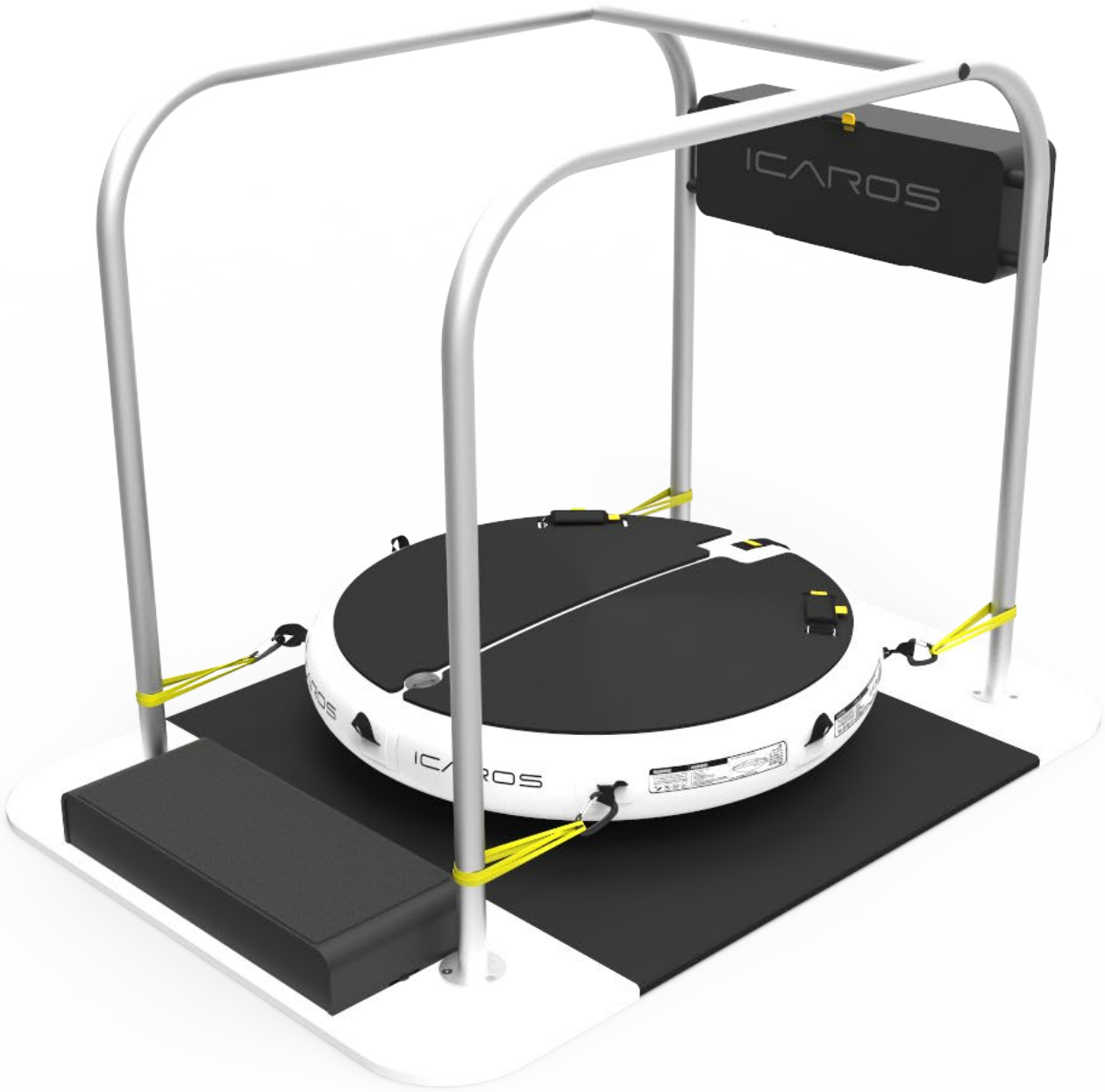
ICAROS GUARDIAN
INSTRUCTIONS FOR USE



Instructions_for_use_ICAROS_Guardian_2023_ v_2_EN
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CE MD

