Erigo® User Script

1. Erigo® Background Information

The Erigo was developed in collaboration with the Spinal Cord Injury Center at the Balgrist University Hospital in Zurich, Switzerland and the Orthopaedic University Hospital in Heidelberg, Germany. Close collaboration with physicians, therapists, patients and scientists led to the development of a patient- and practice-oriented device.

The main goal was to develop a rehabilitation device that would allow locomotion therapy in the upright position at an early stage by overcoming the limitations of conventional passive movement devices such as ergometers, which provide the necessary movement speed but do not generate a physiological foot sole loading pattern, and devices for continuous passive motion which are unable to generate sufficient joint movement speed required for creating adequate afferent stimulation.

The Erigo as a verticalization table with an integrated robotic stepping device was developed as the first device that simultaneously delivers physiologically relevant foot sole loading pattern and leg joints' afferent stimulation by providing adjustable stepping frequency while allowing the user to continuously adjust the amount of verticalization. The Erigo was officially launched in 2005. In 2013, the Erigo product portfolio was extended to two different product versions, based on additional customer feedback. The goal was to develop the next generation of the Erigo with further improved user friendliness, therapeutic value and overall cost/performance ratio.

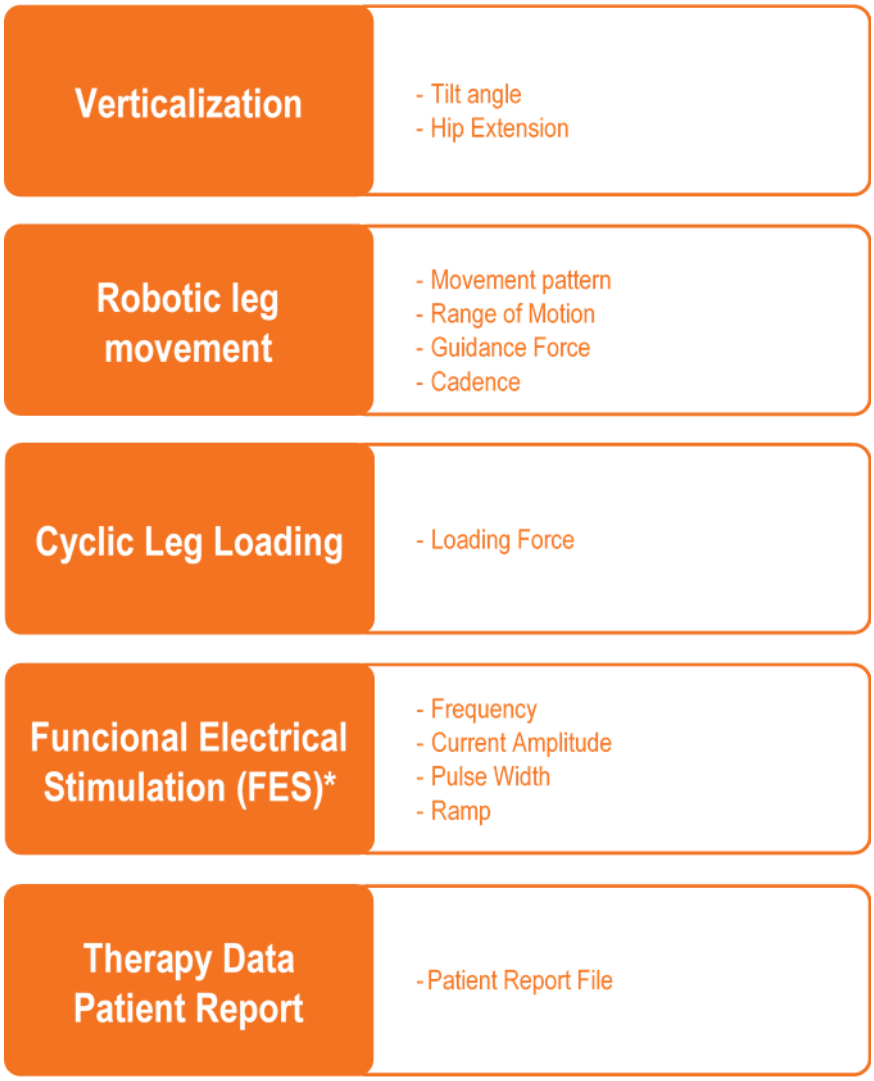
2. Intended use and indications

The Erigo is intended for medical purposes such as to increase tolerance to an upright or standing position in patients with circulatory, neurological, or musculoskeletal conditions. The Erigo is also used for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy / redevelop muscles
3. Increasing local blood circulation
4. Maintaining or increasing joint range of motion

The Erigo is for prescription use only.

