new buttons on the configuration overview. One for each muscle you've already set the stimulus for. These buttons take you directly to the respective stimulus settings, where you can change the parameters.

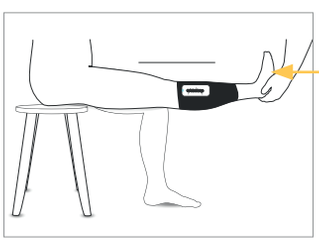
After completing the muscle selection, the button for calibration is activated.

Calibrate



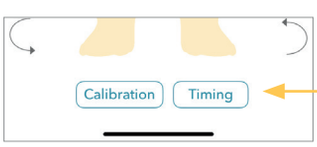
In order to be able to measure the gait, the evomove® sensor must be calibrated. We recommend recalibrating the evomove® every 12 months and if there are irregularities in the stimulation.

1. First, help the patient to bring the evomove® vertically to the floor - while sitting or standing. Make sure that the LED always points towards your head. It lights up turquoise when calibrating.



2. Now help to bring the evomove® parallel to the floor - sitting or standing.

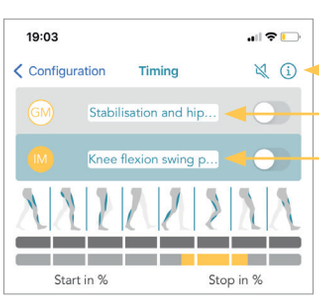
If the calibration is not successful after several attempts, please contact us.



Note: *The configuration and calibration should be checked 12 months after the first use (see service plan).*

After successful calibration, the button for timing is enabled.

Timing

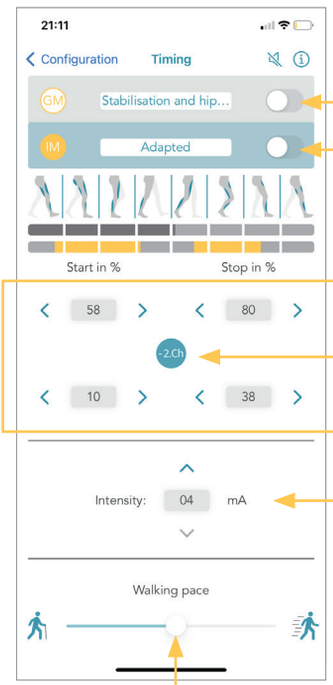


Here you can get more information and switch the audio signals of the control unit on and off as well as switch them quieter and louder by holding the button.

1. In the timing section, you will first be asked to select a strategy for each muscle/muscle group, behind which there are certain default settings that affect the stimulation period in the gait cycle. You can of course adjust and customize these manually in the next step.

When and how long the stimulation is active for the selected muscle group is indicated by a yellow bar under the gait phases. If another muscle is configured but not selected, the stimulation time is shown in another bar in dark gray.

Note: *Set the timing for each selected muscle!*



2. Tap the switches to actively test the stimulation while walking, you can test both combined. During the test you can change the intensity and timing.

3. You can use the arrows to individually adjust the length of the yellow bar and thus the duration of the stimulation. You can also tap the number and choose a value.

4. Here you have the option of adding a second stimulation phase for a muscle group via the button, which is displayed with another yellow bar. Tap the same button to remove the second phase of stimulation.
Attention: Adding a second stimulation phase is only possible for a muscle group and not during an active test.

5. You can also adjust the intensity using the arrows or by tapping on the number.

6. If necessary, scroll down to adapt the algorithm to the walking pace of the patients. To do this, drag the slider to the left or right.

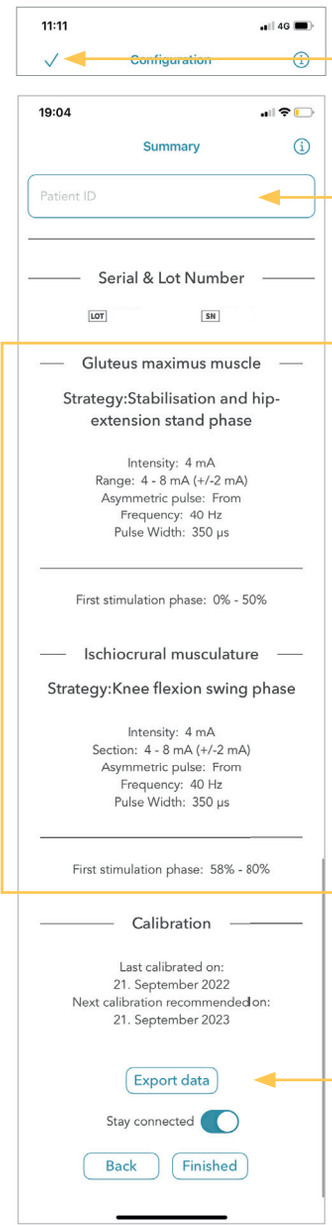
7. Exit the timing using the back button to save the values and continue.

Note: *If the patient does not perceive any impulses despite activated stimulation and an error message is displayed, check whether the cable is properly connected to the evomove®. Also check that the cables are connected to the electrodes. Is there a feeling of numbness in the area where the stimulation is applied? Turn on the device tones to check. If in doubt, please contact our support.*

Note: *If a skin rash / skin injuries / itching occurs in the area of the electrodes or pain occurs during stimulation, the evomove® should no longer be used!*

It is imperative that we are informed about this and that a doctor is consulted.

Finish



When you want to finalize your configuration, tap the finalize button in the top left. You will then get to the summary.

