INSTALLATION AND OPERATION MANUAL

Dynamic Unweighting System

PhysioGait
PG-360

CE

HealthCare International

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CONTENT

1. INTRODUCTION

Congratulations on your excellent choice of our gait therapy device.

PHYSIOGAIT dynamic partial weight bearing gait therapy device is characterized by stability, reliability and ease of use. This results from its ingenious design, technology of manufacturing and product quality assurance system. Lecture of this instruction manual will allow such operation of our therapy device to ensure its safe and long-term use.

GENERAL INSTRUCTION:

1. The product should be operated by qualified personnel who are familiar with the contents of this manual.
2. Use, operation and maintenance of the product in a manner inconsistent with this manual is not permitted and can lead to damages, which are borne by the user, and for which the manufacturer shall not be liable.
3. If the performance and parameters of the product are inconsistent with the description contained in this manual, do not use the product. You must immediately report it to the manufacturer or supplier.
4. Any repair of the product must be performed by the factory or authorized service and registered in the list of repairs attached to the warranty card. Failure to do so will void the warranty of the product.
5. Technical description of the lift with a list of spare parts and their replacement methods is available from the manufacturer on request.
6. Any serious PHYSIOGAIT dynamic partial weight bearing gait therapy device incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient is resident.

Warranty terms will not be respected if the user uses the product in a manner inconsistent with its intended purpose or he will not respect the terms of use stated in this manual.

The manufacturer shall not be liable for the consequences of improper (inconsistent with the conditions set out in this Manual) use of PHYSIOGAIT therapy device.

1.1. Symbols

CAUTION!

In this manner are indicated activities, which if performed inconsistently with the instruction manual may cause deterioration of conditions or safety hazard to the user and/or personnel operating the device.

Such marking is applied on the table where it is essential to read the contents of the Operation Manual and follow its instructions when using the table

Type B Applied Part

Manufacturer
XXXX - year of production

Safe working load of the device

Actuator operation type

Direct current

Degree of protection against foreign solids and against water

Hand control – Raising/lowering the patient

Hand control – Battery level status

Panel control (raising, approval, lowering)

L – left side of the hanger bar – patient's left arm

R – right side of the hanger bar – patient's right arm

Gate adjustment steps (1-5 left side, 5-1 right side)

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device with the equipment is manufacture in accordance with Medical Device Regulation 2017/745 (class 1, rule 13) and has a CE marking, according to the manufacturer declaration.

All electrical and electronic equipment waste must be disposed-of properly at recycling facilities according to the European Union's WEEE directive or equivalent regulations. It is necessary that all devices which contain substances harmful to the environment or humans are recycled properly in relevant facilities and must not be disposed of with general or household waste. Such regulations ensure that the quantity of electronic waste is reduced, and a required number of electronic devices is recycled properly. Proper recycling of electronic waste is important as it may contain substances harmful to the environment and humans.

Recyclable materials

Medical device

Catalogue number

Serial number

2. CHARACTERISTICS OF PARTIAL WEIGHT BEARING GAIT THERAPY DEVICE

2.1. Intended use

CAUTION!

The manufacturer reserves the right to make such changes, non-exposed in the current version of the manual, that do not cause deterioration of the functional parameters and conditions for product safety.

CAUTION!

Qualified personnel decide on legitimacy of the use of PHYSIOGAIT Partial Weight Bearing Gait Therapy Device for handling the patient.

PHYSIOGAIT Dynamic Partial Weight Bearing Gait Therapy Device system is intended to accomplish dynamic patient support used in the rehabilitation and gait reeducation. The device is used for therapeutic and diagnostic purposes (training balance and gait). It is ideal for working with neurological and orthopedic patients.

Patients who have been recommended for rehabilitation by a doctor are intended to use the PHYSIOGAIT Dynamic Partial Weight Bearing Gait Therapy Device.

Users of the PHYSIOGAIT Dynamic Partial Weight Bearing Gait Therapy Device are qualified personnel who have familiarized themselves with the precautions and operating principles of the PHYSIOGAIT lift, as contained in the user manual.

The PHYSIOGAIT Dynamic Partial Weight Bearing is intended for use in hospitals, sanatoriums, nursing homes or any other care facilities.

2.2. Technical parameters

Parameters		**PHYSIOGAIT**
Depth [cm]	no more than	**53” (135 cm)**
Outside Width of Adjustable Base	minimum	**32”-1/4” (82 cm)**
	maximum	**40” – ½” (103 cm)**
Inside Width of Adjustable Base	minimum	**30” (76 cm)**
	maximum	**38” (97 cm)**
Height adjustment [cm]	minimum	**4’9” (145 cm)**
	maximum	**7’ 9” (236 cm)**
Patient height [cm]	minimum	**-**
	maximum	**7’ 2” (218 cm)**
Patient Height on 6” Treadmill	maximum	**6’8” (203 cm)**
Range of relief movement [cm]	no more than	**12,5**
Operation mode		**Discontinuous with short-term load (10%) max. 2 minutes operation (ON), min. 18 minutes pause (OFF)**
Load of the device		**≤ 360 lbs (symbol indicates the maximum safe load of the device when lifting-lowering the arm)**
Weight of the device	up to	**98 kg / 216 lbs**
Weight of the operator’ s seat	up to	**4,5 kg / 10 lbs**
Electrical supply and safety precautions	voltage	**24 V ⎓ (battery supply)**
	battery capacity	**5Ah**
	applied part	**type B,** 
Protection level		**IP40**
Environment conditions (temperature, relative humidity, air pressure)	work	**+10°C up to +40°C, from 30% to 75% non-condensing, 700-1060 hPa**
	storage	**+5°C up to +45°C, not exceeding 75% non-condensing, 700-1060 hPa**
	transport	**-10°C up to +45°C, from 20% to 95% non-condensing, 700-1060 hPa**

Table 1 - Technical parameters of PHYSIOGAIT Partial Weight Bearing Gait Therapy Device Subject to Change at any time

3. CONSTRUCTION AND OPERATION OF PHYSIOGAIT PARTIAL WEIGHT BEARING GAIT THERAPY DEVICE

3.1. Construction components

CAUTION!

It is strictly forbidden to modify the device without written authorization of the Manufacturer.

The construction of PHYSIOGAIT Partial Weight Bearing Gait Therapy Device is made of steel powder coated frame to which is attached the body of lifting column made of durable aluminum alloy. The construction of the device consists of the following units:

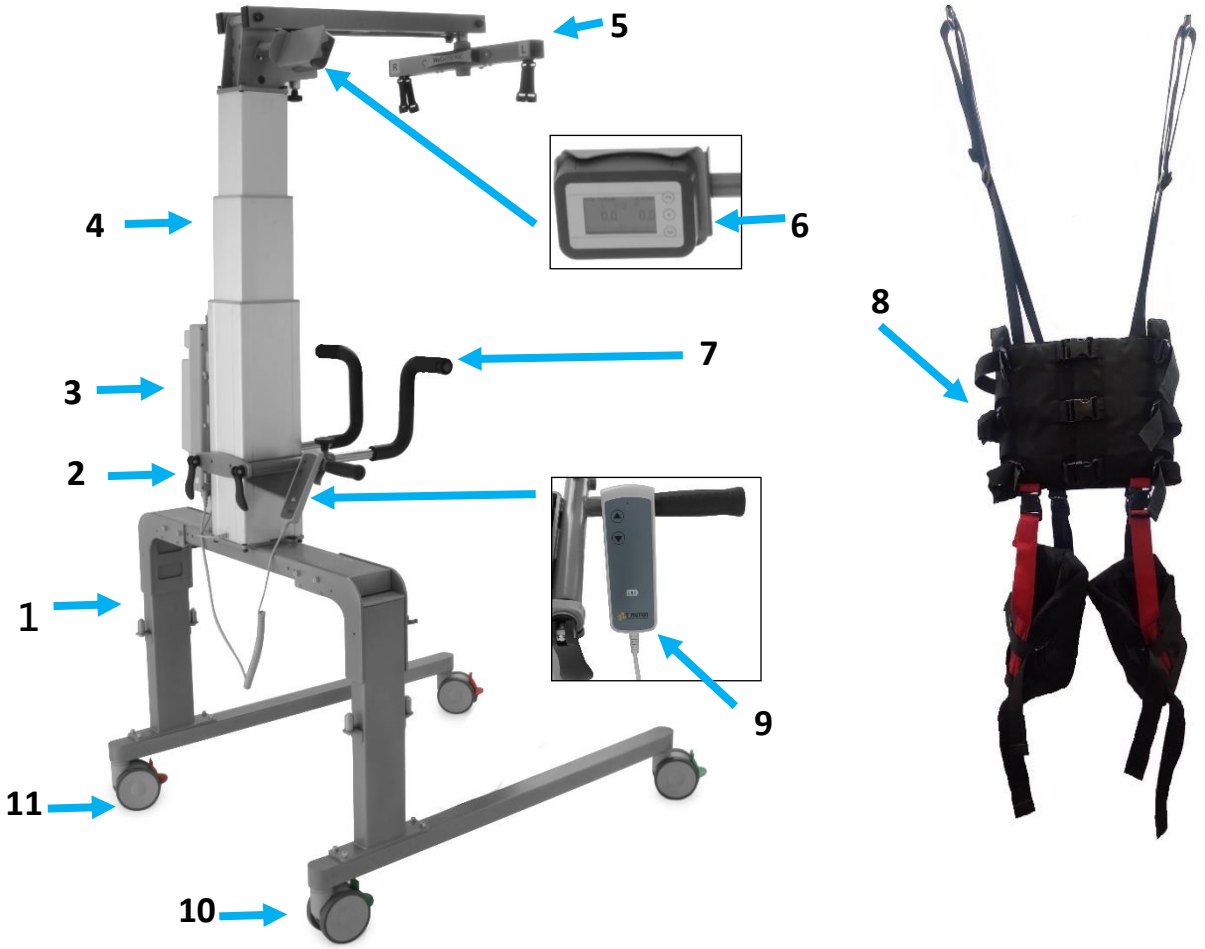


Figure 1 - Construction elements of PHYSIOGAIT Partial Weight Bearing Gait Therapy Device

1	**Wheeled base** Lift support base, equipped with four mobile wheels with a brake.

