MYRO®

GEBRAUCHSANWEISUNG / USER MANUAL

tyromotion

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Contact information:

Manufacturer:

TYROMOTION GmbH
Bahnhofgürtel 59
8020 Graz
AUSTRIA

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

Distributor (Germany, Switzerland):

TYROMOTION GmbH
Bahnhofgürtel 59
8020 Graz
AUSTRIA

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

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1 Introduction

1.1 Introduction

We are happy to provide this user manual as an introduction for the usage of the MYRO® therapy system. The following user manual addresses the essential functions that are necessary for understanding the functionality and usage of MYRO®.

1.1.1 Regarding the usage of this documentation

It is absolutely imperative that every user completes the training course and has read the user manual prior to using MYRO®!

For legibility reasons, the following pages only refer to the male gender, which, however, always implies the female gender as well. TYROMOTION GmbH rejects any liability for damages to persons or material if safety regulations and instructions relevant to the usage of the MYRO® system are not observed!

1.1.2 Symbols in the user manual

	*Warnings: Severe risk of injury or hazard results when this symbol is displayed in the user manual and notices are not observed. Be especially mindful of these notices!*
	*Follow the user manual.*

1.1.3 System content

The MYRO® system consists of the following components, included in the delivery:

- Table frame consisting of foot stabilizers with castors, lifting column (including controls), table top, storage container, 3 transport restraints, 3 covers for the transport restraint openings, control cabinet with integrated PC and screen
- Mouse, mouse pad and keyboard
- USB-Stick (Quickstart Guide, User Manual, SetUp, Software)
- Power plug
- Headphone jack adapter (from 6.3 mm to 3.5 mm)
- MYRO® objects

- Coin
- Ball
- Cup
- Handle
- Empty platform for individual objects

- Suction cup for traction and/or pressure applications

Accessories or spare parts such as MYRO® objects can be obtained directly from the manufacturer.

Only use original accessories from the manufacturer.

Only the supplied suction cup may be used for traction and pressure applications due to safety considerations.

1.1.4 The therapy system

MYRO® is a therapy table that, for the first time, allows the therapeutic usage of real objects, swinging exercises as preparation for graphical-motor training and spatial-explorative elements in a motivating and task-oriented manner.
The selected technology makes it possible to concurrently detect several points of contact or objects, which provides the advantage of interactive and intuitive controls and therapy without additional media and thus, by and large, barrier-free accessibility. Daily movements can be trained and motor skills gradually re-learned with this therapy-supporting device. All processes are recorded statistically and can be utilised for later documentations and assessments.

Image 1: Symbol photo MYRO® therapy system

1.1.5 Intended purpose

The MYRO® therapy system is generally used for neurological rehabilitation of the upper extremities. The target group not only includes neurological, but also orthopedic and pediatric patients. Depending on national variances, the MYRO® system is typically used in ergotherapy and/or physiotherapy as therapeutic support, enhancement and intensification in addition to conventional therapy forms. Repetitive active exercise and training promotes the neuronal plasticity and thus the alteration (adaptation) of synapses, nerve cells or even entire cerebral areas for the purpose of regaining lost functionality.

1.1.6 Notices

Familiarize yourself with the user manual prior to system usage and re-read the manual in regular intervals.
System users are also required to read the provided user manual for the tyroS software and the accompanying papers!

Medical personnel and properly trained therapists responsible for the MYRO® system are required to admonish technicians, patients and other persons within the vicinity of the device to fully observe the contained safety precautions. The system may only be operated by properly trained personnel. Training can be requested as required. Ensure that the system is not manipulated by unauthorized personnel. The system is unpacked

and installed by service personnel authorized by TYROMOTION GmbH. Never attempt to install the system by yourself.

1.1.7 Safety

The MYRO® therapy system must be activated by persons who have read and understood chapter 1.1.7 and 1.1.8. Modifications by users can compromise safety and system performance. All modifications must be performed by persons certified by TYROMOTION. The information in section 1.1.8.familiarizes users with potential hazards of system usage and warns about injuries and damages resulting from non-observance of safety precautions. Users are obligated to familiarize themselves with these safety instructions and avoid conditions that may lead to injuries or damages.

1.1.8 Warnings

Warnings are always identified in the user manual by the symbol displayed in chapter 1.1.2 (yellow triangle with exclamation mark).
All warnings from the chapters are collectively stated in the following in order to ensure the applicability of this user manual.

Warnings from chapter 1

Initial usage:
It is absolutely imperative that every user completes the training course and has read the user manual prior to using MYRO®!

Accessory:
Only use original accessories from the manufacturer.

Only the supplied suction cup may be used for traction and pressure applications due to safety considerations.

Warnings from chapter 2

Electromagnetic compatibility:
MYRO® is classified as a medical electronic device and therefore subject to specific precautionary measures relating to electromagnetic compatibility (EMC). It is absolutely imperative to observe the following EMC indications. Portable and mobile HF communication equipment may affect MYRO®.

