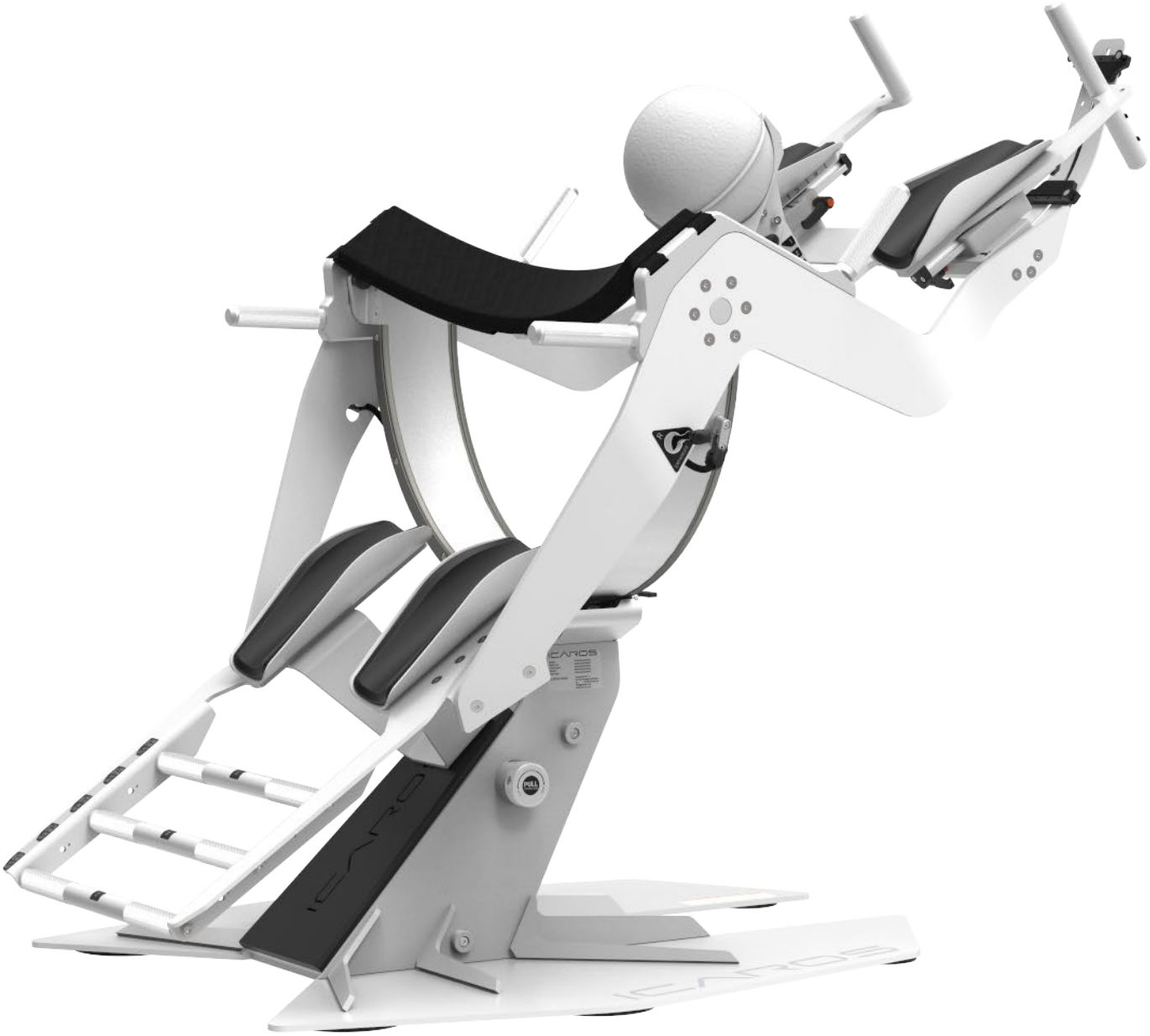


ICAROS HEALTH
INSTRUCTIONS FOR USE

EN_Instructions_for_use_ICAROS_Health_2023_ v_3
14.07.2023

ICAROS GMBH
Fraunhoferstr. 5
82152 Martinsried
GERMANY

Contact Details

Manufacturer

ICAROS GmbH

Fraunhoferstr. 5
82152 Martinsried
GERMANY

TEL	+49 89 414 1821 00
MAIL	info@icaros.com
WEB	www.icaros.com

Distributor

ICAROS GmbH

Fraunhoferstr. 5
82152 Martinsried
GERMANY

TEL	+49 89 414 1821 00
MAIL	info@icaros.com
WEB	www.icaros.com

CE MD

Icons

This product is a medical device.

Caution. Read the instruction for use before use.