2	**Grip** To adjust the height of the patient handrail.
3	**Control box with disconnected battery** Control box for raising the arm when calling the function from the hand remote control. Equipped with emergency STOP button and high-capacity battery.
4	**Lifting column** Stable three-segment design for electrical height adjustment of weight bearing frame.
5	**Weight bearing arm** Equipped with a beam mounted on a swing arm with wireless transducers and radio transmission data - WeCoTRONIC. The harness is attached to the beam. The arm has two knobs, one for adjusting the load range and the other for changing the position of the beam in the plane.
6	**Panel** Equipped with a screen showing the degree of weight bearing and control buttons. Panel is movable and attached magnetically, allowing it to be placed on the elements of the metal structure of the device in a convenient position for the operator.
7	**Handrails** Are the application part of partial weight bearing therapy device, provide stable support for patient's hands during gait therapy.
8	**Harness for patient stabilization** Is the application part of partial weight bearing therapy device, allows stable support of the patient during gait therapy.
9	**Hand remote control** Allows to control height adjustment.
10	**Wheels with a brake (green or gray color of the brake)** Allows to maintain linear motion during the gait therapy;
11	**Wheels braked (fully lockable)** together with locked wheels allow to maintain directional stability at a standstill;

3.2 Gate of the PHYSIOGAIT Therapy Device

CAUTION!

Before installing the unit as a whole, the gate spacing must be adjusted to individual needs.

The gate is factory-set to internal dimension of 730mm.

The gate construction allows it to be set up from 730 to 930 with 25mm movement (see Fig.2) - 8 possible settings in total.

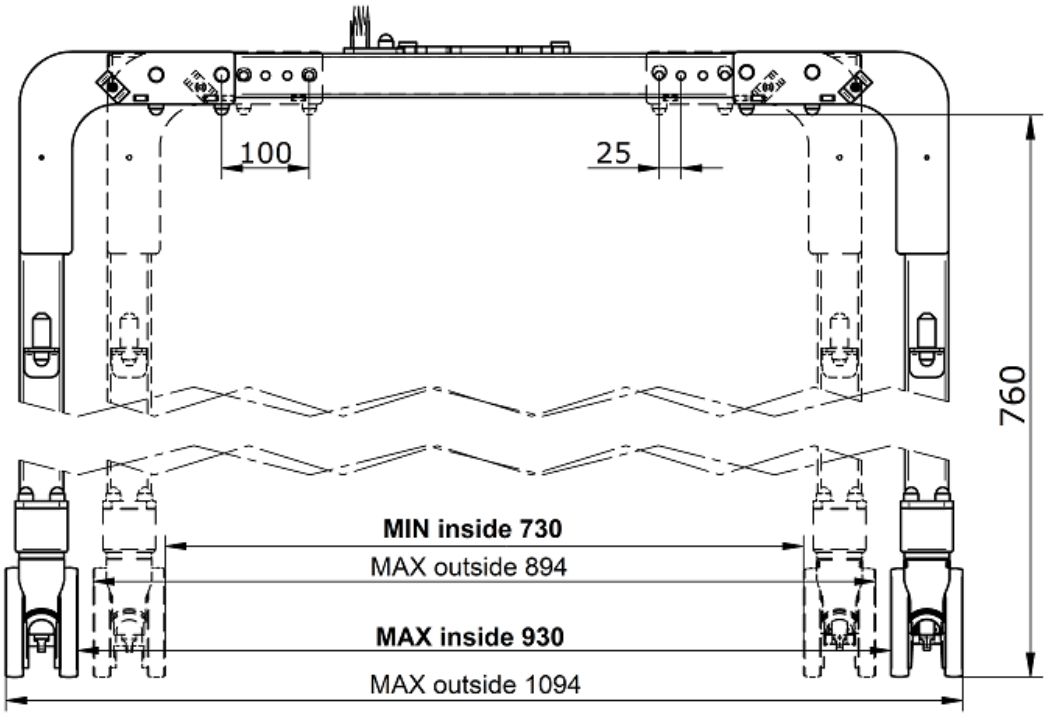
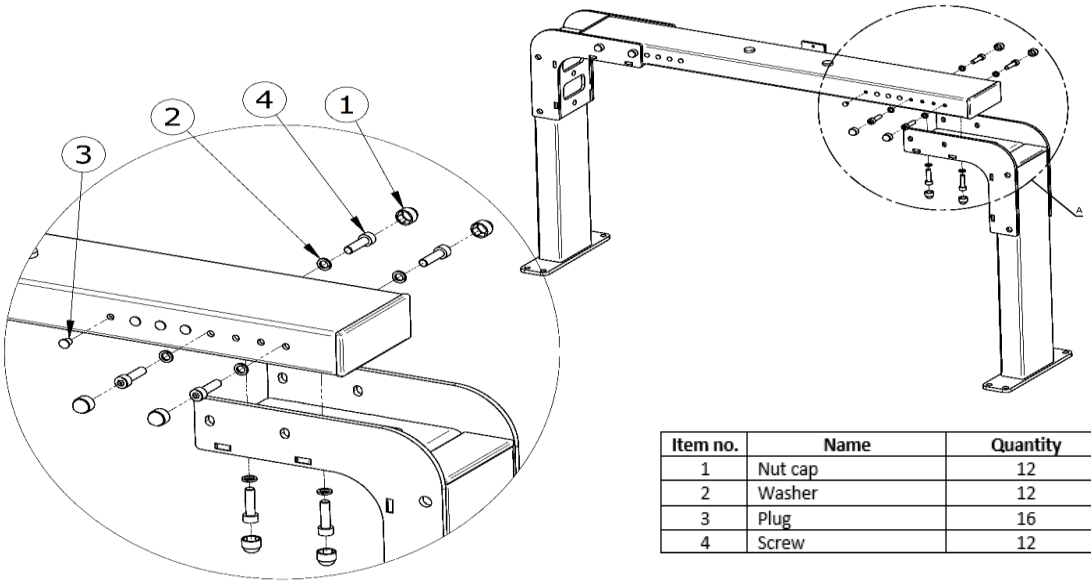


Figure 2 – Gate dimensions & spacings

To adjust the gate, unscrew the screws (see Fig.3 pos.4) on one side of the frame (see Fig.3), then move it by the desired dimension to obtain the correct width of the gate and screw it in (screw tightening torque not less than 30nm).

Repeat for the other frame: set it symmetrically in relation to the lifting column (e.g. when increasing the distance every 25mm, set the dimension only on one of the frames, if every 50mm, adjust it from both sides).



Item no.	Name	Quantity
1	Nut cap	12
2	Washer	12
3	Plug	16
4	Screw	12

Figure 3 – Changing the gate spacing of the PHYSIOGAIT therapy device

3.3. Accessories and additional equipment

Harness for the patient is made of soft, well-contracting to the patient's body components, enabling to maintain the feeling of comfort during treatment. Gripping part of the handle is covered with PU foam, providing a reliable and stable grip. Upholstered seat stool for the therapist, is made of PU foam for comfortable operation during partial weight bearing gait therapy.

In addition, the following accessories are available: - high capacity additional battery.

3.4. Device set

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device	as per order
User Manual	1 pc.
Harness	1 pc.
Charging station with power supply	1 pc.
Charger for the panel/scale module including an extension cable	1 pc.
Accessories and additional equipment	as per order

Table 2 – Device set of PHYSIOGAIT Partial Weight Bearing Gait Therapy Device

3.5. Transport and storage

Ambient conditions for storage and transport are shown in Table 1. PHYSIOGAIT Partial Weight Bearing Gait Therapy Device is transported to the customer a cardboard box on a pallet. The outer edges are additionally protected by a plastic bubble wrap and stretch foil. During the transport of PHYSIOGAIT Partial Weight Bearing Gait Therapy Device indoors, you should proceed in such a way as not to expose its outer edges to impact and rubbing.

4. SAFETY PRECAUTIONS

CAUTION!

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device has a limited ability to load up.
The patient's weight at lifting-lowering as well as during the partial weigh bearing should not exceed 160kg.

CAUTION!

Do not allow controller mounted on the column to contact (flooding) with liquid (e.g., coffee tea, water, cleaning agents and disinfectants).

CAUTION!

The system uses a special harness to support the patient. It is important that the harness is properly fitted to the patient.

CAUTION!

Before starting the treatment, attach the harness to the lift by lowering the relief arm to the optimal position and locking the caster wheels. After the treatment is completed, remove the harness by locking the caster wheels and lowering the relief arm to the optimal position.

CAUTION!

