

Instructions for Use

Skywalk Clinic Adult 1.0

UDI-DI: 7649988134111

Language: EN

Version: V1

Date of issue: 2026-09-16

Skywalk Clinic Adult 1.0 is in conformity with Regulation (EU) 2017/745 on medical devices (MDR).

Please read all instructions before use.



automyo USA LLC
325 Sentry Parkway
Blue Bell PA, 19422
USA

Contents

1	Abbreviations and Definitions of Terms	4
2	Intended Use	4
3	Indications	4
4	Contraindications	4
5	Intended Users	4
6	Use Environment	5
7	Warnings and Precautions	6
7.1	Warnings	6
7.2	Precautions	6
7.2.1	Mechanical safety	6
7.2.2	Harness and user contact	6
7.2.3	Inspection and maintenance	6
7.2.4	Mobility	7
8	Overview of Operating Elements, Components and Setup	7
8.1	Structural Support Assembly	8
8.2	Suspension Module	9
8.2.1	Adjustable support	10
8.2.2	Safety limitation system	10
8.2.3	Suspension set	11
8.2.4	Harness system	11
8.3	Handrails	11
8.4	Mobility	11
9	Facilities and Supervision	11
10	Operating Instructions	12
10.1	Pre-Use Checks	12
10.2	Preparation and Setup	12
10.2.1	Positioning of the Device	12
10.2.2	Harness Installation	12
10.2.3	Connection to the Suspension System	13
10.3	Adjustment of the Suspension System	14
10.4	Operating Procedure	16
10.5	End-of-Use Procedure	17
10.6	Post-Up Inspection	17
10.7	Emergency Procedures	17
10.7.1	Quick-Release Mechanism	17
11	Clinical Benefits	18

12	Cleaning and Disinfection	18
13	Residual Risks and Side Effects	18
13.1	Residual Risks	18
13.2	Side Effects	19
13.3	Benefit-Risk Consideration	19
14	Preventive Maintenance	20
14.1	Inspection Before Each Use	20
14.2	Periodic Maintenance	20
14.3	Maintenance Responsibility	21
15	Storage and Operating Conditions	21
16	Lifetime	21
17	Disposal	21
17.1	Safety Precautions for Disposal	22
17.2	Contaminated Devices	22
17.3	Material Separation	22
17.4	Responsibility	22
18	Support Information	22
19	Symbols Glossary	23

1 Abbreviations and Definitions of Terms

HCP	Healthcare professional
MMT	Manual muscle testing

2 Intended Use

Skywalk Clinic Adult 1.0 is a medical device in the family of bodyweight support devices. It allows people with limited standing and walking ability, limited balance control, or with load limitation measures on the lower body to safely perform rehabilitation exercises under the supervision of a physical therapist or other clinicians.

3 Indications

Skywalk Clinic Adult 1.0 is indicated for any condition requiring rehabilitation exercises with body weight support.

Examples for such indications are:

- Stroke
- Cerebellar ataxia
- Multiple sclerosis
- Patients following an orthopedic injury
- Surgery with load limitation measures or risk of falls

4 Contraindications

Other than the limitations on weight and height, there are no general contraindications. Treating HCPs have to check whether the physical and mental status of the patient allows treatment with the device.

5 Intended Users

Skywalk Clinic Adult 1.0 is intended to be used by professionals including physical therapists, occupational therapists, nurses, adapted(adaptive) training coaches or other clinicians.

Skywalk Clinic Adult 1.0 is intended to support body weight in patients with limited standing and / or walking abilities, limited balance control or with load limitation measures on the lower body. Through this, it is intended to allow rehabilitation exercises under the supervision of a physical therapist or other clinicians.

The device is intended for:

- Male and female patients
- Patients skeletally mature
- Patient weights between 100 lbs / 45 kg and 550 lbs / 250 kg
- Patient measures between 5 ft / 152 cm and 7 ft / 213 cm

Doctor must assess the patient ability to use the device.

6 Use Environment

Skywalk Clinic Adult 1.0 is intended to be used in **standard clinical and rehabilitation environments**, including:

- Physiotherapy facilities
- Hospital rehabilitation departments
- Outpatient rehabilitation clinics
- Nursing homes and long-term care centers
- Specialized rehabilitation centers

The following environmental conditions and constraints apply:

- Hygienic conditions
 - Non-sterile environment
 - Hand-contact surfaces (e.g., handles) are disinfectable with standard clinical disinfectants
 - Harness worn over regular clothing; no direct skin contact required
 - Cleaning between users following facility hygiene protocols
- Ambient conditions
 - Operating temperature approximately +10°C to +35°C
 - Storage temperature approximately 0°C to +40°C
 - Relative humidity 20–80%, non-condensing
- Lighting and noise
 - Suitable for typical indoor clinical lighting conditions
 - Unaffected by normal hospital noise levels
- Electromagnetic environment
 - Non-powered device, not sensitive to electromagnetic disturbances
 - Incompatible with standard hospital EM environments
- Space and installation requirements
 - Requires a stable indoor floor surface
 - Requires sufficient space around the device for patient movement and clinician access
 - Intended for use under professional clinical supervision
- Frequency and mode of use
 - Designed for repeated daily clinical use
 - Components in contact with users can be cleaned quickly between sessions
- Transport and storage
 - Can be moved within the clinical facility (room-to-room)
 - Not intended for outdoor transport or mobile medical units
 - Must be stored indoors in clean, dry conditions
- Personal protective equipment
 - Standard clinical PPE (e.g., gloves) according to facility protocols
 - No additional PPE required