1. In the summary, you can enter the patient's ID in the field above.

All your settings are displayed here and you can check whether everything is correct. If you have forgotten something or the settings are invalid, the respective position will be displayed in red.

Below you can see when the evomove® was last calibrated and when the next calibration is recommended.

2. Here you can export the list with the parameters. A PDF file with all information is generated and you can choose where it should be saved. In addition, the PDF file is saved on your iPhone in an evomove® folder under Files> Search> On my iPhone.

3. With the switch you can set whether the connection to the evomove® should be maintained or should be disconnected in the next step.

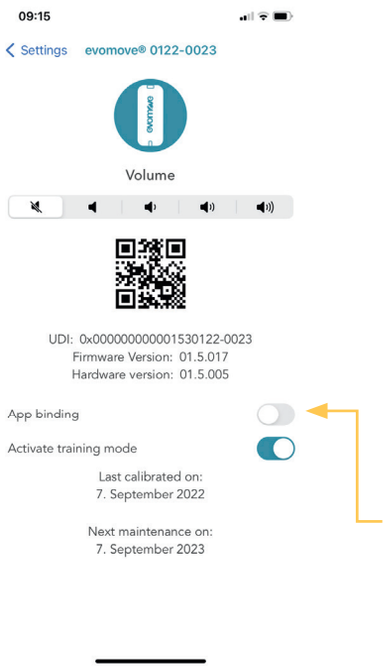
4. To complete the configuration, tap "Finish" to go to the main menu and test the stimulation or "Back" to correct settings.

Training Mode

In addition to stimulating the configured muscles while walking, it is also possible to train them during rest periods or on less active days. For this it is necessary to activate the training mode in the expert area. You choose which muscle group can be trained.

To do this, go to the settings and tap on the connected control device. Then toggle the switch for "Activate training mode".
An additional button then appears for patients, which takes them to the training mode.

Canceling the App Binding



This function enables continuous stimulation in the gait even if a stable Bluetooth connection between the control device and evomove® is not guaranteed. Please note, however, that in this case the stimulation is only active for another 2 hours and can no longer be controlled via the app or the control device.

The evomove® can therefore only be switched off by disconnecting the plug connection. In the event of an error message while the app binding is active or to switch stimulation on again, it is essential to restore the Bluetooth connection.

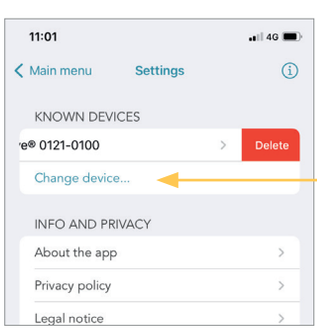
You can access this section from Settings, then tap the connected evomove® and tap the App binding on/off.

Note: *This function can only be used by experts!*

New or Additional Device

If another control device is connected to the evomove®, your current control device cannot connect to it.

To disconnect, close the app completely by either double-pressing the home button or swiping up from the bottom of the screen and pausing for a moment, then you can swipe up the corresponding app.



You can also remove the device by swiping from right to left in the respective line.

To connect a new device, you have to tap on "Change device" in the settings and scan the QR code of the new device.

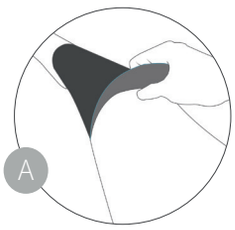
Handover to Patients

Smartphone, iPad, iPod

Upon delivery, patients receive their own evomove® box. In the inner lid of the box, patients will find brief instructions for "the first steps" with the evomove®. This quick start guide includes the following:

Download the evomove® app for free to use the evomove® to use.

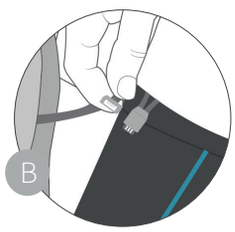
1. Put on the Cuff



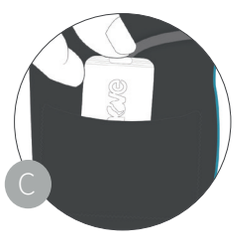
Pull the cuff smooth side out over your leg (A). Make sure the cuff and electrodes are properly seated.

Note: Please apply enough electrode gel to the electrodes.

2. Connect the Control Unit

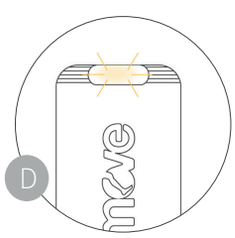


Variant 1: evomove®orthokit - evomove® plus Orthosis
Plug the control unit into the holder of your orthosis (LED on top and outside). Put on the orthosis as usual and connect the control unit cable to the cuff cable (B).



Variant 2: evomove®solokit - Standalone Use of the evomove®
Route the control unit cable up on the back and put the control unit in the pocket of your cuff (LED on top and outside) (C). Connect the control unit cable to the cuff cable.

3. LED Signals

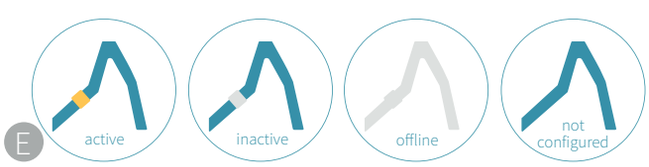


The LED (D) shows you the status of the evomove®.

4. Connect App - Establish Connection

- Start the evomove® app, follow the first steps and make sure that Bluetooth and location (Android) are activated.

- Check in the app whether the evomove® is connected. You can see the connection status (E) in the main menu.



- The LED flashes **blue** when the connection is established.

Note: Wake up the evomove® from standby mode by turning it around its longitudinal axis.

