The Levity.

Walking With You.

User Manual V2.0

2025 – 01 – 30

ORA Medical

Content

Content 1
1. Important Information 2
1.1 Warnings and Safety Notice 2
1.1.1 General Warnings 2
1.1.2 Symbols Glossary 3
1.2 Intended Use 3
1.3 Contraindications 3
1.4 Technical Information 3
2. Initial Levity Set-Up 4
2.1 Box Content 4
2.1.1 Basic Items 4
2.1.2 Optional 4
2.2 Initial Assembly 5
2.2.1 Unfold the Frame 5
2.2.2 Install the Harness 5
2.2.3 Install the Weight-Bearing Module 5
2.2.4 Enjoy your Levity! 5
3. Description of Product 6
3.1 Device Presentation 6
3.1.1 General Description of the Product 6
3.1.2 Principal Components 6
3.1.3 Product Compliance 6
3.2 Operating instructions 7
3.2.1 Frame 7
3.2.2 Casters and Wheels 8
3.2.3 Weight-Bearing Mechanism 9
3.2.4 Harness 11
3.3 Additional components description 14
3.3.1 Weight-Bearing Module 14
3.3.2 Upper Body Backplate Support 14
3.3.3 Lower Body Backplate Support 15
3.3.4 Chest Harness 16
3.3.5 Ankle Prompt 17
3.3.6 Headrest 18
4. Care 20
4.1 Maintenance 20
4.2 Cleaning 20
5. Warranty 20

1. Important Information

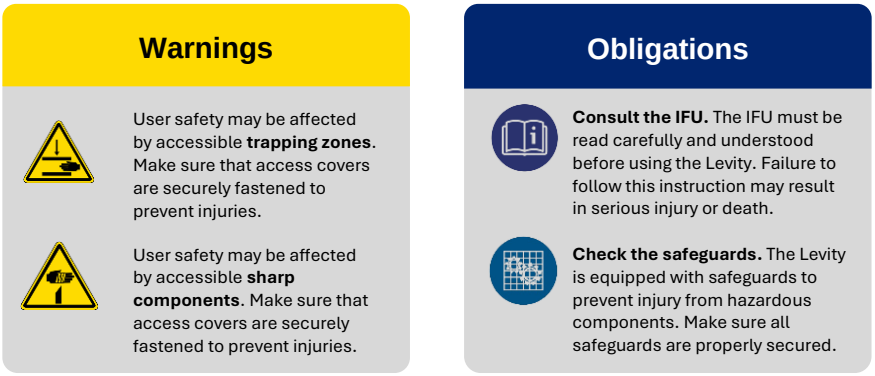
1.1 Warnings and Safety Notice

1.1.1 General Warnings

- Adult supervision is required at all times.
- The device is designed for daily use not exceeding four hours a day.
- The Levity is intended for indoor use only. Do not use the Levity on rough or uneven terrain. Never use the Levity near stairs or swimming pools.
- Users should be dressed when using the device.
- Never use a broken or damaged Levity.
- Any unauthorized modification to the Levity may affect the user's safety and result in serious injury or death.
- The user's weight must be supported by the harness seat only. The harness belt must only prevent the user from losing balance.
- Keep fingers clear of all moving parts when using, folding or adjusting the Levity.
- The selection of the weight-bearing balance module and components such as the lower body support must be made with the help of a professional care giver or health specialist to make sure it's well adjusted to the patient's weight and physical ability.
- When adjusting the harness width, leave at least 2,5 cm (1 inch) of rail when tightening the fasteners. Use the indicator sticker to make sure the harness is sufficiently inserted in the rail.
- The Levity's wheels and carriage brake lever should always be locked when the device is not used and when no weight-bearing module is in place.
- All straps, levers, and other fastening elements must be securely fastened before use or transport.
- Ensure the brakes are locked and no user is installed in the harness before adjusting the weight-bearing mechanism.
- The access cover must be closed at all times with the exception of changing the weight-bearing module.
- For storage and transport ensure the harness is at its highest position and that the harness brakes are engaged. Detach the weight-bearing module and ensure the Levity's wheels are locked.
- Ensure that the straps are sufficiently clear of the user's neck when using the Levity to avoid any risk of strangulation.
- In case of any serious incident that has occurred in relation to the device, the user and/or patient should report the incident to Ora Medical and the Therapeutic Goods Administration or EU competent authority of the Member State in which the user and/or patient is established.

For updated information, please refer to the eIFU at: https://www.oramedical.ca/eifu

1.1.2 Symbols Glossary



1.2 Intended Use

Intended to provide adjustable weight support for people with walking disabilities who lack strength, good balance, or endurance.

1.3 Contraindications

The device might be contraindicated for patients having recent wounds located near the harness area or those who are living with a condition causing irritability of the skin.
Consult your health professional for any contraindication before considering using the device.

