TYMO® G6

INSTRUCTIONS FOR USE

tyromotion

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CE

Declaration of Conformity

This product conforms to the requirements of the Medical Devices Regulation (2017/745). The CE mark must be removed when rebuilding the product or when using other than original TYMO® accessories.

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Figure 1

< 180 kg
< 396.8 lbs

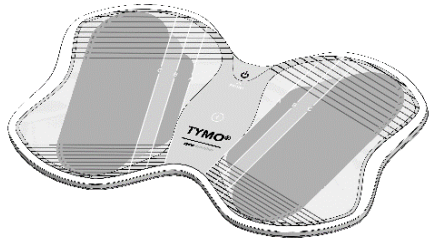


Figure 2

< 180 kg
< 396.8 lbs

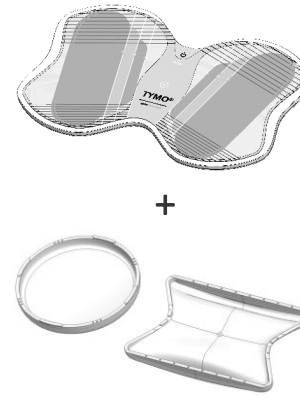


Figure 3

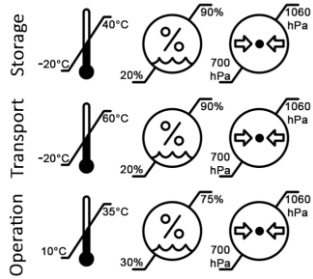


Figure 4

Figure 5

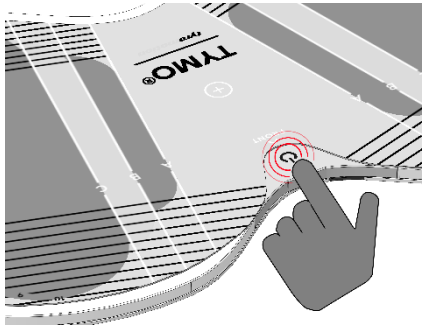


Figure 6

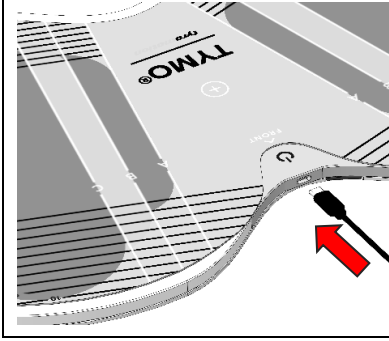


Figure 7

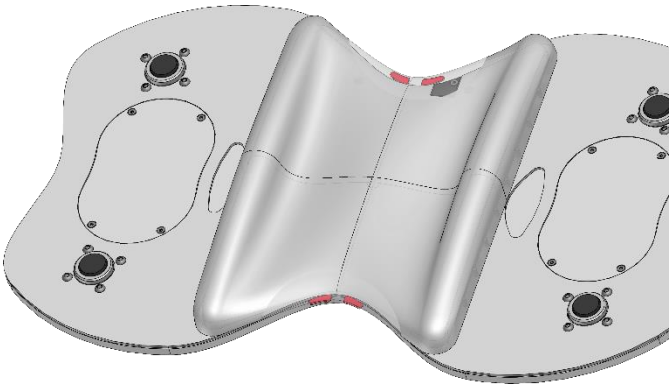


Figure 8

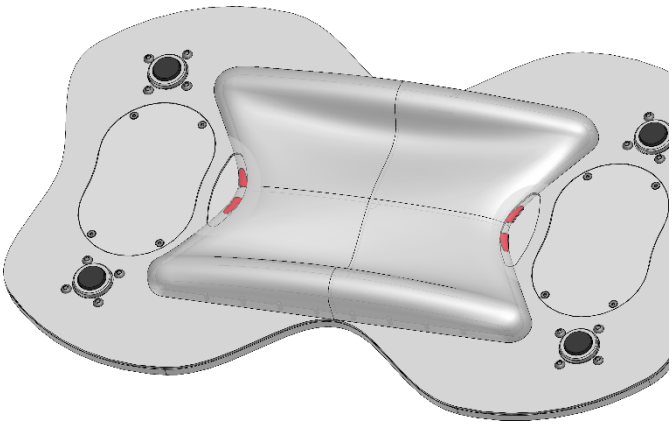
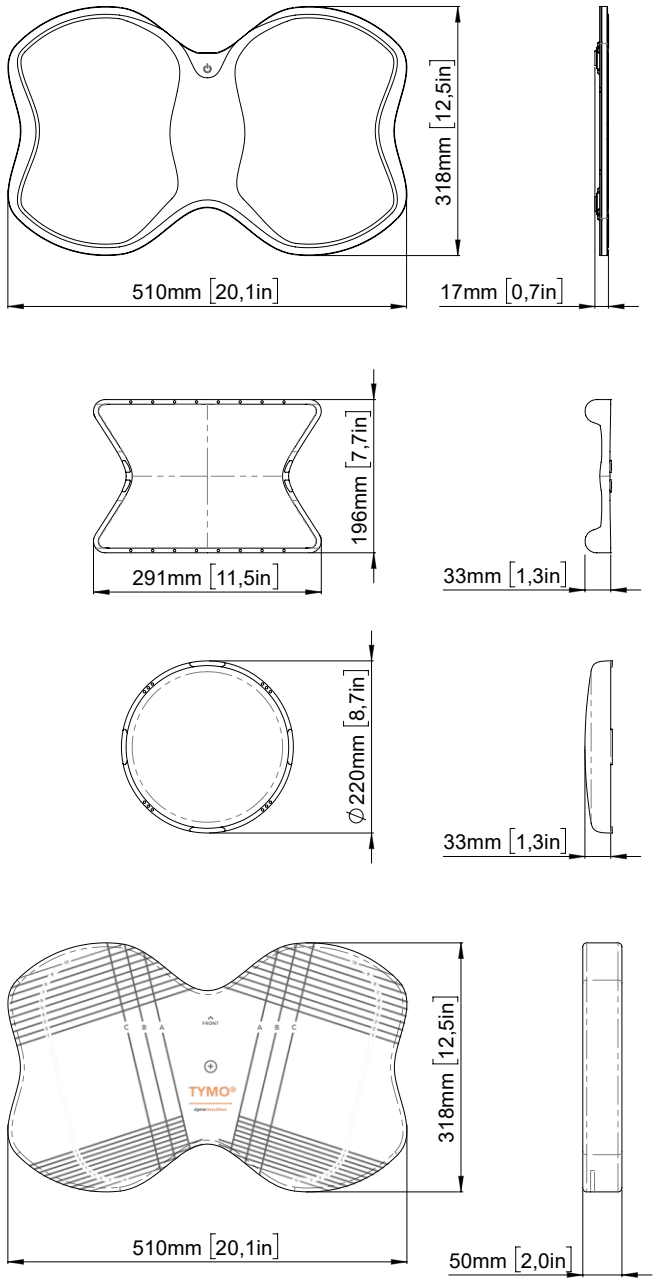


Figure 9

Figure 10


318mm [12,5in]
510mm [20,1in]
17mm [0,7in]
196mm [7,7in]
291mm [11,5in]
33mm [1,3in]
∅220mm [8,7in]
33mm [1,3in]
318mm [12,5in]
510mm [20,1in]
50mm [2,0in]
TYMO

1 Introduction

We appreciate your choice of a new product from Tyromotion GmbH. To fully benefit from the options offered by this product read these instructions for use and save it for future use.

1.1 Training concept

TYMO® is a complex technical device. Users of TYMO® 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 TYMO®. 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 TYMO®.

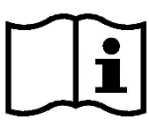
Users can perform initial and repeated therapies training with TYMO®. Users are not permitted to instruct other persons in the usage of TYMO®. Users are trained by a member of Tyromotion GmbH or by another trainer delegated by Tyromotion GmbH.

