DIEGO®
GEBRAUCHSANWEISUNG / USER MANUAL

tyromotion

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1 Introduction

We are pleased to provide this user manual as an introduction for the usage of the DIEGO® arm and shoulder therapy system (in the version DIEGO® or DIEGO® system).
The manual addresses the essential functions necessary for the operation and usage of the DIEGO® system.
The DIEGO® arm and shoulder therapy system was developed in cooperation with the Private Clinic Laßnitzhöhe, (Styria/Austria) and the FH Joanneum Graz (Polytechnic Joanneum Graz). An optimal project result for all involved persons was only made possible due to the targeted and efficient cooperation of medical practitioners, therapists and technicians.
We, of course, remain interested in the continuous optimization of the therapy system through direct feedback from patients as we aim to improve the usability of our devices. We are, therefore, especially interested in ideas and suggestions from our long-term users.
If you have any questions, ideas or suggestions, please contact TYROMOTION GmbH (contact information in this user manual).

1.1 System content

The DIEGO® system includes the following delivery contents:

- Device suspension including internal electrical cables
- 2 ArmUnits - DIEGO® offers therapeutic treatment for one or both arms.
- 6 hand/arm sling sets (application part type BF) in the following sizes:
  - 2x small (white marking)
  - 2x medium (orange marking)
  - 2x large (black marking)

  Each set includes the following components:
  - Elbow sling
  - Handle with foam lining
  - Straight plastic insert
  - Angled plastic insert
  - Short plastic insert
  - Fabric cover for plastic inserts „straight“ and „angled“
  - 3 wrist slings of various lengths
  - 3 fixation Velcro strips of various lengths
  - 5 hygienic cloths
- All-In-One PC including mouse and keyboard
- Device power plug-in (only within the EU or in other countries with the same ground wire connection)
- User manual
- Assembly instructions

- The following is included in the assembly material:
  - 2x hexagon screw M10x20 per ArmUnit

- 4x hexagon screw M10x20 for wall mounting (only 2 hexagon screws required for free-standing setup
- 4x knurled head screw M4x10 for VESA screen assembly
- 4x hexagon panhead screw M6x16 for fastening connecting rod

Consumption materials, as e.g. the hand-arm slings or replacement ropes, are available directly from the manufacturer.

1.2 Description of the system's functions

The DIEGO® system is a modern, mechatronic shoulder-arm rehabilitation device for rehabilitating patients with limited arm function; it can measure the arm's movement range and also perform functional arm therapy.

The DIEGO® arm and shoulder therapy system consists of two ArmUnits that hang above the patient (therapy units) and allow separate therapeutic treatments for each arm. Two dangling ropes pull the patient's arm upward at two locations (attached to the wrist and elbow). The tractive upward force can be adjusted individually.

The system can be operated with one or two ArmUnits. Both arms can be treated simultaneously if the operation for two ArmUnits is enabled.
Each ArmUnit contains two electric motors, which allow an independently adjustable weight easing of one arm at the patient's elbow and wrist.
The DIEGO® system provides a weight easing function for the patient's arm, which not only extends the movement range but also improves coordination and reduces evasive movements. Various assessments assist the therapist in determining the therapy process with DIEGO®; these assessments can also be presented to the patient.

A combination of integrated sensors makes it possible to perform all known therapy applications by TYROMOTION GmbH in any position or with any movement. The sensors integrated in the system can even detect any arbitrary arm position in a 3D space, making it possible to, for the first time, perform virtual therapy sessions.

Bilateral therapy

The DIEGO® system provides bilateral therapy (use of both arms simultaneously). This function complies with state-of-the-art neuro-rehabilitation procedures for the upper extremities and provides a unique distinguishing feature compared to other competing products. Specific therapy programs require the coordination of both arms in order to achieve a certain goal.
However, the system also offers unilateral therapy in which only one of the ArmUnits is operational. Numerous therapy applications also offer motivational therapy for unilateral operation.

Free-standing assembly with castor wheels

The mounting frame makes it possible to easily move the entire system in the therapy room, which makes therapy sessions much more flexible.

Always deactivate the device and unplug the power cable before moving the DIEGO® system. Remove loose components (e.g. computer mouse and keyboard) from the supporting table before moving the device. Apply all 4 castor wheel brakes before beginning the next therapy session.

It may not be possible to move the device through doors, room dividers etc. in an upright position due to the height dimension of the system. Take note of the device dimensions indicated in the user manual.

Wall mounting

The DIEGO® system can be optionally mounted in a fixed position with the mounting bracket. This mounting method provides better accessibility for patients with wheelchairs and walking aids since access to the system is not impeded by frame components on the ground. Contact TYROMOTION GmbH for further information.
Observe the included assembly instructions for the proper assembly and mounting of the system.

1.3 Intended purpose

The intended purpose of the DIEGO® system is the therapeutic treatment of neuronal damage in the CNS caused by strokes or traumatic brain injury. The system is primarily used in occupational therapy as a supporting device for traditional forms of therapy.

The DIEGO® system supports patients with limited arm function during therapy. Ropes connect each of the patient's arms at two points (wrist and elbow) to the DIEGO® system. These ropes are controlled by the tyroS software; the mechanism alleviates the arm movement requiring the patient to only lift part of the weight. The resulting repetitive movements of the elbow and shoulder joint generate afferent signals, which are transmitted to the central nervous system. This promotes the restructuring of the central nervous system and alleviates the movement recovery process while expanding the patient's movement range.

1.3.1 Main control functions

The DIEGO® system is designed to treat partial paralysis of the upper extremities after suffering neurological damage in the form of a stroke or traumatic

brain injury. The most frequently used therapy functions of the DIEGO® system are listed in the following:

- Assessments for the evaluation of patients
- Passive therapy in which the device moves the patient's arm
- Assistive therapy: The patient is prompted to perform a movement, which is supported by DIEGO® as required.
- Motivational therapy programs, designed to encourage the patient during therapy

A complete list of all functions is provided in the accompanying user manual for the tyroS software.

1.4 Regarding the usage of this documentation

Every user is required to complete a training course and read the user manual before beginning therapy with DIEGO®!

The user manual contains technical specifications and all necessary information for operating the DIEGO® system. It is structured according to the chronological sequence of initial and repeated training sessions (see chapter 3- Clinical application).

1.4.1 Symbols in the user manual

Safety notice – This symbol indicates important safety information relevant to the safety of patients and users.
(Chapter 1.7.6 provides a list of all warnings included in the user manual).

For legibility reasons the following pages only refer to the male gender, which, however, always implies the female gender as well.

TYROMOTION GmbH is not liable for any damage to persons or material if safety provisions and instructions relevant to the usage of the DIEGO® system are not observed.

1.5 Symbols attached to DIEGO®

STOP	**Emergency shutdown (only for one part of the device)** Emergency shutdown button for disconnecting the power
	**Do not discard with household waste.**
	**Application part, type BF**
	**Alternating current**
	**CE mark with the number for the notified body**
	**Follow the user manual.**
	Information about the **manufacturer** of DIEGO®, including the full mailing address, is displayed next to the **factory symbol.**
IPX0	**Protection class for foreign objects and water** X = No protection indication for penetration of solid objects 0 = No protection against water penetration
	**Warning symbol: Tipping hazard while pushing the device** The symbol warns the user that the device might tip if it is moved. Keep this in mind when pushing the device.