3. What does the Erigo® consist of?



**Only ErigoPro*

The Erigo includes several features to provide safe early mobilization and active stimulation of the patient. All in all, the Erigo combines gradual **verticalization** with **robotic leg movement** and **cyclic leg loading** to ensure the safety which is necessary for the stabilization of the patient in the upright position.

Using ErigoPro, the patient stimulation is additionally enhanced by synchronized **functional electrical stimulation (FES)**.

Each feature can be adjusted by different parameters to the patient's needs according to the therapeutic goal of the treatment.

All **therapy data** will be saved in a **patient report file**.

All these features and parameters will be shown in detail one by one during this training course.

Verticalization

A main feature of the Erigo is of course the verticalization function which allows bringing the patient gradually into an upright position for mobilization therapy.

TILT ANGLE

With the Erigo you can verticalize the patient in a tilt angle range from 0° to 90°.

Why do we verticalize the patient?

Verticalization is part of the conventional rehabilitation therapy of bedridden patients. By verticalization we induce orthostatic stress on the patient's cardiovascular system which forces the system to adapt to this stressful situation. Verticalization is further meant to change the patient's body position to prevent damages due to being bedridden (e.g. decubitus). However, this conventional verticalization on a tilt table can be dangerous for the patient because the heart can easily be overstrained. Due to eventual undersupply of the brain tissue with oxygen and sugars, this could lead to syncope, collapse and secondary brain damages. Thus, the duration of conventional tilting may be very limited. Dynamic verticalization, as it is provided with the Erigo, offers the possibility to lengthen verticalization duration and to make verticalization more secure.

HIP EXTENSION

An adjustable hip extension angle between -10° and +10° enables an optimal alignment of the device to the patient's body shape.

Note: The hip extension can only be adjusted at a verticalization angle of more than 10°.

Robotic leg movement

The robotic leg movement of the Erigo is individually adjustable to each patient's abilities and needs. The adjustable parameters include different movement patterns, customizable range of motion (ROM), guidance force of the leg drives and walking cadence (speed).

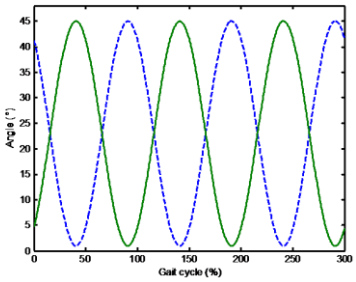
What is the robotic leg movement for?

Even the passive movement of the legs in combination with loading on the feet leads to an activation of the leg muscles and therefore increases venous blood backflow due to the muscle pump effect. Due to this support of the cardiovascular system, the blood pressure and stroke volume can be maintained even if the patient gets verticalized. Therefore earlier verticalization of the patient is feasible and safe because the loaded leg movement prevents the patient from an eventual collapse or secondary brain damages by antagonizing orthostatic stress. Additionally, passive movement helps to avoid secondary damages of the musculoskeletal system.

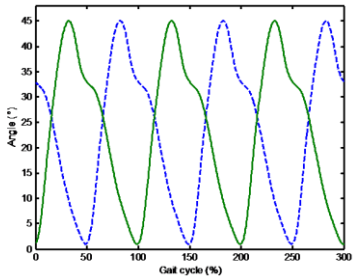
MOVEMENT PATTERN

The standard movement pattern of the Erigo is the sinus pattern. In the ErigoPro, there are two additional movement patterns available

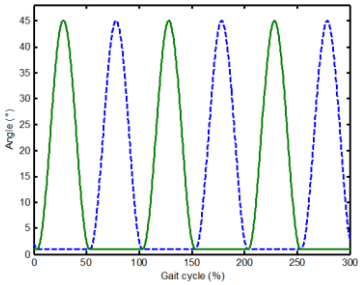
- **Sinus**: hip and knee joints alternate regularly between extension and flexion. In this case, the cycles for the right leg intersect with those for the left leg.