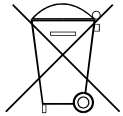
1.2 Symbols

1.2.1 Symbols in the instructions for use

	*Warnings: This symbol indicates a possible risk of injury to your own health or to the health of others. Be especially mindful of these notices!*

1.2.2 Symbols on TYMO®

	*Follow the instructions for use*
	*Applied part, type BF*

	*Do not discard with household waste*
	*CE mark*
	*Information about the manufacturer of TYMO®, including the manufacturer's full mailing address is displayed next to the factory symbol.*
	*Date of manufacture*
	*Serial number of the device*
	*Medical device*
	*The UKCA mark is a product label used for medical devices marketed in the United Kingdom (England, Wales, Scotland) and shows the conformity.*
	*Shows CH Authorized Representative*
	*On-switch for TYMO® Therapy plate*

1.3 Content

TYMO® consists of the following components, included in the delivery:

- 1x TYMO® Therapy plate
- 1x TYMO® Rolling Element 1D
- 1x TYMO® Rolling Element 2D
- 1x TYMO® Multipad X
- 1x TYMO® power supply
- 1x USB charging cable
- 1x USB extension
- 1x Bluetooth adapter
- 1x USB-Stick (TyroS Software)

1.4 Intended purpose

TYMO® is a monitoring and therapy device for the rehabilitation of patients suffering from motoric dysfunctions; it is primarily used for neurological rehabilitation purposes.

The target group not only comprises neurological, but also orthopedic and pediatric patients with dysfunctional motion- and force control, accuracy, coordination, body control and balance. Depending on national variances, TYMO® is typically used in ergotherapy and/or physiotherapy as therapeutic support, enhancement and intensification in addition to conventional therapy forms.

1.5 Warranty and legal disclaimer

Tyromotion GmbH issues a warranty to the original medical device purchaser that it 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 product 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 medical device 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 device 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 product 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 product 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 product.

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.

2 Technology

2.1 Overview

Type description:	TYMO®
Classification:	*TYMO® is an active, therapeutic class I medical device according to rule 13 of Medical Device Regulation (EU) 2017/745.*
Type of applied part:	Type BF
Protection against electric shock:	Internally powered medical device
Electromagnetic compatibility:	Class B device (CISPR 11) *TYMO® is suitable for usage in all establishments including residential areas and areas that are directly connected to the PUBLIC SUPPLY GRID, which also supplies residential buildings.*
Country of origin:	AUSTRIA
Power supply voltage:	100 – 240V *alternating current*
Supply frequency:	50/60Hz
Electricity/Power consumption:	5V DC / 2A / 10W
Battery:	*Polymer-lithium-ion battery, 3.7V, 470mAh.* *The battery must not be replaced.*
Radio transmission frequency:	*ISM Band (Bluetooth BLE)*
Radiated transmission power:	*Max. 1.79mW* *Operational area: 10 meters given uninterrupted view between TYMO® plate and PC*
Operating type:	*Continuous operation*
Measurement range:	*force: 0 – 1765,8N (0-180 kg)* *angle : ±90°*
Measurement deviation:	*force: ± 2% of actual value ± 200g* *angle: ± 3°*
Weight:	*< 4 kg*
Device Requirements:	• *Windows 10; Home or Professional* • *Intel or AMD Processor with >= 3 GHz* • *at least 8 GB RAM* • *Display resolution 1280x768* • *Microsoft .NET framework 4.5.2 (installed by default)* • *Unity3D Webplayer Plugin (installed by default)* • *One free USB port*

2.2 Area of application

The product is for indoor use.

TYMO® 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 stated indications for EMC. Portable and mobile HF communication devices may affect the TYMO®.