Consult the instructions for use before use.

This icon marks the name, address and contact details of the manufacturer.

This icon marks the day of production.

Both the device and the packaged device must be protected from moisture.

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.

This icon marks the UDI-number.

This icon marks the serial number.

Table of Contents

1 Introduction

The ICAROS Health is a mechanical movement therapy device designed for supervised use in physical therapy.

Intended purpose: ICAROS Health is intended for core and balance training for orthopedic patients suffering from unspecific low back pain. It is designed for professional use in orthopedic therapy and rehabilitation. The developed system is to be used for orthopedic patients (lower back pain) and stroke patients especially from phase C onwards for active mobilization, improvement of postural control (body posture), reduction of the risk of falls, and improvement of sensory function and fine and gross motor skills.

Patients exercise in plank position with knees laid down (half plank) on the training device by using active weight shifting to move the ICAROS Health in two axes. An advantage of the half plank on the ICAROS Health device compared to the regular half plank is the increased muscle activity, as a result of the balance component of the workout, which requires the coordination of all muscle groups, while also activating the deep muscles.

The ICAROS Health System can optionally be used in combination with virtual reality headsets or smartphones and tablets to provide additional visual feedback.

These instructions for use comprehensively describe functions, operating conditions and use from the perspective of safety.

Expected clinical benefit:

- Reduction of low back pain by improving functionality, stability and reactivity as a result of strengthening the trunk muscles.
- Relaxation of the deep trunk muscles through specific mobilization.
- Reduction of the risk of chronification of low back pain by promoting a symmetrical build-up of the stabilizing trunk musculature.
- Promotion of spinopelvic balance and postural control.

Application duration and frequency:

- 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 treatments per week.
- Prescription of the individual number of applications and duration by the treating health care professional.

2 Safety ⚠

2.1 Indications / Contraindications

The ICAROS Health movement therapy system targets 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, trunk control, posture 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 movement therapy system ICAROS Health as to manually administered therapeutic treatment. Make sure whether there are any contraindications for the patient before performing training with the ICAROS Health.

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

Frequent indications:

- Unspecific low back pain
- Stroke (from phase C)
- Core, shoulder and trunk muscle training
- Balance exercises in rehabilitation
- Remobilization of the hip joints

⚠ **Contraindications:**

- Earlier than 14 days after surgery
- Fever
- Brain aneurysm
- Ocular hypertension
- Vertigo
- LBP acute phase
- Spine injuries
- Unidentifiable pain
- Pregnancy
- Stroke acute phase
- Stage 3 and 4 osteoporosis
- Acute inflammatory diseases
- Retinal detachment
- Bone fractures
- Inflammations of the ear
- General medical contraindications

Potential risks for patients:

- falling off the device
- injuries caused by moving parts
- injuries caused through incorrect body posture

Potential risks for operators:

- injuries caused by moving device components and users

2.2 Responsibility of the Operator

⚠ **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 patient's condition

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 Health System may only be performed by trained and qualified personnel.

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

The owner is responsible for storing the ICAROS Health 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 Health 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.

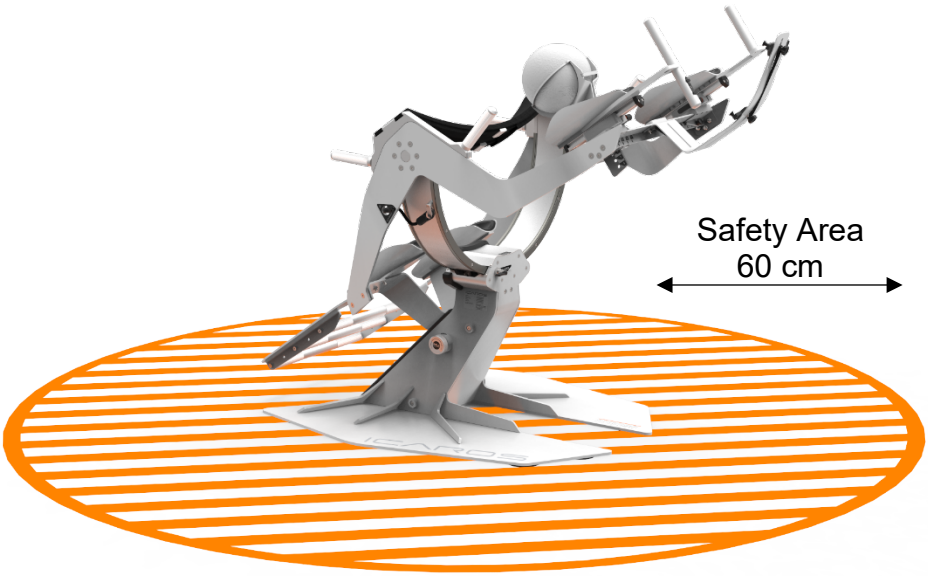
ICAROS and its third party suppliers make no representations or warranties that the system will meet the owner's requirements or will operate without interruption, error or defect. In no event shall ICAROS be liable for any indirect, incidental, special, consequential, or punitive damages including, 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 Health, 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 Health