Table of Contents

1 Introduction

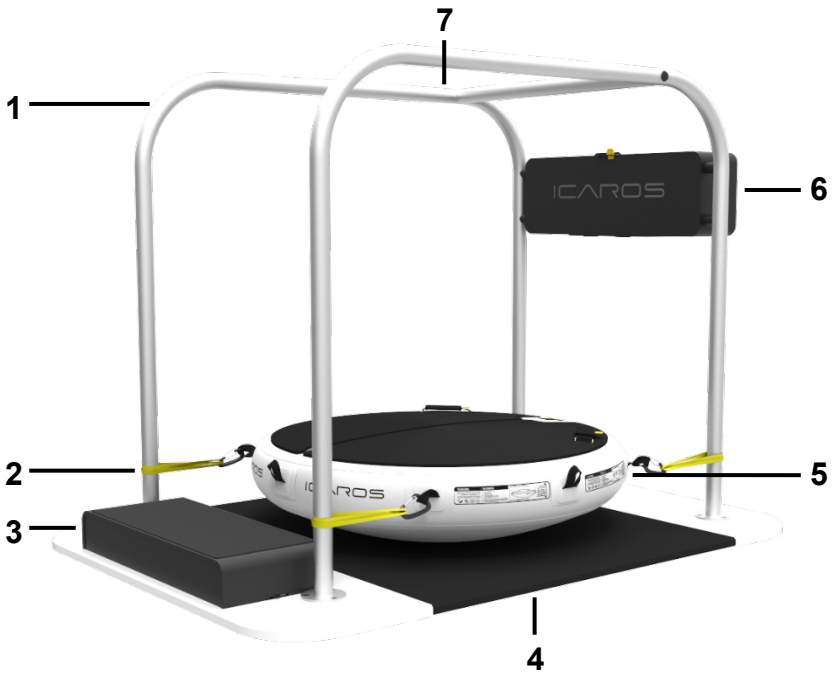
The ICAROS Guardian movement therapy system is aimed at professional users and is designed for supervised use by doctors and therapists.

Intended purpose: ICAROS Guardian is designed for stability and balance training for orthopedic patients suffering from walking disorders. It is designed for professional use in orthopedic & neurological therapy and rehabilitation. The developed system is used for orthopedic and stroke patients, especially from phase C for active mobilization, improvement of postural control (posture), reduction of fall risk and improvement of fine and gross motor skills.

Patients exercise standing on the training device by moving on the ICAROS Cloud 360 balance platform with the help of active weight shifting. Meanwhile, the patients can hold on to the handrails of the ICAROS Guardian.

These operating instructions describe in detail the functions, operating conditions and use from the point of view of safety.

1.1 Device



(1) Handrail
(2) Expander
(3) Step
(4) Board
(5) Balance platform ICAROS Cloud 360
(6) Accessories box
(7) Cross handrail

1.2 Warning Notices

Please note the following information.

⚠ WARNING!

Warns of a potentially dangerous situation that will result in death or serious injury if not avoided.

⚠ ATTENTION!

Warns of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or damage to the device.

1.3 Availability and validity of the operating instructions

These instructions for use comply with Regulation (EU) 2017/745.

Operating elements as well as the instructions for use have been developed for trained professionals with normal vision, without reading disabilities and cognitive abilities.