	**Reaching in prohibited** This symbol forbids persons from reaching into the ropes of the device as this poses an increased risk for users and patients.
	**Making knots prohibited** Making knots in the ropes of the device is forbidden as this might result in incorrect initial values. The symbol also indicates that the ropes of the device must be checked daily for knots.
	**Usage prohibited for children between the ages of 0 and 5** Performing therapy with DIEGO® is too dangerous for children between the ages 0 and 5 due to the size of their bodies. Also note that different accessories are required for light persons.
	**Sitting prohibited** Sitting on or bracing oneself against the device or device parts is forbidden. This especially applies to the keyboard table and the PC.
	**Labeling on the power switch:** I means the device is activated (top position). O means the device is deactivated (lower position).
	**Lock/Unlock symbols:** These symbols are located on the top side of the DIEGO® ArmUnit. The ArmUnit is secured for transport by inserting a knurled head screw into the position “Lock”.

Illustration 1: Type label including CE mark

The type label (see Illustration 1) designates DIEGO® as a medical product.

In addition to the type label displayed in Illustration 1, each ArmUnit also has a serial number, which is documented for the internal purposes of the manufacturer. The serial number of the arm is displayed, as shown in Illustration 2, on the top side of the ArmUnit.

Illustration 2: Serial number decal for single arm unit

1.6 Training concept

The DIEGO® system is a complex, technical device. Users of the DIEGO® system are required to complete a training course and read the user manual before operating the device in order to ensure a successful patient training and the safety of patients, users and the device itself. Merely reading the present user manual provides insufficient information for the proper usage of the device. Users require basic medical training (e.g. physiotherapy or occupational therapy). TYROMOTION GmbH is not liable for damage resulting from training that was not performed by a trained user.

The DIEGO® delivery contents include training for prospective users. Users are divided into two classes. See chapter 1.6.1 and 1.6.2.

The user (therapist) must complete a training course according to chapter 1.6.1 as a precondition for performing therapy with DIEGO® as an end user. The (hospital) operator must ensure that the DIEGO® device is only operated by properly trained personnel.

1.6.1 End user

- Users are permitted to perform initial and repeated trainings with DIEGO®.
- Users are not permitted to instruct other persons in the usage of DIEGO®.
- Users are trained by a member of TYROMOTION GmbH or by other users that have been authorized by TYROMOTION GmbH (see chapter 1.6.2).

1.6.2 Authorized users

After having received an extensive training, authorized end users are permitted to instruct other end users in the operation of the system.
Authorized users are e.g. distribution partners of TYROMOTION GmbH who are exclusively trained by TYROMOTION GmbH.

1.7 Notices

Familiarize yourself with the user manual before using the system for the first time and continue to do so regularly after the initial use.
Medical personnel and properly trained therapists, who are responsible for the DIEGO® system, are required to urge technicians, patients and other persons within the vicinity of the device to fully observe the indicated safety precautions. The system may only be operated by properly trained personnel. You may request training as required. Ensure that the system is not manipulated by unauthorized personnel. The system must be unpacked and installed by service representatives who are authorized by TYROMOTION GmbH. Never attempt to install the system by yourself.

1.7.1 Owner's responsibilities

The owner is responsible for ensuring that all persons who operate the system have read and understand the 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 that such a person is capable of fixing system errors. The owner must ensure that the installation, maintenance, calibration and repair of the system as well as the fixing of errors is only performed by properly trained and fully qualified personnel. The owner of the DIEGO® system must ensure that only properly trained and fully qualified personnel (authorized users) receive the authorization to operate the system.

Before a person is authorized to operate the system, it must be ensured that this person has read and fully understood the operating instructions contained in this user manual and has been trained either by TYROMOTION GmbH or by other employees of the owner who have been trained by TYROMOTION GmbH. The owner is obligated to maintain a list of authorized operators. The user must contact TYROMOTION GmbH if the system does not work properly or does not respond correctly to the commands described in this user manual.

1.7.2 Errors and omissions

Please contact TYROMOTION GmbH if this manual contains errors or omissions.

1.7.3 Property of TYROMOTION GmbH

The contents of this user manual, including all figures and illustrations, are copyright protected; TYROMOTION GmbH owns this information, and it 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.

1.7.4 Warranty & disclaimer

TYROMOTION GmbH issues a guarantee to the original system purchaser that the system, if used normally, will be free of material and qualitative processing defects for a period of 12 months from the date of installation at the owner's premises and that the system will comply with the mechanical and electrical specifications published by TYROMOTION GmbH (unless the warranty time is extended by an optional service contract). This warranty is granted under the provision that the system is installed, operated and maintained in accordance with the user manual. The customer must submit all warranty claims to TYROMOTION GmbH in written form within 60 days of the occurrence of the problem and before the expiry of the warranty. TYROMOTION GmbH is solely obligated to repair, exchange or correct faulty or non-compliant parts at its own discretion in accordance with the warranty. After the repair or exchange of faulty or non-compliant parts, TYROMOTION GmbH has no further obligations to the owner in regard to these parts. All repairs or maintenance work must be performed by an authorized TYROMOTION GmbH 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 modification are excluded from the warranty.

The above mentioned warranty is granted in place of all other warranties, rights or conditions, and the system is delivered „without deficiency guarantee" in exclusion of this limited warranty. TYROMOTION GmbH and its third party

suppliers specifically and unreservedly reject all other explicit or implicit warranties toward the owner, his personnel and patients, customers, users and any third parties, unreservedly including all warranties for marketability, applicability for a certain purpose, non-injury and any warranties resulting from performance development, business transactions or commercial customs. TYROMOTION GmbH and its third party suppliers do not provide declarations or warranties ensuring that the system will comply with the owner's requirements or function without interruption, errors or deficiencies.
TYROMOTION GmbH is in no way liable for indirect, incidental, specific or consequential damage or for punitive damage compensation, including, among other things, liability for the loss or absence of profits, yield, goodwill or usage, which the owner or third parties may have incurred or liability for damage to connected equipment, costs for replacement products, installations, servicing, exchange elements and idle time or for claims from patients, customers, visitors, the owner's employees or other persons, regardless whether submitted within the context of a contract lawsuit, due to unauthorized handling, strict liability or imposed by law or otherwise even when TYROMOTION GmbH has been informed about the possibility of such damage. TYROMOTION GmbH's liability for damage, resulting from or in connection with this contract, may not in any event exceed the purchasing price of the system.
Some jurisdictions limit the extent of restrictions, the exclusion of legal means, compensations or liability or exclude these, such as the liability for gross negligence or willful misconduct according to the above mentioned content 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, as described above, may not be valid for the owner. Although these restrictions or exclusions are not valid for the legally prohibited extent, they are valid for the highest legally permitted extent. The owner may also have other rights that vary depending on the state or other jurisdictions.

1.7.5 Safety

Before operating the DIEGO® system, personnel are required to read the section „Safety" (see chapter 2 - Technology and chapter 3 - Clinical application in the present user manual).
Modifications by unauthorized users may affect the safety of patients, operating personnel or third parties and compromise system performance. Modifications may only be performed by a person authorized by TYROMOTION GmbH. You must never modify the system or system components (including software, cables etc.) if you have not been authorized to do so.
The information in the section „Safety" familiarizes the user with the hazards that may result from the usage of the system and warns the user about injuries and damage resulting from non-observance of safety precautions.
Users are obligated to familiarize themselves with these safety instructions and avoid conditions that lead to injuries or damage.

