# TENDER SPECIFICATIONS
# LEXO®

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| No. | SPECIFICATION |
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| **1.** | **General** |
| 1.1. | End-effector gait trainer |
| 1.2. | Sensor-based and robot-assisted therapy of the lower extremities |
| 1.3. | Occupational and physical therapy device |
| 1.4. | In-patient and out-patient treatment |
| 1.5. | Acute, sub-acute and chronic phases of rehabilitation |
| 1.6. | Same device for children (see section 2b) and adults |
| 1.7. | Passive walking |
| 1.8. | Assistive walking |
| 1.9. | Active walking |
| 1.10. | Electrically driven weight relief system |
| 1.11. | Body weight relief from 0 - 100% |
| 1.12. | Removable saddle for additional weight relief |
| 1.13. | Electrically driven horizontal and vertical guidance system |
| 1.14. | 2-point suspension of the patient |
| 1.15. | Individual adjustable thorax and pelvis cushions |
| 1.16. | Step width adjustment |
| 1.17. | Electrical adjustment of step length without therapy interruption |
| 1.18. | Flexible shoe size adjustment |
| 1.19. | Pivotable handles for easy patient access |
| 1.20. | Handles' height adjustable during therapy |
| 1.21. | Patient transfer from standing or sitting position (chair, wheelchair) |
| 1.22. | Independent patient transfer with transfer board |
| 1.23. | Two force sensors per footplate for heel strike detection |
| 1.24. | 2 decoupled drives for symmetry detection |
| 1.25. | Pivotable PC with touch screen |
| 1.26. | Emergency switch off |
| 1.27. | USB port |
| 1.28. | Wi-Fi |
| 1.29. | Harnesses and leg loops in sizes S, M, L included |
| 1.30. | Harnesses and leg loops in sizes XXS, XS, XL optional available |
| 1.31. | Harnesses and leg loops of different sizes can be combined for higher individualization |
| 1.32. | Wall storage for accessories available |
| **2.** | **Application** |
| **2a.** | **General application** |
| 2a.1. | Indications: Stroke, Traumatic Brain Injury (TBI), Spinal Cord Injury (SCI), Paraplegia or tetraplegia, spastic and flaccid paralyses, Cerebral Palsy (CP), Multiple Sclerosis (MS), Parkinson's disease (PD), cardiovascular disease as far as permitted by the attending medical expert, Hereditary Ataxia (mild bis moderate), acute or chronic inflammatory demyelinating polyneuropathy, e.g., Guillain Barré Syndrome, CIDP, motor neuron disease, e.g., Amyotrophic Lateral Sclerosis (ALS), spinal muscular atrophy, muscular dystrophy, Myopathy, muscle weakness due to a lack of mobility, postoperative |

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| | rehabilitation, e.g., after knee or hip joint replacement (K-TEP, H-TEP), condition after the reconstruction of the cruciate ligament, fractures and injuries of the lower extremity (remodeling phase), degenerative joint disease of the lower extremity, e.g., arthrosis, amputation |
| 2a.2. | Absolute Contraindications: acute, pronounced pain symptoms despite conventional pain therapy, impossibility to adapt the device to the individual physiological patient's position, e.g., in the event of contractures or severe spasticity (stiff/immobile joint) in the lower extremity, extremely disproportionate growth of the legs and/or spinal column, or conditions that do not allow to wear a harness, body weight of less than 15 kg or more than 180 kg, body size of less than 100 cm or more than 200 cm, insufficient compliance, e.g., psychiatric diseases or medication impairing the compliance ability, intermediate or high risk of fractures, e.g., osteoporosis or osteopenia, osseous instability (non-consolidated fractures, osteogenesis imperfecta, unstable spinal column, pseudoarthrosis), cardiac contraindications, use of ventilators, highly pronounced vascular diseases of the lower limbs, severe Ataxia, open body sites/skin lesions in areas in contact with the device or harness system (decubitus), severely limited range of movement of the lower extremity (e.g., fixated joint contractures, joint arthrodesis) for which even the lightest passive movement training already represents a risk of injury, states of health preventing active rehabilitation (e.g., respiratory diseases, orthopedic diseases, cognitive impairments restricting communication, neuropsychological disorders, infections or inflammatory diseases, osteomyelitis), pregnancy<br><br>For relative contraindications please refer to the user manual. |
| 2a.3. | Verticalization |
| 2a.4. | Stimulation of metabolism |
| 2a.5. | Postural control |
| 2a.6. | Active weight transfer |
| 2a.7. | Passive training |
| 2a.8. | Assistive training |
| 2a.9. | Active training |
| 2a.10. | Therapy in case of zero or limited lower extremity ROM |
| 2a.11. | Perceptual functions (ICF b156) |
| 2a.12. | Functions of the cardiovascular system (ICF b410-b429) |
| 2a.13. | Functions of the respiratory system (ICF b440-b449) |
| 2a.14. | Mobility of joint functions (ICF b710) |
| 2a.15. | Stability of joint functions (ICF b715) |
| 2a.16. | Muscle power functions (ICF b730) |
| 2a.17. | Muscle endurance functions (ICF b740) |
| 2a.18. | Control of voluntary movement functions (ICF b760) |
| 2a.19. | Changing and maintaining body positions (ICF d410-d429) |
| 2a.20. | Walking and moving (ICF d450-d469) |
| 2a.21. | Gait pattern functions (ICF b770) |
| 2a.22. | Structure of lower extremity (ICF s750) |
| 2a.23. | Step initiation |
| 2a.24. | Tonus treatment and regulation |
| 2a.25. | Repetitive movement execution |
| 2a.26. | Bilateral symmetric movement execution |
| 2a.27. | Treatment of contractures |
| 2a.28. | Treatment of edemas |