7 Warnings and Precautions

7.1 Warnings

- Do not use the device without supervision by a qualified healthcare professional (HCP).
- Do not use the device if your weight exceeds **250 kg (550 lbs)**.
- Do not use the device if your height exceeds **213 cm (7 ft)**.
- Keep the neck and head away from elastics, ropes, and harness loops.
- Never place loops around the neck.
- Do not use the device near water, in wet environments, or on conductive surfaces.
- Keep the device away from electrical sources.
- Ensure the device and surrounding environment are dry before use.
- Disinfect all contact surfaces before and after each use.
- Do not use the device if surfaces are contaminated or damaged.
- Do not use the device on open wounds without appropriate protection.
- Do not use on stairs, slopes, uneven, or slippery surfaces.
- Use only on stable, flat, and dry ground.
- Do not use the device if any component is damaged, worn, or missing.

7.2 Precautions

- Ensure proper balance before starting exercises.
- Enter and exit the device slowly and with support (e.g. handrails).
- Do not exceed intended loads or exercise limits.
- Do not adjust elastics without qualified supervision.
- Verify device stability before each use.
- Ensure sufficient clearance around the device.

7.2.1 Mechanical safety

- Keep hands, fingers, and body parts away from:
- Moving parts (handles, pulleys)
- Narrow gaps between components
- Avoid contact with sharp edges, even if protected.
- Keep clear of elastics under tension (risk of snap-back).

7.2.2 Harness and user contact

- Adjust the harness properly before use.
- Avoid excessive friction or pressure on the skin.
- Stop use immediately if irritation, pain, or discomfort occurs.

7.2.3 Inspection and maintenance

- Inspect the device before each use, including:
- Elastics (wear, cracks)
- Harness (fraying, stitching integrity)

- Structure (deformation, cracks, corrosion)
- Suspension system (ropes, pulleys, attachment points)
- Do not use the device if any damage is detected.
- Perform periodic inspection and maintenance (at least annually).

7.2.4 Mobility

- Move the device slowly and with care.
- Keep feet and hands away from wheels during movement.
- Ensure the device is properly positioned and locked before entering or using it.

8 Overview of Operating Elements, Components and Setup

Skywalk Clinic Adult 1.0 consists of a mobile support frame equipped with an integrated dynamic suspension system that partially supports the user's body weight during gait activities. The system includes:

- **Structural support assembly:** Height-adjustable aluminum frame with four lockable castor wheels for mobility and stability.
- **Suspension module:** Adaptive harness connection with elastic to provide body weight support during walking.
- **Adjustable support:** The support can be adapted based on the number of elastic ropes that the user puts under tension.
- **Safety limitation system:** Fail-safe braking system, and load-bearing components.
- **Handrails:** The structure is equipped with two handrails that can be blocked horizontally (when in use), or set vertically, when it is not used, and it restricts the movements of any user.
- **Mobility:** The device is moved around by the active effort of the user(s). External users (e.g. HCPs) can help move the device to ease the patient's experience.

The device operates as a non-powered mechanical aid and does not perform automated control of patient movement.

The system supports part of the user's body weight via a mechanical suspension, reducing load on the lower limbs while maintaining upright posture and dynamic balance. It is also equipped with a fall stop that prevents the user from getting lower than a certain position. This facilitates repetitive, task-oriented gait training while minimizing risk of falls or injury.

In the following sections, information is provided on the different components of the device. Numbering refers to Figs.1,2.

