TENDER SPECIFICATION
OMEGO®, OMEGO® Plus

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No.	SPECIFICATION
1.	**General**
1.1.	Robot-assisted rehabilitation device for functional lower limb therapy
1.2.	End-effector device
1.3.	Occupational and physical therapy device
1.4.	Training for all phases of gait rehabilitation
1.5.	Uni- and bilateral therapy
1.6.	One device for leg press, stepper, cycling, foot lifter and symmetry training
1.7.	Inpatient and outpatient rehabilitation
1.8.	Multifunctional Tyromotion chair (see 3d.)
1.9.	Sensor system for force assessment
1.10.	2 decoupled drives for symmetry detection
1.11.	Fast fixation footrest set
1.12.	Ankle joint training footrest set incl. magnetic connection
1.13.	Tool-free footrest replacement
1.14.	Adjustable footrest position (10 levels)
1.15.	2 footrest straps
1.16.	2 leg splints (therapy in case of limited knee stability)
1.17.	Waist belt and chest belt for patient fixation/stabilization
1.18.	Wheelchair compatible
1.19.	Fixation straps for seat/wheelchair fixation
1.20.	Adaptable handles in height and length
1.21.	Tilt protection
1.22.	OMEGO® Plus therapy poster set (3 large-sized posters showing therapy possibilities)
1.23.	All-in-one PC (19,5") with anti-glare coating
1.24.	Emergency switch off
1.25.	Audio output
1.26.	Scientific i/o interface
1.27.	Wi-Fi
1.28.	USB port
1.29.	For children and adults
2.	**Application**
2.1.	Indications: Stroke (cerebral hemorrhages, ischemic damages), Traumatic brain injury (TBI), Spinal cord injury (SCI), 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 endoprosthetic (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
2.2.	Absolute contraindications: acute pain despite conventional pain therapy, impossibility to adjust system to the patient's individually physiologic position, especially in case of contractures or severe spasticity (joint is fixed/rigid) of the lower region, body weight above 150 kg (330 lbs), Body height 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, cardiac 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, neuro-psychological conditions, infections or inflammatory diseases, Osteomyelitis) For relative contraindications please refer to the user manual.
2.3.	Acute, sub-acute, chronic phases of rehabilitation
2.4.	Proximal and distal lower extremity therapy
2.5.	Therapy in case of zero or limited lower extremity ROM
2.6.	Eccentric, concentric, and isometric training
2.7.	Training of dorsiflexion
2.8.	Active therapy
2.9.	Assistive therapy
2.10.	Passive therapy
2.11.	Verticalization
2.12.	Mobilization of hip, knee, angle
2.13.	Attention functions (ICF b140)
2.14.	Perceptual functions (ICF b156)
2.15.	Functions of the cardiovascular system (ICF b410-b429)
2.16.	Functions of the respiratory system (ICF b440-b449)
2.17.	Mobility of joint functions (ICF b710)
2.18.	Stability of joint functions (ICF b715)
2.19.	Muscle power functions (ICF b730)
2.20.	Muscle tone functions (ICF b735)
2.21.	Muscle endurance functions (ICF b740)
2.22.	Control of voluntary movement functions (ICF b760)
2.23.	Changing and maintaining body positions (ICF d410-d429)
2.24.	Walking and moving (ICF d450-d469)
2.25.	Gait pattern functions (ICF b770)
2.26.	Structure of lower extremity (ICF s750)
2.27.	Treatment of contractures
2.28.	Treatment of edemas
2.29.	Tonus treatment and regulation
2.30.	Sit-to-stand training
2.31.	Step initiation
2.32.	Stimulation of metabolism
2.33.	Repetitive movement execution
2.34.	Bilateral symmetric movement execution
2.35.	Proprioception

2.36.	Gamification to engage and motivate patients
3.	**Software**
3a.	**General**
3a.1	Cross-device TyroS software
3a.2	21 languages
3a.3	User-friendly interface for therapists
3a.4	Therapist control of adjustable movement training parameters
3a.5	Full screen mode
3a.6	Visual and audio feedback for patients during use
3a.7	Control via touchscreen
3a.8	Reporting at the end of the therapy
3b.	**Assessments**
3b.1	Proprioception assessment (feel and replicate a leg movement)
3b.2	Movement modulation assessment (smoothness and symmetry of a cycling movement)
3b.3	Force assessment (max. left/right leg strength; sit-to-stand strength)
3c.	**Therapies**
3c.1	Stepper mode
3c.2	Leg press mode
3c.3	Ankle joint training
3c.4	Sensory training
3c.5	Cycling mode
3c.6	Symmetry and rhythm detection and training
3c.7	Spasticity detection
3c.8	Patient's ROM limitations are set up before therapy starts
3c.9	Movement counting
3c.10	Set speed, assistance, and resistance
3c.11	Direct progression feedback graph
3c.12	Different display modes (assistive, cadence, power, symmetry)
3c.13	Semi-immersive therapy
3c.14	1D therapy programs (accuracy, reaction)
3c.15	1D therapies are controlled by a start and stop position of the patient's legs
3c.16	Directions in 1D therapy programs can be changed easily during active therapy to enhance cognitive functions
3c.17	Active therapy programs with 10 different levels
3c.18	Switching from one level to the next can be done manually or automatically
3c.19	Amount of time for each therapy can be manually adjusted
3c.20	Sensitivity can be changed during active therapy (50%, 75% or 100%)
3c.21	Feedback is given after the end of each level
3c.22	Sequencing option
3c.23	Visually simplified therapy mode
3d.	**OMEGO® Plus (Tyromotion chair)**