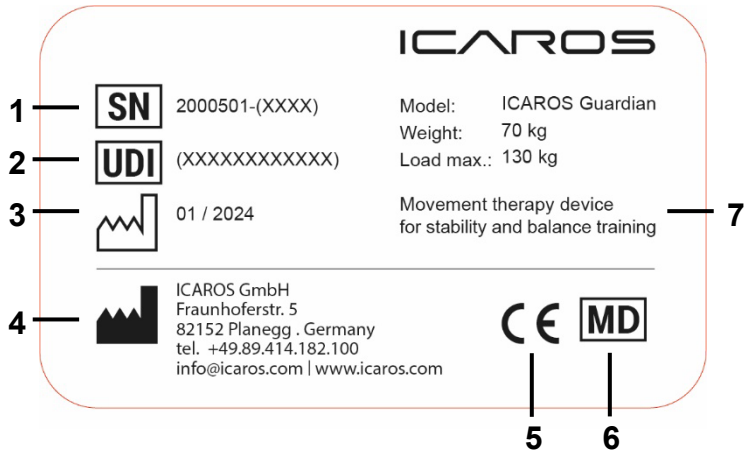
The instructions for use in paper form from the manufacturer or digitally on the manufacturer's website are valid.

Other instructions for use are invalid.

1.4 Icons

	This icon marks a medical product.
	This icon marks the UDI-number.
	This icon marks the serial number.
	This icon marks the day of production.
	This icon marks the name, address and contact details of the manufacturer.
	Market introduction in accordance with regulation (EU) 2017/745
	Consult the instructions for use before use.
	Caution. Read the instruction for use before use.
	The device must not be used if the packaging is damaged. In this case, consult the instructions for use.
	The device and packaging are fragile and must be handled with care.
	Both the device and the packaged device must be protected from moisture.
	This product contains natural latex which might cause allergic reactions.
	This mandatory sign indicates the safety measure of holding onto the handrail.
	This mandatory sign indicates the safety measure of wearing sturdy shoes.

1.5 Product Labeling



(1) Serial number
(2) UDI
(3) Date of manufacture
(4) Manufacturer
(5) Market introduction according to regulation (EU) 2017/745
(6) Medical product
(7) Purpose of use

Expected clinical benefit:

- Reduction of the risk of falls
- Improvement of gait and balance (postural control)
- Proprioception
- Reaction

Duration and frequency of application:

- Duration per session to a maximum of 20 min
- Maximum of three sessions per day with breaks of at least 10 minutes between sessions
- Recommended intervention duration: six weeks with a minimum of three sessions per week
- Prescription of the individual number of applications and duration by treating medical personnel

2 Safety

⚠ WARNING!

Not reading the operating instructions can lead to dangerous situations for the treating personnel and users, which can result in death or serious injury. Be sure to follow the safety instructions.

2.1 Indications / Contraindications

The ICAROS Guardian movement therapy system is aimed at professional users and is designed for supervised use by physicians and therapists. The patient target group includes neurological and orthopedic patients who show deficits in the areas of movement control, strength control, accuracy, coordination, stability and balance.

The treating physician or therapist is responsible for the medical diagnosis, indication and selection of the appropriate therapy. In principle, the same indications and contraindications apply to therapy with the ICAROS Guardian movement therapy system as to manually administered therapeutic treatment. Make sure whether there are any contraindications for the patient before performing training with the ICAROS Guardian.

It should be noted that patients may also have additional indications and/or contraindications that are not listed here but are relevant and the following list does not claim to be exhaustive.

Common indications	Contraindications
• Remobiliziation of the walking apparatus • Balance exercises rehabilitation • Fall prophylaxis • Disturbed walk pattern • Stroke (from phase C) • Leg and hip muscle training	• Earlier than 14 days after surgery • Fever • Brain aneurysm • Vertigo • Unidentifiable pain • Stroke acute phase • Osteoporosis stage 3 and 4 • Acute inflammatory deseases • Acute injuries of ligaments or tendons • Bone fractures • General medical contraindications

2.2 Responsibility of the Operator

⚠ WARNING!

Measures for risk free operation.

- Continuous monitoring of the therapeutic success of the patients
- Observation of current studies in the subject area
- Discontinuation of therapy in case of deterioration of the patients condition
- Supervision of the application is carried out by trained personnel
- The qualified personnel must be at the user's side during the entire training in order to be able to react to dangerous situations.