The manufacturer shall not be liable for the consequences of improper (inconsistent with the conditions set out in this Manual) use of PHYSIOGAIT therapy device.

CAUTION!

The device may not be operated in rooms with high relative humidity, especially in rooms intended for hydrotherapy treatments.

CAUTION!

In order to ensure safety of use, a minimum height of 2.5m must be maintained.

5. PREPARATION FOR USE

CAUTION!

Two people are required to install the unit.

5.1. Location conditions

CAUTION!

When determining or changing the place of use of PHYSIOGAIT therapy device you should pay particular attention to ensure that the space under the frame was free from any items. You should prevent uncontrolled access to the place of use of the device by children and pets (cat, dog, etc.).

1. The operation location of partial weight bearing therapy device should be chosen so that to ensure a minimum 80 cm gap from each side and enough space in front and behind the device to enable free movement. The device should be placed and used only on horizontal and level surfaces.
2. After removing the individual lifting units from the packaging and unpacking them from the transport foil, to complete the product, follow the enclosed installation and packaging instructions. After completing the proper installation and pre-setting of the PHYSIOGAIT lift, you can begin work.

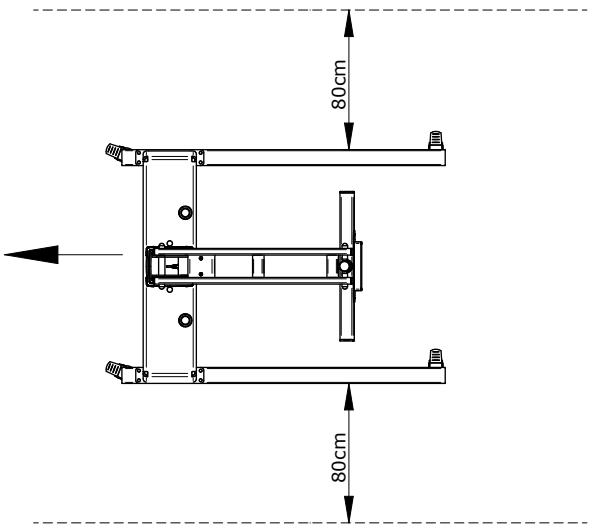


Figure 4 - The recommended location of PHYSIOGAIT therapy device

6. ASSEMBLY OF THE DEVICE

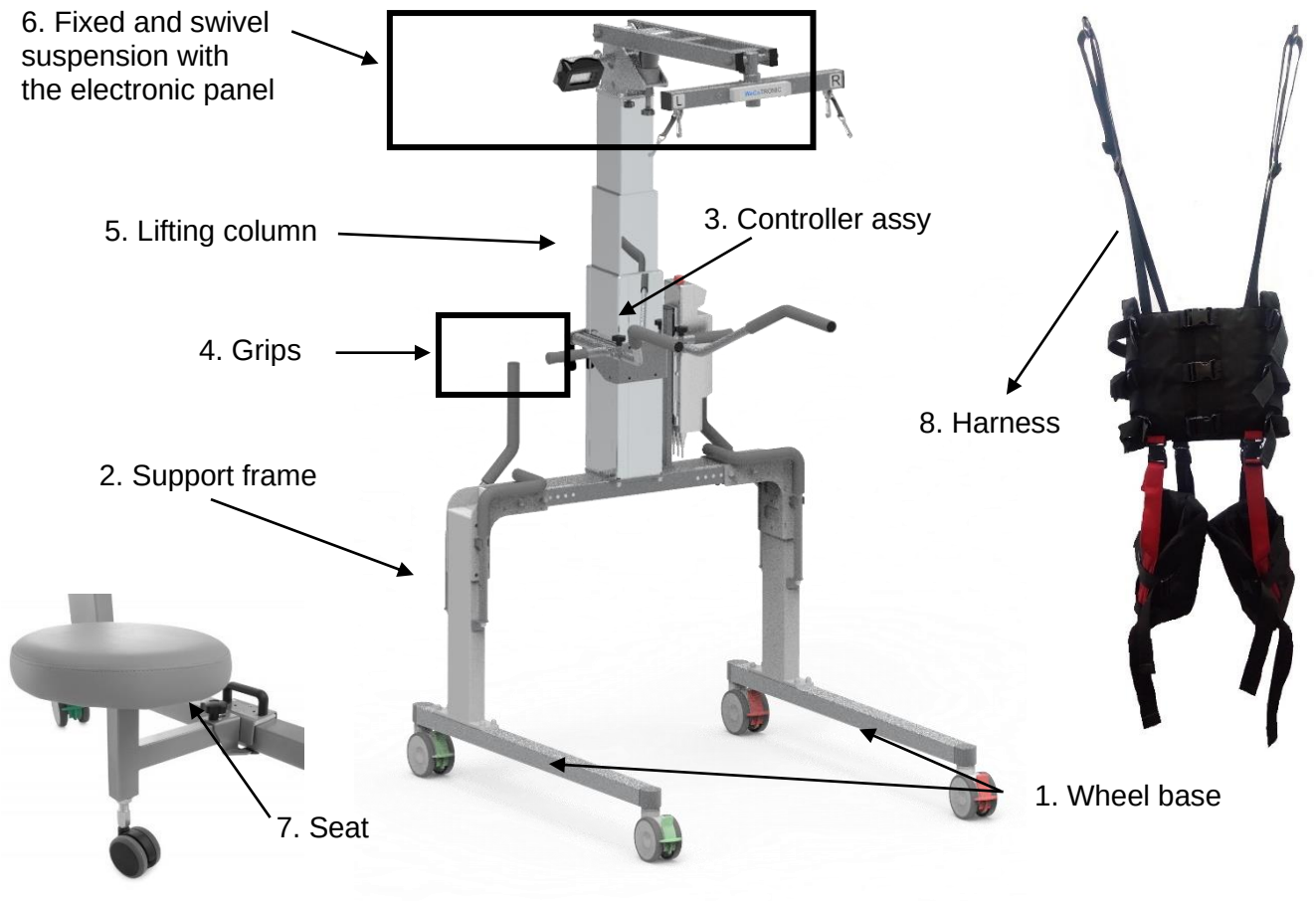
CAUTION!

Before installation, unpack all carton assemblies. Prepare allen hex keys and/or other tools needed for assembly (type: screwdrivers, etc.).

CAUTION!

Two people are needed for installation, as the device consists of heavy parts

The device to the customer is delivered disassembled into assemblies (8 packages).



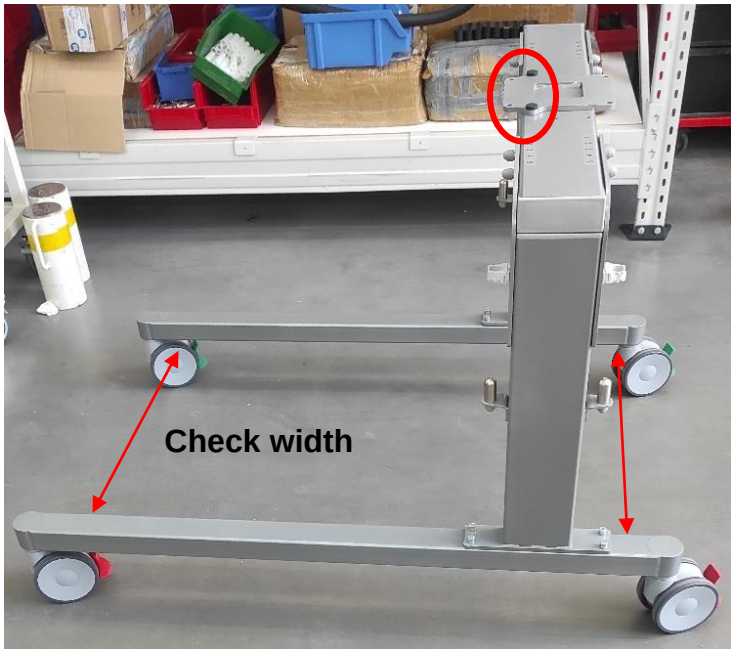
1	**Wheel base**	pcs. 2	screw with washers	set.8
2	**Support frame**			pc.1
3	**Controller assembly**		control box, battery, remote control, charging cradle, power adapter, charger, adapter	set.1
			mounting plate + screw	set. 1
			screws for the power supply	pcs.2
			plastic washers	pcs.2
			screws	pcs.2
4	**Grips**		long handles R+L	pcs.2
			short handles R + L	pcs.2
			fixing (clamp + sheet)	set.1
			knobs + clamp	pcs.4
5	**Lifting column**	pc.1	high-strength screw	pcs.8
			washers	pcs.8
6	**Fixed and swivel suspension with the electronic panel**		with panel	set.1
7	**Seat**			pc.1

8	**Harness**	standard	pc.1
		XL	pc.1

1. You need to assemble the gate components together - set the vertical parts of the gate to the desired width. The design of the gate allows spacing from the dimensions of 730 mm to 930 mm, in 25 mm increments. There are 8 possible settings of the gate.