1.7.6 Warning notices

Warning notices in the user manual are always designated by the symbol displayed in chapter 1.4.1 (triangle with exclamation mark). All warning notices from each chapter are listed in the following in order to ensure the applicability of this user manual.

Warning notices in chapter 1

Moving the device

Always deactivate the device and unplug the power cable before moving the DIEGO® system. Remove loose components (e.g. computer mouse and keyboard) from the supporting table before moving the device. Apply all 4 castor wheel brakes before beginning the next therapy session.

Height of the device

It may not be possible to move the device through doors, room dividers etc. in an upright position due to the height dimension of the system. Take note of the device dimensions indicated in the user manual.

Reading the user manual

It is absolutely imperative that every user completes the training course and has read the user manual before beginning training with DIEGO®!

User training

The user (therapist) is required to complete a training course as an end user according to chapter 2.6.1 in order to receive the authorization to perform therapy with DIEGO®. The (hospital) operator must ensure that the DIEGO® device is only operated by properly trained personnel.

Applicability of the therapy

Check the following in order to ensure that the system is suitable for the intended therapy:

- Consistent evaluation of the patient's therapy results
- Observation of current studies relevant to the topic
- Therapy adjustment in case of an unusual deterioration of the patient's condition, which can be traced back to the usage of the DIEGO® system

Take note of symbols

Observe the warning, prohibition and notification symbols attached to DIEGO®.

Accessories

Only accessories designated by the manufacturer may be used. The usage of parts and materials not designated by the manufacturer may result in the endangerment of patients.

Holding of objects
Injuries may result if the patient is holding objects while performing the therapy. While performing gripping, sorting or other exercises, it is forbidden to hold objects that are potentially dangerous to the patient, user or other persons. Objects in the patient's hand may not be hot, pointy, sharp, fragile or heavier than 200 grams. The therapist is responsible for choosing appropriate objects. The manufacturer is not liable for damages to patients, users, the discussed objects or DIEGO® itself.

Power supply
The system may only be connected to a socket with protective ground wiring since the electrical protection would otherwise be insufficient.

The system may only be connected to circuits with 30mA residual current protection or IT circuits.

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

Free ports in the All-In-One PC
USB ports are provided on the supplied All-In-One PC. These may only be used by the manufacturer for service purposes. Connecting peripheral devices (printer etc.) is not permitted.

Touching live parts
Some system parts may conduct electricity. The operator may NOT concurrently touch the patient and any of these parts. The patient may also not touch these parts directly. This refers, among other things, to all touchable computer interfaces.
- USB interfaces
- SD/MMC interfaces
- Audio and video interfaces
- Network interfaces
- Assembly arm for keyboard support

Therapy only in seated position
Therapy may only be performed in a seated position. Patients whose balance is impaired even while sitting must be supervised and supported for the entire duration of the therapy. Using an elevated seat during therapy may affect the measurement range. Performing therapy while standing increases the risk of falling and may result in faulty measurement results; standing is, therefore, prohibited.

Notification obligation of the patient
Patients must be instructed prior to therapy to notify personnel if they experience pain or other problems of any kind.

Usage for other body parts
The DIEGO® system is solely suited for the therapeutic treatment of the upper extremities. Using DIEGO® for other body parts is contradictory to the usage regulations and poses a danger for the involved persons and the therapy device itself.

Tipping hazard
The following items must be observed due to the increased risk of tipping:
- Never move the device while a patient is close by.
- Exercise caution while crossing thresholds.
- Take note of the notice signs attached to the device „Tipping hazard while pushing the device".

Using exported data
Do not import the exportable data of the therapy report into diagnostic software tools and do not use it for other means of diagnosing the patient's condition.

Warning notices in chapter 2
Device usage is principally limited to clean, dry interiors.
Accompanying documents for non-medical devices are included and must be observed.

Do not connect any additional devices to unoccupied ports of the All-In-One PC included in the delivery contents without first obtaining information from the manufacturer beforehand. Do not connect the All-In-One PC to networks and do not establish an Internet connection from the PC.

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

Ensure that only software components are installed on the supplied All-In-One PC that have been previously approved by the manufacturer.
The ArmUnit is only operational when both knurled head screws have been screwed into the „UNLOCK" position.

It is absolutely imperative to screw the knurled head screws back into the „LOCK" position when shipping the ArmUnit; otherwise transport damages may result.

Set up the device with its backside against a wall. Ensure that this setup does not hinder you from disconnecting the power supply.

The functional checks described in table 4 and table 5 must be performed **daily**. Patients may be endangered if this check is neglected.

The functional checks described in table 6 and table 7 must be performed at least **once a month**. Patients may be endangered if this check is neglected.
Do not perform any further training on the device and contact the manufacturer if you detect any other damages (not listed in tables 4 to 7).

Please renew the ropes of all ArmUnits every 6 months (even when there are no apparent signs of wear). Exclusively use original spare parts by TYROMOTION GmbH due to safety reasons.

Therapeutic treatment with DIEGO® must cease immediately if damage to a rope is detected. Therapeutic treatments with DIEGO® must also be aborted if you detect any other damage to the device, which has not been specified here. Only use spare parts provided by the manufacturer when replacing ropes.

Warning notices in chapter 3

Prior to therapy, patients must be asked about one or multiple contraindications.

All configuration possibilities must be determined together with the physician prior to the initial application (this particular applies to the maximum tractive force of DIEGO®).

Only trained personnel may be close to the patient and the therapy system during training. Therapy personnel should ideally be positioned next to the patient during therapy in order to give instructions from there.
Therapy must be interrupted if the therapist is no longer within range where the patient can see or hear him.

A maximum therapy duration must be configured in the software and the automatic restart of the level deactivated for patients with limited cognitive abilities. (refer to the user manual for tyroS software).

Ensure that the ropes of the ArmUnit are automatically retracted as soon as the PC integrated in the system is activated. The device will warn the user with an acoustic signal. Ensure beforehand that the ropes are not impeded as they retract.

Only approach the device with the patient when the ropes have been retracted into the device. Patients may reach into the ropes (and get entangled) if the ropes of the DIEGO® system are not retracted.

Caution: Before attaching the hand/arm slings to patients, ask the patients about circulatory disorders or problems with the lymph transport in the arm region. The patient must regularly be examined and questioned about pain, swelling and skin discolorations during therapeutic treatment with DIEGO® if indications for these disorders exist. Therapy must be interrupted if any of these signs are detected.

Wrist watches, bracelets or similar jewelry must be removed prior to therapy.

The arm slings are the only parts of the device that may be touched by the patient. Instruct the patient to not reach into or brace himself against the ropes, the PC or other parts of the device.

Please note that other restrictions may apply in addition to body weight restrictions. Refer especially to chapter 3.1.1 Contraindications.

Exclusively use the DIEGO® shoulder and arm therapy system with the supplied original arm slings and magnet couplings; otherwise the patient may be exposed to unpredictable risks.

Please check one more time prior to therapy whether the patient is properly attached to the mechanism and seated comfortably!

Attention: The magnet couplings are automatically positioned at an easily accessible height after the reference run (approx. 190 cm above the ground). Only pull down on the magnet couplings when the couplings have reached this height and remain there.

Ensure that the patient has assumed the designated position before attaching him to the DIEGO® system.

