# AMADEO®

# GEBRAUCHSANWEISUNG / MANUAL

tyromotion

Sprachen / Languages: Deutsch (DE), English (EN)Ausgabedatum der Gebrauchsanweisung: 14. Sept. 2017 /
Issue Date of User Manual 14th Sept. 2017

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# 1 Introduction

## 1.1 Introduction

We are pleased to provide this user manual as an introduction to the AMADEO® hand-therapy system and its application.
The following manual addresses the essential functions that are necessary for understanding the functionality and application of AMADEO®.

### 1.1.1 Regarding the usage of this documentation

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

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

### 1.1.2 Symbols in the user manual

| | |
|---|---|
|  | *Safety notices: Patients may be at risk whenever this symbol is displayed in the user manual. Pay very close attention to these notices!* |
|  | *Follow the user manual.* |

Table 1

### 1.1.3 System content

The AMADEO® system consists of the following components included in the scope of delivery:

- Table frame consisting of base plate with castors, lifting column (including controls), table surface, 2 plaster dispensers and control cabinet with integrated PC and monitor
- Hand unit including 2 exchangeable hand/arm supports (application part type B)
- 1x hand-arm support for adults
- 1x hand-arm support for children
- Mouse, mouse pad and keyboard
- Control cabinet key
- Power plug
- Finger plasters
- Adults (2 packages, 500 pieces each)
- Children (2 packages, 500 pieces each)
- Finger supports
    - L – 2 packages, 5 pieces each (white finger supports)
    - M – 2 packages, 5 pieces each (orange finger supports)
    - S – 2 packages, 5 pieces each (grey finger supports)
- USB-Stick (Quickstart Guide, User Manual, SetUp-Manual, Manual Monitor, accompanying document Monitor, Telescopic pillar, Software)

Consumption material such as finger plasters, finger supports or padding for the hand-arm support can be ordered directly from the manufacturer.

### 1.1.4 The hand-therapy system

AMADEO® is a modern mechatronic finger-hand therapy system for the rehabilitation of patients with motor dysfunction in the distal upper extremity. AMADEO® system consists of the hand unit, containing the electrically powered movement mechanism, the hand-arm support, finger supports and finger plasters, a height-adjustable load-bearing frame with table surface, control panel and a PC-based control and operating unit for configuring therapy parameters. The overall setup is depicted in figure 1.

Figure 1: Symbol photo: AMADEO® finger-hand therapy system

AMADEO® moves the fingers and thumb according to specific patterns indicated by the software. The finger sliders can perform a bending or extending movement, either individually and sequentially for each finger or simultaneously. Alternating or random movement sequences are also possible. The movement capability, specific to each patient (entanglement of individual fingers), must be kept in mind. The movement of individual fingers can therefore be deactivated or severely limited. Principally, the range of motion (determined one-dimensionally) can be configured separately for each finger. The patient is positioned directly in front of the device in a comfortable position. The hand-arm support is brought into position and supports the weight of the upper and lower arm and the hand. An automatic movement sequence is initiated after the finger tips have been fastened to the designated finger and thumb supports and the respective movement end positions have been configured. The patient can be completely passive or actively involved in the therapy, depending on requirements. An integrated sensor system allows a quantitative recording and evaluation of occurring finger strengths. AMADEO® moves the fingers and thumbs according to movement parameters, which can be configured in the tyroS software. The finger sliders can bend or extend individual fingers either sequentially or simultaneously for all digits. Alternating or random movement sequences are also possible. The range of motion (ROM) is configured one-dimensionally (bending-extending) and individually for each patient and finger while taking the anatomical and physiological movement limitations into account.

Additionally, the possibility exists to severely limit or deactivate the range of motion for individual fingers.
The patient is first placed in an individual physiological position for therapy. Either the hand-arm support for children or the support for adults is connected to the hand unit, depending on the size of the patient. The hand-arm support supports the weight of the

patient's arm and helps maintain the correct positioning of the hand and arm. The electronically powered movement mechanism of the AMADEO® system moves the finger sliders, which in turn move the thumb and fingers of the right or left hand. Thumb and finger supports connect the patient's fingers to the movement mechanism with magnets. The system offers various finger-support sizes and finger plaster sizes in order to accommodate the various finger/hand sizes of patients. The suitable finger support is glued and fastened to the finger with a suitable finger plaster. The magnetic connection between the fingers of a patient and the movement mechanism of AMADEO® is a safety feature. Fingers are automatically disconnected from the movement mechanism and the hand is released in case excessive forces occur.

Various therapy modules and movement parameters can be selected in the tyroS software in order to reach the therapy goal. The integrated sensor system for each finger allows a quantitative recording, which provides realtime bio-feedback and the evaluation of occurring active and passive finger strengths and the ROM. CPM therapy (Continuous Passive Motion) allows the execution of automatic movement sequences, even when the patient remains passive. Assistive therapy supports the patient in actively moving the fingers as much as possible on his own. AMADEO® takes over the movement up to the full ROM if a full extension or flexion of the fingers is not possible. Furthermore, patients can use interactive therapies to exercise and practice finger strength, finger movement, movement control, selective activation and finger agility, reaction or timing by means of finger strength or movement, strength metering, strength endurance as well as gripping and releasing.