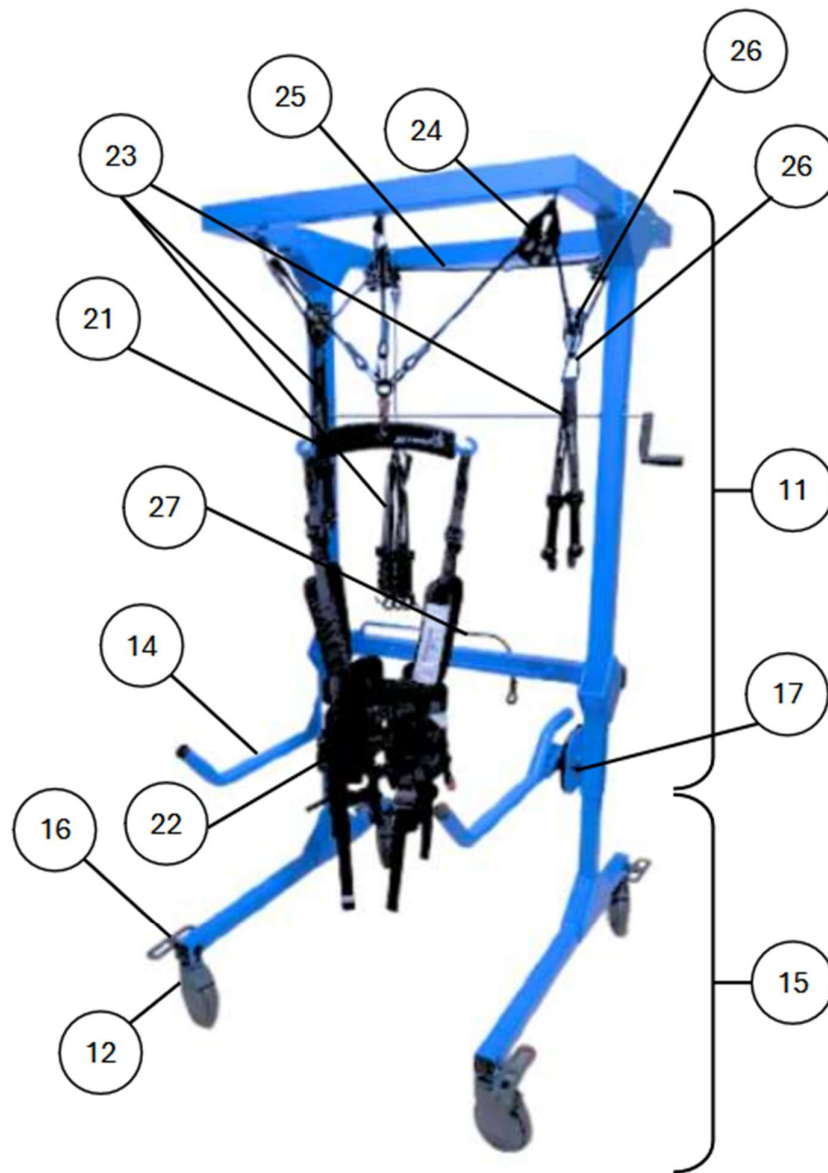


Figure 1: Overview of the Skywalk Clinic Adult 1.0 with reference numbers.

8.1 Structural Support Assembly

The structural support assembly forms the primary load-bearing structure of the device. It includes:

- **Upper structure (11):** Telescopic columns enabling height adjustment. Equipped with anchoring points for pulleys and elastic elements, and with foldable hand bars (14) featuring locking positions.
- **Lower structures (15):** Base frame providing stability. Equipped with four castor wheels (12) offering free-rolling, directional lock, and full lock/brake modes via pedals (16).

Functionality: Provides a stable and mobile platform for the suspension set, ensures correct vertical alignment of the user, and allows maneuverability during therapy. The hand bars assist with balance and transitions.

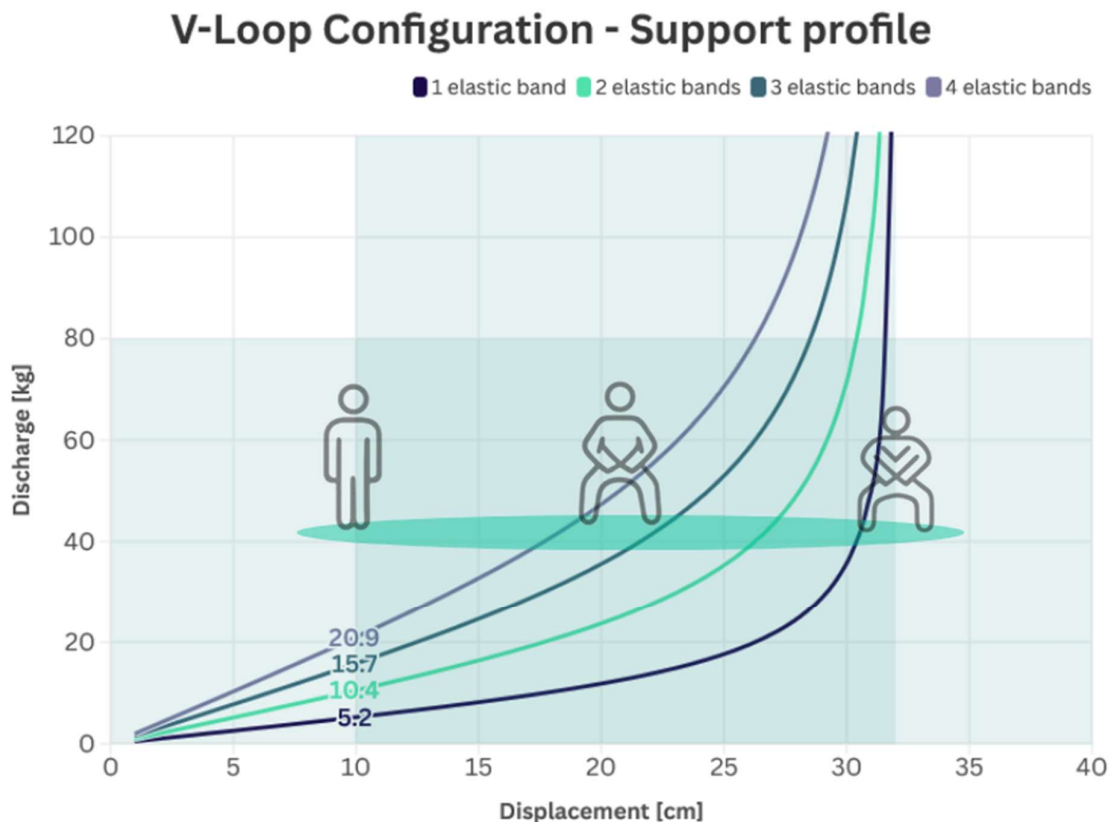
8.2 Suspension Module

Skywalk Clinic Adult 1.0 incorporates multiple rope-and-pulley configurations to achieve different mechanical behaviors. Components include:

- Fixed pulleys (24) mounted on the upper structure
- Free pulleys (23) used in the V-loop configuration
- Ropes (25) routed through pulleys and secured with bowline knots
- Rigid rope segment (27) for the variable stop configuration

