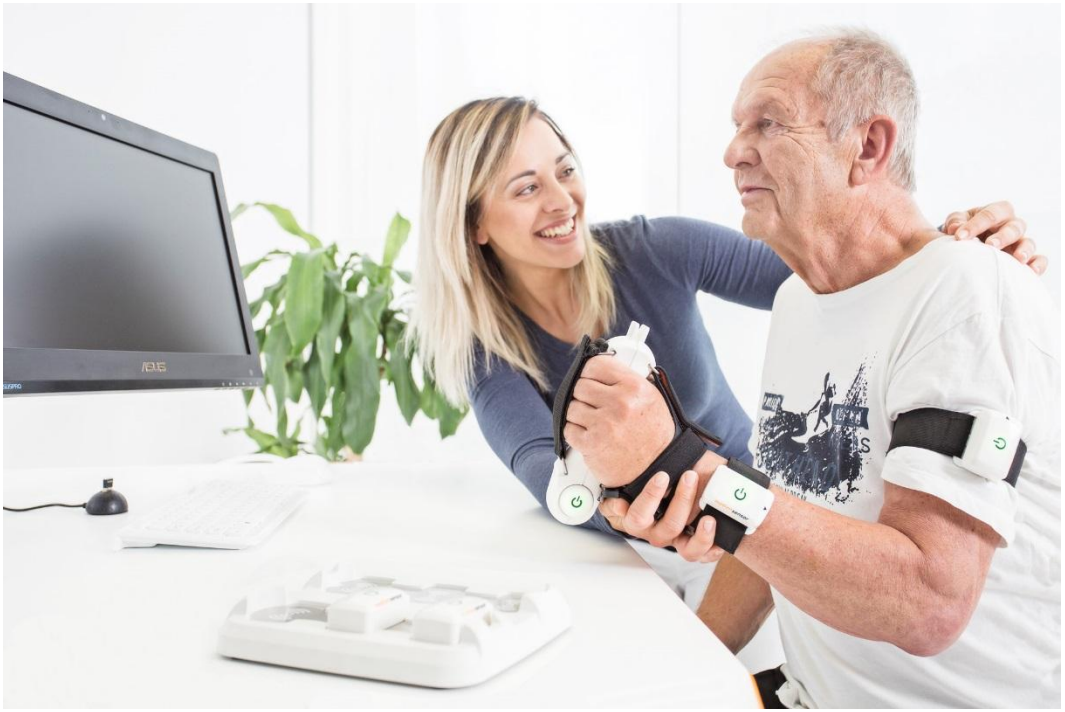
PABLO® G5

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 PABLO® accessories.

Table of contents

1 Introduction

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

It is absolutely imperative that every user completes the training course and has read the instruction for use and accompanying documents prior to using PABLO®!