### 1.1.5 Intended purpose

The AMADEO® system is intended for robot-supported finger-hand therapy of patients with neurological damage to the central nervous system, caused by typical indications such as stroke or traumatic brain injury. Depending on national variances, the AMADEO® system is typically used in ergotherapy and/or physiotherapy in addition to conventional therapy forms as therapy support, enhancement and intensification. The repetitive movements of finger joints generate intrinsic and extrinsic stimuli that benefit the reorganisation of the brain. Repetitive active exercise and training promotes neuronal plasticity and thus the changes (adaptations) of synapses, nerve cells or even entire cerebral areas in order to reclaim lost movements.

### 1.1.6 Notices

*Familiarise yourself with the user manual before using the system and continue to do so on a regular basis.*
*Reading the co-applicable user manual for the tyroS software is also obligatory for system users!*

Medical personnel and properly trained therapists, responsible for the AMADEO® system, are required to exhort 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. Training can be requested as required. Ensure that the system is not manipulated by unauthorized personnel. The system is unpacked and installed by service personnel authorized by TYROMOTION. Never attempt to install the system by yourself.

### 1.1.7 Safety

Persons operating the AMADEO® system are required to have read and understood the section "Safety" (see part 2 and part 3). Never modify the system including system components, software, cables etc. User modifications can endanger user safety and compromise system performance. All modifications must be performed by persons who have been certified by TYROMOTION. The information in the section "Safety" familiarizes users with the hazards that may result from using the system and warns about injuries and damages resulting from the non-observance of safety precautions. Users are obligated to familiarize themselves with these safety instructions and avoid conditions that may lead to injuries or damages. Jewelry such as rings, bracelets or necklaces can become entangled in the finger mechanics and must be removed prior to therapy.

Tensile force of the finger sliders:

*The force limits have been adjusted to the requirements of physiotherapeutic training. The responsible physician must assess whether a patient is suitable for AMADEO® therapy.*

Overextension of the finger of finger base joints:

*The range of motion is possibly set incorrectly and should be checked.*

Limitation of the means of escape:

*A patient may require more time to evacuate in case of hazardous situations (e.g. fire alarm) due to the mechanical fixation of the patient's lower arm to the device. The patient should, therefore, be monitored by trained personnel who can release the fixation to the device if such situations occur*

Patient changes the sitting position:

*Patients who are not able to keep their upper body in an upright position by themselves must be fixated with respective sitting supports in a suitable position.*

Touching electrically live parts:

*Some system parts may conduct electricity. The operator may NOT concurrently touch the patient and any of these parts. The patient may also not touch these parts directly. This applies to all touchable computer interfaces:*

- *USB interfaces*
- *SD/MMC interfaces*
- *Audio and video interfaces*
- *Network interfaces*

Consumption of food or beverages:

*For safety reasons, consuming food or beverages is not permitted in the vicinity of the device.*

**Tipping hazard for the device:**

*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.*
- *Observe the notices attached to the device: "Do not push the device" and "Do not sit on the device".*

Transport:

*The lifting column must be lowered completely prior to transport due to the increased risk of tipping.*
*An increased risk of tipping exists during transport.*

Pinch point hazard:

*Body parts may be pinched when lowering the lifting column. Observe the notices attached to the device: "Warning crushing hazard" and "No entry".*

### 1.1.8 Owner's responsibilities

The owner is responsible for ensuring that all persons who operate the system have read and understand 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 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 are only performed by properly trained and fully qualified personnel. The owner of the AMADEO® system must ensure that only properly trained and fully qualified personnel (certified users or operators) 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 understands 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. The owner is obligated to maintain a list of authorized operators. The operator must contact TYROMOTION if the system does not work properly or does not respond correctly to the commands described in this user manual.

### 1.1.9 Errors and omissions

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

### 1.1.10 Property of TYROMOTION GmbH

TYROMOTION GmbH owns the copyright-protected content of this user manual, 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 is prohibited.

### 1.1.11 Warranty & disclaimer

TYROMOTION GmbH issues a warranty to the original system purchaser that the system shall be free of material and qualitative processing defects for a period of 12 months under normal usage from the date of installation on the owner's premises and that the system complies with the mechanical and electrical specifications published by TYROMOTION (unless the warranty term is extended by an optional service contract). This warranty is granted under the provision that the system is installed, operated and maintained in accordance with the user manual. The customer must submit all warranty

