

OMEGO® Basic

GEBRAUCHSANWEISUNG / MANUAL

tyromotion



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1 Introduction

1.1 Introduction

We are happy to provide this user manual as an introduction for the usage of the OMEGO® Basic pre-gait therapy systems. The following user manual addresses the essential functions that are necessary for understanding the functionality and usage of the OMEGO® basic system.

For more information about our products visit our website or contact us personally.

1.1.1 Regarding the usage of this documentation



It is absolutely imperative that every user completes the training course and has read the user manual prior to using OMEGO® Basic systems.

For legibility reasons, the following pages only refer to the male gender, which, however, always implies the female gender as well. TYROMOTION GmbH rejects any liability for damages to persons or material if safety regulations and instructions relevant to the usage of the OMEGO® Basic system are not observed!

1.1.2 Symbols in the user manual



	<p><i>Warnings: Severe risk of injury or hazard results when this symbol is displayed in the user manual and notices are not observed. Be especially mindful of these notices!</i></p>
	<p><i>Follow the user manual</i></p>

Table 1

1.1.3 System content

The OMEGO® Basic system consist of the following components, included in the delivery:

- Base unit
- All-IN-ONE PC
- 2x foot rest sets
 - 1x set for normal Therapy (item number O.G200 and O.G201)
 - 2x wide Velcro straps for foot fixation
 - 2x narrow velcro straps for foot fixation
 - 1x set for drop foot therapy (item number O.G250 and O.G251)
 - 1x set magnetic coupling for foot fixation drop foot rest
- 2x tilt protection
- Power cable with 3 power plugs for various country configurations
- USB stick (with instruction manual for TyroS and OMEGO® Basic, assembly instruction, accompanying documents, software)
- instruction manual for TyroS and OMEGO® Basic, assembly instruction, accompanying documents
- 1x hexagon screwdriver for changing the foot rests
- 1x allen key for monitor mounting
- 2x microfuse 16A T 250V

1.1.4 The pre-gait therapy system

The OMEGO® Basic is a mechatronic therapy system for the rehabilitation of the relevant criteria that are necessary for walking. Pre-gait therapy is the targeted rehabilitation of one or more prerequisites necessary for physiological walking.

The OMEGO® Basic System consists of the base unit, which contains the electrically driven movement mechanism, the pedestal unit, the foot fixations, foot shells and a computer-based control and operating unit for setting the therapy parameters.



Image 1: Symbolic image: OMEGO® Basic Pre-Gait Therapy System

The OMEGO® Basic is a unique device for the rehabilitation of the relevant pre-gait prerequisites: balance, locomotion, musculoskeletal integrity and neurocognitive control.

Whether uni- or bilateral leg training with symmetry detection, leg press, stepper, ergometry / cycling, vibration, sensor therapy or therapy of dorsiflexion: OMEGO® Basic combines all functions in one device.

1.1.5 Intended purpose

The OMEGO® Basic is a robotic pre-gait therapy system for the rehabilitation of patients with neurologic disorders. The target population includes neurologic, orthopedic, geriatric and pediatric patients. The therapy and feedback system is used for the rehabilitation of patients with dysfunctional conditions which are essential for gait.

Depending on national variances, typically physiotherapy utilizes the OMEGO® Basic system as therapeutic support, enhancement and intensification in addition to conventional therapy forms. Repetitive movement of the legs offers intrinsic and extrinsic stimuli which promote brain reorganization. Repeated activity and training triggers neuroplasticity and thus the alteration (adaptation) of synapses, nerve cells or even entire cerebral areas for regaining lost functionality.

1.1.6 Notices



Familiarize yourself with the instructions for use before using the system and at regular intervals.

It is also mandatory to read the supplied instructions for use of the software tyroS for the use of the system!

Give the marked notes the greatest possible attention!

Medical personnel and properly trained therapists responsible for the OMEGO® Basic system are required to warn technicians, patients and other persons within the vicinity of the device to fully observe the contained safety precautions. The system may only be operated by properly trained personnel. It is imperative that each user attended training and read the instructions before using the OMEGO® Basic system for the first time. Ensure that the system is not manipulated by unauthorized personnel. The system is unpacked and installed by service personnel authorized by TYROMOTION GmbH. Never attempt to install the system by yourself.



The OMEGO® Basic system must not be changed without the manufacturer's permission.

1.1.7 Safety

Persons who commission the OMEGO® Basic therapy system must first have read and understood Chapters 1.1.7 and 1.1.8. Never modify the system including system components, software, cables, etc. Modifications by users can compromise security and affect system performance. All modifications must be made by a person qualified by TYROMOTION. The information in Section 1.1.8 is intended to familiarize the user with the hazards that may result from using the system and warn them of the injuries and damage that can result if the safety precautions are not met. Users are required to familiarize themselves with these safety instructions and to avoid conditions that could result in injury or damage.

1.1.8 Warnings

Warnings are indicated by the symbol as depicted in chapter 1.1.2 (yellow triangle with exclamation mark).

To ensure the applicability of this manual all warnings from the different chapters are compiled in the following list.

Chapter 1 warnings

Use of this documentation:

It is a prerequisite that all users attend an instruction and read the user manual prior to using the OMEGO® Basic System for the first time.

Please note:

The OMEGO® Basic System may not be modified or adjusted in any way without the manufacturer's consent.

Chapter 2 warnings

Electromagnetic compatibility:

The OMEGO® Basic is a medical device and as such is subject to special safety measures regarding electromagnetic compatibility. The following instructions are to be adhered to at all times. Portable and mobile HF communication systems can influence OMEGO® Basic functionalities.

Consumption of food and drinks:

The consumption of food and drinks in the device's immediate vicinity is prohibited due to safety reasons.

Connection of external devices:

Do not connect any external devices to free PC ports without having obtained the necessary manufacturer information.

The mains connection at the front of the device is provided for the sole use of connecting specified Tyromotion accessories. Do not connect any other devices or accessories!

Accessories:

Only accessories specified by the manufacturer may be used.

Hazards posed by tangible parts that are NOT application parts:

The therapist has to instruct the patient to neither hold or lean onto device parts (frame, PC, etc.) nor touch them.

Power supply:

WARNING: In order to avoid the risk of an electrical shock, the device may only be connected to the power supply via a ground wire.

The system may not be connected to the power supply via extension cables.

Repairs:

Always contact the manufacturer for repairs!

Height adjustment of monitor handle bracket:

The height of the monitor handle bracket may only be adjusted by a therapist.

The height is to be adjusted slowly and taking into consideration spatial requirements as well as the patient's range of motion.

Always hold the handle/PC carrier tube with one hand before pulling out the catch bolt in order to prevent the handle/PC carrier tube from falling to the ground or tilting backwards, as this could pose a risk of injury for both the therapist and the patient or could damage the All-IN-ONE PC!

Monitor handle jamming risk

Adjust the position of the monitor handle bracket with care and never grasp the bracket's locking mechanism.

Pedal radius adjustment:

Adjusting the pedal radius while the cranks are in motion or during therapy poses a jamming hazard:

While the cranks are spinning or a therapy session is in process, neither the operator nor any other person may modify the device's pedal radius. Always end the therapy session before entering the main menu for modifications.

Never attempt to modify a moving part!

Foot rest replacement:

Trying to replace the foot rests while the cranks are in motion or during therapy poses a jamming hazard:

While the cranks are spinning or a therapy session is in process, neither the operator nor any other person may modify the device's pedal radius. Always end the therapy session before entering the main menu for modifications.

Never attempt to modify a moving part!

Wheelchair positioning:

Please make sure the wheelchair brakes have been locked before starting exercise with the OMEGO® Basic. If you exercise with an electric wheelchair the wheelchair has to be switched off and in braking position.

