

TYROS6

SAFE USE INSTRUCTION

tyromotion



Contact information:**Manufacturer:**

tyromotion GmbH
Bahnhofgürtel 59
8020 Graz
AUSTRIA

PHONE +43 316 908 909
FAX +43 316 231123 9144
EMAIL office@tyromotion.com
WEB www.tyromotion.com
SUPPORT support@tyromotion.com

Distributor (Austria, Germany, Switzerland, USA):

tyromotion GmbH
Bahnhofgürtel 59
8020 Graz
AUSTRIA

PHONE +43 316 908 909
FAX +43 316 231123 9144
EMAIL office@tyromotion.com
WEB www.tyromotion.com
SUPPORT support@tyromotion.com

Swiss Authorized Representative

CMC Medical Devices GmbH
Rigistrasse 3
CH-6300 Zug
SWITZERLAND

UK Responsible Person

CMC Medical Devices Ltd.
Office 32 19-21 Crawford Street
London, W1H 1PJ
UNITED KINGDOM

**Declaration of Conformity**

This product conforms to the requirements of the Medical Devices Regulation (EU) 2017/745.

You receive a paper-based version of instructions for use (IFU) with your device. Tyromotion also offers these instructions for use in a digital format (PDF) in addition to the paper-based version. If you would need a digital format in addition to the paper based version please follow the instructions on our website <https://tyromotion.com/> and contact our product management department at productmanagement@tyromotion.com to receive the IFU in digital format.

1.1. Intended Use

The TyroS is a therapy software specifically developed for AMADEO®, DIEGO®, PABLO®, TYMO®, MYRO®, OMEGO® and LEXO®. In combination with these devices, it is used for the therapy of neurological, orthopedic, geriatric, or pediatric patients with motoric disorder of the upper and lower extremities. TyroS offers a multitude of assessment and therapy possibilities which can be chosen by the user depending on the needs of the patient. Thus, TyroS supports the patients during training to recover from motoric, sensory, and cognitive deficits. The intuitive software allows for easy and fast operation by the user.

2. Safety

2.1. Safety Concept

In order to prevent problems with the use of the TyroS software the following instructions for proper use are also to be adhered to.

Therapists

- Every therapist must have read the instructions for use of TyroS and the respective device before using. Tyromotion GmbH rejects any liability for damages to persons or material if safety regulations and instructions relevant to the usage of TyroS are not observed!
- Only use original accessories from the manufacturer that are supplied in the system contents.
- After purchasing a Tyromotion device, therapists and clinicians must be trained in the general use of the device. The basic training includes safety features, indications, and contraindications, as well as the device's and software's basic features.
- Clinical application training is required and mandatory for all robotic-assisted devices (AMADEO®, DIEGO®, OMEGO®, LEXO®).

- If there is any doubt about the continued safe or secure use of TyroS or if any parts should fail or become defective, stop using the product immediately and contact Tyromotion GmbH or your local dealer.

Product

- No modifications of TyroS are allowed.
- Always contact the manufacturer for repairs.

2.2. Residual Risk

An unpredictable residual risk remains despite all safety precautions. In rare cases, the user 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 as long as all safety instructions in the present instructions for use and the device specific instructions for use are observed. Tyromotion GmbH can provide a detailed risk analysis upon request.

If you think that you or someone who used TyroS has experienced an injury due to the use of TyroS please report this to the manufacturer and to your national health authority.

2.3. Contraindications

As the software supports various devices, the indications and contraindications vary from device to device. Please refer to the specific device instruction for use for a complete listing of indications and contraindications.

Absolute contraindications: The device must not be used in the case of!

- Epilepsy

Please observe the specific device instruction for use for a complete listing of indications and contraindications.

2.4. Warnings



When using PCs not purchased from Tyromotion or connecting the device PC to a network, the user must ensure that the network the PC is connected to is properly protected from any malware as well as data theft. Please consult an IT specialist. The Tyromotion GmbH assumes no liability for any resulting damages.



Before using the TyroS software in combination with a Tyromotion device the according Manual from the device has to be read as well.



The patient must assume the final seating position before you can begin calibrating the shoulder position. Ensure that the patient remains in this position throughout the entire therapy. Recalibrate the shoulder position if necessary.



The function limits the maximum height and not the shoulder angle. If the patient's seating height changes after the calibration (e.g. when using a height-adjustable chair or when the patient slouches during therapy), a steeper shoulder angle than determined in the calibration might result since the shoulder is lower, but the device still pulls the elbow and wrist to the same configured height. If this occurs, recalibrate the shoulder positions and movement limits.



Movements outside of the movement range can be painful for the patient.



The configured tractive forces of the device are turned on and off by pressing the activation button. Familiarise yourself with the control elements and their effects before attaching a patient to the device for

the first time. Before activating the tractive forces, check whether the set values have been configured for the patient.



Please note that the results are only an approximate progression estimation. The software does not make diagnoses or recommendations for further therapy.



Prior to each therapy the therapist has to make sure that the patient can safely perform a full circular movement while sitting at the OMEGO®.



Always read the user manual for the respective EMG system prior to using the EMG functions of the TyroS software.



Before using the LEXO®, it is utmost important that the operator attends a LEXO® training and has read the manual.



All settings, specially the maximum speed, maximum steplength and maximum track width, need to be determined by the attending doctor



Only trained personal is allowed around the patient and the therapy system during the training. Ideally, there is a therapist during the therapy next to the patient for additional instructions.



Don't use the data from the therapy report to import it to diagnostic software tools and don't assume diagnoses about the patient's condition.