OMNISTAND®

Dynamic Balance System

User Manual

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OMNISTAND®

ACP manufactures a premier line of rehabilitation technologies to assist health care professionals with improved outcomes and quality-of-life for patients. The ACP product line includes Pain Control Systems, Muscle Stimulators, Interferential Therapy, Therapeutic Ultrasound, Pulsed Shortwave Diathermy devices, and advanced Therapeutic Exercise Systems. Our **OMNICYCLE®, OMNIVR®, OMNISTAND®, OMNISWD®, OMNIVERSA®, OMNIFLOW®, and SYNCHRONY DYSPHAGIA SOLUTIONS BY ACP®** represent the most recent worldwide advances available for therapeutic application of electro medical devices and other rehabilitation technology.

Manufactured for ACP
by: Medica
Medizintechnik GmbH
Blumenweg 8
88454 Hochdorf Germany

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AVAILABILITY AND VALIDITY OF THE USER MANUAL

This User Manual complies with Regulation (EU) 2017/745.

- Distributor must comply with country-specific laws/regulations.
- Controls and User Manuals are designed for trained professionals with normal vision, cognitive abilities and no reading disabilities.

Availability

This User Manual is available digitally from the manufacturer on the ACP website home page: https://acplus.com/acp-technology-user-manuals or can be requested from acp-customersupport@hanger.com.

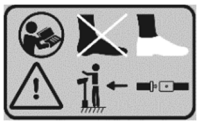
The User Manual can also be requested from the manufacturer beyond the service life of the product.

Validity of User Manual

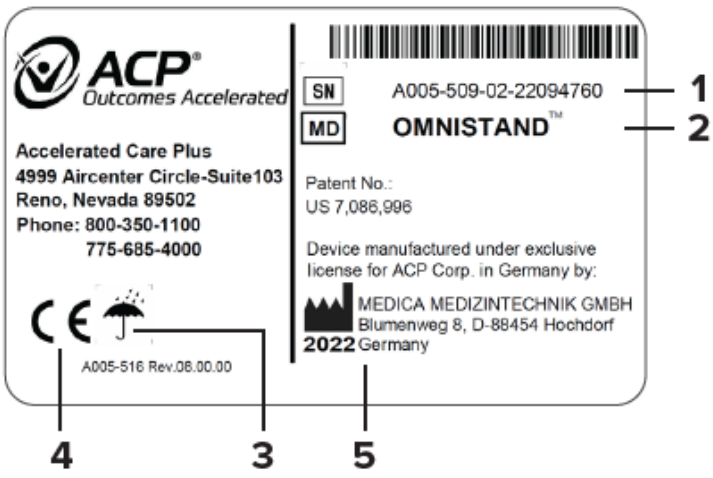
1. Valid in paper form from the manufacturer.
2. Valid digitally on the manufacturer's homepage (https://acplus.com/acp-technology-user-manuals).
3. Other User Manuals are not valid.

NOTE: The purpose of this manual is to acquaint medical professionals with the OmniStand®. Please read the manual carefully before attempting to operate the OmniStand®. If questions remain unanswered, contact your ACP Clinical Program Consultant or call ACP Customer Support at (800) 350-1100. Outside the USA, call +1 (775) 685-400.

SYMBOLS ON THE PRODUCT

	Observe the user manual	MD	Medical device
	Manufacturer	CE	Market launch in accordance with Regulation (EU) 2017/745
SN	Serial number	UDI	Unique device identifier
	Protect product from humidity		Warning label – see Contraindications, Warnings, and Precautions
	Setting spring resistance – see Setting spring resistance		Setting balance function – see Setting balance function
	Correct use of pelvic safety belt with support sling – front view – see page 17 **NOTE:** this label is on the pelvic safety belt		Correct use of pelvic safety belt with support sling – lateral view – see page 17 **NOTE:** this label is on the balance unit

PRODUCT LABEL



1 – Serial number
2 – Medical device
3 – Protect product from humidity
4 – Market launch in accordance with Regulation (EU) 2017/745
5 – Manufacturer

INTRODUCTION

The OmniStand® is a dynamic balance system designed specifically for individuals who have poor standing tolerance and impairments with static or dynamic standing balance. The OmniStand® creates a “fall-safe” environment that can be used during supervised therapeutic exercise and can also be combined with virtual rehabilitation exercise devices (e.g., OmniStand®). Research shows that virtual reality biofeedback significantly enhances patient outcomes by encouraging greater patient participation, exercise effort, and/or exercise duration.

When used in rehabilitation, the OmniStand® provides safe static or dynamic support and eliminates the need for the clinician to assist the patient during standing. This allows the clinician to more effectively cue, engage, and guide the patient. If an additional clinician is required to assist or physically support the patient, once the patient is positioned in the OmniStand®, only one clinician would be needed to provide the exercise. This balance system provides safer, more efficient care with improved outcomes.

TRAINING AND USE

Patients

- Individuals who use the OmniStand® for initial or recurring training.
- Patients are instructed by the manufacturer or by specialists trained by the manufacturer.
- Patients may not instruct other patients in the use of the OmniStand®.