claims to TYROMOTION in written form within 60 days of the occurrence of the problem and before the expiry of the warranty. TYROMOTION is exclusively obligated to repair, exchange or correct faulty or non-compliant parts at its own discretion in accordance with the warranty. TYROMOTION has no further obligations to the owner in regard to these parts after the repair or exchange of faulty or non-compliant parts. All repairs or maintenance work must be performed by an authorized TYROMOTION service representative in accordance with this warranty. The above mentioned warranty becomes null and void if repairs, maintenance or other work is performed by third parties. Moreover, problems resulting from accidents, improper use, incorrect application, storage damage, negligence as well as system or component 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 warranty" in exclusion of the limited warranty. TYROMOTION and its thirdparty suppliers specifically and unreservedly reject all other explicit or implicit warranties claimed by the owner, his personnel and patients, customers, users and any third parties, including unreservedly all warranties for marketability, applicability for a specific purpose, non-injury and any warranties resulting from performance development, business transactions or commercial customs. TYROMOTION and its third-party suppliers do not provide declarations or warranties that guarantee the system's compliance with the owner's requirements or 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 have incurred 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 charge, due to unauthorized handling, strict liability or imposed by law or otherwise even when TYROMOTION has been informed about the possibility of such damage. TYROMOTION'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 or exclude the extent of restrictions, the exclusion of legal means, compensation or liability, such as the liability for gross negligence or wilful misconduct according to the abovementioned extent or in the abovementioned extent or do not permit the exclusion of implicit warranties. In such jurisdictions, the restriction or exclusion of warranties, legal means, compensations or liabilities, as described above, may not be valid for the owner. Even when these restrictions or exclusions are not valid in the legally prohibited extent, they nonetheless apply in the highest legally permitted

extent. The owner may also have other rights that vary depending on the state or other jurisdictions.

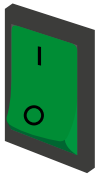
## 1.2 Training concept

The AMADEO® system is a complex technical device. Users of the AMADEO® system are required to complete training and read the user manual before operating the device in order to ensure successful patient training and the safety of patients, users and the device itself. Merely reading the present manual does not convey sufficient competence for handling AMADEO®. As a precondition, prospective users also require basic medical training (e.g. physiotherapy). TYROMOTION GmbH rejects all liability for damages resulting from training that was performed by an untrained user. The AMADEO® scope of delivery includes training for prospective users.

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

## 1.3 AMADEO® symbols

| | |
|---|---|
| STOP | *Off (only for one part of the device)*<br>*Emergency shutdown button for disconnecting the power supply to the motors of the finger sliders* |
|  | *Do not discard with household waste.* |
|  | *Application part, type B* |
|  | *Alternating current* |
| CE | *CE mark with the number for the notified body* |

| | |
|---|---|
|  | *Information about the manufacturer of AMADEO®, including the full mailing address, is displayed next to the factory symbol.* |
|  | *Follow the user manual.* |
|  | *Warning symbol: Tipping hazard while pushing the device*<br>*The symbol warns users that the device might tip when moved.*<br>*Keep this in mind when pushing the device.* |
|  | *Warning symbol: Crushing hazard warning* |
| IP20 | *Protection class against foreign objects and water:*<br>*2 means protection against penetration of solid objects with a diameter ≥ 12,5 mm. 0 means no protection against ingress of water.* |
|  | *No entry*<br>*Entering the area is prohibited due to pinch point hazard.* |
|  | *Sitting prohibited*<br>*Sitting on or bracing oneself against the device or device parts is prohibited.* |
|  | *Labelling on the power switch:*<br>*I means the device is activated (top position).*<br>*O means the device is deactivated (bottom position).* |

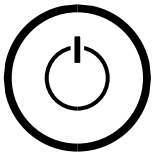
| | |
|---|---|
|  | *Children under the age of 3 are excluded from usage due to insufficient compliance.* |
|  | *PC Power switch*<br>*When switched on, the status light glows green.* |

Table 2

### 1.3.1 Type label

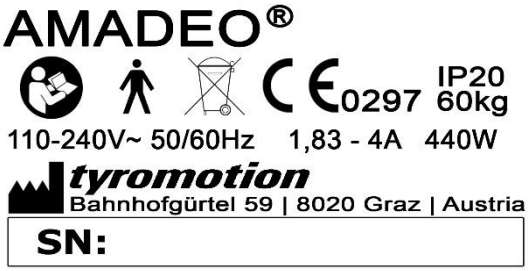



Figure 2: Type label AMADEO®

The type label designates AMADEO® as a medical product.

# 2 Technology

## 2.1 Technology

### 2.1.1 Overview

| | |
|---|---|
| *Type designation:* | **AMADEO®** |
| *Build year:* | *Can also be determined from the serial number, e.g. SN: AR7***2015***–XXX refers to the year 2015.* |
| *Classification:* | *According to regulation 9 of the Council Directive 93/42/EEC, appendix IX and the current supplement 2007/47/EC, the AMADEO® system is an active, therapeutic* **Class IIa medical product.** |
| *Type of application part:* | **Type B** |
| *Protection against electric shock:* | **Protection Class I device – Protective grounding** |
| *Electromagnetic compatibility:* | **Class B device (CISPR 11)** *The AMADEO® system may only be used in residential areas under the supervision of a medical professional. EN 60601-1-2:2001 requirements fulfilled* |
| *Country of origin:* | **Austria** |
| *Power supply voltage:* | **110 – 240V alternating current** |
| *Supply frequency:* | **50 / 60Hz** |
| *Electricity/Power consumption:* | **1,83 - 4A/440W** |
| *Supply grid:* | **Only connect to supply grids with protective ground wiring.** |
| *Operating type:* | **Continuous operation** |
| *Fuses:* | *secured for all poles (2x T4A L 250V)* |
| *Supply voltage for motors:* | **24V DC** |
| *Max. speed:* | *210 mm/sec* |
| *Nominal power of motors:* | *3 Watts/Motor* |
| *Max. power of motors:* | *30N/Motor* |
| *Max. permissible finger strength:* | *30N* |
| *Measurement range of strength sensors:* | *±20N* |