2.3 Responsibility of the Owner

The owner is responsible for ensuring, that all persons operating the system have read and understood these instructions for use.

Installation, maintenance, calibration, repairs and modifications of the ICAROS Guardian System may only be performed by trained and qualified personnel.

If the ICAROS Guardian System does not function properly, the owner must contact ICAROS GmbH.

The owner is responsible for storing the ICAROS Guardian System after and between therapies in such a way, that damage and unsafe use by unauthorized persons are excluded.

In this context, please also refer to chapter 2.5 - Warranty and Disclaimer.

2.4 Error and Incompleteness

If you find any errors or incompleteness in these instructions for use, please contact ICAROS GmbH.

- Contact details on page 1

2.5 Warranty and Disclaimer

ICAROS GmbH warrants to the purchaser of the system, that the system will be free from defects in materials under normal use for a period of 12 months from the date of installation at the owner's premises and that it will conform to the mechanical specifications published by ICAROS (unless the warranty period is extended by an optional service contract). This warranty is provided on the condition, that the system is properly installed, operated and maintained in accordance with these instructions for use.

If the ICAROS Guardian or a part of the system was damaged wilfully, by improper use or by the consequences of wrong storage, no liability can be assumed on the part of ICAROS GmbH.

The customer must submit all warranty claims in writing to ICAROS within 60 days of the occurrence of a problem and prior to the expiration of the warranty. ICAROS' sole obligation under the warranty shall be to repair, replace or correct such defective or non-conforming parts at its sole discretion. After repair or replacement of the defective or nonconforming parts, ICAROS shall have no further obligation to the owner with respect to such defective or nonconforming parts. All repairs or maintenance under this warranty shall be performed by an authorized ICAROS service representative.

Should any repairs, maintenance or other work be performed by a third party, the above warranty will become null and void. In addition, problems resulting from accidents, misuse, misapplication, bearing damage, negligence or modification of the system or its components are excluded from the above warranty.

The above warranty is given in lieu of all other warranties, rights or conditions, and the system is provided "as is" except for such limited warranty. ICAROS GmbH and its third party suppliers specifically disclaim, without limitation, all other warranties, expressed or implied, to the owner, its personnel and patients, customers and users, and any third parties, including without limitation any warranties of merchantability, fitness for a particular purpose, or non-infringement, and any warranties arising from a course of performance, or course of dealing.

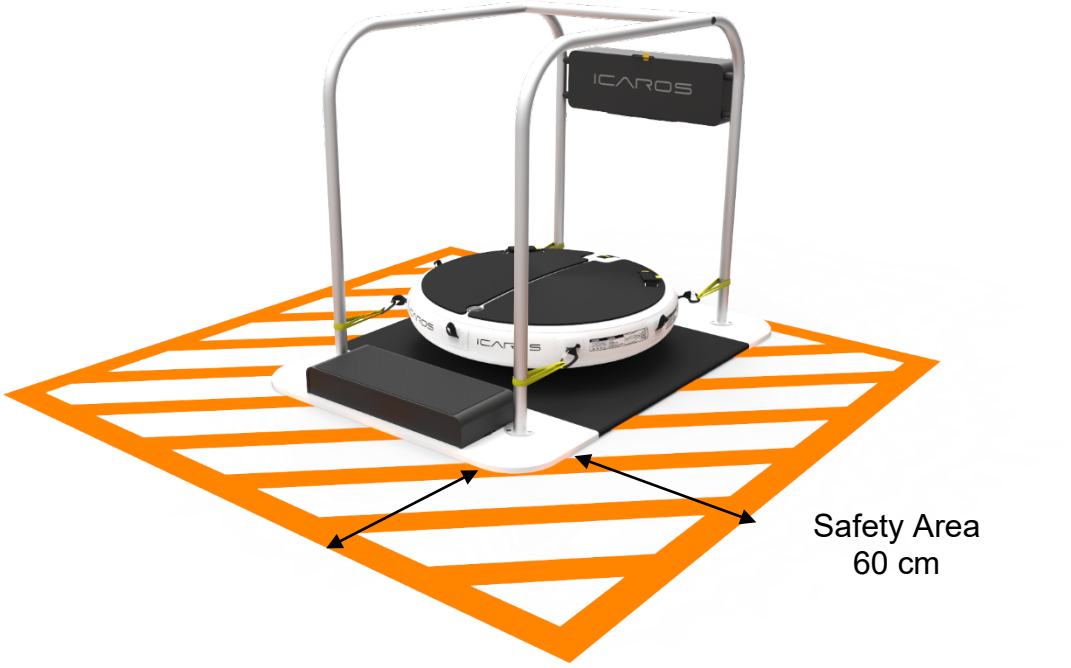
ICAROS and its third party suppliers make no representations or warranties that the system will meet the owner's requirements or will operate without interruption, error or defect. In no event shall ICAROS be liable for any indirect, incidental, special, consequential, or punitive damages including, but not limited to, loss or loss of profits, revenue, goodwill, or use incurred by the owner or any third party, or for damages to any related equipment, replacement product, equipment, service replacement element or downtime costs, or for claims by patients, customers, visitors, or employees of the owner or others, whether in an action in contract, tort, strict liability, or as imposed by law or otherwise, even if ICAROS has been advised of the possibility of such damages.