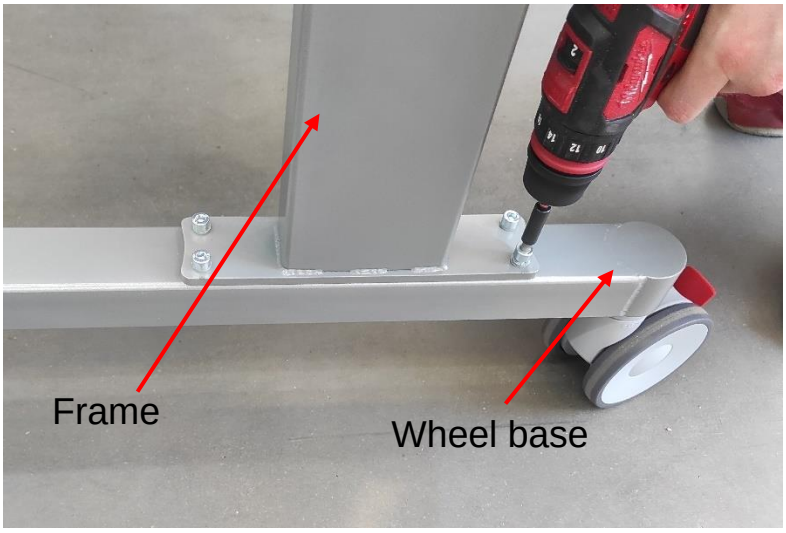
The color of the wheels indicates their function. The **GREEN** color refers to wheels with locking in the direction of travel. The color of the wheels **RED** indicates total locking (no movement).

Then check that the dimension between the stringers - is the same along the entire length.

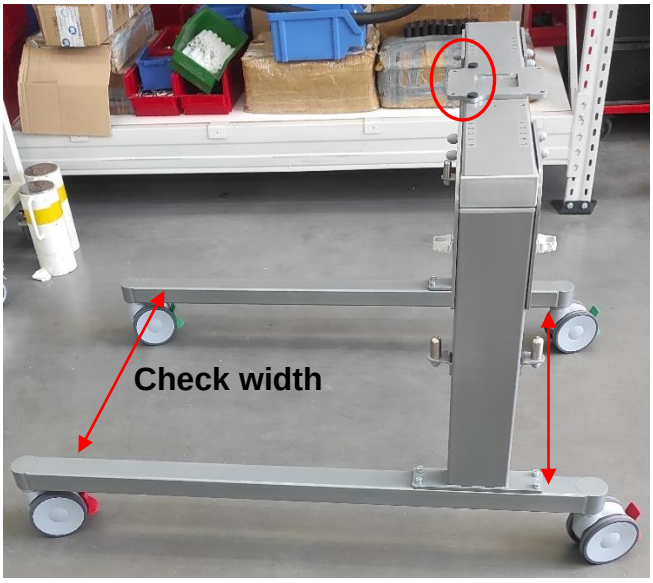


Gate dampers must be positioned on the side of the patient's entrance.

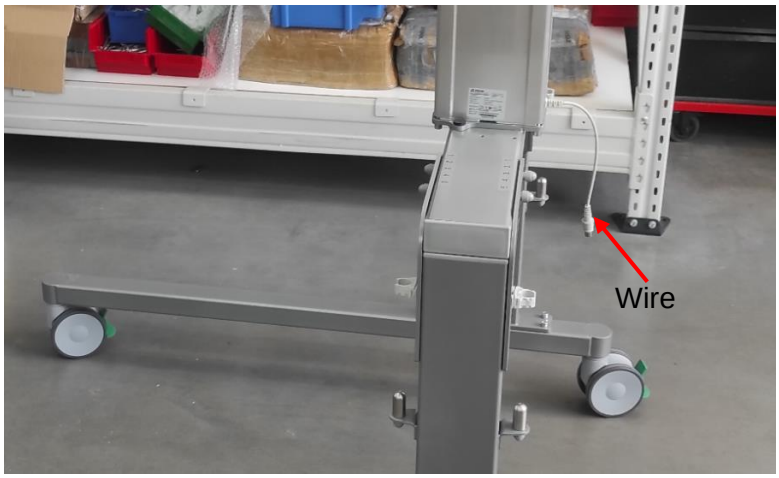
2. Assemble the stringers (pcs.2 - stringer with wheels with total locking, stringer with wheels with locking in the direction of travel) together with the gate. Pay special attention to the parallelism of the stringers with respect to each other. Tighten the M8x30 bolts with a force of **26 Nm**.



Check that the distance between them at the beginning and at the end is of the same value.

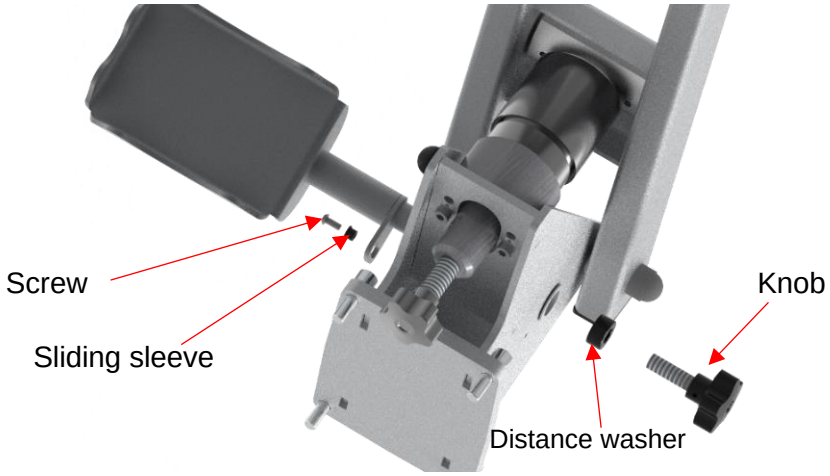


3. Assemble the column on the gate. Ensure that the cable exits from the back of the mounted column. Tighten the M8x30 screws with a force of **26 Nm**.



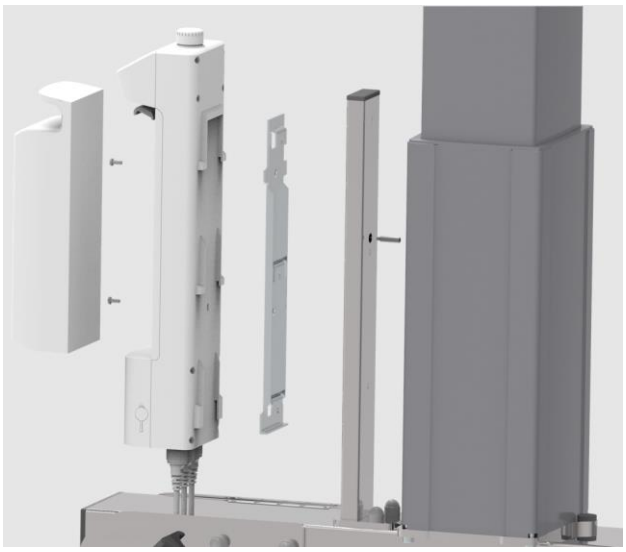
4. Assemble the fixed sling with the swivel, the electronics with the column. Tighten the M8x30 screws with a force of **26 Nm**. Ensure that the sling is fixed towards the stringers.

5. Assemble the desktop mount by screwing in one side of the knob with the spacer, the other side of the sliding sleeve, slide screw to freely adjust the range of motion of the mount.



6. Assemble the controller on the strikers, then screw in the security screw.

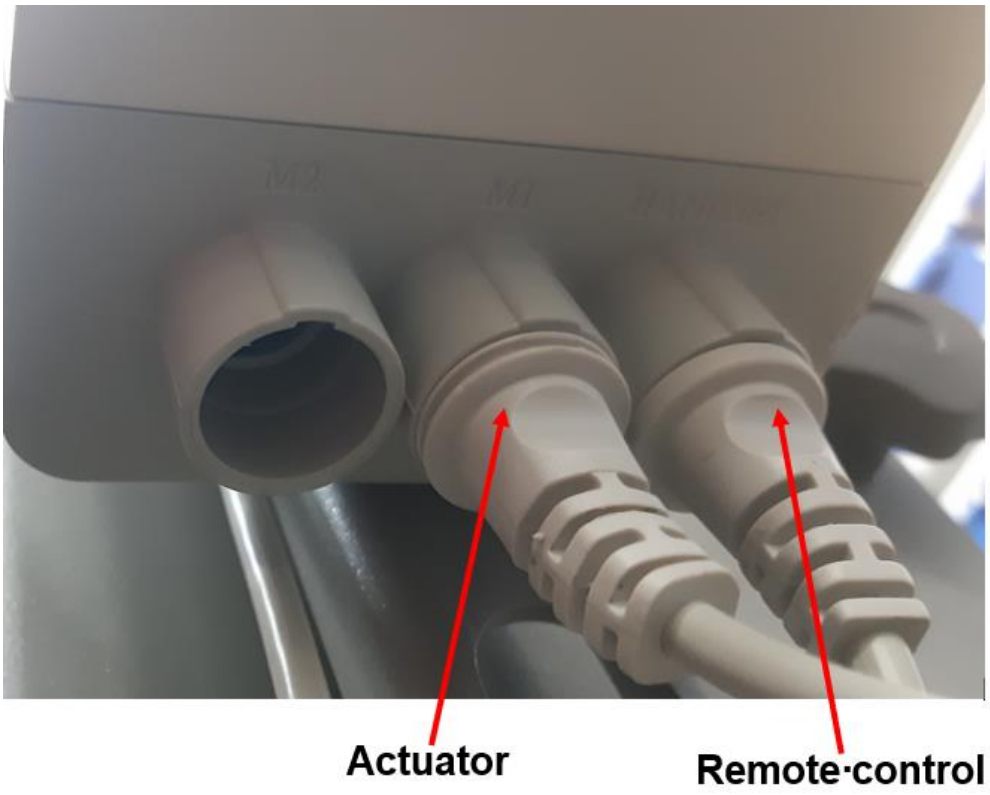
Assemble the controller with the bracket to the gate with two screws. Tighten the M8x30 screws with a force of **26 Nm**.



