

# TENDER SPECIFICATION DIEGO®

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No.	SPECIFICATION
<b>1.</b>	<b>General</b>
1.1.	Robot-assisted rehabilitation device for functional therapy of shoulder, arm and hand
1.2.	End-effector device
1.3.	Occupational and physical therapy device
1.4.	Uni- and bilateral therapy
1.5.	Intelligent weight relief for the upper extremity (individually adjustable)
1.6.	Inpatient and outpatient rehabilitation
1.7.	Flexible arm attachment system
1.8.	Magnetic couplings between arm slings and cords (The magnetic couplings disengage the connection between arm slings and rope traction mechanics if the tractive force is exceeded by 60 N / 25 N for child magnets)
1.9.	Variable, full to partial, support of upper limb weight
1.10.	Free arm and hand movement in a 3-dimensional space
1.11.	Integration of real life objects
1.12.	Wheelchair compatible
1.13.	Steering rollers for mobility
1.14.	2 arm units
1.15.	Arm sling set
1.16.	Cleanable and replaceable straps
1.17.	Portable rack built-in PC and Monitor (23,8")
1.18.	Mouse, mouse pad and keyboard
1.19.	Emergency switch off
1.20.	Audio output
1.21.	Scientific i/o interface
1.22.	Wi-Fi
1.23.	USB port
1.24.	For children and adults
<b>2.</b>	<b>Application</b>
2.1.	Indications: Stroke (cerebral hemorrhages, ischemic damages), Traumatic brain injury (TBI), Spinal cord injury (SCI), Brain tumor, Parkinson's disease, chronic diseases, e.g. Multiple Sclerosis (MS), Cerebral Palsy (CP), motor neuron diseases, e.g. Amyotrophic Lateral Sclerosis (ALS), muscular dystrophies, amputation, post joint surgery, post joint replacement, fractures and injuries (remodeling phase), musculoskeletal disorders, e.g. tendon injuries, attention deficit hyperactivity disorder (ADHD), neglect
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 trained body region, children under the age of 5 years or patients with similar body structure to children (risk of injury), insufficient compliance, e.g. patients suffering from severe psychotic diseases or severe neurotic disorders, high grade Ataxia, severe osteoporosis (risk of fractures), unstable or still inadequately consolidated fractures of the body region to be trained  For relative contraindications please refer to the user manual.
2.3.	Acute, sub-acute, chronic phases of rehabilitation
2.4.	Proximal and distal arm therapy

2.5.	Therapy in case of limited upper extremity ROM
2.6.	Assistive therapy
2.7.	ADL-therapy
2.8.	Attention functions (ICF b140)
2.9.	Memory functions (ICF b144)
2.10.	Psychomotor functions (ICF b147)
2.11.	Perceptual functions (ICF b156)
2.12.	Mobility of joint functions (ICF b710)
2.13.	Stability of joint functions (ICF b715)
2.14.	Muscle power functions (ICF b730)
2.15.	Muscle endurance functions (ICF b740)
2.16.	Carrying, moving and handling objects (ICF d430-d449)
2.17.	Self-care (ICF d510-d599)
2.18.	Household tasks (ICF d630-d649)
2.19.	Structure of upper extremity (ICF s730)
2.20.	Control of voluntary movement functions (ICF b760)
2.21.	Complex movements in 3-dimensional space
2.22.	Achieving active and efficient motions without compensation
2.23.	Repetitive movement execution
2.24.	Bilateral symmetric movement execution
2.25.	Proprioception
2.26.	Gamification to engage and motivate patients
<b>3.</b>	<b>Software</b>
<b>3a.</b>	<b>General</b>
3a.1	Cross-device TyroS software
3a.2	21 languages
3a.3	User-friendly interface for therapists
3a.4	Full screen mode
3a.5	Therapist control of adjustable movement training parameters
3a.6	Visual and audio feedback provided to patients during use
3a.7	Reporting at the end of the therapy
<b>3b.</b>	<b>Assessments</b>
3b.1	Shoulder joint adduction-abduction
3b.2	Shoulder joint flexion-extension
3b.3	Shoulder joint horizontal
3b.4	Shoulder joint rotation
3b.5	Elbow flexion-extension
3b.6	Angle measurement in neutral-zero methode
<b>3c.</b>	<b>Therapies</b>
3c.1	Autonomous task-oriented training with motivational aspect