Functionality: Redirects forces to achieve the desired support profile. Enables the following configurations (Fig.2):

- **V-loop:** non-linear support with built-in mechanical stop
- **Direct:** linear support proportional to elastic elongation



Direct Configuration - Support profiles

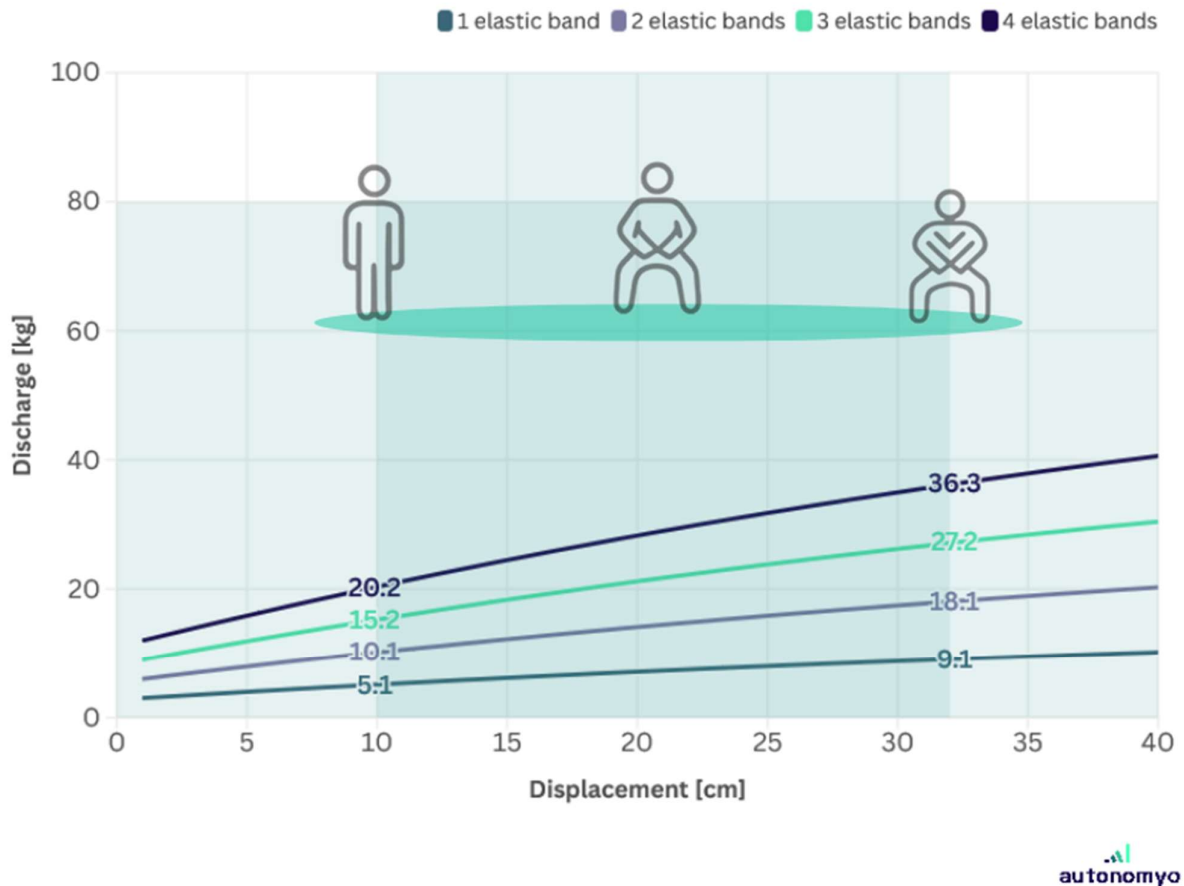


Figure 2: Schematic Overview of the support profile depending on configurations: V-Loop (Top), Direct Configuration (Bottom)

8.2.1 Adjustable support

Elastic (23) elements are closed-loop elastics equipped with carabiner and handles interfaces. The stiffness level available is 20 kg at 100% elongation.

Functionality: Provide dynamic body-weight support. Allow fine adjustment of unloading by adding or removing elastic elements. Absorb movement and ensure smooth vertical assistance.

8.2.2 Safety limitation system

The device incorporates passive mechanical safety features, including:

- Rope (25) length defining maximum downward travel
- Optional rigid rope segment (27) for variable stop
- Knot-based stop for the Direct configuration

Functionality: Prevents the user from reaching the ground. Ensures predictable and safe limits of motion without requiring electronic control.

8.2.3 Suspension set

The suspension set connects the user to the support system and transmits vertical unloading forces. It includes:

- **Hanger bar (21):** Freely rotating via a vertical pivot joint, enabling natural transverse-plane rotation.
- **Carabiners (26):** Standardized connectors enabling secure and rapid attachment of ropes and elastic elements.

Functionality: Ensures safe load transfer to the user, allows rotational freedom, and provides a modular interface for different support configurations

8.2.4 Harness system

The harness (22) is a wearable component that interfaces directly with the user's body. It includes:

- Adjustable torso belt
- Pelvic support structure
- Two leg straps passing under the pelvis
- Multiple size options

Functionality: Secures the user within the device, distributes vertical loads across the trunk, pelvis, and upper thighs, and prevents slipping or unsafe postures during unloading.