5. Switch stimulation on and off

- In the main menu of the app, tap on the stimulation area and activate "stimulation" using the switch (F).

- You have the option of adjusting the intensity of the stimulation to your daily form and testing it first while you are resting. To do this, double-tap the test button. It is then advisable to take a few steps to determine the optimal level.

- The LED flashes **yellow** when stimulation is active.

- Switch off the evomove® using the switch (F) if you will not go for a long time.

6. Training mode

You can access the training mode via "Modules". Here, in the upper part, it is first decided which muscle groups are to be trained (single or combined) and then the desired intensity level (1-5) is set.

The training duration (5-30 min) can be set by tapping the dumbbell symbol. After selection, the training starts automatically and the remaining duration is indicated by a yellow circle. Tapping the dumbbell button again ends the training session before the time expires.

The following repetitive training scheme serves as a basis: Active stimulation for 5s, followed by a 8s break.

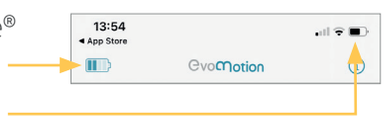
Note: *The intensity level can be adjusted during training.*

7. Close App - Disconnect

- **Close the evomove® app completely** to disconnect the connection. The Bluetooth connection is then automatically terminated.
- The LED **goes out** when the connection is disconnected.

8. Charge the Battery

- Before use, check the battery level of your smartphone and the evomove® in the main menu of the app.



- Charge the evomove® with the included charger.
- The LED **flashes** green when the control unit is charging. When the battery is fully charged, the LED **lights up** green.

Apple Watch

→ Download the evomove® app for free to use the evomove®.

Follow all the steps from **1 to 3** as on the previous pages.

Proceed as follows to connect the evomove® and your Apple Watch:

1. Activate the Bluetooth function and location access, make sure there is internet and give the appropriate permissions.
2. Wake up the evomove® by rotating it around the longitudinal axis, a short tone sounds.
3. Open the evomove® app.
4. Follow the instructions on your watch.

3.5 Order, Variants and Calculation

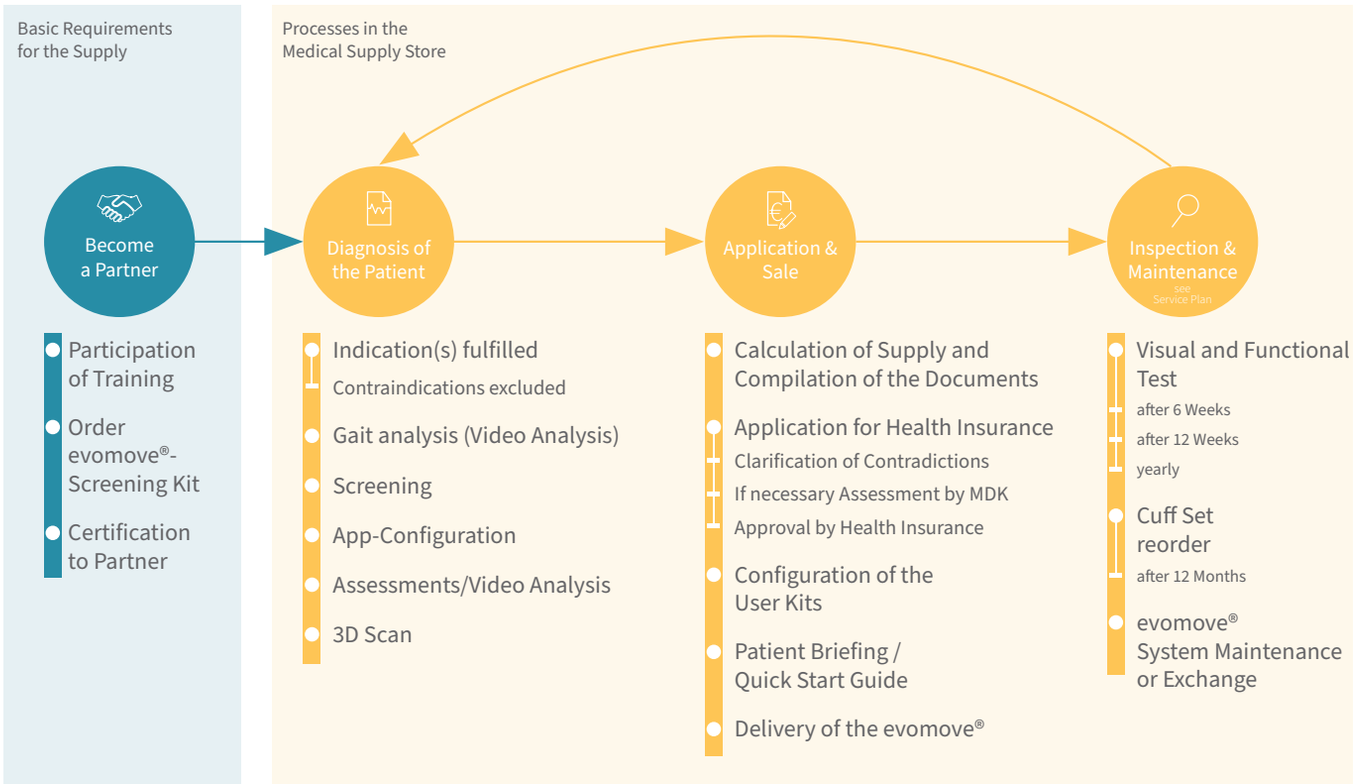


Fig. 12: Patient care process

Screening Kit and Screening Kit Duo:

After you have participated in our training and are a certified Evomotion partner, you are allowed to carry out the screening on your own. For this you need the screening kit or the screening kit duo. With this screening kit, you can use a test fitting to record the patient's data, which is necessary for the production of the individualized evomove®. You can inquire about the current prices for the following products in customer service.