1.4 Technical Information

User's Dimensions		Levity's Dimensions	
Min. Waist Size cm (in)	**38 (15)**	**Length** cm (in)	**106 (42)**
Max. Waist Size cm (in)	**84 (33)**	**Width** cm (in)	**68 (27)**
Min. Crotch Height cm (in)	**32 (12.5)**	**Height** cm (in)	**108 (42.5)**
Max. Crotch Height cm (in)	**56 (22)**	**Wheel Diameter** cm (in)	**12.5 (5)**
Min. Armpit Height cm (in)	**60 (23.5)**	**Weight** kg (lbs)	**15 (33)**
Max. Weight kg (lbs) ⚠	**45 (100)**	**Max. Weight Bearing** kg (lbs)	**22 (48.5)**

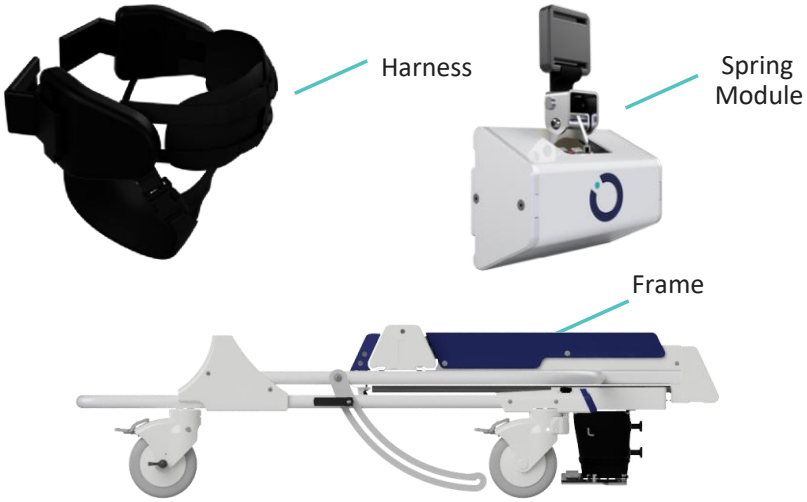
2. Initial Levity Set-Up

Congratulations, your Levity is here!

Please check that all items specified in your order are included in the box. All items are shipped together and are partially assembled. If any component is missing or damaged on arrival, please contact us.

2.1 Box Content

2.1.1 Basic Items



2.1.2 Optional

Upper Body Backplate Support

Lower Body Backplate Support

Chest Harness

Additional Spring Module

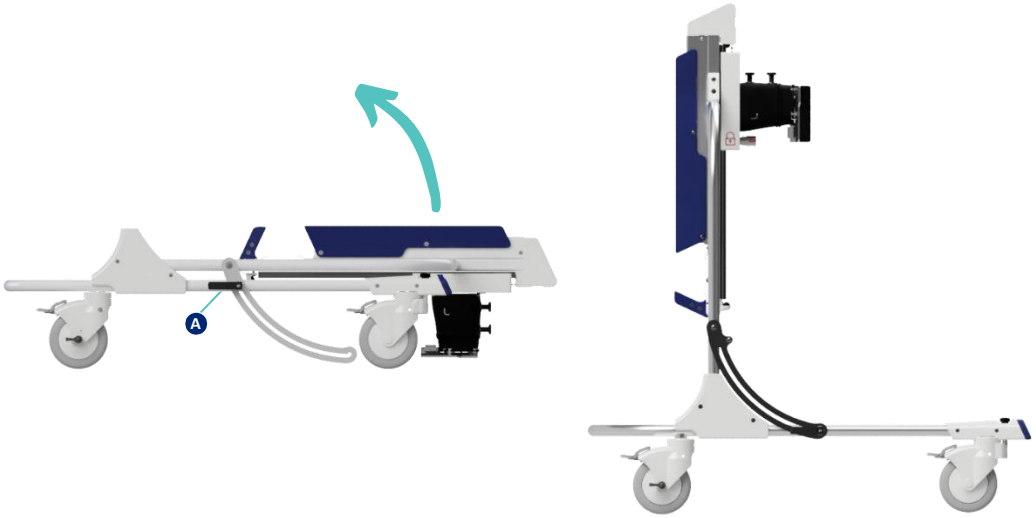
Ankle Prompts

Headrest

2.2 Initial Assembly

2.2.1 Unfold the Frame

1. Release the levers (A) on both sides of the frame.
2. Lift the upper part of the frame while holding down the lower part until the levers on both sides of the frame clip into the safety notches of the metal slides.
3. Tighten both levers (A).



2.2.2 Install the Harness

1. Slide the harness hip pads on both sides of the rail, make sure the harness is untangled.
2. Tighten the adjustment knob to secure the hip pad position.

2.2.3 Install the Weight-Bearing Module

For guidance on installing the weight-bearing module, refer to Section 3.2.3 Weight-Bearing Mechanism.

