OmniCycle® Connect

Advanced Active-Assist Cycle

User Manual

Revised 06/12/2024

Part No. A009-295 Rev 06

Congratulations!

Opting for a OmniCycle® Connect was a great choice.

This user manual will help you get to know your OmniCycle® Connect better. It will safely guide you through all functions and control options and provide you with tips and information on how best to use your new device. Before starting the unit for the first time, please read and observe chapter 2 “Safety and dangers”.

If you have any further questions or comments, your trained supplier/distributor or healthcare professional will be happy to help.

Have fun and get moving with your OmniCycle® Connect.

The distributor must comply with country-specific laws/regulations.

1 USER GUIDE

The user manual and product are marked with a variety of symbols. These symbols and their functions help you to use the product safely and efficiently.

1.1 Warnings

Structure of warnings

⚠ SIGNAL WORD!
Type and source of danger! ▶ Action to avoid the danger.

1.2 Warning categories

⚠ DANGER!
Indicates an immediate risk which, if not avoided, will result in death or serious injury.
⚠ WARNING!
Indicates a potentially hazardous situation which, if not avoided, will result in death or serious injury.
⚠ CAUTION!
Indicates a potentially hazardous situation which, if not avoided, will result in minor or moderate injury.
NOTE!
Indicates a potentially hazardous situation which, if not avoided, will result in material or environmental damage.

Information on the efficient use of the product.

1.3 Symbols in the user manual

Instructions

Structure of instructions:

▶ Instruction to do something.

Presentation of results if required.

Lists

Structure of non-numbered lists:

❑ List level 1
  – List level 2

Structure of numbered lists:

1. List level 1

2. List level 1

2.1 List level 2
2.2 List level 2

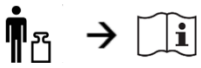
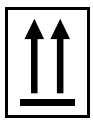
USER SECTION

❑ Instructions for users.

EXPERT SECTION

❑ Describes handling and use for trained suppliers/distributors and healthcare professionals.

1.4 Symbols on the product

	Review the user manual!		Danger due to movable parts
	Follow the user manual!		Alternating current: The OmniCycle® Connect uses alternating current.
	Manufacturer		Device of protection class II
	Unique device identifier		Can be damaged due to static charging
	Do not stack		Danger due to OmniCycle® Connect slipping. Do not lean on safety handle/upper body exerciser.
	Serial number		Do not stand on covers or in foot rests.
	Type BF medical devices		Do not sit on safety handle/upper body exerciser.
	Disposal Do not dispose of product with the regular household waste. Dispose of product in accordance with local regulations.	IP21	Protected against solid foreign bodies with a diameter as of 12.5 mm. Protection against dripping water that falls vertically.
	Protect product from humidity.	MD	Medical device
	Refer to User Manual for maximum permissible weight of patient		Only wear close-fitting clothes
	Maximum extension of device base or supporting arm of upper body exerciser/safety handle.		Only wear closed shoes and tuck in laces
	Always exercise with foot rests		This side up

	Caution fragile		Temperature limit: between -25 °C (-13 °F) and +75 °C (+165 °F)

2 SAFETY AND DANGERS

Danger

- Before beginning training, consult a healthcare professional to clarify whether users with cardiovascular diseases are allowed to exercise with the OmniCycle® Connect.
- Use OmniCycle® Connect exclusively with an undamaged and functional power cord.
- Only use original power cords provided by the manufacturer.
- In case of possible infection due to contaminated attachments/optional parts, always wear personal protective equipment (e.g., gloves, mask) when cleaning OmniCycle® Connect.

Warning

- If the user has a cardiac pacemaker, consult a qualified healthcare professional before the first training session.
- Review and follow the user manual.
- Repair work is only to be carried out by trained suppliers/distributors.
- In case of damage, malfunctions, etc. of the OmniCycle® Connect, contact the trained supplier/distributor immediately.
- In case of amputated limbs, always wear prostheses when exercising with OmniCycle® Connect.
- Consult the manufacturer before any modification and modify the OmniCycle® Connect exclusively with the manufacturer's approval.
- When laying power cord, make sure that
  - user’s movements are not limited.
  - the movements of the OmniCycle® Connect are not limited.
  - there is no risk of persons falling over or being obstructed by power cords.
- Position the OmniCycle® Connect so that the power plug is easily accessible and can be pulled out of the power socket quickly in case of emergency.
- Before any training, make sure that safety equipment is working correctly.
- Before opening the housing, make sure that power plug is unplugged.
- Make sure that power cord is disconnected before adjusting any settings on foot rests with stepless radius adjustment.
- For parts with the symbol “Can be damaged due to static charging”:
  - Do not touch with hands or tools.
  - Discharge potential static electricity, e.g. touch device frame with metal part.
- The OmniCycle® Connect is designed for seated use only. Do not climb into the footrests with your entire body weight while standing
- If used, ensure that all transport castors of the device base with four castors are blocked during therapy.
- The greater the distance between the OmniCycle® Connect and the patient’s seat/wheelchair, the more the knee, hip and UE joints are extended. Start at a closer distance to avoid overextending the joints while providing the

appropriate range of motion (ROM). This is particularly important when using the OmniCycle® Connect with patients recovering from fractures, total hip or knee replacement procedures, etc.

- Start with an initial exercise session of no longer than 15 minutes at a low load. Gradually increase the duration and intensity of subsequent sessions to suit the patient's individual capabilities and load level.

Caution

- Use OmniCycle® Connect exclusively when device is in good and functional condition.
- Regularly check screws for firm seat.
- Before first use, arrange for instruction in the use of the product by your trained supplier/distributor or healthcare professional.
- Before starting the training, consult a healthcare professional and clarify whether OmniCycle® Connect can be used without assistance.
- Place OmniCycle® Connect and chair/wheelchair on even and slip-proof floor.
- Make sure that adjustable device base is locked.
- The OmniCycle® Connect is designed to be used in a sitting position only. Patients should never stand on the covers or foot rests.
- Only wear closed shoes and tuck in laces when training.
- Always wear close-fitting clothes when training.
- Remove any jewelry and accessories before starting the training session.
- If used make sure that the self-operated anti-tip protection is safely fastened to the wheelchair.
- Before starting the exercise, check with a healthcare professional regarding which exercise parameters match the user's level of fitness.
- Before starting the exercise, check with a healthcare professional regarding which forces can act on the users joints and limit motor power as required for the user and his or her physical state (e.g., osteoporosis).
- Adjust range of motion to appropriately match the user's flexibility.
- Tie back hair when longer than shoulder-length.
- Exercise exclusively when both hands are able to hold the therapy grips or are secured to the therapy grips with wristbands.
- If any symptoms of illness occur during or after the exercise, seek medical advice immediately.
- Children must be constantly supervised when someone is exercising on the OmniCycle® Connect. Never leave the OmniCycle® Connect unsupervised when children are present.
- Take care not to pinch any fingers when adjusting settings on the OmniCycle® Connect.
- Keep animals and playing children away from OmniCycle® Connect.
- Transport OmniCycle® Connect only with transport castors on even and stable floors.

- In the case of paralysis, abnormal tone, muscle spasms, or instability, use OmniCycle® Connect exclusively with the leg support option.
- When device is in use, do not touch moving parts (e.g., crank, radius adjustment, foot rests, etc.).
- Make sure that power cord is disconnected before adjusting any settings on movable parts.
- Make sure that arm rests are safely attached to therapy grips or cranks when exercising the upper body.
- Exercise exclusively with two therapy grips or two arm rests.
- Exercise exclusively with both feet correctly positioned in the foot rests. Training with only one footrest is not permitted
- When exercising in an electric wheelchair, switch off electronic control/driving function.
- Set sensitivity of spasm detection to fit the user's needs.
- Make sure that the user exercises with a stable chair that will not wobble or tip over.
- Before every training session using a wheelchair or a chair with castors, make sure that
  - it is possible to lock the wheels/castors.
  - inadvertent unlocking of the wheels/castors while exercising is not possible.
- Make sure that it is not possible for the chair/wheelchair to tip over.
- Before starting upper body exercise, pull out device base at least 10 cm(4 inches).
- Make sure that children do not swallow or inhale any small parts (e.g. covers of USB interfaces, wireless receivers, retaining screws).

Note

- Do not use safety handle or upper body exerciser as standing aid.
- Do not use OmniCycle® Connect in wet, humid, or hot environments.
- Do not smoke while exercising.
- Only exercise with the OmniCycle® Connect after a training program was started.
- Make sure that no liquids get into OmniCycle® Connect.
- Make sure that the OmniCycle® Connect or the chair/wheelchair do not slip while exercising.
- Use exclusively cleaning agents and disinfectants approved by the manufacturer.
- Make sure that OmniCycle® Connect does not get wet.
- Use exclusively the manufacturer's original parts.
- Make sure to run power cord in such a way that there is no risk of strangulation.

- The OmniCycle® Connect may only be operated with the mains voltage indicated on the type plate. Only connect the device to a properly grounded power socket.
- Leave OmniCycle® Connect at room temperature for 1 hour before using it for the first time or after transporting it for a longer period of time.
- Use exclusively power cord supplied by the manufacturer.
- Use USB interface exclusively with options (USB stick, wireless receiver) approved by the manufacturer.
- The radius adjustment must not be adjusted while the motor is running. Only adjust the radius adjustment when there are no legs in the footrests. Tighten the locking screw and check for tightness before each training session.
- In the case of contractures or limited joint mobility, the foot rests with stepless radius adjustment must be used.
- If the OmniCycle® Connect is used by a patient in a wheelchair, the use of anti-tip protection straps to prevent accidental tip-over during exercise is required

3 INTENDED USE

General description of the product

The system is a therapeutic device for circular assisted, active-assisted or active movement of the upper and lower extremities. The transition from assisted to active therapy is seamless. The system is used in a seated position, e.g., in a wheelchair or suitable therapy chair.

The movement is managed by two drive units which differentiate in upper and lower extremities. The drive unit for lower extremities is limited in extent by the selected crank radius. The drive unit for upper extremities is limited to one crank radius. Both drive units are never moved simultaneously.

The therapy drive units for leg and arm do drive a supportive accessory for legs (footrests) and arms (therapy grips, arm support or arm rest) in a circular motion. The different accessories are interchangeable by the operator.

With the user interface the operator is able to select a training type (upper extremity or lower extremity training) which activates the corresponding therapy drive unit.

The medical device guarantees a non-slip and tilt resistant stand during the training preparation of the device as well as during the training. The device can be easily transported to different places of use or storage by means of castors and transport belt.

The interfaces of the upper drive unit are designed in such a way that other accessory options are easy to attach. The requirements for the use of these accessories are derived from the degree of disability of the user.

The training of the upper extremities should be possible as an option and does not have to be present as a matter of principle.

Physical principle

The physical principle is based on a software controlled electrical motor-driven rotating treatment unit, designed to drive extremities in a circular motion that are picked up at the end effector (hand or forearm/foot) or offer resistance to the extremities in a circular motion, so that the user can work with his own muscle power.

Place of application

To provide a safe training environment, the user is sitting in a chair/ wheelchair where further support can be added (e.g., by anti-tip protection). Furthermore, the upper or lower extremity is fixed at the hands or feet by e.g., a strap. An optional lower leg or lower arm support can provide additional support.

Operational life

The operational life time is 10 years or 5,000 operating hours, whichever occurs first.

3.1 Medical purpose

OmniCycle® Connect is a powered training device, used in rehabilitation for the relief/treatment of mild to severe impairments of movement-related functions.

3.2 Indications and patient target group

Indications

Mild to severe impairments of the movement-related functions.

3.3 Contraindications

Do not use OmniCycle® Connect

- ❑ In case of severe pain during movement
- ❑ for patients with open wounds in contact with the device (e.g. ulcer)
- ❑ with bone instability/bone metabolic diseases (fractures, osteoporosis, osteogenesis imperfecta)
- ❑ for patients with severe contractures or severely limited range of motion, where even light passive movement training poses a risk of injury.
- ❑ for acute inflammations e.g. of the joints
- ❑ for patients with acute thrombosis
- ❑ for patients with neurological deficits like seizures or strokes at the time of training or directly before
- ❑ in case of pre-damaged tendons (danger of rupture)
- ❑ for patients who run the risk of falling off during the training.
- ❑ for patients with a body weight of more than 120 kg (264.5 lbs.) if footrests with stepless radius adjustment are used
- ❑ for patients with a body weight of more than 180 kg (396.8 lbs.) if footrests with two step radius adjustment are used
- ❑ for patients with a body height of less than 120 cm (3 feet 11.24 Inches) or more than 200 cm (6 feet 6.67 inches)

3.4 Side effects

Side effects that are generally observed with the cycling and movement devices like the OmniCycle® Connect:

- ❑ In rare cases:
  - Skin injuries (e.g., pressure ulcer)
  - Pressure sores
  - Sore muscles in particular after eccentric training
  - Pain (e.g., stress-related pain)
  - Muscle soreness
  - Exhaustion
  - Awkward feeling up to light pain

3.5 Misuse

Do not use OmniCycle® Connect:

- ❑ for diagnosis
- ❑ for outdoor exercise
- ❑ in environmental conditions that do not meet the requirements (e.g., in conjunction with other products that emit ionizing radiation, in rooms with explosive substances or enriched oxygen or in the presence of flammable anesthetics or volatile solvents)
- ❑ for unsupervised exercise, if the user cannot operate the medical device without assistance

3.6 Biocompatibility

All components and options of the OmniCycle® Connect the patient will touch continuously when using the unit as intended are designed to meet the biocompatibility requirements of the applicable standards.