System:

Mechanical core, trunk and balance movement therapy and training system

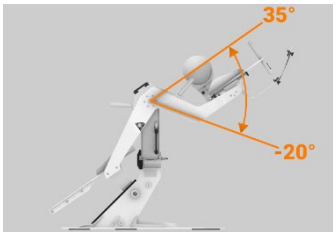
Scope of supply:

- 1 ICAROS Health
- Instructions for use: ICAROS Health
- Spare parts

ICAROS Health dimensions:

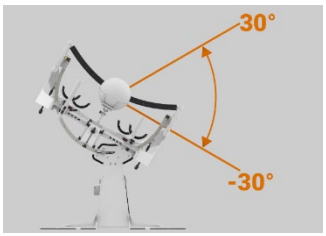
- Weight: 131 kg
- Length 203 cm x Width 96 cm x Height 104 cm

Pitch axis:



- Maximum pitch angle: +35°, -20°
- Adjustable pitch angle: +10°, 0°, -10°
- Pitch lock: +35°

Roll axis:



- Maximum roll angle: -30°
- Roll damping: Medium from -25°, Easy from -10°
- Roll lock: 0°

References on the ICAROS Health:

- Label
- Warning
- CE-Label
- Reference to the instructions for use
- Manufacturer

Certification:

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

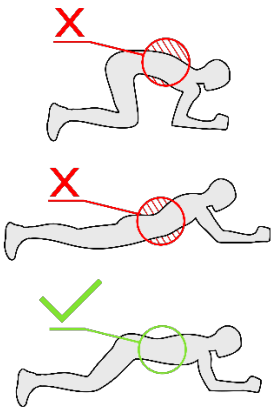
4 Commissioning

The commissioning of the device is carried out exclusively in the care of trained personnel.

4.1 Device Settings for Body Size

The correct setting of the ICAROS Health is particularly relevant, as an incorrect setting represents a risk in the application. Incorrect size setting may result in injuries/pain through wrong body posture.

Since the proportions of patients can vary greatly, the attending physician or therapist must make the correct adjustment of the ICAROS Health for each patient individually. Only optimal adjustment of the device enables safe and effective use of the ICAROS Health.



Correct posture:

The body's center of gravity must be neither too high nor too low. At the same time, overextension and compression must be avoided.

- Shoulders above the elbows
- Straight back
- Active abdominals
- Upper leg and lower leg at an angle between 130° and 150°

It is advisable to document the user's individual settings and adjust them as necessary to optimize the course of therapy.

Physical requirements of the user:

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

4.1.1 Footrests and Legrests

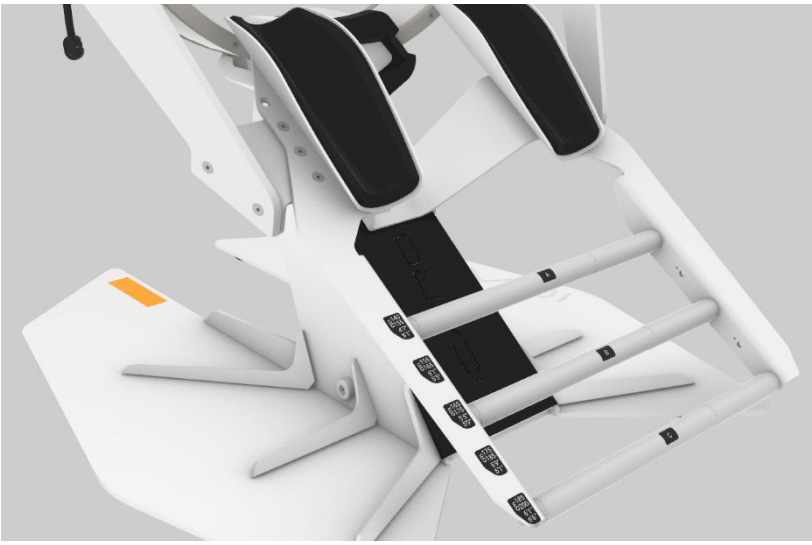
Use the information on the left side of the footrests to determine the correct footrest for the patient.