The hygienic instructions stated in the user manual must be strictly observed. The manufacturer is not liable for damage that occurs on account of liquid penetration (e.g. beverages).

The arm slings must be detached from the magnet coupling before the device is turned off in order to prevent the ropes from unraveling by themselves in the deactivated state.
Never try to push the ropes back into the interior of the device as this may unhinge the ropes from the designated positions and cause a defect.

Warning notices in the tyroS user manual:

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

Note that the configured tractive forces of the device are turned on and off by pressing the activation button. Familiarize yourself with the control elements and their effects before attaching a patient to the device for the first time. Before activating the tractive forces, check whether the set values have been configured for the patient.

Please note that the measurement results are only approximate reference points for the therapy progression.

2 Technology

2.1 Technical data

Type designation: DIEGO®

Build year:

The manufacturing year can be identified with the serial number, e.g. SN: DR1-2015–XXX refers to the year 2015.

Applied standards:

- EN ISO 15223-1:2012
- EN 1041:2008
- EN 60601-1:2006
- EN 60601-1-2:2007
- EN ISO 13485:2012
- EN 14971:2012
- EN 62366:2008
- EN 62304:2006
- EN ISO 10993-1:2009 /AC:2010
- EN ISO 14155:2011

Classification:

According to Regulation 9 of the Council Directive 93/42/EEC Annex IX and the current supplement 2007/47/EC, the DIEGO® system is an active therapeutic **medical product, Class IIa** since the energy transferred from the DIEGO® to the patient does not pose a danger for the patient or user.

Type of application part: Type BF

Protection against electric shock: Protection class I device – Protective grounding

Electromagnetic compatibility: Class A device (CISPR 11)
The DIEGO® system is intended for clinical use (under the supervision of professional medical personnel).

Properties of traction ropes:

Diameter: 0.6 mm
Material: Dyneema mesh
Load-bearing capacity: 90.6 kg

Max. speed at end of rope: 2.5 m/s
Maximal tractive easing: Approx. 3 kg per rope

Nominal power of motors:
Max. power of motors: 70 Watts/Motor
Measurement range of force sensors: 0-100N per sensor (limited by the holding strength of magnet couplings)

Sensors:
- Angle measurement accurate to 1 degree (equal to approx. 1.7 cm for a rope extraction of 1 m)
- Static noise for approx. ± 0.5 degrees

Power supply voltage: 100 – 250V~ Alternating current
Supply frequency: 50/60Hz
Electricity/Power consumption: 1,5-2,5A/500W
Power supply grid: Only connect to supply grids with protective ground wiring.
Operating type: Continuous operation
Device fuses: All poles secured (4x T 5A H 250V)
Fuses within internal (not accessible) power supply unit: T4A
Supply voltage for motors: 24 VDC
Weight: Approx. 55 kg including both ArmUnits (each 8 kg) (weight of the computer system not included)
ArmUnit dimensions: (LxWxH): Approx. 34x18x20 cm.
Total system dimensions: (LxWxH): Approx. 90x128x240 cm.
Penetration protection: IPX0

Country of origin: Austria

2.1.1 Application area and operating conditions

Device usage is principally limited to clean, dry interiors.

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

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

Caution:
The DIEGO® system may not be used in explosion-prone zones AP and APG according to EN 60601-1:2006.
This means, among other things:

The usage of easily inflammable and explosive anesthetic inhalation materials and mixtures thereof are not permitted within the vicinity of the DIEGO® system. These materials include:
- Ether pro narcosi (diethyl ether)
- Cyclopropane

Accompanying documents for non-medical devices are included and must be observed.

Do not connect any additional devices to the unoccupied ports of the All-In-One PC included in the delivery contents without obtaining information from the manufacturer beforehand. Do not connect the All-In-One PC to networks and do not establish an Internet connection from the PC.

DIEGO® 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 DIEGO®.

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS		
The DIEGO® system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the DIEGO® system 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*	*The DIEGO® system 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*	*The DIEGO® system 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 2: Guidelines and manufacturer's declaration – Electromagnetic emissions

2.1.2 Disposal

The DIEGO® system may not be discarded with household waste. Legal regulations must be observed. The device can be returned to TYROMOTION GmbH if desired.

2.1.3 Repair

If requested, circuit diagrams and spare parts lists etc. are provided by the manufacturer for parts that the manufacturer has designated as repairable.
The DIEGO® system contains four safety fuses that can be accessed from the exterior; these fuses deactivate the device in case of an electric overload. Fuses may only be replaced by technical personnel. The following procedure must be observed:

Open the fuse panels with an appropriately sized, slotted screwdriver.	
Pull the fuse panels out; then push the fuses from the back with a thin object (e.g. paper clip) until they are dislodged from the fuse panel.	
Check fuse for defects (use measuring device) and replace if necessary.	
Reinsert fuse panel and close with screwdriver.	

Table 3: Replacing fuses

2.1.4 Installation

All necessary software has already been installed ex-factory on the All-In-One PC. Further software installations are therefore neither necessary nor provided.

Note that it is only permissible to install software components on the supplied All-In-One PC that have been previously approved by the manufacturer.

2.2 The DIEGO® electrical system

The operator is not required to perform any other activities since the installation work (e.g. device setup, ArmUnit assembly) may only be executed by the manufacturer or by personnel commissioned by the manufacturer. Assembly instructions for personnel, who have been commissioned by the manufacturer, are included.

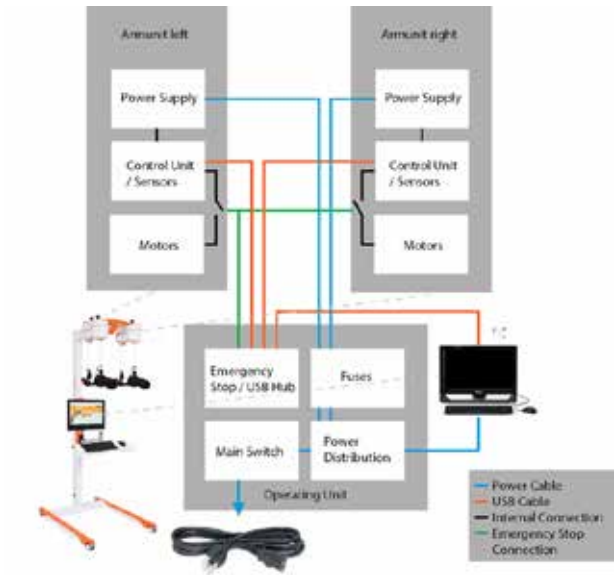


Illustration 3: Diagram for the DIEGO® electrical system and its components.

2.3 Preparation for usage

A few preparatory steps are necessary before the DIEGO® system can be used. These activities may only be performed by the manufacturer or by personnel commissioned by the manufacturer.

2.3.1 Loosening and inserting the transport lock

The transport lock must be removed before the ArmUnits can be used; these locks protect the device from damage during transport.
Remove both knurled head screws from the „LOCK" position at the top side of the ArmUnits and screw them back into the „UNLOCK" position.

This releases the sensors on the inside of the ArmUnit and the device is ready for use.

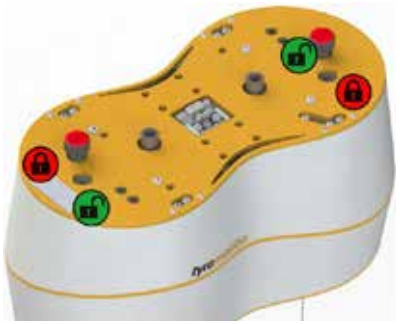


Illustration 4: Example for the possible positioning of the transport locking screws (sensor on left is locked and secured; sensor on right is released).

