Erigo® User Script

1. Erigo® Background Information

Immobility is experienced by many hospitalized patients in the acute phase after an injury or illness but also in the chronic phase of various disorders ranging from complete immobility and being bed bound to mobility issues of not being able to walk, to stand or using a wheelchair for mobility. Prolonged immobilization and reduced mobility have large consequences on the physical health status of the patient and can lead to musculoskeletal complications including loss of muscle strength, contractures and soft tissue changes, reduced range of motion in joints and immobilization induces osteoporosis; cardiovascular complications including decreased cardiac reserve, orthostatic hypotension or increased heart rate and respiratory system complications such as pneumonia (Rengel et al. 2019, McKendry et al. 2020, Vanhorebeek et al. 2020). Rehabilitation is at most relevance to minimize the effects of immobilization. Conventional therapy to counteract these negative effects contains a large variation of exercises such as sitting on the edge of the bed, transferring from bed to a chair, ambulation, hoist therapy, tilt table therapy and active resistance exercises (Castro-Avila et al. 2015). The standing position improves circulation and pulmonary ventilation, as well as stimulates the autonomous activity, it also reduces cardiac compression stress and aids to maintain proper fluid distribution and inferiorization of the abdominal viscera (Toccolini et al. 2015).

Dynamic tilt tables can be used for severely deconditioned patients to support in active exercise to increase strength and stimulate to carry weight on the lower extremities (Koester et al. 2018). However, disruptions of therapy due to presyncopal symptoms are common during tilt table and could potentially lead to a reduced therapy time (Kuznetsov et al. 2013, Leung et al. 2014, Calabrò et al. 2015, Krewer et al. 2015, Ancona et al. 2019).

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 Erigo as a verticalization table with an integrated robotic stepping device was developed as the first device that simultaneously delivers physiologically relevant leg loading, a stepping 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 a robotic device intended to provide safe verticalization and early functional mobilization of the lower extremity in patients with very reduced or no ambulation ability and/or reduced transfer and standing abilities, who are immobile in bed or in need of a wheelchair for mobility. The Erigo combines robotic supported stepping movements, verticalization through a tilt-table approach and weight-bearing on the lower extremity. The Erigo allows the therapist to adapt the therapy parameters on a user interface to individualize therapy and address patient-specific needs. The Erigo registers the training parameters (inclination angle, stepping frequency, robotic guidance, leg loading) and provides therapy reports. In the ErigoPro, a functional electrical stimulation module allows to stimulate the leg muscles in synchrony with the robot guided stepping movement.

Literature has shown that, in the patient group mentioned above, verticalization and mobilization with the Erigo leads to a clinically relevant improvement in:

- lower extremity muscle strength
- state of consciousness

- functional independence in activities of daily living

In addition, combined verticalization and mobilization with the Erigo leads to significantly less therapy disruptions than verticalization with a tilt table.

Indications and intended Patient Population

The Erigo is intended for rehabilitation of patients with very reduced or no ambulation ability and/or reduced transfer and standing abilities, who are immobile in bed or are in need of a wheelchair for mobility and are undergoing rehabilitation and for whom safe verticalization and early functional mobilization of the lower extremity is indicated according to the judgement of the treating clinician.

The Erigo was designed to be used in intensive care units, medium care units, specialized units for early rehabilitation, rehabilitation hospitals, hospitals with rehabilitation departments or outpatient rehabilitation clinics. And for whom safe verticalization and early functional mobilization of the lower extremity is indicated according to the judgement of the treating clinician.

The weight and leg length of the patient must fall within the following ranges:

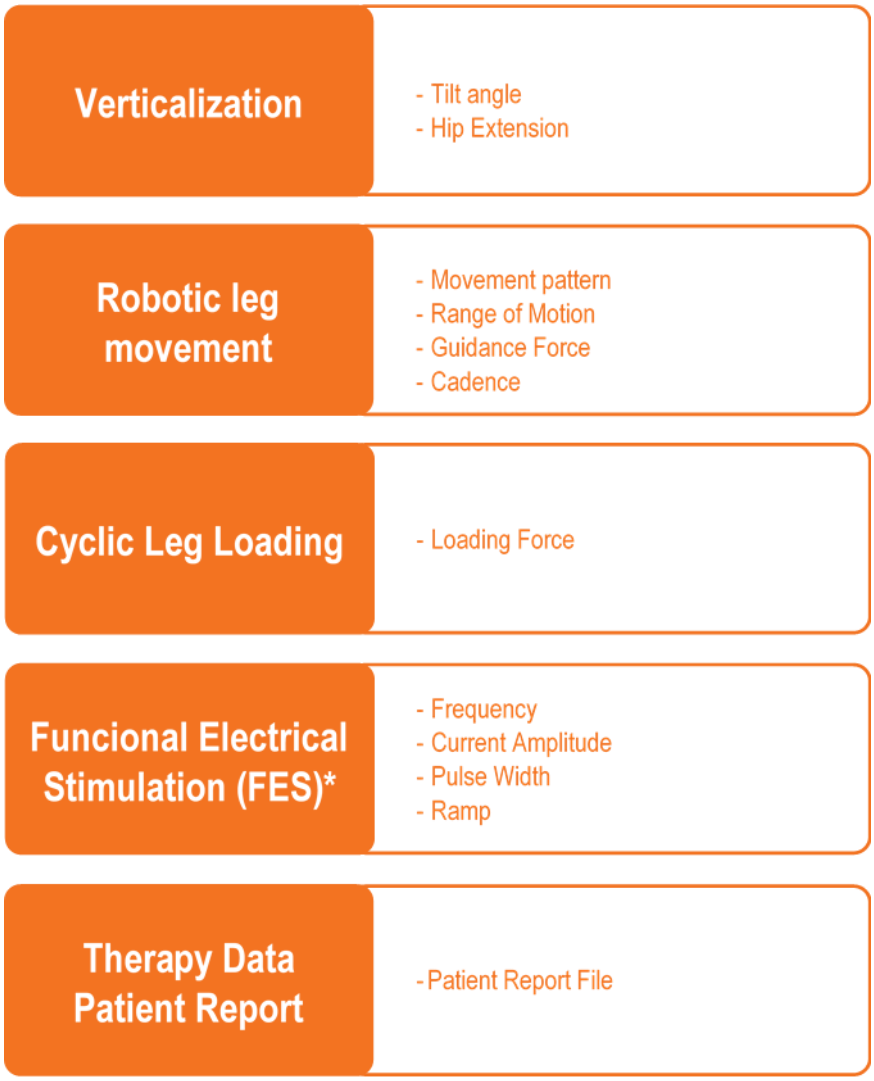
• Body weight < 135 kg (297 lb)

• Leg length measured from the foot sole to the greater trochanter > 69 cm (27 in.) and < 104 cm (41 in.)

The continuum of rehabilitation with the Erigo reaches from the acute stage to the chronic stage. Consider that the application of the device differs according to the abilities of the patient.

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. This leads to significantly less therapy disruptions compared to a classic tilt table approach**.

In the ErigoPro, a functional electrical stimulation **(FES)** module allows to stimulate the leg muscles in synchrony with the robot guided stepping movement.

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

The main feature of the Erigo is 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 ranging 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). The use of tilt tables is a common therapeutic strategy to verticalize the patient. However, due to the fixation of the lower extremity, blood tends to pool in the lower extremity which in turn can lead to a drop of the central blood pressure. As a consequence, presyncopal symptoms or even a syncope are experiences by the patient (Luther et al. 2008, Frazzitta et al. 2016)]. As a consequence, disruptions of therapy due to presyncopal symptoms are common during tilt table and could potentially lead to a reduced therapy time (Kuznetsov et al. 2013, Leung et al. 2014, Calabrò et al. 2015, Krewer et al. 2015, Ancona et al. 2019). Literature has shown that significantly less disruptions of therapy occur in Erigo therapy then in tilt table therapy, potentially allowing for a longer duration of therapy.

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).

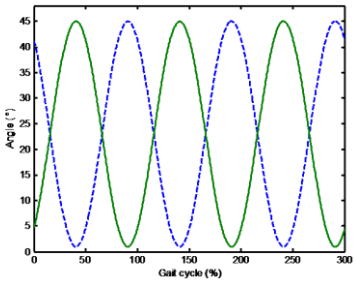
What is the robotic leg movement for?

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 by antagonizing orthostatic stress.

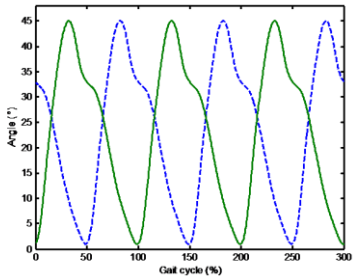
MOVEMENT PATTERN

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

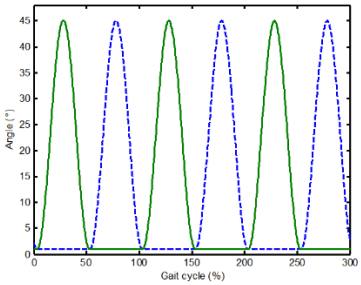
- **Sinus**: hip and knee joints alternate regularly between extension and flexion. In this case, the cycles for the right leg intersect with those for the left leg.



- **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 and continuously 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. The 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 mobilize the patient's legs, you should let him train with a ROM close to his maximum ROM.

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 train 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 if you notice that the patient gets increasingly fatigued. 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 perform.

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.

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?

During leg loading, the weight bearing on the lower extremity increases. This supports the activation of the muscles in the lower extremity and the positive consequences thereof. The loading force can be adjusted in a range between 0 and 50 kg.

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. In order to set the correct amount of leg loading, it is important to see if a physiological leg movement is possible. If the patient moves with too much flexion in the stance phase, potentially the leg loading is too high and the patient is unable to carry this much weight on the legs.

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 muscles and potentially support with the activation the muscle pump of the lower extremity to support with stabilization of the blood pressure during verticalization. Furthermore, the FES application counteracts muscle atrophy of patients who are immobile in bed or in need of a wheelchair for mobility. 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?