2.2.4 Enjoy your Levity!

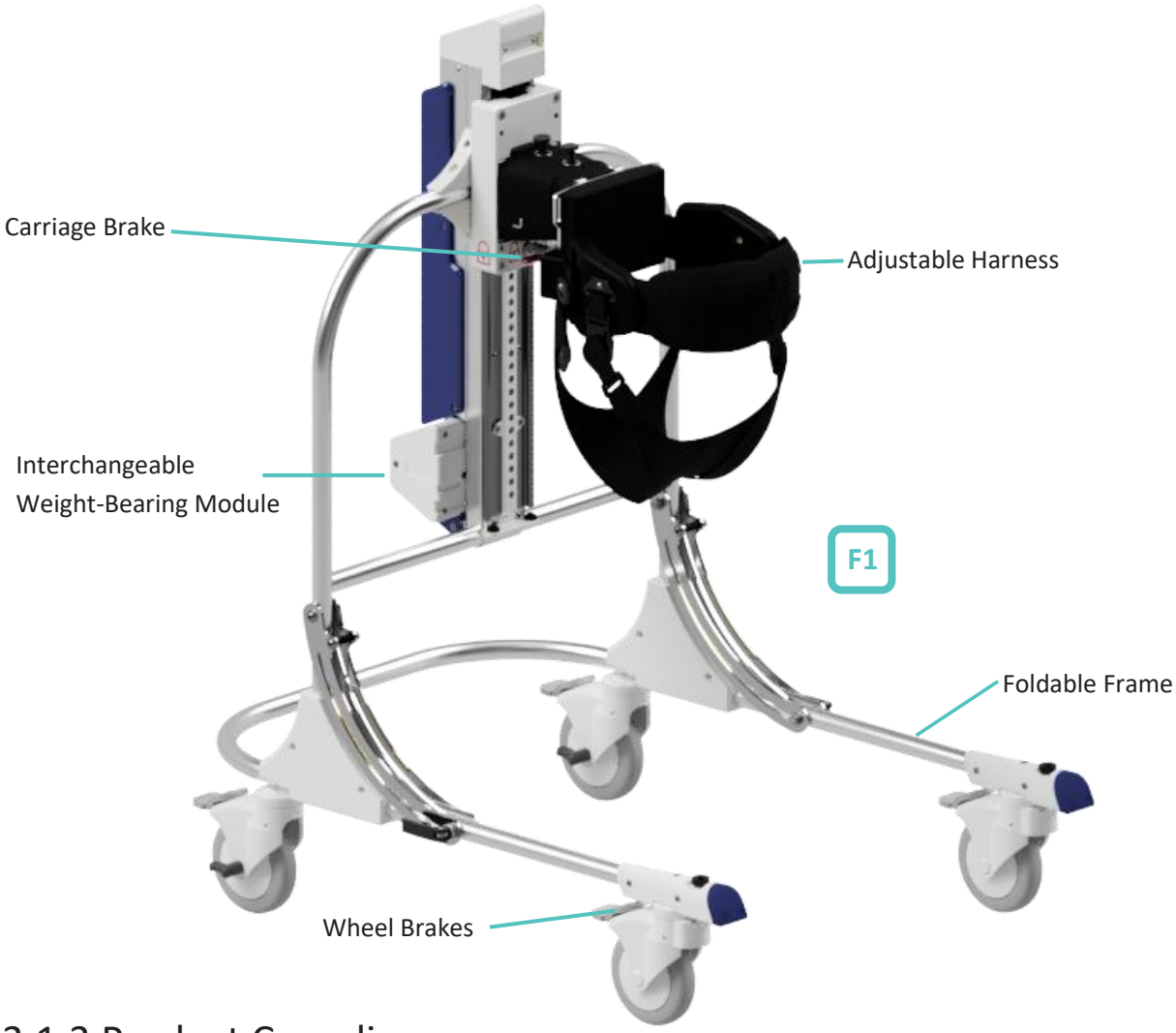
3. Description of Product

3.1 Device Presentation

3.1.1 General Description of the Product

Ora Medical's Levity walking aid is designed to partially or fully support the patient's weight. The weight-bearing mechanism is adjustable according to the user's weight and capabilities to gain the maximum benefit of the system. The adjustable harness allows the user to move with a more natural walking pattern than traditional gait trainers.

3.1.2 Principal Components



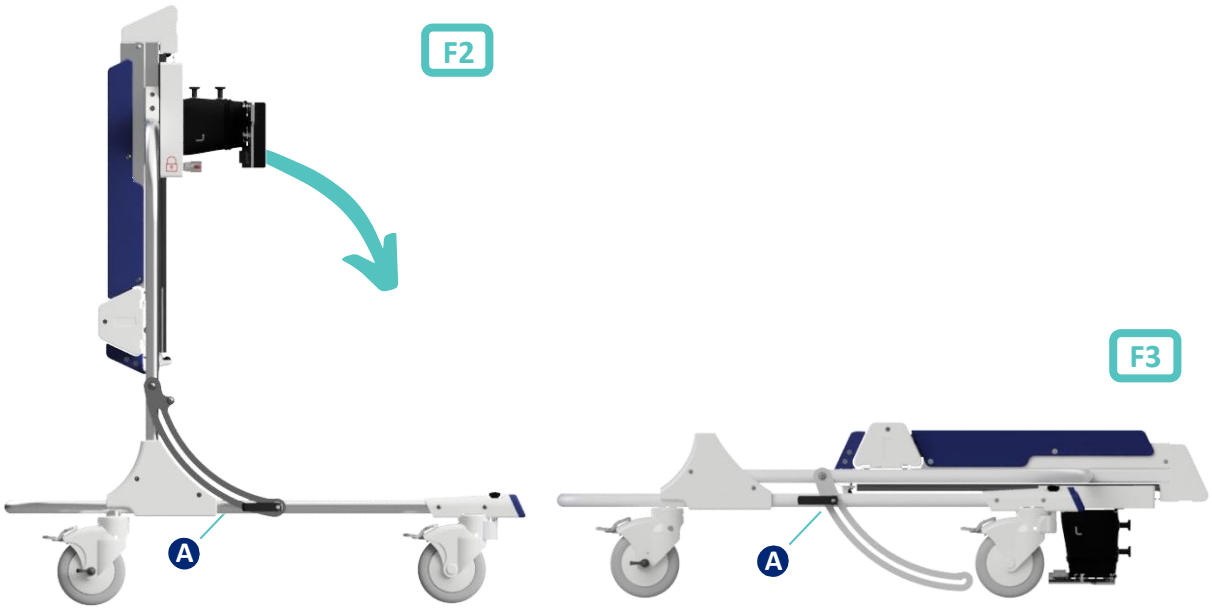
3.1.3 Product Compliance

Ora Medical declares that the Levity gait trainer conforms to applicable class I medical device requirements. All product feedback related to Ora Medical's Levity device, including complaints, should be reported to the manufacturer.