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS		
TYMO® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of TYMO® must ensure that it is used in such an environment.		
Interference emission measurements	**Agreement**	**ELECTROMAGNETIC ENVIRONMENT – Guidelines**
HF emissions according to CISPR 11	*Group 1*	*TYMO® exclusively uses HF energy for its internal FUNCTIONS. HF emissions are very low and unlikely to disrupt electronic devices within range.*
HF emissions according to CISPR 11	*Class B*	*TYMO® is suitable for usage in all establishments including residential areas and areas that are directly connected to the PUBLIC SUPPLY GRID, which also supplies residential buildings.*
Harmonics emissions according to IEC 61000-3-2	*Class A*	
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	*Not applicable*	

Table 1: Guidelines and manufacturer's declaration – Electromagnetic emissions

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC IMMUNITY			
TYMO® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of TYMO® must ensure that it is used in such an environment.			
Immunity Test	**IEC 60601-Test Level**	**Compliance Level**	**ELECTROMAGNETIC ENVIRONMENT - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	*± 8 kV contact* *± 15 kV air*	*± 8 kV contact* *± 15 kV air*	*Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.*

Electrical Fast Transient/Burst IEC 61000-4-4	*± 2 kV for power supply lines* *± 1 kV for input/output lines*	*± 2 kV for power supply lines* *Not applicable*	*Mains power quality should be that of a typical commercial or hospital environment.*
Surge IEC 61000-4-5	*± 1 kV differential mode* *± 2 kV common mode*	*± 1 kV differential mode* *Not applicable*	*Mains power quality should be that of a typical commercial or hospital environment.*
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	*< 5 % U_T (> 95 % dip in U_T) für 0.5 cycles* *70 % U_T (30 % dip in U_T) for 25 cycles* *< 5 % U_T (> 95 % dip in U_T) for 5 s*	*< 5 % U_T (> 95 dip in U_T) for 0.5 cycles* *70 % U_T (30 % dip in U_T) for 25 cycles* *< 5 % U_T (> 95 % dip in U_T) for 5 s*	*Mains power quality should be that of a typical commercial or hospital environment.*
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	*30 A/m*	*30 A/m*	*Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.*
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 2: Guidelines and Manufacturer's declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration— ELECTROMAGNETIC IMMUNITY			
TYMO® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of TYMO® must ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	IEC 60601-Test Level	Compliance Level	ELECTROMAGNETIC ENVIRONMENT - Guidance
			Recommended Separation Distance:

Conducted RF *IEC 61000-4-6*	*6 V_{rms}* *150 kHz to 80 MHz*	*6 V*	$d = 0.58\sqrt{P}$
Radiated RF *IEC 61000-4-3*	*10 V/m* *80 MHz to 2.7 GHz*	*10 V/m*	$d = 0.35\sqrt{P}$ *80 MHz to 800 MHz* $d = 0.7\sqrt{P}$ *800 MHz to 2.5 GHz* *where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).* *Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]* *Interference may occur in the vicinity of equipment marked with the following symbol:* 

NOTES:
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which TYMO® is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating TYMO®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [4] V/m.

Table 3: Guidelines and Manufacturer's declaration – Electromagnetic Immunity

Recommended separation distances between portable and mobile RF communications equipment and TYMO®			
TYMO® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment			
Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = 0.58\sqrt{P}$	*80 MHz to 800 MHz* $d = 0.35\sqrt{P}$	*800 MHz to 2.5 GHz* $d = 0.7\sqrt{P}$
0.01	*0.058*	*0.035*	*0.07*
0.1	*0.18*	*0.11*	*0.22*
1	*0.58*	*0.35*	*0.70*
10	*1.83*	*1.11*	*2.21*
100	*5.80*	*3.50*	*7.00*
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *NOTES:* *- At 80 MHz and 800 MHz, the higher frequency range applies.* *- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*			

Table 4: Recommended separation distances between portable and mobile RF communications equipment and TYMO®

FCC Statement

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

3 Clinical application

3.1 Indications/Contraindications

TYMO® is mainly used in neurologic rehabilitation. The target population includes not only neurologic but also orthopedic and pediatric patients with deficits in balance and postural control. Typical indications are frequently linked with problems in weight distribution, weight bearing ability, weight shifting, and symmetry. Application is possible supporting with the upper extremity on the TYMO® Therapy plate as well as sitting or standing on the TYMO®.

As in the case of every other therapy, the doctor in charge is responsible to make medical diagnosis and decide for the type of intervention. In principle, the same indications and contraindications apply for TYMO® therapy as those for manually applied therapeutic treatment. Knowledge of the contraindications is essential in order not to put the patient at risk. Before applying TYMO® therapy to a patient, check carefully if one or more contraindications exist. Also, be aware that your patient may have additional indications and/or contraindications that have not been listed here but may be relevant. The following listings have no claim to completeness.