COMMENT: Administrations may also permit the setup and operation of class A devices – with all necessary measures – in residential areas and facilities that are directly

connected to the PUBLIC POWER GRID despite the fact that class A threshold values are derived for industrial and commercial service rooms.

Consumption of food or beverages:

It is not permitted to consume or set down food or beverages near or on the device due to safety considerations.

Liquids:

It is not permitted to set down liquids (for example, disinfectants) near or on the device due to safety considerations.

Load capacity:

Caution: The therapy table is not designed to support a person who is standing or sitting on it. The maximum load for the MYRO® application part is 60kg. The indicated load limit only applies to the application part (device part that necessarily comes into physical contact with the patient during proper usage so the device can function).

Power supply MYRO®:

The system may only be connected to a safety outlet as such an outlet provides the necessary protection.

The system may only be connected to electric IT circuits equipped with max. 30mA RCCB protection.

The system may not be connected to the electric circuit with extension cables.

A USB port is provided at the control cabinet. Connecting peripheral devices (printer, etc.) is not permitted.

Touching electrically live parts:

Some system parts may conduct electricity. The operator may NOT concurrently touch the patient and any of these parts. The patient may also not touch these parts directly. This applies to the following components:

- *Lifting cylinder of the linear drive for the tilt adjustment of the table*

Repair:

Always contact the manufacturer for repairs!

Safety instructions - MYRO® adjustment:

Body parts may be pinched when lowering the lifting column or tipping the table. Ensure that no body parts of yours, the patient or a third person are close to the tipping mechanism while tipping the device.
Observe the notices attached to the device: "Warning crushing hazard" and "No entry".

Ensure that no objects are located on MYRO® when adjusting the height or tilt of the system as these objects may fall.

The MYRO® control panel must only be operated by therapists.

Height adjustment MYRO®:

The height adjustment must always be performed while taking space requirements and the patient's range of motion into account.

Adjust the height of the system to ensure optimal operation during therapy. The therapist is responsible for making this adjustment.

Lowering the lifting column: It is possible to pinch body parts under MYRO® while lowering the lifting column. Observe the warnings attached to the device! Only therapists may lower the lifting column.

Tilt adjustment MYRO®:

The tilt adjustment must always be performed while taking space requirements and the patient's range of motion into account.

Tilt of the therapy table: It is possible to pinch body parts while adjusting the tilt of the therapy table. Observe the warnings attached to the device! Only therapists may adjust the tilt of the therapy table.

System/Headphones volume control:

Make sure that the volume level is appropriate when using headphones in order to avoid hearing damage and check the volume before use on patient.

Tipping hazard while moving the device:

It is imperative that the following items are observed due to the increased tipping hazard:

- *Never move the device while a patient is close by.*
- *Always move the MYRO® therapy system in the collapsed mode (tabletop not tilted, lowest position).*
- *Exercise caution while crossing thresholds.*
- *Observe the warning "Sitting prohibited", which is attached to the device.*

Monthly functionality check:
Immediately cease using the system if one of the malfunctions described in chapter 2.5.1 occurs or is suspected.

Warnings from chapter 3

Suitability of the system for the envisaged therapy:

- *Consistent evaluation of the patient's therapy results*
- *Discontinuation of therapy in case of disproportionate deterioration of the patient's condition.*

Safety concept – Clinical application:
Never use objects made of glass, ceramics, metal or sharp, pointy, hot objects or liquids that may injure the user/patient or damage the MYRO® therapy system.

The responsible therapist must assess whether and for how long the patient should perform therapeutic work independently before starting the therapy. Cognitive abilities and the general condition of the patient's health must be taken into consideration.

Therapy must be interrupted if the therapist is unable to either see or hear the patient.

Therapy with cognitively impaired children or patients requires constant supervision by the therapist.

Individual objects must not be used for patients under 3 years of age, as these constitute a swallowing and injury hazard.

Performing the therapy while standing increases the falling risk and requires constant supervision by the therapist.

Patients who are unable to keep their upper body in an upright position by themselves require sitting supports to secure them in a seated position that is suitable for the respective therapy.

Please also observe the user manual for the tyroS software.

Performing training:
Please always observe the tyroS software user manual throughout the entire training.

Only trained personnel may be near the patient and therapy system during therapy. Therapy personnel are ideally located beside the patient during therapy by the control panel in order to give instructions and quickly activate the emergency shutdown in case of emergency!