8.3 Handrails

Handrails (14) are mounted on a tilting mechanism activated via a locking pin (17). Two positions are configured: vertical, if needed for use of the device and horizontal, in case of unuse.

8.4 Mobility

The device is mounted on four swivel castors (15). Each castor can be locked in directionality (green pedal (16) side) to ensure easier guiding of the system's mobility. Each castor can also be locked to ensure a full locked system (red pedal (16) side).

9 Facilities and Supervision

The device is intended to be used under the supervision of a qualified HCP with appropriate training in patient handling and rehabilitation practices.

Users must be adequately instructed on the correct use of the device, including:

- safe entry and exit procedures
- correct adjustment of harness and elastics
- recognition of unsafe conditions

No specific installation facilities are required. However, the device must be used in an environment that meets the conditions described in these Instructions for Use, including:

- sufficient space around and clearance above the device
- a stable, flat, and dry floor
- adequate lighting to ensure safe operation

The responsible organization must ensure that all personnel involved in the use, maintenance, and supervision of the device are appropriately trained and familiar with the instructions provided in this manual.

10 Operating Instructions

10.1 Pre-Use Checks

Before each use, the operator shall perform the following checks:

- Ensure the structural frame is stable and free from visible damage.
- Verify that all wheels are in good condition and that brakes (if present) are engaged.
- Inspect the suspension system, including:
 - ropes and cables (no fraying, cuts, or wear)
 - pulleys (smooth rotation, no obstruction)
 - carabiners and connectors (proper closure and no deformation)
- Check the harness for:
 - integrity of straps and stitching
 - proper functioning of buckles and fasteners
- Confirm that the maximum allowable load is not exceeded.
- Ensure the environment is safe:
 - flat and stable floor
 - no obstacles around the device

Do not use the device if any component is damaged or malfunctioned.

10.2 Preparation and Setup

10.2.1 Positioning of the Device

- Place the device on a flat, stable surface.
- Ensure sufficient space around the device for safe operation.
- Set the appropriate height of the suspension system for the user's height via the crank. The hanger bar should be above the user's head (Fig.5).
- Engage the wheel brakes.
- It is possible to move the brake pedal either internal or external to the device (Fig.7).
- Handrails can be used in any comfortable position.

10.2.2 Harness Installation

- Position the harness on the user, ensuring good fit on thigh straps (3).
- Adjust all straps to ensure a secure and comfortable fit (1,2).
- Ensure the harness is properly aligned with the user's body.

It is also possible to attach the harness directly to the user while it is suspended in the device.



Figure 3: Skywalk Clinic Adult 1.0 harness and its straps.

10.2.3 Connection to the Suspension System

- Attach the harness to the hanger bar using the designated attachment points (Fig.4).
- Ensure all carabiners are fully closed and locked.
- Verify that the load is evenly distributed across all suspension points.



Figure 4: Attachment of the hanger bar (Left) and attachment of the harness on the hanger bar (Right)

10.3 Adjustment of the Suspension System

Adjust the system according to the user's needs:

- Use two hands to adjust the elastic bands.
- Gradually apply tension to the suspension system to partially support the user's weight.
- Adjust the elastic amount to achieve the desired level of weight support (Fig. 6).
- Ensure the correct alignment and balance of the user within the device.
- The variable stop can be activated by pulling the designated rope or deactivated by disengaging it (Fig.8).

All adjustments shall be performed gradually and under supervision.

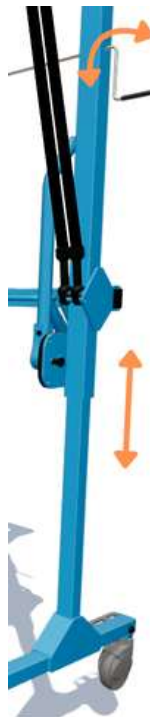


Figure 5: Height adjustment system via the crank.