1.1 Labels and Dimensions

Figure 1: Label PABLO Handsensor

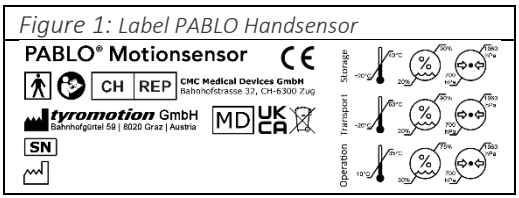


Figure 2: Label PABLO Motionsensor

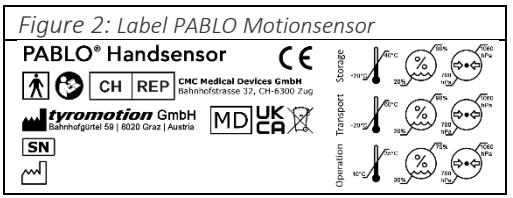


Figure 3: Label PABLO Multiboard

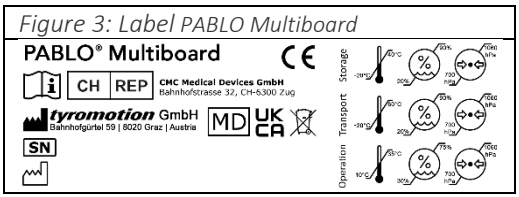


Figure 4: Label PABLO Multiball

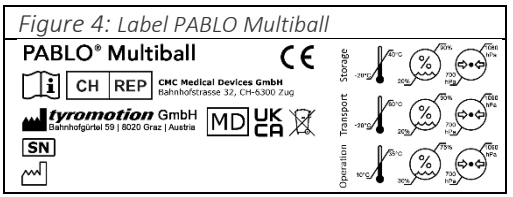


Figure 5: Label PABLO Multipad small

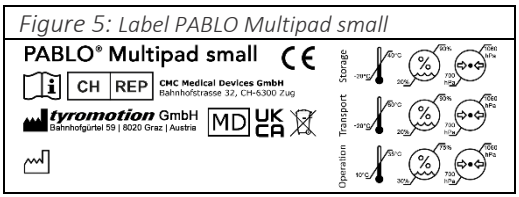


Figure 6: Label PABLO Multipad large

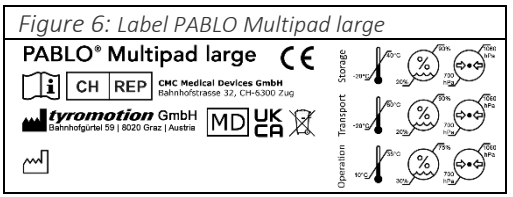


Figure 7: Label PABLO Charger

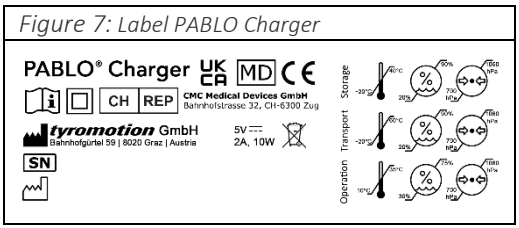


Figure 8: Label PABLO

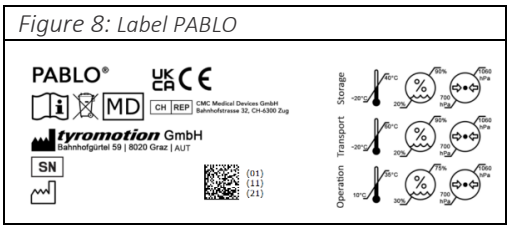


Figure 8: Switch on/off PABLO Handsensor

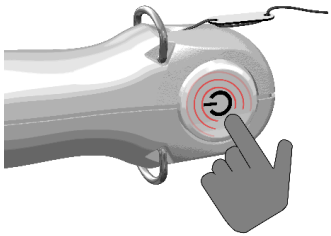


Figure 9: Switch on/off PABLO Motionsensor

Figure 10: PABLO power supply and USB-C connector

Figure 11: Label PABLO Motionsensor

Figure 12: Label PABLO Multitboard

Figure 13: Label PABLO Mulitball

Figure 14: Label PABLO Handsensor front

Figure 15: Label PABLO Handsensor back

Figure 16: PABLO Handsensor and Motionsensor

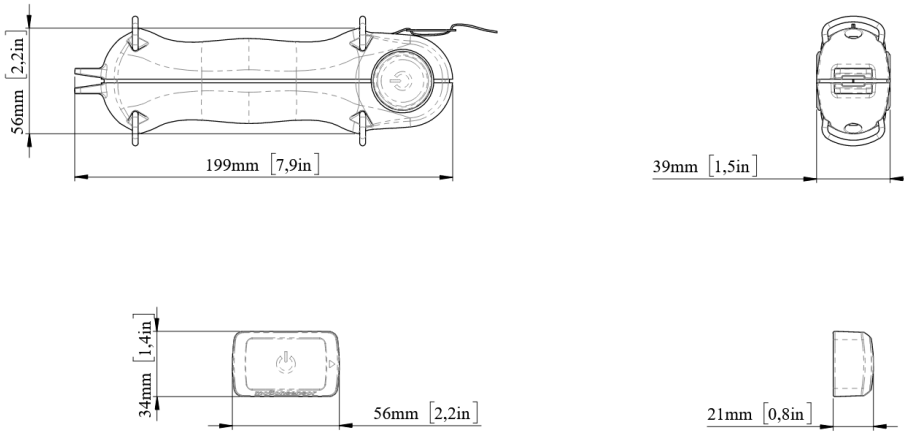


Figure 17: PABLO power supply

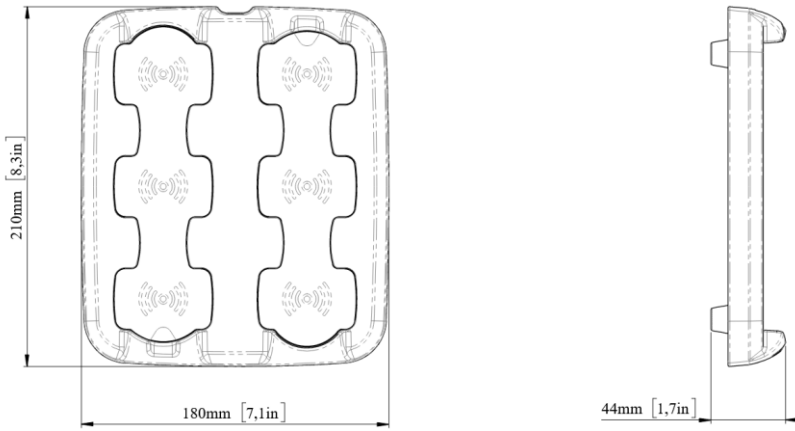


Figure 18: PABLO Multiball

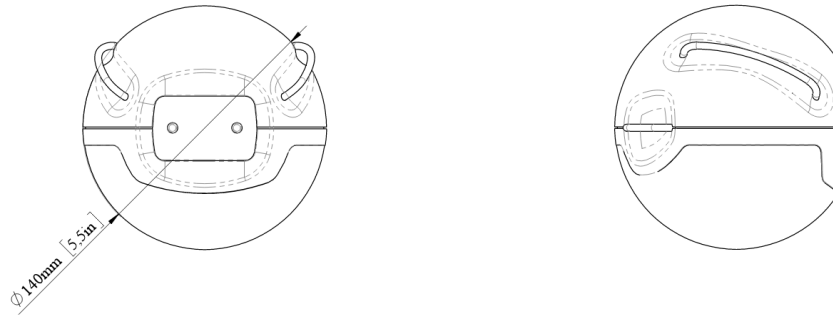
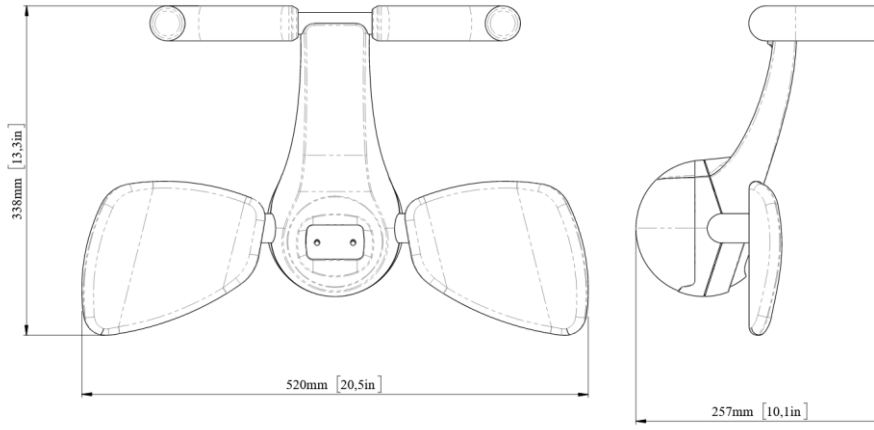


Figure 19: PABLO Multiboard



1.2 Symbols

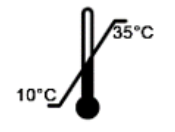
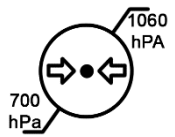
1.2.1 Symbols in the instructions for use

	*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!*
	*Follow the instructions for use*

Table 1: Symbols in the instruction for use

1.2.2 Symbols on PABLO®

	*Do not discard with household waste*
	*Applied part, type BF*
	*Information about the manufacturer of PABLO®, including the manufacturer's full mailing address is displayed next to the factory symbol.*
	*Date of manufacture*
	*Serial number of the device*

MD	*Medical device*
UK CA	*The UKCA mark is a product marking which is used for medical devices placed on the Great Britain (England, Wales, Scotland) market that confirms conformity.*
CH REP	*Swiss Authorised Representative*
(XX)XXXXXXXXXXXXX (XX)XXXXXX (XX)XXXXXXXXX	*Unique Identifier of Medical Device*
	*Upper and lower limit of temperatur:* *Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.*
	*Humidity limitation:* *Indicates the range of humidity to which the medical device can be safely exposed.*
	*Atmospheric pressure limitation:* *Indicates the range of atmospheric pressure to which the medical device can be safely exposed.*
	*Consult instructions for use*
	*Follow the user manual.*
	*On-switch for PABLO® Handsensor and PABLO® Motionsensor*

	*Contact area for wireless battery charging*
	*Direction indicator for correctly attaching the PABLO® Motionsensor*

Table 2: Symbols on PABLO®

1.3 Warranty and legal disclaimer