The ArmUnit is only operational when both knurled head screws are screwed into the „UNLOCK" position again.

It is absolutely imperative to screw the knurled head screws back into the „LOCK" position when shipping the ArmUnit; otherwise transport damages may result.

2.3.2 Connecting the power supply

The electric power supply to the DIEGO® system is established by connecting the device socket on the side of the DIEGO® frame to the power supply (Illustration 5). Use a device plug-in that is suitable for the respective electric power grid in order to ensure contact for all of the plug-in's poles and ground contacts.

Illustration 5: Power supply with device plug-in

2.3.3 Device positioning in the therapy room

Correctly positioning the DIEGO® system in the therapy room significantly improves device handling and contributes to the safety of patients and users.

Set up the device with its backside against a wall. Ensure that this setup does not hinder you from disconnecting the power supply.

In daily therapeutic practice, therapists are required to stand beside the device in order to instruct patients and operate the device. Set up the device so that sufficient space remains on both sides (approx. 1 m).

Set up the device so that neither the device nor the space on the side required by the therapist falls within the swiveling range of doors and windows.

2.4 Checking the device

2.4.1 Checklists – Functional check

The function check described in table 4 and trable 5 must be performed **daily.** Patients may be endangered if this check is neglected.

Check in deactivated state (daily)		
Area to be checked	**Malfunction (as an example)**	**Required action**
Are the fabric parts hygienically clean?	*Fabric parts are damp.* *Fabric parts are dirty.*	*Clean the contaminated parts according to the cleaning provisions of chapter 3.6.2*

Table 4: Daily check in deactivated state

Check in activated state (daily)		
Area to be checked	**Malfunction (as an example)**	**Required action**
Can you hear an acoustic signal after starting the PC?	*Rope retraction begins without an acoustic signal.*	*Contact manufacturer.*
Are the ropes free of knots and are the ropes being fully retracted after starting the PC (and the sounding of the acoustic signal)?	*Rope retraction ends before the ropes have been fully retracted.*	*- Further training prohibited* *- Contact manufacturer*

Table 5: Daily check in activated state

The function checks described in table 6 and table 7 must be performed at least **once a month**. *Patients may be endangered if this check is neglected.*

Perform the check stated in table 6 and table 7 even when a malfunction notification is generated by DIEGO® and especially if

- you notice unusual sounds or
- obvious damage to the device, device parts or device accessories;
- the device responds unusually,
- the device rattles unnaturally while extracting the ropes,
- ropes are not fully retracted during the reference run

The person commissioned by the operator to perform the stated functional check is required to participate in user training beforehand according to chapter 1.6.1. TYROMOTION GmbH recommends keeping records about the performance of functional checks. A suitable template can be found in chapter 2.6.

Check in deactivated state (monthly)		
Area to be checked	**Malfunction (as an example)**	**Required action**
Protective covers (casing)	*• Cover rattles. • Cover is missing. • Cover is defective.*	*→Further training prohibited →Contact manufacturer*
Externally visible damage	*• Parts are bent out of shape. • Parts are discolored. • Parts are broken.*	*→Further training prohibited →Contact manufacturer*
Rope condition (Rope must be fully unwound.)	*• Ropes are coarse due to abrasion. • Ropes are torn.*	*→Further training prohibited →Observe instructions in chapter 2.4.3.*
Fabric and Velcro parts	*• Fabric and Velcro parts are coarse, show signs of wear.*	*→Further training prohibited →Contact manufacturer*
Cleaning	*• Ropes are dirty. • DIEGO® is dirty. • Hand/Arm slings are dirty.*	*→Clean the contaminated parts according to cleaning instructions in chapter 3.6.2 and 3.6.3*
Magnet couplings	*• Parts are bent out of shape. • Elastic is partially or fully torn. • Elastic is porous.*	*→Further training prohibited →Contact manufacturer*

Table 6: Monthly check in deactivated state

Check in activated state (monthly)		
Area to be checked	**Malfunction (as an example)**	**Required action**
Rope retraction and extraction	*• Ropes cannot be pulled out of the device (or extraction is difficult). • Ropes are not retracted into the device.*	*→Further training prohibited →Contact manufacturer*
Emergency shutdown button	*Rope is retracted despite the activation of the shutdown button. (Note: The emergency shutdown only deactivates the motors.)*	*→Further training prohibited →Contact manufacturer*

Table 7: Monthly check in activated state

Do not perform further training sessions on the device and contact the manufacturer if you detect other damages (not listed in table 4 to table 7).

2.5 Regular maintenance work

2.5.1 Rope replacement

The ropes of the DIEGO® arm/shoulder therapy device wear out even during proper usage and without the occurrence of malfunctions. Especially ensure that the entire length of the rope is not damaged while performing the rope check as described in table 5. The entire length of the rope should be consistently thick and show no signs of abrasion.

Please renew the ropes of all ArmUnits every 6 months (even when there are no apparent signs of wear). Exclusively use original spare parts by TYROMOTION GmbH due to safety reasons.

The manufacturer is not liable for defects or damages (to persons or the device) that result from negligent maintenance work.

Therapeutic treatment with DIEGO® must cease immediately if damage to a rope is detected. Therapeutic treatments with DIEGO® must also be aborted if you detect any other damage to the device, which has not been specified here. Only use spare parts provided by the manufacturer when replacing ropes.

The following components are contained in the spare parts set:

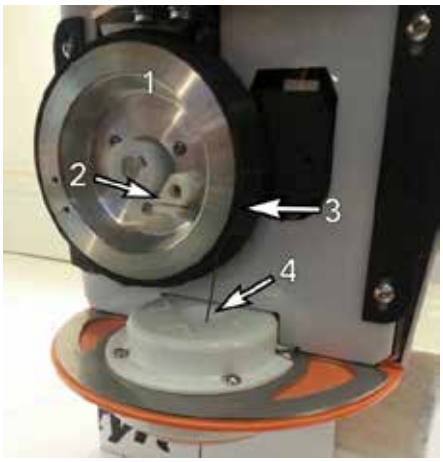
1: Replacement rope with pre-mounted rope screw *2: Threading aid with hook tool* *3: New safety elastics and Velcro fasteners with integrated magnets* *Allen wrench size 2 mm (not depicted)* *(The rope screw, safety elastic and Velcro fasteners are also replaced along with every rope replacement.)*	

Due to the design of the rope suspension, it is possible for a professionally qualified person to replace a rope within only a few minutes. Rope replacements are performed according to the following steps:

1. Opening the ArmUnit
2. Removing the old rope
3. Mounting the new rope
4. Closing the ArmUnit

These 4 steps are described in the following.

Opening the ArmUnit

Deactivate the device and pull the power plug.	*Power switch to position O (not illuminated).*
Loosen both screws on the top side of the ArmUnits casing (see illustration on right) in order to remove the round casing parts.	
After removing both screws, pull the casing part at the upper edge of the ArmUnit in order to then lift it from its anchoring on the bottom. *Please proceed in the opposite manner when closing the casing again.*	
The following components can be seen after removing the casing part: *1 – Rope spool* *2 – Rope clamp* *3 – Rope catching cage* *4 – Funnel opening*	

Removing the old rope

Pull the rope screw until the entire rope has been unwound. In case of a torn rope, the end of the rope has to be threaded through the opening of the thread catching cage with tweezers. Only then will you be able to pull the rest of the rope from the rope spool.	
Loosen the rope from the rope clamp (use the provided hook tool). *Then cut off the knot with sharp scissors.*	
Pull the rest of the rope down and out of the device; discard it with the household waste.	
Repeat these steps for the second rope of the ArmUnit.	