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| 2a.29. | Proprioception |
| 2a.30. | Gamification to engage and motivate patients |
| 2a.31. | Semi-immersive training |
| **2b.** | **Pediatric application (with LEXO® Pediatric Kit)** |
| 2b.1. | Small, pivotable handrails (3 cm diameter) |
| 2b.2. | Velcro fastening footrests for shoesize 23-36 EU |
| 2b.3. | Attachable cushion for better trunk support |
| 2b.4. | Pediatric saddle |
| 2b.5. | Harnesses and leg loops in sizes XS, XXS |
| 2b.6. | Tablet / mobile phone mount for individualized motivation |
| 2b.7. | Wall panel for accessory storage |
| **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 feedback provided to patients during use |
| 3a.7 | Control via 22” touchscreen |
| **3b.** | **Therapies** |
| 3b.1 | Passive walking |
| 3b.2 | Assistive walking |
| 3b.3 | Active walking |
| 3b.4 | Specific gait element and task-oriented training |
| 3b.5 | LEXO® Walk semi-immersive therapy |
| 3b.6 | Performance feedback on gait velocity, walking distance, time |
| 3b.7 | Visual force feedback on weight bearing, weight shifting, stance phase, swing phase and initial contact |
| 3b.8 | Electrically adjustment of parameters without therapy interruption |
| 3b.9 | Adjustment of step length |
| 3b.10 | Adjustment of cadence |
| 3b.11 | Adjustment of pelvis displacement |
| 3b.12 | Adjustment of vertical body displacement |
| 3b.13 | Assistance can be added during training |
| 3b.14 | Reporting at the end of the therapy |
| **3c.** | **Database** |
| 3c.1 | HL7 interface, version 2.3 |
| 3c.2 | Database includes detailed therapy history of each patient |
| 3c.3 | Patient data can be archived, saved, deleted, imported and/or exported |
| 3c.4 | Automated data backup |

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| 3c.5 | Access to patient data from all Tyromotion devices via server | |
| 3c.6 | Database facilitates collaboration between different therapy departments | |
| 3c.7 | Databank capacity for more than 500 patients | |
| 3c.8 | Data protection can be enhanced by concealing single columns | |
| 3c.9 | Scientific i/o interface | |
| **4.** | **Technical Specification** | |
| 4.1. | Classification | In accordance with rule 9 of the Council Directive 93/42/EEC, Annex IX and the latest amendment 2007/47/EC, the LEXO® robotic gait trainer is an active therapeutic Class IIa medical device. |
| 4.2. | Type of application part | Type B |
| 4.3. | Protection against electric shock | Protection class I device – protective grounding |
| 4.4. | CE | CE certification |
| 4.5. | Country of Origin | Austria |
| 4.6. | Electromagnetic compatibility | Class A device (CISPR 11)<br>The LEXO® system is intended for clinical use (under the supervision of professional medical personnel). |
| 4.7. | Power supply voltage | 100 – 240V alternating current 50 Hz 16A-7A / 1600W-1700W<br>100 – 220V alternating current 60 Hz 16A-8A / 1600W-1700W |
| 4.8. | Supply frequency | 50/60 Hz |
| 4.9. | Electricity/Power consumption | 16A – 7A/1600W-1700W 50 Hz<br>16A – 8A/1600W-1700W 60 Hz |
| 4.10. | Fuses | Circuit breaker, two-pole, 16A |
| 4.11. | Power supply drives | 48V DC /24V DC |
| 4.12. | Maximum Steps per minute | 100 Steps/min |
| 4.13. | Nominal drive performance | 400W/800 Watt |
| 4.14. | Maximum torque | 2,5Nm / 5Nm |
| 4.15. | Transmission oil | Omala S4 WE<br>Viscosity: ISO VG-320<br>Type; CLP-PG-Synthetic |
| 4.16. | Stride length in cm | 27-62 cm |
| 4.17. | Stride width | 12-20 cm |
| 4.18. | Patient suspension | 2-point suspension |
| 4.19. | Weight relief | 0-100% of the patient's body weight |
| 4.20. | Patient size | 100-200cm |
| 4.21. | Patient weight | 15-180kg + 15kg accessories |
| 4.22. | Device weight | 930 kg / 2050.3 lbs |
| 4.23. | Penetration protection | IP X0 |
| 4.24. | Dimensions (LxWxH): | 3600 x 1190 (1887 extended patient lift) x 2310mm |
| 4.25. | Operation | Temperature: 10 ... 30 °C<br>Humidity: 30 ... 75 % relative humidity<br>Air pressure: 70 kPa … 106 kPa |

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| 4.26. | Storage and transport | Temperature: -20 ... 60 °C<br>Humidity: 20 ... 90 % relative humidity, non-condensing<br>Air pressure: 70 kPa … 106 kPa |
| **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 (in case Tyromotion remote support is installed on the LEXO® system) | |
| 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. | FD 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. | Disinfection of the handrail, transfer board, saddle, pelvis and thorax support after each treatment | |
| 7.2. | Disinfection of the harness system after treatment | |
| **8.** | **Clinical Application Training** | |
| 8.1. | Clinical application training material | |
| 8.2. | On-site clinical application training with Tyromotion clinical application specialist (2 days) | |
| 8.3. | Follow up training for experienced users to become advanced users | |
| 8.4. | E-Learning platform TyroAcademy | |