Tyromotion GmbH issues a warranty to the original medical device 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 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 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 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 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 above mentioned 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.

Please note that the PABLO® Strap Set is not covered by our manufacturer's warranty. The straps are consumables, in other words wear parts.

1.3.1 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 PABLO® 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 PABLO® 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.

1.3.2 Errors and omissions

Please contact Tyromotion if this instruction for use contains errors or omissions (addresses are listed at the beginning of the document and on our website www.tyromotion.com).

1.3.3 Property of Tyromotion GmbH

Tyromotion GmbH owns the copyright-protected content of this instruction for use, including all figures and illustrations; this information is exclusively provided for operational, maintenance and repair purposes. Any distribution for other purposes or copying without prior written approval by Tyromotion GmbH is prohibited.

2 Product Description

2.1 The therapy device

PABLO® is a wireless sensor-based rehabilitation device for the measurement of various parameters of the human body and for therapeutic movement exercises.
The PABLO® Handsensor offers measuring options for various grasping patterns of the human hand, including resulting force, and allows the depiction of trends. The hand's extension and flexion forces can be measured by means of force sensors inside the cylindrical handles. Additionally, the range of motion of the arm (shoulder, elbow and wrist) can be determined by means of position sensors.
The PABLO® Motionsensor can be used both independently and in combination with the PABLO® Multiball, PABLO® Multiboard, PABLO® Multipads or the included strap set. It is a portable, compact, and wireless sensor for monitoring spatial movement. The sensors can be attached to various parts of the upper and lower extremities as well as to the torso with the straps included in the set. PABLO® also provides a quick and easy gait analysis for various gait parameters, such as walking speed, stride length and step frequency. Furthermore, the duration of individual gait phases as well as movement deviations can be determined. This makes it possible to objectively assess and document pathological gait patterns, movement asymmetries, and changes over time.

Furthermore, the PABLO® Handsensor and the PABLO® Motionsensors offer the possibility of a haptic feedback rendition by means of vibration.
Every interaction with the system is recorded and can be seen in the documentation. This recorded data shows therapy results and the therapy progress, based on that the therapy can be individually adapted for each patient. While using modern technology the focus is on therapeutic relationships and on individual therapy.

