FIOR & GENTZ
ORTHOPÄDIETECHNIK MIT SYSTEM

Instructions for Use for Patients
System Ankle Joint NEURO HiSWING R+

EN

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Instructions for Use for Patients
System Ankle Joint **NEURO HiSWING R+**

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ electrohydraulic system ankle joint from a qualified specialist in orthopaedic technology.

1. Safety Instructions

1.1 Classification of the Safety Instructions

⚠ **DANGER**	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ **WARNING**	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ **CAUTION**	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

All serious incidents according to Regulation (EU) 2017/745 which are related to the product have to be reported to the manufacturer and to the competent authority of the Member State in which the qualified specialist in orthopaedic technology and/or the patient is established.

1.2 All Instructions for Your Safety

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Gather information about all issues concerning safety and security and potential dangers before driving a motor vehicle with orthosis.

⚠ DANGER

Risk of Strangulation Due to Improper Handling of the Cables
Use the orthosis as described in these instructions for use. During use, pay particular attention to the connection cable of the orthosis as well as to the charging cable of the controller.

⚠ WARNING

Jeopardising the Therapy Goal by Not Providing the Necessary Free Movement
Check if the system joint moves freely in order to avoid restrictions of the joint function.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
Do not engage in sport activities with the orthosis that expose it to excessive load. If your patient data has changed (e.g. due to weight gain, growth or increased activity), consult a qualified specialist in orthopaedic technology and have them check the suitability of your orthosis with regard to the changed load. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Improper Handling
Have a qualified specialist in orthopaedic technology inform you about the correct use of the system joint and potential dangers. Do not use the orthosis if you notice any damage on the system joint.

⚠ WARNING

Risk of Falling Due to Improper Handling
System joint components and orthosis components may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the system joint and the orthosis from your side that goes beyond the activities described in these instructions for use is not permitted. Do not make any modifications to the system joint other than those specified as permissible in these instructions for use. In particular, do not loosen any screws on the system joint.

⚠ WARNING

Risk of Falling Due to Improper Handling
Only change the lower leg-to-plumb line angle in Relax mode with little effort and slowly. Avoid putting weight on the orthosis in Relax mode (e.g. by walking, running or cycling).

⚠ WARNING

Risk of Falling Due to Improper Dirt Removal
In order to avoid a failure of the lock function, remove dirt from the orthosis and the system joint as described in these instructions for use. Do not grease the system joint on your own. If necessary, consult a qualified specialist in orthopaedic technology.

⚠ WARNING

Risk of Falling Due to Damages to the Orthosis
Avoid damage to your orthosis and to the integrated electronics (e. g. due to shocks, knocks and fall). However, if your orthosis is damaged, consult a qualified specialist in orthopaedic technology.

⚠ WARNING

Risk of Falling Due to Incorrect Walking with the Orthosis
Consult a qualified specialist in orthopaedic technology about the correct use of your orthosis and the particularities of the system joint. If necessary, we recommend a physiotherapeutic gait re-education.

⚠ WARNING

Risk of Falling when Cycling
Switch the controller of the ankle joint system into standby when you want to cycle with your orthosis.

⚠ WARNING

Risk of Falling Due to Changes in the Orthosis
If you notice any changes in the orthosis (e.g. loosely attached joint components, loosened screws, play in the system joint or change in performance), immediately contact a qualified specialist in orthopaedic technology. Do not secure screws for the system joint on your own. All settings must be checked by a qualified specialist in orthopaedic technology before handing over the orthosis and during the maintenance appointments. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Use of Unauthorised Accessories
Use only the accessories specified or supplied by the manufacturer (adapter, charging cable) in order to avoid increased electromagnetic emissions and reduced electromagnetic immunity of the ankle joint system.

⚠ WARNING

Risk of Falling Due to Use of the Orthosis without a Shoe
If you want to wear the orthosis without a shoe, your orthosis must fulfil the necessary requirements. A qualified specialist in orthopaedic technology must attach a fixation for your foot to the foot piece of the orthosis and a slip-resistant sole. Only wear the orthosis without a shoe in consultation with a qualified specialist in orthopaedic technology.