Fig. 13: Screening Kit Duo

Screening Kit:

- 1 evomove® control unit
- 1 power supply unit with cable
- 1 electrode cable
- 1 bracket for the control unit
- 1 screening cuff set (S, M and L)
- 5 packs each with 4 large adhesive electrodes (4.5 x 9.5 cm)
- 5 packs each with 4 small adhesive electrodes (5 x 5cm)
- 1 manual
- 1 partner card
- 1 block with configuration sheets

Screening Kit Duo:
- 2 evomove® control units
- 2 power supplies with cables
- 2 electrode cables
- 2 brackets for the control unit
- 2 screening cuff sets (S, M and L)
- 10 packs each with 4 large adhesive electrodes (4.5 x 9.5 cm)
- 10 packs each with 4 small adhesive electrodes (5 x 5 cm)
- 1 manual
- 1 partner card
- 1 block with configuration sheets

If you already have a screening kit, you can order an update after you have completed a thigh training. You have the following options:

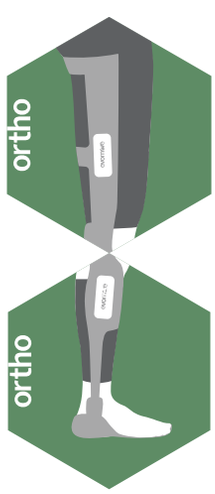
Update thigh:
- 1 screening cuff with Velcro surface (size L)
- 1 sample shorts
- 10 packs each with 4 large adhesive electrodes (4.5 x 9.5 cm)

Order of the evomove®:

To order the evomove®, a configuration sheet is filled out during the screening. There is a configuration sheet for the thigh and one for the lower leg. These contain all the information required to manufacture the cuff / radler, including the position of the electrodes and patient measurements. It is up to you whether you transmit the measurement and position data to us by photo or by 3D scan. The entire thigh or lower leg must be shown on the 3D scan and the electrode position must be clearly visible.

On the configuration sheet, in step 1, tick whether you want to order an evomove®orthokit or an evomove®solokit. In the following, the different variants are explained and possible combinations are shown.

evomove®orthokit:



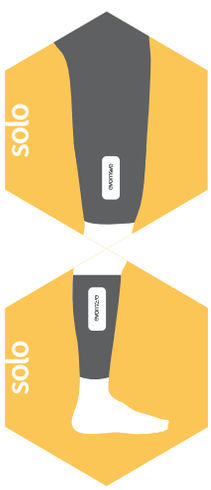
Area of application: The evomove®orthokit is intended for the conception and combination with an orthosis. In the home area, for example (if less support / security is required due to familiar surroundings), the evomove® can also be used without an orthosis if the concept is appropriate.

Product group: It acts as an orthosis component and is in the
To be classified in **PG23.**

Scope of order:
- 1 evomove® control unit
- 2 custom-made cuffs with sewn / glued in electrodes and fabric cables (thigh or lower leg system) OR 2 custom made cycling shorts with sewn / glued in electrodes and fabric cables (thigh system)
- 1 bracket for the control unit
- 1 tube of electrode gel
- Manual
- A casting dummy for integrating the holder for the control unit into the orthosis is available separately.

Function: The evomove® ensures muscular activity in the orthosis, which is functional on the leg on the knee (avoiding genu recurvatum and / or initiating forward swing leg movement (push-off)), actively stabilizing the ankle while taking on the load and maintaining the Ankle joint mobility in dorsiflexion and plantar flexion has a positive effect. With the thigh system, not only the quadriceps and the hamstring muscles can be activated, but for the first time also the muscles surrounding the hip joint (gluteus maximus, minimus and medius).

evomove®solokit:



Area of application: The evomove®solokit is to be seen as a solitary solution.

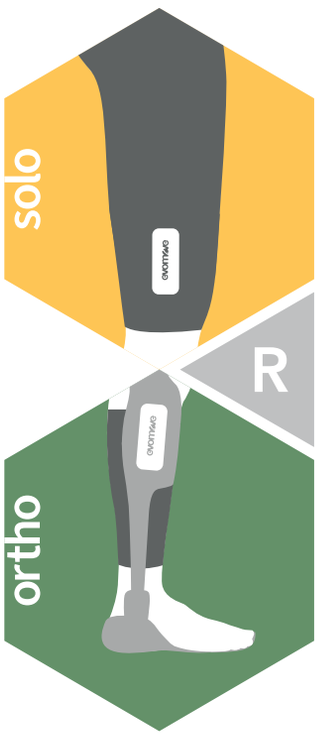
Product group: Similar to other FES systems on the market, the evomove® solokit is part of the **PG9.**

Scope of order:
- 1 evomove® control unit
- 2 custom-made cuffs with sewn / glued in electrodes and fabric cables (thigh or lower leg system) OR 2 custom made cycling shorts with sewn / glued in electrodes and fabric cables (thigh system)
- 1 tube of electrode gel
- Manual
- With the evomove®solokit, the evomove® is placed in a pocket on a cuff or cycling shorts made by us.

Function: On the lower leg, the focus is mostly on correcting the foot drop (stimulating the tibialis anterior muscle). The second channel (our unique selling point) can also stimulate the calf muscles to improve knee control and increase endurance (push-off). In the thigh system, the quadriceps, the hamstring muscles and the muscles surrounding the hip joint (gluteus maximus, minimus and medius) can be activated.