Fastening/unfastening the chair safety catch:

A spasm or particular functions (e.g. leg press) may cause the patient to fall backwards and, in the worst case, topple over. To prevent this, always use the safety catch and/or only use chairs that can be secured with a safety catch.

Always check the wheelchair for stability prior to therapy. If stability is not given the therapy has to be supervised by the therapist at all times.

If a patient is unable to hold onto the handle without assistance the therapy has to be supervised by the therapist at all times.

Device assembly and transport:

The OMEGO® Basic's position may not be changed nor may the device be moved as long as the legs are attached and/or in use.

Position the OMEGO® Basic on a flat surface without constant human traffic.

Never move the OMEGO® Basic when patients are in its vicinity. Be careful when moving it over thresholds or bumps.

Monthly functionality check / recurring check:

The use of the device has to be stopped immediately in case one of the malfunctions listed in Table 9 occurs or is suspected.

Casing damages (e.g. caused by transportation):

Never activate the device if the casing is damaged as this may have unpredictable consequences (e.g. electric shock). Check each point listed in the checklist before activating the device and, if necessary, contact Tyromotion.

Chapter 4 warnings

Indications/contraindications:

Is the system suitable for the designated therapy:

- 1. Constant monitoring of the patient's therapy progress.*
- 2. Observatiob of current relevant studies.*
- 3. Adjustment of therapy in case the patient's condition deteriorates excessively.*

Safety:

The patient's suitability for therapy with the OMEGO® Basic is to be assessed by the treating physician or therapist.

The suggested therapy duration is approx. 30-60 min/day but the actually permissible duration is highly dependent on each patient's general condition and capacity and thus has to be assessed individually.

Prior to therapy the treating physician or therapist has to assess if and how long the patient can manage independently, taking into consideration the patient's cognitive capacities as well as the general condition.

Deterioration of postural stability: Patients suffering from impaired balance while sitting have to be monitored and supported throughout the therapy.

The device and its control elements (software) may only be operated by trained therapists. Make sure the patient does not change any settings during therapy.

If the therapist is leaving the patient's range of vision and/or is out of earshot, the therapy has to be paused.

Patients with limited cognitive capabilities have to be monitored at all times.

The OMEGO® Basic may not be moved nor may its position be changed during an ongoing therapy.

Only start the OMEGO® Basic once the patient is secured.

Over-extension of the knees: The range of motion may have been set inaccurately, which can cause a high mechanic pressure on the knee joint and/or hip. Please always check the range of motion settings.

Trying to adjust the device while the cranks are in motion or during therapy poses a jamming hazard:

While the cranks are spinning or a therapy session is in process, neither the operator nor any other person may modify the device's mechanic settings (pedal radius, height adjustment of handles, foot rest replacement etc.).

Never attempt to modify a moving part!

Limiting the means of escape: The mechanic fixation of the foot shovel to the device may result in the patient's delayed departure (e.g. in case of fire alarm). Make sure a trained person who in the case of a dangerous situation can unfasten the fixation supervises the patient.

The therapy of children (6 years and older) has to be supervised by a therapist at all times.

The suitability of children over the age of 6 years has to be assessed by the treating physician or therapist. Due to their body structure and insufficient compliance children aged 5 years and younger are not suited for therapy with the device.

For a height below 130cm special care has to be taken with regards to the range of motion.

Application:

Only attachment systems provided by Tyromotion may be used to attach the patient. Other attachment systems may pose a hazard.

Risk of injury by stuck clothes: The patient has always wear suitable, tight clothes. Wide pants, long scarves and shawls, long hair etc. may get caught in the pedals. The patient has not wear necklaces, jewelry or similar. The patient has always wear closed footwear without laces.

All settings, especially maximum speed, maximum force and maximum range of motion have to be determined by the treating physician prior to the first therapy session.

During therapy, only trained personnel may be around the patient and therapy system. Ideally, the therapist is right next to the patient to instruct him/her during therapy.

Patients who cannot sit upright unassisted have to be brought into a position suitable for therapy and secured by appropriate means.

Foot fixation:

Fastening the foot fixation too tightly may cause reduced blood supply to legs and feet. Prior to therapy, make sure the fixation is conveniently fastened and/or ask the patient if he/she experiences circulatory disorders.

Jamming hazard caused by incorrect fixation of the feet in the foot rests:

Always make sure the patient's feet are firmly secured in the foot rests.

Application of foot drop therapy:

A special training for operators performing this therapy is compulsory.

Please note that a separate mechanic foot attachment with magnetic coupling is available for this application. This will restrict the maximum force and thus allow for a quick release from the foot rest in case of an emergency.

Cleaning the OMEGO® Basic System and accessory parts:

Transmission of germs between patients:

Always adhere to the cleaning instructions as stated in this manual.

Compulsory disinfection measure:

Disinfect handles after therapy.

1.1.9 Owner's responsibility

The owner is responsible for ensuring that all persons who operate the system have read and understood this user manual. However, we cannot guarantee that every person who has read this manual is qualified to operate, inspect, check, calibrate, repair or modify the system or fix system errors. The owner must ensure that the installation, maintenance, calibration and repair of the system as well as the fixing of errors are only performed by properly trained and fully qualified personnel. The owner of the OMEGO® Basic system must ensure that only properly trained and fully qualified personnel (certified users or operators) receive the authorization to operate the system. It must be ensured that the user has read and fully understood the operating instructions contained in this user manual and has been trained either by TYROMOTION or by other employees of the owner who have been trained by TYROMOTION before being authorized to operate the PABLO® system. The owner is obligated to maintain a list of authorized operators. The operator must contact TYROMOTION if the system does not work properly or does not respond correctly to the commands described in this user manual.

1.1.10 Error and omissions

Please contact TYROMOTION GmbH if this user manual contains errors or omissions (addresses are listed at the beginning of the document and on our website www.tyromotion.com).

1.1.11 Property of TYROMOTION GmbH

TYROMOTION GmbH owns the copyright-protected content of this user manual, including all figures and illustrations; this information is exclusively provided for operational and maintenance purposes. Any distribution for other purposes or copying without prior written approval by TYROMOTION is prohibited.

1.1.12 Warranty and legal disclaimer

TYROMOTION GmbH issues a warranty to the original system purchaser that the system shall be free of material and qualitative processing defects for a period of 12 months under normal usage conditions from the date of installation on the owner's premises and that the system complies with the mechanical and electrical specifications published by TYROMOTION (unless the warranty term is extended by an optional service contract). This warranty is granted under the provision that the system is installed, operated and maintained in accordance with the user manual. The customer must submit all warranty claims to TYROMOTION in written form within 60 days of the occurrence of the problem and before the expiry of the warranty. TYROMOTION is exclusively obligated to repair, exchange or correct faulty or non-compliant parts at its own discretion in accordance with the warranty. TYROMOTION has no further obligations to the owner in regard to these parts after the repair or exchange of faulty or non-compliant parts. All repairs or maintenance work must be performed by an authorized TYROMOTION service representative in accordance with this warranty. The above mentioned warranty becomes null and void if repairs, maintenance or other work is performed by third parties. Moreover, problems resulting from accidents, improper use, incorrect application, storage damage, negligence as well as system or component modifications are excluded from the warranty.

The above mentioned warranty is granted in place of all other warranties, rights or conditions, and the system is delivered "without deficiency warranty" apart from the limited warranty. TYROMOTION and its third-party suppliers specifically and unreservedly reject all other explicit or implicit warranties held by the owner, his personnel and patients, customers, users and any third parties, unreservedly including all warranties for marketability, applicability for a specific purpose, non-infringement and any warranties resulting from performance development, business trends or commercial customs. TYROMOTION and its third-party suppliers do not provide declarations or

warranties for system compliance with the owner's requirements or for functionality without interruption, errors or deficiencies.