| | |
|---|---|
| *Deviation force measurement:* | *< 10%* |
| *Weight:* | *60kg* |
| *Dimension (WxLxH) collapsed (in mm):* | *(in mm): 1160 x 754 x 1209 extended*<br>*(in mm): 1160 x 754 x 1589* |
| *Penetration protection:* | *IP 20* |

Table 3

*AMADEO® 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 EMC indications. Portable and mobile HF communication equipment may affect AMADEO®.*

| Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS | | |
|---|---|---|
| *The AMADEO® system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the AMADEO® 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 AMADEO® 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 AMADEO ® 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 4: Guidelines and manufacturer's declaration – Electromagnetic emissions*

| Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| *The AMADEO ® system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the AMADEO ® system 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* | *± 6 kV contact*<br>*± 8 kV air* | *± 6 kV contact*<br>*± 8 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*<br>*± 1 kV for input/output lines* | *± 2 kV for power supply lines*<br>*Not applicable* | *Mains power quality should be that of a typical commercial or hospital environment.* |

| | | | |
|---|---|---|---|
| *Surge*<br>*IEC 61000-4-5* | *± 1 kV differential mode*<br><br>*± 2 kV common mode* | *± 1 kV differential mode*<br><br>*± 2 kV common mode* | *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*<br>*IEC 61000-4-11* | *< 5 % $U_T$*<br>*(> 95 % dip in $U_T$) for 0.5 cycles*<br><br>*40 % $U_T$*<br>*(60 % dip in $U_T$) for 5 cycles*<br><br>*70 % $U_T$*<br>*(30 % dip in $U_T$) for 25 cycles*<br><br>*< 5 % $U_T$*<br>*(> 95 % dip in $U_T$) for 5 sec.* | *< 5 % $U_T$*<br>*(> 95 % dip in $U_T$) for 0.5 cycles*<br><br>*40 % $U_T$*<br>*(60 % dip in $U_T$) for 5 cycles*<br><br>*70 % $U_T$*<br>*(30 % dip in $U_T$) for 25 cycles*<br><br>*< 5 % $U_T$*<br>*(> 95 % dip in $U_T$) for 5 sec.* | *Mains power quality should be that of a typical commercial or hospital environment.* |
| *Power Frequency (50/60 Hz) Magnetic Field*<br>*IEC 61000-4-8* | *3 A/m* | *3 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 Manufacturers's declaration – Electromagnetic Immunity*

| Guidance and Manufacturer's Declaration— ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| *The AMADEO ® system is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of the AMADEO ® system 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*<br>*IEC 61000-4-6* | *3 Vrms*<br>*150 kHz to 80 MHz* | *4 V* | ***Recommended Separation Distance:***<br>$d = 0{,}875\sqrt{P}$ |

| | | | |
|---|---|---|---|
| *Radiated RF*<br>*IEC 61000-4-3* | *3 V/m*<br>*80 MHz to 2.5 GHz* | *3 V/m* | $d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz*<br><br>$d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz*<br><br>*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).*<br><br>*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]*<br><br>*Interference may occur in the vicinity of equipment marked with the following symbol:*<br><br>  |

*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 the device 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 the device.*

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

*Table 6: Guidelines and Manufacturers's declaration – Electromagnetic Immunity*

| Recommended separation distances between portable and mobile RF communications equipment and AMADEO® system | | | |
|---|---|---|---|
| *This device 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* $d = 0{,}875\sqrt{P}$ | *80 MHz to 800 MHz* $d = 1{,}17\sqrt{P}$ | *800 MHz to 2,5 GHz* $d = 2{,}33\sqrt{P}$ |
| *0,01* | *0,09* | *0,12* | *0,23* |
| *0,1* | *0,28* | *0,37* | *0,74* |
| *1* | *0,88* | *1,2* | *2,33* |
| *10* | *2,77* | *3,7* | *7,37* |
| *100* | *8,75* | *12* | *23,3* |
| *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.*<br><br>*NOTES:*<br>*- At 80 MHz and 800 MHz, the higher frequency range applies.*<br>*- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.* | | | |

*Table 7: Recommended separation distances between portable and mobile RF communications equipment and AMADEO® system*

### 2.1.2 Usage area

Device usage is principally limited to clean, dry interiors in professional health care establishments.