Specialized Staff

- Persons who gained their skills and expertise by means of professional training in the medical or medical- technical sector (e.g. doctors, therapists).
- Persons who, due to their professional experience and by means of instruction/training by the manufacturer, are able to assess safety-relevant regulations and recognize potential risks in their field of work (e.g. assistants).
- Operates the software and makes settings.
- Persons trained by the manufacturer (e.g. sales partners of the manufacturer) are able to instruct others on how to use the system.

Exercise Sessions

- Attended training:
    - Clinician is in proximity to the patient and can react immediately to hazardous situations during the entire training.
    - Attended training with the OmniStand® is recommended for:
        - Patients who do not meet the requirements for sole/independent training.
        - Patients where it is necessary to use the knee system to secure the knees.
        - For fall protection, if no pelvic safety belt with support sling is used.

- Supervised training:
    - Clinician is located within the room (not directly beside the patient) during the training session.
    - Clinician is present throughout the training to ensure that safe training is taking place.
    - In hazardous situations, the clinician is available to intervene immediately.
    - Supervised training with the OmniStand® is recommended only if:
        1. Patient is able to stand upright and can actively straighten the body.
        2. Patient is in no danger of losing consciousness or weakness during the training.
        3. Patient is able to operate the OmniStand® alone.
        4. Patient can independently secure themselves in the OmniStand® (can at least put on the pelvic safety belt with support sling).

The OmniStand® is a therapeutic exercise device and not a medical instrument for diagnostic purposes.

Please note that ACP cannot provide medical advice. If you have specific medical questions, please contact the attending physician.

INDICATIONS

The OmniStand® is generally suitable in the following situations:

- Considerable impairment of standing and balancing ability.
- Complete / incomplete hemiplegia / hemiparesis or tetraplegia / tetraparesis maybe also with involvement of the trunk muscles as a result of a brain disease (e.g. Stroke (I60-69), Multiple sclerosis (G35-37)).
- The OmniStand® is also indicated to take a standing position, e.g. in preparation for gait training and / or to achieve positive effects of an upright body position (e.g. with regard to circulation regulation or bone metabolism).

NOTE:

- Patients may have additional indications and/or contraindications that are not listed here but are relevant.
- The list does not claim to be exhaustive. Contact trained suppliers if you have any questions.
- In principle, the same indications and contraindications apply to therapy with the OmniStand® as to manual therapeutic treatment. Knowledge about contraindications is essential in order not to put patients at risk.
- Before each therapy session, check whether there are any contraindications.

CONTRAINDICATIONS

- Weight more than 309lbs. (140 kg)
- Height shorter than 4'5" (135cm)
- Height taller than 6'7" (200cm)
- Severe imbalance
- Significant trunk and lower extremity joint contractures
- Ulcers or damaged skin that would come in contact with the unit
- Users with extreme osteoporosis
- Users with Osteogenesis imperfecta
- Users with compromised circulation and/or unstable blood pressure or heart rate
- Do not use for outdoor exercise
- Do not use for patient transport
- Unattended or unsupervised use or training
- Do not use in combination with other products emitting ionizing radiation

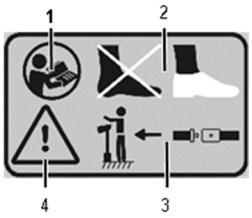
Use the OmniStand® in consultation with a doctor in the case of:

- Severe pain during movement
- Epilepsy
- Luxation of the hip
- Acute neurologic deficit
- Cardiovascular disease (unstable cardiovascular system, cardiac insufficiency, cardiovascular weakness, artificial heart).

WARNINGS

- Failure to read and follow the user manual and service instructions, may result in a potentially hazardous situation for patients and healthcare professionals, resulting in death, injury, or property and environmental damage.
- Before beginning training, consult a healthcare professional or clarify whether patients with cardiovascular diseases are allowed to exercise with the OmniStand®.
- Attended or supervised training should occur with the OmniStand®.
- Before any training, make sure that safety equipment is working correctly.
- Before any training, make sure that the OmniStand® is working correctly.
- Exclusively train with simple knee support and the pelvic safety belt with support sling for patients with strong spasticity.
- Disinfect OmniStand® before every training.
- In case of possible infection due to contaminated attachments/optional parts, always wear personal protective equipment (gloves, mask) when cleaning the OmniStand®.
- In case of damage or malfunctions to the OmniStand®, contact the supplier immediately.
- Risk of injury due to wheelchair tipping over
    - Install all segments of the tread extension on even and slip-proof floor.
    - Connect sections of the tread extension so that they are flush.
    - Before the patient sits down, block the wheelchair.
    - Ensure that the wheelchair does not impose on the basic unit, which can cause the wheelchair to tip over.
- If the knee is not properly secured during simple knee support removal, there is danger that the patient can fall down. Ensure that the patient can fully support the lower extremities, and that there is no danger of unconsciousness or weakness during training.
- During installation and before any training, secure the table.
- Make sure the OmniStand® is used with the pelvic safety belt and support sling, if no assistant is available to prevent patient from falling.

Warning Label



1 – Follow the user manual.

2 – Use the OmniStand® only with closed shoes (clinicians and patients).

3 – Use the pelvic safety belt with support sling and ensure that the belt buckle clicks audibly into place.

4 – Follow the safety instructions.