TYROMOTION is in no way liable for indirect, incidental, specific or consequential damage or for punitive damage compensation including, among other things, the loss or absence of profits, yield, goodwill or usage, which the owner or third parties may incur or for damage to connected equipment, costs for replacement products, installations, servicing, exchange elements or idle time or for claims from patients, customers, visitors, the owner's employees or other persons, regardless whether submitted within the context of a contractual claim, due to unauthorized behavior, strict liability or imposed by law or otherwise even when TYROMOTION has been informed about the possibility of such damages. TYROMOTION's liability for damages resulting from or in connection with this contract may not in any event exceed the purchasing price of the system.

Some jurisdictions limit or exclude the extent of restrictions, the exclusion of legal means, compensation or liability, such as liability for gross negligence or willful misconduct according to or in the abovementioned extent or do not permit the exclusion of implicit warranties. In such jurisdictions, the restriction or exclusion of warranties, legal means, compensations or liabilities described above may not be valid for the owner. Such restrictions or exclusions apply according to the highest legally permitted extent even if they are not valid according to the legally prohibited extent. The owner may also have other rights that vary depending on the specific country or other jurisdictions.



Maintenance works may only be carried out if there are no patients in the device's direct vicinity.

1.2 Training concept


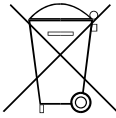







The OMEGO® Basic system is a complex technical device. Users of the PABLO® system are required to complete a training course and read the user manual in order to ensure the safety of patients, users and the device itself. Merely reading the present manual does not convey sufficient competence for operating OMEGO® Basic. Prospective users are also required to have basic medical training (e.g. physiotherapy/occupational therapy). TYROMOTION GmbH rejects all liability for damages resulting from therapy that was performed by an untrained user. Prospective users are trained after delivery of the OMEGO® Basic system.

Users are able to perform initial and repeated therapies training with the OMEGO® Basic system. Users are not permitted to instruct other persons in the usage of the OMEGO® Basic system. Users are trained by a member of TYROMOTION GmbH or by another trainer delegated by TYROMOTION GmbH.

Training content:

- OMEGO® Basic System/component overview
- Functionality and application
- Indications
- Definite contraindications
- Relative contraindications
- Starting the OMEGO® Basic System
- Starting the TyroS software
- Patient selection/creation of a patient file
- Height adjustment of monitor handle bracket
 - Height adjustable parts warning
- Adjustment of pedal radius
 - Pedal warning
- Adjustment of ALL-IN-ONE PC
- Wheelchair positioning
 - Wheelchair warning
- Using/loosing of chair safety catch
 - Chair warning
- Patient attachment
 - Patient attachment warning
- Pedal replacement and foot drop therapy application
- Therapy selection
- Steering type
- Adjustment of starting position and steering range
- Therapy games
- Movement therapies
 - Stepper
 - Leg press
 - Foot drop
 - Sensor therapy
 - Cycling
- Application with kids
- Report evaluation
- Cleaning of device
- General warnings
- Clinical use warnings

1.3 Symbols on OMEGO® Basic

	<p><i>Emergency stop switch for interrupting the power supply of the drives</i></p>
	<p><i>Do not discard with household waste.</i></p>
	<p><i>Application part, type B</i></p>
	<p><i>Alternating current</i></p>
	<p><i>CE mark with the number for the notified body</i></p>
	<p><i>Information about the manufacturer of OMEGO® Basic, including the full mailing address, is displayed next to the factory symbol.</i></p>
	<p><i>Follow the user manual: To be read thoroughly prior to activation.</i></p>
	<p><i>Warning symbol: Crushing hazard warning.</i></p>
	<p><i>General warning for accessory port: Only accessories specifically labeled by Tyromotion may be connected. Do not connect any other devices or accessories.</i></p>





IP20	<p><i>Protection class against foreign objects and water:</i> <i>2 means protection against penetration of solid objects with a diameter $\geq 12,5$ mm. 0 means no protection against ingress of water.</i></p>
	<p><i>Labelling on the power switch:</i> <i>1 means the device is activated.</i> <i>0 means the device is deactivated.</i></p> <p><i>When the power switch is pressed, the entire device is switched to live / de-energized.</i></p>
	<p><i>Do not touch</i> <i>This symbol indicates that it is prohibited to touch the device's moving foot rests as this may pose an increased risk for operator and patient.</i></p>
	<p><i>No entry</i> <i>Entering the area is prohibited due to pinch point hazard.</i></p>
	<p><i>Children aged 0 to 5 years are prohibited</i> <i>Children under 6 are exempt from use due to inadequate compliance and physical structures.</i></p>

Table 2

1.3.1 Type label



Image 2: OMEGO® label

The type label designates OMEGO® Basic as a medical product.

2 Technology

2.1 Technology

2.1.1 Overview

Type description:	OMEGO® Basic
Build year:	Can also be determined from the serial number, e.g. SN: OR1-2017-XXX refers to the year 2017.
Classification:	According to rule 9 of the commission guideline 93/42/EWG, appendix IX, the OMEGO® System is an active therapeutical Medical Device Class IIa .
Type of applied part:	Type B
Protection against electric shock:	Protection class I device – protective grounding
Electromagnetic compatibility:	Class B device (CISPR 11) The OMEGO® Basic System may only be used in the living area under the responsibility of a health care professional. EN60601-1-2: 2001, the requirements are fulfilled.
Country of origin:	AUSTRIA
Power supply voltage:	110 – 240V alternating current
Supply frequency:	50/60Hz
Electricity/Power consumption:	16A – 7 A/1800W-1700W
Supply grid:	Only connect to supply grids with protective ground wiring.
Operating type:	Continuous operation
Fuses:	<i>Secured for all poles (2x T16A L 250V)</i>
Power supply drives:	48V DC
Maximum velocity:	<i>80 U/min</i>
Nominal drive performance:	<i>800 Watt / drive</i>
Maximum torque:	<i>65 Nm unilateral/ 50 Nm bilateral</i>
Measurement range torque measurement:	<i>±70Nm</i>
Measurement error torque measurement:	<i>< 10%</i>

Weight:	75kg
Dimension (WxLxH) in mm:	1017 x 825 x 1225
Penetration protection:	IP 20

Table 3: Technical data



OMEGO® Basic is classified as a medical electronic device and therefore subject to specific precautionary measures relating to electromagnetic compatibility (EMC). It is absolutely imperative to observe the stated EMC indications. Portable and mobile HF communication equipment may affect OMEGO® Basic.

Guidelines and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS		
The OMEGO® Basic system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the OMEGO® Basic system must ensure that it is used in such an environment.		
Interference emission measurements	Agreement	ELECTROMAGNETIC ENVIRONMENT – Guidelines
HF emissions according to CISPR 11	Group 1	The OMEGO® Basic system exclusively uses HF energy for its internal FUNCTIONS. HF emissions are very low and unlikely to disrupt electronic devices within range.
HF emissions according to CISPR 11	Class B	The OMEGO® Basic system is suitable for usage in all establishments including residential areas and areas that are directly connected to the PUBLIC SUPPLY GRID, which also supplies residential buildings.
Harmonics emissions according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	

Table 4: Guidelines and manufacturer's declaration – Electromagnetic emissions

Guidelines and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY

The OMEGO® Basic system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the OMEGO® Basic system must ensure that it is used in such an environment.