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

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

Caution:
The AMADEO® 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 anaesthetic inhalation materials and mixtures thereof are not permitted within the vicinity of the AMADEO® system. These materials include:
- Diethyl ether
- Cyclopropane

*Accompanying documents for non-medical devices are included.*

*Do not connect any additional devices to the unoccupied ports of the PC included in the scope of delivery without obtaining information from the manufacturer beforehand. Do not connect the PC integrated in the control cabinet to networks, and do not establish an Internet connection from the PC.*

## 2.2 The AMADEO® System

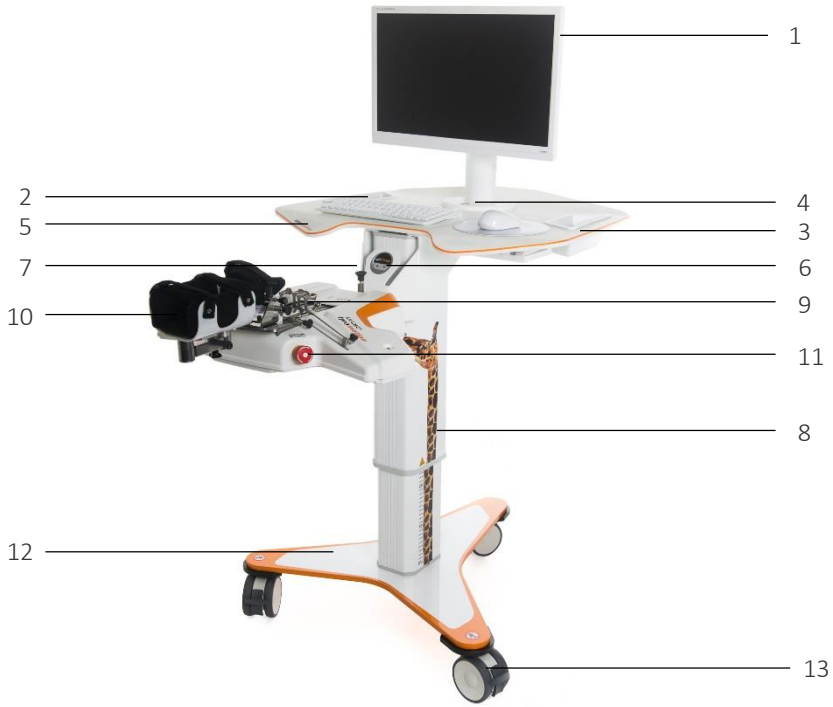



Figure 3


Figure 4


Figure 5

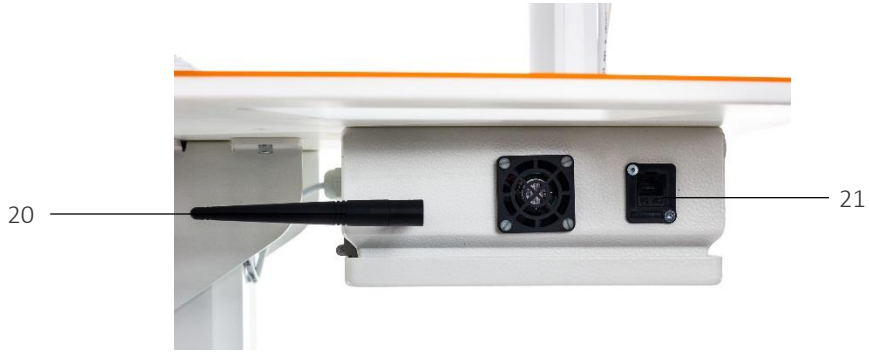



Figure 6


Figure 7

| | |
|---|---|
| *1* | *Monitor* |
| *2* | *Control devices (keyboard + mouse)* |
| *3* | *Plaster dispenser* |
| *4* | *PC activation button with status light* |
| *5* | *Table surface for operation* |
| *6* | *Control lifting column* |
| *7* | *Adjustable tilt axis with locking pin* |
| *8* | *Electronic lifting column* |
| *9* | *Movement mechanism* |
| *10* | *Hand and arm support* |

| | |
|---|---|
| 11 | *Emergency shutdown button twice* |
| 12 | *Base plate* |
| 13 | *Guide castors adjustable* |
| 14 | *Thumb slider left* |
| 15 | *Finger sliders* |
| 16 | *Thumb slider right* |
| 17 | *Spreading adjustment* |
| 18 | *Locking bolt hand unit* |
| 19 | *Safety bolt hand unit* |
| 20 | *WLAN antenna* |
| 21 | *LAN connection* |
| 22 | *USB port* |
| 23 | *Power switch* |
| 24 | *Monitor attachment* |
| 25 | *Power supply* |

Table 8

*Only accessories designated as suitable by the manufacturer may be used.*

### 2.2.1 Power supply AMADEO®

Please note that the AMADEO® system is connected to the designated power supply. The power switch is located directly on the control cabinet.

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

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

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

*A USB port is provided on the control cabinet, which may only be used for service purposes. Connecting peripheral devices (printer etc.) is not permitted.*

### 2.2.2 Installation

The on-site installation is limited to the connection of the hand unit to the table system, the assembly of the monitor and the power supply since the necessary software has already been installed prior to the delivery of the PC. The exact instructions for assembling the AMADEO® system can be found in the attached setup instructions.