2.2 Content

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

- 1 x PABLO® Handsensor (incl. Safety strap)
- 2 x PABLO® Motionsensor
- 1 x PABLO® Multiball
- 1 x PABLO® Multiboard
- 1 x PABLO® Charger
- 1x PABLO® power supply (manufacturer: Adapter Technology, model: ATM012T-W050VU)
- 1 x USB charging cable with USB-C magnetic connector
- 2 x Multipad small
- 1 x Multipad large
- PABLO® Strap Set
  - 1 x Wrist strap – PABLO® Handsensor
  - 1 x Finger strap – PABLO® Handsensor
  - 2 x Hand straps, backside - PABLO® Multiball (1 x short, 1 x long)
  - 1 x Wide strap - PABLO® Multiball
  - 7 x Straps - PABLO® Motionsensor incl. connector (2 x short, 2 x medium, 2 x long, 1 x extra-long)
  - 4 x foot straps for PABLO® Motionsensor (2 x short, 2 x long)
  - 2 x heel loops
  - 2 x connectors for PABLO® Motionsensor
- 1 x Bluetooth Adapter
- 1 x USB extension
- 1 x Hex driver (for PABLO® Multiboard installation)
- USB stick (User manual, TyroS® Software)

Accessories or spare parts such as PABLO® Strap Set can be obtained directly from the manufacturer.

2.3 Intended Medical Indication

PABLO® is a 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 grasping control, grasping accuracy, coordination, body control and balance. Depending on national variances, PABLO® is typically used in occupational therapy and/or physiotherapy as therapeutic support, enhancement, and intensification in addition to conventional therapy forms. Repetitive active exercise and training promotes neuronal plasticity and thus the alteration (adaptation) of synapses, nerve cells or even entire cerebral areas for the purpose of regaining lost functionality.

2.4 Characterization of User Profile

The user must have basic medical training (e.g., physiotherapy or occupational therapy) and experience in conventional therapy. Users are able to perform initial and repeated training sessions with PABLO. Users are not allowed to instruct other persons in the use of the device. Users are trained by a member of Tyromotion GmbH, by a trainer delegated by Tyromotion GmbH. Users should have a basic education in EDP and be able to operate Windows-based software with conventional input devices such as mouse and keyboard.
Self-use of the device by the patient is not intended. The presence of trained personnel within sight and hearing distance of the patient during therapy is therefore mandatory.

2.5 Characterization of Patient Population

PABLO® is mainly used in neurologic rehabilitation of the distal upper extremity. The target population includes not only neurologic but also orthopedic and pediatric patients with deficits in movement control, force application, force control, aiming accuracy, coordination, trunk control and balance. Upper extremity, lower extremity and trunk application is possible. 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 PABLO® 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 PABLO® 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.

2.5.1 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 post traumatic hand surgery sequelae

2.5.2 Contraindications

Absolute Contraindications: The device must not be used!

- Acute pain despite conventional pain therapy
- Adjustment and patient position: Do not carry out training with PABLO® 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 PABLO® 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. PABLO® does not influence heart pacemakers if the distance between pacemaker and device is more than 15 cm.
- Infections

- Joint problems: Repetitive training may cause pain and irritation in case of weak joints.
- Neglect
- Osteoporosis
- Orthostatic circulatory problems
- 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.
- Swellings of the upper extremity

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).

2.6 Characterization of Use Environment

2.6.1 Overview

Table 3: Technical overview

Type description:	PABLO®
Classification:	*PABLO® is an active, therapeutic class I medical product according to rule 1 and 13 of the 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) *PABLO® 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. 10mW* *Operational area: 10 meters given uninterrupted view between PABLO® and PC*
Operating type:	*Continuous operation*
Measurement range:	*Hand Force Sensor: 1000N flexion, 200N extension* *Finger Force Sensor: 100N* *Resolution force measurement: 0,1N (0 – 1000N)* *Wrist Joint: Extension/Flexion (90°-0°-90°); Ulnar-/Radial deviation (90°-0-40°)* *Elbow Joint: Extension/Flexion (10°-0°-170°); Pro-/Supination (120°- 0°-120°)* *Shoulder Joint: Extension/Flexion (40°-0°-190°); Abduktion/Adduktion (180°-0°-40°)*
Measurement deviation:	*Deviation of force measurement: < ±2% ± 2 N (-200N to 1000N)* *Deviation of angle measurement: < ±3°* *Operational area: 10 meters given uninterrupted view of computer device*
Weight:	*PABLO® Handsensor (in g): 290* *PABLO® Motionsensor (in g): 40* *PABLO® Charger (in g): 950* *PABLO® Multiball (in g): 750* *PABLO® Multiboard (in g): 1600*
Device Requirements:	• *Windows 10 64 Bit; Home or Professional* • *Intel- or AMD-Prozessor with >= 2 GHz* • *DX10 compatible GPU or iGPU* • *Storage 8 GB RAM* • *Storage space 8GB* • *Display resolution 1366x768* • *Bluetooth 5.0*

2.7 Area of application

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

Operation:

Temperature: 10 ... 35 °C

Humidity: 30 … 75 % relative humidity

Air pressure: 700 hPa … 1060 hPa

Storage:

Temperature: -20 ... 40 °C

Humidity: 20 ... 90 % relative humidity, no dew

Air pressure : 700 hPa … 1060 hPa

Transport :
Temperature: -20 ... 60 °C
Humidity: 20 ... 90 % relative humidity, no dew
Air pressure: 700 hPa … 1060 hPa

PABLO® 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 PABLO®.