3.2 Operating instructions

3.2.1 Frame

The Levity's frame is made of anodized aluminium for its durability, low weight, and ease of cleaning. The frame can be folded to facilitate transport and storage.



To unfold the Levity into a normal use position (F2)

1. Ensure that all securing levers, knobs, and buckles are engaged to prevent unwanted movement (including the rear wheel brakes and harness brakes).
2. Release the levers (A) on both sides of the frame.
3. Lift the upper part of the frame while holding down the lower part until the levers on both sides of the frame clip into the safety notches of the metal slides.
4. Tighten both levers (A).

To fold the Levity into a transport or storage position (F3)

1. Ensure that all securing levers, knobs, and buckles are engaged to prevent unwanted movement (including the rear wheel brakes and harness brakes).
2. Untighten the levers (A) on both sides of the frame.
3. Lift the metal slides on both sides of the frame out of their notches.
4. Push the upper frame toward the floor.
5. Tighten both levers (A) to prevent unwanted movement in the folded position.

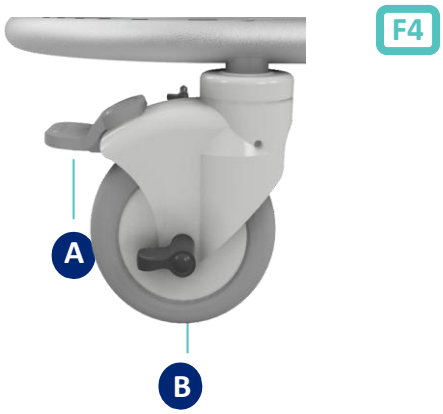
Warnings

- Tighten both handles to prevent unwanted folding of the device.
- Always keep hands and fingers clear of moving parts when folding the device.

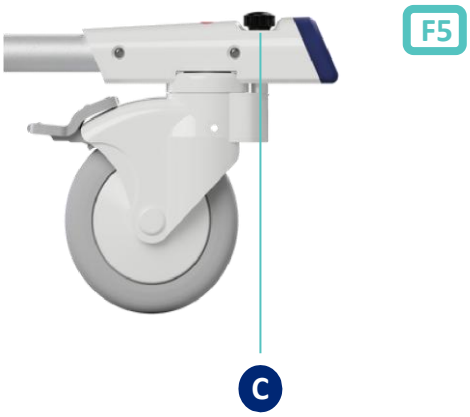
3.2.2 Casters and Wheels

The Levity has two swivel casters in the front and two fixed casters in the back. All wheels are equipped with brakes that are activated by a lever. The rear wheels have adjustments for anti-rollback and drag. The front wheels have adjustments for a partial and complete swivel lock.

Rear Wheels



Front Wheels



Adjustments - Brakes (F4)

To prevent all wheel movement, push down the lower part of the locking levers (A) behind each castor. To release the brakes, press the upper part of the locking levers (A). All four wheels are equipped with brakes to improve accessibility.

Adjustments - Full Swivel Lock (F5)

To prevent any swivel change of the front wheels:

1. Line up both wheels with the frame of the Levity. Ensure that the locking lever (A) faces the back of the Levity.
2. Push the swivel lock knobs (C) completely toward the frame to prevent any swivel movement.

Adjustments - Partial swivel lock (F5)

To limit swivel, allowing for rotation of the front wheels to 15 degrees:

1. Line up both wheels with the frame of the Levity. Ensure that the locking lever (A) faces the back of the Levity.
2. Push both swivel lock knobs (C) until it is halfway inserted to limit the swivel movement.

Adjustments - Wheels' drag (F4)

The adjustable drag knob (B) can be used to put more resistance in the movement of the Levity. Turn the lever clockwise to increase the resistance and counterclockwise to decrease it. Make sure to use the same resistance on both rear wheels.

Warnings

- Ensure the brakes are locked at all times when the Levity is being adjusted, transported or stored.