PRECAUTIONS

- Prior to every training session, adapt simple knee support to the user's individual needs.
- Adjust simple knee support so as to prevent hyperextension of joints and damage to muscles, tendons or ligaments.
- Make sure that pelvic safety belt with support sling is not damaged (i.e. intact seams, stitching).
- Make sure that pelvic safety belt with support sling is correctly positioned and safely attached to buckles.
- Set spring resistance to fit the user's activity, body size and body weight.
- Always position chair/wheelchair directly behind patient and lock brakes when transferring from OmniStand® to a wheelchair.
- Before initial startup, a trained clinician should instruct you on how to use the OmniStand®.
- For safe and effective operation, use the OmniStand® only in the defined area of use/installation conditions.
- Prepare the OmniStand® correctly for a training session:
    - Castors are locked before the patient steps onto the OmniStand®.
    - The height adjustment has been locked before a patient gets into the OmniStand®.
    - The balance function is locked before the patient steps into the OmniStand®.
    - The tread unit is dry and clean before and during the training.
- Before starting the training, consult with a healthcare professional about which training parameters match the patient’s level of fitness. Avoid excessive strain.
    - Set the spring resistance of the OmniStand® to fit the patient’s activity, height, and body weight.
    - Select the range of motion according to the patient’s therapy goals:
        - The patient should not be overexerted.
        - If the patient does not reach the range of motion, reduce the spring stiffness.
        - If the patient constantly reaches the range of motion with the end stop, increase the spring stiffness.
- Keep sufficient distance between the OmniStand® and walls and obstacles.
- Make sure that no body parts get pinched when adjusting the OmniStand®.
- Protect the OmniStand® from liquids.
- If the patient holds the upper pipe frame continually or supports him/herself, use the cushion set for the upper pipe frame.
- Make sure that the OmniStand® is transported correctly:
    - Do not use the OmniStand® as a training device during transport.
    - Never use the OmniStand® to transport patients.
    - Only transport the OmniStand® with double steering castors on level and firm ground.
- If any symptoms or illness occur during or after training, seek medical advice immediately.

- Never leave children unattended.
- Only use cleaning agents and disinfectants approved by the manufacturer.

ADVERSE INCIDENT REPORTING REQUIREMENT

- All serious incidents occurring in connection with the product shall be reported immediately to ACP (as the distributor), as well as the manufacturer and competent authority.

CONSIDERATIONS

Biocompatibility

- All components and optional accessories of the OmniStand® that the user might come in contact with when using the device as intended are designed to meet the biocompatibility requirements of the applicable standards.

Medical Purpose

- The OmniStand® is a non-powered training device that provides a safe environment to train standing and balance (postural control) and for neuromuscular re-education.

The OmniStand® is a medical device. The medical purpose includes the usage as a medical device.

MISUSE / SIDE EFFECTS

Misuse:

Do not use the OmniStand® in the following cases:

- for outdoor exercise.
- in ambient conditions not conforming the requirements.
- for transport (e.g., of the patient).
- for unsupervised exercise, if the patient cannot operate the medical device without assistance.
- for very dynamic exercising, i.e. sport (like table tennis).

OmniStand® is not suitable for:

- Diagnosis
- Monitoring
- Measuring

Side effects: In rare cases:

- Pain (stress-related pain)
- Skin injuries (e.g. pressure ulcer)
- Pressure sores

DELIVERY, UNPACKING, AND TRANSPORTING

Delivery

Upon receipt of your OmniStand®, inspect the shipping container and contents for any obvious or concealed damage. All ACP products are packaged carefully for rapid, safe delivery. We guarantee delivery in perfect condition to the postal or delivery services. However, any damage or loss incurred during transportation or delivery is the postal or delivery company responsibility. If damage or loss to the product and/or container is obvious or suspected, appropriate notation must be made on the signed freight bill at the time of delivery. All damage claims should be promptly filed with the delivering carrier and must be initiated by the addressee where the package was to be delivered. Retain the original shipping container and inserts for validation of damage claim for use at a later date.

Unpacking

- Remove OmniStand® from packaging and leave at room temperature for 1 hour before using it for the first time.
- Check OmniStand® for all accessories/options and for transport damage. A list of enclosed accessories is provided with each unit to assist you in identification of the type and number of accessories.
- Check if delivery is complete.
- Inform supplier or forwarding agent immediately about any damage.

Area of application/Set-up conditions

The OmniStand® is limited for indoor use in an environment such as professional health care facilities (e.g., patient rooms, therapy rooms).

For safe and effective use, note the following conditions.

- Ambient conditions during use – see Technical Specifications table.
- Do not use the OmniStand® in wet, humid or hot environments.
- Only use the OmniStand® on level, firm, and slip-proof floors.

Transporting

The OmniStand® is equipped with wheels for ease of movement. However, the wheels are not suitable for moving the unit over uneven surfaces. The OmniStand® should be moved using an elevator and must not be carried up or down stairs. To move the unit, unlock the wheels and push it in front of you.