- **Gait** (only in ErigoPro): Simulates the movement of the legs during normal walking. The regular interchange between the extension and the flexion of the hip and knee joints is broken up by a short pause as would be expected when the heel touches the ground (initial contact) during normal walking. The cycles for the right and the left leg intersect.



- **Alternate** (only in ErigoPro): Based on the sinus pattern described above, but without intersection of the right and the left leg. An extension phase (stance) therefore alternates with a flexion phase, with only one leg in motion at a time.



What are the different movement patterns for? When do I use which movement pattern?

Which movement pattern to use depends on the therapy goal set by the therapist.

The **sinus pattern** provides the most comfortable movement as both legs are moved simultaneously in the complete therapy ROM to simulate stepping movements. Furthermore the movement is very simple. Thus, sinus pattern is suited for maintaining or improving the patient's ROM. The muscle pump effect and therefore the venous backflow from the lower limbs is strongly stimulated. Therefore sinus pattern is well tolerated already in very early Erigo therapy.

As the **gait pattern** is adapted to the movement of walking, the difference to the sinus pattern is that not the complete ROM is covered during the stepping movement. In addition, the gait pattern is more complex than the sinus pattern. Therefore gait pattern is meant for advanced Erigo patients to prepare them for Lokomat® training or for walking.

The **alternate pattern** suits well for conscious patients for whom it is easier to only concentrate on the movement of one leg at a time (e.g. patients with hemiparesis). This pattern is also used for relearning to stand in the upright position.

RANGE OF MOTION (ROM)

The ROM is adjustable individually for each leg in a range of 0°-46°. Prior to every therapy session on the Erigo, the therapist measures the patient's maximum value for flexion and extension. The default therapy ROM is 80% of the measured maximum ROM. You can change and adjust the therapy ROM throughout the therapy session.

How do we choose the therapy ROM?

The therapy ROM has to be set individually for each patient. You have to find the personal maximal flexion/extension without causing any pain. You always have to pay attention on the patient's reaction or expression. If you notice any sign for discomfort you will have to adjust the ROM. Consider that the ROM often differs between the two legs (especially in patients with hemiparesis). During a therapy session the ROM can increase in some patients (e.g. due to decreasing muscle tone). Therefore always readjust the therapy ROM to the patient's condition and needs. The therapy ROM depends on the therapy goal set by the therapist.

If it is the goal to improve the ROM of the patient, you should let him train with a ROM close to his maximum ROM. The bigger the ROM, the bigger is the afferent stimulus.

If your main goal is to improve cardiovascular performance of the patient, you may challenge the system by reducing the ROM, which decreases the muscle pump effect and therefore the heart of the patient has to work harder.

GUIDANCE FORCE

The guidance force represents the support of the leg drives for the movement of the patient's legs. Default value is 100%, which means that the stepping movement of the patient can be totally passive. By reducing the guidance force, the patient needs to get actively involved in the movement. The guidance force is adjustable individually for each leg in a range between 0% (no support) and 100% (full support).

When do we reduce the guidance force?

The guidance force can only be reduced in patients with remaining motor function of the legs. You only reduce the guidance force, if you want to challenge the patient to actively participate and relearn the leg movement and also to prepare for Lokomat treatment. If you do so, you can reduce the guidance force to the value where the patient is still capable of completing the desired movement properly. The patient will fatigue during such an active therapy session. Therefore you might again increase the guidance force during the session with increasing fatigue. You can also reduce the guidance force and simultaneously increase FES stimulation to support the “active” leg movement.

Reducing the guidance force can also be a tool to assess how much voluntary movement the patient can fulfill.

CADENCE

The cadence is the speed of the stepping movement expressed in steps per minute. For sinus and gait pattern, the range of cadence is between 8 and 80 steps/min, between 8 and 60 steps for the alternate pattern respectively. Be aware that in the alternate pattern the leg movement is performed twice as quickly than with the other patterns at the same cadence because there is no intersection of the movement of the two legs.