Cleaning the MYRO® system (see chapter 3.5.2):
Mandatory, standardized disinfection measures:

- *Disinfection of MYRO® objects after therapy*
- *Disinfection of the MYRO® control surface after therapy*

1.1.9 Owner's responsibility

The owner is responsible for ensuring that all persons who operate the system have read and understood this user manual. However, we cannot guarantee that every person who has read this manual is qualified to operate, inspect, check, calibrate, repair or modify the system or fix system errors. The owner must ensure that the installation, maintenance, calibration and repair of the system as well as the fixing of errors are only performed by properly trained and fully qualified personnel. The owner of the MYRO® therapy system must ensure that only properly trained and fully qualified personnel (certified users or operators) receive the authorization to operate the system. It must be ensured that the user has read and fully understood the operating instructions contained in this user manual and has been trained either by TYROMOTION or by other employees of the owner who have been trained by TYROMOTION before being authorized to operate the MYRO® system. The owner is obligated to maintain a list of authorized operators. The operator must contact TYROMOTION if the system does not work properly or does not respond correctly to the commands described in this user manual.

1.1.10 Errors and omissions

Please contact TYROMOTION GmbH if this user manual contains errors or omissions (addresses are listed at the beginning of the document and on our website www.tyromotion.com).

1.1.11 Property of TYROMOTION GmbH

1.1.12 Warranty and legal disclaimer

TYROMOTION GmbH issues a warranty to the original system purchaser that the system shall be free of material and qualitative processing defects for a period of 12 months

under normal usage conditions from the date of installation on the owner's premises and that the system complies with the mechanical and electrical specifications published by TYROMOTION (unless the warranty term is extended by an optional service contract). This warranty is granted under the provision that the system is installed, operated and maintained in accordance with the user manual. The customer must submit all warranty claims to TYROMOTION in written form within 60 days of the occurrence of the problem and before the expiry of the warranty. TYROMOTION is exclusively obligated to repair, exchange or correct faulty or non-compliant parts at its own discretion in accordance with the warranty. TYROMOTION has no further obligations to the owner in regard to these parts after the repair or exchange of faulty or non-compliant parts. All repairs or maintenance work must be performed by an authorized TYROMOTION service representative in accordance with this warranty. The above mentioned warranty becomes null and void if repairs, maintenance or other work is performed by third parties. Moreover, problems resulting from accidents, improper use, incorrect application, storage damage, negligence as well as system or component modifications are excluded from the warranty.

The above mentioned warranty is granted in place of all other warranties, rights or conditions, and the system is delivered "without deficiency warranty" apart from the limited warranty. TYROMOTION and its third-party suppliers specifically and unreservedly reject all other explicit or implicit warranties held by the owner, his personnel and patients, customers, users and any third parties, unreservedly including all warranties for marketability, applicability for a specific purpose, non-infringement and any warranties resulting from performance development, business trends or commercial customs. TYROMOTION and its third-party suppliers do not provide declarations or warranties for system compliance with the owner's requirements or for functionality without interruption, errors or deficiencies.

TYROMOTION is in no way liable for indirect, incidental, specific or consequential damage or for punitive damage compensation including, among other things, the loss or absence of profits, yield, goodwill or usage, which the owner or third parties may incur or for damage to connected equipment, costs for replacement products, installations, servicing, exchange elements or idle time or for claims from patients, customers, visitors, the owner's employees or other persons, regardless whether submitted within the context of a contractual claim, due to unauthorized behavior, strict liability or imposed by law or otherwise even when TYROMOTION has been informed about the possibility of such damages. TYROMOTION's liability for damages resulting from or in connection with this contract may not in any event exceed the purchasing price of the system.

Some jurisdictions limit or exclude the extent of restrictions, the exclusion of legal means, compensation or liability, such as liability for gross negligence or willful misconduct according to or in the abovementioned extent or do not permit the exclusion of implicit warranties. In such jurisdictions, the restriction or exclusion of warranties, legal means, compensations or liabilities described above may not be valid for the owner.

Such restrictions or exclusions apply according to the highest legally permitted extent even if they are not valid according to the legally prohibited extent. The owner may also have other rights that vary depending on the specific country or other jurisdictions.

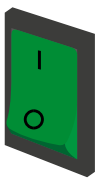
1.2 Training concept

The MYRO® therapy system is a complex technical device. Users of the MYRO® system are required to complete a training course and read the user manual in order to ensure the safety of patients, users and the device itself. Merely reading the present manual does not convey sufficient competence for operating MYRO®. Prospective users are also required to have basic medical training (e.g. physiotherapy/ergotherapy). TYROMOTION GmbH rejects all liability for damages resulting from therapy that was performed by an untrained user. Prospective users are trained after delivery of the MYRO® therapy system.

Users are able to perform initial and repeated therapies training with MYRO®. Users are not permitted to instruct other persons in the usage of MYRO®. Users are trained by a member of TYROMOTION GmbH or by another trainer delegated by TYROMOTION GmbH.