Lock transport castors with brake/wheel locks

Prevent OmniStand® from moving as follows:

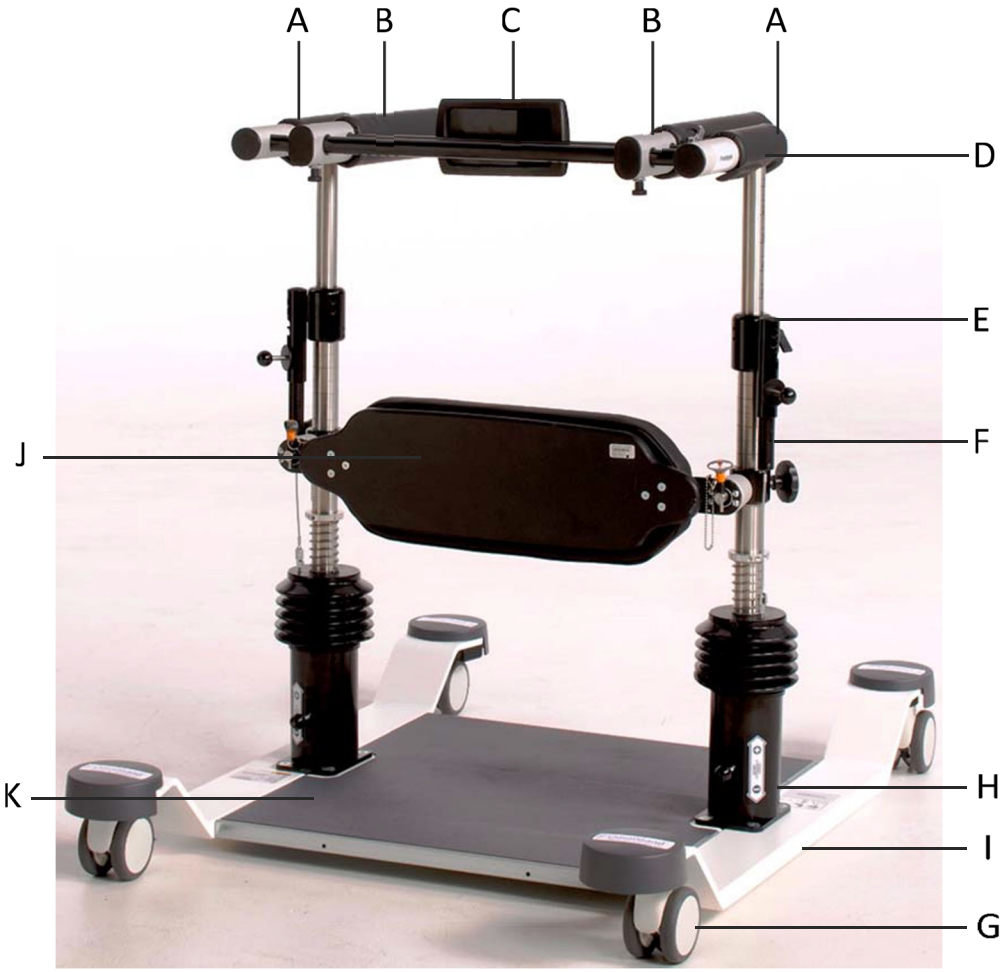
- Before EVERY USE, lock all four transport castors with brake/wheel locks.
- Push down locking lever on transport castors with brake/wheel locks.

Release transport castors with brake/wheel locks

To transport OmniStand®:

- Release locking lever on transport castors with brake/wheel locks.

CONTROLS AND FUNCTIONS



A. Upper pipe frame
B. Stay tube
C. Abdominal cushion
D. Vertical pipe of balance unit
E. Release lever for dynamic standing function
F. Height adjustment of simple knee support
G. Transport castors with brake
H. Balance unit with settings for spring resistance
I. Base unit
J. Knee support
K. Tread unit

OPERATIONAL GUIDELINES

Exercise Program Planning

The frequency and duration of exercise sessions on the OmniStand® should be individually planned based on each patient's health profile, status, and condition. Proper patient-specific exercise dosing with the OmniStand® is extremely important if optimal improvements in balance, mobility, strength, cardiovascular performance, and endurance are to be achieved. It is recommended that relative to patient-specific needs and capabilities, exercise sessions start at an easier intensity and shorter duration. As patients demonstrate better exercise tolerance, progressive increases in intensity and/or duration are recommended, dependent on each user's goals and health status.

Basic Operational Sequence

Caution

Risk of injury due to insufficient preparation!

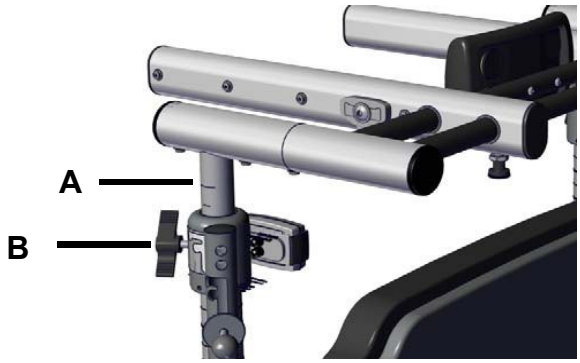
- Before starting any exercise, make sure that the OmniStand® is properly assembled, and fully operational.
- Before every use, lock all four transport castors with brake/wheel locks.
- Disinfect the OmniStand® before every training.