Immunity Test	IEC 60601-Test Level	Compliance Level	ELECTROMAGNETIC ENVIRONMENT - Guidance
<i>Electrostatic Discharge (ESD) IEC 61000-4-2</i>	<i>± 8 kV contact ± 15 kV air</i>	<i>± 8 kV contact ± 15 kV air</i>	<i>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.</i>
<i>Electrical Fast Transient/Burst IEC 61000-4-4</i>	<i>± 2 kV for power supply lines ± 1 kV for input/output lines</i>	<i>± 2 kV for power supply lines Not applicable</i>	<i>Mains power quality should be that of a typical commercial or hospital environment.</i>
<i>Surge IEC 61000-4-5</i>	<i>± 1 kV differential mode ± 2 kV common mode</i>	<i>± 1 kV differential mode ± 2 kV common mode</i>	<i>Mains power quality should be that of a typical commercial or hospital environment.</i>
<i>Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11</i>	<i>< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 1 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec.</i>	<i>< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 1 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec.</i>	<i>Mains power quality should be that of a typical commercial or hospital environment. If the Users of the OMEGO® Basic System Continued FUNCTION also requests the occurrence of power interruptions, it is recommended that OMEGO® Basic System consists of an uninterruptible Power supply or a battery to feed.</i>
<i>Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8</i>	<i>30 A/m</i>	<i>30 A/m</i>	<i>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</i>

NOTE: U_T is the AC mains voltage before application of the test level.

Table 5: Guidelines and Manufacturers's declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration— ELECTROMAGNETIC IMMUNITY			
The OMEGO® Basic system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the OMEGO® Basic system must ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the OMEGO® Basic system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	IEC 60601-Test Level	Compliance Level	ELECTROMAGNETIC ENVIRONMENT - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Recommended Separation Distance: $d = 1,17\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	$d = 0,35\sqrt{P}$ 80 MHz to 800 MHz $d = 0,7\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:



NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OMEGO® Basic system is used exceeds the applicable RF compliance level above, the OMEGO® Basic system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OMEGO® Basic system.

^b

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [4] V/m.

Table 6: Guidelines and Manufacturers' declaration – Electromagnetic Immunity

Recommended separation distances between portable and mobile RF communications equipment and OMEGO® Basic system			
This OMEGO® Basic system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of OMEGO® Basic system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the OMEGO® Basic system as recommended below, according to maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1,17 \sqrt{P}$	$d = 0,35 \sqrt{P}$	$d = 0,7 \sqrt{P}$
0,01	0,12	0,035	0,07

0,1	0,37	0,11	0,22
1	1,2	0,35	0,7
10	3,7	1,1	2,2
100	12	3,5	7
<p><i>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</i></p> <p><i>NOTES 1: At 80 MHz and 800 MHz, the higher frequency range applies.</i></p> <p><i>NOTES 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</i></p>			

Table 7: Recommended separation distances between portable and mobile RF communications equipment and OMEGO® Basic system

2.1.2 Usage area

Device usage is principally limited to clean, dry interiors in professional health care establishments.

Operation

Temperature: 10 ... 30 °C

Humidity: 30 ... 75 % relative humidity

Air pressure: 70 kPa ... 106 kPa

Storage und transport

Temperature: -20 ... 60 °C

Humidity: 20 ... 90 % relative humidity. No dew

Air pressure: 70 kPa ... 106 kPa

Caution:

The OMEGO® Basic system may not be used in explosion-prone zones AP and APG according to EN 60601-1/2006+A1/2013.

This means, among other things:

The usage of easily inflammable and explosive anaesthetic inhalation materials and mixtures thereof are not permitted within the vicinity of the AMADEO® system. These materials include:

- Diethyl ether
- Cyclopropane



Due to safety reasons the consumption of food and drinks in the vicinity of the device is not permissible.



Do not connect any additional devices to the unoccupied ports of the PC included in the scope of delivery without obtaining information from the manufacturer beforehand. Do not connect the PC integrated in the control cabinet to networks, and do not establish an Internet connection from the PC.



The port at the front of the device may only be used to connect accessories specifically labeled by Tyromotion.

Do not connect any other devices or accessories.

2.2 The OMEGO® Basic System



Image 3: Symbolic image OMEGO® Basic (front side)

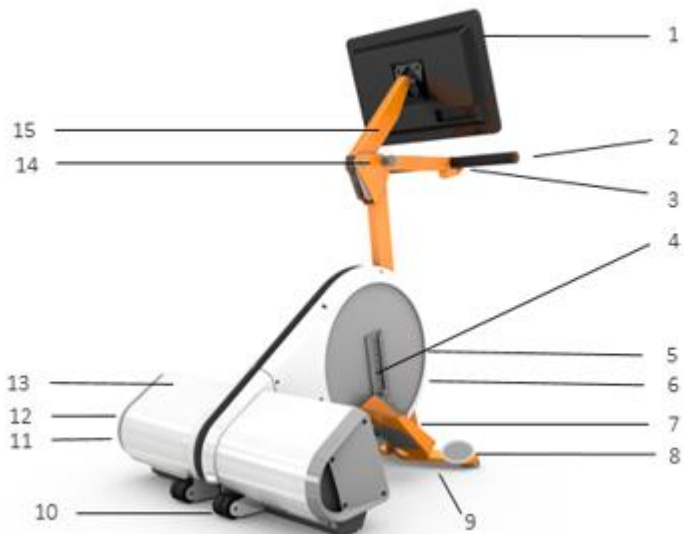


Image 4: Symbolic image OMEGO® Basic (rear side)

1	<i>All-In-One PC with tilt adjustment joint</i>
2	<i>Handles</i>
3	<i>Emergency stop button</i>
4	<i>Pedal radius adjustment mechanism</i>
5	<i>Transportation handle</i>
6	<i>Accessory port</i>
7	<i>Foot rest</i>
8	<i>Self-operable tip-up protection</i>
9	<i>Front standing unit with adjusting feet</i>
10	<i>Rear standing unit with transport castors</i>
11	<i>Power switch</i>
12	<i>Power supply</i>
13	<i>Drive unit</i>
14	<i>Adjustment joint with catch bolt for monitor bracket</i>
15	<i>Monitor arm bracket</i>

Table 8: OMEGO® Basic System components



Only accessories designated as suitable by the manufacturer may be used.



*Hazards posed by tangible parts that are NOT application parts:
The therapist has to instruct the patient to neither hold or lean onto device parts (frame, PC etc.) nor touch them.*

2.2.1 Power supply OMEGO® Basic

Please note that the OMEGO® Basic system is connected to the intended power supply. The power supply switch is located directly on the housing of the drive unit.



WARNING: *To reduce the risk of electric shock, this equipment must only be connected to a supply network with protective earth.*



The system may not be connected to the electric circuit with extension cables.

2.2.2 Installation

Since the required software was already installed on the PC at the time of delivery, the installation on site is limited to the installation of the basic unit, the mounting of the monitor and the power supply.

The system will be unpacked and installed by authorized service representatives of TYROMOTION GmbH (details can be found in chapter 2.5). Do not try to install the system alone.

2.2.3 Repair



Please contact always the manufacturer for repairs!

2.2.4 Disposal – Customer informatin

According to the 2012/19/EU directive on waste electrical and electronic equipment (WEEE-RL) as well as applicable national laws the OMEGO® Basic System may not be disposed of with general domestic waste. The product may only be disposed of at a specialized disposal facility. The product has to be disposed of at a designated disposal facility or at disposal and recycling facility for waste electrical and electronic equipment. It can also be returned to TYROMOTION GmbH.

2.3 OMEGO® Basic adjustment options

2.3.1 Height adjustment of the monitor handle bracket

You have the option to adjust the bracket of the OMEGO® Basic's monitor handle to the patient's height. Hold the PC handle (1) or the monitor handle bracket (2), pull out the catch bolt (3) and keep it in position. You now have the choice of several height positions for the monitor handle bracket. Let go of the catch bolt once you have established a suitable height and it will automatically snap into place



Image 5: Height adjustment of the monitor handle bracket



The monitor handle bracket's height may only be adjusted by the therapist.