### 2.2.3 Repair

*Please contact always the manufacturer for repairs!*

### 2.2.4 Disposal

The AMADEO® system may not be disposed with normal waste, but must be returned to the company TYROMOTION GmbH.

## 2.3 Adjustment possibilities AMADEO®

### 2.3.1 Height adjustment table frame

*The height adjustment must always be performed slowly while taking space requirements and the range of motion (shoulder joint) of the patient into account.*

**Lowering the lifting column:**

*Lowering the lifting column may result in pinching the patient under the hand unit.*
*Lowering the lifting column may result in pinching toes and fingers.*
*The lifting column may only be lowered by the therapist.*

### 2.3.2 Adjustment hand/arm support

*The hand/arm support must always be adjusted for therapy with the fingers connected to the mechanism since a correct configuration is not possible otherwise.*

*The hand and arm positions must be adjusted with utmost care. The AMADEO® system only functions flawlessly if the hand is positioned correctly!*

*A photo has been provided for clarification purposes!*

Figure 8

Attachement straps too tight

*The patient may suffer blood stasis if the therapist attaches the hook and loop fasteners too tightly around the patient's arm. Check the proper fit of the hook and loop fasteners before starting therapy.*

### 2.3.3 Spreading adjustment

Superficial injuries due to finger spreading that has been set too narrowly:

*The patient may scratch his hands with his own finger nails if the finger sliders are placed too close to each other.*

*The therapist must observe the hand and ensure proper device settings while initially configuring the device for hand size. The patient's fingers must never touch during therapy.*

### 2.3.4 Tilt adjustment mechanics


Figure 9

Figure 10

*Ensure that the locking pin is locked in place*

*Ensure that the AMADEO® system is at the correct height (the lifting column must be slightly extended in relation to the horizontal position).*

*The locking lever at the arm support must be applied.*

## 2.4 Device setup and movement

The device must be placed on an even, non-slanted surface and all three locking breaks on the castors must be applied when setting up the device; furthermore, the device must be positioned at a minimum distance of 30 cm from other devices, furniture etc. to avoid the pinch point hazard due to the lowerable table surface.

*Touching metallic parts accessible from the outside may result in electric shock. The control cabinet key must be removed and stored separately after setting up the device since the control cabinet contains touchable parts that conduct electricity. The control cabinet key is delivered separately with the device.*

The AMADEO® system rests on three adjustable castors, which make it possible to transport the device throughout the hospital.

### Procedure for transporting the device:

- Disconnect the power cable.
- Loosen the locking brakes of all three castors.

### Moving the device while the patient is strapped in:

***Accidental movements of the device may result in twisting the patient's arm.***

1. Set the device up on an even surface away from permanentpeople traffic.
2. Mount and tighten the device's castor brakes to minimise themovement in case the device is pushed accidentally.

## 2.5 Monthly functionality check/Recurring check

### 2.5.1 Functionality checklist

The functionality check described here must be performed every month. Perform the check even if AMADEO® indicates a malfunction (e.g. in case of unusual sounds, jolting movements, elementary damages etc.). The person responsible for the check must be a certified AMADEO® user.

| Inspection: | Malfunction | Resulting measure: |
|---|---|---|
| *Protective covers* | • *Covers rattle*<br>• *Covers missing*<br>• *Covers defective* | » *Further training is prohibited.*<br>» *Contact TYROMOTION GmbH.* |
| *Externally visible deformations* | • *Parts bent out of shape*<br>• *Parts asymmetrical*<br>• *Parts defective* | » *Further training is prohibited.*<br>» *Contact TYROMOTION GmbH.* |
| *Tracks* | • *Tracks loose*<br>• *Excessive resistance/friction of track sliders* | » *Further training is prohibited.*<br>» *Contact TYROMOTION GmbH.* |
| *Emergency stop button* | • *Emergency stop does not engage when the button is pressed.* | » *Further training is prohibited.*<br>» *Contact TYROMOTION GmbH.* |
| *Cleaning* | • *Finger sliders are contaminated.*<br>• *AMADEO® is contaminated.*<br>• *Hand/Arm support is contaminated.* | » Further training is prohibited.<br>» *Clean the contaminated parts as described in the chapter 3.5.2.* |

Table 9: Points for inspection

*Usage of the device must be stopped immediately if one of the malfunctions specified in Table 9: Points for inspection occurs or is suspected.*

### 2.5.2 Recurring check

Recurring checks differ from the checks in chapter 2.5.1; the legislator may demand the check described here while the checks in chapter 2.5.1 are intended, among other things, to detect acute damage or wear of parts that necessitates replacement. The device operator is responsible for performing both checks.

TYROMOTION GmbH has determined an interval of one year for recurring checks.
Recurring checks may only be carried out by professional and qualified personnel. The device operator must ensure that the intervals for the recurring checks stipulated by him are observed. Usage of the AMADEO® system must cease if the inspection intervals are not observed.