NOTE: *Before every exercise session, adjust settings of OmniStand® to match the user's individual needs.*

Adjusting the Height of the Upper Pipe Frame

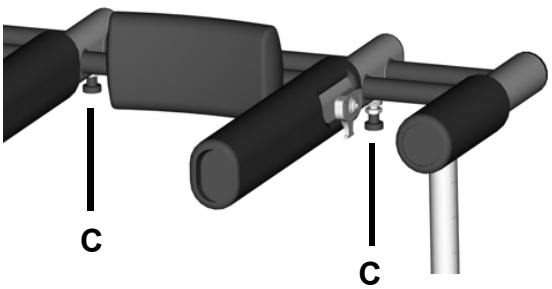
NOTE: A pneumatic spring supports the height adjustment

- Release winged screw (see **B**) on first vertical pipe.
- Set height using the marks (see **A**).
- Tighten winged screw (see **B**) on first vertical pipe.
- Repeat process to set height on second vertical pipe.
- Use the marks to ensure the left and right vertical pipes are set to the same height.



Adjusting the Width of the Stay Tubes

- Pull out and hold the safety catch (see **C**).
- Adjust stay tubes to fit the width of the patient's pelvis.
- Release safety catch (see **C**) to lock in place.
- Ensure safety catch audibly clicks into place.
- Ensure the left and right stay tubes are adjusted equally.



Adjusting the Height Knee Support

Caution

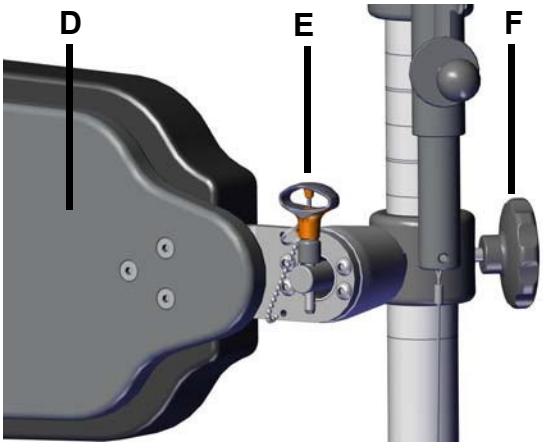
Risk of injury due to incorrectly adapted simple knee support!

- Prior to every training session, adapt knee support to the patient's individual needs.
- Adjust knee support so as to prevent hyperextension of joints and damage to muscles, tendons or ligaments.
- If removing the knee support, ensure that the patient can fully support the lower extremities, and that there is no danger of unconsciousness or weakness during training.
- If the knee is not properly secured during knee support removal, there is danger that the patient can fall down.
- Ensure the patient has sufficient lower extremity strength, endurance, and control to stand independently.

NOTE: *The simple knee support provides support for the user when rising and standing or during balance exercise. Adjusting the simple knee support does not require any tools.*

In order to be able to lower the patient quickly, put a chair or wheelchair directly behind the OmniStand® during the training session.

Mounting the Knee Support



- Mount the knee support (see **D**), before the patient stands in the OmniStand®.
- Move the knee support onto the securing system.
- Insert the ball catch pin (see **E**) into the securing system.
- Ensure that the ball catch is inserted completely.
- Before every training, ensure that the knee support (see **D**) is secured.

Setting the Height

- Loosen star-shaped handle (see **F**) on first vertical pipe.
- Set height using marks.
- Tighten star-shaped handle (see **F**) on first vertical pipe.
- Repeat process to set height on second vertical pipe.
- Use the marks to ensure the left and right vertical pipes are set to the same height.

Removing the Knee Support

- Remove the knee support (see **D**) before the patient stands in the OmniStand®.
- Pull ball catch pin (see **E**) out of securing system.
- Move the knee support (see **D**) out of securing system.
- Ensure patient is able to maintain upright standing position safely and without assistance.

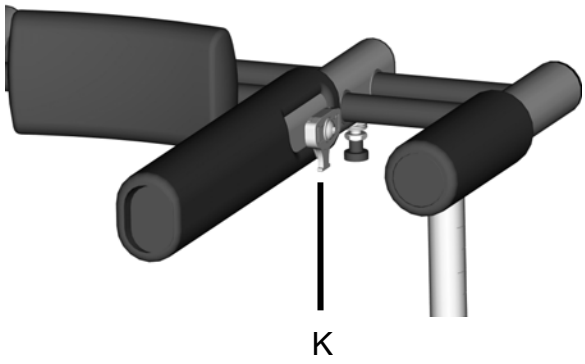
Putting on the Pelvic Safety Belt with Support Sling

Caution

Risk of injury due to incorrectly adapted simple knee support!

- Make sure that pelvic safety belt with support sling is not damaged (i.e. intact seams, stitching).
- Make sure that pelvic safety belt with support sling is correctly positioned and safely attached to buckles.
- Make sure the OmniStand® is used with the pelvic safety belt and support sling if no assistant is available to prevent patient from falling.

NOTE: *The pelvic safety belt with support sling safely supports the patient's pelvis in the back. Use of the OmniStand® pelvic safety belt with support sling and seat pad is dependent upon patient's level and abilities.*



Pelvic Safety Belt with Support Sling

Position the user in an optimal training position:

- The pelvic safety belt with support sling and seat pad functions as a saddle style harness for patients that need more support.
- Attach belt buckles (see **G**) in securing system (see **K**) on stay tubes.
  - Select the same position for left and right side.
- Make sure that buckle audibly clicks into place.
- Make sure that the orange pelvic safety straps run below the stay tubes, and the blue pelvic safety straps run above the stay tubes.
- Shorten pelvic safety strap by pulling on both straps equally (see **H**).
- If necessary, lengthen pelvic safety strap by opening upper and lower clamping locks (see **I**).