In no event shall ICAROS' liability for damages arising out of or in connection with this Agreement exceed the purchase price of the system.

Some jurisdictions limit the scope of, or exclude remedies or indemnities or liability, such as liability for gross negligence or willful misconduct as described above, or to the extent described above, or do not allow the exclusion of implied warranties. In such jurisdictions, the limitation or exclusion of warranties, remedies, indemnities or liabilities as described above may not apply to the owner. Even if such limitations or exclusions do not apply to the extent prohibited by law, they apply to the maximum extent permitted by law. The owner may also have other rights that vary by state or other jurisdiction.

2.6 Location and Operating Conditions

The use of the device is limited to sufficiently tempered, clean and dry rooms. The temperatures in the room should be between 17°C and 30°C. Rooms with more than 65% humidity are not suitable for use. To meet these operating conditions, the rooms must be sufficiently air-conditioned and ventilated.



The device must be placed on a stable, horizontal and level area. In addition, the place of use must be sufficiently illuminated so that safety instructions on the device can be read by the user. Make sure that there is a 60 cm wide safety area around the ICAROS Guardian, which allows safe access and exit and is free of objects, training equipment, furniture and persons. Only the treating therapist may enter this safety area, while the device is being used. Any objects or persons in the safety area can cause collisions, which may result in injuries.

3 Technical Specifications

3.1 ICAROS Guardian

System:

Stability and balance movement therapy training system

Scope of supply:

- 1 ICAROS Guardian board with cross handrail
- 1 balance platform ICAROS Cloud 360
- Instructions for use: ICAROS Guardian
- Instructions for use: ICAROS Cloud 360
- Spare parts kit

ICAROS Guardian dimensions:

- Weight: 70 kg
- Length 169 cm x Width 120 cm x Height 123 cm

References on the ICAROS Guardian:

- Label
- Warning
- CE-Label
- Reference to the instructions for use
- Manufacturer
- Date of production
- Serial Number
- UDI-Number
- Weight

Certification:

- EU: Medical product class I according to MDR (EU) 2017/745 (MDR)

4 Installation

Before commissioning, the installation of the device must be completely finished. For this purpose, it is necessary to assemble the ICAROS Guardian in accordance with the assembly instructions and to place it at an operating location that corresponds to the specific operating conditions.

To check the assembly, go through the steps in the assembly instructions and make sure that they have been carried out correctly and completely.

5 Comissioning

⚠ WARNING!

The device is commissioned exclusively under the supervision of trained personnel.

Make sure that the user meets the physical requirements. If these are exceeded or fallen short of, this may result in damage to the device or injury to the user.