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)
- Muscular dystrophies
- Paralysis due to a herniated vertebral disc
- Orthopedic events such as e.g., amputation, joint surgery, or joint replacement

Absolute Contraindications: The device must not be used!

- Acute pain despite conventional pain therapy
- Adjustment and patient position: Do not carry out training with TYMO® 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 body region
- Insufficient compliance, e.g., children, 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 TYMO® therapy is suitable for the patient in case of:

- Apraxia
- Arthritis
- Reduced compliance: e.g., children, patients with cognitive impairments
- Consolidated fractures
- Epilepsy
- Heart pacemakers and similar devices/implants: Pacemakers can react differently to external influences. Therefore, knowledge about possible dangerous influences relevant for each specific device is essential. Inform patients that magnets are built into the charging connection. The TYMO® 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 training may cause pain and irritation in case of weak joints.
- Neglect
- 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. Therefore, the therapist must be especially attentive in such cases.
- 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.

Please be aware that your patients may have other contraindications that are not listed here. In the case of questions or feedback, please contact Tyromotion GmbH (for contact data see start of the document).

3.2 Safety

3.2.1 Safety concept

TYMO® is an active, therapeutic device that is above all to be used with patients with restricted physical and/or mental abilities. To prevent problems with the use of the device the following instructions for proper use are also to be adhered to.

Users are obligated to familiarize themselves with these safety instructions and avoid conditions that may lead to injuries or damage. Users are also required to have basic medical training (e.g. physiotherapy/occupational therapy).

Users

- Every user must have read the instructions for use prior to using TYMO®. Tyromotion GmbH rejects any liability for damages to persons or material if safety regulations and instructions relevant to the usage of TYMO® are not observed!
- The user 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.
- Only use original accessories from the manufacturer that are supplied in the product contents.
- The user must take appropriate measures to stabilize the user during therapy.
- If there is any doubt as to the continued safe use of TYMO® or if any parts should fail or be defective, stop using the product immediately and contact Tyromotion GmbH or your local dealer.
- The cleaning instructions stated in these instructions for use must be strictly observed.

Environment

- Only use TYMO® on a firm surface.

Product

- No modifications of TYMO® are allowed.
- Always contact the manufacturer for repairs!

Please also observe the instructions for use of the TyroS software.

3.2.2 Residual risk

An unpredictable residual risk remains for 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 instructions for use are observed. Tyromotion GmbH can provide a detailed risk analysis upon request.

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

4 TYMO®

4.1 First steps

The time required for TYMO® to warm/cool from the min./max. storage temperature between uses until the device is ready for its intended use at ambient temperature is one hour. Please wait for this period before operating the unit.

4.1.1 Charging TYMO®

The TYMO® Therapy plate is equipped with a rechargeable battery. Before using TYMO® for the first time, fully charge the device using the supplied USB cable and power supply unit (*Figure 6*). The charging time is 6 hours when the battery is completely empty.

The use of the supplied medical power supply unit for charging the TYMO® Therapy plate is mandatory. No other power supply units may be used.

Power supply: Adapter Technology, model: ATM012T-W050VU

4.1.2 Installation of the Software

You will find a detailed installation guide in the instructions for use of the TyroS Software. For this version of TYMO, TyroS version 6.3 or higher can be used and is compatible.

4.1.3 Installation of the Bluetooth adapter

TYMO® is connected to your PC with Bluetooth technology. To produce this connection, it is first necessary to connect the Bluetooth adapter included in the scope of delivery to your PC and to install it. If you have purchased a PC from Tyromotion this installation will already have been carried out.

Otherwise, connect the Bluetooth adapter to the USB extension and then to a free USB port of your PC and follow the installation instructions of your PC.