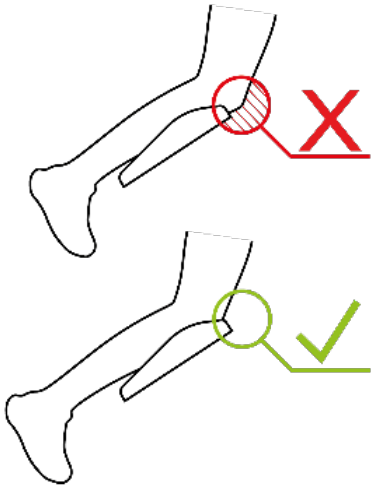
The choice of footrest depends not only on the body size, but also on the proportions of the patient.

The thigh and lower leg should form an angle of between 130° and 150° to each other on the back of the body.

- 150 - 155 cm, Footrest A
- 165 - 175 cm, Footrest B
- 185 - 200 cm, Footrest C
- The positioning of the knees allows for fine adjustment.

⚠ **Make sure that the user's knees do not protrude from the legrests to avoid collisions between the knee and the base.**





4.1.2 Handles and Armrests

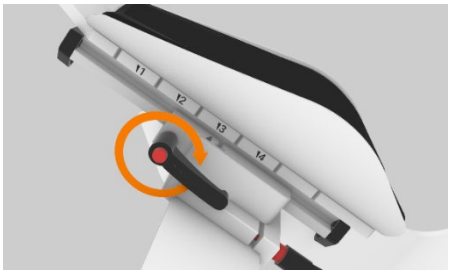
The armrests can be adjusted independently in the longitudinal and transversal axes. The correct size setting is particularly important to enable effective and safe training.

Longitudinal adjustment:

The 1-4 scale is used for orientation. Setting 1 is suitable for users with a height of 150-155 cm, while 4 is suitable for heights between 185 - 200 cm.

1.
Loosen clamping lever. (Turn counterclockwise. Do not press the red button)

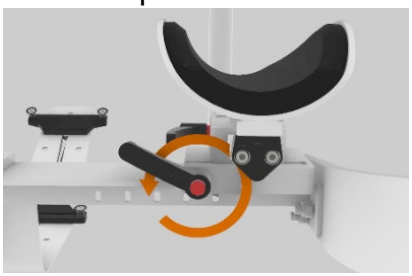
2.
Move the armrest lengthwise.



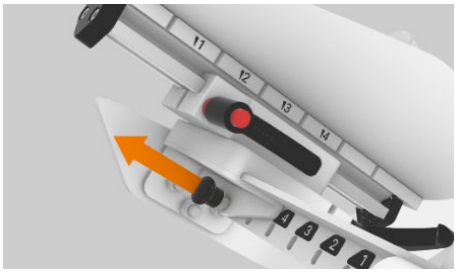
3.
Tighten the clamping lever. (Turn clockwise)

Transverse adjustment:

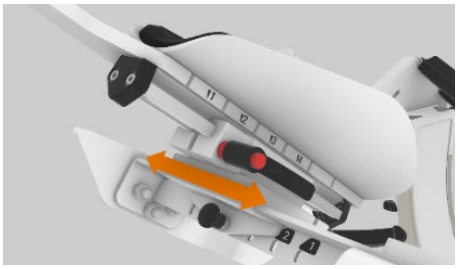
The scale 1-6 serves as orientation. The distance between the armrests should correspond to the shoulder width of the user.



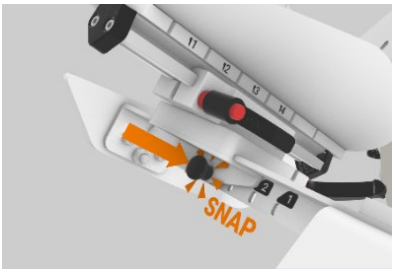
1.
Loosen clamping lever. (Turn counterclockwise)



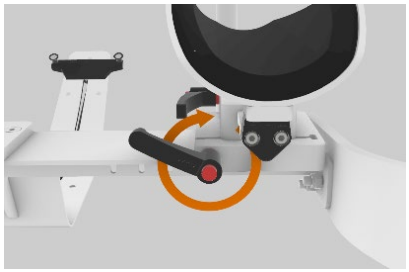
2.
Pull out the safety bolt.



3.
Move armrest lateralwise.



4.
Engage the safety bolt. (Audible engagement)



5.
Tighten the clamping lever. (Turn clockwise)

4.1.3 Hip Support

The hip belt is used to support the patient during training on the ICAROS Health. The use of the belt relieves the supporting muscles. Furthermore, the belt can be used to counteract an incorrect posture (hollow back).

The tighter the belt is tensioned, the higher will be the support function of the hip belt. A belt that is too tight will make it more difficult to perform the pitch and roll movement.