7. Assemble the brackets with the column mount. Check that all the sliders are inserted into the bracket mount – a total of 12 pieces.

8. Assemble the other components of the elevator: straps, remote control.

9. Placement of wires in the control box.



7. OPERATING THE DEVICE

CAUTION!

Always maintain a safe distance from the lifting mechanism operating during the height adjustment. The movable parts of mechanisms present a risk of crushing.

CAUTION!

Always secure the device against movement. Wheel brakes should be released only during gait therapy.

CAUTION!

Conducting gait therapy on a treadmill requires all four castors to be locked.

CAUTION!

Operating personnel must be present at all times during therapy and monitor its progress.

CAUTION!

In the event of a malfunction or deviations from normal operation, stop rehabilitative activities on PHYSIOGAIT therapy device and contact HEALTHCARE INTERNATIONAL service department.

In case of treadmill treatment, you should unconditionally lock the wheels of PHYSIOGAIT. The patient should be dressed in suitable to performed procedures clothing. Clothes made of synthetic materials, thick and rough fabrics or other having thick embroidery details (jeans) and fastenings in the straps mounting points are not recommended. Long cotton sweatpants are recommended.

7.1. Height adjustment - lifting / lowering weight bearing arm

CAUTION!

Danger of head injury.

In the Partial Weight Bearing Gait Therapy Device height adjustment is done with manual remote control. The status of the lifting function is indicated by the green LED (see Fig.14), located on the remote control. Lifting (lowering) the frame lasts as long as the button on the remote control (▲ - up / ▼ - down) is held. After reaching the extreme maximum and minimum height, column drive switches off automatically.

7.2. Adjusting the dynamic partial weight bearing system

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device is equipped with a dynamic partial weight bearing system. Adjustable characteristics of weight bearing arm movement enables the simulation of mounting mobility in the range of 0 - 12,5 cm. Change of the characteristics of the arm is done by means of an adjustable weight bearing knob (see Fig.5). To adjust the dynamic partial weight bearing, suitable for each patient you should turn the adjusting screw. Unscrewing the screw (direction "+") increases the dynamic weight bearing. Screwing the screw (direction "-") reduces the dynamic weight bearing, until complete blockage of arm movement and turn off the Dynamic Partial Weight Bearing function (full weight bearing of the patient).

Adjusting dynamic partial weight bearing Locking dynamic partial weight bearing

Figure 5 - Adjusting dynamic partial weight bearing system

7.3. Locking castors/direction of travel

CAUTION!

Locking the castors prevents the rotation of the device during gait training but does not protect against castors slipping on the ground. The device should be placed and used only on horizontal and level surfaces away from the longitudinal slides, stairs, etc.

CAUTION!

Directional wheels should be locked after determining the direction of the Partial Weight Bearing Gait Therapy Device.

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device is equipped with four castors. The two castors on the left side are equipped with directional lock (green brake mechanism), while the two castors on the right side with a full lock (see Fig.6).

Sequence of setting the directional lock:

1. Set the device in the space provide to carry out the gait therapy.
2. Set the device in such a way that the castor lined up parallel to the axis of the device, in accordance with the travel direction.
3. Lock directional castors.
4. Castors with full lock are not blocked.
5. PHYSIOGAIT therapy device is ready for safe forward movement.
6. In the return direction, unlock the directional wheels and repeat steps 1-5, ensuring wheels moving in the right direction along with the device.

Figure 6 - Location of the castors in PHYSIOGAIT Partial Weight Bearing Gait Therapy Device

A - MOVEMENT B – DIRECTIONAL LOCK

Figure 7 – Directional/total lock of the castors in the frame

7.4. Mounting the straps to slings - harness

CAUTION!

Only harness distributed by HEALTHCARE INTERNATIONAL can be used with PHYSIOGAIT Partial Weight Bearing Gait Therapy Device.

CAUTION!

The harness should be used according to the manufacturer's guidelines.

Straps for suspending the patient - harness (see Fig. 8) are used for stable fastening as well as supporting the patient during gait training. Prior to the session you should select and individually adjust the straps for each patient. Strap fasteners should be mounted with a slight play - the width of the palm, in order to pull it up later on adjusting elements. The pads sewn into the straps improve patient comfort during gait training.

Figure 8 - The harness for suspending patient to PHYSIOGAIT therapy device

Fastening the harness in upright position:

1. Place the patient on his back.
2. Place one end of the harness in the middle abdomen.
3. Turn the patient to left or right side.
4. Place the harness on the back of the patient so that the strips with hooks have an equal length in relation to the axis of the spine.
5. Place the lowest strap of the harness at the height of the great trochanter of the femur.
6. Pull the inguinal straps between the legs, fasten strap buckles in front of the harness.
7. While holding the harness turn the patient on his back

8. Fasten front mounting buckles.
9. Check if the harness is located symmetrically with respect to the axis of patient's body - adjust the position of harness if necessary.
10. Tighten evenly - as far as possible the inguinal strips. This is an important step for comfort and even support of the patient.
11. After tightening the remaining straps, the harness is ready for use with Partial Weight Bearing Gait Therapy Device.

Fastening the harness in upright position:

1. Place the harness on patient's torso.
2. Place the lowest strap of the harness at the height of the great trochanter of the femur.
3. Fasten front mounting buckles.
4. Tighten front straps.
5. Pull the inguinal straps between the legs, fasten strap buckles in front of the harness.
6. Check if the harness is located symmetrically with respect to the axis of patient's body - adjust the position of harness if necessary.
7. Tighten evenly - as far as possible the inguinal strips. This is an important step for comfort and even support of the patient.

7.5. Mounting the harness to PHYSIOGAIT therapy device

CAUTION!

Before each session, check the condition of the harness. Any damage to the harness and any part of it, disqualifies the harness from further use.

The harness is attached to the lifter over the patient's head with special fasteners sewn into the adjustable harness straps. The harness is suspended from the swivel sling using four fasteners (see Fig.9)

Figure 9 - Mounting the harness to the weight bearing arm

Mounting the harness to PHYSIOGAIT therapy device:

1. Lock the castors.
2. Adjust harness mounting height to the weight bearing arm about 10 cm above the patient's head.

3. Adjust the length of the upper harness straps ensuring free reach to grips on weight bearing arm.
4. Fit the straps to the fastening harnesses in the relief arm or the fastening hooks in the swivel bracket.
5. Attach additional safety hook (in relief strain).
6. Tighten upper straps all the way.
7. Mounted to the device harness with the patient is ready for use on a solid ground or in cooperation with a treadmill.

7.6. Adjustment - replacing the handrail

CAUTION!

Rigidly lock the handrail in the mounting hole. It is not allowed to block the railing by just inserting the pin through mounting holes – the pin should be further secured by tightening.

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device is equipped with adjustable and interchangeable rails for supporting the patient during gait training (see Fig.10).

Figure 10 - Handrails for PHYSIOGAIT therapy device

Handrails can be adjusted in accordance with the mounting holes in handrail profile (see Fig.11). To change the handrail or the position of the handrail remove the retaining pin by unscrewing and removing it from the retaining hole. After changing the type or location of the handrail, lock the retaining pin by inserting and tightening it in the fixing hole (see Fig.12).

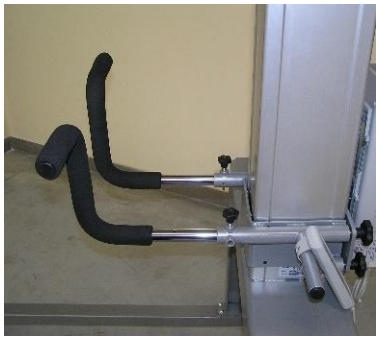


Figure 11 - Example of handrail mounting in PHYSIOGAIT therapy device

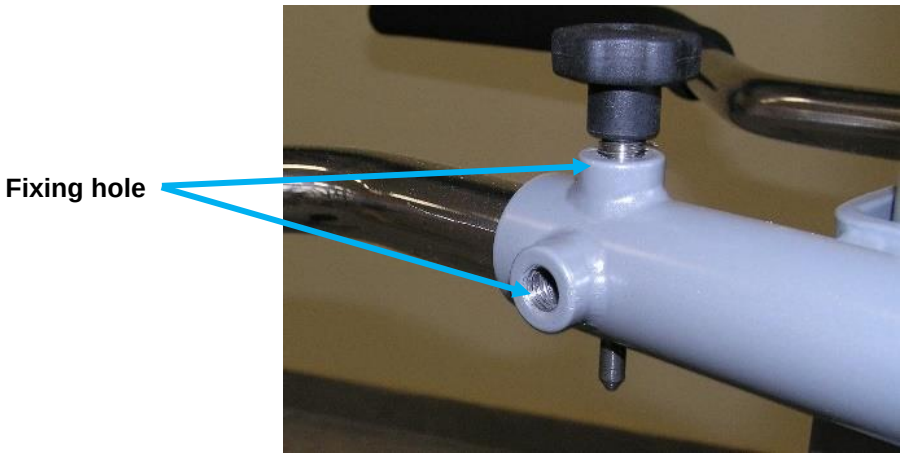


Figure 12 - Correct lock of the handrails in mounting holes

It is possible to adjust the height of the handrail to the individual height of the patient. To do this, unlock the eccentric levers by lifting them up, all the while holding them set at the desired height, then lock the levers by pressing them down. If the clamping pressure is too low, tighten the unlocked eccentric levers by turning them clockwise or counterclockwise to loosen the clamping pressure. The bracket including the handrails should not lower under the pressure caused by the patient leaning against it.