Figure 11: Bluetooth adapter

Figure 12: Bluetooth adapter incl. USB extension

4.1.4 Connecting TYMO® to the PC

Important points before the installation:

- The TYMO® Therapy plate must be fully charged before being used for the first time.
- If you previously used another Bluetooth adapter with your computer, be sure to remove any drivers or software for this adapter before installing the pluggable adapter. Built-in Bluetooth adapters must be deactivated (see chapter 4.1.5 and the Quickstart Guide).
- The TYMO® Therapy plate must not be more than 10 meters away from the PC.

- The TYMO® Therapy plate must be turned on.
- Installation is completed and the TYMO® is now ready for use.

4.1.5 Deactivate the integrated Bluetooth adapter

To ensure that TYMO® works correctly with the provided Bluetooth adapter it might be useful to deactivate the integrated Bluetooth adapter (if available) in your PC.

If you have purchased a PC from Tyromotion this deactivation has already been carried out. To deactivate the integrated Bluetooth adapter, go to the control panel and choose Device Manager. Look for the Bluetooth- (or Bluetooth Radios) entry. Right-Click on the integrated Bluetooth adapter and choose “Disable”.

4.2 Use of TYMO®

TYMO® evaluates and trains the musculoskeletal system and is specifically used in therapy of impaired balance and asymmetry of patients. By definition it is used to display trends. Hence the software consists of integrated measuring modules and interactive therapy modules with audiovisual feedback.

4.2.1 TYMO® Application

To use TYMO®, carry out the following steps:

- TYMO® can be activated after it has been properly installed (chapter 4.1) and connected.
- Starting therapy:
    1) Switch on the TYMO® Therapy plate by pushing the LED button for approx. 3 seconds (*Figure 5*). The LED button should now start blinking green.
    2) Start the TyroS Software
    3) The TYMO® Therapy plate connects itself automatically to your PC via Bluetooth technology as soon as you start a therapy session with TYMO®. Please note the LED display at the TYMO® Therapy plate (chapter 4.2.3). This gives information on which status the TYMO® plate are currently in.
- Performing therapy:
    1) Apply now the TYMO® and follow the instructions given by the TyroS Software.
    2) If errors occur during the therapy, they are handled in the TyroS Software.

- Completing therapy:
    1) Terminate the application by exiting the TyroS Software and shutting down the PC.
    2) Switch of the TYMO® Therapy plate by pushing the LED button for approx. 5 seconds (*Figure 5*). The LED color will then change to solid violet. Press the button again for two seconds to switch off the TYMO®. If the TYMO® Therapy plate is disconnected from the software for more than an hour, it will switch off automatically.
    3) Make sure all TYMO® components are securely stowed after use so they cannot fall to the floor and thus cause harm to patients.

Please also observe the instructions for use of the TyroS Software.

Despite its robust and high-quality construction, the TYMO® Therapy plate only has a limited ability to withstand shocks. If the device falls from table onto the floor, defects can occur in the sensors or the battery. These defects may possibly not become recognizable until sometime after a fall. Therefore, do not use the TYMO® Therapy plate after a fall; instead, immediately contact Tyromotion GmbH or the dealer from whom you bought the TYMO® Therapy plate.

Some application possibilities of TYMO® are shown below.

Figure 13: Static application while sitting (optional with Multipad X on TYMO®)

Figure 14: Static application for training the movement transition sit to stand.

Figure 15: Static or dynamic application with 1D or 2D Rolling Element while standing.

4.2.2 TYMO® Rolling Element 1D and 2D

The Rolling Elements 1D and 2D are used in the „dynamic" mode. The Rolling Elements are attached to the underside of TYMO® where they are fixed by integrated magnets (*Figure 7*, *Figure 8* and *Figure 9*)

Note: As long as there is a Rolling Element attached to the underside of TYMO®, a static measurement (force measurement) cannot be performed.

Please note that the teeth of the Rolling Element are positioned exactly as shown in Figure 7, Figure 8 and Figure 9. Otherwise, the Rolling Element could detach itself from the TYMO® Therapy plate.

Please check the Rolling Elements for mechanical damage before each use. Do not use the Rolling Elements if there is any damage and contact Tyromotion GmbH or the dealer from whom you bought the TYMO® Therapy plate.