Possible Combinations

There are different care groups that have different resources and restrictions and thus require individual care (see chapter "Care groups"). It is also possible to combine evomove® variants, thus realizing bilateral supplies and prescribing several evomove® control units.



Example:
In this example, the patient was supplied with one control unit per segment. On the lower leg, the evomove® functions as an orthokit in conjunction with an orthosis. The patient can nevertheless decide freely in everyday life when only the FES is needed and when additional support from the orthosis makes sense. The second control unit is located on the thigh as a solo kit in the Radler variant. Ultimately, four different muscle groups can be individually controlled at the same time (2 per segment).

3.6 Maintenance, Service, Returns, Return Form

Our evomove® control unit has an approximate service life of 60 months. In order to guarantee this and a satisfactory customer care, regular maintenance and, if necessary, repair and replacement work are necessary, which can be found in the service plan. Some services are carried out by you, the Evomotion partners, and others by our support department. Associated costs are listed in our price lists, whereby the maintenance and repair costs are usually covered by the health insurance company.

All information about returns and the return slip can be obtained from our support on request.

Maintenance Schedule

for evomove® Systems

Delivery of the system to the patient

With the partners in the medical supply store:

after approx. 6 weeks: Review and, if necessary, follow-up control of the stimulation parameters.

after approx. 12 weeks: Review and, if necessary, follow-up control of the stimulation parameters.

yearly: Visual and functional check * as well as a follow-up check of the stimulation parameters including recalibration.
Exchange and, if necessary, adjustment of the cuffs / shorts **.

At Evomotion:

after 2 and 4 years: System maintenance (if necessary, battery replacement) ***.

after 5 years: End of life cycle as well as end of service and support discontinuation.
Proper disposal.

*: Optical and functional control of the evomove® and the Radler cuffs.
**: With changed electrode positions and / or leg proportions.
***: After the system maintenance, a 1 year guarantee comes into effect again.

4 Supply Documentation and Studies

4.1 Assesment Sheets

In order to be able to prove the effectiveness of an aid, it is important that the tests required for this are carried out in a standardized manner. This chapter is intended to provide you with instructions on how to carry out the assessments for the assessment sheet. Each assessment is initially carried out without evomove ® or with the previous supply and then with evomove ® or with a combination supply. The change in everyday mobility with the evomove ® can be read from the difference between the documented results. It makes sense to record the tests on video in order to also be able to assess the quality of the movement sequence as part of a gait analysis. In addition to the presentation of the specified test procedure, a definition of the assessment, the ICF scores and the required materials can be found.

We decided on the following assessments, as these are demonstrably reliable for our patient group and their combination offers results that are easy to interpret. In addition, the implementation is comparatively quick and the setting is uncomplicated. In addition, in contrast to a purely video-based gait analysis, no subjective parameters are included in the assessment, only objective parameters.

> *"[...] Nevertheless, the reliability (reliability) is very good. The agreement of two 6-minute walk tests performed on 23 patients within ten days of brain injury was excellent. The "Intraclass Correlation Coefficient" (ICC) - a measure of the reliability of a test - was 0.94. That is a very good number. An equally high level of reliability was found in patients after a stroke (ICC 0.95–0.99) [14] and after paraplegia (ICC> 0.97). In other patient groups, studies on the reliability of the walking tests led to similarly good results. In order to ascertain the various aspects of validity, the walking tests were compared with different assessments. For example, walking speed has proven to be a suitable measuring instrument for measuring the degree of mobility. […] It has also been shown that the walking speed measured over a distance of ten meters of 14 patients after a stroke was significantly faster than that over a longer distance. The authors therefore recommend both measuring walking speed over ten meters and measuring endurance over six minutes (Wirz, 2019) (translated from German to English by Evomotion). "*

4, 6 or 10 Meter Walking Test

The test checks the time the patient needs to cover the corresponding walking distance. The walking speed is recorded, which allows conclusions to be drawn about the degree of mobility (Wirz, 2019).

ICF- Scores:

- d4500 Walk a short distance

Material:

- 6-, 8- or 12-meter level walking distance
- stopwatch
- 2 floor markings

Execution:
One meter each is measured and marked to reach walking speed and to slow down. In addition to the type of aid that may be used, the number of steps required should also be noted (Willkomm, 2013). The test person starts approx. 1-2 m in front of the start marking and as soon as this is exceeded, the time is stopped until the target marking is crossed.

Timed Up and Go Test (TUG)

The Timed Up and Go Test (TUG) is a test to assess a person's ability to walk, balance and everyday mobility (Pfeiffer, Hilfiker, 2012).

ICF- Scores: (Pfeiffer, Hilfiker, 2012)
- d410 Change an elementary body position
- d4103 Sit down and stand up
- d4104 Change standing position
- d4500 Walk short distances

Material:
- stopwatch
- chair
- 3 meter level walking distance
- Object to curve around (e.g. hat, rod, etc.)

Execution:
The test person first sits on a chair and touches the backrest with their back. The person stands up on command. The time measurement starts as soon as the subject's back leaves the backrest. The test person turns the hat 3 m away and goes back to the chair as quickly as possible. The time is stopped when the subject's back touches the backrest (Pfeiffer, Hilfiker, 2012).

2-, 4- or 6-Minute Walk Test

The 6-minute walking test (6MWT) is an everyday, little-time-consuming functional test to determine functional capacity. It is useful, among other things, for therapy control (Kroegel, 2013). Less common variants are the versions with a 2- and 12-minute walk or run as well as the shuttle walking test (see below). The results of the 2-, 6- and 12-minute walking tests correlate well with one another ($r = 0.86–0.95$) (Kroegel, 2013).