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

# 3 Clinical application

## 3.1 Indications/Contraindications

The AMADEO® finger-hand therapy system is principally used for the neurological rehabilitation of the distal upper extremity. The target group not only includes neurological but also orthopaedic and paediatric patients. As for any other therapy, the treating physician is responsible for the medical diagnosis, indication statement and selection of a suitable therapy. Principally, the same indications and contraindications apply for therapy with AMADEO® as for manually performed therapeutic treatment. Knowledge of contraindications is essential in order to keep patients safe. Ensure whether contraindications exist for the patient before beginning therapy with AMADEO®. It must be pointed out that patients can also exhibit additionally relevant indications or contraindications that are not listed here; the following list does not claim to be exhaustive.
Please contact TYROMOTION GmbH for clarification or feedback (addresses listed at the beginning of the document and on our homepage www.tyromotion.com).

### 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: Device usage is prohibited!

- Acute and pronounced pain symptoms despite conventional pain therapy in the affected upper extremity
- Adjustment and patient position: Do not carry out training with the AMADEO® 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
- The AMADEO® system is not suitable for children under 3 years of age (risk of swallowing small parts, i.e. finger supports).
- Insufficient compliance, e.g. children, patients with severe psychotic or neurotic disorders
- High-grade ataxia
- Advanced osteoporosis: fracture risk
- Fractures: Do not perform training in case of unstable or insufficiently consolidated fractures.

## Relative contraindications:

The treating physician or therapist evaluates the patient individually and must assess whether the AMADEO® therapy system is suitable for the patient in case of:

- Apraxia
- Arthritis in joints and upper extremity
- Reduced compliance, e.g. children, patients with cognitive impairment
- Consolidated fractures in the upper extremity
- Epilepsy
- Pacemakers and similar devices/implants: Pacemakers can react differently to external influences. It is, therefore, important to be aware of relevant or possibly dangerous influential factors for the specific pacemaker model. Patients must be informed that magnets are located in the finger supports or magnet couplings.
- The AMADEO® therapy device does not affect pacemakers at a distance of more than 15 cm between the pacemaker and the device (or between the pacemaker and the magnet).
- Infections
- Joint problems: Joint strain during hand training can cause pain and irritation in case of diminished load-bearing capacity.
- Neglect
- Osteoporosis
- Orthostatic circulation problems: increased risk of falling
- Pain, e.g. complex regional pain syndrome (CRPS)

- Perceptual disorders, e.g. patients with sensor impairments cannot give feedback on possibly occurring pain.
- Skin problems: Before and after every training, check for previously existing wounds and wounds or pressure points caused by training, in particular in bodily areas that contact the device.
- Material intolerances, e.g. allergies to washing detergent, adhesive intolerances (adhesive in the finger plasters contains zinc oxide; plasters without zinc oxide are available)
- Shoulder-hand syndrome/Subluxation
- Swelling/Skin ulcerations in the upper extremity

**Suitability of the system for the envisaged therapy:**

1. *Consistent evaluation of the patient's therapy results*
2. *Observation of current studies relevant to the topic*
3. *Discontinuation of therapyin case of disproportionate deterioration of the patient's condition.*

## 3.2 Safety

### 3.2.1 Safety concept

The AMADEO® hand-therapy device is an active therapeutic aid with five individually powered finger or thumb sliders. The motors are controlled centrally via the software executed from a 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 range of motion:

- The maximum force of the motors is physically limited to 30N for maximum motor voltage.
- The forces impacting the sliders are constantly measured during therapy, and the motor voltage is deactivated in case of exceedance of the configured threshold value.
- The fingers are connected via magnetic couplings and are not firmly attached to the sliders. Fingers are automatically released from the sliders if the magnet strength is exceeded.
- 2 emergency shutdown buttons are located on the left and right side of the device if the patient experiences discomfort or is endangered during therapy for some reason. Activating the emergency shutdown function separates the motors from the power supply while the software displays the notification "Emergency shutdown button activated".
- Consistent monitoring of the therapy by a user is recommended in any case.

*Therapy must be interrupted if the therapist is unable to either see or hear the patient (for longer than the time period specified above).*

*A maximum therapy duration must definitely be configured in the software for patients with limited cognitive abilities.*

*Therapy with children requires constant supervision by the therapist.*


*Children under the age of 3 are excluded from usage due to insufficient compliance.*

*Please also observe the user manual for the tyroS software.*

### 3.2.2 Residual risk

An unpredictable residual risk remains for manual hand 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. TYROMOTION GmbH can provide a detailed risk analysis upon request.

## 3.3 Prior to training

### 3.3.1 Activating the AMADEO® system

The system can be activated after it has been properly connected. Activate the device with the power switch. All components are now being supplied with electricity. Then turn on the PC power switch to boot the PC. The PC status light indicates that the PC has been turned on. The operating software can now be started after logging into Windows.

### 3.3.2 Consumption materials

The following consumption materials can be obtained from the manufacturer.
*As for example:*

- Finger plasters
- Finger supports
- Hand/arm support padding

*Only use original consumption material from the manufacturer.*

## 3.4 Performing training

Device settings must be configured according to the patient if the AMADEO® therapy is being performed for the first time with a specific patient. The configuration is performed automatically while creating a new patient.