▶ For any questions, contact a trained supplier/distributor.

3.7 Adverse incident reporting requirement

All serious incidents occurring in connection with the product shall be reported immediately to the manufacturer and to the competent authority.

3.8 Clinical benefits

Regulation of muscle tone and reduction of spasticity

It is known that physical activity can help to regulate muscle tone, so it can be assumed that rhythmic cycling training with the motor driven exercise device can achieve the goal of regulating muscle tone.

Maintenance and strengthening of the leg and/ or the arm muscles

It is known that endurance or strength training induce different signaling pathways in the muscle cell for protein synthesis and muscle development, so it can be assumed that cycling training with the exercise device, especially with the focus on strength and strength endurance, can achieve the goal of maintenance and strengthening of the legs and / or arm muscles.

Improvement of mobility, walking ability and ADLs

It is known that physical activity in general has a huge impact on mobility, walking ability and activities of daily living. Humans are meant to move, and movement is the natural foundation of physical and mental health. To remain independent and mobile, to be able to walk and to perform everyday tasks, you need to move. So, it can be assumed that practicing movement is conducive to these goals.

Improvement of joint mobility

It is known that physical activity can help to improve joint mobility, so it can be assumed that especially the repetitive cycling training with different movement ranges can help to achieve the goal of improving joint mobility.

Activation or stabilization of the blood circulation

It is known that regular physical activity can lead to an economization of pulse, blood pressure and stabilization of the circulatory system, so it can be assumed that physical activity with the cycling device can contribute to this goal of activation or stabilization of the blood circulation.

Decrease of pain

It is known that physical activity has the potential to reduce pain (e.g., reduction of increased muscle tone or avoidance of uncomfortable spasticity, improved mobility), so it can be assumed that physical activity with the cycling device can contribute to this goal.

Improvement of coordination and symmetry of movement

It is known that within a movement execution, the coordinative abilities always interact with the conditional, cognitive and mental abilities or characteristics. A coordination training consists of the following training components: confidently mastered skills + variety of information processing/information demand + pressure conditions (e.g., time, precision, workload), therefore it can be assumed that physical exercise in combination with biofeedback with the device can contribute to this goal.

Decrease of disability
It is well known that physical activity helps to reduce disability, which is why exercise therapy is an essential part of the overall rehabilitation process in most rehabilitation programs, so it can be assumed, that cycling training supports the decrease of disability.
Improvement of balance
It is known that physical activity helps patients with movement disorders to improve their balance. The exact type of activity carried out may not be of greatest importance, but participation in any form of exercise, as opposed to being sedentary, is crucial. Thus, it can be assumed that cycling training helps patients improve their ability to balance.
Psychological benefits
It is known that physical activity has a lot of psychological benefits like positive effects on depressive symptoms, improved self-esteem, or well-being. So it can be assumed that cycling training can evoke psychological benefits.
Improvement of cardiorespiratory functions and endurance
It is known that endurance can be improved with physical activity, especially with endurance-oriented activities such as cycling, so it can be assumed that the goal of improving endurance can be achieved with this cycling device.

4 SCOPE OF DELIVERY AND EQUIPMENT

This user manual describes all accessory options available for the OmniCycle® Connect. Depending on the equipment variant, the user manual may include accessory options not featured by the OmniCycle® Connect.

4.1 Scope of delivery

The delivery note contains all information about the scope of delivery.

4.2 Basic equipment

Basic equipment of the OmniCycle® Connect:

- ❑ Device base unit
- ❑ Foot rests
- ❑ Upper body exerciser
- ❑ Control and display unit
- ❑ Self-operated anti-tip protection
- ❑ Leg support
- ❑ Foot fixing
- ❑ Grip adapter
- ❑ Therapy grips
- ❑ Software package
- ❑ User manual for OmniCycle® Connect
- ❑ Power cord

4.3 Removable Parts

- ❑ Self-operated anti-tip protection
- ❑ Leg support
- ❑ Foot fixing
- ❑ Grip adapter
- ❑ Therapy grips
- ❑ Therapy grips straight
- ❑ Control and display unit 7”/ Control and display unit 2.7”
- ❑ Safety handle/Safety handle short
- ❑ Upper body exerciser
- ❑ Device base four castors / two castors / height / flat
- ❑ Wheel set
- ❑ Arm support with bar-shaped grips / Wristbands for arm support with bar-shaped grips
- ❑ Arm support for Tetraplegia
- ❑ Arm support for therapy grips
- ❑ Wristbands
- ❑ Wireless receiver for PC
- ❑ Wireless sender for 7”
- ❑ Tablet holder

Use exclusively the options listed by the manufacturer. If the crank lengths are set differently, no meaningful evaluation of the symmetry is possible when using the biofeedback.

4.4 Available options

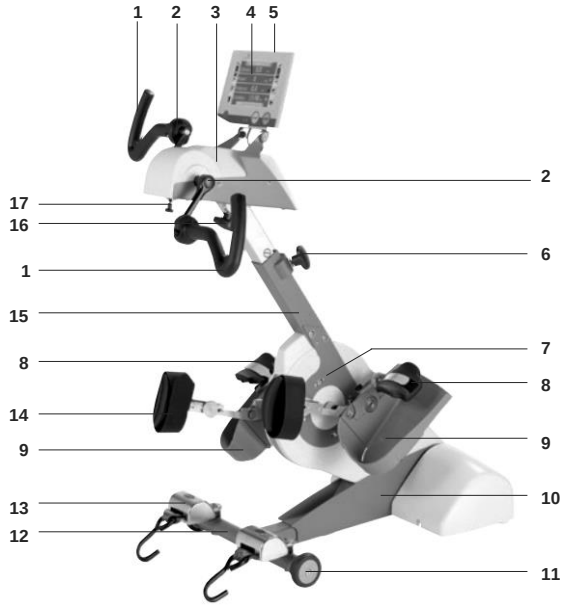
	Name	Article no.
	Molded arm rest attachment - Left	60239
	Molded arm rest attachment - Right	54565
	10ft Hospital Grade Power Cord	19856
	Barrier Film, 3" Tubing, 1200’/roll	63574

4.5 Model overview

OmniCycle® Connect

Basic functionality	Type overview, name on type plate	Serial number range 115 V	Available control and display unit
Leg exerciser combined with upper body exerciser module	OmniCycle® Connect	A009-290	7" color screen

5 OVERVIEW



(1) Therapy grips
(2) Crank (application part Type BF)
(3) Upper body exerciser
(4) Control and display unit 7"
(5) USB interface
(6) Locking-pin handle for height adjustment of safety handle/upper body exerciser
(7) Adjustment of inclination for safety handle/upper body exerciser
(8) Foot fixing
(9) Foot rest (application part type BF)
(10) Base unit
(11) Transport castor
(12) Device base with transport castors
(13) Self-operated anti-tip protection
(14) Leg support
(15) Supporting arm pipe for safety handle/upper body exerciser
(16) Star-shaped handle for horizontal adjustment of safety handle/upper body exerciser
(17) Lock button for upper body exerciser

The equipment variants of the OmniCycle® Connect offer different equipment variants. The mode of operation of the movement training is not changed through these different equipment variants. The contents (such as safety instructions, intended use) of this user manual are valid for all equipment variants of the type OmniCycle® Connect.

6 START-UP

⚠ WARNING!

Danger to life due to magnetic field!

- ▶ Make sure that there is no direct body contact with the OmniCycle® Connect in the vicinity of the pacemaker or defibrillator.
- ▶ Maintain a safety distance of at least 5 cm (2 inches).

6.1 Unpacking

Unpack the OmniCycle® Connect:

- ▶ Remove the OmniCycle® Connect from packaging.
- ▶ Check the OmniCycle® Connect incl. all accessories/options for transport damage.
- ▶ Check if delivery is complete.
- ▶ Inform supplier or forwarding agent immediately of any damage.

6.2 Set-up conditions

⚠ WARNING!

Risk of explosions and fires due to usage of the device in environments with flammable gases or oxygen enrichment!

- ▶ Make sure to follow the set-up instructions

- ▶ For safe and effective use, observe the following conditions.

Ambient conditions during use:

- Temperature: 5 °C - 40 °C
- Humidity: 15 % - 93 % Rh
- Air pressure: 700 hPa - 1,060 hPa
- Do not use OmniCycle® Connect in wet, humid, or hot environments.
- Only use the OmniCycle® Connect on even and slip-proof floors.
- Do not use the OmniCycle® Connect for outdoor exercise.

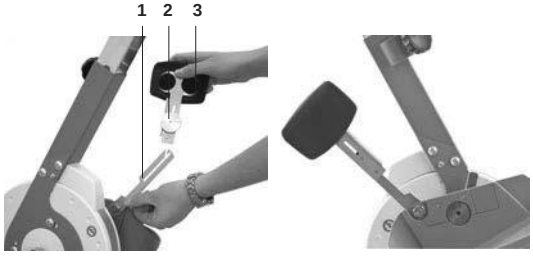
6.3 Installing the OmniCycle® Connect

Installing the leg support

⚠ WARNING!

Risk of injury due to missing cushion!
If no leg support is being used:

- ▶ Fold securing system of leg support behind foot rest (secured by magnet).



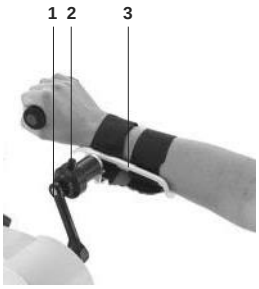
- ▶ Fold up securing system **1** of leg support by foot rest.
- ▶ Loosen knurled head (small ridges) screw **2**.
- ▶ Insert leg support **3** the right way around into slot of securing system.
- ▶ Tighten knurled (small ridges) head screw.

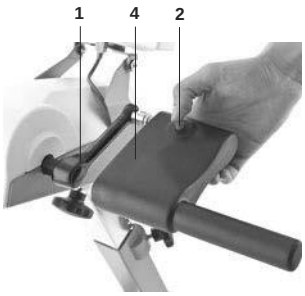
Installing the grips and arm supports

⚠ CAUTION!

Risk of injury due to incorrectly attached therapy grips / armrests!

- ▶ Slide therapy grips/armrests onto crank axle up to the stop.
- ▶ Make sure that the locking bolt audibly clicks into place.





- ▶ Press locking bolt **2**.
- ▶ Slide therapy grips/arm rest **3** or grip adapter **4** onto crank **1** up to the stop.
- ▶ Release locking bolt.
- ▶ Make sure that locking bolts audibly click into place.
- ▶ When installing the grip adapter, make sure that lock button of cranks locks audibly.

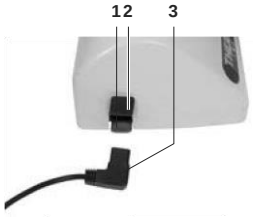
The grip adapter turns the upper body exerciser into an upper part with safety handle function.

Connecting the power cord

NOTE!

Material damage due to incorrect installation!

- ▶ Make sure that device plug is plugged into the device correctly when connecting power cord.
- ▶ Observe position of plug.



- ▶ Use exclusively power cord supplied by the manufacturer.
- ▶ Open protective lid **2**.

▶ Insert device plug **3** into port **1**.

▶ Connect power cord plug **4** to AC power socket.

The OmniCycle® Connect is ready for use.

6.4 Switching on or off

⚠ CAUTION!

Risk of injury due to the OmniCycle® Connect starting up.

▶ Make sure that no arms or legs are in the OmniCycle® Connect during start-up.

Switching on

To switch on the OmniCycle® Connect:

▶ Connect power plug to power socket.

OmniCycle® Connect boots up. Following the start-up, the OmniCycle® Connect is ready for operation.

