

TENDER SPECIFICATION AMADEO®

Table of content

- 1. General**
- 2. Application**
- 3. Software**
 - 3.a General
 - 3.b Assessments
 - 3.c Therapies
 - 3.d EMG Module
 - 3.e Database
- 4. Technical Specification**
- 5. Installation, Service and Warranty**
- 6. Certificates**
- 7. Cleaning and Disinfection**
- 8. Clinical Application Training**



No.	SPECIFICATION
1.	General
1.1.	Robot-assisted rehabilitation device for functional therapy of the hand, fingers and thumb
1.2.	End-effector device
1.3.	Occupational and physical therapy device
1.4.	Sensor system for isometric force and tone measurement and dynamic ROM and spasticity assessment
1.5.	Guided finger and hand movements
1.6.	Magnetic attachment system (also possible in the case of severe spasticity)
1.7.	Left and right hand training possible without modification of the device
1.8.	Isolation of individual fingers for assessment or therapy
1.9.	Specific treatment options for patients with spasticity or changes in tone
1.10.	Inpatient and outpatient rehabilitation
1.11.	Force range of motors: 0 to 50N extension and flexion for each finger
1.12.	Force range of sensors: 0 to 40N extension and flexion for each finger
1.13.	Velocity range: grasping movement frequency up to 1Hz equals 60 grasping movements per minute
1.14.	ROM range: full grasping movement 0° – 180° for each finger and the thumb
1.15.	Combined motor and cognitive exercises
1.16.	Hand unit incl. 2 armrests (adult, pediatric)
1.17.	Individual adjustment possibilities for both armrests
1.18.	Finger tips in 3 different sizes (S, M, L)
1.19.	Finger tip dispenser
1.20.	Wheelchair compatible
1.21.	Steering rollers for mobility
1.22.	Shoulder angle can be adjusted by rotating the robotic hand unit
1.23.	Integrated PC and monitor (23,8")
1.24.	Mouse, mouse pad, and keyboard
1.25.	Height adjustment with electric telescopic pillar
1.26.	Emergency switch off
1.27.	Audio output
1.28.	Scientific i/o interface
1.29.	Wi-Fi
1.30.	USB port
1.31.	For children and adults
2.	Application
2.1.	Indications: Stroke (cerebral hemorrhage, ischemic damage), Traumatic brain injury (TBI), Spinal cord injuries, brain tumor, Parkinson's disease, chronic illnesses such as multiple sclerosis (MS), Cerebral palsy (CP), Motor neuron diseases, e.g. amyotrophic lateral sclerosis (ALS), Meningitis, Encephalitis, Muscle dystrophy, signs of paralysis caused by slipped disc in the cervical spine, fractures and injuries of the distal upper extremity (remodeling phase)
2.2.	Absolute contraindications: Acute and pronounced pain symptoms despite conventional pain therapy in the affected upper extremity, impossibility to adjust the system to the patient's individually physiologic position, especially in case of contractures or severe spasticity (joint is fixed/rigid) of the

	<p>trained upper extremity, children under 3 years of age (risk of swallowing small parts, i.e. finger tips), insufficient compliance, e.g. children, patients with severe psychotic or neurotic disorders, high-grade ataxia, advanced osteoporosis (fracture risk), unstable or insufficiently consolidated fractures</p> <p>For relative contraindications please refer to the user manual.</p>
2.3.	Acute, sub-acute, chronic phases of rehabilitation
2.4.	Therapy in case of zero or limited hand and/or finger function
2.5.	Attention functions (ICF b140)
2.6.	Memory functions (ICF b144)
2.7.	Psychomotor functions (ICF b147)
2.8.	Perceptual functions (ICF b156)
2.9.	Mobility of joint functions (ICF b710)
2.10.	Stability of joint functions (ICF b715)
2.11.	Muscle power functions (ICF b730)
2.12.	Muscle tone functions (ICF b735)
2.13.	Muscle endurance functions (ICF b740)
2.14.	Carrying, moving, and handling objects (ICF d430-d449)
2.15.	Self-care (ICF d510-d599)
2.16.	Household tasks (ICF d630-d649)
2.17.	Structure of upper extremity (ICF s730)
2.18.	Control of voluntary movement functions (ICF b760)
2.19.	Repetitive movement execution
2.20.	Proprioception
2.21.	Gamification to engage and motivate patients
3.	Software
3a.	General
3a.1	Cross-device TyroS software
3a.2	User-friendly interface for therapists
3a.3	21 languages
3a.4	Therapist control of adjustable movement training parameters
3a.5	Visual and audio feedback provided to patients during use
3a.6	Full-screen mode
3a.7	Reporting at the end of the therapy
3b.	Assessments
3b.1	Force Assessment (isometric grip force in extension and flexion for every finger and thumb, as well as the total grip force of the hand)
3b.2	ROM Assessment (active ROM for individual fingers and thumb as percentage of the passive ROM)
3b.3	Tone Assessment (measurement of muscle tone in resting position)
3b.4	Spasticity Assessment (according to Modified Ashworth Scale/MAS and Modified Tardieu Scale/MTS)
3c.	Therapies
3c.1	Autonomous task-oriented training with motivational aspect