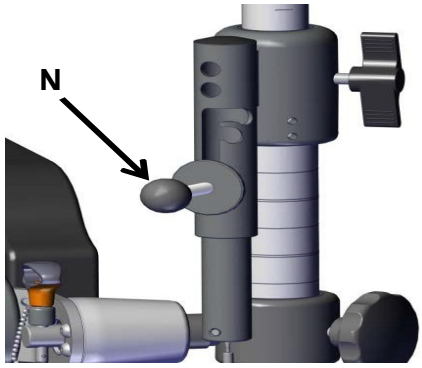
Setting Dynamic Standing Function

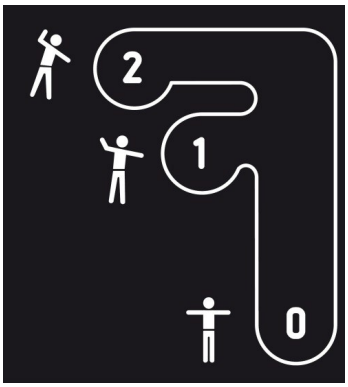
Caution

Before every training session:

- Lift OmniStand® by upper pipe frame on left and right side.
- If the vertical pipe can be lifted out of the balance unit, do not use the OmniStand®. Contact ACP Customer Service.

Set release lever (see **N**) to position 2, 1, or 0 on both vertical pipes. Make sure that release lever is completely latched in place. Assure release lever is set to the same position on both sides.



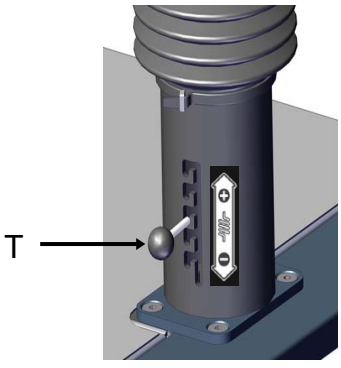


- Position 2 = dynamic standing function enabled with full range of movement (up to 11°)
- Position 1 = dynamic standing function enabled with limited range of movement (up to 6°)
- Position 0 = dynamic standing function disabled

Spring Resistance Settings

Set spring resistance to fit the user's activity, size, and weight:

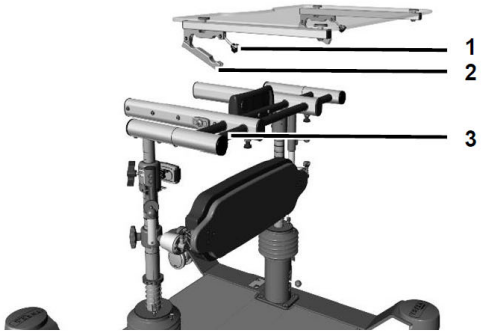
- Set release lever **N** to 0.
- Use lever (see **T**) on balance unit to set spring resistance.
  - Down = low spring resistance
  - Up = high spring resistance
- Make sure that release lever latches.
- Assure that spring resistance is set to the same level on both sides.

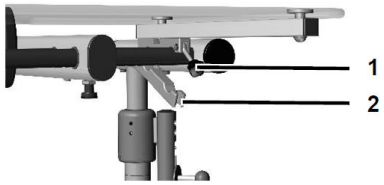


Securing the OmniStand® Table

Warning

Risk of injury due to not using a chair/wheelchair!
- During installation and before every training, secure the table.





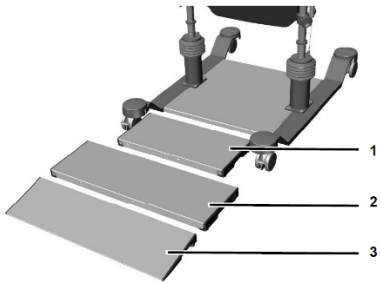
- Open the star handle **1** until both latches **2** can be opened.
- Place the table unit on the upper pipe frame **3**.
- Close latches **2** and secure with booth star handle **1**.
- During installation, ensure the table unit is securely connected to the upper pipe frame.

NOTE: *Maximum load of table unit is 44 lbs (20 kg).*

Installing the Tread Extension

To install, place segments together so that they are flush and connect them magnetically.

- Connect the individual components in the correct order.
- Connect the connection part **1** with the tread unit. The connection part is always needed in order to use any of the other parts.
- Optionally, connect the mid part **2** with the connection part **1**.
- Optionally, connect the ramp **3** with the mid part **2**. If no mid part 2 is used, connect the ramp 3 with the connection part 1.



All tread extensions do not need to be used, however the connection part must be used to use the additional tread extensions.

NOTE: *Do not transport the OmniStand® with the tread extension plate installed.*

Positioning and Assisting Patient Into and Out of OmniStand®

Warning

Risk of injury due to not using a chair/wheelchair!

- Always position chair/wheelchair directly behind patient.
- Lock brakes of wheelchair.
- Ensure that the wheelchair does not impose on the basic unit, which can cause the wheelchair to tip over.