Stand-by mode

The OmniCycle® Connect will switch to stand-by mode if

- ❑ no button is pressed for a certain period of time (not during training).
- ❑ the STOP button on the control and display unit 7'' is pressed and held.

The screen light switches off.

To activate OmniCycle® Connect:

▶ Press any button.

OmniCycle® Connect boots up. Following the start-up, the OmniCycle® Connect is ready for operation.

Switching off

To switch off the OmniCycle® Connect:

▶ Remove power cord plug from power socket.

NOTE!

Disconnection from the mains supply is only guaranteed when the plug is removed from the power socket. Always disconnect the power plug before opening the housing. Never operate the OmniCycle® Connect with the housing open or damaged.

6.5 Transporting the OmniCycle® Connect

⚠ CAUTION!

Risk of injury due to incorrect transport!

- ▶ Pull OmniCycle® Connect with transport castors exclusively across even and stable floors.
- ▶ Transport OmniCycle® Connect with at least two persons up steps.

Transport OmniCycle® Connect with device base including transport castors as follows:

- ▶ Tilt OmniCycle® Connect on device base including transport castors **3**.
- ▶ Pull OmniCycle® Connect to desired position.

Transport OmniCycle® Connect with flat device base as follows:

- ▶ Transport OmniCycle® Connect with at least 2 persons.
- ▶ Lift OmniCycle® Connect by transport strap **1** and under drive unit **2**.
- ▶ Put OmniCycle® Connect down in desired position.

7 OPERATION

7.1 Exercise preparation

⚠ DANGER!

Risk of infection due to contaminated OmniCycle® Connect!

- ▶ Wear gloves during cleaning and disinfection.
- ▶ Observe general precautions to prevent users from being exposed to blood-borne pathogens.
- ▶ Wear personal protective equipment (gloves, masks, lab coats) when contact to bodily fluids such as saliva, blood, semen, or vaginal secretion is likely to occur.
- ▶ No direct patient contact by health care professionals who have weeping wounds or skin inflammations.

When having direct patient contact as a health care professional who has weeping wounds or skin inflammations, wear appropriate protective clothing (gloves, scrub caps, etc.).

⚠ Warning!

Risk of injury due to trapped shoelaces, clothes, or accessories!
During training:

- ▶ Always wear closed shoes.
- ▶ Tuck shoelaces into shoes
- ▶ Wear close-fitting clothes.
- ▶ Do not wear jewelry or other accessories while exercising.
- ▶ Tie back hair when longer than shoulder-length.

⚠ CAUTION!

Risk of injury due to insufficient preparation!

- ▶ Disinfect the OmniCycle® Connect before every training session (see Processing instructions).
- ▶ Make sure that cranks are turning freely.

⚠ CAUTION!

Risk of injury due to tipping over or slipping of the OmniCycle® Connect!

- ▶ Place the OmniCycle® Connect on even and slip-proof floor.
- ▶ Place chair/wheelchair on even and slip-proof floor.
- ▶ Do not use OmniCycle® Connect as training device in transport status.
- ▶ Position the OmniCycle® Connect so that the power cord plug is easily accessible and can be pulled out of the power socket quickly in case of emergency.

7.2 Device base unit

Variants:

- ❑ Device base with transport castors **1**
- ❑ Device base flat **2**
- ❑ Flat device base with wheel set **3**

The following applies for all variants:

- – Extendible device base for enlarging the base area.
- – Depending on the equipment, two transport castors for easy transport and positioning.

Height-adjustable device base with wheel set

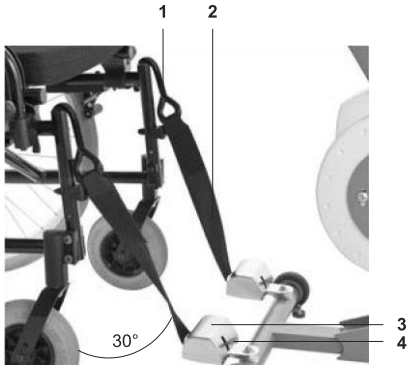
It is possible to adjust OmniCycle® Connect to a height of between 50 and 150 mm without tools.

To reduce the distance between the user and the foot rests further, you can set the front and rear of the device to different heights.

To adapt height of OmniCycle® Connect to seat height:

- ▶ Release locking-pin handle **1**.
- ▶ Tilt OmniCycle® Connect and relieve rubber foot **2**.
- ▶ Pull out locking-pin handle **1** and set rubber foot **2** to required height.
- ▶ Make sure that locking-pin handle **1** latches.
- ▶ Tighten locking-pin handle **1**.
- ▶ Repeat with the other rubber feet.

7.3 Self-operated anti-tip protection



To prevent the chair/wheelchair from tipping up during the training session, attach the self-operated anti-tip protection as follows:

- ▶ Move chair/wheelchair in training position in front of OmniCycle® Connect.
- ▶ Push down red lever **4** on self-operated anti-tip protection **3**.
- ▶ Pull out belt **2** by hook **1**.
- ▶ Attach hook to a stable part of the chair/wheelchair frame at an angle of approx. 30°.
- ▶ Make sure that hook is safely attached.

The belt will tighten automatically.

Release self-operated anti-tip protection as follows:

- ▶ Push down red lever **4** on self-operated anti-tip protection **3**.
- ▶ Pull up the hook and unhook it from chair/wheelchair frame.
- ▶ Let belt retract completely.

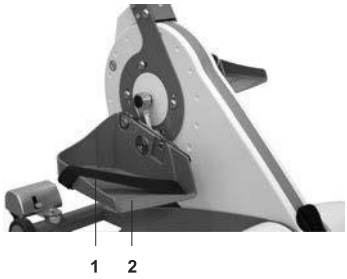
7.4 Foot fixing/leg support

⚠ CAUTION!

Risk of injury through unprotected metal parts!

▶ Do not remove foot rests for upper body exercise.

Foot rests



Secure feet in foot rests as follows:

▶ Make sure that the OmniCycle® Connect is not in training mode.

▶ Secure feet exclusively when seated.

▶ Make sure that feet are correctly positioned in foot rests **2**.

▶ Wrap velcro strap **1** tightly around instep of the foot.

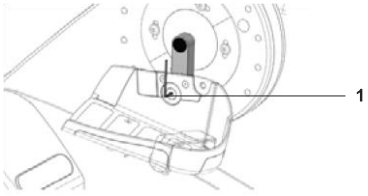
▶ Fasten velcro strap to outside of the foot rests.

If the foot fixing with a velcro strap is not sufficient for the user to exercise safely, the manufacturer recommends using the foot fixing option.

Foot rests with two step radius

The crank radius can then be set to 75 mm/3 inches or 110 mm/4.3 inches.

The crank radius must only be set if necessary. The crank radius of 75 mm/3 inches is standard.



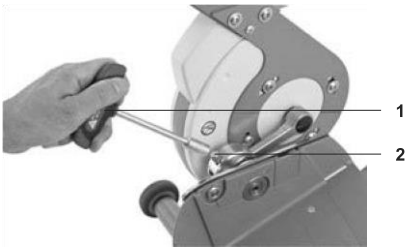
Adjust the setting as follows:

▶ Remove power plug from power socket.

- ▶ Make sure that feet are not in foot rests.
- ▶ Unscrew screws **1** using a suitable tool.
  - – right-hand crank = right-hand thread, unscrew screws in anti-clockwise direction
  - – left-hand crank = left-hand thread, unscrew screws in clockwise direction
- ▶ Set crank radius on right-hand and left-hand crank to 75 mm/3 inches or 110 mm/4.3 inches.
- ▶ Tighten screws with thread locking adhesive (Loctite 243).

Foot rests with stepless radius

The stepless radius adjustment is designed for users with limited joint mobility (contractures). Stepless radius adjustment enables every user to reach an individual range of motion depending on their mobility.



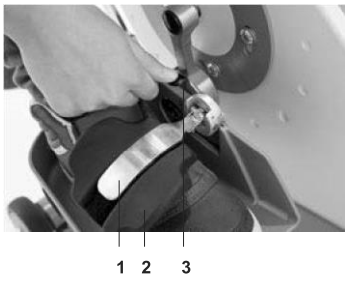
Set stepless crank radius as follows:

- ▶ Remove power plug from power socket.
- ▶ Make sure that feet are not in foot rests.
- ▶ Loosen retaining screws **2** of the radius adjustment system with the T-key **1** provided.
- ▶ Set crank radius on right-hand and left-hand crank as required 65 mm (2.6 inches) -115 mm (4.5 inches).
- ▶ Tighten safety screws.
- ▶ Before every training session, make sure that retaining screw is securely tightened.

It is possible to set different lengths for the right-hand and left-hand crank, e.g., if the user has legs of different length or different levels of mobility. When using biofeedback, meaningful symmetry evaluation is not possible.

Foot fixing

For unassisted, quick and simple securing of feet in foot rests (e.g., in case of paralysis, spasticity, etc.).



Secure feet in foot rests as follows:

- ▶ Make sure that the OmniCycle® Connect is not in training mode.
- ▶ Press release lever **3** on foot fixing **2**.

Retaining bracket **1** opens.

- ▶ Put feet into foot rests.
- ▶ Make sure that feet are correctly positioned in foot rests.
- ▶ Press down foot fixing and secure feet.
- ▶ Make sure that the user is able to remove the foot fixing without assistance if necessary, or that an assistant is available.

Release foot fixing as follows:

- ▶ Press down lightly on retaining bracket **1** and activate release lever **3** at the same time.

Retaining bracket opens.

Leg support

The leg support is mandatory for users suffering from paralysis, spasticity.

Apply leg support as follows:

- ▶ Make sure that the OmniCycle® Connect is not in training mode.
- ▶ Put feet into foot rests.
- ▶ Make sure that feet are correctly positioned in foot rests.
- ▶ Use velcro strap **1** to secure calves on leg support **2**.
- ▶ Make sure that the user is able to remove the velcro strap without assistance if necessary, or that an assistant is available.

7.5 Upper body exerciser

⚠ CAUTION!

Risk of injury due to moving parts!

- ▶ The therapy grip must only be gripped in the designated grey marked area during the training.

Upper body exerciser

- ❑ Permits active or assisted exercise for the entire upper body.
- ❑ Changing the different types of therapy grips and arm rests allows the training to be adapted to fit each user's individual needs. Please note the gray marked grip areas which are intended for holding.
- ❑ Short upper body exerciser:
  The short upper body exerciser is especially suitable for users with a short upper body or a low seated height. The height setting is lower in comparison with the upper body exerciser (see Setting height of upper body exerciser/safety handle).

▶ Before starting the training with the upper body exerciser, pull out device base at least 10 cm (4 inches).

Short crank

- ❑ recommended for spasticity and contractures in the upper body.
- ❑ required when using the upper body exerciser.
- ❑ length approx. 75 mm (3 inches).

Long crank

- ❑ recommended for muscle weakness and lack of coordination of the upper body.
- ❑ required when using the upper body exerciser.
- ❑ length approx. 110 mm (4.3 inches).

Safety handle

- ❑ Provides the user with support during training (e.g., for active training, spasticity, or lack of upper body stability).
- ❑ Height and inclination of the safety handle are adjustable.
- ❑ The safety handle is equipped with an anti-slip handle made of foam rubber.
- ❑ Short safety handle:
  The short handle is especially suitable for users with a short upper body or a

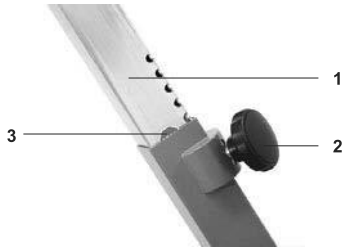
low seating position. The height setting is lower than the safety handle (see Setting height of upper body exerciser/safety handle).

Setting height of upper body exerciser

⚠ CAUTION!

Risk of crushing!

▶ Take care not to pinch any fingers when pushing the pipes together.



To adapt upper body exerciser/safety handle individually to body size and sitting position:

▶ Loosen locking-pin handle **2** on pipe **1** by approx. one rotation.

▶ Pull up upper body exerciser/safety handle and relieve locking-pin handle.

▶ Pull out locking-pin handle.

▶ Set height of body exerciser/safety handle so that crank axis is at shoulder height.

▶ Pull out supporting arm pipe until center of STOP mark **3** at a maximum.

⚠ WARNING!

Risk of injury due to insufficient height

Make sure that the height of body exerciser is set so that the knees do not collide with the body exerciser/safety handle.

▶ Let go of locking-pin handle.

▶ Make sure that locking-pin handle latches.

▶ Tighten locking-pin handle.