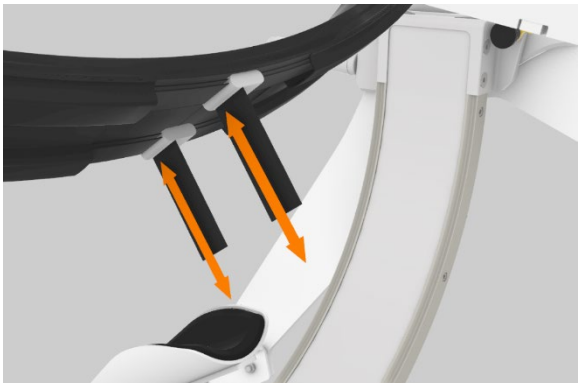
Patients who do not require support should always keep their distance from the hip belt and not rest their hips on the belt.

Tighten hip support:

1. Open buckles. (Keep buckle clamp levers pressed.)
2. Pull both straps through the buckles at the ends.
3. Release buckle clamp levers. (Buckles clamp belt tightly)

Loosen hip support:

1. Open buckles. (Keep buckle clamp levers pressed.)
2. Pull on the straps. (Loose ends become shorter)
3. Release buckles. (Buckles clamp belt tightly)



After the ideal belt tension for a patient is set, the waist belt tension can be checked using a ruler or measuring tape. Measure the distance between the top of the belt and the "Measure Here" mark. The patient`s individual setting can be noted to provide the optimal setting for the next training session.

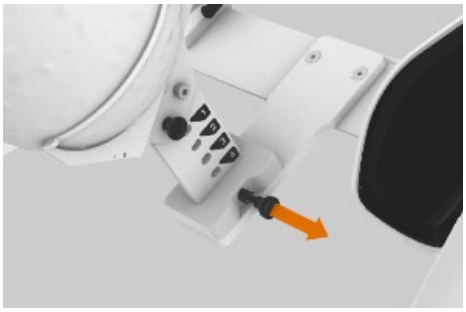
4.1.4 Chest Support

The chest support serves as a support module for patients, who can not hold the half plank position without support. It can be adjusted vertically in height and angle of inclination. If no chest support is required, it can be dismantled.

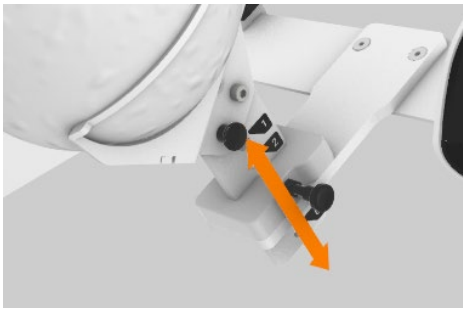
The chest support is meant to provide some play, in order to provide support for the patient without restricting the movement.

Height adjustment of the chest support:

The height setting needs to provide maximum support with minimal limitation. A too low set chest support, can not support the patient, while a too high adjustment restricts the patient`s movement.



1.
Pull out the safety bolt.

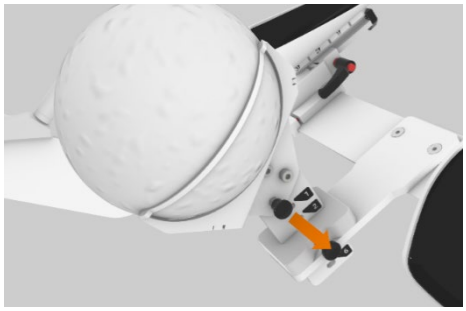


2.
Move or disassemble chest support.

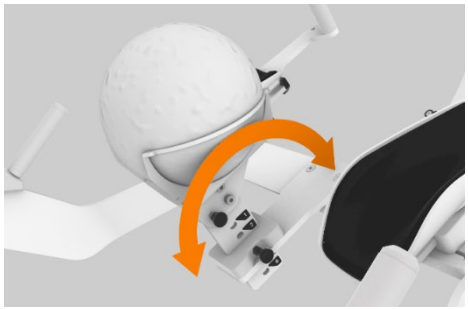
3.
Engage the safety bolt.

Inclination adjustment of the chest support:

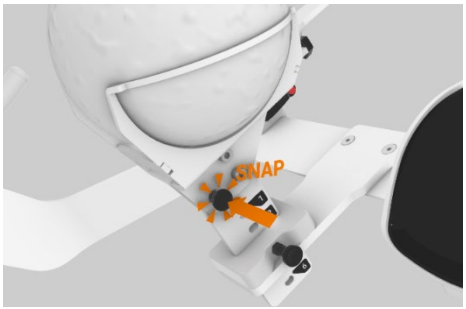
The inclination angle adjustment is used to position the chest support in the middle of the chest. Neither stomach nor throat should rest on the chest support.