Figure 6: Setup of elastics

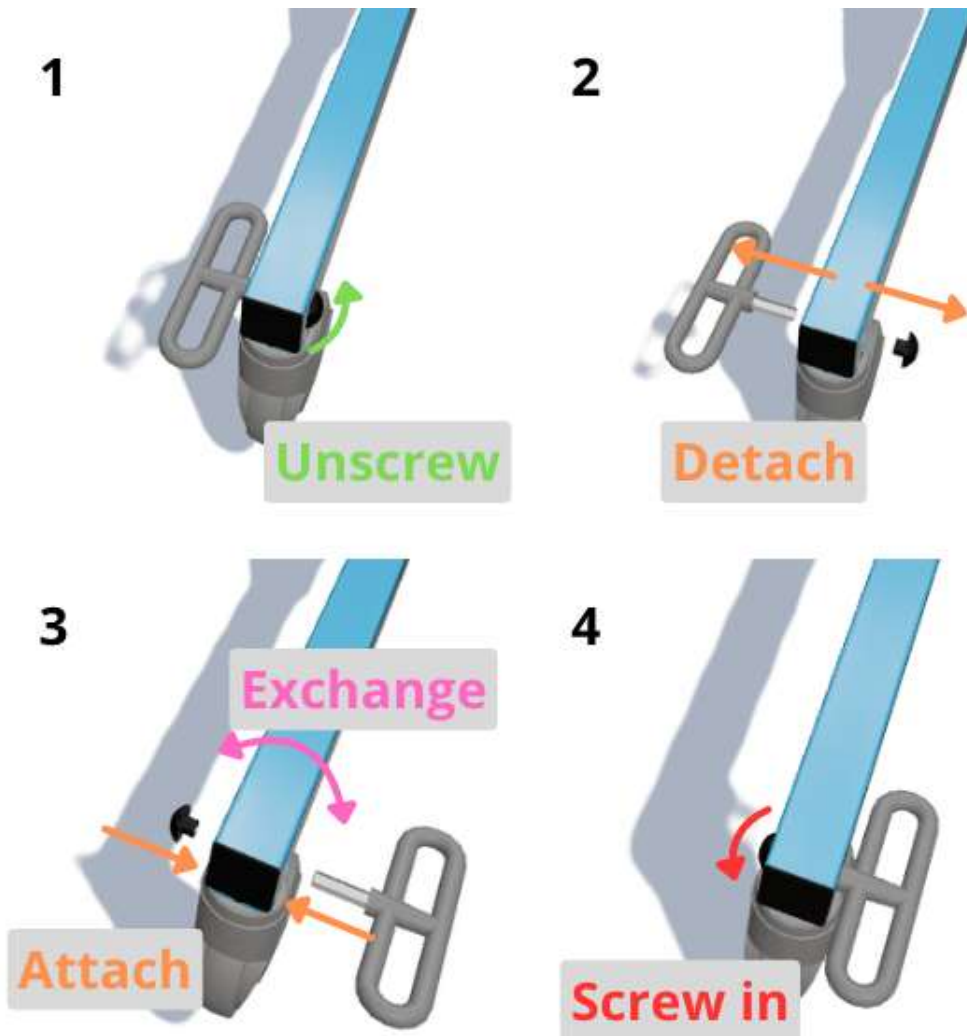


Figure 7: Shifting brake pedal position procedure.

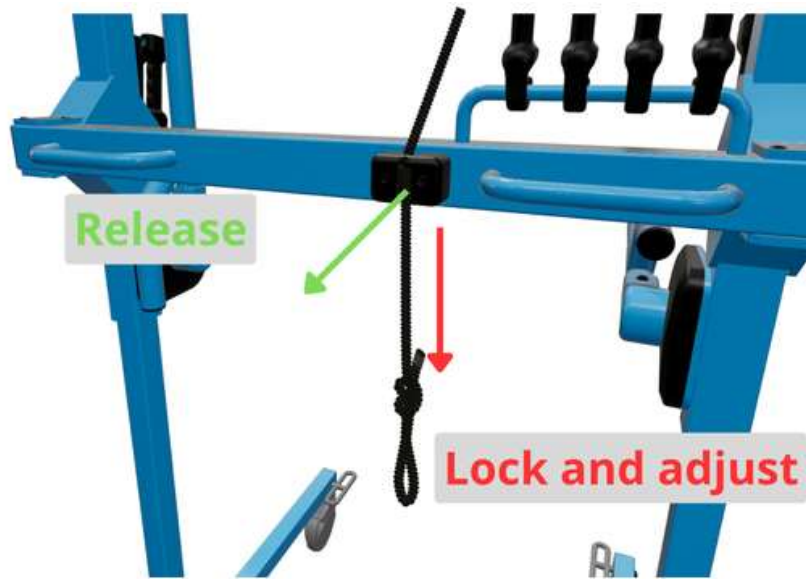


Figure 8: Variable stop mechanism.

10.4 Operating Procedure

- Confirm that the user is stable and properly positioned.
- Begin the intended activity (e.g., standing, walking, or therapeutic exercises).
- If required, the handrails can be raised to avoid their use (Fig.9).
- Continuously monitor:
 - User posture
 - Stability
 - Comfort and safety

The user must never be left unattended while supported by the device.

If any abnormal condition occurs (discomfort, instability, unusual noise), stop the operation immediately.

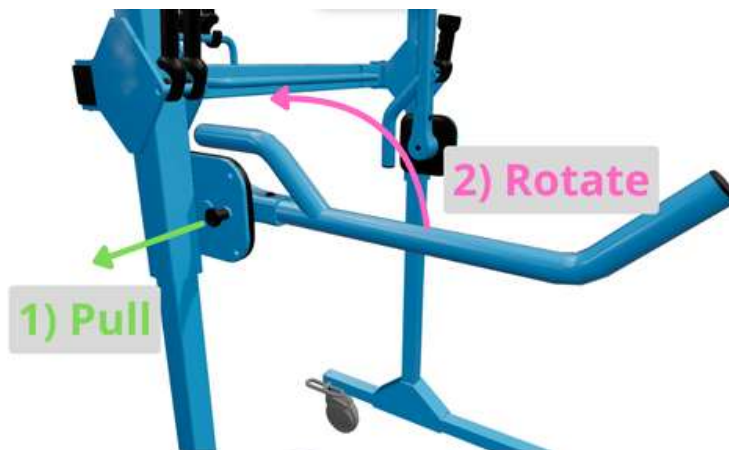


Figure 9: Handrail lifting mechanism.

10.5 End-of-Use Procedure

- Secure the device by locking the brakes to prevent unintended movement.
- Gradually release the tension from the suspension system (using two hands).
- Safely return the user to a fully supported standing or seated position.
- Disconnect the harness from the suspension system or the user from the harness.
- Remove the harness from the user.
- Cleaning procedure must be performed.