ICF- Scores:
- b7401 Endurance of muscle groups
- d4501 Walk a long distance

Material:
- stopwatch
- if necessary, measured distance (ideally 30 m) + lap counter
- distance measuring device if necessary

Execution:
The walking test should preferably be carried out indoors, if the prerequisites are good, outdoors. A distance of around 30 m is best so that the test subjects do not have to turn around too often. An oval or round walking route is also possible. The use of a treadmill is not recommended as the walking speed is usually influenced too much. The patients are of course allowed to take breaks and use an aid. This should be noted accordingly. The person to be tested stands at the start line and as soon as they start walking the time is taken. The tester shouldn't walk next to the test person in order not to influence the pace. Shortly before the time runs out, this is announced to the subject and he * she stops after 2, 4 or 6 minutes. The distance covered is measured or added up (ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002).

Gait Analysis

The observational gait analysis is not about recognizing the smallest changes in joint angles. Rather, it is about recognizing and interpreting the normal functions of walking (Götz-Neumann, 2011, p. 93).

ICF- Scores:
- b770: Functions of movement patterns
- b7150: Stability of a single joint

Feedback from the Users

Any objective proof of effectiveness does not mean anything if the user does not subjectively determine support for coping with everyday life through the supply. For this reason, an ICF-based feedback sheet is also filled out and included in the evaluation.

ICF- Scores:
- b7150: Stability of a single joint
- b770: Functions of movement patterns
- d4502: Walking on different surfaces
- d4501: Walk a long distance
- d4503: Avoid obstacles
- d4500: Walk short distances

Evaluation:
The findings from the assessments carried out are compiled on the following sheet, "Evaluation according to ICF". For this purpose, sheets 3-5 with their respective markings on the edge (A-E) are placed in the appropriate places on the evaluation sheet (A to A, B to B, etc.). The relevant number is entered in the field next to the ICF designation. If there are several numbers there, these are added together.
Finally, the results of the assessments are summed up and transferred to the “final evaluation (ICF score)” scale below.

Summary:
The last page of the assessment sheet is intended to concisely summarize the previously collected findings and to make a care recommendation. In addition, the correctness of the information and the validity of the information is underpinned by the signature of the persons involved.

4.2 Sources / Studies on Efficacy

"Evidence-based medicine (EbM) is the conscientious, explicit and reasonable use of the best external scientific evidence currently available to make decisions about the medical care of individual patients. The EbM practice means the integration of individual clinical expertise with the best available external evidence from systematic research (The Cochrane Collaboration, 2021) to evaluate in order to guarantee the best possible treatment results and to continuously develop the product. External evidence on the solitary use of the FES in combination with an orthotic fitting as well as the effectiveness of comparable products is used. Together with the individual clinical expertise of the experts, evidence-based care can take place. Below you will find a table with exemplary and relevant studies.

	Type	Sample	Method	Results
1.	***Alnajjar F., Khalid S., Zaier R., Gochoo M. (2021). Trends and Technologies in Rehabilitation of Foot Drop: A Systematic Review, Expert Review of Medical Devices.***			
	Review	24 studies over the past 5 years, n = 61 (FES studies); Patients with Dorsiflexion weakness	Studies with a focus on rehabilitation using robot-assisted orthotics or FES-assisted therapy. Among other things, comparable FES systems such as L300 Go (Otto Bock), MyGait (Otto Bock), WalkAide (ACP), ActiGait were considered.	The FES approach is very promising and there is plenty of room for future improvement. It has great potential to help patients regain their motor skills and improve their quality of life. Criticism: • Use of alternatives to the self-adhesive electrodes • Use of batteries with a long service life • Free positioning of the electrodes
2.	***Martin D., Patriciu A., Schulz A. K., Schackert G. (2021). Long-term results following electrical stimulation of the peroneal nerve using the ActiGait® system in 33 patients with central drop foot. In: Innovative Surgical Sciences 6 (1), S. 3-9.***			
	Long-term study (36 months)	N = 33 foot lifter problems (27 stroke, 5 MS)	Implantation of the ActiGait system, assessments: gait endurance, gait speed, risk of falling, quality of life	Complications from implanted electrodes: postoperative lesions of the peroneal nerve (2/33), breakage of the electrode cable (1/33), impaired wound healing (3/33), edema in the thigh area (1/33). Positive findings: increase in walking speed (increase: 41.8%); Increase in gait endurance (increase: 88.12%), decrease in the risk of falling (decrease by 36.6%), improvement in quality of life (93.9% of test persons).