Caution

Risk of injury due to not using a chair/wheelchair!

- When exercising in an electric wheelchair, switch off electronic control/driving function.

NOTE: *When using the OmniStand® it may be necessary to lift or lower the patient with the help of an assistant who is trained for the procedure.*

Positioning and Assisting the Patient into the OmniStand®

- Set height of the knee support and upper pipe frame.
- Ensure transport castors with brake/wheel are locked.
- Position patient directly behind OmniStand® with a chair or wheelchair.
- Lock wheelchair brakes.
- Position patient’s feet on the tread unit.
- If simple knee support is used, place knees on knee support prior to standing. If simple knee support is not used, ensure that patient can fully support lower extremities during the exercise and that there is no danger of falling.
- Assist the patient into the standing exercise position.
- Apply pelvic safety belt with support sling and secure the patient using the belt buckles.

Assisting the Patient Out of the OmniStand®

- Move chair or wheelchair directly behind the OmniStand®.
- Lock wheelchair brakes.
- Unbuckle and remove pelvic safety strap with support sling.
- Seat patient in chair or wheelchair.
- Remove the patient's feet from the tread of the OmniStand®.

INFECTION CONTROL EQUIPMENT AND PRINCIPLES OF USE

Barrier Film

Intermediate-level disposable protective plastic film is designed to cover any surface that may be touched during a patient treatment, in order to help prevent cross-contamination. Barrier film is single-use only.

Germicidal Disposable Wipe

Low level and/or intermediate level disposable germicidal disinfectant wipe for use on OmniStand® system and accessories.

Universal Precautions

Universal Precautions must be implemented to prevent transmission from occupational exposure to bloodborne pathogens and other body fluids containing visible blood. Health care workers with exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves.

Cleaning/Disinfecting the OmniStand®

All OmniStand® equipment shall be cleaned/disinfected per facility infection control policy. ACP recommends the following guidelines:

Low-Level Disinfection

This is a recommended daily housekeeping practice to keep the equipment clean and free of contaminants which could contribute to transmission of infection. The following practices are recommended for use when treating intact skin without the presence of physiologic fluids such as blood, respiratory droplets, or urine:

- After each use, wipe common contact surfaces (e.g. table unit) with ACP germicidal wipes or facility approved equivalent, and allow to air dry.
- This technique will inactivate M. Tuberculosis as well as most bacteria and viruses. This will also facilitate removal of organic material contaminants from equipment.

Intermediate-Level Disinfection

The following practices are recommended for use when treating non-intact skin, or intact skin with the presence of physiological fluids such as blood, respiratory droplets, or urine:

- Perform low-level disinfection first.
- With a second ACP germicidal wipe, cover the surface and leave it wet for at least 5 minutes, and then allow to air dry.

PREVENTIVE MAINTENANCE AND BEST OPERATING PRACTICES

Preventive maintenance is recommended to be performed at least annually. This should include at minimum a safety inspection and to verify proper operation of your OmniStand®.

Always keep the system clean and keep any debris, such as paper, string, cloth, or clothing away from the moving parts.

There is a risk of injury if maintenance instructions are not followed.

- Service or repair work should only be carried out by trained suppliers.
- Regularly check screws.
- Use exclusively the manufacturer's original parts.

Replacing the Pelvic Safety Strap with Support Sling:

According to the manufacturer's specifications, the pelvic safety strap of the OmniStand® must be replaced after five years.

Servicing the OmniStand®

For repair or service of ACP products and accessories, please call (800) 350-1100 and follow the prompts. Normal hours of operation are 6:00am to 5:00pm Pacific Standard Time. After hours, please leave a message and a technician will return your call during the next scheduled workday.

Proper Disposal

Proper disposal procedures shall be observed as required by specific state and/or local regulations. It is the responsibility of the owner of the device to follow applicable laws and regulation on disposal guidelines.

Technical Specifications

GENERAL		
Basic OmniStand® Dimensions	Length: Width: Height: Weight:	48in. (122cm) 36in. (93cm) 51in. (130cm) 178lbs. (81kg)
Medical Device Class	FDA	Class I
Protection Category	UL	IP2X
Sound Emission	dB	LpA < 45 dB(A)
Ambient conditions for use	°F/°C Rh hPa	41°F(5 °C) to 104°F(40 °C) 5% to 93% Rh 700 to 1,060 hPa
Ambient conditions for transport/delivery	°F/°C Rh hPa	-13°F(-25 °C) to 158°F(70 °C) 5% to 93% Rh 700 to 1,060 hPa
Suitable for users with • Body height • Body weight	Height Min. Height Max. Max Weight	53in. (135cm) 78in. (200cm) 309lbs. (140kg)
Materials Used		Steel, stainless steel, aluminum, rubber, plastics (POM, PA6, ABS, & PE)
Economic life-time; OmniStand®	Yrs.	5 to 7
Standards		MDD 93/42 EEC DIN EN ISO 13485 DIN EN 12182