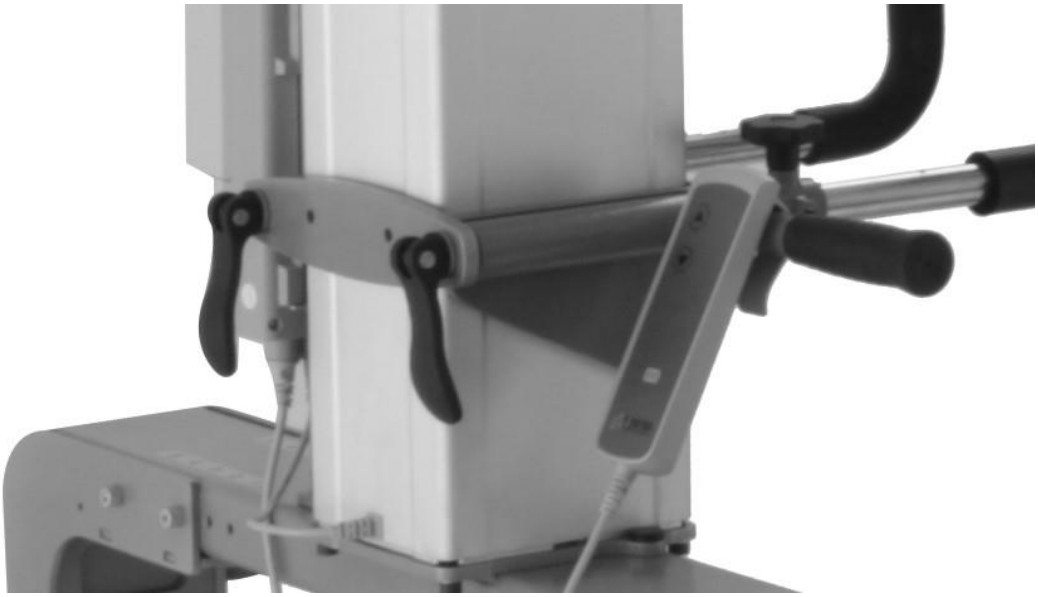


Figure 13 - Adjusting the height of the handrail in PHYSIOGAIT therapy device

7.7. Adjusting swivel sling

PHYSIOGAIT Partial Weight Bearing Gait Therapy Device is equipped with additional swivel sling to lift the patient (see Fig.14). Additional sling is used to change the movement of the device along with the patient. Range of rotation is 360°. The rotation is locked in 90° increments using the knob in the middle. In order to change the position of the rotary sling loosen the locking knob, turn the swivel sling to the left or right (as needed) by 90° and lock the position by tightening the locking knob.

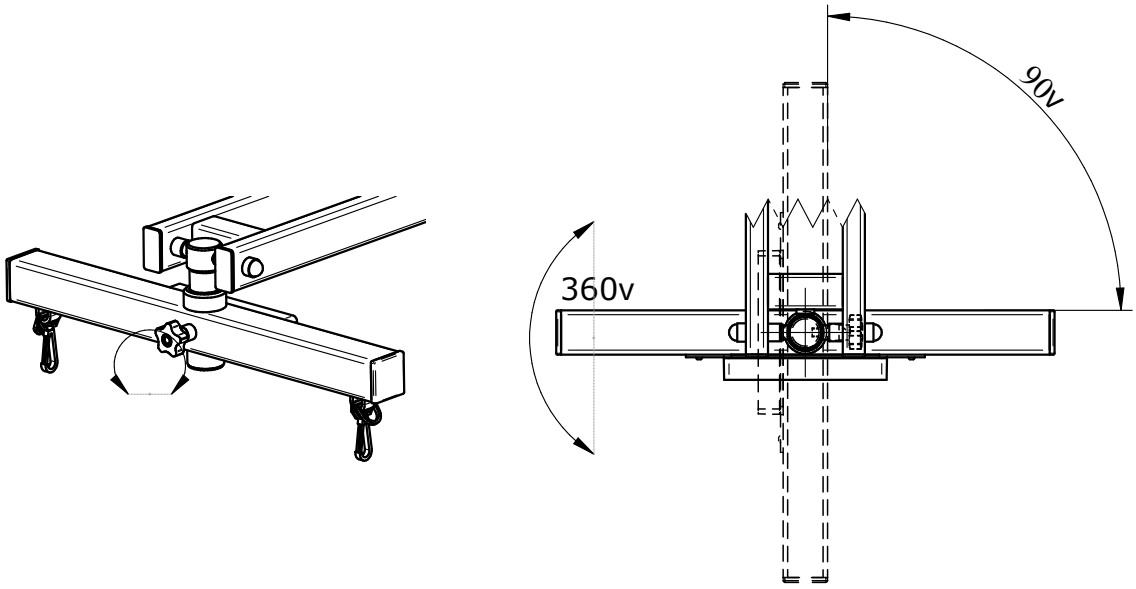


Figure 14 - Adjusting the swivel sling

7.8. Installation and adjustment of operator’s stool

CAUTION!

After mounting or changing the position of the stool, block the position lock.

In order to improve ease of use of PHYSIOGAIT Therapy Device, there is possibility of mounting a stool at one of the beams of the frame. Stool can be moved along the rail, which allows optimal adjustment of the position for individual needs. Stool installation requires no tools. Stool arm mounted on the supporting wheel is fixed to the frame beam with a magnetic lock and pressure made by a knob. In order to move the stool, it is necessary (see Fig.15):

- release the lock by unscrewing the knob until the pressure can be slid out from under the device leg;
- slide out the lock;
- pull the handle lifting the entire stool;
- determine the new position;
- lower the handle;
- slide the lock under the leg of the device;
- tighten the lock with the knob.

The magnetic lock works automatically (see Fig.15). The wheel under the stool is used to adjust the position relative to the ground. If necessary, the wheel should be unscrewed or screwed until the stool arm is optimally positioned.

Figure 15 – Installation and adjustment of operator’s stool

7.9. Checking battery status

Checking the battery charge (see Fig. 16) is done by visual inspection of the indicator on the hand remote control. Three dashes indicate battery full charge and free operation. A dash on the indicator indicates that the battery charge level may be insufficient for free operation and should be recharged.

← LED indicating the status of the lifting function (see section 6.1)

High level of charge

← LED indicating the status of the lifting function (see section 6.1)

Low charge

Figure 16 - Checking the battery charge level

6.10. Charging the lifting column battery

CAUTION!

After each finished charging, disconnect the power supply from the wall socket, and the battery from the docking station.

CAUTION!

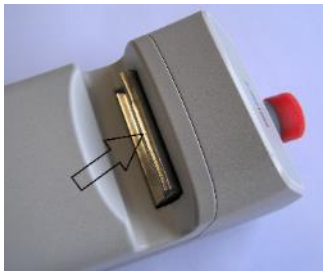
Storing the battery outside of the controller enclosure must prevent a direct connection of battery terminals.

Battery charging (see Fig.17) is possible with the use of a dedicated docking station and power supply purchased with the therapy device. In case of lack of power supply from the battery, release the battery by pressing the lock, remove it from the body of the controller and fit it in the dock. Docking station must be connected to the power supply, which must be connected into the power outlet 100-240 VAC 50/60 Hz. Charging status is indicated by indicator located on the power supply:

- charging (yellow);
- charging finished (green).

The light on the docking station is a power indicator.

After removing the battery from the docking station, you should put it back in the controller housing in a manner ensuring locking of the mounting hitch.



Removing the battery from controller housing	Connecting power supply to the docking station	Battery in the docking station	Inserting the battery into controller housing

Figure 17 - Charging and handling the battery

7.11. Lock button

CAUTION!

After each finished work, press the lock button preventing the launch of therapy device control function.

PHYSIOGAIT therapy device is equipped with height adjustment function lock button (see Fig.18).

LOCK WORK UNLOCK

Figure 18 - Mechanism of protection against unauthorized access

Adjustment function is locked when the power lock button ① is pressed. Control function is enabled when the power lock button is not pressed ①. Lock release is done by turning the button ① in direction as indicated on its surface.

7.12. Elements of the weight bearing measurement system

The system consists of two devices. Weighing module and operator panel. The table together with two weight transducers has been provided for use as an indicator of dynamic patient weight bearing used in rehabilitation and gait reeducation. The task of the weighing module is to measure the unloading of the left and right sides and sending them to the operator panel. The task of the panel is to communicate with the weighing module and to present the received data to the operator panel.

