

Device:

TyroS 6

UDI-DI 9120077180229

Legal Manufacturer:

Tyromotion GmbH

Bahnhofgürtel 59

AT-8020 Graz

Safety Instructions

TyroS is intended to be used exclusively to operate Tyromotion's robotic and sensory rehabilitation devices. To prevent problems with the use of the TyroS software, the following instructions for proper use are also to be adhered to.



Therapists must familiarize themselves with these safety instructions and avoid conditions that may lead to injuries or damages.

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, Omega, Lexo).
- If there is any doubt about the continued safe use 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.

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.

Security

To ensure safety and performance, the TyroS software is intended to be used offline or within a local network only connected to other Tyromotion devices. This network should be operated in isolation from any other network. Tyromotion provides such a network with every shared database. All data is processed or stored within this network. Any personal data, including personal data

concerning health, is encrypted. Tyromotion does not have access to or receive any data remotely, nor does Tyromotion share any data with any third parties.

It is the responsibility of the user to comply with local data security regulations. If you suspect a vulnerability to a system provided by Tyromotion, please contact Tyromotion GmbH or your local distributor.

The device must not be used in the case of epilepsy.

The following warnings and precautions exist when using TyroS



It is absolutely imperative that every user complete the training course and read the user manual and accompanying documents before using TyroS!



Therapists must familiarize themselves with these safety instructions and avoid conditions that may lead to injuries or damages.



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. Tyromotion GmbH assumes no liability for any resulting damages.



Please note: The assessment programs serve exclusively for the illustration of trends. The software does not make diagnoses or recommendations for further therapy.

The TyroS Software allows for archival, deletion and export of data. Regular backups of your patient data should be performed in order to avoid data loss.

Please be aware of the following risks if you choose to integrate the device into your network.

- Data loss or corruption
- Disclosure or Alteration of Sensitive Data
- Performance Degradation by Automated Installation of Software Updates or Additional Software such as:
 - Software Freezes
 - Connectivity Issues
- Other unknown risks to the patient, operator or third parties

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.

It is imperative that all patient data be removed, and the PC be reset before disposal of any device with TyroS installed.