Standard and Optional Accessories

ITEM	ITEM NO.	DESCRIPTION
	**A005-509-EQUIP**	OMNISTAND® DYNAMIC BALANCE SYSTEM Shipping Weight: 178 lbs. (81 kg)
ACCESSORY	**ITEM NO.**	**DESCRIPTION**
	**81582**	OmniStand® Premium Pelvic Safety Belt with Support Sling
	***84315**	OmniStand® Table Top
	***81160**	OmniStand® Tread Extension Ramp
	**Click here for manuals or scan:** Scan for ACP User Manuals	OmniStand® User Manual

**** This item is an optional accessory and may not be included with the unit.***

Infection Control Supplies

ITEM	ITEM NO.	DESCRIPTION
	**52479**	Barrier Film for Surfaces, Infection Control, 4" x 6" perforated sheets – 1200 sheets/roll
	66431	Barrier Film for Surfaces, Infection Control, 6" x 9" perforated Sheets – 800 sheets/roll
	50593	Barrier Film – for Surfaces, Infection Control, 12" x 14" perforated Sheets – 514 sheets/roll
	**63574**	Barrier Film, 3" Tubing, 1200'/roll
	55536	Alcohol Wipes, Single Use Packets (50 pk/bx)
	44425	Alcohol Wipes, Tub (160/tub)

STANDARD LIMITED PRODUCT WARRANTY

The warranty information provided in this section is applicable only to products purchased from ACP, directly or through an authorized dealer. This section does not apply to leased products. The terms of maintenance and repair of any leased products are detailed in the separately executed agreement between the parties.

Warranty Coverage

This warranty provides coverage, for Equipment purchased, against manufacturer's defects in material and workmanship, and extends to the original owner of the product during the warranty period for that product. Only those items returned to the ACP Service Center within the warranty period, and also within thirty (30) days after notification to ACP of the defect, shall be eligible for repair under the Standard Limited Product Warranty. Buyer is responsible for shipping cost associated with sending the Equipment to the ACP Service Center. ACP shall ship Equipment to Buyer after repair at no cost to the Buyer provided repair is deemed to be under warranty. ACP may, at its discretion and only for valid warranty claim, repair or replace any part(s) that prove to be defective during the warranty period.

Warranty Exclusion

Any and all warranty coverage will be void if any of the following have occurred:

1. The product contains repairs or replacement parts not furnished by ACP.
2. The product is damaged resulting from misuse or negligence.
3. The product has been tampered with and/or altered, including serial number alteration.
4. The product was used with accessories and/or supplies, including electrodes, not approved by ACP for use with the product.

Warranty Period

The following coverage is provided at no additional cost to the Buyer:

New Equipment / Product – Products purchased as new from ACP are warranted against manufacturer's defects in material and workmanship for a period of one (1) year from the date of purchase.

Refurbished Equipment / Product – Products purchased specifically as Refurbished Equipment are warranted against manufacturer's defects in material and workmanship for a period of six (6) months from the date of purchase.

Accessories – All accessories for ACP equipment / products are warranted against manufacturer's defects in material and workmanship for a period of three (3) months from the date of purchase.

Warranty Validation

The following information needs to be provided to the ACP Customer Support representative prior to the product being returned under warranty coverage:

1. Buyer name or account number as it appears under the "Bill TO" on the dealer invoice.
2. Invoice Date and Number.
3. Model number, description, and serial number of equipment.
4. Detailed description of the problem.

Return of Defective Equipment

Any Equipment returned to the ACP Service Center under warranty coverage must have the Warranty coverage validated and must receive authorization from ACP Customer Support prior to being received at the Service Center.

Shipping charges, insurance, and any other costs incurred in sending product to ACP Service Center is the responsibility of the customer and will not be refunded. ACP shall cover the shipping charges and related costs to return the unit to the customer, provided repair is deemed to be under warranty.

ACP is not responsible for any loss or damage to the Equipment prior to receipt at the ACP Service Center. Equipment returned for warranty service must be shipped complete with all accessories (except for manuals), in its original packing or equivalent so as not to be damaged while in transit.

NOTE: *Any Equipment sent to the ACP Service Center that is not covered by the ACP Limited Product Warranty is subject to a minimum service and handling fee.*

IMPORTANT:

DO NOT SHIP THE EQUIPMENT TO ACP SERVICE CENTER WITHOUT FIRST SECURING AUTHORIZATION TO DO SO. PLEASE CALL CUSTOMER SERVICE AT (800) 350-1100 FOR AUTHORIZATION. EQUIPMENT SENT IN WITHOUT AUTHORIZATION FROM ACP CUSTOMER SUPPORT WILL NOT BE ACCEPTED.

RETURNED MATERIALS ADDRESS:

Accelerated Care Plus Leasing Attn: ACP Service Center
4999 Aircenter Circle, Suite 103
Reno, NV 89502
Phone: 800.350.1100
Fax: 800.350.1102
Email: customersupport@acplus.com
Internet: www.acplus.com

MANUFACTURER:

OmniStand®
Medica Medizintechnik GmbH Blumenweg 8
88454 Hochdorf, Germany
Phone: +49 7355-93 14-0
Fax: +49 7355-93 14-15
E-mail: info@thera-trainer.de
Internet: www.thera-trainer.de

The manufacturer hereby declares that the OmniStand® complies with Regulation (EU) 2017/745. The full text of the EU Declaration of Conformity and further declarations of conformity are available at the following Internet address: www.acplus.com.