10.6 Post-Up Inspection

After each use:

- Inspect all components for signs of wear or damage.
- Check ropes, pulleys, and connectors for proper condition.
- Verify that the harness remains in good condition.
- Report and address any defects before the next use.

10.7 Emergency Procedures

In case of emergency:

- Immediately stop the activity.
- Ask for assistance.
- Bring the patient in a safe and stable position.
- Gradually release tension from the suspension system.
- Safely remove the user from the device using the quick-release mechanism.

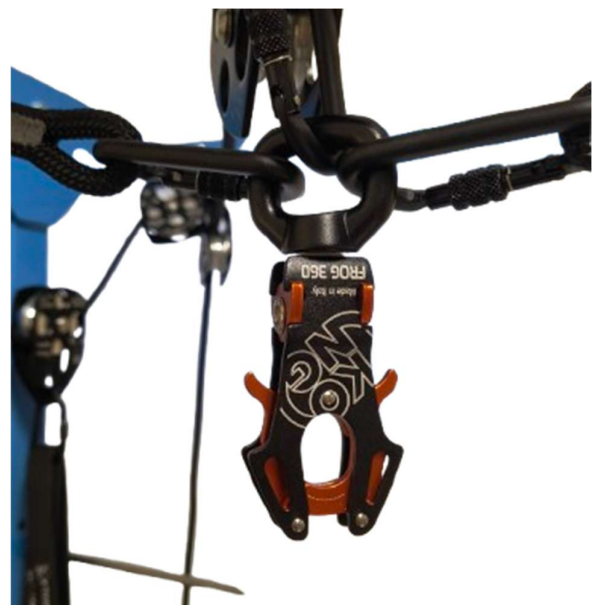
10.7.1 Quick-Release Mechanism

The quick-release mechanism is composed of a special carabiner named Frog 360. This mechanism allows only two stable positions: open or closed (Fig.4).



Figure 10: Frog 360 in open position (Left) and closed position (Right)

Do not load the quick-release mechanism to open it.



11 Clinical Benefits

- *Skywalk Clinic Adult 1.0* is able to support the body weight of patients sufficiently and dynamically to allow safe execution of therapeutic exercises.
- Support level is modulated through seven (7) elastic bands, enabling a continuous range from minimal (10 lbs (4.5 kg)) to maximal (150 lbs (68 kg)) assistance.
- The support force profile increases progressively from standing (low support) to sitting (high support).

12 Cleaning and Disinfection

The device must be cleaned and disinfected regularly to reduce the risk of contamination and ensure safe use. Cleaning and disinfection shall be performed **before and after each use**, or immediately if contamination is suspected.

Visible dirt should be removed using a soft cloth and a mild cleaning agent compatible with the device materials. All surfaces in contact with the user (e.g. harness, handles, and structural contact areas) must then be disinfected using an appropriate medical-grade disinfectant.

Recommended disinfectants: quaternary-ammonium-based disinfectant wipes or spray, or accelerated hydrogen peroxide (AHP, 0.5–1.4%) disinfectant, applied per the product's instructions for use and contact time. 70% isopropyl alcohol may be used for occasional spot-cleaning but is not recommended for routine, repeated disinfection, as prolonged exposure may gradually affect the surface finish.

Do not use sodium hypochlorite (bleach) or other chlorine-releasing agents, strong solvents (e.g. acetone, methyl ethyl ketone, xylene), phenolic disinfectants, or abrasive cleaning products: these may discolor or degrade the surface coating and promote corrosion of the aluminum frame.

After cleaning and disinfection, all components must be allowed to dry completely before reusing. The device must not be immersed in water or exposed to excessive moisture, as this may lead to material degradation or increased safety risks.

Only cleaning and disinfection agents compatible with the device materials (e.g. metals, plastics, textiles) shall be used. The use of unsuitable products may damage the device and compromise its performance and safety.

Appropriate personal protective equipment (e.g. gloves) should be worn when handling contaminated devices. After cleaning, the device should be inspected for any signs of damage, wear, or degradation.

The device must not be used if any abnormal condition is identified.

13 Residual Risks and Side Effects

13.1 Residual Risks

Despite the implementation of risk control measures, residual risks remain associated with the use of the device. These risks have been evaluated and are considered acceptable when the device is used in accordance with its intended purpose and the instructions provided in this manual.

Residual risks include:

- **Risk of falls**
Loss of balance may occur during use, or when entering or exiting the device, potentially resulting in injuries such as bruises, sprains, fractures, or, in rare cases, head trauma.
- **Mechanical interaction risks**
Contact with moving parts, elastics under tension, or narrow gaps may still lead to pinching, contusions, or minor injuries despite protective measures.
- **Mechanical failure risks**
Although reduced through design controls and maintenance instructions, unexpected failure of components (e.g. elastics, structure, harness, or suspension system) may still occur and could lead to loss of support or injury.
- **Entrapment risks**
There remains a residual risk of body parts becoming trapped in certain areas of the device, particularly in cases of improper use.
- **Infection risk**
Insufficient cleaning and disinfection may result in contamination and risk of infection.
- **Environmental risks**
Use of the device in unsuitable environments (e.g. uneven, unstable, stairs, or slippery surfaces) may increase the risk of device instability or user injury.
- **Emergency situations**
In rare cases, difficulty in exiting the device during an emergency may occur despite the presence of a quick-release system.
- **Electrical hazard**
Improper use in environments involving water or electrical sources may result in a risk of electric shock.