3d.1	Multifunctional chair to expand therapy possibilities
3d.2	Manufacturer: Lemi Group (IT)
3d.3	According to rule 9 of the commission guideline 93/42/EWG, appendix IX, the Tyromotion chair is Medical Device Class I.
3d.4	Therapy in sitting, standing and lying position
3d.5	Height-adjustable
3d.6	Adjustable back angle and position
3d.7	Neck cushion
3d.8	Armrests
3d.9	180° pivotable chair for easy access
3d.10	Steering rollers for mobility and easy access
3d.11	Wheel fixation
3d.12	Remote control unit
3d.13	Emergency button
3e.	**FES Module** (availability according to regional certificates)
3e.1	FES-enhanced therapy for stepper, leg press, cycling
3e.2	RehaMove Stimulator incl. accessories
3e.3	OMEGO® FES Software License
3e.4	Up to 8 channels simultaneously
3e.5	Stimulation frequency 10 – 50 Hz in steps of 5 Hz
3e.6	2 electrode cables
3e.7	Surface electrodes
3e.8	Quick stop button
3e.9	Medical IIa device according to EU guidelines MDD 93/42/EWG
3e.10	Certified according to the international standards EN 60601-1 and EN 60601-2-10 for medical technical devices and systems
3f.	**Database**
3f.1	HL7, version 2.3
3f.2	Database includes detailed therapy history of each patient
3f.3	Patient details store assessment and therapy history (date, time, duration, type of therapy, device, comments)
3f.4	Patient report is generated and reflects progression
3f.5	Report sheet can be customized by the therapist
3f.6	Report sheet can be exported (print/PDF/TXT)
3f.7	Patient data can be archived, saved, deleted, imported and/or exported
3f.8	Automated data backup
3f.9	Access to patient data from all Tyromotion devices via server
3f.10	Database facilitates collaboration between different therapy departments
3f.11	Databank capacity for more than 500 patients
3f.12	Data protection can be enhanced by concealing single columns
4.	**Technical Specification**

4.1.	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.
4.2.	Type of application part	Type B
4.3.	Protection against electric shock	Protection class I device – protective grounding
4.4.	Electromagnetic compatibility	Class B device (CISPR 11) The OMEGO® system may only be used in the living area under the responsibility of a health care professional. EN60601-1, the requirements are fulfilled.
4.5.	Country of Origin	Austria
4.6.	Power supply voltage	110 – 240V~ Alternating current
4.7.	Supply frequency	50/60 Hz
4.8.	Electricity/Power consumption	16A – 7A / 1800W – 1700W
4.9.	Supply grid	Only connect to supply grids with protective ground wiring
4.10.	Operating type	Continuous operation
4.11.	Fuses	Secured for all poles (2x T16A L 250V)
4.12.	Power supply drives	48V DC
4.13.	Maximum velocity	80 U/min
4.14.	Nominal drive performance	800 Watt / drive
4.15.	Maximum torque	65 Nm unilateral / 50 Nm bilateral
4.16.	Measurement range torque measurement	±70Nm
4.17.	Measurement error torque measurement	±2Nm±5%
4.18.	Weight	75kg / 165 lbs
4.19.	Dimensions (WxLxH)	985 x 827 x 1145 mm
4.20.	Penetration protection	IP 20
4.21.	Operation	Temperature: 10 ... 30 °C Humidity: 30 ... 75 % relative humidity
4.22.	Storage and transport	Temperature: -20 ... 60 °C Humidity: 20 ... 90 % relative humidity, no dew
5.	**Installation, Service and Warranty**	
5.1.	Standard installation (shipping and special installation costs on request)	
5.2.	One-year standard warranty of all equipment items includes parts, scheduled and breakdown services by qualified maintenance personnel	
5.3.	Helpdesk and remote support	
5.4.	Reaction time within 24 hours	
5.5.	Maintenance carried out by a Tyromotion certified technician 1x per year	
6.	**Certificates**	
6.1.	CE Certificate	
6.2.	FDA listed	
6.3.	Certificate ISO 13485 EN	
6.4.	Certificate Annex II 93/42/EEC	
6.5.	Please see list for specific country approvals	

7.	**Cleaning and Disinfection**
7.1.	Disinfect OMEGO® handles after usage
7.2.	Disinfect OMEGO® Chair after usage
7.3.	Disinfection of straps and splints after each treatment
8.	**Clinical Application Training**
8.1.	Clinical application training material
8.2.	On-site clinical application training with Tyromotion clinical application specialist
8.3.	Follow up training for experienced users to become advanced users
8.4.	E-Learning platform TyroAcademy