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS		
PABLO® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of PABLO® must ensure that it is used in such an environment.		
Interference emission measurements	Agreement	ELECTROMAGNETIC ENVIRONMENT – Guidelines
HF emmissions according to CISPR 11	*Group 1*	*PABLO® 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*	*PABLO® 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*	

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC IMMUNITY			
PABLO® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of PABLO® 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 5: Guidelines and Manufacturer 's declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration— ELECTROMAGNETIC IMMUNITY			
PABLO® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of PABLO® 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**
Conducted RF IEC 61000-4-6	*6 V_{rms} 150 kHz to 80 MHz*	*6 V*	***Recommended Separation Distance:*** $d = 0.58\sqrt{P}$
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 PABLO® 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 PABLO®.*

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

Table 6: Guidelines and Manufacturer's declaration – Electromagnetic Immunity

Recommended separation distances between portable and mobile RF communications equipment and PABLO®			
PABLO® 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.			

Table 7: Recommended separation distances between portable and mobile RF communications equipment and PABLO®

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.

2.8 Training concept

The PABLO® system is a complex technical device. Users of the PABLO® system are required to complete a training course and read the user manual to ensure the safety of patients, users and the device itself. Merely reading the present manual does not convey sufficient competence for operating PABLO®. 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 PABLO® system.
Users can perform initial and repeated therapies training with the PABLO® system. Users are not permitted to instruct other persons in the usage of the PABLO® system. Users are trained by a member of Tyromotion GmbH or by another trainer delegated by Tyromotion GmbH.

3 Safety Information

3.1 Warnings and Remaining Risks

3.1.1 Safety concept

PABLO® 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. Caregivers are also required to have basic medical training (e.g. physiotherapy/occupational therapy).

Users

- Every user must have read the instructions for use prior using PABLO®. Tyromotion GmbH rejects any liability for damages to persons or material if safety regulations and instructions relevant to the usage of PABLO® 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.
- No other objects than the PABLO® Sensors must be placed on the PABLO® Charger, as they may cause harm to the device as well as to people.
- The user must take appropriate measures to stabilize the patient during therapy.
- If there is any doubt as to the continued safe use of PABLO® or if any parts should fail or 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.

Product

- No modifications to PABLO® are allowed.
- Always contact the manufacturer for repairs!

- Battery-operated devices must not be dismantled or opened.
- Battery-operated devices must not be subjected to mechanical shocks.
- If liquid escapes from the device, it must not come into contact with the skin or eyes. If contact has occurred, wash the affected area with plenty of water and seek medical attention.

Only the supplied power supply may be used to charge PABLO®. The use of any other power supply may lead to unforeseeable risks or damage.

- Power Supply:
  - Model: ATM012T-W050VU
  - Manufacturer: Adapter Technology

Caution
PABLO® may not be used in explosion-prone zones AP and APG according to EN 60601-1.

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 PABLO® system. These materials include:

- Diethyl ether (Ether pro narcosi)
- Cyclopropane

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

3.1.2 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 PABLO® has experienced an injury due to the use of PABLO® please report this to the manufacturer and to your national health authority.

4 System Requirements

4.1 First steps

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

4.1.1 Charging PABLO®

PABLO® is equipped with a rechargeable battery. Before using PABLO® for the first time, fully charge the DEVICE using the supplied PABLO® charger (6.2.6). The charging time is 4 hours when the battery is completely empty.

The use of charging units that have not been recommended by Tyromotion GmbH is expressly forbidden, because unforeseen risks could arise for people and equipment.

The PABLO® charger is connected to the mains supply via a plug. Please place PABLO® in a way that the plug is easily accessible.

4.1.2 Installation of the Software

You will find a detailed installation guide in the instruction manual of the TyroS software.

4.1.3 Installation of the Bluetooth adapter

PABLO® is connected to your PC with Bluetooth technology. In order 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 there is no Internet access, the driver must be installed manually. You will find the necessary drivers on the supplied Tyromotion USB stick. 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 20: Bluetooth adapter

Figure 21: Bluetooth adapter incl. USB extension

4.1.4 Connecting PABLO® to the PC

Important points before the installation:

- The PABLO® Sensors 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 3.3.4).
- The PABLO® Sensors must not be more than 10 meters away from the PC.
- The PABLO® Sensors must be turned on.
- Settings Windows 10
    - Enter "Settings" in the Windows search and start the app of the same name.
    - In the new window, click on "Devices" and switch to the tab "Bluetooth and other devices".
    - Click "Add Bluetooth or other device". Then the window "Add device" will open and click on "Bluetooth".
    - Windows 10 automatically searches for available devices that can be connected.
    - After a while, all nearby Bluetooth devices appear. Select the entry “Serial Adapter” or the device with the PABLO® serial number and click on “Next”. Then click on “Close”.
    - Installation is completed and the PABLO® Sensor is now ready for use.
    - Repeat these steps for all PABLO® Sensors.

4.1.5 Deactivation of the integrated Bluetooth adapter

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

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-entry. Right-Click on the integrated Bluetooth adapter and choose “Disable”.