The height is to be adjusted slowly and taking into consideration spatial requirements as well as the patient's range of motion.



Always hold the handle/PC carrier tube with one hand before pulling out the catch bolt in order to prevent the handle/PC carrier tube from falling to the ground or tilting backwards, as this could pose a risk of injury for both the therapist and the patient or could damage the All-IN-ONE PC!



*Monitor handle jamming risk
Adjust the position of the monitor handle bracket with care and never grasp the bracket's locking mechanism.*

2.3.2 Pedal radius adjustment

You have the option to adjust the OMEGO® Basic's pedal radius to the patient's needs and the chosen therapy application.

- Loosen the screw on the foot rest with the provided hexagon screwdriver.
- Hold the foot rest and pull out the catch bolt (1).
- You can now adjust the radius of the foot rest on a scaled rail system (2).
- Let go of the catch bolt once you have established a suitable position and it will automatically snap into place.
- Tighten the screw again with the hexagon screwdriver.

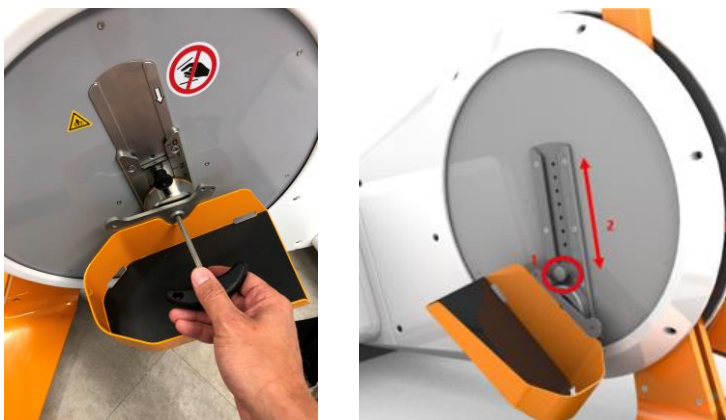


Image 6: Adjustment of the pedal radius

Adjusting the pedal radius while the cranks are in motion or during therapy poses a jamming hazard:

While the cranks are spinning or a therapy session is in process, neither the operator nor any other person may modify the device's pedal radius. Always end the therapy session before entering the main menu for modifications.



Never attempt to modify a moving part!

2.3.3 Foot rest replacement

- Loosen the screw on the foot shell with the provided hexagon screwdriver.
- For the replacement of the foot rest pull out the catch bolt and, on the rail, pull out the foot rest (1).
- Take a new foot rest, pull out the catch bolt, and on the rail push the new foot rest into the desired position (2).
- Let go of the catch bolt once you have established a suitable position and it will automatically snap into place.
- Tighten the screw again with the hexagon screwdriver.

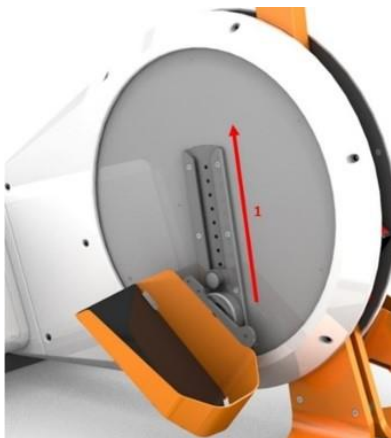


Image 7: Removing the foot rest



Image 8: Mounting the foot rest



Trying to replace the foot rests while the cranks are in motion or during therapy poses a jamming hazard:

While the cranks are spinning or a therapy session is in process, neither the operator nor any other person may modify the device's pedal radius. Always end the therapy session before entering the main menu for modifications.

Never attempt to modify a moving part!

Two foot rest sets are included with the device, one for normal therapy and one for foot drop therapy. For distinguishing purposes the sets are labeled with different article numbers. These article numbers can be found at the bottom of the foot rests and for foot drop therapy foot rests additionally on the foot fixations with magnetic couplings.

Foot rest set – normal therapy



*Image 9: Left foot rest – article number
O.G201*



*Image 10: Right foot rest – article
number O.G200*

Foot rest set – foot drop therapy



*Image 11: Left foot rest – article number
O.G251*



*Image 12: Right foot rest – article
number O.G250*



Image 13: Foot fixation with magnetic coupling

2.3.4 ALL-IN-ONE PC adjustment

When adjusting the height of the handles (see chapter 2.3.1.) the PC height will be modified automatically. Additionally, you can adjust the tilting angle of the tilting joint (1) on the PC's VESA bracket. To do so you only have to hold the monitor on the side and tilt it until it has reached the desired position.



Image 14: All-In-One PC adjustment option

2.4 Wheelchair positioning

When using the OMEGO® Basic with a wheelchair, position the wheelchair as close to the device as possible. Always start with the shortest possible distance between the wheelchair and the OMEGO® Basic. Increase the distance with the progression of the therapy in order to increase the extension of knee and hip joints.



Image 15: Wheelchair positioning



Please make sure the wheelchair brakes have been locked before starting exercise with the OMEGO® Basic. If you exercise with an electric wheelchair the wheelchair has to be switched off and in braking position.

2.4.1 Fastening/unfastening the tilt protection

To prevent the chair/wheelchair to topple during therapy, fasten the tilt protections as follow.

- Position the chair/wheelchair in training position in front of the OMEGO® Basic. (Image 1-4)
- Pull out the belt, hook it to a fixed frame part of the chair/wheelchair and make sure it is securely fastened (Image 2-4)
- Belt stretches. (Image 3-4, image 4-4)



Image 1-4



Image 2-4



Image 3-4

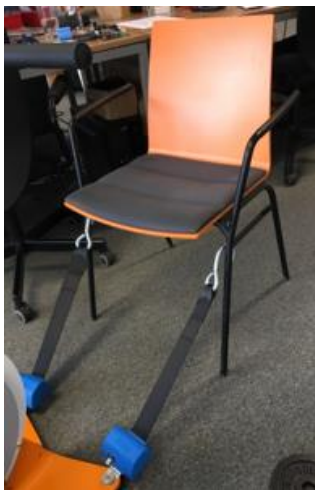


Image 4-4

Image 16: Attaching the safety catch

Unfasten the safety catch as follows (see *Image 17*):

- Push down belt dispenser lever.
- Pull up hook and unclasp it from the chair/wheelchair frame.
- Allow belt to fully retract.



Image 17: Unfastening of safety catch



A spasm or particular functions (e.g. leg press) may cause the patient to fall backwards and, in the worst case, topple over. To prevent this, always use the safety catch and/or only use chairs that can be secured with a safety catch.



Check the wheelchair for stability prior to therapy. If stability is not given the therapy has to be supervised by the therapist at all times.



If a patient is unable to hold onto the handle without assistance the therapy has to be supervised by the therapist at all times.

2.5 Device setup and movement

When installing the device, make sure that the device is placed on an even, non-slanted surface. If necessary, place the device against a wall. The device must be placed at least 30 cm away from other devices, furniture, etc., to ensure optimum ventilation for the drive units.

The OMEGO® Basic System is equipped with 2 rollers that allow the device to be transported within the medical facility.

Procedure for transporting the device:

1. Unplug the cable
2. Pull the transportation handle out of the parking position below the handle.
3. Tilt the OMEGO® Basic onto the 2 transport castors using the transportation handles and move the device.



Image 18: Pull transportation handle out of parking position



Image 19: Tilt OMEGO® Basic using the transportation handles



The OMEGO® Basic's position may not be changed nor may the device be moved as long as the legs are attached and/or in use.



Position the OMEGO® Basic on a flat surface without constant human traffic.



Never move the OMEGO® Basic when patients are in its vicinity. Be careful when moving it over thresholds or bumps.