3.	***Feuvrier F., Sijobert B., Azevedo C., Griffiths K., Alonso S., Dupeyron A., Laffont I., Froger J. (2019). Inertial measurement unit compared to an optical motion capturing system in post- stroke individuals with foot-drop syndrome. In: Annals of Physical and Rehabilitation Medicine (2020), 63 (3), S. 195- 201.***			
	Mono-centered, prospective Pilot study	N = 26 ambulatory Stroke patients with dorsiflexion weakness	Comparison of the VICON camera system and inertial sensors as instruments for movement reconstruction. Assessment: dorsiflexion angle during initial contact and during the mid-swing phase. In addition, stride length, walking speed and maximum dorsiflexion angle.	The inertial sensor based examination is an effective method for the treated target group. Its precision also makes it possible to recognize signs of fatigue and to adjust the FES accordingly.
4.	***Böhm H., Döderlein L. , Dussa C. U. (2020). Functional electrical stimulation for foot drop in the upper motor neuron syndrome: does it affect 3D foot kinematics during the stance phase of walking? In: Foot & Ankle, 18, pp. 115-124.***			
	Consecut-ive Case study	N = 16 patients with upper motor neuron disease, GMFCS (Groo Motor Function Classification System) I and II or foot drop, walking distance> 10m	Objective: To determine the effect of FES on the 3D foot movement in the corridor. Gait analyzes with and without FES and determination of the foot position using an Oxford model. Systems used: L300 Go (OttoBock, Duderstadt), MyGait (OttoBock, Duderstadt) and WalkAide (ACP - Accelerated Care Plus Corporation, Reno, NV)	FES leads to an increase in dorsiflexion during the swing phase (4.7 degrees). Rearfoot eversion and forefoot abduction during initial contact increased 1.9 degrees and 3.7 degrees, respectively. This foot position was largely retained in the stance phase. This effect is beneficial for clubfoot positions but is a hindrance for buckled foot deformities.
5.	***Schifino G., Cimolin V., Pau M., da Cunha M.J., Leban B., Porta M., Galli M., Souza Pagnussat A. (2021). Functional Electrical Stimulation for Foot Drop in Post-Stroke People: Quantitative Effects on Step-to-Step Symmetry of Gait Using a Wearable Inertial Sensor. In: Sensors, 21 (921).***			
	Quasi-ex-periment mental clinical study	N = 32, stroke patients, walking distance> 30m, mild, moderate or severe hemiparesis	Objective: Effects of the FES on trunk acceleration and step symmetry. 10 applications each with 20min treadmill training with WalkAide (Innovative Neurotronics, Austin, TX, USA) FES system and wearing an inertial sensor.	The walking speed has improved significantly with the help of the WalkAide system.
6.	***Busk H., Stausholm M. B., Lykke L., Wienecke T. (2019). Electrical Stimulation in Lower Limb During Exercise to Improve Gait Speed and Functional Motor Ability 6 Months Poststroke. A Review with Meta-Analysis. In: Journal of Stroke and Cerebrovascular Diseases, 29 (3) (2020).***			
	Review	7 studies with patients <6 months post-stroke, n = 191	Objective: Effects of FES and movement on functional motor skills and walking pace. Assessments: walking speed, Barthel Index and Berg Balance Score	Despite the poor comparability of the studies and the poor quality in some cases, a significant improvement in walking speed can be determined.

The table continues on the next page →

7.	***Nascimento L. R., da Silva L. A., Araújo Barcellos J. V. M., Teixeira-Salmela L. F. (2020). Ankle-foot orthoses and continuous functional electrical stimulation improve walking speed after stroke: a systematic review and meta-analyses of randomized controlled trials. Journal Pre- proof. In: Physiotherapy.***			
	Systematic review, meta analysis	11 studies, n = 1135 stroke patients with a walking pace of> 2m / s or more independently Walking ability	Effects of AFO versus FES on walking speed and balance. Assessments: Walking speed and mountain balance score	Both AFO and FES have a positive effect on walking speed. The effects on balance are unclear.
8.	***Arya B. K., Mohapatra J., Subramanya K., Prasad H., Kumar R., Mahadevappa M. (2012). Surface EMG Analysis and Changesin Gait following Electrical Stimulation of Quadriceps Femoris and Tibialis Anterior in Children with Spastic Cerebral Palsy. In: Conference proceedings: ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society, S. 5726- 5729.***			
	Randomized, controlled study	N = 10, 7-14 years old, diplegic or hemiplegic CP	Objective: Effects of neuromuscular electrical stimulation of the M. quadriceps femoris and M. tibialis anterior on improvement of gait and functional results. Intervention group (n = 5): Physiotherapy, muscle strengthening exercises, superficial electrical muscle stimulation. Control group (n = 5): Physiotherapy, muscle strengthening exercises. Period: 4 weeks.	• Significant increase in walking speed (7.83m / min, p <0.002) • Significantly increased cadence (23.33 steps / min, p <0.004) • Better energy efficiency when walking (-1.32 heartbeats / m) • No differences in the EMG • Physiotherapy combined with superficial electrical stimulation improves walking ability and functional results more than physiotherapy alone.
9.	***Cauraugh J. H., Naik S. K., Hsu W.H. , Coombes S. A., Holt K.G. (2010). Children with cerebral palsy: a systematic review and metaanalysis on gait and electrical stimulation. In: Clinical Rehabilitation, 24 (11), S. 963- 978.***			
	Systematic review and meta analysis	40 studies too electrical stimulation and CP, 17 studies on gait, n = 238 intervention group, n = 224 control group	Two subgroups were created in relation to walking problems: Impairments and activity restrictions. The calculations followed conventional data extraction and meta-analysis techniques.	The present systematic review article and meta-analysis determined mean effect sizes for electrical stimulation on the walking disabilities and activity restrictions of children with cerebral palsy.
10.	***Sheffler L. R., Hennessey M. T., Naples G. G., Chae J. (2006). Peroneal nerve stimulation versus an ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation. In: Neurorehabiltation and Neural Repair, 20(3), S. 355- 360.***			
	Study	N = 14 stroke patients with foot lift problems (> 90 days poststroke)	Objective: To compare the effectiveness of a transcutaneous peroneal nerve stimulation device (ODFS) with an ankle-foot orthosis (AFO) in terms of improving functional walking ability. 3 test runs: 1) ODFS, 2) AFO and 3) no aid. Assessment: modified Emory Functional Ambulation Profile	The AFO and the ODFS are comparable in their effect on the improvement of the functional walking ability, compared to no aid. The difference in functional locomotion between AFO and ODFS showed a trend towards statistical significance only in the tests on the floor (P = 0.065) and when standing up and walking (P = 0.082). When choosing between the ODFS and the AFO for the long-term correction of the foot lifting problem, the participants indicated a preference for the ODFS.