5 Safety and Maintenance

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.

5.1 Monthly functionality check

The functionality checks described here must be performed on a monthly basis. Perform the checks even if PABLO® 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 PABLO®.

Inspection:	Malfunction:	Resulting measure:
Protective covers	• *Covers shake* • *Covers missing* • *Covers damaged*	• *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	• *PABLO® system contaminated*	• *Further use is prohibited.* • *Clean the contaminated parts as described in chapter 0*
Safety strap PABLO® Handsensor	• *Safety strap missing or damaged*	• *Further use is prohibited* • *Contact Tyromotion GmbH*
Click closure for connecting PABLO® Motionsensor	• *Connection PABLO® Motionsensor does not hold*	• *Further use is prohibited* • *Contact Tyromotion GmbH*
Battery	• *Battery life drops below 2h* • *housing deformations due to an inflated battery occur*	• *Further use is prohibited* • *Contact Tyromotion GmbH*

Table 1: Inspection points

5.2 Periodic checks

Periodic checks differ from the checks described in chapter 1.1 as the legislator may demand the check described here while the checks in chapter 1.1 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. PABLO® must not be used if the test intervals have not been complied with.

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

5.3 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.

5.4 Cleaning instructions

Mandatory, standardized disinfection measures:

- *Disinfection of PABLO® objects 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.

5.4.1 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.

5.4.2 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.

5.4.3 Instruments

Clean, lint-free and non-abrasive cloths.
Do not use scouring agents, metal brushes or scouring pads.

5.5 Repair

Always contact the manufacturer for repairs!

5.6 Disposal

PABLO® 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.

6 Using the Device

6.1 PABLO® Handsensor

Figure 22: PABLO® Handsensor (incl. Safety strap)

The PABLO® Handsensor is connected to the PC via Bluetooth, offers measuring options for various grasping patterns of the human hand, including resulting force, and allows the depiction of trends. The hand's extension- and flexion forces can be measured by means of force sensors inside the cylindrical handles. The special design of the PABLO® Handsensor allows for measuring the force of functional grasp motions such as pincer-, lateral- and interdigital grips. Additionally, the range of motion of the arm (shoulder, elbow and wrist) can be determined by means of position sensors.

Furthermore, the PABLO® Handsensor offers the possibility of a haptic feedback rendition by means of vibration.

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

Observe the LED display on the PABLO® Handsensor (see chapter 6.2.8). This provides information on the status of the PABLO® Handsensor.

6.1.1 Preparation of the PABLO® Handsensor

In order to prevent any therapy disruption as well as damage to the PABLO® Handsensor, the sensor can be attached to the patient's hand with the hand strap included.

1. Take the PABLO® Handsensor, the wrist strap and the finger strap and place them in front of you. Make sure the PABLO® Handsensor is positioned with the on-symbol visible on the top.

Figure 23: PABLO® Handsensor with straps

2. Pull the finger strap through the two strap clamps on the left-hand side of the PABLO® Handsensor, starting from the bottom. Then, pull the wrist strap through the strap clamps on the right-hand side of the PABLO® Handsensor. Make sure the orange Velcro® strap is pulled through the upper-, and the black Velcro® strap is pulled through the lower strap.

Figure 24: Fixation of the finger strap - 1

Figure 25: Fixation of the finger strap – 2

Figure 26: Fixation of the wrist strap - 1

Figure 27: Fixation of the wrist strap - 2

3. Pull the strap for the wrist through the black loop and fasten the Velcro®

6.2 PABLO® Motionsensor

Figure 28: PABLO® Motionsensor

The PABLO® Motionsensor is connected to the PC via Bluetooth and can be used both independently and in combination with the PABLO® Multiball, PABLO® Multiboard or the included strap set. It is a portable, compact, and wireless sensor for monitoring spatial movement. The sensors can be attached to various parts of the upper and lower extremities as well as the torso with the straps included in the set.

Furthermore, the PABLO® Motionsensor offers the possibility of a haptic feedback rendition by means of vibration.
The sensors included in the set offer a variety of therapeutic possibilities when used in combination with the TyroS software.

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

Observe the LED display on the PABLO® Motionsensor (see chapter 6.2.8). This provides information on the status of the PABLO® Motionsensor.

6.2.1 Preparation PABLO® Motionsensor

The PABLO® Motionsensor can be mounted to and dismounted from the PABLO® Multiball or the PABLO® Multiboard with the buckle release, or connected with the strap system.
When mounting the PABLO® Motionsensor, make sure that the arrow on the housing always points in the correct direction.

PABLO® Multiball

Figure 29: Correct alignment of the PABLO® Motionsensor on the PABLO® Multiball

PABLO® Multiboard

Figure 30: Correct alignment of the PABLO® Motionsensor on the PABLO® Multiboard

Correct alignment of the PABLO® Motionsensor in conjunction with straps

Figure 31: Correct alignment of the PABLO® Motionsensor in conjunction with straps

Figure 32: Foot strap set - Individual components (heel loop, foot strap, connector for PABLO® Motionsensor, clip)

Figure 33: Foot strap set - step 1: Threading the clips and heel loop

Figure 34: Foot strap set - step 2: Threading the connector for PABLO® Motionsensor

Figure 35: Foot strap set for connecting PABLO® Motionsensor

6.2.2 PABLO® Multiboard

Figure 36: PABLO® Multiboard

The PABLO® Multiboard, in combination with the PABLO® Motionsensor, is used for active training of the entire upper extremity and the torso. With this component, the elbow- and shoulder-joints can be moved in different directions.