3.2.3 Weight-Bearing Mechanism

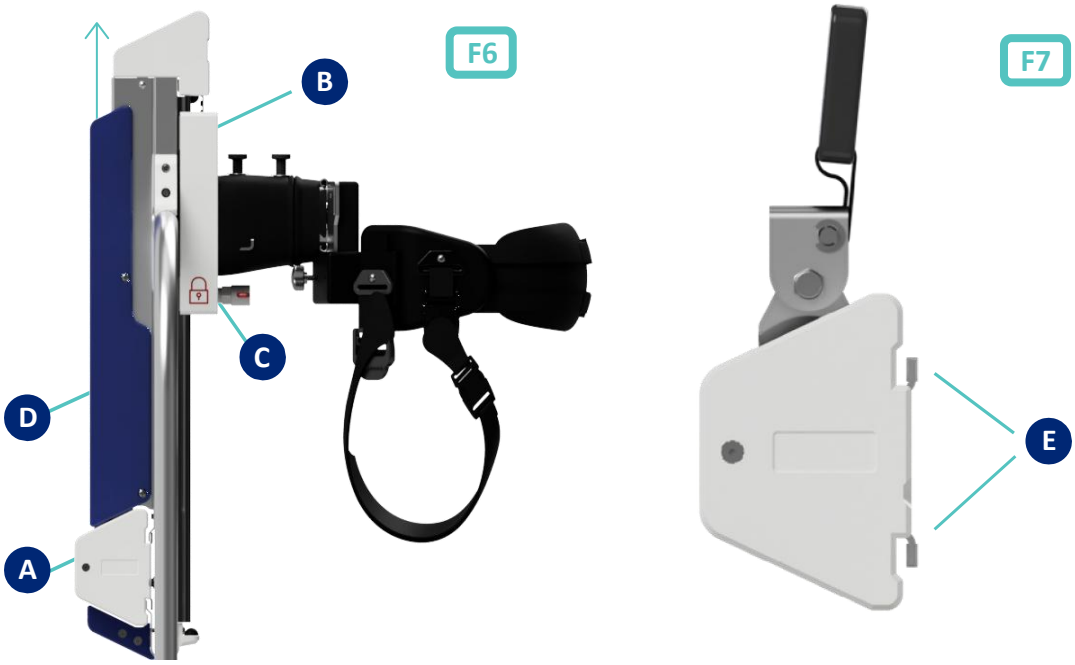
The weight-bearing mechanism partially supports the user's weight with a spring-loaded harness. By changing the weight-bearing module (A), the support given to the user is adjusted. The selection of the proper weight bearing module should be made with the help of a professional caregiver.

Available weight-bearing modules:

8kg (17.5lbs), 10kg (22lbs), 12kg (26.5lbs), 15kg (33lbs), 18kg (39.5lbs) and 22kg (48.5lbs).

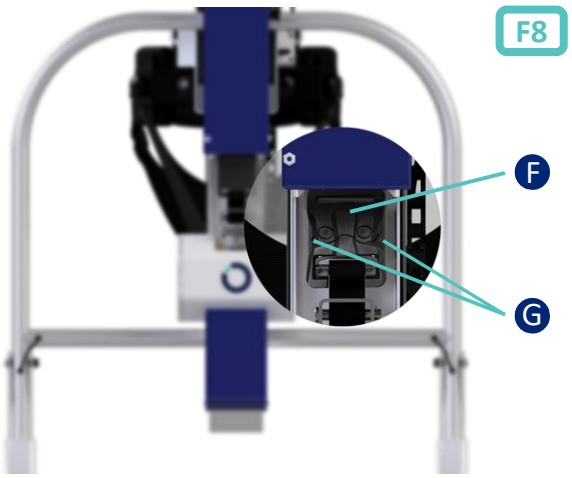
To Install a Weight-Bearing Module (F6, F7 & F8)

1. Ensure all wheels are locked, and no user is installed in the harness before adjusting the weight-bearing mechanism.
2. Lift the harness carriage (B) to its highest position and lock the brake on the carriage (C) to lock the harness in place securely.
3. Lift the access cover (D) until it is at its highest position.
4. Slide module (A) in place. Make sure both tabs (E) are inserted into the sliders of the device.
5. Attach the buckle (F). Make sure the buckle is securely fastened.
6. Lower the access cover until it is at its lowest position.



To Remove a Weight-Bearing Module (F6, F7 & F8)

1. Ensure all wheels are locked, and no user is installed in the harness before adjusting the weight-bearing mechanism.
2. Lift the harness carriage (B) to its highest position and lock the brake (C) on the carriage to lock the harness in place securely.
3. Lift the access cover (D) until it is at its highest position.
4. Detach the module's buckle (F) by pressing the small levers (G) on its sides and slide the module until both tabs (E) are out of the sliders.
5. Lower the access cover until it is at its lowest position.



Warnings

- Ensure that all wheels are locked, and no user is installed in the harness before adjusting the weight-bearing mechanism.
- The carriage brake lever must be securely locked at all times when no weight-bearing module is in place. Failure to do so can result in serious injuries.
- The access cover must be closed at all times with the exception of changing the weight-bearing module.
- Make sure the weight-bearing module is well-adjusted to the patient's weight and physical ability. Always consult a healthcare professional.

3.2.4 Harness

Levity's adjustable and ergonomic harness consists mainly of neoprene to maximize the user's comfort. It presents two degrees of freedom (obliquity and rotation) to allow the user to walk naturally. The waist size can be adjusted. Two distinct sizes of harnesses are available to ensure comfort for all users.

Belt - User dimensions			
Belt size	Age (approx.)	Waist size *(cm(in))*	Max Weight *(kg (lbs))*
Small	2 to 6	38 (15) to 64 (25)	45 (100)
Large	5 to 15	55 (22) to 84 (33)	45 (100)