Mounting the new rope

Push the wire of the threading aid down from the top through the funnel opening, and then open the wire sling.	
Place the end of the replacement rope into the wire sling (1). *Carefully pull the rope up into the inside of the ArmUnit.* *(2 + 3)*	  

Turn the rope spool by hand until the rope clamp sits at the recessed position of the rope cage (1). *Thread the end of the rope through the recess of the rope cage and the drill hole of the rope spool (2).*	 
Tie a double knot into the end of the rope and insert it into the rope clamp.	
Pull the rope until the knot comes up against the rope clamp.	
Place the rope in front of the ArmUnit or let it hang down freely.	
Repeat these steps for the second rope of the ArmUnit.	

Closing the ArmUnit

Close the casing of the ArmUnit by inserting the casing part at the bottom into the anchoring and then press the top side in the direction of the ArmUnit. Take the screws that had been previously removed and screw them back in.	
Repeat the process for the other side of the ArmUnit.	
Mount the safety elastics included in the spare rope set onto each magnet coupling. Open the rope screw and push the free eyelet over the screw. Now close the screw and tighten it by hand. The entire system must look as depicted on the right.	
Always exchange all ropes for DIEGO® at the same time.	
Record the performed work in the rope replacement log.	
Then start DIEGO® as described in chapter 3.3.	

2.6 Recurring check

The recurring check is different from the checks in chapter 2.4.1; the legislator may demand the check described here while the checks in chapter 2.4.1 are intended, among other things, to detect acute damage or wear of parts that require replacing. The device operator is responsible for performing both checks.

TYROMOTION GmbH has determined that recurring checks must be performed every twelve months.

Recurring checks may only be carried out by professional and qualified personnel. The device operator must ensure that the intervals for the recurring checks imposed by him are observed. Usage of the DIEGO® system must cease if the checking intervals are not observed.

The recurring check must be performed according to EN 62353:2008.

2.7 Logs

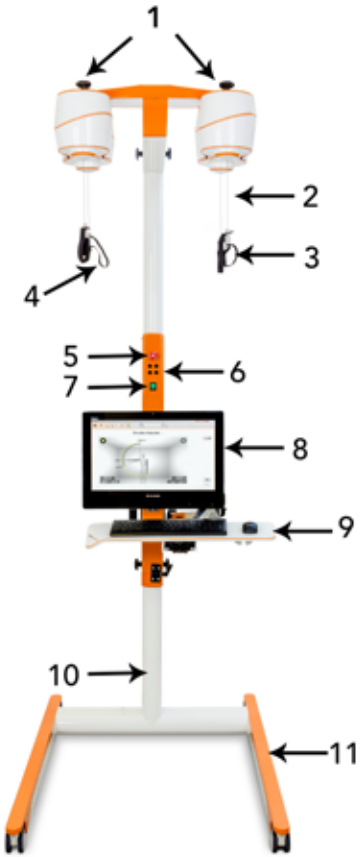
2.7.1 Functional check log (monthly)

Month/Year	Performed by	Performed activities	Detected deficiencies
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*
			☐ *Yes, namely the following:* ☐ *no*

2.7.2 Rope replacement log (semi-annually)

Rope exchange no.	Performed by	Performed on (date)	Signature
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

3 Clinical application



1	*Arm Units*
2	*Ropes*
3	*Magnet couplings*
4	*Catch elastic with connection mechanism*
5	*Emergency shutdown button*
6	*Device fuses (externally accessible)*
7	*Power switch*
8	*All-In-One PC*
9	*Support table for keyboard and mouse*
10	*Device plug-in*
11	*Mobile mounting frame*

3.1 Safety

The DIEGO® shoulder and arm therapy device was developed and manufactured according to the results of legally stipulated risk and usability analysis processes. This chapter presents all information from these processes relevant to users and patients.

3.1.1 Indications/Contraindications

The DIEGO® arm-shoulder therapy device is mainly used in neurologic rehabilitation of the upper extremity. The target population includes not only neurologic but also orthopedic and pediatric patients with deficits in movement control, movement against gravity, aiming accuracy and coordination of the proximal upper extremity. As in the case of every other therapy, the doctor in charge is responsible to make medical diagnosis and deciding for the type of intervention. In principle, the same indications and contraindications apply for DIEGO® 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 DIEGO® 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.

Frequent indications:

- Stroke (cerebral haemorrhage, ischaemic damage)
- Traumatic brain injury (TBI)
- Spinal cord injuries
- Brain tumour
- Parkinson's disease
- Chronic illnesses such as multiple sclerosis (MS)
- Cerebral palsy (CP)
- Motor neuron diseases, e.g. amyotrophic lateral sclerosis (ALS)
- Meningitis, encephalitis
- Muscle dystrophy
- Signs of paralysis caused by slipped disc in the
- cervical spine
- Fractures and injuries of the distal upper extremity (remodelling phase)

Absolute contraindications:

The device must not be used in case of:

- Acute pain despite conventional pain therapy in the region of the affected upper extremity
- Age and body structure: Children under the age of 5 years are excluded. They are at risk of severely injuring their fingers if they reach into the rope mechanism. The same applies to patients whose body structure is similar to those of children in this age.

- Adjustment and patient position: Do not carry out training with the DIEGO® system if the adjustment to the patient's individually physiologic position is not possible, especially in case of contractures or severe spasticity (joint is fixed/rigid) of the trained upper extremity
- Insufficient compliance, e.g. 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 DIEGO® therapy is suitable for the patient in case of:

- Apraxia
- Arthritis of upper extremity joints
- Reduced compliance: e.g. children, patients with cognitive impairments
- Consolidated fractures of the upper extremity
- Epilepsy
- Heart pacemakers and similar devices/implants: Pacemakers can react differently to external influences. Therefore, the knowledge about possible dangerous influences relevant for each specific device is essential. Inform patients that magnets are built into the magnet couplings. The DIEGO® 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 arm training may cause pain and irritation in case of weak joints.
- Low body weight: For patients with less than 50 kg body weight, special accessories must be used during therapy so that the connections between patient and device are released at lower forces.
- Material intolerance, e.g. detergent
- Neglect
- Osteoporosis
- Orthostatic circulatory problems: increased risk of falling
- 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.
- Pain, e.g. complex regional pain syndrome (CRPS)

- Patients with insufficient joint stabilization: The medical expert in charge must evaluate if forces, joint angles and movement speed during DIEGO® therapy pose a risk for the patient, e.g. shoulder-hand syndrome/subluxations of the shoulder.
- Infections/swellings/fractures/prolonged problems from former injuries, especially in the region of the trained upper extremity
- Patients with lymphatic system problems: DIEGO® arm slings may cause stasis in the patient's arm(s) which can affect the lymph transport from the affected/connected arm. Therefore, the therapist has to be especially attentive in such cases.

Please contact TYROMOTION GmbH if you have further questions or if something is unclear. (Contact data is displayed at the beginning of the document and on our homepage (www.TYROMOTION.com).