3c.2	Patient's ROM limitations are set up before therapy starts	
3c.3	Feel free active therapy program (facing the screen or ADL-training with intelligent weight relief)	
3c.4	Symmetry therapy	
3c.5	Movement counting	
3c.6	1D therapy programs (accuracy, reaction)	
3c.7	1D therapies are controlled by a start and stop position of the patient's fingers	
3c.8	Directions in 1D therapy programs can be changed easily during the active therapy to enhance cognitive functions	
3c.9	2D therapy programs (motoric, cognitive)	
3c.10	2D therapies in frontal/sagittal plane or the transversal plane	
3c.11	Neuropsychological training by Verena Schweizer	
3c.12	Active therapy programs with 10 different levels	
3c.13	Switching from one level to the next can be done manually or automatically	
3c.14	Amount of time for each therapy can be manually adjusted	
3c.15	Sensitivity can be changed during active therapy selecting from 50%, 75% or 100%	
3c.16	Feedback in form of stars is given after the end of each level	
3c.17	Sequencing option	
3c.18	Visually simplified therapy mode	
<b>3d.</b>	<b>DIEGO® VR</b>	
3d.1	Semi-immersive therapy	
3d.2	Immersive therapy	
3d.3	Pico Neo 3 VR Goggles	
3d.4	Disposable Hygiene Covers for VR Goggles	
3d.5	TyroS software incl. VR package	
<b>3e.</b>	<b>Database</b>	
3e.1	HL7, version 2.3	
3e.2	Database includes detailed therapy history of each patient	
3e.3	Patient details store assessment and therapy history (date, time, duration, type of therapy, device, comments)	
3e.4	Patient report is generated and reflects progression	
3e.5	Report sheet can be customized by the therapist	
3e.6	Report sheet can be exported (print/PDF/TXT)	
3e.7	Patient data can be archived, saved, deleted, imported and/or exported	
3e.8	Automated data backup	
3e.9	Access to patient data from all Tyromotion devices via server	
3e.10	Database facilitates collaboration between different therapy departments	
3e.11	Databank capacity for more than 500 patients	
3e.12	Data protection can be enhanced by concealing single columns	
<b>4.</b>	<b>Technical Specification</b>	
4.1.	Classification	According to Regulation 9 of the Council Directive 93/42/EEC Annex IX and the current supplement 2007/47/EC, the DIEGO® system is an

		active therapeutic medical product, Class IIa since the energy transferred from the DIEGO® to the patient does not pose a danger for the patient or user.
4.2.	Type of application part	Type BF
4.3.	Protection against electric shock	Protection class I device – protective grounding
4.4.	Electromagnetic compatibility	Class B device (CISPR 11) The DIEGO® 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.	Properties of traction ropes	Diameter: 0.6mm Material: Dyneema mesh Load-bearing capacity: 90.6 kg
4.7.	Max. speed at end of rope	Active mode (unloaded): 1.7 m/s Passive mode: 2 m/s
4.8.	Strain relief / tensile force	Maximum adjustable strain relief per rope: 20 N Maximum possible tensile force per rope : 35 N
4.9.	Nominal power of motors	Max. power of motors: 70 Watts/Motor Measurement range of force sensors: 0-100N per sensor (limited by the holding strength of magnet couplings, see manual) Force measurement accuracy: $\pm 2 \text{ N} \pm 5 \%$
4.10.	Angle measurement	Angle measurement accuracy: $\pm 1^\circ$
4.11.	Power supply voltage	110 – 240V~ Alternating current
4.12.	Supply frequency	50/60 Hz
4.13.	Electricity/Power consumption	5-2A / 500W
4.14.	Power supply grid	Only connect to supply grids with protective ground wiring
4.15.	Operating type	Continuous operation
4.16.	Device fuses	All poles secured (2x T 5A H 250V, Dimension: 5x20mm)
4.17.	Supply voltage for motors	24V DC
4.18.	Weight	65kg / 143 lbs
4.19.	Save workload	60N / rope (4 ropes)
4.20.	Total system dimensions (LxWxH)	1273 x 900 x 2406 mm
4.21.	Penetration protection	IPXO
4.22.	Operation	Temperature: 10 ... 30 °C Humidity: 30 ... 75 % relative humidity
4.23.	Storage and transport	Temperature: -20 ... 60 °C Humidity: 20 ... 90 % relative humidity, no dew
<b>5.</b>	<b>Installation, Service and Warranty</b>	
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	
<b>6.</b>	<b>Certificates</b>	

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
<b>7.</b>	<b>Cleaning and Disinfection</b>
7.1.	Wash the smart arm slings and hygienic cloth at 30°C using a gentle cycle and a hygienic detergent for disinfection.
7.2.	Disinfect VR goggles after usage
<b>8.</b>	<b>Clinical Application Training</b>
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