7.13. Weighing module

① **-** Indicating LED ② **-** Reset button ③ **-** Charger socket

Figure 19 - Weighing module

Description of weighing module functions:

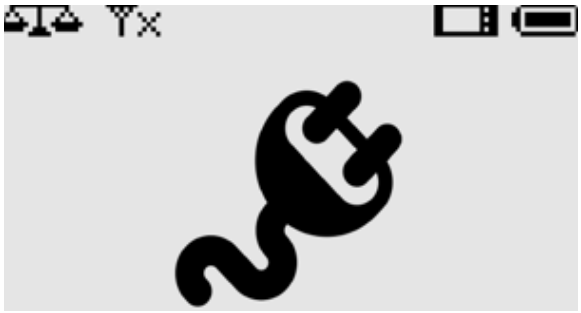
Turning on/off weighing module	The weighing module is switched on by changing the load on one of the sides by a minimum of one kilogram for about 1 second. The indicator light flashes with a short pulse twice per second, signaling the wait for the connection to the panel. If the connection is not established within 60 seconds, the device will automatically go into sleep mode. The LED stops flashing.
Connecting with the panel	The connection state to the panel will be signaled by a short pulse diode every 1 second. When the connection is interrupted, the beam will enter the wait for the connection mode, which will be indicated by a diode short pulse of 0.5 second.
Low level of battery charge	In operation mode, the diode uses green light to indicate the operating status. When the battery level is low, the status light is orange.
Resetting the device	The RESET button is located on the unit's housing. In case of a problem with the device, use a thin object and press it into the hole.

7.14 Charging panel battery

CAUTION!

Do not use a power cord and charger other than provided by the manufacturer.

To charge the built-in battery, use the supplied plug-in power supply DC 5V/1A. Jack for connecting the power supply is placed on the side wall of the panel housing. During charging, the battery symbol will be animated to indicate the charging process. Connecting the charger when the device is off will turn on the desktop and display a charging screen. Press any button to enter the operating mode. When the backlight is on, after 30 seconds it will turn off and the first push of any button will turn on the backlight.



After connecting the charger to the device, the LED will turn orange and will turn off after charging the battery. Connecting the charger when the device is charged will cause the orange LED to turn on, which will turn off after about 1.5 minutes. During charging, the operating status is indicated by green pulses, as in the case when the charger is disconnected from the device.

7.15 Operator Panel

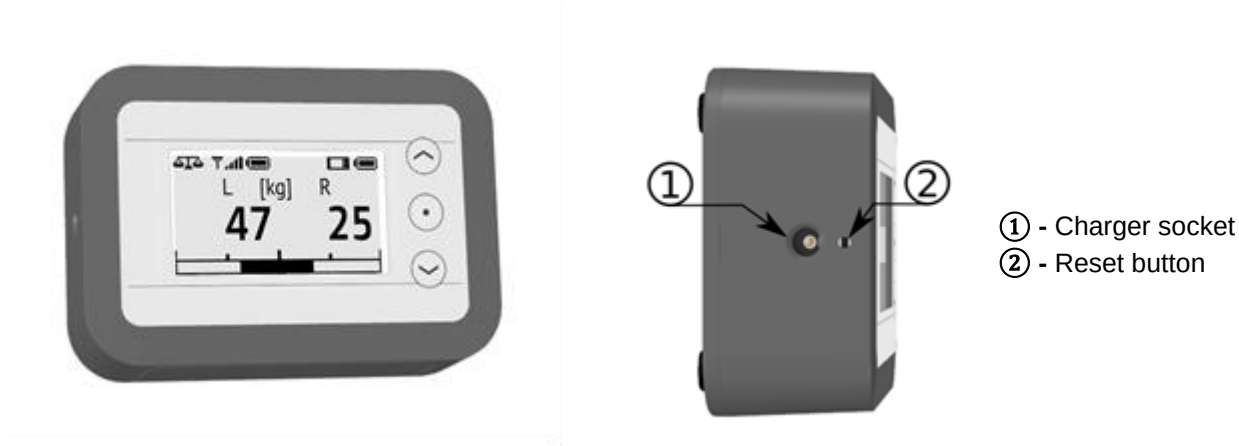


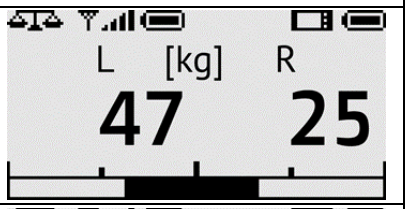
Figure 20 – Operator Panel

Description of panel functions:

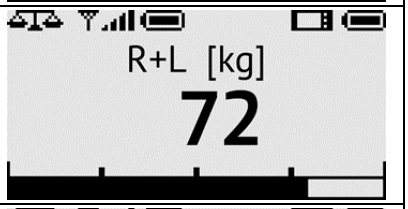
Turning on the panel	To activate the panel, press any button and hold it for more than 0.5 s.	
Turning off the panel	In case if no button is pressed for the programmed time or the load does not change by 1 kg, the panel will automatically turn off. To immediately switch off the panel from the main screen or connection waiting screen, press and hold for more than 0.5s. or button.	
Status bar	 The status bar is always visible at the top of the screen. Indicates the connection status and battery level of the weighing module and operator panel.  - symbol of weighing module. The icons on the right apply to the weighing module.  - signal strength. When the panel is not connected to the weighing module, the symbol  is displayed and the battery symbol is not visible.  - symbol of the battery charge level of the weighing module / operator panel.  - operator panel symbol. The icons on the right apply to the operator panel.	
Connection waiting screen		When the panel is started, a screen will be displayed informing you that you are trying to connect to a weighing module whose ID is displayed on the bottom line. If the connection is not established after the time of automatic shutdown and no button is pressed, the device switches off. When connected, the main screen is displayed.
		If the panel is not paired with a weighing module or the pairing has been deleted (Connection → Disconnect menu), the information will display about the lack of device with which the panel can connect.
Main screen		

On the main screen measured values of weight relief of left and right side are displayed. Graphic indicator shows the measured weight bearing value against programmed patient's weight. The relief can be shown in percentage or in selected units of the scale. Switching between display modes is done by pressing ⌄ or ⌃. The measured relieving values of the left side are displayed on the main screen and right.

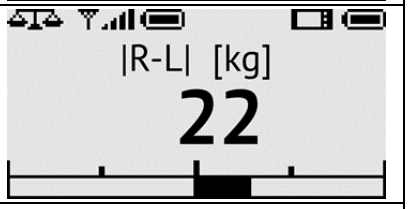
INDICATION FOR BOTH SIDES - simultaneously weight bearing value on the left and right side is presented.



INDICATION OF SUM - the sum of weight bearing of left and right side is presented.



INDICATION OF DIFFERENCE - difference of weight bearing of left and right side is presented.

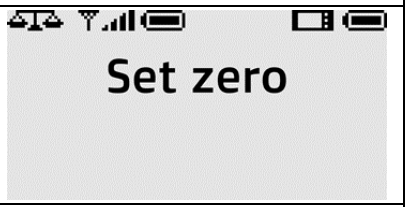


MAINTAINING RELIEF PEAK LOAD - Pressing the ⊙ button will activate the peak load relief mode. The display under the battery indicator of the operator's panel displays the symbol P-H.This mode is active in all display modes. To switch off the peak hold mode, press the ⊙ button again. When the Peak Hold mode is activated, the display shows the highest recorded offload. It will be maintained for the time set in the user settings in *Peak Hold.* The graphical weight bearing indicator will be represented by the current strain weight bearing and additionally, there will be indications of the peak value.

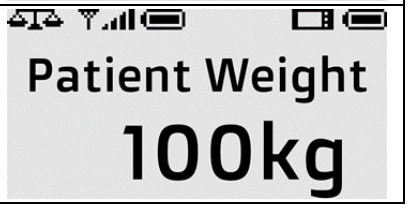
Configuration of user settings

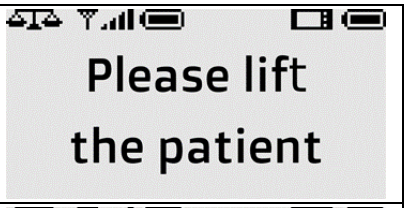
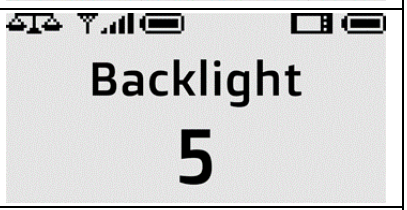
To change user settings when displaying the main screen or connection waiting screen press and hold ⊙ button (approx. 0.5 sec). When entering a menu from the home screen position, the menu is set to *Set Zero* and when entering a menu from the standby screen position, it is set to *Connection*. While the connection is not established, *Set Zero* is not shown in the menu. Pressing the button ⌄ moves to the next menu item and the button ⌃ to the previous one.

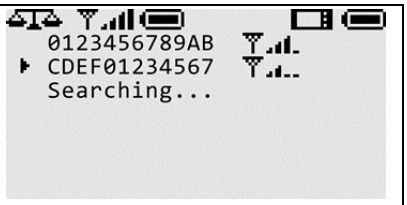
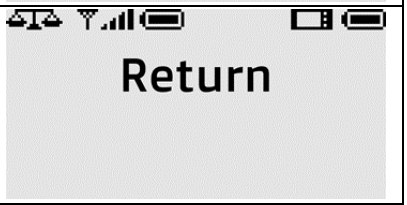
MEASUREMENT RESET - to reset the display when empty harness (without the patient) is mounted, press and hold ⊙ button.
Wait ... will appear on the screen indicating the ongoing reset procedure. After a few seconds the procedure will be completed and the main screen will occur. This parameter is stored in the weighing module of PHYSIOGAIT.