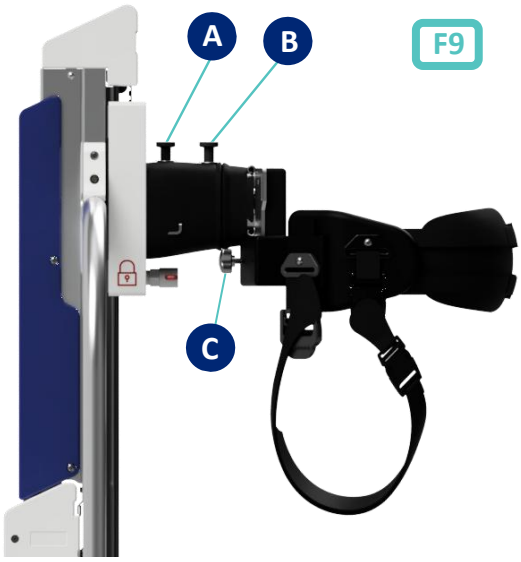
Pelvic Support - User dimensions			
Seat size	Age (approx.)	Crotch Height *(cm(in))*	Max Weight *(kg (lbs))*
Small	2 to 6	32 (12.5) to 40 (15.5)	45 (100)
Large	5 to 15	37 (14.5) to 56 (22)	45 (100)

To adjust the Obliquity Movement (F9 & F10)

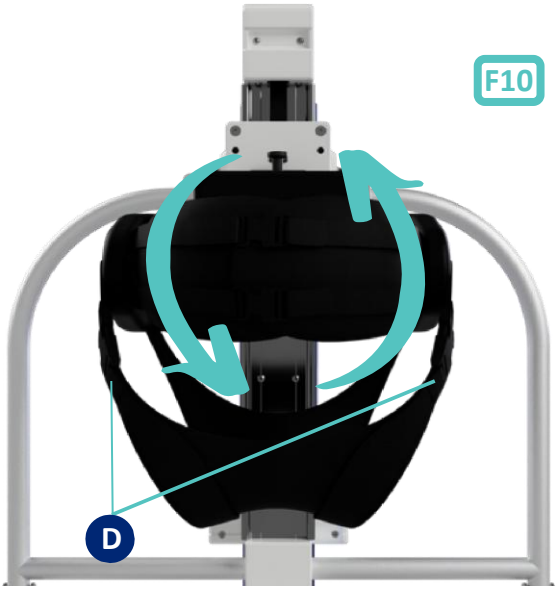
The obliquity knob (A) can be set to block the obliquity movement or allow a ± 10-degree freedom. The obliquity is blocked when the knob (A) is at its lowest position. This setting can be helpful for users who need additional lateral support. To allow obliquity, lift the knob (A) and twist it so that it stays at its highest position.

To Adjust the Rotation Movement (F9 & F11)

The rotation knob (B) can be set to either block the rotation movement or to allow a rotation of ± 15 degrees. The rotation is blocked when the knob (B) is at its lowest position. This setting can be helpful for users that need better lateral support. To allow rotation, lift the knob (B) and twist it so that it stays at its highest position.



F9



F10

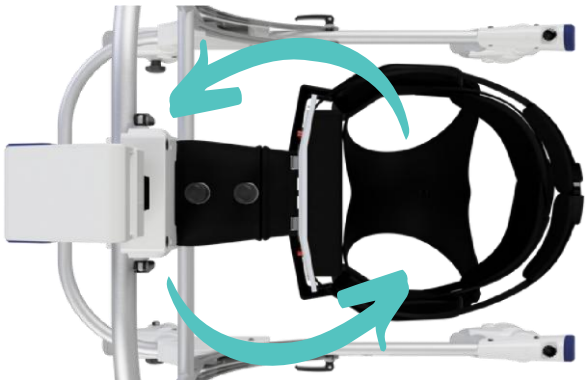
To adjust the hip pad width (F9)

1. Loosen the width fasteners (C) on both sides of the harness.
2. Slide the harness's hip pads on both sides to the desired width.
3. Securely tighten the width fasteners on both sides of the harness. Ensure that there is at least 1 inch of rail engaged prior to tightening the fasteners.

To adjust the seat and belt strap length (F12)

1. Remove the excess length of the strap from the securing slide.
2. Lift the buckle's lower section (E) to release the tension from the strap.
3. Pull the strap's free end (F) to tighten the harness or pull the harness side (G) to loosen it.
4. Put the excess length back in the securing slide.

F11



F12

To install the user in the harness (F10)

1. Lower the harness to the user's hip height and engage the harness brake firmly. Unbuckle the seat and belt buckles to allow for a more effortless transfer.
2. Bring the Levity into position from behind the user. If necessary, a small bench or stool can help support the user during installation.
3. Engage the wheel brakes to prevent unwanted movement of the device.
4. Bring the harness seat clips to the front of the user by passing them between their legs.
5. Connect the seat clips (D) to the hip pads on both sides of the user. Removing all folds and bends in the user's clothes can help improve the user's comfort.
6. Wrap the belt around the user's belly and connect both clips.
7. Make sure that all straps of excessive length are passed through the slides.

Warnings

- Adjusting the harness while a user is installed may affect the user's safety and result in serious injury or death.
- Make sure all knobs, levers, and fasteners are securely fastened before installing the user.
- When adjusting the harness width, leave at least 1 inch of rail when tightening the fasteners. Use the indicator sticker to make sure the harness is sufficiently inserted in the rail.
- The user's weight must be supported by the harness seat only. The harness belt must only prevent the user from losing balance.

3.3 Additional components description

3.3.1 Weight-Bearing Module

The Levity comes with weight-bearing module(s) to allow for weight bearing adjustments. Each module bears weight equivalent to the mass specified on the module. Refer to Section 3.2.3. for more information and for instruction on installation and removal of the weight-bearing module.