Adjustment ranges:

❑ Upper body exerciser: 91.5 cm (36 inches) – 100.5 cm (39.6 inches)

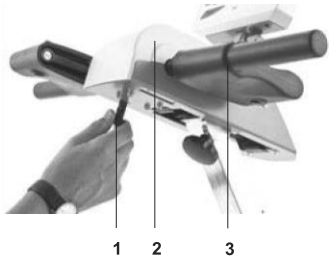
❑ Short upper body exerciser/short safety handle: 87 (34.3 inches) cm - 94 cm (37 inches)

Setting distance of upper body exerciser

To set the distance:

- ▶ Loosen star-shaped handle **1** below upper body exerciser.
- ▶ Put upper body exerciser in required horizontal position.
- ▶ Tighten star-shaped handle.

7.6 Locking/unlocking the crank



The cranks are locked when using the OmniCycle® Connect as a leg exerciser to serve as a safety handle for the user. For this purpose, install grip adapter 3.

When using the OmniCycle® Connect as an upper body exerciser, the therapy grips or arm rests must be installed and the crank unlocked.

To lock cranks:

- ▶ Pull out lock button **1** on lower side of upper body exerciser **2**.
- ▶ Turn lock button by 90° and let go.
- ▶ Turn crank so that it is in horizontal position.
- ▶ Make sure that lock button audibly clicks into place.
- ▶ Make sure that crank locks audibly and does not move any more.

Crank is locked

To unlock crank:

- ▶ Pull out lock button on lower side of upper body exerciser.
- ▶ Turn lock button by 90° and let go.

Crank is unlocked.

7.7 Hand/arm fixing

Grip adapter

⚠ CAUTION!

Material damage due to incorrect use!

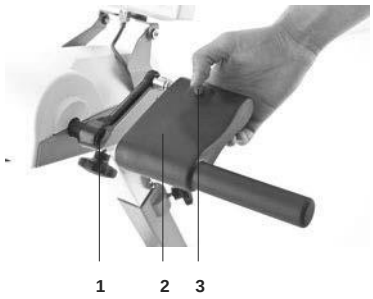
▶ Do not use grip adapter to support body weight.

⚠ CAUTION!

Risk of injury due to incorrectly installed grip adapter!

▶ Slide grip adapter onto crank axle up to the stop.

▶ Make sure that the locking bolt audibly clicks into place.



The grip adapter turns the upper body exerciser into an upper part with safety handle function.

Install grip adapter as follows:

▶ Press locking bolt **3**.

▶ Slide grip adapter **2** onto crank **1** up to stop.

▶ Release locking bolt.

▶ Make sure that locking bolt latches.

▶ Make sure that crank locks audibly.

▶ The grip adapter is suitable exclusively for holding.

Therapy grips

Therapy grips:

❑ offer variable grip positions.

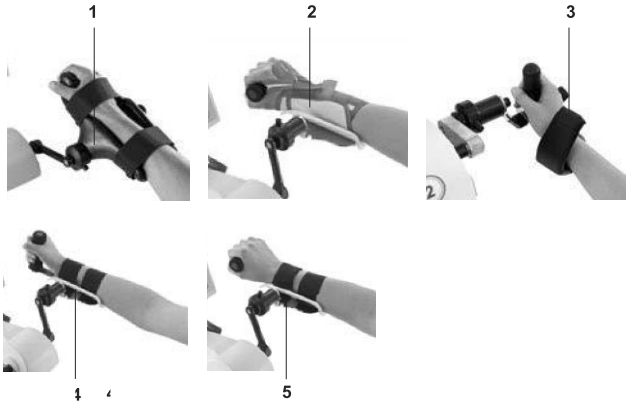
❑ are exclusively usable if the user's ability to hold the grips safely is sufficient.

▶ For installing or changing the therapy grips, see Installing the grips and arm rest.

▶ Have a healthcare professional adjust the therapy grips individually.

▶ If necessary, use wristband to secure arm on therapy grips.

Arm rests



Variants:

- ❑ Arm rests for therapy grips **1**
- ❑ Wristbands for arm rests with bar-shaped grips **2**
- ❑ Tetra special grips **3**
- ❑ Arm rests with bar-shaped grips, vertical **4**
- ❑ Arm rests with bar-shaped grips, horizontal **5**

Arm rests serve to secure the arms of users with

- ❑ symptoms of paralysis.
- ❑ increased muscle tone.
- ❑ contractures or joint deformities.

Secure arms as follows:

- ▶ Have a healthcare professional adjust the arm rests individually.
- ▶ Put arm into plugged-in arm rest of upper body exerciser.
- ▶ Secure in arm rest with velcro strap.

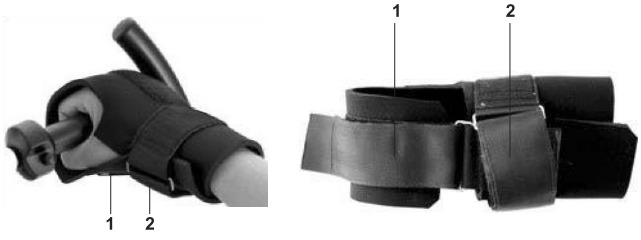
- OR

- ▶ Put arm rest on a table or the user's thigh.
- ▶ Secure arm in arm rest with velcros.
- ▶ Plug arm rest onto crank of upper body exerciser.

NOTE!
Make sure that the arm rests are firmly connected to the therapy grips or the cranks during upper body training. Make sure that the arms cannot detach from the arm rests.

Wristbands for therapy grips

Securing hand using wristbands for therapy grips



The wristbands for therapy grips allow paralyzed/weakened hands to be fixed quickly and easily to the therapy grips.

Securing both hands is exclusively possible with the help of an assistant.

- Always have an assistant supervise training sessions with two secured hands.
- With only one secured hand, unassisted training is possible.
- For cleaning the wristbands, see chapter 13 processing instructions.

Secure hand(s) as follows:

- Put open wristband for therapy grips on table or thigh.
- Put hand into wristband for therapy grips.
- Thread velcro **2** through bracket and secure wrist.
- Put paralyzed/weakened hand around therapy grip.
- Thread velcro **1** through bracket and secure paralyzed/weakened hand on therapy grip.

7.8 Safety equipment

⚠ CAUTION!

Risk of injury due to damaged safety equipment.
To protect thumb against injuries:

- ▶ Before every training, make sure that safety equipment is working correctly.
- ▶ In case of any malfunction, have the unit repaired by a trained dealer/distributor.

Voice-controlled emergency stop

When the arms are fixed in the upper body exerciser so that manual control is not possible:

- ▶ Stop OmniCycle® Connect by giving a loud shout.

Set microphone sensitivity in sub menu Basic settings/Configuration.

Anti-spasm-control

Possible causes for response of anti-spasm-control:

- ❑ Recognized spasm
- ❑ Irregular pedaling
- ❑ Uncontrollable muscular activity
- ❑ Set motor power exceeded

When anti-spasm-control responds:

- ❑ OmniCycle® Connect interrupts power supply to cranks.
- ❑ Cranks are freely movable.
- ❑ SPASTICITY or MAX. appears on control and display unit. MOTOR POWER EXCEEDED or spasm symbol.
- ❑ After 5 seconds, OmniCycle® Connect restarts at a speed reduced by 5 rpm.
- ▶ Set crank direction in sub menu after a spasm was detected.

If anti-spasm-control responds repeatedly:

- ▶ Stop training session.
- ▶ Restart OmniCycle® Connect.
- ▶ Reduce distance between seat and OmniCycle® Connect.
- ▶ Reduce crank length (see Foot fixing/leg support).
- ▶ Reduce number of revolutions.
- ▶ Increase motor power (see Motor power/joint force).

EMERGENCY STOP button

- ▶ Press the EMERGENCY STOP button in dangerous situations.

The OmniCycle® Connect stops immediately and the number of revolutions and the training resistance slow down to 0.

The control and display unit displays STOP.

To arrange for the EMERGENCY STOP:

- ▶ Press START button.

- OR -

- ▶ Disconnect power cord plug.
- ▶ Wait 5 seconds.

▶ Reconnect power cord plug.

If the OmniCycle® Connect immediately starts with the training after you have pressed the START button:

▶ Press EMERGENCY STOP button.

▶ Contact trained supplier/distributor and notify them about the defect.

▶ Do not use the OmniCycle® Connect for further training.

The OmniCycle® Connect is in START mode.

▶ Press the START button again to begin the new training session.

USER SECTION

The user section addresses the user and describes how to use the OmniCycle® Connect.

8 TRAINING REQUIREMENTS

⚠ WARNING!

Danger to life due to magnetic field!

- ▶ Make sure that there is no direct body contact with the OmniCycle® Connect in the vicinity of the pacemaker or defibrillator.
- ▶ Maintain a safety distance of at least 5 cm (2 inches).

⚠ CAUTION!

Risk of injury due to insufficient preparation!

- ▶ Disinfect OmniCycle® Connect before every training session (see Cleaning and disinfection).
- ▶ Make sure that cranks are turning freely.

Before starting the training:

- ▶ Consult trained supplier/distributor or healthcare professional whether safe training without an assistant is possible or whether an assistant is required.
- ▶ Undergo instruction from a trained supplier/distributor
- ▶ Read the user manual.
- ▶ Position the OmniCycle® Connect so that the power cord plug is easily accessible and can be pulled out of the power socket quickly in case of emergency.
- ▶ Have a healthcare professional compile a training schedule.
- ▶ Make sure that the chair/wheelchair does not tip over.
- ▶ Make sure that the parameters fit the user's individual needs (motor power, spasm detection, training time, exercising resistance, etc.).
- ▶ Make sure that the range of motion is adapted to fit the user's individual needs.
- ▶ Make sure that foot rests/arm rests feature sufficient safety equipment.
- ▶ Before beginning leg training, manually rotate the footrests once in a circle (without motor power) with the legs inserted and fixed to ensure that the cranks are free to move, the correct crank radius is set, and the legs are free to move (no entrapment).
- ▶ Before starting the upper body exercise, make sure that the crank moves freely. Turn crank with secured arms manually (with muscle power).
- ▶ Contact your healthcare professional or trained supplier/distributor if you have any questions, problems, or if error messages are displayed.
- ▶ Press START button to start training session.

During training:

- ▶ Start training slowly.
- ▶ Increase training to 70% of individual performance limit.
- ▶ Avoid overstraining (e.g., overstretching of joints)
- ▶ Secure arms or legs sufficiently.

8.1 Correct posture

- ▶ Exercise in an upright posture.
- ▶ Assume physiological training position.
- ▶ If necessary, consult a healthcare professional.

8.2 Training schedule

To improve mobility, strength, and endurance:

- ▶ Exercise regularly.
- ▶ Exercise in short units to avoid overstrain.
- ▶ Begin with training sessions of max. 15 minutes.
- ▶ Start with slow assisted exercise to warm up and then switch to light active exercise with little exercising resistance.
- ▶ Increase training time and speed in small steps and do more active muscular exercise with higher exercising resistance.
- ▶ Several training sessions per day are possible, provided that there are no negative side effects and the user's individual capacity is not exceeded.

8.3 Active and assisted training

Assisted training

- ❑ The OmniCycle® Connect moves the user.
  – The users do not use their own muscle power.
- ❑ OmniCycle® Connect provides the required energy.
- ❑ When switched on, the OmniCycle® Connect will always start with assisted exercise at the set number of revolutions.
- ❑ By actively moving the user in the same direction, the OmniCycle® Connect will automatically switch to active exercise.

Active training

- ❑ The users use their own muscle power to work against the set training resistance

8.4 Increased muscle tone/spasms

Muscle tone reduction

- ❑ with slow, even rotations
- ❑ with small crank radius

It is possible for the tone reduction to last for several hours.

- ▶ Adapt the training program with the help of a healthcare professional.

If a spasm occurs during the training session:

- ❑ The electronic system of OmniCycle® Connect will recognize the spasticity.
- ❑ If the anti-spasm-control is activated (factory setting), the motor will stop immediately.
- ❑ OmniCycle® Connect will continue in forward direction after a short delay (factory setting).

Depending on individual requirements, it is possible to reverse the direction of rotation after a spasm was recognized.

9 TRAINING WITH OmniCycle® Connect

⚠ CAUTION!

Risk of injury due to lack of independence!
If the user cannot operate the OmniCycle® Connect without assistance:

▶ Make sure that the user exercises exclusively with a trained assistant.

⚠ CAUTION!

Danger of injury due to unsuitable chair/wheelchair.

▶ Make sure that the chair/wheelchair does not tip over or slip.

▶ Use exclusively chairs/wheelchairs with backrests of sufficient height.

To start the training:

▶ Position a stable chair or wheelchair/electric wheelchair with a back of sufficient height in front of the OmniCycle® Connect.