Physical requirements of the user:

There must be no contraindications.

- Minimum height: 150 cm
- Maximum height: 200 cm
- Maximum weight: 130 kg

6 Usage

6.1 Checklist

⚠ WARNING!

Check the ICAROS Guardian in the order of the checklist. If one or more items in the following checklist do not apply, they must be corrected before the device may be used.

1. Safety area is free of people and objects.
2. Device is completely assembled and undamaged.
3. The balance platform ICAROS Cloud 360 is positioned centrally on the carpet of the ICAROS Guardian and fixed with the enclosed flexible safety straps.
4. The air pressures of the balance platform ICAROS Cloud 360 correspond to the values in the instructions for use.

6.2 Mounting and Dismounting

⚠ WARNING!

Make sure that the step of the ICAROS Guardian is free of objects. The user must wear comfortable and non-slip shoes.

Provide assistance to the user as needed and perform the following steps during ascent and descent.

6.2.1 Mounting

- The user should stand upright in front of the ICAROS Guardian step. To stabilize balance, the user should grasp both handrails.
- Now the user can place both feet on the step of the ICAROS Guardian.
- Then the user may step onto the ICAROS Cloud 360 balance platform with both feet shoulder-width apart and centered.

6.2.2 Dismounting

- To stabilize balance, the user should grasp grasp both handrails if possible.
- The user may step backwards with both feet one after the other from the balance platform ICAROS Cloud 360 onto the step of the ICAROS Guardian.
- Now the user can place the two feet one after the other from the step of the ICAROS Guardian on the floor.
- First the user should stabilize the balance before releasing the handrails.

6.3 Training

Balance, strength, conditioning and coordination exercises can be performed on the ICAROS Guardian. The type of exercises should be selected according to the therapy and is to be determined by the treating medical professional.

Balance

- One-legged or two-legged exercises

Strength

- Squats
- Leg Raises

Endurance

- Fast rocking
- Constant swaying

Coordination

- Targeted weight shift to the right, left, front or back
- Circling or swaying movements

7 Maintenance

Perform the following routine checks to ensure proper operability and safety of the ICAROS Guardian system.

Daily:
Clean the padding and contact surfaces with a clean and damp cloth after each use. Avoid the use of abrasive cleaners and chemical substances containing petrol or acetone.

Monthly:
Check the condition of all connecting pieces and screw connections and retighten them if necessary. Use the supplied tool for this and hand-tighten the Allen screws clockwise. Check whether the air pressure of the ICAROS Cloud 360 balance platform corresponds to the values in the assembly instructions.

Do not continue to use the device until a defect has been rectified.

Contact the ICAROS GmbH (*see page 1, contact details, manufacturer*). Please do not carry out any independent repairs without professional advice.

8 Use with Connectable Devices

The ICAROS Guardian device can be equipped with monitor Apple TV, Magic Trackpad and iPad.

Please note that the CE label ICAROS of the Guardian training device refers only to the mechanical ICAROS Guardian training device, not to the connectable electronic devices and software.

For detailed information, please refer to the document "Connectable devices_ICAROS Guardian_2023_v1".

9 Storage

In environments with temperatures below 10°C and above 40°C, the device may only be stored for 24 hours. Also rooms with over 65% humidity are not suitable for storage. Make sure the storage room is clean, ventilated and meets the stated temperature and humidity requirements. In case of longer storage, it is recommended to keep the device in its original packaging.

10 Disposal Information

The ICAROS Health System does not contain any hazardous substances and can be disposed of in a regular manner (e.g. in bulky waste).

11 Incidents

The ICAROS Health System is a class 1 medical device.

Incidents must be reported to the manufacturer and the competent authority in the member state of the user.

Thank You

We are grateful that you have decided to purchase the ICAROS Guardian. The whole ICAROS team wishes you success and joy in using it.

If you need more information about our products, please feel free to visit our website, contact us by phone or write an email. We will be glad to be of service to you.

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