Patients must be asked about one or multiple contraindications prior to therapy.

3.1.2 Safety concept

Each ArmUnit of the DIEGO® system includes two independent electronic motors for moving the patient's arms. These motors are controlled centrally via the software executed on the All-In-One PC. Several safety precautions are implemented during therapy in order to prevent the occurrence of excessive forces (e.g. in case of sudden spasticity) or an excessive movement range:

- The patient's arm is connected via the supplied arm slings with integrated magnet coupling to the ropes (and thereby to the motors). The magnet couplings disengage the connection between arm slings and rope traction mechanics if the tractive force is exceeded by approximately 60 newton (25N for child magnets). (Note: The integrated elastic prevents the patient's arm from dropping in an uncontrolled manner when the magnets open). Please refer to chapter 3.4.2 for information about selecting proper magnets.
- An emergency shutdown button has been integrated into the system, which can be activated in case the patient feels uncomfortable or endangered for any reason. Pressing the emergency shutdown button turns off the electricity supply to all motors. The emergency shutdown button is released again by turning the button clockwise. The software also requires a confirmation for the emergency shutdown system.
- It is recommended for the user to consistently monitor the therapy process.
- Regular replacement of worn ropes prevents the endangerment of patients.

3.1.3 Residual risk

An unpredictable residual risk remains for the arm therapy in spite of all safety precautions. Patients may suffer light injuries in rare cases (e.g. by falling) even when the device is operated properly. Patients or users may also deliberately reach into the ropes, which is a possibility that cannot be precluded. However, the probability of such occurrences is very low, and the resulting injuries should not be severe as long as all safety indications stated in the present user manual are observed. A detailed risk analysis can be provided by TYROMOTION GmbH upon request.

3.1.4 Preparation for the (initial) training

The settings of the device must be adjusted for the patient when training with DIEGO® is performed for the first time. At the beginning of therapy the default settings ensure maximum safety.

All configurations must be determined together with the physician prior to the initial application (this particular applies to the maximum tractive force of DIEGO®).

Only trained personnel may be in the vicinity of the patient and therapy system during training. Therapy personnel should ideally be positioned next to the patient during therapy in order to give instructions from there.

3.2 Patient information

3.2.1 Patient characteristics

The patient target group is only limited by the contraindications indicated in chapter 3.1.1. Age, weight etc. are not decisive factors when deciding whether therapy can be performed with DIEGO® or not.
However, the attending therapist must determine prior to therapy whether and how long the patient can work independently during therapy. Cognitive abilities, body posture stability and the general state of health of the patient must be taken into consideration.

Therapy must be interrupted if the therapist is no longer within range where the patient can see or hear him.

A maximum therapy duration must be configured in the software and the automatic restart of the level deactivated for patients with limited cognitive abilities (refer to the user manual for tyroS software).

We recommend a therapy duration of approx. 30-60 min per day. However, the actually permissible therapy duration depends to a great extent on the patient's general state of health and receptiveness and must be individually determined by the therapist.

3.2.2 Data storage

Patient-specific information is saved with the tyroS software, which simplifies the procedure for performing multiple therapy sessions with the DIEGO® system.
This information includes:

- Personal data such as e.g.
  - Name
  - Age
  - Gender
- Therapy-specific data such as e.g.
  - Movement range
  - Strength
  - Type of performed therapies and assessments
  - Results from already performed therapies and assessments
  -

The data are saved locally on the supplied All-In-One PC and are used for the targeted evaluation of the therapy process. The manufacturer is not liable for compliance with the country-specific data protection regulations.

3.3 Activating the DIEGO® system

The device can be activated once the system has been installed according to chapter 2.1.4. All ArmUnits mounted on the same frame are supplied with power via a central power switch. The device is activated if the power switch is set to the position I (vertical) and the switch is illuminated. The All-In-One PC must be started separately. The accompanying documents provide instructions on how to start the PC. The control software can be loaded after logging into Windows – more detailed information in the included user manual for the tyroS software.
Ensure the following before activating the device:

- The device has been set up in a stable manner.
- The device is not damaged in any way.
- No patient is connected to the DIEGO® system.

Note that the ropes of the ArmUnits are automatically retracted as soon as the PC included in the system is activated. The device will warn the user with an acoustic signal. Ensure beforehand that the ropes are not impeded as they retract.

Only approach the device with your patient when the ropes of the device have been retracted. Patients may get entangled if the ropes of the DIEGO® system are not retracted.

The automatic retraction process for the ropes is performed with reduced speed; the process is halted

- when the ropes have reached the final position,
- if an unexpected resistance is detected during the retraction process

The process can be repeated at a later time.

3.4 Connecting the patient to the system

3.4.1 Putting on hand/arm slings

The hand/arm slings connect the patient to the device (with magnet couplings).

Caution: Before attaching the hand/arm slings to patients, ask the patients about circulatory disorders or problems with the lymph transport in the arm region. The patient must regularly be examined and questioned about pain, swelling and skin discolorations during therapeutic treatment with DIEGO® if indications for these disorders exist. Therapy must be interrupted if any of these signs are detected.

Wrist watches, bracelets or similar jewelry must be removed prior to therapy.

Notice: The arm slings set described here is size M (medium). Sizes S (Small) and L (Large) are also included in the standard delivery. Please note the different color markings on the slings:

- Small →White color marking
- Medium →Orange color marking
- Large →Black color marking

Illustration 6 shows all individual components of the hand/arm slings included in the delivery contents.

Illustration 6: Individual components of the hand/arm sling system

Top left: Wrist supports (short, long-straight, long-angled) with fabric covering
Top middle: Wrist slings with adjustable connection piece (3 different lengths)
Top right: Elbow sling with recess for inside of the elbow and 5 connection pieces
Lower left: Hygienic cloths (white)
Lower right: Fixation strips
Notices regarding the slings system:

- Wrist supports can be selected freely and provide customization options for the individual patient. It is also possible to not wear any wrist support at all.
- The three available wrist sling lengths can accommodate various arm lengths of patients.
- The 5 connection pieces at the elbow slings can be used to customize DIEGO® for individual patients. The selected connection piece determines the extent of the external rotation of the patient's arm.
- The fixation strips can be used to tighten the hold of the arm slings around the patient's arms.

Proceed according to Illustration 7 to Illustration 10 when putting on arm slings.
Select the best suitable wrist support for the patient. The various wrist supports provide the following advantages:

- Short: Use especially for patients who can maintain a stable wrist position or for patients who are even capable of training the wrist.
- Long-straight: Prevents the wrist from hanging down if the patient's arm is limp and paralyzed; the wrist is in a straight position.
- Long-angled: Like long-straight; the angled form additionally positions the patient's wrist physiologically.
- No wrist support: Wrist supports can be omitted when it is sensible to do so (e.g. in case the hand of the patient is spastically closed).

Use a suitable fabric cover for the selected wrist sling. The long part of the fabric cover is not necessary for the „short" support. Push the wrist support into the fabric covering and close it with the Velcro fasteners.

Illustration 7: Place patient's arm into the arm slings. The cut-out hole in the elbow sling is always on the inside of the arm. Use a fresh hygienic cloth each time.

Illustration 8: Ensure that the connection pieces of the elbow sling come up against the patient's underarm. The recess of the elbow sling must come up against the inside of the elbow (on the side that bends).