▶ When using a wheelchair/electric wheelchair, put on the brakes.

▶ Before every training session using a chair with castors, make sure that
  – it is possible to lock the castors.
  – inadvertent unlocking of the castors while exercising is not possible.

▶ Secure chair/wheelchair with self-operated anti-tip protection.

▶ Use only the leg exerciser or upper body exerciser.

▶ Before starting the leg exercise, make sure that the crank moves freely. Turn crank with secured legs manually (with muscle power).

▶ Before starting the upper body exercise, make sure that the crank moves freely. Turn crank with secured arms manually (with muscle power).

▶ Depending on the type of training,
  – place and secure legs in foot rests.
  – place arms in arm rests or secure arms.
  – hold therapy grips.

▶ Select OmniCycle® Connect training program on control and display unit.

▶ Press START button on control and display unit.

9.1 Leg exercise

⚠ WARNING!

Risk of injury due to unlocked arm trainer!

▶ During leg training, the cranks of the arm trainer must be locked horizontally. Otherwise, the thigh may become trapped.

- ▶ OmniCycle® Connect enables active or assisted leg exercise.
- ▶ Lock cranks of upper body exerciser in horizontal position.
- ▶ Do not use safety handle, therapy grips or upper body exerciser as standing aid.
- ▶ Do not stand in foot rests.
- ▶ Exercise exclusively with both feet in the foot rests.

9.2 Upper body exercise

⚠ CAUTION!

Risk of injury!

- ▶ Do not put feet into foot rests during upper body training.
- ▶ Unlock cranks before every training session with the upper body exerciser.

⚠ CAUTION!

Risk of injury through unprotected metal parts!

- ▶ Do not remove foot rests for upper body exercise.

- ▶ OmniCycle® Connect permits active or assisted upper body exercise.
- ▶ Make sure that therapy grips/arm rests are safely attached to the crank when exercising the upper body.
- ▶ Make sure that the arms cannot inadvertently come free from therapy grips/armrests.
- ▶ Before beginning with upper body exercise, unlock the lock button of upper body exerciser.
- ▶ Exercise exclusively with two therapy grips or two arm rests.

9.3 Training programs

Before starting the training, have a healthcare professional or trained dealer/distributor adapt the training program to suit the user's individual needs and instruct the user.

To start training program:

- ▶ Press START button.

Pause training program:

- ▶ Press STOP button.

To end training program:

- ▶ Press STOP button twice.

Training programs/Training

Neuro (basic setting)

Training program for users with neurological disorders such as hemiplegia, paraplegia, multiple sclerosis, Parkinson's disease.

- ❑ Training type: Pre-Set resistance.
- ❑ Training resistance setting will remain constant within the entire rpm range.
- ❑ Higher pedaling frequency = higher performance

Ortho

Training program for users with orthopedic problems, e.g., after knee or hip surgery.

- ❑ Required performance level is pre-set.
- ❑ The training program Ortho prescribes the performance level for the exercise in Watts.
- ❑ OmniCycle® Connect regulates the exercising resistance automatically depending on the number of revolutions, so that the required performance always remains at the selected level.

Isokinetic

Training program for users with coordination problems.

- ❑ Number of revolutions is pre-set.
- ❑ OmniCycle® Connect keeps the number of revolutions constant during the entire training session (independently of the pedaling power).
- ❑ By active pedaling, the user generates on the OmniCycle® Connect a certain pedaling power without increasing the number of revolutions.

Soccer

Training program for active training

- ❑ for leg and upper body trainer
- ❑ User controls by increasing the speed or reducing the speed of the avatar
- ❑ The higher the level of difficulty, the smaller and faster the balls.

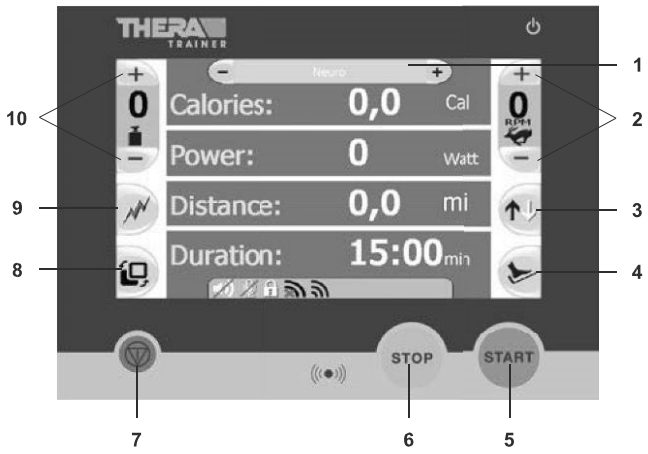
Virtual cycling

Training program for establishing a wireless connection to external software Virtual cycling.

- ❑ corresponds to Neuro training program
- ❑ Further information can be found in the user manual.

10 CONTROL ELEMENTS

10.1 Control and Display Unit 7"



(1) Button Switch training program
(2) Buttons Number of revolutions
(3) Button Direction of rotation
(4) Button Easy entry (only activate for leg training)
(5) START button
(6) STOP button
(7) Emergency-Stop button
(8) Button Switch training program
(9) Button Anti-spasm-control
(10) Buttons Exercising resistance

The control and display unit with 7" color screen is operated using touchscreen fields.

Functions of the control and display unit

START button

- ▶ Press button.
- ▶ Select leg or upper body workout (only with a combination trainer for legs and upper body).
  - – Countdown is displayed.
  - – The OmniCycle® Connect starts at 10 rpm.
- ▶ Press button after interruption (pause): Training session resumes.

STOP button

- ▶ Press button: OmniCycle® Connect interrupts current training session (break).
- ▶ Press button twice: OmniCycle® Connect stops current training session.
- ▶ Control and display unit shows report of the training session.

EMERGENCY STOP button

- ▶ Press button: the OmniCycle® Connect stops training immediately.
- ▶ In dangerous situations, the number of revolutions and the exercising resistance immediately slow down to 0 when you press the EMERGENCY STOP button.
- ▶ The control and display unit displays STOP.

To leave the EMERGENCY STOP:

- ▶ Press START button.

- OR -

- ▶ Disconnect power cord plug.
- ▶ Wait 5 seconds.
- ▶ Reconnect power cord plug.

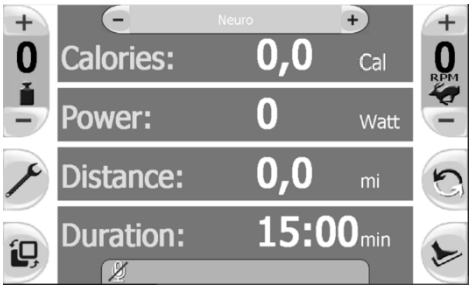
If the OmniCycle® Connect immediately starts with the training after you have pressed the START button:

- ▶ Press EMERGENCY STOP button.
- ▶ Contact trained supplier/distributor and notify them about the defect.
- ▶ Do not use the OmniCycle® Connect for further training.

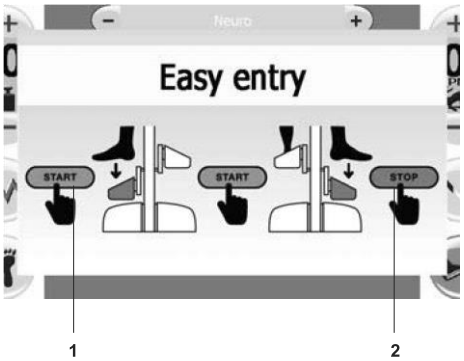
The OmniCycle® Connect is in START mode.

- ▶ Press the START button again to begin the new training session.
- ▶ Press button: Instructions for using easy entry appear.

User interface elements - 7" User Interface



Button Easy entry



- ▶ Press START button 1: Crank moves into first entry position.

- ▶ First foot rest is down.
- ▶ Put first foot into foot rest.
- ▶ Press the START button 1 again: Crank moves into second entry position.
- ▶ Second foot rest is down.
- ▶ Put second foot into foot rest.
- ▶ Secure first foot with velcro strap or foot fixing/leg support.
- ▶ Press the START button 1 again: Crank moves into first entry position.
- ▶ Secure second foot with velcro strap or foot fixing/leg support.
- ▶ Press STOP button 2. Easy entry function ends.

Button Direction of rotation

- ▶ Press button: OmniCycle® Connect reverses the direction of rotation.

OmniCycle® Connect slows down to 0 rpm and resumes in the opposite direction with a pre-set number of rotations.

- ❑ Black arrow shows current direction of rotation.

Anti-spasm control button

- ▶ Press button: OmniCycle® Connect deactivates anti-spasm-control.
  - – Lightning symbol is inactive (grey lightning).
- ▶ Press button again: OmniCycle® Connect activates anti-spasm-control.
  - – Lightning symbol is active (red lightning).

Button Exercising resistance

- ▶ Press button +: OmniCycle® Connect gradually increases the exercising resistance.
- ▶ Press button -: OmniCycle® Connect gradually reduces the exercising resistance. Press and hold the button: Increase or reduce exercising resistance continuously until maximum or minimum is reached.
- ❑ Current exercising resistance is adjustable in 15 steps.
- ❑ Maximum exercising resistance:
  - – Leg exerciser: 22 Nm
  - – Upper body exerciser: 8 Nm
- ❑ Training resistance setting will remain constant within the entire rpm range.
- ❑ Higher pedaling frequency = higher performance.

Button Number of revolutions

- ▶ Press button +: OmniCycle® Connect gradually increases the number of revolutions.
- ▶ Press button -: OmniCycle® Connect gradually reduces the number of revolutions.
- ▶ Press and hold the button: Increase or reduce number of revolutions continuously until maximum or minimum is reached.
- ❑ Maximum number of passive revolutions: 75 rpm.

Button Switch training program

Press the +/- button 

or  : You can switch training program before you start your training session.

- – Button will be inactive during training session.
- ▶ Press + button: scroll forwards.
- ▶ Press - button: scroll backwards.

- ▶ Press  : scroll forwards.
- ▶ Only select training programs recommended by healthcare professional or trained supplier/distributor.

Button lock

- ▶ Press button combination STOP button + button  : OmniCycle® Connect activates button lock.
  - – It is still possible to adjust settings for 30 seconds after activating the button lock.
  - – Status bar indicates active button lock by displaying a padlock symbol  .
- ▶ Activate button lock before starting the training session.
- ▶ Press button combination STOP button + button  again: OmniCycle® Connect deactivates button lock.

Change training time

- ▶ Press button:  OmniCycle® Connect increases training time by one minute time at a time.
- ▶ Press button:  OmniCycle® Connect reduces training time by one minute at a time.
- ▶ Press and hold buttons: Increase or reduce training time continuously until maximum or minimum is reached.
  - – Factory setting: 15 min.
  - – Adjustment range: 1-180 min.

Setting the training time is possible during the training session.

START/STOP buttons are always active.

Reset parameters to default

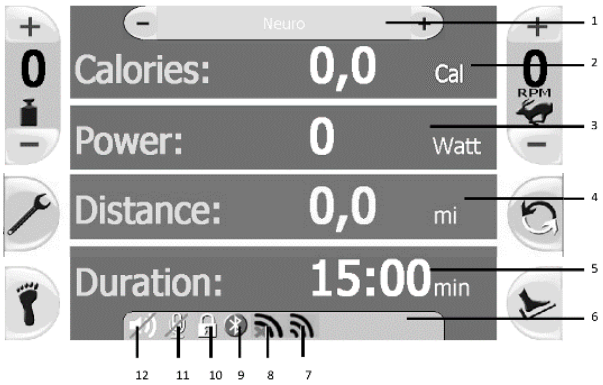
- ▶ Press button  to restore the default parameter settings.

Enter the sub menu

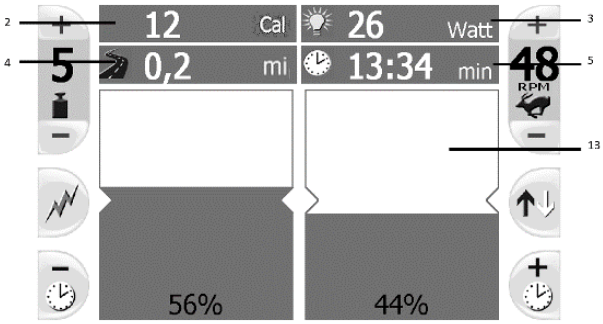
- ▶ Press button  to enter the sub menu.