4.2.2.1 TYMO® Rolling Element 1D

The Rolling Element 1D enables TYMO® to tilt in one direction and prevents a tilting movement in another direction. The following tilting movements are possible:

- Forwards/Backwards
- Left/Right

Depending on the direction in which the TYMO® should be tilted, the Rolling Element 1D must be properly mounted on the underside of the TYMO® Therapy plate.

Figure 16: 1D – Mounting direction for the tilt movement left/right

Figure 17: 1D – Mounting direction for the tilt movement forwards/backwards

Do not try to tilt TYMO® Therapy plate in the direction which is prevented by the Rolling Element 1D. This could cause the Rolling Element 1D to detach itself from the TYMO® Therapy plate and an increased risk of falling is given.

4.2.2.2 TYMO® Rolling Element 2D

The Rolling Element 2D enables a simultaneous tilting movement of TYMO® in both tilting directions. This makes it possible to perform additional therapeutic applications.

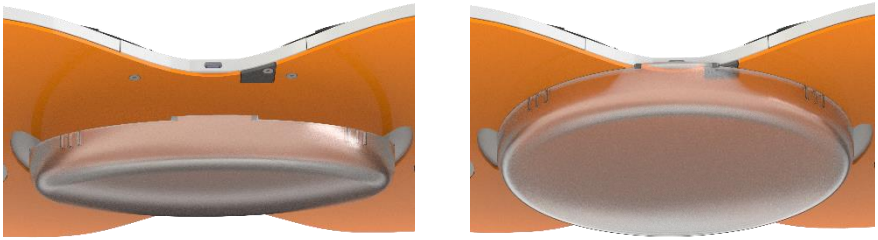


Figure 18: Mounting 2D Rolling element

4.2.3 LED Status TYMO®

Observe the LED display on the TYMO® Therapy plate. This provides information on the status of the TYMO® Therapy plate.

LED-Display	Meaning	Necessary Action
Shining ORANGE	*Connection with software okay, battery level under 15%*	Charging of the battery (*section 4.2.4)*
Flashing ORANGE	*No connection with software, battery level under 15%*	Charging of the battery (*section 4.2.4)*
Shining GREEN	*Connection with software okay, battery level okay*	*None*
Flashing GREEN	*No connection with software, battery level okay*	*None*
Shining BLUE	*Battery is fully charged*	*None*
Flashing BLUE	*Battery is being charged*	*None*
Off	*Battery of the device is completely empty, or the device is switched off*	*Charging of the battery or switch on the device (section 4.2.4)*

Table 5: LEDs

4.2.4 Battery

Charging battery:

The integrated battery in the TYMO® Therapy plate can be charged via the TYMO® power supply included in the procuct content (*Figure 6*). The TYMO® Therapy plate switches into the charging mode automatically after connecting the TYMO® to the power supply.

NOTE: The TYMO® Therapy plate may be used in charging mode.

Duration of Charging:

The duration of charging depends, among other things, upon whether the battery was fully uncharged at the start of the charging process or not. However, the charging process should not last longer than 6 hours.

Charging Cycles and Lifespan:

Due to the use of high-quality lithium-polymer batteries, it is ensured that the battery running times still meet the requirements even after many charging cycles. Nevertheless, no guarantee can be given for the lifespan of batteries going beyond 12 months after the date of purchase.

If you adhere to the following advice, you can certainly save the battery of your device and thereby extend its lifespan:

- Do not expose cells or batteries to heat or fire. Avoid direct exposure on TYMO® to sunlight in order to prevent the battery inside the device from becoming too hot.
- Use exclusively the power supply provided by Tyromotion GmbH for the recharging of the battery.
- Do not dismantle, open or shred secondary cells or batteries.
- Do not subject cells or batteries to mechanical shock.
- In the event of a cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Do not use any cell or battery which is not designed for use with the equipment.

Battery life:

In use, the battery operating time is minimum 10 hours when fully charged.

5 Hardware Configuration

5.1 Hardware test

The TYMO® hardware test is an integrated diagnostic program that automatically checks the plausibility of sensor values. It is not necessary to perform this test in normal operation; it is merely a tool for the manufacturer to easily prepare a diagnosis.