13.2 Side Effects

The following side effects may occur during or following use of the device:

- Skin irritation, redness, or pressure marks
- Superficial abrasions or minor bruise
- Discomfort or pain due to improper adjustment or excessive load
- Muscle soreness or joint strain related to physical activity
- Localized impact effects caused by contact with elastics or moving components

13.3 Benefit-Risk Consideration

The residual risks associated with the device are considered acceptable when weighed against the expected benefits, provided that the device is used as intended, and all warnings and precautions described in these Instructions for Use are followed.

Users must be informed of the residual risks and possible side effects prior to use.

14 Preventive Maintenance

Regular preventive maintenance is essential to ensure safe and effective operation of the device throughout its lifetime.

The responsible personnel must perform routine inspections and maintenance as described in this section. The device must not be used if any defects or damages are identified.

14.1 Inspection Before Each Use

Before each use, visually and functionally inspect the device, including:

- **Elastics:** Check for cracks, wear, loss of elasticity, or deformation
- **Harness:** Inspect for fraying, worn fabric, or damaged stitching
- **Structure:** Check for cracks, bending, deformation, or corrosion
- **Suspension system:** Inspect ropes, pulleys, and attachment points for wear or damage
- **General condition:** Ensure all components are properly assembled and secured

14.2 Periodic Maintenance

Note: Before any maintenance activity, you should clean the device to remove any risk of contamination.

In addition to pre-use inspection, the following preventive maintenance must be performed regularly:

- **Periodic inspection (at least once per year)**

Complete inspection of all mechanical and structural components

- No wear or crack on the structure
- Telescopic mechanism functionality
- Handrails mechanism functionality
- Wheels integrity
- Braking components integrity and functionality

Verification of stability and integrity of the device

- **Replacement of worn components**

Replace elastics (at least every 6 months)

- Elastics can be ordered by mail at service@autonomyo.com
- Elastics are provided with a service manual

Harness elements

- Replace harness if it is showing signs of wear or degradation
- Harness can be ordered by mail at service@autonomyo.com

Other components showing signs of wear or degradation

- If you have any questions about integrity of the structure, ask our customer service at service@autonomyo.com

- **Verification of moving parts**

Ensure smooth operation of pulleys, joints, and other moving parts by testing in case of use

Check for unusual noise, resistance, or misalignment

Records of periodic maintenance should be kept by the responsible organization.

14.3 Maintenance Responsibility

Maintenance must be performed by:

- The operator, when performing routine inspections
- Trained personnel, for periodic inspection and component replacement

15 Storage and Operating Conditions

The device must be stored within the following temperature range:

- **Temperature: 5 °C to 40 °C**

The device must be stored in a clean and dry environment and protected from conditions that could lead to material degradation. Avoid exposure to:

- Moisture
- Extreme temperatures
- Direct sunlight over prolonged periods of time

Ensure elastics and textile components are not under tension during storage.

16 Lifetime

The expected lifetime of the device is **10 years**.

The lifetime is based on:

- Normal use conditions in accordance with the intended use
- Compliance with all instructions provided in this Instructions for Use
- Regular inspection and preventive maintenance as described in Section 12

The actual lifetime of the device may vary depending on:

- Frequency and intensity of use
- Environmental conditions (e.g. humidity, temperature, cleanliness)
- Proper handling, storage, and maintenance

The device must be removed from service before the end of its expected lifetime if:

- Any structural damage is detected
- Repeated component failures occur
- Signs of excessive wear or degradation are observed
- Safe use can no longer be ensured

17 Disposal

The device, its accessories, and any associated components must be disposed of safely at the end of their lifetime. Dispose the device in accordance with local regulations.

17.1 Safety Precautions for Disposal

To ensure safe disposal, the following precautions must be observed:

- Ensure the device is stable and secured during handling and disassembly
- Wear appropriate personal protective equipment (PPE) (e.g. gloves) when handling the device, especially if damage is present
- Be cautious of:
 - Sharp edges
 - Mechanical components
 - Moving or unstable parts
- Release or remove tensioned components (e.g. elastics) before disposal to prevent sudden recoil or injury

17.2 Contaminated Devices

If the device has been used in a clinical or potentially contaminated environment:

- Clean and disinfect the device prior to disposal
- Handle and dispose of the device in accordance with applicable regulations for potentially contaminated medical devices

17.3 Material Separation

Where applicable:

- Separate materials (e.g. metal, plastic, textile components) to facilitate appropriate disposal or recycling
- Dispose of each material according to applicable local waste management regulations

17.4 Responsibility

The responsible organization is responsible for ensuring that disposal is carried out safely and in compliance with applicable regulations.

18 Support Information

Contact Information Manufacturer:

autonomyo USA LLC
325 Sentry Parkway
Blue Bell PA, 19422
USA

service@autonomyo.com

<https://autonomyo.com>

Note to patient and/or user of the device: Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

19 Symbols Glossary

	Manufacturer
	Catalogue number
	Date of manufacture Format: YYMMDD
	Lot number Format: USYYYYXX
	Serial number Format: XXX
	Instructions for Use
	Unique Device Identifier: (01) is followed by the UDI-DI (11) is followed by the manufacturing date (YYMMDD) (10) is followed by the lot number (USYYYYXX) (21) is followed by the serial number (XXX)
	Temperature limit
	Presence of natural rubber latex
	Rx Only – Use only under prescription
	Body weight