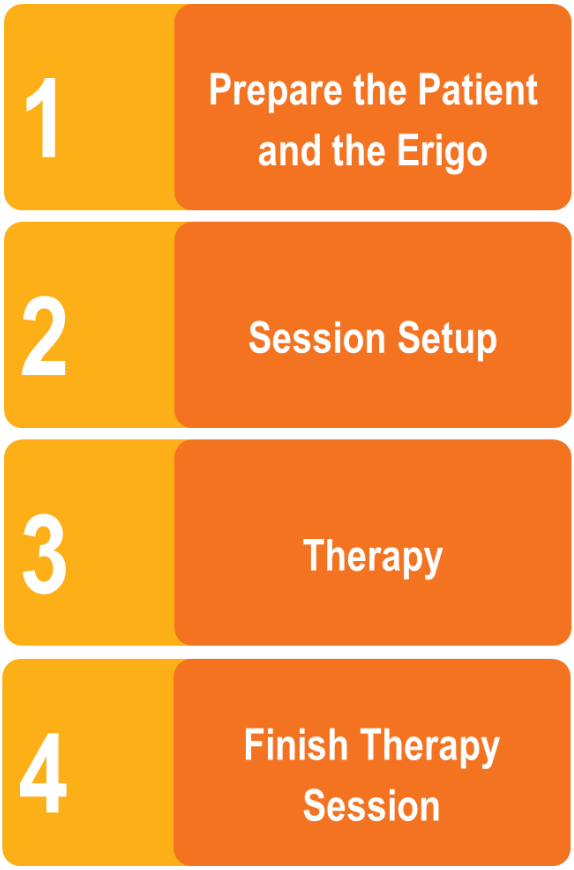
The **stimulus intensity**, which is crucial for achieving the threshold for contraction or not, results out of the multiplication of current and pulse width. Therefore, you can either increase current or pulse width to achieve the same stimulus intensity to evoke a muscle contraction. For the muscle 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. The report can be extracted from the device via USB.

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**, insert the patient data into the software, select the correct orthopedic equipment and roughly preset the Erigo leg length, thigh length and track width according to 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, thus ensuring 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**.

References

Ancona, E., A. Quarenghi, M. Simonini, et al. (2019). "Effect of verticalization with Erigo® in the acute rehabilitation of severe acquired brain injury." Neurol Sci **40**(10): 2073-2080.

Calabrò, R. S., A. Naro, M. Russo, et al. (2015). "Do post-stroke patients benefit from robotic verticalization? A pilot-study focusing on a novel neurophysiological approach." Restor Neurol Neurosci **33**: 671-681.

Castro-Avila, A. C., P. Serón, E. Fan, et al. (2015). "Effect of Early Rehabilitation during Intensive Care Unit Stay on Functional Status: Systematic Review and Meta-Analysis." PLoS One **10**(7): e0130722.

Frazzitta, G., I. Zivi, R. Valsecchi, et al. (2016). "Effectiveness of a Very Early Stepping Verticalization Protocol in Severe Acquired Brain Injured Patients: A Randomized Pilot Study in ICU." PLoS One **11**(7): e0158030.

Koester, K., H. Troeller, S. Panter, et al. (2018). "Overview of Intensive Care Unit-Related Physical and Functional Impairments and Rehabilitation-Related Devices." Nutr Clin Pract **33**(2): 177-184.

Krewer, C., M. Luther, E. Koenig and F. Muller (2015). "Tilt Table Therapies for Patients with Severe Disorders of Consciousness: A Randomized, Controlled Trial." PLoS One **10**(12): e0143180.

Kuznetsov, A. N., N. V. Rybalko, V. D. Daminov and A. R. Luft (2013). "Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation." Stroke Res Treat **2013**: 946056.

Leung, J., L. A. Harvey, A. M. Moseley, et al. (2014). "Standing with electrical stimulation and splinting is no better than standing alone for management of ankle plantarflexion contractures in people with traumatic brain injury: a randomised trial." J Physiother **60**(4): 201-208.

Luther, M. S., C. Krewer, F. Muller and E. Koenig (2008). "Comparison of orthostatic reactions of patients still unconscious within the first three months of brain injury on a tilt table with and without integrated stepping. A prospective, randomized crossover pilot trial." Clin Rehabil **22**(12): 1034-1041.

McKendry, J., A. C. Q. Thomas and S. M. Phillips (2020). "Muscle Mass Loss in the Older Critically Ill Population: Potential Therapeutic Strategies." Nutr Clin Pract **35**(4): 607-616.

Rengel, K. F., C. J. Hayhurst, P. P. Pandharipande and C. G. Hughes (2019). "Long-term Cognitive and Functional Impairments After Critical Illness." Anesth Analg **128**(4): 772-780.

Toccolini, B. F., E. F. Osaku, C. R. de Macedo Costa, et al. (2015). "Passive orthostatism (tilt table) in critical patients: Clinicophysiologic evaluation." J Crit Care **30**(3): 655 e651-656.

Vanhorebeek, I., N. Latronico and G. Van den Berghe (2020). "ICU-acquired weakness." Intensive Care Med **46**(4): 637-653.