1.3 Symbols on MYRO®

STOP	*Emergency shutdown button for interrupting the power supply to the actuators (lifting column, lifting cylinder of the linear drive for adjusting the tilt of the table)*
	*Do not discard with household waste.*
	*Application part, type B*
	*Alternating current*
	*CE mark*

	*Information about the manufacturer of MYRO®, including the manufacturer's full mailing address is displayed next to the factory symbol.*
	*Follow the user manual.*
	*Warning symbol: Tipping hazard while pushing the device* *The symbol warns users that the device may tip when moved. Keep this in mind when moving the device.*
	*Warning symbol: Crushing hazard warning*
IP20	*Protection class against penetration of foreign bodies and water: 2 means protection against penetration of solid bodies ≥ 12.5 mm Ø. 0 means NO protection against water penetration.*
	*No entry!* *Entering the area is prohibited due to potential pinch point and breakage hazard.*
	*Sitting prohibited!* *Sitting on or bracing oneself against the device or device parts is prohibited.*
	*Labelling on the power switch:* *I means the device is activated (top position, switch lights up green).* *O means the device is deactivated (bottom position).*

	MYRO® activation button

1.3.1 Type label

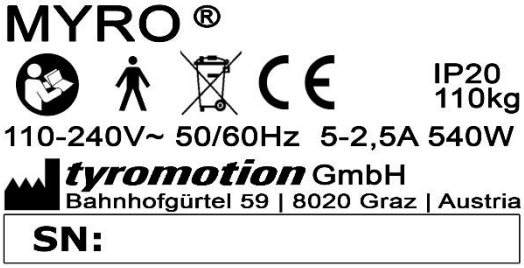


Image 2: Type label MYRO®

The type label designates MYRO® as a medical product.

2 Technology

2.1 Technology

2.1.1 Overview

Type designation:	MYRO®
Build year:	*Can also be determined from the serial number, e.g. SN: MR1-*2016 *– XXX refers to the year 2016.*
Classification:	*The MYRO® system is an active, therapeutic* ***class I medical product*** *according to regulation 1 and 12 of the Council's Directive 93/42/EEC, appendix IX and the current supplement 2007/47/EC.*
Type of application part:	Type B
Protection against electric shock:	Protection class I device – protective grounding
Electromagnetic compatibility:	Class A device (CISPR 11) *The MYRO® system is suitable for usage in all other facilities apart from apartments and residential dwellings that are directly connected to the PUBLIC POWER GRID that supplies the building. EN60601-1-2:2001, requirements have been fulfilled.*
Country of origin:	Austria
Power supply voltage:	110 – 240V alternating current
Supply frequency:	50/60Hz
Electricity/Power consumption:	5 – 2,5A / 540W
Supply grid:	Only connect to supply grids with protective ground wiring.
Operating type:	Continuous operation Electrical adjustment drives interval operation (2 min. on/18 min. off)
Fuses:	*Secured for all poles (2x T6, 3A L 250V)*
Power supply voltage: Drives:	12/24V DC
Max. tipping speed:	*13-16 mm/second*
Max. drive power:	*500N pushing/pulling*
Measurement range:	*pressure (table horizontal): screen center 0 – 300N* *pressure (table vertical): screen center 0 – 200N* *traction (table horizontal or vertical): screen center 0 – 50N*
Measurement deviation strength assessment:	*< ±5%*
Weight:	*110kg*

Dimensions (WxLxH)	*Collapsed (in mm): 1504 x 890 x 703* *Extended (in mm): 1504 x 890 x 1363* *Max. height in extended and tipped state (in mm): 1730*
Penetration protection:	*IP20*

MYRO® is classified as a medical electronic device and therefore subject to specific precautionary measures relating to electromagnetic compatibility (EMC). It is absolutely imperative to observe the following EMC indications. Portable and mobile HF communication equipment may affect MYRO®.

Guidelines and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS		
The MYRO® system is exclusively designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the MYRO® therapy system must ensure that it is used in such an environment.		
Interference emission measurements	Compliance	ELECTROMAGNETIC ENVIRONMENT – Guidelines
HF emissions according to CISPR 11	*Group 1* *Class A*	*MYRO® system exclusively uses HF energy for internal functionality. Therefore, HF emissions are very low and unlikely to disrupt electronic devices within range.*
Harmonics emissions according to IEC 61000-3-2	*Class A*	*The MYRO® therapy system is suitable for usage in all other facilities apart from apartments and residential dwellings that are directly connected to the public power grid that supplies the building.*
Voltage fluctuations/flicker emissions according to IEC 61000-3-3	*Not applicable*	

COMMENT: Administrations may also permit the setup and operation of class A devices – with all necessary measures – in residential areas and facilities that are directly connected to the PUBLIC POWER GRID despite the fact that the threshold values for class A are derived for industrial and commercial service rooms.

2.1.2 Area of application

Device usage is principally limited to clean, dry rooms within professional health care establishments.

Operation:
Temperature: 10 ... 30 °C
Humidity: 30 ... 75 % relative humidity

Storage and transport:
Temperature: -20 ... 60 °C
Humidity: 20 ... 90 % relative humidity, no dew

Caution:
The MYRO® therapy system may not be used in explosion-prone zones AP and APG according to EN 60601-1/2006.