6.2.3 Preparation of the PABLO® Multiboard

The PABLO® Multiboard is disassembled when delivered (main arm, two hand rests, one handle). Mount the single components of the PABLO® Multiboard with the 6 raised flathead screws included. Use the hex driver included.

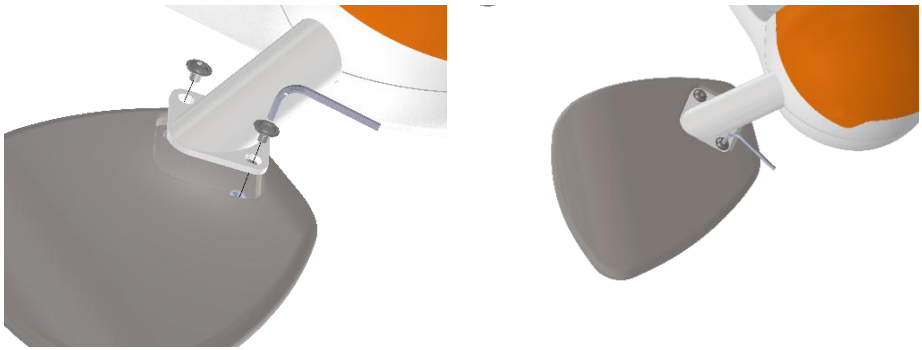


Figure 37: Mount the hand rests to the main arm

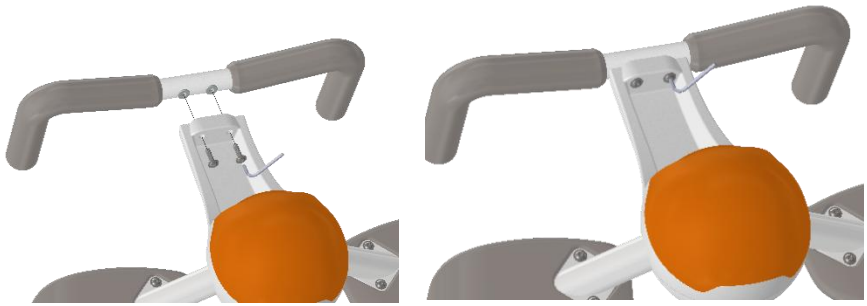


Figure 38: Mount the handle to the main arm

6.2.4 PABLO® Multiball

Figure 39: PABLO® Multiball

The PABLO® Multiball, in combination with the PABLO® Motionsensor, is used for exercising the distal motions of the upper extremity. Using the functional ball, the patient trains pro- and supination as well as dorsal flexion and -extension.

6.2.5 Preparation of the PABLO® Multiball

In order to prevent any therapy disruption as well as damages to the PABLO® Multiball, it can be attached to the patient's hand with the strap included.

1. Remove the PABLO® Multiball and the supplied straps from the packaging and place them in front of you. Make sure the short Velcro® straps (with stoppers) are at the back, and the long Velcro® straps are at the front.

Figure 40: PABLO® Multiball with straps

2. Now, thread the short Velcro® straps with the stoppers through the narrow strap clamps at the back of the PABLO® Multiball. Make sure the Velcro® fastener faces upwards. The stoppers prevent the short Velcro® straps from slipping off the strap clamps when unfastened.

Figure 41: Threading the short straps at the back

3. Now, thread the long Velcro® straps through the wide strap clamps at the front of the PABLO® Multiball. Make sure the Velcro® fastener faces upwards.

Figure 42: Threading the long straps at the front

4. Now, thread the wide strap through the wide strap clamp at the front of the PABLO® Multiball. Make sure the Velcro® fastener faces upwards.

Figure 43: Threading the wide strap at the front

6.2.6 PABLO® Charger

Figure 44: PABLO® Charger

You can charge up to six PABLO® Motionsensors respectively up to two PABLO® HandsensorS with the PABLO® Charger. Place the PABLO® Sensors in the designated positions.

6.2.7 PABLO® Multipad small, PABLO® Multipad large

PABLO® Multipads can be used for additional stability training and as a support tool.

Figure 45: PABLO® Multipads large (left), PABLO® Multipads small (right)

6.2.8 Explanation of the LED Display at PABLO®

LED-Display	Meaning	Necessary Action
Shining ORANGE	*Connection with software okay, battery level under 15%*	*Charging the battery (section 6.2.9)*
Flashing ORANGE	*No connection with software, battery level under 15%*	*Charging the battery (section 6.2.9)*
Shining GREEN	*Connection with software okay, battery level okay*	*None*
Flashing GREEN	*No connection with software, battery level okay*	*None*
Shining BLUE	*Battery is charged*	*None*
Flashing BLUE	*battery is being charged*	*None*
Off	*Battery of the device is completely flat, or the device is switched off*	*Charging the battery or switch on the device (section 6.2.9).*

Table 8: LEDs

6.2.9 Battery

Charging Battery:

In order to charge the batteries, first connect the PABLO® Charger to a plug and then put the PABLO® Sensors onto the charging sockets destined for the sensors. The PABLO® Sensors switches into the charging mode automatically (Note the LED display described in Chapter 6.2.8).