How do we choose the cadence for the therapy?

The higher the cadence, the higher is the muscle pump effect and the afferent stimulus on the patient. If the therapy goal is functional locomotor rehabilitation, you choose a rather high cadence (60-80 steps/min) as the number of repetitions of a movement is crucial for the motor learning process. In case you want to challenge the patient’s cardiovascular system, you choose a lower cadence.

High cadence, especially in combination with high tilting angle, can change patient’s body position and can cause skin irritations at the groins. So, put special attention on patient’s comfort if you use high cadence.

Cyclic Leg Loading

LOADING FORCE

The leg loading feature allows providing pressure on the patient’s lower limbs during the extension phase (stance) by springs which are located below the footplates. The loading force can be adjusted in a range between 0 and 50 kg.

What is the leg loading for?

The loading which is caused by the leg movement combined with pressure on the feet leads to an increased activation of the motoric centers and therefore to an enhanced muscle pump effect which boosts the venous blood backflow from the periphery to the central system.

Additionally, the impact on the musculoskeletal system due to the loading counteracts muscle atrophy and bone weakness.

How do we choose an appropriate leg loading?

Before starting the Erigo session you should apply a leg loading of maximum 5 kg in the horizontal position. When verticalizing, the patient will slip down a few centimeters and the loading on the legs will increase. During the tilted therapy session we recommend a loading of about 30% - 70% of the patient's body weight. Whether you should apply as much or as less loading as possible, again depends on the therapy goal. If you apply too much loading you will notice a non-physiological leg movement (e.g. knee extension is not possible) which is to avoid. With a lower loading you can challenge the patient's cardiovascular system because the muscle pump effect is decreased.

Funcional Electrical Stimulation (FES)*

Functional electrical stimulation is a therapy method in which the motoric nerve of a muscle is stimulated with electrical current to provoke a muscle contraction. This stimulation occurs by two electrodes which are placed on the skin above each muscle or muscle group. On the Erigo we apply biphasic low frequency stimulation (20 Hz - 50 Hz).

What is the effect of FES in Erigo?

With FES we have the possibility to actively contract the muscles. The primary purpose of FES in the Erigo is to activate the muscle pump of the lower extremity to further stabilize the cardiovascular system and therefore to maintain the cerebral blood flow while the patient is in a tilted position. Furthermore, the FES application counteracts muscle atrophy of bedridden patients due to intensive activation of the muscle. FES aims to contract muscles to generate a functional movement of the patient's limbs. In the Erigo the stepping movement and the electrical impulses are fully synchronized.

How does FES work?

Each nerve has a stimulus threshold above which an action potential is provoked. Therefore the intensity of the external electrical stimulus has to be high enough to exceed this threshold and thus contract the muscle. This can be achieved by adjusting different parameters.

FREQUENCY

The impulse frequency is the number of electrical impulses per second in Hertz (Hz). On Erigo we want to achieve a tetanic muscle contraction, which starts at a frequency of about 20 Hz. The frequency of the stimulation determines the muscle fiber type which is activated. Low frequency (< 30 Hz) stimulates type I fibers (slow twitch), higher frequency (> 30 Hz) stimulates type II fibers (fast twitch). The impulse frequency further determines the muscle fatigue. The higher the frequency, the higher is the fatigue. In Erigo you can adjust the frequency across all channels.

CURRENT AMPLITUDE

The current is the flow of electric charge per second, measured in milliampere (mA). The amplitude of the current is the main determinant of spatial muscle fiber recruitment (low amplitude = superficial recruitment / high amplitude = deeper recruitment) and thus of evoked force (the force of muscle contraction and the amount of current applied are linearly related). An increase in amplitude will result in quicker and greater muscle fatigue. You can adjust the amplitude for each channel separately.

PULSE WIDTH

The pulse width describes the duration of a single impulse, measured in microseconds (µs). Together with the current amplitude, the pulse width determines the stimulus intensity. The pulse width has a direct influence on the

recruitment and firing of nerve fibers and therefore on the “size” of the contraction. The strongest contractions are usually obtained with pulse durations of 300-400 µs. In Erigo you can adjust the pulse width across all channels.