INDICATION OF PATIENT WEIGHT - press ⊙ to enter manually the weight of a new patient, then use the ⌄ and ⌃ button to set the desired value from 25 to 200 kg (or 55 to 440 lb) and confirm the setting with ⊙.



PATIENT WEIGHT MEASUREMENT - to weigh the patient, keep the button pressed until the information screen appears. When the patient is fully lifted, press the button to weigh him/her. After a while, the weighing process is completed and the result will be shown. The value is not remembered when you turn off the desktop.	
WEIGHT UNIT - press to change the unit, then use and button to switch between kilograms and pounds and confirm the setting with .	
RELIEF DISPLAYMENT - Relief can be displayed as a percentage of the patient's weight or selected units of body weight. To change, press the button , then use and buttons and set the selected mode.	
SELECTION OF AUTOMATIC OFF TIME - press to change the programmed time, then use and to set the desired value from 3 to 60 minutes and confirm by pressing .	
HOLD TIME OF PEAK LOAD RELIEF - Press the button to change the programmed time, then use the and buttons to set the desired value between 1 second and 60 minutes at 1 second intervals ranging from 1 to 10 seconds, every 5 seconds in the range of 10 to 60 seconds and every 1 minute in the range of 1 to 60 minutes and confirm with the button.	
SELECTION OF BACKLIGHT LEVEL - press to change the brightness of the backlight, then use and to set the desired value from 0 (backlight off) to 5 (max brightness) and confirm the setting .	
CONNECTION TO THE WEIGHING MODULE – press in order to enter the menu that manages the connection to the weighing module.	
SEARCHING FOR DEVICES - To connect to the PHYSIOGAIT weighing module, select *Search for device* from the Connection menu and press the to confirm. The procedure for finding compatible devices will start. The search screen will appear.	

SEARCH SCREEN - The search screen shows the IDs of the found devices and the signal strength. The number of devices is limited to 7. Use and to select ID to which the connection is to be made. A symbol appears next to the selected ID. Then Press the to confirm. The ID is saved in the panel. The connection waiting screen appears. To cancel the search, press and hold until the menu appears.	
DISCONNECTING - To disconnect the connection to the PHYSIOGAIT weighing module and delete the saved ID from the panel memory, select Disconnect in the Connection menu and press to Disconnect and remove the ID from the memory and return to the menu.	
SCREEN ORIENTATION - The device can be configured to work with buttons on the left or right side of the screen (left and right hand) or automatically change the orientation. To change the orientation, press the button . Under Orientation inscription appears the current setting. Use and , and select the desired configuration and press to confirm.	
	
SELECT LANGUAGE - Press the button to change the interface language, then use and to select one from available versions and press to confirm. Available languages: English, Polish, Russian.	
RETURN TO THE MAIN SCREEN - press to exit the Setup menu and return to the main screen.	

8. PHYSIOGAIT THERAPY DEVICE OPERATING CONDITIONS

CAUTION!

Surfaces of the handle and device supporting structure must be prophylactically cleaned and/or disinfected after each use (after every patient) which allows to maintain proper hygiene conditions.

CAUTION!

The expected service life of the device is 7 years. After 7 years from the date of manufacture of the device (and its equipment) manufacturer is no longer liable for defects of the device (and its accessories) and the resulting consequences.

8.1. Cleaning patient contact surfaces

1. The surface of the handles should be cleaned and maintained as follows:
   - for small dirt on the handrail or suspension, use a solution of mild detergent (such as soap or sani cloth) and clean in warm water with a dampened soft cloth or sponge; after cleaning, wipe with a dry soft cloth;
   - if the handrail or suspension is more dirty, rub with a dampened soft brush; after cleaning, wipe with a dry soft cloth;
   - Harness is non-permeable and can be wiped with Sani cloth. Or the harness can be hand washed at low temperature (up to 40˚C), dry hanging;
   - avoid getting wet;
   - do not dry-clean;
   - accessible surfaces of handrails and structures can be disinfected using a product such as Incidin Foam;
   - disinfection of casters is only necessary if there is visible contact with infected or potentially infected material.
2. Do not use:
   - pastes, waxes, sprays;
   - strong detergents, solvents and cleaning agents containing solvents, alcohol and leather cleaning agents.

The use of such agents can cause stiffness and cracking of the material, as well as changing surface gloss, not covered by the warranty.

8.2. Maintenance of support structure mechanism

1. Metal parts of the structure can be cleaned with a soft, damp cloth. Cleaned surfaces should be wiped dry each time.
2. All the mobile nodes should be (with the exception of the column) lubricated once every six months or when loud noises occur during their work. Such nodes include:
   - transport wheels axles,
   - arms bearing bushes.

   As a lubricant, we recommend using commercially available penetrating and lubricating formulations. Avoid contact with upholstered surfaces, and any spills of such preparations should be immediately removed with a dry cloth.
3. Periodically - every six months – carry out an inspection of threaded connections and, if necessary, remove the emerging backlash with a cross tip screwdriver with, hex keys (No. 4, 5, 6, 8 and 10), a spanner (17). Such connections include:
   - weight bearing arm screws,
   - lifting column fixing screws.
   - transport wheels fastening screws.
   - screws securing legs stringers in the frame.

All irremovable backlash on connections should be reported to the manufacturer service department followed by ceasing operation of table until removal of the cause.

8.3. Check of the column

PHYSIOGAIT is equipped with an electric column to change patient suspension height. In order to ensure proper operation, quarterly inspections of column verifying its correct functioning and the occurrence of sounds other than resulting from a normal operation, for example rattles, squeaks, creaks. Detection of any irregularities in the operation of the actuator must be immediately reported to the HealthCare International followed by ceasing operation of the device until removal of the causes.

8.4. Battery maintenance

The PHYSIOGAIT battery should be charged continuously for at least 24 hours in the following situations:

- first use of the lift,
- before long storage without connecting the AC adapter,
- as the first step after a long period of storage.

8.5. Periodic inspections of electrical safety

At least once every two years and each time after a failure/repair of table and panel motor/ automation, technical services of the user must perform or commission an inspection of the table in terms of electrical safety.

The minimum scope of the inspection should include:

- check if there were no mechanical damages of wiring;
- check whether there is any mechanical damages of controller housing, battery and columns;
- check the status of height adjustment function switches.

Inspection should be documented each time with entry in the Table. Operating personnel must follow the instructions contained in this manual.

9. ADDITIONAL OPTIONS

CAUTION!

Conducting gait therapy on a treadmill requires all four castors to be locked.

CAUTION!

Do not exceed 10% of the treadmill upliftment, as it may damage the combined device system.

The PHYSIOGAIT patient lift in combined with most treadmills.

Figure 21 – Method of connecting the PHYSIOGAIT dynamic partial weight bearing gait therapy device to the treadmill for rehabilitation

Connecting the treadmill to the PHYSIOGAIT suspension system should be p

10. TROUBLESHOOTING

Symptoms of malfunction	Description of the procedure
The device does not respond to function activation on the manual remote control	1. Check if the emergency STOP button is not turned on. 2. Check the status of battery charge. 3. Check if the hand control cable is connected. 4. Check if the battery is properly connected. 5. Check if the charging cable is connected. 6. Check the connection of the other cables. 7. Contact the service.
The battery is not charging	1. Check if the battery is properly connected. 2. Check if the charging cable is connected. 3. Check if the service LED is flashing. 4. Contact the service.

Stopping operation of the device while lifting a patient	1. Check the status of battery. 2. Check that the battery is properly inserted in the control box. 3. Check that the maximum load on the device (SWL) has not been exceeded. 4. Contact the service.
The device produces abnormal noises (cracking, cross-over, etc.)	1. Contact the service.
The lift cannot be moved from its place	1. Check that the brakes on the rear casters are not engaged. 2. Contact the service.

If the symptoms of the malfunction do not disappear, stop using the hoist and contact the supplier or manufacturer.

11. RECYCLING INFORMATION

Metals

Electrical and electronic equipment waste

Battery (Pb) or Li-ION

Figure 24 – Recycling of PHYSIOGAIT

Battery (Pb)	Electronic equipment waste				
	Control box	Remote control	Lifting column	Panel control	Weight transducer support module
					

12. ELECTROMAGNETIC COMPATIBILITY – GUIDANCE AND MANUFACTURER'S DECLARATION

CAUTION!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION!

Device may be susceptible to electromagnetic disturbances, but Basic Safety and Essential Performance are maintained.

Essential Performance - from the risk management documentation shows the lack of essential functioning characteristics for this product *.

** PHYSIOGAIT Partial Weight Bearing Gait Therapy Device*

Guidance and manufacturer's declaration – electromagnetic emissions		
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The equipment* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The equipment* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV (contact) ± 2/4/8/15 kV (air)	± 8 kV (contact) ± 2/4/8/15 kV (air)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz	±2 kV for power supply lines 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment* requires continued operation during power mains interruptions, it is recommended that the equipment* be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	10 V/m 80MHz do 2,7GHz	10 V/m 80MHz do 2,7GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	EN 60601-1-2:2015, Table 9 *(see below)*	Complies	
	☒ *home healthcare environment*	☒ *home healthcare environment*	

Proximity fields from RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50 % duty cycle square wave signal. [c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Dynamic Partial Weight Bearing Gait
PHYSIOGAIT

Date, signature and stamp of the Guarantor*:*

SN: | | | | | | **-** | | | | |

Repair registry	**User comments**