Among other things, this means:
The usage of easily flammable and explosive, anesthetic inhalation materials and mixtures thereof is not permitted within the vicinity of the MYRO® therapy system. These materials include:

- Ether pro narcosi (diethyl ether)
- Cyclopropane

It is not permitted to consume or set down food or beverages near or on the device due to safety considerations.

It is not permitted to set down liquids (for example, disinfectants) near or on the device due to safety considerations.

Caution: The therapy table is not designed to support a person who is standing or sitting on it. The maximum load for the MYRO® application part is 60 kg. The indicated load limit only applies to the application part (device part that necessarily comes into physical contact with the patient during proper usage so the device can function).

2.2 The MYRO® system

Image 3

Image 4

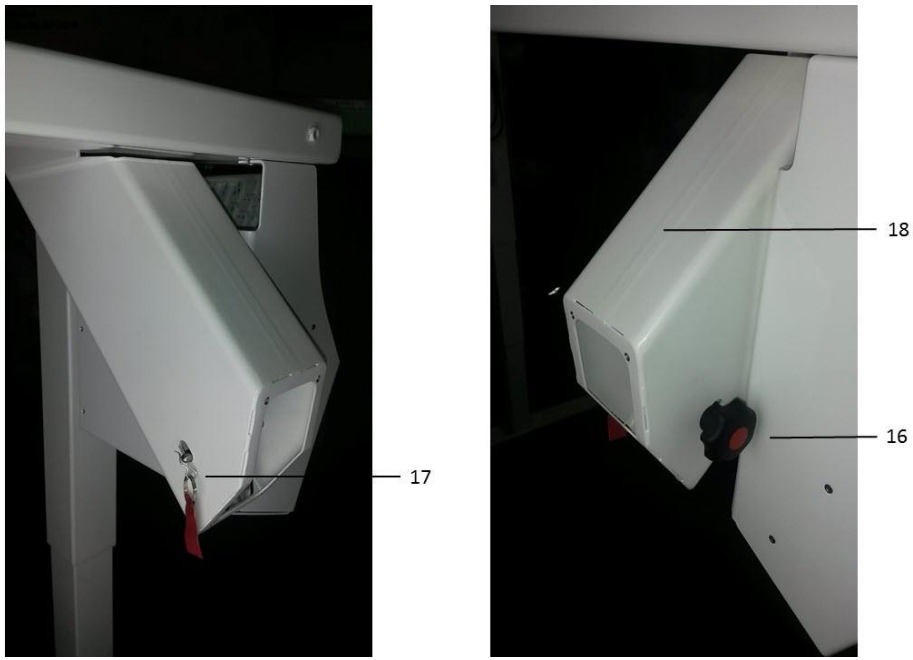


Image 5

1	*Table top*
2	*Monitor*
3	*Loudspeakers (2 in total)*
4	*Storage container*
5	*Control cabinet (including LAN connection and WLAN antenna)*
6	*Power supply*
7	*Electric lifting column*
8	*Foot stabilisers*
9	*Adjustable guide castors*
10	*Transport restraints (3 in total)*
11	*Control panel (including safety bar under the control panel)*
12	*Headphone connection (3.5mm or 6.3mm jack)*
13	*USB port*
14	*Emergency shutdown button*
15	*Power switch*

16	*Safety bolt*
17	*Spring splint for securing the bolt*
18	*Lifting cylinder of the linear drive for the tilt adjustment of the table*

2.2.1 Power supply MYRO®

Please ensure that MYRO® is connected to the designated power supply. The power connection is located directly at the control cabinet.

The system may only be connected to a safety outlet as such an outlet provides the necessary protection.

The system may only be connected to electric IT circuits equipped with max. 30mA RCCB protection.

The system may not be connected to the electric circuit with extension cables.

A USB port is provided at the control cabinet. Connecting peripheral devices (printer, etc.) is not permitted.

Touching electrically live parts:

Some system parts may conduct electricity. The operator may NOT concurrently touch the patient and any of these parts. The patient may also not touch these parts directly. This applies to the following components:

- *Lifting cylinder of the linear drive for adjusting the tilt of the table*

2.2.2 Installation

On-site installation is limited to connecting the system to the power supply since the necessary software has already been installed on the PC prior to the delivery. The exact instructions for assembling the MYRO® system can be found in the assembly instructions.

2.2.3 Repair

Always contact the manufacturer for repairs!

2.2.4 Disposal

The MYRO® system must not be disposed of in the same manner as normal waste, but returned to the company TYROMOTION GmbH.

2.3 Adjustment options MYRO ®

The height and tilt of MYRO® can be adjusted via the control panel in order to optimally adapt the device to the requirements of patients and allow for other application cases or levels of difficulty (therapy while standing or sitting) during therapy.

For safety reasons, adjusting the MYRO® therapy system (height and tilt) is only possible when the safety bar and adjustment button are simultaneously pressed on the control panel.