1.
Pull out the safety bolt.



2.
Rotate chest support.



3.
Engage the safety bolt.

4.2 Device Safety Settings

The safety settings of the ICAROS Health manage the freedom of movement of the device. The roll and pitch inclination can be reduced, extended or locked.

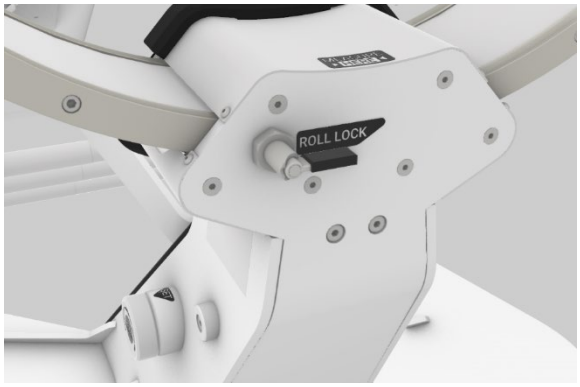
The roll and pitch function must be locked for safe ascent and descent. Make sure that the rolling and pitching axis is locked at all times when not in use. A user can fall during the mounting process, if pitch and/or roll axis are not locked.

4.2.1 Adjustment of the Rolling Axis

The roll axis enables a roll movement of the ICAROS Health device. The roll movement can be locked as well as damped. The three damping modes can be used to reduce or increase the rotation of the roll axis. When mounting or dismounting the roll and pitch axis of the device has to be locked at any time in order to be safe.

Locking:

1.
Turn Roll Lock lever 180° and engage. Lever points to Roll Lock.



2.
Check locking.

Unlocking:

1.
Turn Roll Lock lever 180° and engage in locking recess.

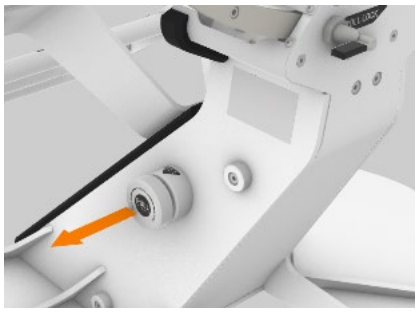
2.
Check unlocking.

Damping of the rolling axis:

The adjustment wheel on the right side of the unit base allows selection between three modes. The lower the preload, the greater the roll rotation until damping sets in.

For new patients, always use the EASY mode. Also use the EASY mode for patients who are insecure, 180 cm or taller or weigh above 90 kg.

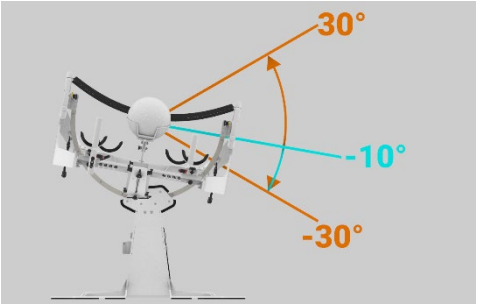
Operation of the mode dial:



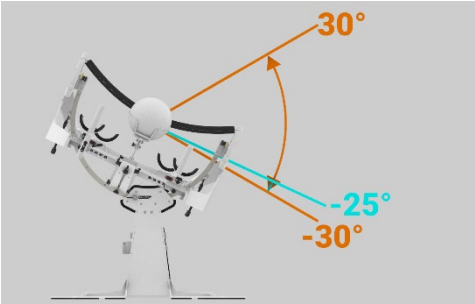
1.
Pull the mode dial.
(Away from the base)

2.
Turn desired mode of the mode dial to 12 o'clock.
(Set marker)

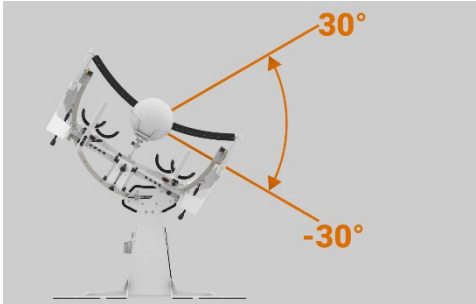
3.
Engage the mode dial.
(Audible snap)



EASY
Strong preload,
-10° to damping



MEDIUM
Medium preload,
-25° to damping

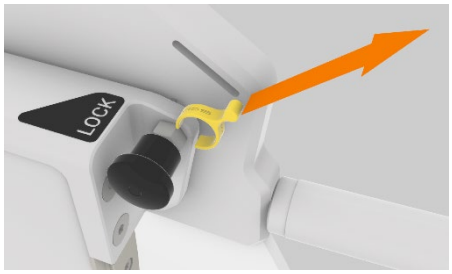


HARD
Low preload,
-30° to damping

4.2.2 Adjustment of the Pitch Axis

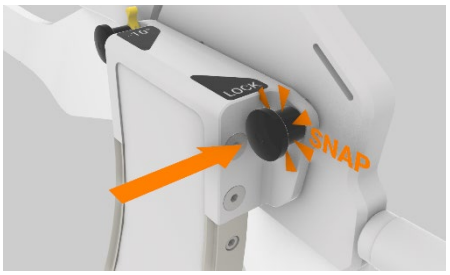
The pitch axis allows the ICAROS Health unit to be pitched forward or backward. The pitch axis can be locked, limited and damped in order to meet the patients individual needs.