2.6 Monthly functionality check/Recurring check

2.6.1 Functionality checklist

The functionality check described here must be performed every month. Perform the check even if OMEGO® Basic indicates a malfunction (e.g. in case of unusual sounds, jolting movements, elementary damages etc.). The person responsible for the check must be a certified OMEGO® Basic user.

To be checked:	Malfunction:	To do:
Protective casing	<ul style="list-style-type: none"> • Casings are unstable • Casings are missing • Mounting bolts are missing or loose • Casings are damaged 	<ul style="list-style-type: none"> • Do not perform any further therapies • Contact TYROMOTION GmbH
Visible external deformations	<ul style="list-style-type: none"> • Parts are deformed • Parts are asymmetrical • Parts are faulty 	<ul style="list-style-type: none"> • Do not perform any further therapies • Contact TYROMOTION GmbH
Emergency off-switch	<ul style="list-style-type: none"> • Activating emergency off-switch does not trigger emergency stop 	<ul style="list-style-type: none"> • Do not perform any further therapies • Contact TYROMOTION GmbH
Cleaning	<ul style="list-style-type: none"> • Handles are dirty • OMEGO® Basic is dirty • Foot rests are very dirty 	<ul style="list-style-type: none"> • Do not perform any further therapies • Clean the dirty parts as described in chapter 4.5.2
Locking	<ul style="list-style-type: none"> • Monitor handle bracket locking mechanism is faulty • Foot rest locking mechanism is faulty • Chair safety catch locking mechanism is faulty 	<ul style="list-style-type: none"> • Do not perform any further therapies • Contact TYROMOTION GmbH kontaktieren
Stability	<ul style="list-style-type: none"> • Device skids increasingly during therapy 	<ul style="list-style-type: none"> • Do not perform any further therapies • Check the anti-skid pads on the device's underside • Contact TYROMOTION GmbH

Table 9: Checklist



Usage of the device must be stopped immediately if one of the malfunctions specified in the Table 9: Points for inspection occurs or is suspected.



*Casing damages (e.g. caused by transportation):
Never activate the device if the casing is damaged as this may have unpredictable consequences (e.g. electric shock). Check each point listed in the check list before activation of the device and contact Tyromotion if necessary.*

2.6.2 Recurring check

Recurring checks differ from the checks in chapter 2.6.1; the legislator may demand the check described here while the checks in chapter 2.6.1 are intended, among other things, to detect acute damage or wear of parts that necessitates replacement. The device operator is responsible for performing both checks.

TYROMOTION GmbH has determined an interval of one year for recurring checks. Recurring checks may only be carried out by professional and qualified personnel. The device operator must ensure that the intervals for the recurring checks stipulated by him are observed. Usage of the OMEGO® Basic system must cease if the inspection intervals are not observed.

The recurring check must be performed according to EN 62353:2014.

3 Preparation / Basics

3.1 Set-up and assembly

3.1.1 Assembly

The OMEGO® Basic is shipped pre-assembled. However, certain installation works can only be carried out once the device has been set up at its final destination. The system will be unpacked and installed by specially trained TYROMOTION GmbH staff. The following steps have to be executed prior to the OMEGO® Basic's initial operation:

Fixation of monitor/handle bracket

Fix the monitor/handle bracket in place by moving the bracket towards the catch bolt, then push the rail into the tilting joint until the catch bolt latches. Secure the bracket with the adequate screw to make sure it cannot tilt forwards during adjustments.



Image 20: Monitor/handle bracket, not fixed in place



Image 21: Holding the catch bolt



Image 22: Securing the bracket

Mounting the All-IN-ONE PC on the monitor arm

The All-IN-ONE PC comes fixed to a VESA-bracket and needs to be mounted on the monitor arm. Secure the All-IN-ONE PC with a screw on the monitor arm.

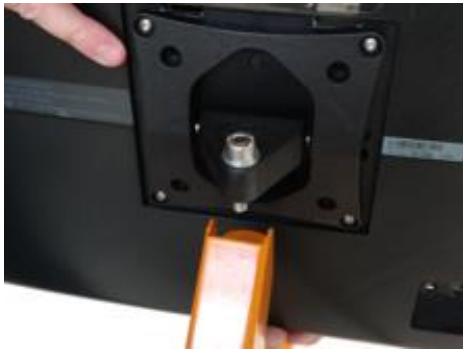


Image 23: Place the All-IN-ONE PC on the bracket



Image 24: Secure the All-IN-ONE PC with a screw on the monitor arm

Then unscrew the cover on the lower right side of the ALL-IN-ONE PC. Take the black round plug for the power supply and plug it into the right connector on the far left. Then take the white USB plug and plug it into one of the two free USB 2.0 ports, which are quite right.

Clamp the cables into the hooks as shown in Figure 29 (a picture is also on the back of the detach cover) and replace the cover over the connectors.



Image 25: All-IN-ONE PC backside



Image 26: cover open



Image 27: Connect power cable



Image 28: Connect USB cable



Image 29: Position of the connections

Mounting the foot rests

As a final step, mount the foot rests. Choose the desired foot rests, pull out the catch bolt and on the slides, push the foot rests into position. Let go of the catch bolt as soon as you have found the desired position and it will automatically lock in place. Also see chapter 2.3.3.

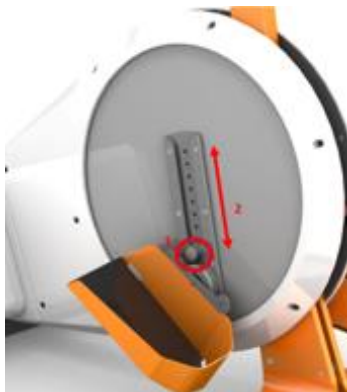


Image 30: Mounting the foot rests

4 Clinical application

4.1 Indications/Contraindications

The OMEGO® Basic Pre-Gait Therapy System is used for the lower extremities rehabilitation. The target group encompasses neurologic, orthopedic, geriatric and pediatric patients with deficits in terms of strength, strength control, endurance, mobility, mobility control, balance, and coordination.

As with any other therapy, the treating medical expert is responsible for medical diagnosis, indication and choice of suitable treatment and therapy. Generally, the same indications and contraindications apply for robotic and computer supported therapies with the OMEGO® Basic as for any manual therapeutic treatment. Knowledge about contraindication is essential in order to not expose the patient to any risks. Always ascertain whether there are one or more contraindications before starting therapy with the OMEGO® Basic. Please note there may be additional indications and/or contraindications that are not listed here but are relevant, and that the following list is not intended to be exhaustive.

Please contact TYROMOTION GmbH in case of any questions or feedback. (Addresses are listed at the beginning of this document as well as on our homepage www.tyromotion.com).

Common indications:

- Stroke (brain hemorrhage, ischemic damage)
- Traumatic brain injury (TBI)
- Spinal cord injuries
- Paraplegia, tetraplegia
- Spastic flaccid paralysis
- Cerebral palsy (CP)
- Chronic conditions like multiple sclerosis (MS)
- Morbus Parkinson
- Geriatrics
- Cardiovascular diseases, if approved by the treating physician
- Motor neuron diseases, e.g. amyotrophic lateral sclerosis (ALS)
- Post-operative rehabilitation, e.g. after knee or hip endoprosthetics (K-TEP, H-TEP), s/p cruciate ligament reconstruction
- Lower extremity fractures and injuries (remodeling phase)
- Degenerative joint disease (lower extremity) (e.g. arthrosis)
- Myopathy
- Muscular dystrophy

- Amputation
- Edema

Absolute contraindications: To not use the device!