Displayed parameters - 7" User Interface

Display before training session



Display during training session



(1) Display Training program
(2) Calorie display
(3) Power display
(4) Covered distance
(5) Remaining training time
(6) Status bar
(7) Wireless connection present
(8) Wireless connection not present
(9) Bluetooth on
(10) Button lock on
(11) Voice-controlled emergency stop off
(12) Speakers off
(13) Display Biofeedback

Explanation of display units

Status bar

- ❑ Shows e.g., button lock, sound off, wireless connection present/not present.
- ❑ Hidden during training session.

Display Training program

- ❑ Indicates active training program on home screen.
- ❑ The active training program is hidden during the active training session.

Power display

- ❑ Shows performance in watt.
- ❑ Exclusively for active muscle training.

Covered distance

- ❑ Shows total distance covered in km.

Remaining training time

- ❑ Indicates remaining training time.

Wireless connection

- ❑ Connection symbol without X: Existing wireless connection between a OmniCycle® Connect and a PC.
- ❑ Connection symbol with X: No existing wireless connection between a OmniCycle® Connect and a PC.

If connection symbol with X is displayed:

▶ Check that

- Virtual cycling training program is selected.
- PC with Virtual cycling installed is switched on.
- Virtual cycling software on PC is opened and launched.
- PC is within range of wireless connection (approx. 5 meters).
- Wireless receiver is correctly connected.
- PC is correctly connected to mains.
- The correct wireless connection is assigned in the sub menu.

If no connection is established after the possible causes listed above have been checked and ruled out:

▶ Select a different training program and return to training program Virtual cycling from there.

Button lock on

- ❑ Shows that the button lock is activated.

Speakers off

- ❑ Shows that the speakers are switched off.

Display Biofeedback

- ❑ Shows biofeedback Symmetry bar or Symmetry road as factory setting.
- ❑ It is still possible to adjust settings for 30 sec. It is possible to set further biofeedback illustrations in the sub menu.

EXPERT SECTION

The expert part describes how to use the OmniCycle® Connect for the trained supplier/distributor or healthcare professional.

11 USING CONTROL AND DISPLAY UNIT 7"

11.1 Sub menu

All information in this chapter is more information for the healthcare professional.

Information on basic operation is contained in the user section.

The software of the control and display unit with 7" ' color screen has a sub menu that enables the setting of several parameters to adapt the OmniCycle® Connect to the user's individual needs.

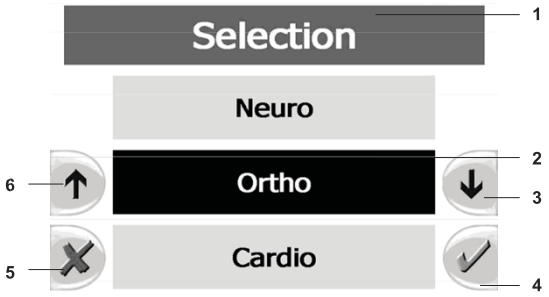
Calling up the sub menu

▶ Press **STOP button** and button simultaneously.

Software switches to sub menu.

▶ Use the sub menu button for quick access of the sub menu

Navigation in sub menu



Areas in the sub menu:

- ❑ Neuro
- ❑ Ortho
- ❑ Isokinetic
- ❑ Soccer
- ❑ Virtual cycling
- ❑ System

1. Current section in sub menu

2. Current selection

3. Down/reduce

▶ Move down in direction of arrow.

▶ In menu items where a value is entered (e.g., motor power), the value entered will reduce.

4. Save/confirm changes

▶ Save settings.

▶ In menu items with sub-items, go to next menu item.

5. Cancel/reject changes

▶ Go one level up.

6. Up/increase

▶ Move up in direction of arrow.

▶ In menu items where a value is entered (e.g., motor power), the value entered will increase.

Menu structure control and display unit

1. Level	2. Level	Adjustable values, functions	Factory settings
Neuro	Training time	1-180 min	15 min
	Direction of rotation automatic	on/off	off
	Biofeedback	Symmetry bar Symmetry road Assisted off	Symmetry bar (coordination for upper body training)
	Motor power	2-22 Nm (2-8 Nm for upper body exerciser)	10 Nm
	Spasm detection	fine medium rough	medium
	Spasm program	forward backward alternating follow	Forward
	Autom. speed adaptation	on/off	off

1. Level	2. Level	Adjustable values, functions	Factory settings
Ortho	Training time	1-180 min	15 min
	Biofeedback (inactive for upper body training)	Symmetry bar Symmetry road Assisted off	Symmetry bar
	Motor power	2-22 Nm (2-8 Nm for upper body exerciser)	10 Nm
	Muscle support	on/off	on
Isokinetic	Training time	1-180 min	15 min
	Biofeedback	Symmetry bar Symmetry road Assisted off	Symmetry bar (coordination for upper body training)
	Motor power	2-22 Nm (2-8 Nm for upper body exerciser)	10 Nm
	Spasm detection	fine medium rough	medium
	Spasm program	forward backward alternating follow	Forward
Soccer	Training time	1-180 min	15 min
	Level of difficulty	easy medium difficult	easy
	Motor power	2-22 Nm (2-8 Nm for upper body exerciser)	10 Nm
	Spasm detection	fine medium rough	medium

1. Level	2. Level	Adjustable values, functions	Factory settings
Virtual cycling (available as additional option)	Training time	1-180 min	15 min
	Motor power	2-22 Nm (2-8 Nm for upper body exerciser)	10 Nm
	Spasm detection	fine medium rough	medium
System	Volume	0 (off) 1-10	5
	Microphone sensitivity	0 (off) 1-10	0
	Language		Language of the country
	Contrast	1-40	20
	Configuration	Code-protected service menu for trained dealers/distributors	-
	Operating hours	-	-
	Time/date	indiv. setting	-
	Wireless connection	Virtual cycling	-

Training time

Value range: between 1 and 180 minutes

Factory setting: 15 minutes.

Direction of rotation automatic

If automatic direction of rotation is activated

- ❑ the direction of rotation will change every four minutes during assisted training.
- ❑ during active training exercise, the direction of rotation will not change.

Biofeedback

- ❑ Only the training programs Neuro, Ortho and Isokinetic permit changing the biofeedback.
- ❑ Shows biofeedback symmetry bar or symmetry road as factory setting.

Setting options in sub menu:

- – Symmetry road
- – Symmetry bar
- – Assisted
- – Off

Motor power

▶ It is possible to limit the maximum motor power in the sub menu.

The motor power allows individual settings for every training program.

⚠ CAUTION!

Risk of injury due to inappropriate motor power!

▶ Before every training session and every time when changing the training program, check motor power setting.

Spasm detection

Enables setting the barrier at which the sensor system recognizes an impermissible user's movement and in order to minimize the risk of overstrain, stops the motor.

❑ The larger the crank radius, e.g., the lower the motor power, the more sensitive the reactions of the anti-spasm-control system.

Setting options:

❑ **Fine**
  – Users with very sensitive joints and tendons.
  – Motor will stop even at slight resistance.

❑ **Medium**
  – Users with less sensitive joints.

❑ **Rough**
  – Users with severe spasms. Motor will stop only at strong resistance.

Spasm program

Enables setting the direction of rotation in which the exercise will resume after a spasm has been recognized.

Setting options:

❑ Forward
  – Always start in forward direction after a spasm was recognized (recommended if user tends to have stretch spasms).

❑ Backward
  – Always start in backward direction after a spasm was recognized (recommended if user tends to have flexion spasms).

❑ Alternating
  – Change direction of rotation after a spasm was recognized.

❑ Follow
  – Start in direction used previous to spasm being recognized.

Automatic speed adjustment

When the automatic speed adjustment is set to ON, the assisted lead speed (motor) will automatically adapt itself during active exercise to a higher performance made by the user.

Upper limit: 35 rpm

Example

If the user is working at 30 rpm instead of the set number of revolutions (lead speed) of 15 rpm, the OmniCycle® Connect will gradually adjust the lead speed to 25 rpm after approx. 10 seconds. If the user becomes passive again, OmniCycle® Connect continues at 25 rpm. This way the user acquires his individual speed and if he becomes passive, the exercise will continue at a number of revolutions closer to his active level.

Muscle support

This function supports users with very low or one-sided residual power. This function supports the available residual power in such a way that smooth rotation is guaranteed at all times.

Active muscle support

- ❑ boosts the user's activity
- ▶ takes over the work of the inactive side and acts as an electronic flywheel for users with amputated legs.

Level of difficulty

Set level of difficulty for training programs Soccer in sub menu

3 steps:

- ❑ easy
- ❑ medium
- ❑ difficult

- ▶ To set volume in sub menu Basic settings:
  - – Loudspeakers on control and display unit
  - – Volume of control buttons
  - – Acoustic feedback of training programs

Range: 0 (off) to 10

- ❑ Too high a volume might activate the voice-controlled emergency stop.
- ❑ A symbol in the status bar indicates the status.

Microphone sensitivity

- ❑ Permits voice-controlled emergency stop
- ❑ 0 (off)
  - – when too loud ambient noise causes the OmniCycle® Connect to switch off inadvertently
  - – A symbol in the status bar indicates the status.
- ❑ 1 - 3
  - – for very loud ambient noise
- ❑ 4 - 6
  - – for normal ambient noise
- ❑ 7 - 10
  - – for very little ambient noise

- ▶ Perform a practical test to check whether setting is correct.
- ▶ Press START button to continue the training session.

Language

- ▶ Various languages are available.

Factory setting: Language of the country of delivery.

- ▶ Adjust contrast of color screen in menu Basic settings/Contrast.

Operating hours

Display of operating hours in hours for:

- Upper body training
- Leg exercise
- Total

Configuration

It is possible to set the necessary configuration under menu item Configuration.

❑ The configuration requires an access code and is only to be used by trained suppliers/distributors.

Time/date

▶ Set date and time in sub menu:

❑ When switching between summer and winter time.
❑ After OmniCycle® Connect has been without power supply for a long time.

Wireless connection

Requirements:

❑ Wireless receiver (A006-672) must be plugged into the USB interface of the control and display unit.
❑ PC requirements to set up a wireless connection.
- activated Bluetooth

- OR -

- Wireless receiver is plugged into the USB interface of the PC.

❑ Requires Virtual cycling for the training programs
❑ Wireless symbol indicates existing connection.
▶ In the Technology section in the sub menu, click on wireless connection.

Two Virtual cycling areas are displayed.

▶ Select one of the areas.

A search for all wireless connections within a radius of 5 meters is then made.

▶ Select the relevant PC.

When the training program Virtual cycling is selected, an attempt is made to set up a wireless connection.

Set params as default

▶ See table Menu structure.

❑ Settings will remain unchanged if the power supply is cut off. The training session will start with the same settings.

Reset parameters to default

Reset to parameters to default:

▶ Press button  .

Default parameter settings are restored.

The settings in the section System remain unchanged.

12.1 Biofeedback

❑ Gives the user feedback on his course of movement during the training session.
❑ Shows the power difference between right and left leg in forward or backward direction.
❑ Shows how evenly the power is distributed between the arms moving the crank, i.e., whether they are pushing and pulling to the same degree.
❑ Exclusively for active exercise.

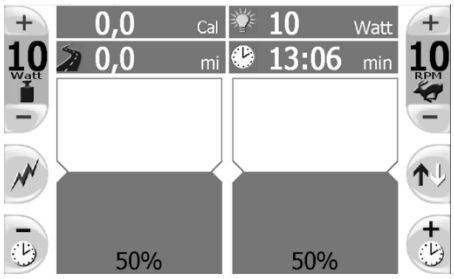
- ❑ The leg exercise results will be falsified if
  - – the cranks are set to different radii.
  - – then user is not seated in the center.
  - – the leg pushes and pulls.

The colors of the biofeedback display can be adjusted in the sub menu by a trained supplier/distributor to accommodate users with red-green blindness (Basic settings/ Configuration).

Biofeedback for leg exerciser

- ▶ Select illustration in sub menu:
  - – Symmetry bar
- ▶ Biofeedback can be deactivated in the relevant training program via the sub menu.

Symmetry Bar



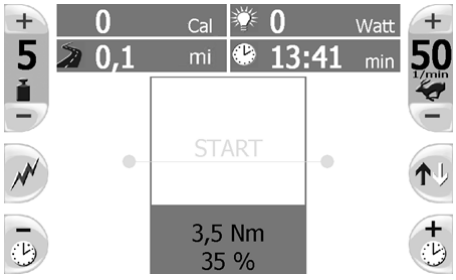
Bar diagram shows activity distribution between lower extremities. The total of both bars is always 100%.

Symmetry road

Depending on the power distribution, a bike on the street illustration will move to the left or to the right.

When the obstacle has been successfully avoided, it lights up in green.

Biofeedback “Assisted”/muscle tone



- ❑ shows movement of arms or legs with current motor power (bar) during assisted training.
- ❑ gives information on muscle tone.