Pinch point hazard:

Body parts may be pinched when lowering the lifting column or tipping the table. Ensure that no body parts of yours, the patient or a third person are close to the tipping mechanism while tipping the device.
Observe the notices attached to the device: "Warning crushing hazard" and "No entry".

Ensure that no objects are located on MYRO® when adjusting the height or tilt of the system as these objects may fall.

Only therapists may operate the MYRO® control panel.

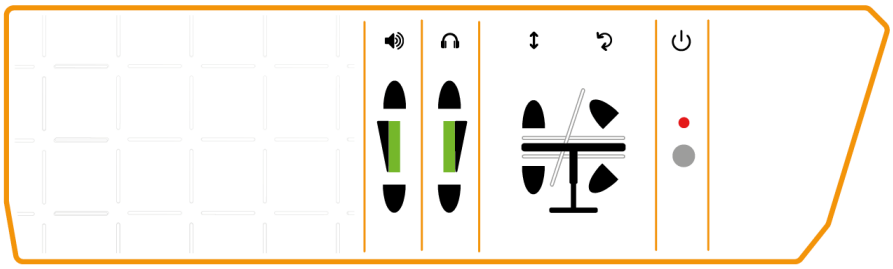


Image 6: Symbol photo MYRO® control panel

	System volume control
	Headphones volume control
	Height adjustment
	Tipping function
	MYRO® activation button *The status light is 'green' when activated. The status light flashes 'blue' in standby mode. The status light flashes 'red' if the emergency shutdown button is pressed.*

2.3.1 Height adjustment MYRO®

The height adjustment must always be performed while taking space requirements and the patient's range of motion into account.

Adjust the height of the system so that optimal operation is ensured for the therapy session. The therapist is responsible for making this adjustment

Lowering the lifting column:

It is possible to pinch body parts under MYRO® while lowering the lifting column. Observe the warnings attached to the device!

Only therapists may lower the lifting column.

2.3.2 Referencing the MYRO® lifting columns

A reference run of the MYRO® lifting columns is necessary when:

- MYRO® is assembled for the first time.
- The electricity supply of the device is interrupted while height adjustment (does not apply for the STOP button).
- The MYRO® lifting columns are inclined.
- The MYRO® lifting columns don‘t move for no reason.

Proceed as follows to perform a reference run of the MYRO® lifting columns:

1. Press and hold the safety bar.
2. Simultaneously push height adjustment button “down”.
3. MYRO® starts reference run.
4. Hold the push height adjustment button ‘down’ and the safety bar simultaneously until the lifting columns are completely retracted and then release the buttons!
5. Wait for 2-3 seconds.
6. Press again the safety bar and the height adjustment button "down" simultaneously for 6-8 seconds.
7. Referencing completed. The system is lowered and raised 5 mm during reference run.
8. The device can be used again.

2.3.3 Tilt adjustment MYRO®

Image 7

The tilt adjustment must always be performed while taking space requirements and the patient's range of motion into account.

Tilt of the therapy table:

It is possible to pinch body parts while adjusting the tilt of the therapy table. Observe the warnings attached to the device!

Only therapists may adjust the tilt of the therapy table.

2.3.4 System/Headphones volume control

The system volume or the volume of plugged-in headphones can be controlled via the control panel. Use only high quality and Over-Ear headphones with suitable impedance (24 Ohm).

Make sure that the volume level is appropriate when using headphones in order to avoid hearing damage and check the volume before use on patient.

2.4 Device setup and movement

Ensure that the device is placed on a level, unslanted surface and all locking breaks are applied when setting up the device. The device must also be positioned at least 30 cm from the nearest device, wall, furniture, etc. to ensure that the adjustable tabletop does not pose a pinch point hazard.

The MYRO® therapy system rests on four adjustable castors for transporting the device throughout the facility.

Procedure for transporting the device:

1. Lower MYRO® to the lowest position
2. Shut down the system correctly
3. Disconnect the power supply cable of the deactivated device
4. Loosen the locking brakes for all four castors

Tipping hazard for the device:

It is imperative that the following items are observed due to the increased tipping hazard:

- *Never move the device while a patient is close by*
- *Always move the MYRO® therapy system in the collapsed mode (tabletop not tilted, lowest position)*
- *Exercise caution while crossing thresholds*
- *Observe the warning "Sitting prohibited", which is attached to the device*

2.5 Monthly functionality check / Recurring check

2.5.1 Check list functionality test

The functionality check described here must be performed on a monthly basis. Perform the check even if MYRO® indicates a malfunction (e.g. in case of unusual sounds, elementary damages, etc.). The person responsible for checking the device must be trained in handling and operating MYRO®.