5.2 Calibrating the sensors

Due to the sensors chosen and the high-quality construction, the TYMO® Therapy Plate is very robust against long-term effects. nevertheless, it may be necessary to carry out a calibration.

Proceed with the calibration of the TYMO® Therapy Plate as follows:

1. Make sure that the battery is sufficiently charged (for more information refer to the TYMO® instruction manual).
2. Remove any TYMO® rolling elements attached to the TYMO® therapy plate.
3. Place the TYMO® therapy plate on an even and stable surface.
4. Ensure that nothing lays upon the therapy plate during the calibration process and that nobody stands or presses upon it.
5. Press the button „Calibrate Sensors“ in the hardware configuration area in order to start the calibration.
6. Wait until the progress display is at 100% and the green instruction window appears with the text, „Calibration OK“.

If the calibration has not run correctly, you will receive the warning message „Calibration failed“. In this case, make sure that the TYMO® therapy plate is ready for use and carry out the above-mentioned points again.

6 Service information

Maintenance of a medical device is wholly the responsibility of the owner of that device. Failure to maintain a device in accordance with the instructions for use may invalidate the device's warranty. Furthermore, failure to maintain a device may compromise the clinical condition or safety of users.

6.1 Monthly functionality check

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

Inspection:	Malfunction:	Resulting measure:
Protective covers	• *Covers shake* • *Covers missing* • *Covers damaged*	• *Further use is prohibited* • *Contact Tyromotion GmbH*
Rolling Elements 1D and 2D	• *Rolling elements damaged or broken*	• *Further use is prohibited* • *Contact Tyromotion GmbH*
Externally visible deformations	• *Parts bent out of shape* • *Parts asymmetrical* • *Parts defective*	• *Further use is prohibited* • *Contact Tyromotion GmbH*

Cleaning	• *TYMO® contaminated*	• *Further use is prohibited.* • *Clean the contaminated parts as described in chapter 6.4*
Battery	• *Battery life drops below 2h* • *housing deformations due to an inflated battery occur* •	• *Further use is prohibited* • *Contact Tyromotion GmbH*

Table 6: Inspection points

6.2 Periodic check

Periodic checks differ from the checks described in chapter 6.1 as the legislator may demand the check described here while the checks in chapter 6.1 are intended, among other things, to detect acute damage or wear parts that require replacement. The operating company of the device itself is responsible for carrying out both tests.

An interval of one year is defined by Tyromotion GmbH for carrying out the periodic tests. Periodic tests may only be carried out by service representatives. The operating company of the device must ensure that the test intervals imposed for the periodic test are complied with. TYMO® must not be used if the test intervals have not been complied with.

The periodic test must be carried out according to EN 62353:2014.

6.3 Lifetime

The lifetime of this product in normal use is 7 years if all maintenance and servicing is carried out in accordance with the manufacturer's instructions and demonstrably recorded.

6.4 Cleaning instructions

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

Thorough cleaning and wiping are 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 Tyromotion GmbH must be cleaned and disinfected after delivery before the first and any further use on the patient.

6.4.1 Disinfection

The product can be disinfected with a 70% disinfectant IPA solution. It is recommended to wipe off any residue and dirt from the product, using a cloth with warm water and a mild detergent/soap without chlorine and let it dry before disinfection.

6.4.2 Cleaning process

To minimize the risk of germ transmission, all surfaces that are touched by both the patient and the user should be periodically cleaned and disinfected and at least before any further use on the patient.

1. If the patient perspires heavily during use, dry the TYMO® components after use before disinfecting them.
2. Moisten the disposable cloth, according to the product information leaflet, only slightly with disinfectant. Wipe the TYMO® components with the clean, soft and 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.
5. Always store the TYMO® components in clean and dry rooms or facilities after use.

6.5 Repair

Always contact the manufacturer for repairs!

6.6 Disposal

TYMO® must not be disposed of as household waste according to the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE-RL) and the respective national legislation. The product must be disposed of at the intended collection point or at a collection point approved for the recycling of waste electrical and electronic equipment. It can also be returned to Tyromotion GmbH.

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