- Acute, pronounced pain despite conventional pain therapy
- Adjustability and patient position: Do not use the OMEGO® Basic System for training if it is impossible to adjust the device and the individual physiological patient position, especially in case of contractures or severe spasticity (stiff/rigid joints) of the lower body region.
- Body weight above 150 kg (330 lbs)
- Shorter than 130 cm (4 ft 3) or taller than 200 cm (6 ft 6)
- Insufficient compliance, e.g. patients with severe mental illnesses or severe neurotic disorders.
- Osseous instability (non-consolidated fractures, osteopenia, severe osteoporosis, osteogenesis imperfecta, unstable vertebral column, pseudoarthrosis)
- Cardial contraindications
- Lower extremity angiopathies
- Severe ataxia
- Osteomyelitis
- Open wounds and ulcers in areas that will be in contact with the device (decubitus)
- Severely impacted range of motion that can be jeopardized by low-level passive movement training (risk of injury)
- Medical conditions that prohibit active rehabilitation (e.g. respiratory diseases, orthopedic disorders, cognitive deficits that limit communication; neuropsychological conditions, infections or inflammatory diseases, osteomyelitis)

Relative contraindications:

Assessment of a patient's suitability for the OMEGO® Basic Therapy System in case of the following is up to the treating physician or therapist:

- Apraxia
- Arthritis of the lower extremity joints
- Risk of autonomous dysreflexia (severity level TH6 or higher; prior AD increases the risk of exacerbation)
- Reduced compliance, e.g. patients with cognitive limitations, medication
- Uncooperative or (auto-)aggressive behavior (e.g. transient psychotic syndrome)

- Cardiac diseases, e.g. heart failure and thoracotomy, uncontrolled orthostatic hypotension or other circulatory problems, circulatory disorders of the lower limbs
- Recent joint operations, e.g. total endoprosthesis, knee- or hip joint replacement, reconstruction of the cruciate ligament or meniscus
- Consolidated fractures in the lower extremities area
- Epilepsy
- Infections/swellings/ulcers/after-effects of prior injuries, especially of the lower extremities
- Mechanical respiration
- Longterm infusions (e.g. Baclofen pump, intrathecal pumps, PEG tube ...), other stimulators (e.g. pacemaker, nerve stimulators)
- Enterostomies/ostomies/Anus praeter (artificial anus)
- Osteoporosis
- Sensory impairments of the lower extremities and torso, especially impaired experience of pain. Patients with sensory impairments may be unable to feel possibly occurring pain.
- Skin problems: Check for existing wounds and pressure sores or wounds and pressure sores resulting from training with the device before and after each therapy session, and pay special attention to body parts exposed to the device.
- Pregnancy
- Patients with inadequate joint stabilization. It is up to the treating medical expert to decide whether forces, joint angles and speed of movement during the therapy pose a risk for the patient.

Is the system suitable for the designated therapy:



- 1. Constant monitoring of the patient's therapy progress.*
- 2. Monitoring of current relevant studies.*
- 3. Therapy adjustment in case the patient's condition deteriorates excessively.*

4.2 Safety

4.2.1 Safety concept

The OMEGO® Basic is a mechatronic therapy system used for the rehabilitation of all gait-relevant bodily functions.

The 2 separate motors are centrally controlled by the software installed on the PC. In order to preclude the exertion of strong forces during therapy (e.g. in case of sudden spasticity) or too big a range of motion on the patient several safety measures have been put in place:

- The motors' separate speed is limited to a maximum of 80 RPM.
- During therapy, the forces exerted on the motors are being constantly measured so they can be switched off immediately in case the limit is exceeded.
- For the foot drop therapy, there are clearly separated mechanic foot connections that limit the maximum force exerted on the patient by means of a magnetic coupling. In case the magnetic force limit (> 70N) is exceeded, the foot will automatically be released from the foot rest.
- The device has an emergency shutdown button for cases of unpleasant or (seemingly) risky situations during therapy. By activating the emergency shutdown function the motors will be deactivated, and the software will display the message "The Emergency-button has been pressed".
- A continuous supervision of the therapy by a therapist or physician is recommended in any case.



The patient's suitability for OMEGO® Basic is to be assessed by the treating physician or therapist.



The suggested therapy duration is approx. 30-60 min/day but the actually permissible duration is highly dependent on each patient's general condition and capacity and thus has to be assessed individually.



Prior to therapy the treating physician or therapist has to assess if and how long the patient can manage independently, taking into consideration the patient's cognitive capacities as well as the general condition.



Deterioration of postural stability: Patients suffering from an impaired balance while sitting have to be monitored and supported throughout the therapy.



The device and its control elements (software) may only be operated by trained therapists. Make sure the patient does not change any settings during therapy.



If the therapist is leaving the patient's range of vision and/or is out of earshot, the therapy has to be paused.



Patients with limited cognitive capabilities have to be monitored at all times.



The OMEGO® Basic may not be moved nor may its position be changed during an ongoing therapy.



Only start the OMEGO® Basic once the patient is secured.



Over-extension of the knees: The range of motion may be set inaccurately, which can cause a high mechanic pressure on the knee joint and/or hip. Please always check the range of motion settings.



Trying to adjust the device while the cranks are in motion or during therapy poses a jamming hazard:

While the cranks are spinning or a therapy session is in process, neither the operator nor any other person may modify the device's mechanic settings (pedal radius, height adjustment of handles, foot rest replacement etc.).

Never attempt to modify a moving part!



Limiting the means of escape:

The mechanic fixation of the foot shovel to the device may result in the patient's delayed departure (e.g. in case of fire alarm). Make sure a trained person who, in the case of a dangerous situation, can unfasten the fixation supervises the patient.



The therapy of children (6 years and older) has to be supervised by a therapist at all times.



The suitability of children over the age of 6 years has to be assessed by the treating physician or therapist. Due to their body structure and insufficient compliance children aged 5 years and younger are not suited for therapy with the device.



For a height below 130cm special care has to be taken with regards to the range of motion.



Please also refer to the tyroS software manual.

4.2.2 Residual risk

An unpredictable residual risk remains for manual hand therapy despite all safety precautions. In rare cases, the patient may experience minor pinching or crushing injuries even during proper operation. However, the probability of such injuries is very low, and the injuries should not be severe. TYROMOTION GmbH can provide a detailed risk analysis upon request.

4.3 Prior to training

4.3.1 Activating the OMEGO® Basic systems

The system can be activated after it has been properly connected. Activate the device with the power switch. All components are now being supplied with electricity. Then turn on the PC power switch to boot the PC. The PC status light indicates that the PC has been turned on. The operating software can now be started after logging into Windows.

4.4 Application

The device settings have to be adjusted to the respective patient prior to his/her first therapy session with the OMEGO® Basic.

Furthermore we recommend suggesting the patient washes and disinfects his/her hands.

Choose the OMEGO® Basic in the tyroS menu "Device selection". The OMEGO® Basic will then run a reference run. Once this is completed, the foot rests lock into the easy entry position and the feet can be secured in the foot rests.



Only attachment systems provided by Tyromotion may be used to attach the patient. Other attachment systems may pose a hazard.



Risk of injury by stuck clothes: The patient has always wear suitable, tight clothes. Wide pants, long scarves and shawls, long hair etc. may get caught in the pedals. The patient has not wear necklaces, jewelry or similar. The patient has always wear closed footwear without laces.



All settings, especially maximum speed, maximum force and maximum range of motion have to be determined with the treating physician prior to the first therapy session.



During therapy, only trained personnel may be around the patient and therapy system. Ideally, the therapist is right next to the patient to instruct him/her during therapy.



Patients who cannot sit upright unassisted have to be brought into a position suitable for therapy and secured by appropriate means.



For the entire therapy, please also refer to the tyroS software manual.