3c.2	Continuous Passive Motion therapy (CPMplus)
3c.3	Assistive therapy
3c.4	Spasticity treatment
3c.5	Sensitivity training
3c.6	Motility training
3c.7	Tip pinch movement
3c.8	Finger isolation
3c.9	Movement counting
3c.10	Vibration
3c.11	1D therapy programs (accuracy, reaction)
3c.12	1D therapies are controlled by a start and stop position of the patient's fingers
3c.13	Directions in 1D therapy programs can be changed easily during the active therapy to enhance cognitive functions
3c.14	2D therapy programs (motoric, cognitive)
3c.15	2D therapies are controlled by the amount of movement possible by the patient
3c.16	Neuropsychological training by Verena Schweizer
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	Adjustment of velocity, delay time, and force
3c.21	Sensitivity can be changed during active therapy (50%, 75% or 100%)
3c.22	Feedback is given after the end of each level
3c.23	Sequencing option
3c.24	Visually simplified therapy mode
3d.	EMG Module (availability according to regional certificates)
3d.1	Classification IIa medical device
3d.2	MyOnyx system
3d.3	2 EMG channels
3d.4	Calibration & EMG Preview (individual measurement of EMG signal for flexors and/or extensors that is needed to control the applications)
3d.5	Trigger & Go (as soon as the EMG signal exceeds the threshold, the finger slides move to full flexion/extension; threshold can be adjusted)
3d.6	Trigger & Maintain (as long as the EMG signal exceeds the threshold, the finger slides move towards flexion/extension; threshold can be adjusted)
3d.7	Trigger & Coordinate (as long as the EMG signal of the agonist exceeds the EMG signal of the antagonist for a certain threshold, the finger slides move towards flexion/extension; threshold can be adjusted)
3d.8	Emergency stop button
3e.	Database
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	
4.	Technical Specification	
4.1.	Classification	According to regulation 9 of the Council Directive 93/42/EEC, appendix IX and the current supplement 2007/47/EC, the AMADEO® system is an active, therapeutic Class IIa medical product.
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 AMADEO® system may only be used in residential areas under the supervision of a medical professional. EN 60601-1 requirements 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	1,83 – 4,4A/440W
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 T6, 3A L 250V)
4.12.	Power supply voltage drives	24V DC
4.13.	Max. speed	210 mm/second
4.14.	Nominal power of motors	3 Watts/Motor
4.15.	Max. power of motors	30N/Motor
4.16.	Max. permissible finger strength	30N
4.17.	Measurement range of strength sensors	±20N
4.18.	Deviation force measurement	< 10%
4.19.	Weight	60kg / 132 lbs
4.20.	Dimensions (WxLxH)	collapsed: 1250 x 754 x 1110 mm extended: 1250 x 754 x 1620 mm
4.21.	Penetration protection	IP 20
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
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.	Single-use plasters
7.2.	Disinfection of the AMADEO® fingertips after each therapy
7.3.	Disinfection of the AMADEO® armrest after each therapy
7.4.	Hand and arm pads can be washed at 40°C using a gentle cycle, add a hygiene detergent for disinfection.
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