PABLO® Handsensor und PABLO® Motionsensor must be fully charged before being used for the first time.

Figure 46: Correct positioning of the Sensors

Figure 47: Wrong positioning of the sensors (NO charging!)

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. As a general rule, however, the charging process should not last longer than 4 hours.

After prolonged storage, it may be necessary to charge the battery-powered devices for a longer period of time.

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 the PABLO® sensors 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 service life is minimum 6,5 hours (when fully charged).

6.3 Prior to therapy

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*

6.3.1 PABLO® Application

To use PABLO®, carry out the following steps:

- PABLO® can be activated after it has been properly installed (chapter 4.1) and connected.
- Starting therapy:
    1) Switch on PABLO® by pushing the button on PABLO® Handsensor and PABLO® Motionsensor for approx. 3 seconds (Figure and Figure 9).

The sensors vibrates briefly. The LED button should now start blinking green.

2) Start the TyroS software by double-clicking on the TyroS symbol on your desktop.
3) PABLO® connects itself to your PC automatically via Bluetooth technology as soon as you start a therapy session with PABLO®. Please note the LED display on the PABLO® Handsensor and the PABLO® Motionsensor (Chapter 6.2.8). This gives information on the current status of PABLO®.

- Performing therapy:
  1) Apply now PABLO® 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) After use, detach the patient from all used PABLO® components.
  3) Switch off PABLO® by pushing the LED button for approx. 5 seconds. The LED color will then change to solid violet. Release and press the button again for two seconds to switch off the PABLO®. If a PABLO® Sensor is disconnected from the software for more than 60 minutes, it will switch off automatically.
  4) After use, place all PABLO® Sensors (Handsensor and Motionsensor) in the designated positions on the PABLO® Charger. The PABLO® Sensors automatically change into charging mode (see LED display described in chapter 6.2.8).
  5) Make sure all PABLO® 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 for the TyroS software.

Despite its robust and high-quality construction, the PABLO® Handsensor and PABLO® Motionsensor only has a limited ability to withstand shocks. If a sensor falls from the 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 PABLO® after a fall; instead, immediately contact Tyromotion GmbH or the dealer from whom you bought PABLO®.

As the PABLO® Sensors for wireless communication via Bluetooth use a similar bandwidth to Wi-Fi, the signal may be lost occasionally.

6.3.2 Attaching PABLO® to the patient

The straps included in the set are meant to optimally attach the PABLO® components to the patient and thus ensure the best therapy results possible.

Please note: Check for possible existing circulatory disorders before attaching the straps to the patient.
In case of indication of any such disorder, the patient must be regularly examined and checked for pain, swellings, and skin discoloration during therapy with PABLO®. If the patient shows any signs of such indications the therapy is to be suspended.

Attaching the PABLO® Handsensor

Proceed as follows when attaching the hand to the PABLO® Handsensor.

1. Attach the safety strap to the wrist und pull it firmly. The safety strap helps prevent the PABLO® Handsensor from falling to the ground and getting damaged during therapy.

Figure 48: Attached safety strap

2. Place the hand in the wrist strap and close the Velcro® fasteners on both sides of the PABLO® Handsensor.

Figure 49: For fixation of the hand, attach the wrist strap to the PABLO® Handsensor

Attaching the PABLO® Multiball

Proceed as follows when attaching the hand to the PABLO® Multiball.

1. Place the hand on the PABLO® Multiball and fixate the hand with the straps as follows.

Figure 50: For fixation of the hand, attach the strap to the PABLO® Multiball

2. If needed, you can also fixate the thumb using the long Velcro® strap.

Figure 51: Fixation of the thumb on the PABLO® Multiball

Attaching the PABLO® Motionsensor

The sensors can be attached to various parts of the upper and lower extremities as well as the torso with the straps included in the set.

1. Attach the strap to the desired part. Choose a suitable strap length.

Figure 52: Strap for the PABLO® Motionsensor

Figure 53: Fixing possibilities PABLO® Motionsensor

2. Click the PABLO® Motionsensor into the designated bracket. **PLEASE NOTE: When attaching the PABLO® Motionsensor, make sure that the arrow on the housing always points upwards.**

Figure 54: Correctly attaching the PABLO® Motionsensor

For use with foot straps:

1. Attach the foot strap set to the foot.
2. Click the PABLO® Motionsensor into the designated bracket. **PLEASE NOTE: When attaching the PABLO® Motionsensor, make sure that the arrow on the housing always points towards the toes.**

Figure 55: Fixation of the PABLO® Motionsensor on the foot with foot strap set

6.4 Performing therapy

Please always observe the TyroS instruction for use throughout the entire training.

Only trained personnel may be near the patient and the device 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.

6.4.1 Patient information

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

6.5 After therapy

6.5.1 Deactivating the PABLO® system

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

Please also observe the TyroS instruction for use in this regard.

6.5.2 Cleaning PABLO® and associated parts

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., sensors, straps, Multiboard, Multiball, Multipads.
Cleaning must be carried out in accordance with the cleaning instructions in chapter 5.4.

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