Inspection:	Malfunction:	Resulting measure:
Protective covers	• *Covers shake* • *Covers missing* • *Covers damaged*	• *Further training is prohibited* • *Contact TYROMOTION GmbH*
Externally visible deformations	• *Parts bent out of shape* • *Parts asymmetrical* • *Parts defective*	• *Further training is prohibited* • *Contact TYROMOTION GmbH*
Emergency shutdown button	• *Emergency stop does not engage when the*	• *Further training is prohibited*

	emergency shutdown button is pressed	• *Contact TYROMOTION GmbH*
Cleaning	• *MYRO® contaminated* • *MYRO® objects contaminated* • *Glass plate contaminated*	• *Further training is prohibited.* • *Clean the contaminated parts as described in chapter 3.5.2*
Adjustment options MYRO®	• *Tipping/Height adjustment does not work properly.*	• *Further training is prohibite.* • *Contact TYROMOTION GmbH*
MYRO® applications	• *Objects or points of contact are not recognised correctly.*	• *Clean the table surface* • *Remove all objects from the table surface* • *Reboot the system* • *Contact TYROMOTION GmbH if the malfunction is not resolved*
Device temperature	• *MYRO® too hot*	• *Further training is prohibited* • *Check whether the vents underneath are covered* • *Contact TYROMOTION GmbH*

Table 1: Inspection points

Immediately cease using the system if one of the described malfunctions has occurred or is suspected.

2.5.2 Recurring checks

Recurring checks differ from the checks described in chapter2.5.1 as the legislator may demand the check described here while the checks in chapter 2.5.1 are intended, among other things, to detect acute damage or wear parts that require replacement. The device operator is responsible for performing both checks.
TYROMOTION GmbH has determined an interval of one year for recurring checks.
Recurring checks may only be carried out by technically qualified personnel. The device operator must ensure that the intervals for the recurring checks stipulated by him are observed. Usage of the MYRO® therapy system must cease if the inspection intervals are not observed.

Recurring checks must be performed according to EN 62353:2008

3 Clinical application

3.1 Indications/Contraindications

The MYRO® therapy system is generally used for neurological rehabilitation of the upper extremities. The target group not only includes neurological, but also orthopedic and pediatric patients. As for any other therapy, the physician is responsible for the medical diagnosis, indication and selection of a suitable therapy. Principally, the same indications and contraindications apply for therapy with MYRO® as for manually performed therapeutic treatment. Knowledge of contraindications is essential in order to keep patients safe. Ensure whether contraindications exist for the patient before beginning therapy with MYRO®. Patients may also exhibit additionally relevant indications or contraindications that are not listed here; the following list does not claim to be exhaustive.
Please contact TYROMOTION GmbH for clarification or feedback (addresses listed at the beginning of the document and on our website www.tyromotion.com).

Common 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)
- Meningitis, encephalitis
- Muscular dystrophies
- Paralysis due to a herniated vertebral disc of the cervical spine
- Neglect
- Fractures and injuries of the distal upper extremity (remodeling phase)

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

- Acute pain despite conventional pain therapy in the region of the affected upper extremity
- Adjustment and patient position: Do not carry out training with the MYRO® system if the adjustment to the patient's individually physiologic position is not possible,

especially in case of contractures or severe spasticity (joint is fixed/rigid) of the trained upper extremity
- Insufficient compliance, e.g. patients suffering from severe psychotic diseases or severe neurotic disorders
- High grade ataxia
- Severe osteoporosis: risk of fractures
- Fractures: Do not carry out training with unstable or still inadequately consolidated fractures

Relative contraindications:

Each patient has to be conscientiously assessed by the doctor/therapist in charge individually to determine if MYRO® therapy is suitable for the patient in case of:

- Apraxia
- Arthritis of upper extremity joints
- Reduced compliance: e.g. children, patients with cognitive impairments
- Consolidated fractures of the upper extremity
- Epilepsy
- Heart pacemakers and similar devices/implants: Pacemakers can react differently to external influences. Therefore, the knowledge about possible dangerous influences relevant for each specific device is essential. The MYRO® therapy device does not influence heart pacemakers if the distance between pacemaker and device (or pacemaker and magnets) is not less than 15 cm.
- Infections
- Joint problems: Repetitive hand training may cause pain and irritation in case of weak joints.
- Osteoporosis
- Orthostatic circulatory problems: increased risk of falling
- Pain, e.g. complex regional pain syndrome (CRPS)
- Sensory disorders: Patients with sensory impairment cannot report potentially occurring pain.
- Skin problems: Before and after every training carefully check for any skin problems, existing wounds, pressure marks, and/or skin ulceration, in particular of body regions in contact with the device.
- Material intolerances
- Shoulder-hand syndrome/subluxations
- Swellings of the upper extremity

Suitability of the system for the envisaged therapy:

1) Consistent evaluation of the patient's therapy results

2) Discontinuation of therapy in case of disproportionate deterioration of the patient's condition

3.2 Safety

3.2.1 Safety concept

The MYRO® therapy system is an active, therapeutic aid.