11.	***van Swigchem R., Vloothuis J., den Boer J., Weerdesteyn V., Geurts A. C. (2009). Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subjects study of patients' satisfaction, walking speed and physical activity level. In: Journal of Rehabilitation Medicine (2010), 42 (2), S. 117- 121.***			
	Study	N = 26 stroke patients (> 6 months post-stroke) with AFO	Objective: To examine the extent to which stroke patients * who are already treated with an AFO would benefit from switching to an FES system (NESS L300) for stimulating the peroneal nerve. Assessments: walking pace, physical activity, patient satisfaction (at the beginning, after 2 weeks and after 8 weeks).	The AFO and FES system were equally effective in terms of walking speed and activity level. The participants were more satisfied with the FES than with their AFO in terms of effort and stability when walking, quality of the gait pattern, walking distance, wearing comfort and appearance of the device.
12.	***Pool D., Valentine J., Bear N., Donnelly C. J., Elliott C., Stannage K. (2015). The orthotic and therapeutic effects following daily community applied functional electrical stimulation in children with unilateral spastic cerebral palsy: a randomised controlled trial. In: BMC Pediatrics 15:154.***			
	Rando-mized, controlled study	N = 32 children with unilateral spastic cerebral palsy (n = 16 control group, n = 16 Intervention group)	Hypothesis: Children with ICP who are treated with FES (Walk Aide) for eight weeks show improvements in gait, spasticity, mobility and balance compared to conventionally treated children. Intervention group: 8 weeks on 6 days / week 4 hours of FES treatment. Control group: usual orthotic and therapeutic supplies Assessments: gait mechanics, spasticity M. gastrocnemius, mobility balance skills.	FES group shows significant improvement in ankle angle on initial contact ($p < 0.05$) FES group shows significantly reduced spasticity compared to control group ($p < 0.038$) FES group shows maximum dorsiflexion angle in swing phase as well as normalized stride length and normalized length of the standing leg phase. This study supports the use of FES during daily walking activities to improve gait mechanics and to cope with mobility problems in children with unilateral spastic cerebral palsy.
13.	***Everaert D. G., Stein R. B., Abrams G. M., Dromerick A. W., Francisco G. E., Hafner B. J., Huskey T. N., Munin M. C., Nolan K. J., Kufta C. V. (2013). Effect of a foot-drop stimulator and ankle-foot orthosis on walking performance after stroke: a multicenter randomized controlled trial. In; Neurorehabiltation and Neural Repair, 27 (7), S.579- 591.***			
	Multi-cen-tric, rando-mized controlled study	N = 93, patients after a stroke (<12 months poststroke) with foot dorsifle-xion problems	Objective: To compare the ability to walk when receiving care with an AFO or a FES system (Walk Aide (WA)). 3 groups: (1) n = 38, 6 weeks Walk Aide, then 6 weeks AFO, (2) n = 31, 6 weeks AFO, then 6 weeks walk aide, (3) n = 24, 12 weeks AFO. Assessments: walking speed, Physiological Cost Index, mobility, device preference, ...	Both WA and AFO had significant orthopedic (on-off difference), therapeutic (change over time when off) and combined (change over time on vs. baseline off) effects on walking speed. AFO also had a significant orthopedic effect on the Physiological Cost Index. WA had a higher, but not significantly different, therapeutic effect on speed than AFO, while AFO had a greater orthopedic effect than WA (significantly after 12 weeks). The combined effects on speed at 6 weeks did not differ between devices. The users felt just as safe with the WA as with an AFO, but significantly more users preferred the WA.

The studies classified as relevant mainly show the positive influence of training with FES after a stroke. It has been described that the gait speed could be increased compared to training without FES (Busk et al, Schifino et al.), The effect seems to be comparable to the use of an orthosis (Nascimento et al., Sheffler et al.). Long-term studies confirm the positive effects of FES training: an increase in gait endurance, a decrease in the risk of falling and an improvement in the quality of life among users could be observed (Martin et.al.). Similar improvements in gait mechanics were observed for the younger patient group with ICP (Pool et al., Arya et al.), Which enable a certain level of activity in everyday life and preserve the mobility of the joints involved in the best possible way.

Negative observations that were made for comparable products (e.g. L300 Go, MyGait etc.) (Martin et.al, Busk et.al.) can for the most part be excluded for the evomove® or are dealt with by support.

- Postoperative lesions, edema in the thigh area and wound healing disorders as a result of the implantation of the FES system do not occur because the evomove® is not implanted.
- An unfavorable statics when using the FES in the case of a flat foot can be prevented because the stimulation parameters are individually adjusted by trained partners. Suggestions for improvement, as suggested by Alnajjar et.al. are already implemented in the evomove®:
- Electrodes are placed freely by a trained partner during the fitting.
- Electrodes for the users are sewn or glued into the cuff and can be washed together with it.
- The battery has sufficient capacity to support the stimulation throughout the day.

5 Reporting Errors and Incidents

If you are notified of an incident or error related to an Evomotion product, please forward this error message to us immediately. To do this, contact our technical support by email at **support@evomotion.de** or by phone. You can find more information on our website **www.evomotion.de**.

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