F13

F14

Available weight-bearing modules:

8kg (17.5lbs), 10kg (22lbs), 12kg (26.5lbs), 15kg (33lbs), 18kg (39.5lbs) and 22kg (48.5lbs)

Warnings

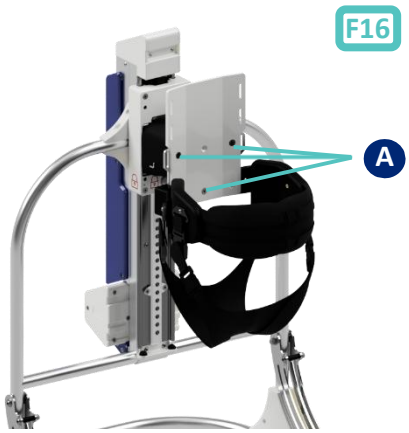
- The selection of the weight-bearing module should be made with the help of a professional caregiver or health specialist.

3.3.2 Upper Body Backplate Support

The upper body backplate support component can be added to the standard Levity harness for users that need a higher level of assistance. Its added belt, which can be attached at two different heights, gives the user increased obliquity and tilt support.

To Install the Upper Body Backplate Support (F15 & F16)

1. Remove the harness back cushion.
2. Position the upper body backplate support on the main harness plate and securely fasten the three (3) bolts (A) provided with the component.
3. Install the large back cushion provided with the upper body backplate support.



Warnings

- Accessories such as the upper body support may only be appropriate for some users. Ask a health specialist to assess the safety of the accessory.
- Ensure that all wheels are locked, and no user is installed in the harness before installing the upper body backplate support.
- The user's weight must be supported by the harness seat only. The upper body support belt must only prevent the user from losing balance.

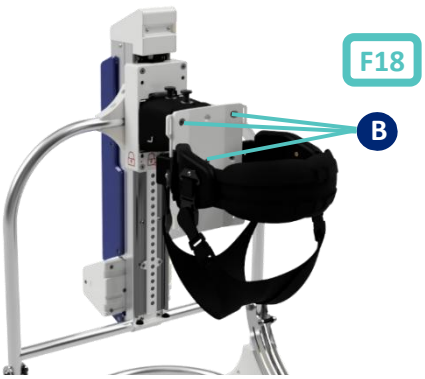
3.3.3 Lower Body Backplate Support

The lower body backplate support can be added to the standard Levity harness for users that need a higher level of assistance.

To install the lower body backplate support (F17 & F18)

1. Remove the harness back cushion.
2. Position the lower body backplate support on the main harness plate and securely fasten the three (3) bolts (B) provided with the component.
3. Install the large back cushion provided with the lower body backplate support.

Note: When mounting the lower and upper body backplate supports, follow the same steps, but instead, position the upper body support on the lower body backplate support.



Warnings

- Accessories such as the lower body support may only be appropriate for some users. Ask a health specialist to assess the safety of the accessory.
- Ensure that all wheels are locked, and no user is installed in the harness before installing the upper body backplate support.

3.3.4 Chest Harness

The chest harness can be added to the standard Levity harness for users that need additional support for their upper body. With straps that connects over the shoulder, it allows to improve the users posture and comfort.

Chest harness – User dimensions			
Harness size	Age (approx.)	Waist size *(cm (in))*	Max Weight *(kg (lbs))*
Small	2 to 6	38 (15) to 64 (25)	45 (100)
Large	5 to 15	55 (22) to 84 (33)	45 (100)

To install the chest support component (F19, F20 & F21)

Note: If the upper body backplate support is not installed, refer to section 3.3.2 of the User Manual prior to proceeding. This component is necessary to use the chest harness.

1. Ensure that the strap on the upper body backplate support is well centered and that it is pointed upward.
2. Connect the chest harness upper buckles with the anchor buckles.
3. Connect the lower buckles from the chest harness to the hip belt.

Warnings

- The chest support can only be used with the upper body support feature installed
- Accessories such as the chest support may only be appropriate for some users. Ask a health specialist to assess the safety of the accessory.
- Ensure that all wheels are locked, and no user is installed in the harness before installing the chest harness component.

3.3.5 Ankle Prompt

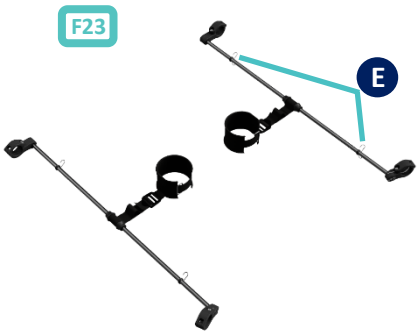
The ankle prompt can be added to the standard Levity for users with excessive adduction. With length adjustment, adjustable-padded ankle straps and the ability to limit stride length, the user can avoid scissoring and improve their gait.

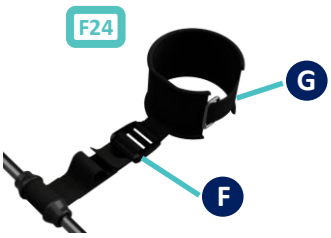
To install the ankle prompt add-on (F21 & F22)

1. Remove the screws from the installation clamps (D) on both rods (F21).
2. Open the clamps and place them around the lower tube frame. Ensure the rods are on the inside of the Levity. Close the clamps around the frame (F22).
3. Use the screws from step 1 to tighten the clamps in place on both rods.