Several safety precautions come into effect during therapy in case of problems:

- An emergency shutdown button is located on the device if, for some reason, the patient experiences discomfort or is endangered in some way during therapy. Pressing the emergency shutdown button disables the lifting and tipping mechanism.
- The MYRO® application part is connected to the lifting cylinder of the linear drive via a safety bolt for adjusting the tilt of the table. The patient can be quickly and safely released due to the spring splint of the safety bolt (see chapter 2.2) if the system malfunctions, a protective measure takes effect or in case of an emergency shutdown or power outage.
- Consistent monitoring of the therapy by a user is recommended in any case.

Never use objects made of glass, ceramics, metal or sharp, pointy, hot objects or liquids that may injure the user/patient or damage the MYRO® therapy system.

The responsible therapist must assess whether and for how long the patient should perform therapeutic work independently before starting the therapy. Cognitive abilities and the general condition of the patient's health must be taken into consideration.

Therapy must be interrupted if the therapist is unable to either see or hear the patient.

Therapy with cognitively impaired children requires constant supervision by the therapist.

Individual objects must not be used for patients under 3 years of age, as these constitute a swallowing and injury hazard.

Performing the therapy while standing increases the falling risk and requires constant supervision by the therapist.

Patients who are unable to keep their upper body in an upright position by themselves require sitting supports to secure them in a seated position that is suitable for the respective therapy.

Please also observe the user manual for the tyroS software.

3.2.2 Residual risk

An unpredictable residual risk remains for hand/arm therapy despite all safety precautions. In rare cases, the patient 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 user manual are observed. TYROMOTION GmbH can provide a detailed risk analysis upon request.

3.3 Prior to training

3.3.1 Activating the MYRO® system

The system can be activated after it has been properly connected. Turn on the device with the activation button in order to boot the system. The status light ("green") indicates that the system is active and operational. The operating software is ready for loading.

3.4 Performing training

Please always observe the tyroS software user manual throughout the entire training.

Only trained personnel may be near the patient and therapy system during therapy. Therapy personnel are ideally located beside the patient during therapy by the control panel in order to give instructions and quickly activate the emergency shutdown in case of emergency!

A maximum age has not been specified.

3.4.1 Patient information

Patient-relevant information is saved in connection with repeated therapy sessions with the MYRO® system. Furthermore, type, duration and results of individual therapy sessions are also logged in order to evaluate this information in a targeted manner. Data protection regulations that are valid in the respective country must be observed!

3.5 After training

3.5.1 Deactivating the MYRO® system

Exit the control software with [close program] and shut down Windows with "Start >> Shutdown" before deactivating the MYRO® system.

Please also observe the tyroS user manual in this regard.

3.5.2 Cleaning the MYRO® system and associated parts

Mandatory, standardized disinfection measures:

- *Disinfection of MYRO® objects after therapy*
- *Disinfection of the MYRO® control surface after therapy*

The following instructions apply to the manual cleaning of medical devices by Tyromotion GmbH.

Thorough cleaning and wiping is essential for the first time and reuse of reusable medical devices. Effective cleaning must be performed to achieve adequate decontamination.

The goal of cleaning is to remove any visibly sticky soil and reduce the number of particles and microorganisms.
Cleaning must be carried out in a manner that minimizes the risks posed by pathogens.
The devices of the Tyromotion GmbH must be cleaned and disinfected after delivery before the first and any further use on the patient.

3.5.2.1 Detergents and disinfectants

When selecting cleaning agents and disinfectants, it is essential to ensure that it is suitable for cleaning and disinfecting medical devices and for acrylic glass. For this purpose, cleaning agents and disinfectants based on ethanol, propanol, H2O2, chlorine are suitable (for example Bacillol®, Bacillol® plus, INCIDIN extra, INCIDIN pro). Detergents should be used at the concentration and duration recommended on the label and product information. Each disinfectant has a specific exposure time (pay attention to the label and product information before use) until the micro-organisms are rendered harmless as far as possible. This interval is to wait before wiping.

3.5.2.2 Water

The quality of the water should be carefully selected for use with cleaning agents and for wiping during the cleaning process. The hardness of the water is crucial because deposits left on the medical devices could result in ineffective cleaning and decontamination.

3.5.2.3 Instruments

Clean, lint-free and non-abrasive cloths.

Do not use scouring agents, metal brushes or scouring pads.

3.5.3 Cleaning process

To minimize the risk of germ transmission, all surfaces and objects that are touched by both the patient and the therapist should be periodically cleaned and disinfected. These include e.g. frame, user interface, lifting column, control panel, mouse, keyboard and MYRO® objects.

1. If the patient perspires heavily during use, wipe the user interface and MYRO® objects dry after therapy before disinfecting them.
2. Moisten the disposable cloth, according to the product information leaflet, only slightly with disinfectant. Wipe the frame, user interface, mast, control panel, mouse, keyboard, and MYRO® objects with the clean, soft, lint-free cloth. Observe the contact time of the disinfectant used according to the label and product information.
3. Depending on the disinfectant, it may be necessary to wipe the disinfected area with water after the exposure time.
4. Dry the area wiped with water with a clean, non-abrasive, soft, lint-free cloth.

tyromotion

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