RAMP

The ramp is defined as the gradual increase in current amplitude of a series of pulses in order to gradually increase spatial recruitment and thus contraction strength. It is equal to the number of pulses to reach the target amplitude. E.g. with a ramp of 5, the pulse width is gradually increased within 5 steps to reach the target pulse width. With a ramp of 1, the target pulse width is set already with the first impulse. With a higher ramp the electrical stimulation is less uncomfortable for the patient. In Erigo you can adjust the ramp across all channels.

How do I achieve muscle contraction?

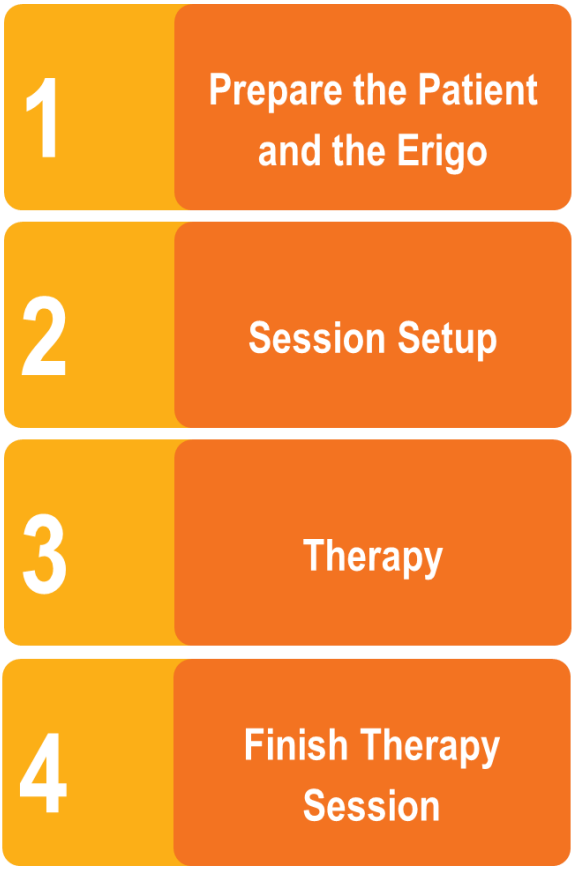
The **stimulus intensity**, which is crucial for achieving the threshold for contraction or not, results out of the multiplication of current and pulse width. Therefore you can either increase current or pulse width to achieve the same stimulus intensity to evoke a muscle contraction. For the muscle contraction the stimulation threshold of the motoric nerve fibers (Aα-fibers) has to be reached. This threshold lies above the threshold of the sensory nerve fibers (Aβ) but below the threshold of pain fibers (Aδ). For the patient it is more comfortable to stimulate with a high pulse width and lower amplitude than vice versa.

Therapy Data
Patient Report

The data of each therapy session is saved in a patient report.

In this report you will find all the data about training progress in all different aspects: duration, verticalization, leg loading, cadence, ROM, guidance force and FES.

4. How are we going to use the Erigo® in a patient therapy session?



First you will need to **prepare the patient and the Erigo**, put the patient data into the software, select the correct orthopedic equipment and roughly preset the Erigo leg length, thigh length and track width according the patients anatomy to ensure a good interface between the patient and the Erigo. Select the patient according to indications/contraindications (User manual).

Then you will **set up the session** by transferring the patient and fixing him on the Erigo. Then you will have to adjust the Erigo dimensions exactly to the patient to ensure that the movement axis of the Erigo matches with those of the patient and thus, to ensure a good posture. You will do this patient setup procedure in a systematic way, step by step, to make it time efficient and to avoid missing a step. Furthermore you have to setup the FES parameters (if required).

Once all is ready, you will **start the therapy**. You will start with the leg movement to induce the afferent stimulation and the muscle pump effect. If you apply FES, the next step is the activation of the stimulation. After further applying the leg loading you will start with the verticalization process. During the Erigo therapy session, you will always have to monitor the patient and adjust parameters if required.

You will use the reverse order of steps as used to setup and start the therapy in order to **finish the therapy session**.