Locking:



1.
Pull off safety clip.

2.
Apply pressure on the footrest. Pull and rotate the safety bolt.



3.
Engage the safety bolt.

Check lock. Do not lift the device, when it`s locked.

Unlock:

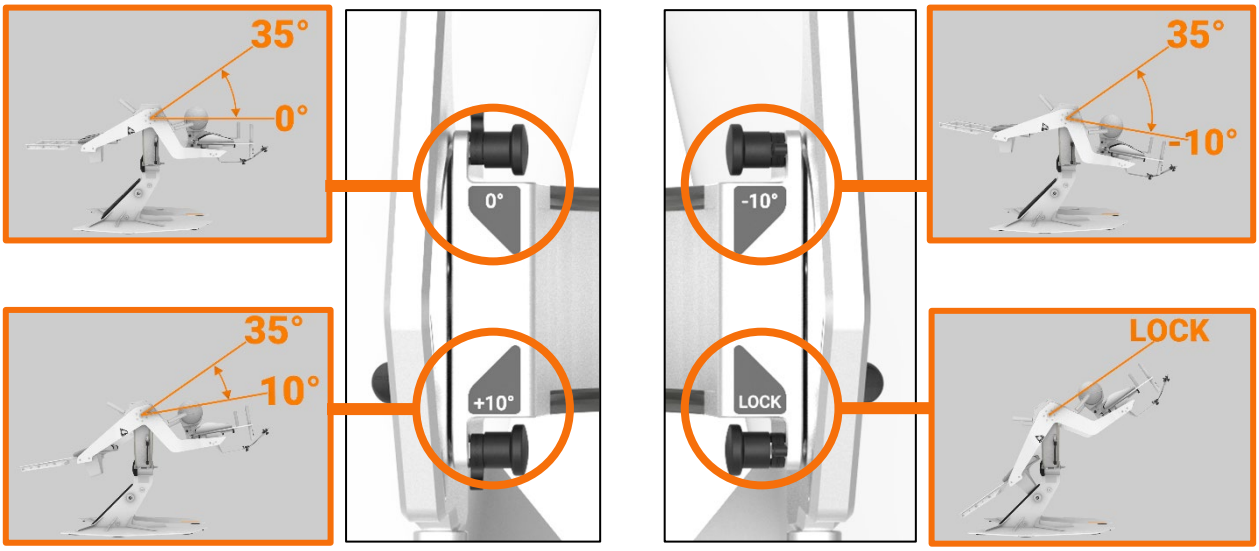
1.
Apply pressure on the footrest. Pull and rotate the safety bolt.

2.
Engage the safety bolt.

3.
Attach safety clip.

Limiting the pitch rotation:

The limiting function adjusts the angle of the pitch rotation, which is by default at -20°. In order to meet the patient‘s individual needs, the maximum pitch angle can be decreased.



In order to adjust the limit of the pitch rotation, choose the appropriate angle for the patient. The closest safety bolt to an angle mark limits the pitch rotation at the according angle, when engaged. The same steps as in the pitch locking procedure apply for the pitch limiting adjustment.

If multiple pitch rotation limits are engaged, the smallest of the pitch rotation limits is active.

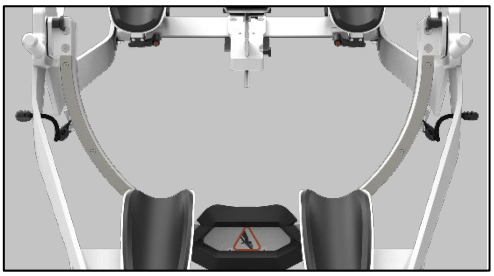
Example: 0° and +10° limits are both engaged, which results in a +10° limit.

Damping the pitch rotation:

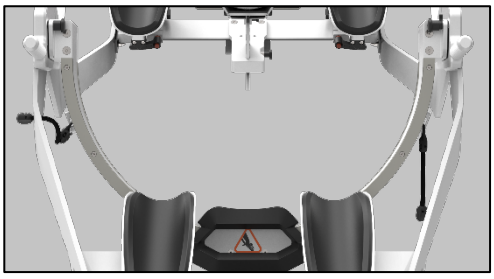
For patients who are insecure, 180 cm or taller or weigh above 90 kg.