To adjust the ankle prompt add-on (F23 & F24)

1. Stride length can be adjusted using the spring clips (E).
2. Stride width can be adjusted using the stride buckle (F).
3. Ankle strap can be tightened, loosened or secured using the adjustment buckle (G).





3.3.6 Headrest

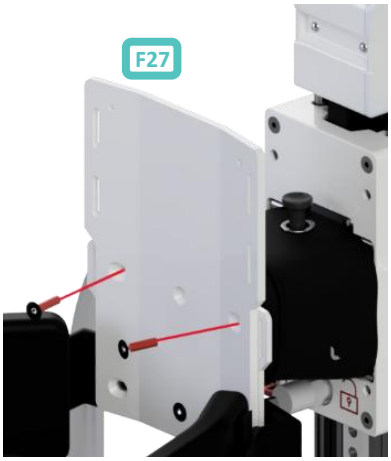
The headrest can be added to the standard Levity for users who require additional head support. With height and depth adjustment, user's comfort and support allow for focus on the user's gait cycle.

To install the headrest add-on (F25 & F26)

1. Place the headrest on the harness link (F25).
2. Put the hardware provided together. Tighten the hardware into the backplate (F26).

To install the headrest add-on <u>with backplate(s)</u> (F27& F28)

1. Remove the backplate cushion.
2. Remove the two (2) top screws of the backplate and install the two (2) longer screws provided, in their place (F27).
3. Reattach the backplate cushion.
4. Place the headrest on the harness link. Ensure that it assembles around the newly installed screws (F28).
5. Install the nut and washer provided. Ensure to hand tighten the nuts (F28).

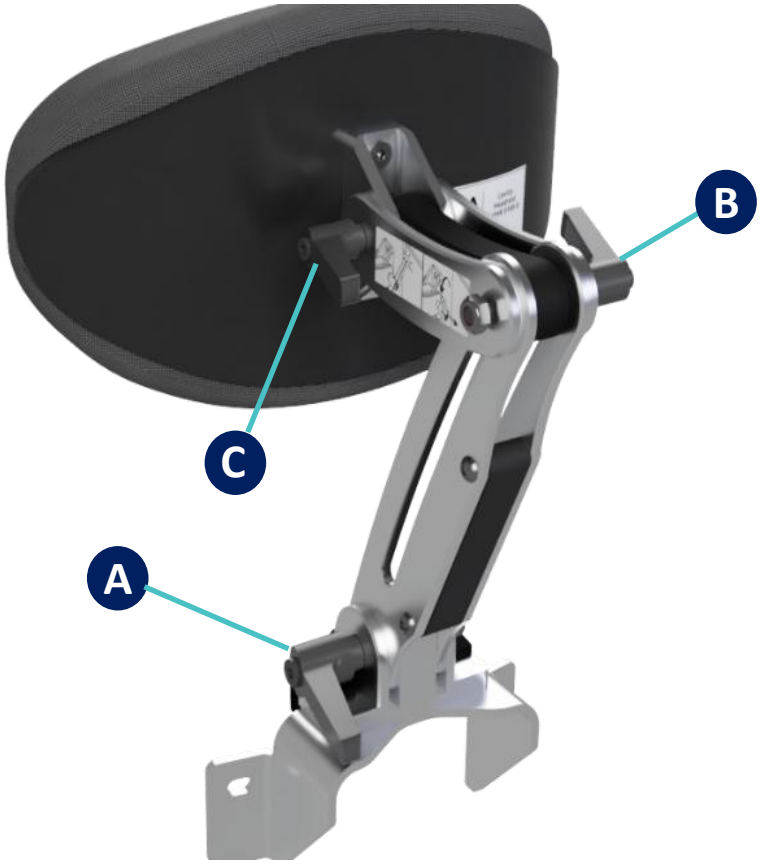


To adjust the headrest (F29)

1. Release all three (3) levers (A, B and C). Ensure to hold the headrest to avoid it dropping (F29)
    A) This lever can be used to rotate the system. This allows for depth adjustment.
    B) This lever can be used to rotate and translate the system. This allows for height and depth adjustment.
    C) This lever can be used to rotate the headrest. This allows for the adjustment of the cushion's angle.
2. Adjust the headrest to an approximate height and depth for the user.
3. Install the user in the Levity.
4. Adjust the headrest to provide optimal support and comfort to the user.

Note: All levers can be pulled out and rotated freely, to avoid being in the user's way

F29



4. Care

4.1 Maintenance

The device’s securing components, such as knobs, levers, clips, straps, covers, and fasteners, must be inspected before each use to prevent injuries. The device’s brakes must also be inspected before each use to ensure proper functioning. The device’s structural integrity should also be verified before each use. If cracks, excessive wear, excessive deformations, general instability, or missing components are detected, the product must be immediately removed from use and Ora Medical should be contacted. Failure to follow the instructions specified in this document may affect the user’s safety.

4.2 Cleaning

The device's metal and plastic components can be cleaned with a reasonable amount of soapy water or a non-abrasive detergent. Any spills while cleaning should be removed as soon as possible to prevent the degradation of components. The fabrics can be cleaned by hand on the device or removed and laundered with non-abrasive detergent.

5. Warranty

Ora Medical guarantees the Levity and any of its components for the first year if used according to the recommendations provided in this manual. The warranty is voided if the device is modified without authorization, subject to extreme wear and tear, or deliberately misused.

eIFU: https://www.oramedical.ca/eifu

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