Maximum height of bar corresponds to 100% of the power set as motor power.

- ❑ Value “START” indicates the average power provided by the motor during the first minute of exercise.
- ❑ The solid part of the bar and the percentage % at the bottom of the bar indicate how many % of the set motor power is required to move the arms or legs.
- ❑ The value indicated in Nm shows the motor power the OmniCycle® Connect has to provide.
- ❑ For leg exercise, a motor power of 22 Nm can be reached.
- ❑ For upper body exercise, a motor power of 8 Nm can be reached.
- ❑ Eccentric exercise of legs or arms is possible when
  - – anti-spasm-control is deactivated.
  - – user works against drive power as much as possible.

Changing the crank radius will influence this biofeedback illustration considerably. The % values of two training sessions are comparable exclusively if crank radius and maximum motor power settings (sub menu) are the same.

This biofeedback illustration does not give any scientifically relevant information, it merely shows the user whether his muscles are relaxed or tense and how muscle tone changes during a training session.

Biofeedback for upper body exercise biofeedback

Biofeedback illustration coordination is exclusively for training programs Neuro and Isokinetic. The biofeedback is inactive for the training program Ortho.

Additional assisted biofeedback is available for upper arm exercise.

Biofeedback illustration:

- ❑ The color of the smiley faces shows the level of coordination of the arm movement when moving the cranks during active training.
- ❑ The solid area indicates the user's level of activity.
- ❑ The goal is to keep the green area at the size of the bold white line **1** as constant as possible.

▶ Deactivate biofeedback via sub menu in respective training program.

Green smiley face:

- ❑ Arms are working together harmonically.

Orange smiley face:

- ❑ Arms not working together harmonically, or they are moving jerkily.

Sleeping smiley face:

- ❑ Too low or no arm activity.

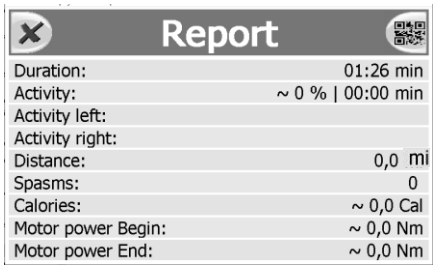
11.3 Training report

NOTE!
The activity display may show incorrect values if you pull on the footrests or have set different crank radii.

After the training session, the OmniCycle® Connect will show a training report.

Requirements:

- ❑ The training session lasted for at least one minute.
- ❑ The training session was started by pressing the START button.



▶ Press the QR-code button to get a QR-Code that contains the training results and can be scanned with the ACPlus-App

The following results are shown:

Training time
- ❑ Total training time without breaks (in minutes).

Active percentage (with muscle power)
- ❑ Percentage of the training time, during which the user used his own muscular power (in %).

Activity left side
- ❑ Percentage of activity for the left leg (in %). (Only for leg exercise)

Activity right side
- ❑ Percentage of activity for the right leg (in %). (Only for leg exercise)

Distance
- ❑ Entire covered distance (in km).

Number of spasms
- ❑ Number of spasms recognized during the training session.

Calories
- ❑ Calories (in kcal).
- ❑ The number of calories indicated corresponds to the energy absorbed by the Omnicycle® Connect
- ❑ The amount of energy (Cal) the Omnicycle® Connect has measured during the training session multiplied by a 5.3 to estimate the Calories burned by the patient.

Motor power beginning
- ❑ Stiffness (muscle tone) at the beginning of the training session (during the first 60 s).

Motor power end
- ❑ Stiffness (muscle tone) at the end of the training session (during the last 60 s).

Level of difficulty
- ❑ Indicates the level of difficulty of the absolved training program in stars (* = easy, ** = medium, *** = difficult).
- ❑ Is indicated exclusively in training program “Soccer”.

Success rate
- ❑ Indicates the success rate.
  - – e.g., for the Keeper training program: 7/8 means that seven out of eight balls were caught.
- ❑ Is indicated exclusively in training program “Soccer”.

Leaving the report

To leave the training report:

▶ Press START button, STOP button or  .

Calling up the training results

- ❑ Pressing the STOP button makes the display switch between training report and standard display.
- ❑ Pressing the STOP button will display the training data until
  - – a new training session is started from the standard display by pressing the START button.
  - – OmniCycle® Connect is restarted (also from stand-by mode).

12 MOTOR POWER/JOINT FORCE

12.1 Motor power for leg exercise

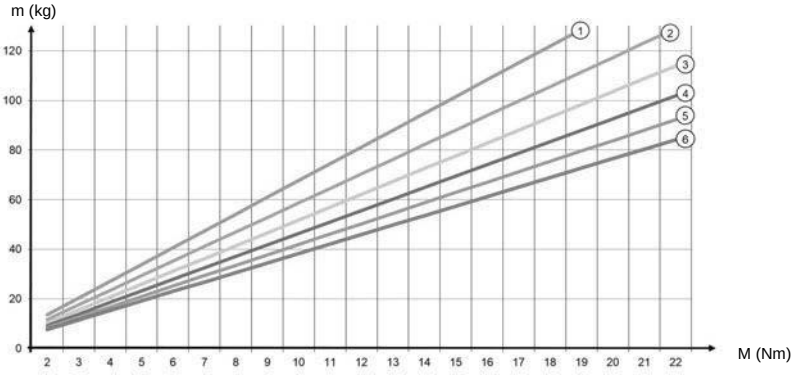
⚠ CAUTION!

Risk of injury due to inappropriate motor power.

- ▶ Check the configured motor power before every training session and adjust it to the user's fitness level.
- ▶ With a small crank radius and a large motor force setting, very large forces can act on the patient. Limit the motor force to the level required for the patient and his training situation.

The motor power

- ❑ is adjustable individually for every training program and every user.
- ❑ has a stronger effect on the user's legs/arms with a small crank radius than with a large crank radius.
- ❑ limits the motor's maximum drive power.
- ❑ for the leg exerciser is adjustable between 2 and 22 Nm.
- ❑ for the upper body exerciser is adjustable between 2 and 8 Nm.



(1) Position 1 = radius adjustment 6.5 cm (2.6 Inches)
(2) Position 2 = radius adjustment 7.5 cm (3 inches)
(3) Position 3 = radius adjustment 8.5 cm (3.4 inches)
(4) Position 4 = radius adjustment 9.5 cm (3.7 inches)
(5) Position 5 = radius adjustment 10.5 cm (4.1 inches)
(6) Position 6 = radius adjustment 11.5 cm (4.5 inches)

The diagram shows recommendations for the motor depending on body weight and radius adjustment. The motor power affects the exercising resistance and the spasm detection function.

m = mass (weight) of the user, M = torque (power) of the motor

- ❑ ①-⑥ = marks of stepless radius adjustment
- ❑ ① = very small radius, for a 2-stepped radius adjustment roughly corresponds to mark 2
- ❑ ⑥ = very large radius, for a 2-stepped radius adjustment roughly corresponds to mark 6

Setting the motor power to fit the user's individual needs:

▶ Limit motor power in sub menu.

- ❑ high motor power:
  - – high exercising resistance
  - – late spasm detection
- ❑ low motor power:
  - – low exercising resistance
  - – early spasm detection
  - – for sensitive joint systems

Upper body exercise

▶ For upper body training, observe marks ② and ⑥.

- ❑ ⑥ = long crank (110 mm or 4.3 inches)
- ❑ ② = short crank (75 mm or 3 inches)

The diagram in chapter 12.2 shows which joint forces can act on the user after setting the motor power.

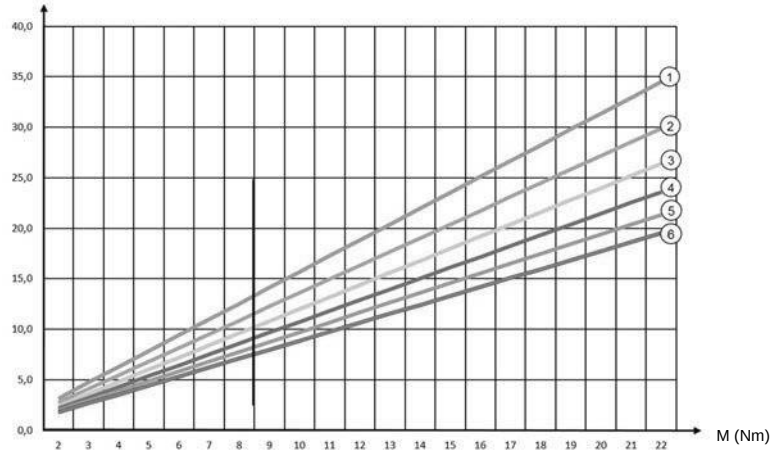
12.2 Motor power for upper body exercise

The joint forces acting on the user

- ❑ must be considered in every training session.
- ❑ increase with reduced radius adjustments and higher motor power settings.

The motor power for the upper body exerciser is adjustable between 2 and 8 Nm.

Joint forces in kg



(1) Position 1 = radius adjustment 6.5 cm (2.6 inches)
(2) Position 2 = radius adjustment 7.5 cm (3 inches)
(3) Position 3 = radius adjustment 8.5 cm (3.4 inches)
(4) Position 4 = radius adjustment 9.5 cm (3.7 inches)
(5) Position 5 = radius adjustment 10.5 cm (4.1 inches)
(6) Position 6 = radius adjustment 11.5 cm (4.5 inches)

The diagram shows the joint forces acting on the user in dependence on the motor power setting and radius adjustment.

M = torque (power) of the motor

- ❑ ①-⑥ = marks of stepless radius adjustment
- ❑ ① = very small radius, for a 2-stepped radius adjustment roughly corresponds to mark 2
- ❑ ⑥ = very large radius, for a 2-stepped radius adjustment roughly corresponds to mark 6

Upper body exercise

▶ For upper body training, observe marks ② and ⑥.

- ❑ ⑥ = long crank (110 mm or 4.3 inches)
- ❑ ② = short crank (75 mm or 3 inches)

Before every training session:

▶ Consult healthcare professional regarding the joint forces admissible for/acting on the user.

▶ Set crank length and motor power accordingly.

13 PROCESSING INSTRUCTIONS

⚠ DANGER!

Risk of infection due to contaminated accessories/options!

- Wear gloves during cleaning and disinfection.

⚠ WARNING!

Danger to life due to electric shock!

Risk of electric shock, fire, or damage to surfaces or materials due to noncompliance with the cleaning and disinfection instructions!

- Prior to any cleaning or disinfection, unplug the power cord plug from the power socket.
- Make sure that no cleaning agent or disinfectant gets into the OmniCycle® Connect.
- If any cleaning agent or disinfectant gets into the OmniCycle® Connect, contact a trained supplier/distributor immediately.
- Do not pour liquids over the device and follow the instructions covering the environmental conditions

NOTE!

Material damage due to incorrect cleaning or disinfection.

- Use exclusively wipe disinfection for the surfaces.
- Clean surfaces only with a soft and damp cloth.
- Clean foils and stickers carefully.
- Never use cleaning agents that are aggressive, abrasive or caustic, or contain solvents.
- For the control and display unit, only use a cleaning agent suitable for screens.
- Use exclusively disinfectants that conform to country-specific regulations.
- Observe the instructions of the manufacturers of cleaning agents and disinfectants as well as the applicable legal regulations.

Classification of the product according to ISO 17664 as a non-critical item.

Non-critical items come into contact with intact skin only. All surfaces of OmniCycle® Connect are intended for intact skin contact only.

The following instructions are recommended but should be adapted to comply with the local or national guidelines and regulations which may apply within the Healthcare Facility or the country of use:

- ❑ Pre-cleaning / cleaning (if necessary)
- ❑ disinfection

Limitations on processing

When the following signs of wear appear, the limit of processing may have been reached:

- ❑ Opacity / unreadability of the display
- ❑ Touch function restriction
- ❑ Visible material changes
- ❑ Contact your trained supplier/distributor in this case.

Preparation before cleaning

- ▶ Disconnect power cord plug.
- ▶ check components and safety labels for damage.
  - – If any damage is found, do not clean but contact trained supplier/distributor.