Position the patient with the wheelchair or chair in front of the OMEGO® Basic and attach the safety catch to the wheelchair or chair. In case you use a chair it should have a shoulder-high backrest. Position the user as close to the OMEGO® Basic as possible and secure the feet in the foot rests (chapter 4.4.2). Always start with the shortest possible distance between the wheelchair and the OMEGO® Basic. Increase the distance with the progression of the therapy in order to increase the extension of knee and hip joints.

4.4.1 Patient information

In the context of repeated therapy, patient specific data (name, range of motion, max. strength, max. speed, asymmetries in leg movement etc.) is saved in the OMEGO® Basic System and an encrypted version is stored in tyroS. Furthermore, type, duration and results are recorded to be used for a targeted evaluation. This data will not be passed on to Tyromotion GmbH but will remain with the device operator. Country-specific data protection laws are to be observed!

4.4.2 Securing the feet

Make sure the OMEGO® Basic is not in training mode while you are trying to secure the patient's feet in the foot rests. If necessary, the OMEGO® Basic can be halted via the operator control module and the display module.

Only secure the feet with the patient in a sitting position. Make sure the feet are firmly and correctly placed in the foot rests.

4.4.2.1 Securing feet with Velcro® straps

Place the Velcro® strap over the bridge of the foot and fasten it tightly on the foot rest's underside.



Image 31: Securing the foot with the Velcro[®] strap



Fastening the foot fixation too tightly may cause reduced blood supply to legs and feet. Prior to therapy, make sure the fixation is conveniently fastened and/or ask the patient if he/she experiences circulatory disorders.



*Jamming hazard caused by incorrect fixation of the feet in the foot rests:
Always make sure the patient's feet are firmly secured in the foot rests.*

4.4.3 OMEGO Basic® Applications

After securing the feet you can choose from the following applications in the tyroS software:

- Cycling
 - The patient performs a circular movement against a defined drag. The aim is for the patient to keep up the step frequency specified by the therapist. The assistive mode supports the patient in achieving the predefined step frequency. The support intensity can be adjusted.
- Stepping
 - The patient performs a climbing movement (similar to climbing stairs) against a defined drag. The aim is for the patient to keep up the step frequency specified by the therapist. The assistive mode supports the patient in achieving the predefined step frequency. The support intensity as well as the intensity of impact at the reverse point can be adjusted.
- Leg press
 - The patient performs a stretching movement with both legs against a defined drag. The aim is for the patient to break through the predefined drag and to perform a set number of repetitions or to perform the exercise for a set amount of time. The assistive mode supports the patient in achieving the predefined step frequency. The intensity of impact at the reverse point can be adjusted.
- Foot drop
 - The patient performs a dorsal- and/or plantar flexion against a defined drag. The aim is for the patient to break through the predefined drag and to perform a set number of repetitions or to perform the exercise for a set amount of time. The intensity of impact at the reverse point can be adjusted.
- Sensoric
 - Aim of the sensoric therapy is the perception of external and internal stimuli as well as different leg and foot positions. The exteroception therapy's aim is for the patient to determine which pedal was vibrating.
- Therapeutic games
 - Interactive therapeutic games (e.g. rhythm or symmetry training) to motivate the patient to actively train leg strength, leg movement, movement control, selective activation of a desired side or reation and/or timing by means of control via strength or range of motion.



You can find more detailed information regarding the application of the various programs in the tyroS software manual.

Depending on mode the patient can be involved passively, assistively or actively. An integrated sensor technology facilitates the capture and evaluation of the leg forces and/or position. The OMEGO® Basic moves the legs according to movement parameters that can be configured in the tyroS software. The uncoupled motors can move the legs either uni- or bilaterally. The range of motion (ROM) can be configured unilaterally (flexion-extension) for each patient and each leg individually and taking into account anatomical and physiological restrictions of the range of motion.

4.4.4 Foot drop therapy applications

With the OMEGO® Basic you have the option to conduct a therapy for foot drop patients. In order to do so you have to mount the foot rests with article numbers O.G250 and O.G251 on the OMEGO® Basic (1-4 and 2-4). The feet will be secured in the foot rests by means of a magnetic coupling (3-4 and 4-4), which allow for a quick and safe release in case of an emergency.



Image 1-4



Image 2-4



Image 3-4



Image 4-4

Image 32: Securing the feet for foot drop therapy



Image 33: Release of the foot rest in case the magnetic force is exceeded (> 70N)

A special training for operators performing this therapy is compulsory.



Please note that a separate mechanic foot attachment with magnetic coupling is available for this application. This will restrict the maximum force and thus allow for a quick release from the foot rest in case of an emergency.

4.5 After application

Release the foot fixation after you have finished the application and move the chair/wheelchair away from the device. Always pay attention to the patient's postural stability.

4.5.1 Turning off the OMEGO Basic® System

Before you can turn of the OMEGO® Basic System you have to exit the operating system, tyroS, [Exit program] and exit Windows via the task "Start >> Shut down". You can now switch off the system via the mains switch.



Please also refer to the tyroS manual.

4.5.2 Cleaning the OMEGO Basic®-Systems and accessory parts



*Transmission of germs between patients:
Always adhere to the cleaning instructions as stated in this manual.*



*Compulsory disinfection measure:
Disinfect handles after therapy.*

The following instructions apply to the manual cleaning of medical devices by Tyromotion GmbH.

Thorough cleaning and wiping is essential for the first time and reuse of reusable medical devices. Effective cleaning must be performed to achieve adequate decontamination. The goal of cleaning is to remove any visibly sticky soil and reduce the number of particles and microorganisms.

Cleaning must be carried out in a manner that minimizes the risks posed by pathogens. The devices of the Tyromotion GmbH must be cleaned and disinfected after delivery before the first and any further use on the patient.

4.5.2.1 Detergents and disinfectants

When selecting cleaning agents and disinfectants, it is essential to ensure that it is suitable for cleaning and disinfecting medical devices and for acrylic glass. For this purpose, cleaning agents and disinfectants based on ethanol, propanol, H₂O₂, chlorine are suitable (for example Bacillol®, Bacillol® plus, INCIDIN extra, INCIDIN pro). Detergents should be used at the concentration and duration recommended on the label and product information. Each disinfectant has a specific exposure time (pay attention to the label and product information before use) until the micro-organisms are rendered harmless as far as possible. This interval is to wait before wiping.

4.5.2.2 water

The quality of the water should be carefully selected for use with cleaning agents and for wiping during the cleaning process. The hardness of the water is crucial because deposits left on the medical devices could result in ineffective cleaning and decontamination.

4.5.2.3 instruments

Clean, lint-free and non-abrasive cloths.

Do not use scouring agents, metal brushes or scouring pads.

4.5.3 cleaning process

To minimize the risk of germ transmission, all surfaces and objects that are touched by both the patient and the therapist should be periodically cleaned and disinfected. These include e.g. also monitor, foot shells, bracket monitor handle, housing, etc.

1. If the patient perspires heavily during use, wipe the OMEGO® Handgrips dry after the therapy before disinfecting them.
2. Moisten the disposable cloth, according to the product information leaflet, only slightly with disinfectant. Wipe OMEGO® Hand Grips, Greaves, Foot Cups with the clean, soft and lint-free cloth. Observe the contact time of the disinfectant used according to the label and product information.
3. Depending on the disinfectant, it may be necessary to wipe the disinfected area with water after the exposure time.
4. Dry the area wiped with water with a clean, non-abrasive, soft, lint-free cloth.

To clean the loops, proceed as follows:

1. Use a disinfectant spray (such as Bacillo® 30 Foam) to disinfect the fabric after each treatment.
2. Clean the loops of the foot cup and the greaves weekly in the washing machine at 40 ° C in the gentle cycle with the addition of a Hygienespülers be cleaned. The use of a wash bag is recommended.

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