The expanders at the side of the sliding rail can be hooked into the pitching element of the ICAROS Health to dampen the pitching tendency.

Suspended Expander on the left side of the device.



1.
Both expanders suspended - maximum damping



2.
One expander suspended - medium damping

5 Usage

⚠ **Before a person is allowed to use the ICAROS Health, it is essential that the correct settings are made individually for this person. The therapist is responsible for checking all settings and correcting them if necessary.**

5.1 Settings Checklist

⚠ **Control the settings of the ICAROS Health in the order of the checklist. If one or more points of the checklist do not apply, they have to be corrected before the device may be used.**

1. Safety area is free from persons and objects. (2.6 and Operating Conditions)
2. Device is complete and undamaged. (2.6 and Operating Conditions)
3. Roll axis is locked. (4.2.1 of the Roll Axis)
4. Pitch axis is locked. (4.2.2 of the Pitch Axis)
5. Pitch axis is set to the correct rotation limit. (4.2.2)
6. Pitch damping is set correctly. (4.2.2 Pitch Axis)
7. Roll damping is set correctly. (4.2.1 of the Roll Axis)
8. Arm rests are correctly adjusted. (4.1.2 and Arm Rests)
9. Hip belt is correctly adjusted. (4.1.3 Support)
10. Chest support is correctly adjusted. (4.1.4 Support)
11. Footrest is correctly selected. (4.1.1 and Leg Rests)

5.2 Mounting and Dismounting

The roll and pitch lock has to be engaged, while mounting or dismounting the device. Unlocked pitch and/or roll axis may cause injuries through falling off the device.

5.2.1 Mounting

1. **Pitch and roll movement are to be locked and checked.**
2. Handles can be used for support.
3. Foot and knee of the first leg are placed correctly on footrest and leg rest.
4. Second leg is placed in the way of the first leg.


5.2.2 Starting Position

1. Hips move backwards and the center of mass shifts to the rear.
2. Patient`s center of mass is kept at the rear
3. Arms are placed in the arm rests and the handles are to be held.


5.2.3 Balancing

1.
Pitch movement gets unlocked.

2.
Patient shifts weight slowly to the front.

3.
Roll movement gets unlocked.

5.2.5 Dismounting

- **Patient`s center of mass is shifted to the rear.**
- **Pitch and roll movement need to be locked and checked, before stepping off the device.**

1.
Pitch movement gets locked.

2.
Roll movement gets locked.

3.
Patient may step off.

5.3 Training

By balancing and shifting the body's center of mass, various positions can be dynamically performed on the device. Even small shifts in weight are sufficient to trigger pitching or rolling movements. Very fast or jolty movements should be avoided. The hands of the patient should be holding the handles without squeezing. Also make sure to keep the body posture as described in chapter 4.1.

5.3.1 Pitch Movement

By shifting the center of gravity forward, the machine is pitched downward. Shifting the center of mass back to align horizontally again.

5.3.2 Roll Movement

By shifting the center of mass to the left and right, movements are initiated in the roll axis.

6 Assembly

Before commissioning, make sure, that the installment is finished and the device is assembled according to the assembly instructions.

7 Maintenance

Perform the following routine checks to ensure proper operability and safety of the device.

Daily:

Clean the padding and contact surfaces with a clean wipe after each use. Avoid using abrasive cleaners and chemical substances containing gasoline or acetone.

Monthly:

Check the condition of all connecting pieces and screw connections and retighten them if necessary. To do this, use the tool provided and hand-tighten the Allen screws clockwise.

Check the pitch damping expanders for possible damage. If one or both expanders are defective, use the supplied replacement expanders to replace the defective parts.

Check the function and smooth running of the moving parts and pay attention to any unusual noises. If you notice jamming or sluggishness of a moving part, contact ICAROS GmbH. Do not continue to use the device until the defect has been fixed.

Annually:

Functional check and maintenance of the roller rail, the ball bearings and the damping system of the roller axis in the base in all three positions of the mode dial (*See page 17, 4.2.1 Adjustment of the roller axis, damping of the roller axis*). Make sure that the smooth running of the rolling rail is ensured. If any deficiencies are found, do not use the device.

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

8 Use with Connectable Devices

The ICAROS Health can be equipped with mobile devices and/or virtual reality systems. Please refer to the document titled “Connectable Devices_ICAROS Health_2023_v1“ for detailed information.

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 Health. 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.

TEL	+49 89 414 1821 00
MAIL	info@icaros.com
WEB	www.icaros.com

https://www.icaros.com/en/