Cleaning and disinfection

- ▶ Clean and disinfect the OmniCycle® Connect after every exercise.
- ▶ Remove contaminants (e.g., blood, tissues, microorganisms, cleaning agents and lubricants) from surfaces of medical devices
- ▶ Contaminants containing protein must be pre-cleaned with a cloth moistened with drinking water, before cleaning and disinfection.
- ▶ Use VAH-listed disinfectant wipes with basis of 2-propanol/ethanol (validated product: mikrozid universal wipes) on all surfaces with frequent hand / skin contact after each use.
- ▶ Do not use disinfection agents containing chlorine.
- ▶ Cleaning and disinfection of velcros and fabrics:
  - o the velcros and fabrics are considered as a hospital laundry
  - o Soak velcros and fabrics in a watery alcohol-based disinfectant solution to disinfect.
  - o In case of visible contamination, wash the velcros and wristbands with a VAH-listed disinfectant detergent at 40°C, following the detergent manufacturer's instructions for effectiveness.
- ▶ Only use disinfectants conforming with country-specific rules and regulations.
- ▶ For the control and display unit, only use a cleaning agent suitable for screens.
- ▶ Ensure that you comply with the exposure conditions (e.g., exposure time) of the cleaning / disinfection agents used.
- ▶ Alternatively, it is also possible to protect the contact surfaces with sterile disposable bags or foils, which are to be changed after every use.
- ▶ In the case of reprocessing due to reuse on a different patient in home care, it is recommended to replace all velcros at the device and at the accessories

Drying

- ▶ Allow cleaned / disinfected parts to dry completely according to the instructions of the disinfectant manufacturer before taking the product into use again.

Maintenance, inspection and testing

- ▶ In case of maintenance, inspection and testing follow the instructions above.

Replacing in home care:

- ▶ In case of replacing in home care follow the instructions above
- ▶ It is recommended to replace all velcros at the device and at the accessories before it is used by a new user/patient.

Packaging

- ▶ In case of return, make sure that the product is cleaned and disinfected according to the instructions above before packaging.

Storage/additional information

▶ Make sure that the clean and disinfected device is stored with a protective cover.

Manufacturer contact

Follow the instructions of the disinfectant manufacturer, as well as applicable legal provisions.

14 MAINTENANCE AND REPAIRS

⚠ WARNING!

Danger to life due to electric shock!

▶ Prior to any maintenance or repair work, unplug the power cord plug. Disconnection from the mains supply is only guaranteed when the plug is removed from the power socket. Always disconnect the power cord plug before opening the housing. Never operate the OmniCycle® Connect with the housing open or damaged.

14.1 Maintenance

NOTE!

Repairs may only be carried out by trained service technicians. In the event of damage/malfunctions to the device or abnormal noises or smells, stop the training immediately, disconnect the power cord plug and notify the trained service technician.

The OmniCycle® Connect is maintenance-free.

If the housing of the OmniCycle® Connect is opened, a technical inspection is required. The corresponding information for the technical check is available from the manufacturer upon request.

14.2 Further use

The OmniCycle® Connect is suitable for further use by a different customer.

Before every further use OmniCycle® Connect

▶ Clean and disinfect OmniCycle® Connect thoroughly (see Processing instructions).

▶ Perform a visual check or a function check.

▶ Ask the manufacturer for the service instructions for safety control.

▶ Check if all accessories and options are complete (see delivery note).

▶ Replace cushions and Velcro straps.

Furthermore, the manufacturer recommends performing a technical check. The corresponding information for the technical check is available from the manufacturer upon request.

15 TROUBLESHOOTING

15.1 Control and display unit 7"

Error code	Troubleshooting
Error 16	❑Pull power plug and plug it back in after approx. 5 s. The OmniCycle® Connect restarts. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 17	OmniCycle® Connect is overheated. ❑Switch off OmniCycle® Connect and pull power plug. ❑Let OmniCycle® Connect cool down for 10 min. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 18	❑Pull power plug and plug it back in after approx. 5 s. The OmniCycle® Connect restarts. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 19	❑Contact trained supplier/distributor.
Error 20	❑Pull power plug and plug it back in after approx. 5 s. The OmniCycle® Connect restarts. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 21	❑Contact trained supplier/distributor.
Error 22	❑Pull power plug and plug it back in after approx. 5 s. The OmniCycle® Connect restarts. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 23	❑Pull power plug and plug it back in after approx. 5 s. The OmniCycle® Connect restarts. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 24	❑Contact trained supplier/distributor.
Error 25	❑Pull power plug and plug it back in after approx. 5 s. The OmniCycle® Connect restarts. If error message occurs repeatedly: ❑Contact trained supplier/distributor.
Error 26	❑Contact trained supplier/distributor.

15.3 General Errors

Error code	Troubleshooting
The OmniCycle® Connect has too little power	❑Reduce crank radius setting. ❑Increase motor power by one level. Damage to tendons or joints due to overstraining is possible. ❑Before changing settings, consult healthcare professional.
Spasm detection responds too often	❑Reduce sensitivity of spasm detection. ❑Reduce crank radius setting. ❑Increase motor power by one level. ❑Optimize sitting position and distance to unit. Damage to tendons or joints due to overstraining is possible. ❑Before changing settings, consult healthcare professional.
Exercising resistance is too high for active muscle exercise	❑Increase crank radius setting. ❑Reduce motor power. Training program Neuro: ❑Reduce exercising resistance setting. Training program Ortho: ❑Reduce target performance.
OmniCycle® Connect is running irregularly	❑Activate motor muscle support (only for control and display unit 7"). ❑Check if crank radius setting is the same on both sides. ❑Correct if necessary. ❑Check if user is sitting exactly in the center (axial position). ❑Correct if necessary. If fault occurs repeatedly: ❑Contact trained supplier/distributor.
Operating the OmniCycle® Connect is not possible	❑Make sure that START button has been pressed. It is possible that OmniCycle® Connect is in stand-by mode. ❑Make sure that power supply cable is intact and correctly connected. ❑Check mains fuse. ❑Pull power plug and plug it back in after approx. 5 s. ❑Press START button. ❑Make sure that correct exerciser type (arm or leg) is selected. ❑Make sure that cranks are unlocked for upper body exercise.
OmniCycle® Connect does not show a training report	❑Exercise for at least 1 min.

Voice-controlled emergency stop does not respond	❑Increase microphone sensitivity setting.
Training settings are incorrect	❑Set and save basic settings again. ❑Reset basic settings to factory settings.
Biofeedback symmetry bar or symmetry road show incorrect values	❑Check if crank radius setting is the same on both sides. ❑Correct if necessary. ❑Check if user is sitting exactly in the center (axial position). ❑Correct if necessary. ❑Make sure that the user's foot movements are correct: correct: push incorrect: pull If fault occurs repeatedly: ❑Contact a trained supplier/distributor. Have OmniCycle® Connect recalibrated.
The following appears on the control and display unit “SPASTICITY”	❑Anti-spasm-control has responded. ❑To continue exercising see chapter 7.8 Safety equipment
The following appears on the control and display unit “MOTOR POWER EXCEEDED”	❑Anti-spasm-control has responded. ❑To continue exercising see chapter 7.8 Safety equipment.
Spasm symbol appears on control and display unit.	❑Anti-spasm-control has responded. ❑To continue exercising see chapter 7.8 Safety equipment.
The following appears on the control and display unit “WARNING OmniCycle® Connect used too strenuously. Reduce pedaling speed”	❑Reduce pedaling speed. ❑Make sure that the user does not exceed the upper limits for number of revolutions (85 rpm) and power (80 Watt). If the user does not reduce power and number of revolutions, the error message will appear again. After three messages, OmniCycle® Connect will stop the training session.
The following appears on the control and display unit “TRAINING STOPPED OmniCycle® Connect used too strenuously”	❑ OmniCycle® Connect stops the training session due to upper limits for number of revolutions or power being continuously exceeded.
The “Unlock” graphic is displayed on the control and display unit:	❑Locking of the crank is closed. ❑Open it to perform upper body exercise. (see chapter 7.6 Locking/unlocking the crank)

16 TECHNICAL DATA

OmniCycle® Connect	
Dimensions: ❑leg exerciser ❑Upper body exerciser	l x w x h approx. 58-83 cm (22.8 – 32.7 inches) x 47.3 cm (18.6 inches) x 63 -119 cm (24.8 – 46.85 inches) approx. 75-90 cm (29.5 – 35.4 inches) x 63.8 cm (25.1 inches) x 110-125.5 cm (43.3 – 49.4 inches)
Weight: ❑leg exerciser ❑Upper body exerciser	 approx. 27-38 kg (59.5 – 83.8 lbs) approx. 39-45 kg (86 – 99.2 lbs)
Crank length leg exerciser: ❑2-stepped ❑stepless	 75 mm/3 inches or 110 mm/4.3 inches 65 mm (2.6 inches) -115 mm (4.5 inches)
Crank length upper body exerciser: ❑short ❑long	 75 mm (3 inches) 110 mm (4.3 inches)
Number of rotations range – assisted training	1-75 rpm
Number of rotations range – active training	1-90 rpm
Torque range ❑leg exerciser ❑Upper body exerciser	 approx. 2-22 Nm approx. 2-8 Nm
Continuous rating	80 Watts
Power input	175 VA
Power supply	230 V~, 50/60 Hz 115 V~, 50/60 Hz
Fuses	2 x T 1.0 A H 250 V (for power supply 230 V) 2 x T 1.6 A H 250 V (for power supply 115 V)
Medical device class	IIa
Protection class	II
Degree of protection	Type BF
Protection category	IP21
Sound emission	LpA < 40 dB(A)
Ambient conditions for use	5 °C to 40 °C 15 to 90% Rh 700 to 1060 hPa

OmniCycle® Connect	
Suitable for users with ❑Body height ❑Body weight	120 cm (3 feet 11.24 Inches) to 200 cm (6 feet 6.67 inches) 180 kg (396.8 lbs.) or120 kg (264.5 lbs.) if footrests with stepless radius adjustment (article no. A001-411) are used
Ambient conditions for transport/ delivery	-25 °C to 70 °C 15% to 93% Rh 700 to 1060 hPa
Materials used	steel, stainless steel, plastics (POM, PA6, ABS, PE), rubber
Operational life OmniCycle® Connect	The operational life time is 10 years or 5,000 operating hours, whichever occurs first.
Power consumption in stand-by mode: ❑Control and display unit with 7" color screen	31 Watts
Software version	Control and display unit with 7" color screen: ❑Software 02.00.x ▶ User manual valid for software versions indicated above or higher.
Dimensions control and display unit with ❑7" color screen	Diagonal: 17.6 cm Width: 15.4 cm Height: 8.6 cm

For users with a body weight of more than the above data it is necessary to use special accessories for the OmniCycle® Connect after consultation with the manufacturer or the trained dealer/distributors.

17 DISPOSAL

To dispose of the OmniCycle® Connect

- ▶ Observe country-specific regulations and specifications.
- ▶ Dispose of metal parts as scrap metal.
- ▶ Dispose of plastic parts according to the type of material.
- ▶ Dispose of electric and electronic components as electronic scrap.

18 NOTES ON ELECTROMAGNETIC COMPATIBILITY

18.1 Lines, line lengths and accessories

The OmniCycle® Connect is to be exclusively used with the original power supply cable.

18.2 Warning notice regarding installation

The OmniCycle® Connect is not to be used in the immediate vicinity of or stacked with other devices. If it is necessary that the OmniCycle® Connect is used next to or in a stack with other devices, one should observe it to check if the arrangement permits it to work as intended.

18.3 Electromagnetic emission and immunity

- ❑ The device is classified according to CISPR 11 in Group 1 Class B; for immunity test levels it is designed according to DIN EN 60601-1-2:2022-01 (EN 60601-1-2:2015+A1:2021, IEC 60601-1-2:2014+A1:2020) for the environment as intended use of Table 2, 4, 5, 8 and 9.
- ❑ No deviations or relaxations are permitted with regard to the immunity test levels mentioned above.
- ❑ With regard to electromagnetic disturbances, no precautions (maintenance activities) are required to maintain the basic safety and essential performance characteristics within the expected operating lifetime.The device is only to use in the room context as defined (see 3. intended use).

The device is not to use in:

- The vicinity of active RF surgical equipment.
- RF screening rooms used for magnetic resonance imaging (MRI) where high-intensity electromagnetic disturbances occur.

18.4 Wireless reception and transmission of HF energy of the control and display unit

Transmitter details / Receiver details:

- Frequency band (ISM band): 2.400 GHz...2.4835 GHz
- Usable frequency band: 2.402 GHz m...2.480 GHz
- Effective radiated power EIRP: < 10 dBm

18.5 User Information acc. to FCC15.21

Only valid for control and display unit OmniCycle® Connect 7" with A006-672

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

18.6 Statement for Class B digital device acc. to FCC 15.105

a) Statement for Class B digital device acc. to FCC 15.105

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio / TV technician for help.*

b) Statement acc. RSS Gen Issue 4, Sect. 8.4

This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

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Art. No.: A009-295_Rev 06
Last update: CW24/2024

For declarations of conformity, see www.thera-trainer.com