Illustration 9: The placement of the elbow sling is correct if the tip of the patient's elbow is visible after closing the sling. Close the Velcro fasteners and ensure that there are no pressure points on the patient's arm.

Illustration 10: Place the wrist sling of proper length over the patient's wrist. It is irrelevant whether the wrist sling is attached to itself or to the wrist support. Ensure that the wrist sling is fixed close to the wrist joint and the thumb remains free. Additional Velcro strips can be used as required.

Repeat the procedure on the other side for bilateral arm therapy.
You may proceed with chapter 3.4.2 if the arm slings have been attached to the patient.

The arm slings are the only parts of the device that may be touched by the patient. Instruct the patient to not reach into or brace himself against the ropes, the PC or other parts of the device.

3.4.2 Connecting the arm modules

The ropes are connected with magnet couplings, which are attached to the ropes of the ArmUnit. These magnet couplings will disengage the connection between the patient and the device if a defined normal force occurs. The rubber elastic prevents the patient's arm from falling in an uncontrolled manner when the connection is disengaged.

Once the device is operational (reference run has been successfully completed), the rope screws are automatically extended and hang at a height of approximately 1.90 m. You can then easily pull the rope screws by hand towards the properly positioned patient.

Please note that the DIEGO® system is delivered with two magnet couplings of varying strengths. The magnet couplings have color markings (orange for adults, white for children). There are different options for connecting the patient depending on the patient's body weight. Illustration 11 shows the various options in relation to body weight.

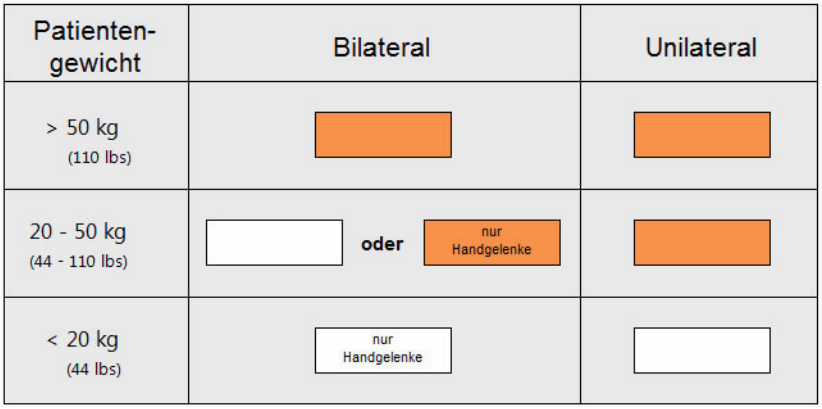


Illustration 11: Applying the correct patient attachment (in relation to body weight)

The color markings displayed in Illustration 11 refer to the colored sewed-on strips on the magnet couplings. The software will also prompt the user to use the correct magnet coupling.
Proceed as follows when changing the magnet couplings:

1. Open any existing connection between magnet coupling and hand sling or arm sling.
2. Open the connection mechanism in the catch elastic. You can now remove the previously used magnet.
3. Connect the new magnet to the connection mechanism of the catch elastic.

Please note that other restrictions may apply in addition to body weight restrictions. Refer to chapter 3.1.1 Contraindications.

When establishing the connection, proceed as shown in Illustration 12 and Illustration 13.

Illustration 12: Pull the Velcro fastener of the magnet coupling through one of the connection pieces of the sling and close the Velcro fastener and clip connections, which connect both elastic parts with each other.

Illustration 13: You may only then close the magnet coupling by joining both magnetic parts to each other.

Exclusively use the DIEGO® shoulder and arm therapy system with the supplied original arm slings and magnet couplings; the patient may otherwise be exposed to unpredictable risks.

Please check one more time prior to therapy whether the patient is properly attached to the mechanism and seated comfortably!

Attention: The magnet couplings are automatically positioned at an easily accessible height after the reference run (approx. 190 cm above the ground). Only pull down on the magnet couplings once the couplings have reached this height and remain there.

3.4.3 Seating position of the patient

The patient must assume the default seating position during therapy. This position is depicted in Illustration 14. The patient's arm may be pulled into improper positions if the patient is seated differently.

Ensure that the patient has assumed the proper position before attaching him to the DIEGO® system.

Illustration 14: Correct preparation for positioning the patient under DIEGO®; when the patient's arms are stretched out in front, the patient's elbow should rest in the middle below the respective arm unit.

3.5 Performing the therapy

Perform the therapy with the DIEGO® system and observe all instructions provided by the software. Different therapy options are described in the separate user manual for the tyroS software.

3.6 After the training session

3.6.1 Disconnecting the patient from the DIEGO® system

Disconnect the patient's arm from the DIEGO® system after training by disengaging the magnet connection and then the Velcro fastening between magnet coupling and hand/arm sling.
You may only then open the fasteners of the hand/arm slings in order to remove the patient's arm.

3.6.2 Cleaning instructions

All parts touched by the patient (including e.g. mouse, keyboard and frame) should be regularly cleaned and disinfected in order to minimize the spreading of germs. Use a cloth that has been slightly dampened with disinfectant. The cloth may also be soaked with alcohol if you encounter hard to clean contaminants. However, strong cleaning agents, soaps or solvents may not be used. Contact TYROMOTION GmbH if you encounter tough contaminants that cannot be cleaned.

Read the hygienic regulations stated in chapter 3.6.3 for cleaning the hand and elbow slings.

3.6.3 Hygienic regulations

The following hygienic instructions must be observed without exception in order to ensure hygienic safety:

- Hands and underarms of the patient must be cleaned with a suitable disinfectant prior to therapy. (Open wounds or body parts where a disinfectant cannot be applied must be covered with bandages or clothing.)
- Insert a freshly washed, dry hygienic cloth (5 cloths are included in the delivery contents) between the wrist joint sling and the patient's hand. Other dry hygienic cloths or disposable cloths etc. made from cotton or the like can also be used – the user is responsible for choosing the appropriate cloth.
- Clean the hygienic cloths after each use: 40°C in the delicate cycle (the use of a wash bag is recommended)
- Weekly cleaning of fabric parts of the hand and elbow slings: 40°C in the delicate cycle (the use of a wash bag is recommended).
- Replacement of hand and arm slings once a year; replacements may be obtained from the manufacturer (contact information at the beginning of this manual).

The hygienic instructions stated in this chapter must be strictly observed. The manufacturer is not liable for damage that occurs on account of liquid penetration (e.g. beverages).

3.6.4 Deactivating the DIEGO® system

The following must be observed when deactivating the system.
An internal rope breaking system does not exist and therefore the ropes can be pulled out when the system is deactivated.

The arm slings must be detached from the magnet coupling before the device is turned off in order to prevent the ropes from unraveling by themselves in the deactivated state.

Never try to push the ropes back into the interior of the device. The ropes may be dislodged from their designated positions on the inside of the device, and this may cause a defect.

You must close the control software with „Close program" and properly shutdown Windows with „Start >> Shutdown" before you can deactivate the DIEGO® system. Both ArmUnits can be deactivated via the central power switch as soon as the PC has been completely shut down. Note: The device can be disconnected from the power supply by either turning the device off at the power switch or unplugging the power cable.

3.7 Consumption materials

The following consumption materials can be obtained from the manufacturer in accordance with the spare parts list.
(Contact information is stated at the beginning of the user manual.)

- Set of hand/arm slings
- Replacement rope set (including safety elastics)

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