*Please always observe the tyroS software user manual for the entire training performance.*

*All configuration possibilities must be determined together with the physician prior to the initial application, which refers specifically to maximum speed, strength and range of motion.*

*Only trained personnel may be near the patient and therapy system during training. Therapy personnel should ideally be next to the patient during therapy in order to provide instructions.*

*The hand unit is the only part of the device which should be touched by a patient. Inform your patients that they must not touch any other parts, such as the monitor, or lean onto the therapy device for support.*

A maximum age has not been specified. Children under the age of 3 are excluded from usage due to insufficient compliance. The treating physician or therapist must assess and approve the application for children three years of age and older. The therapist must pay especially close attention when determining the range of motion for patients with very small hands, in particular for the definition of the flexion end point. Fingers must not be spread unnaturally.

### 3.4.1 Patient information

Patient-specific information (range of motion, max. strength, max. speed, etc.) are saved in the AMADEO® system in connection with recurring therapies. The type, duration and results of individual therapy sessions are also logged in order to evaluate this information in a targeted manner. Data protection regulations, valid in the respective country, must be observed!

### 3.4.2 Selection of finger supports

The varying sizes of finger supports are color coordinated for identification purposes. The smaller the finger supports, the less the strength of the integrated magnets.

| | |
|---|---|
| L | White finger supports |
| M | Orange finger supports |
| S | Grey finger supports |

*Ensure that suitable finger supports are used for the patient.*
*The following illustration is provided for clarification purposes*

| | | | |
|---|---|---|---|
| L |  |  | **Support too large**<br>• Support may shift during usage.<br>• Support may slip from the fingers during usage. |
| S |  |  | **Support too small**<br>An optimal connection between finger/thumb support and movement mechanism is not possible. |
| M |  |  | **Support fits exactly, optimal usage!** |

Table 10

### 3.4.3 Attachment of finger supports

Finger and thumb supports form the connecting element between the finger or thumb tip and the movement mechanism. The finger and thumb supports are connected to the mechanism via a permanent magnet and are thus detachable.

*Disinfect the patient's hand before attaching the finger supports.*

Figure 11

Figure 12

The finger or thumb supports are fastened with two skin-friendly plasters (width <4 mm) to the fingers or thumb. This process is repeated for all fingers and the thumb.

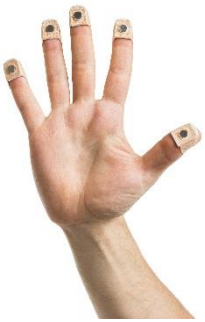


Figure 13

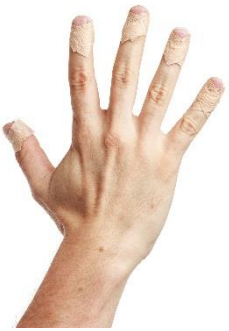


Figure 14

*Suitable finger plasters are to be used, depending on hand size, to ensure the best-possible adhesion.*

Connect the patient's hand to the hand unit.

Figure 15

The usage of hygienic wipes is recommended when connecting the patient's hand to the hand unit to ensure hygienic safety.

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

*The following measures or instructions must be observed to ensure a risk-free operation of the device:*

## Intolerance to finger plaster adhesive:

Intolerance to the adhesive (zinc oxide caoutchouc) in the finger plasters can cause skin irritations.

1. *The therapist should ask the patient about any known intolerances.*
2. *The therapist should monitor the skin on the patient's fingers.*
3. *Only use finger plasters recommended and provided by TYROMOTION to attach the patient.*

## Storage of finger plasters:

*It must be ensured that the finger plasters are not exposed to direct sunlight and stored in a dry environment at 25° C maximum.*

## 3.5 After training

Loosen the magnetic connections that couple the patient's fingers to the device once training is completed. Now carefully loosen the finger supports from the finger tips and open the hook and loop fasteners of the arm support.

### 3.5.1 Deactivating the AMADEO® system

You must close the control software with [Exit program] and shut down Windows with "Start >> Shutdown" before you can deactivate the AMADEO® system. Now you can turn off the system with the power switch.

*Please also take note of the tyroS user manual.*

### 3.5.2 Cleaning AMADEO® and associated parts

Obligatory and imperative disinfection measures:

*Disinfecting the finger and thumb supports after therapy*

- *Wipe the hand and arm supports dry after profuse sweating during therapy.*
- *Disinfect the hand and arm supports after therapy*

The AMADEO® system should also be cleaned in regular intervals in addition to the abovementioned disinfection measures. To minimize the risk of bacterial transmission, all parts which could be touched by patients should be cleaned and disinfected regularly (e.g. Screen, mouse, keyboard, table as well as lifting column). Use a dry or slightly damp cloth. The cloth may also be soaked in alcohol in case of persistent contaminants. However, strong cleaning agents, soaps or solvents must be avoided. Contact TYROMOTION GmbH if you are unable to clean severe contaminants.

Regularly clean the hand and arm supports with a foam cleaner (e.g. furniture cleaning foam used in automotive care), and use a disinfectant subsequently. Hand and arm supports can also be cleaned in the washing machine at 40°C.
Use the delicate cycle (the use of wash bags is recommended).

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