⚠ WARNING

Risk of Falling Due to Electromagnetic Interference
Do not use the ankle joint system in close proximity to or stacked with other portable RF communication devices in order to avoid impairing the function of the ankle joint system. If such use is necessary, observe the ankle joint system and other portable RF communication devices in use to ensure that they function normally.

⚠ WARNING

Risk of Falling Due to Electromagnetic Interference
Use portable RF communication devices (including peripherals such as antenna cables and external antennas) at a safety distance of at least 30cm from all components of the ankle joint system to avoid impairing the function of the ankle joint system. If use at a distance of less than 30cm is necessary, observe the ankle joint system during use to ensure that it functions normally. Also note the safety distances for RF communication devices specified in these instructions for use (see paragraph 18.6).

⚠ WARNING

Risk of Falling Due to Security Gaps in the Software
Carry out regular updates for your mobile device. Make sure that your **User** app and the operating system of your mobile device are always working with the latest version.

⚠ WARNING

Risk of Electric Shock Due to Improper Handling
Only use the supplied accessories to avoid electric shock and damage to the ankle joint system.

⚠ WARNING

Risk of Injury Due to Improper Handling of the Controller
Use the controller as described in these instructions for use. The orthosis may not be worn while it is charging. The controller is a sensitive electronic device with an integrated lithium-polymer battery. When handling the controller please avoid:
- strong heat (e.g. fire, heater, fireplace),
- charging of a battery in direct sunlight,
- knocks and shocks (e.g. by pets) as well as
- immersion in water.

⚠ WARNING

Risk of Injury Due to Improper Handling of the System Joint
Use the system joint as described in these instructions for use.
- Do not immerse the system joint in water. The electronic system components (excluding the accessories) are only protected from water splashing on all sides.
- When using the system joint, an opening is formed between the joint's upper and lower parts, in which clothing or skin could get caught.

NOTICE

Limitation of Joint Function Due to Electrostatic/Magnetic Field
Please note that, while using the orthosis, an electrostatic and magnetic field (e.g. MRI) can lead to joint dysfunction.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Have a qualified specialist in orthopaedic technology inform you about the maintenance intervals to be observed in order to avoid joint dysfunctions. You will find the next maintenance appointment in your orthosis service passport.

NOTICE

Damage to the Controller Due to Improper Handling
Ensure the correct use in order to avoid joint dysfunction. Regarding the controller, avoid:
- opening it as well as
- using it in areas where radio waves are forbidden (e.g. on a plane).
Ask the responsible staff on-site how to use the controller.

In case of problems with the system joint and potentially occurring allergic reactions, contact a qualified specialist in orthopaedic technology or the manufacturer. You can find the manufacturer's contact data on the back page of these instructions for use.

2. Use

2.1 Intended Use

The FIOR & GENTZ automatic electronic system ankle joint is exclusively for use for orthotic fittings of the lower extremity. The system joint is only allowed to be used for producing an AFO or a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg.

2.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/ malfunctions or as a result of physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. A safe handling of the orthosis must be ensured. A qualified specialist in orthopaedic technology selects the appropriate system joints for the orthosis.

All system ankle joints can also be used for the prosthetic treatment of patients with partial foot amputations. For this purpose, the orthosis produced for the patient by a qualified specialist in orthopaedic technology (custom-made product) is combined with a foot prosthesis. Further information can be found in the **Guide to Partial Foot Amputations** (see QR code, fig. 1).

fig. 1

2.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 2.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis that affects more than just part of the foot, for example after amputations of leg segments.

2.4 Qualification

The system joint must only be handled by a qualified specialist in orthopaedic technology.

2.5 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing and parachuting, is excluded. The system joint can be used at temperatures of -10°C to +40°C.

3. Ankle Joint System

The ankle joint system is equipped with Bluetooth® technology* and consists of the following components (fig. 2):

1. **system ankle joint**
2. **controller**
3. **charging cable with adapter** and **User** app for the patient
4. **Expert** app for qualified specialists in orthopaedic technology

The system ankle joint and the controller are built into your orthosis. The qualified specialist in orthopaedic technology uses the **Expert** app to adjust the orthosis. You need the **User** app to operate the orthosis.

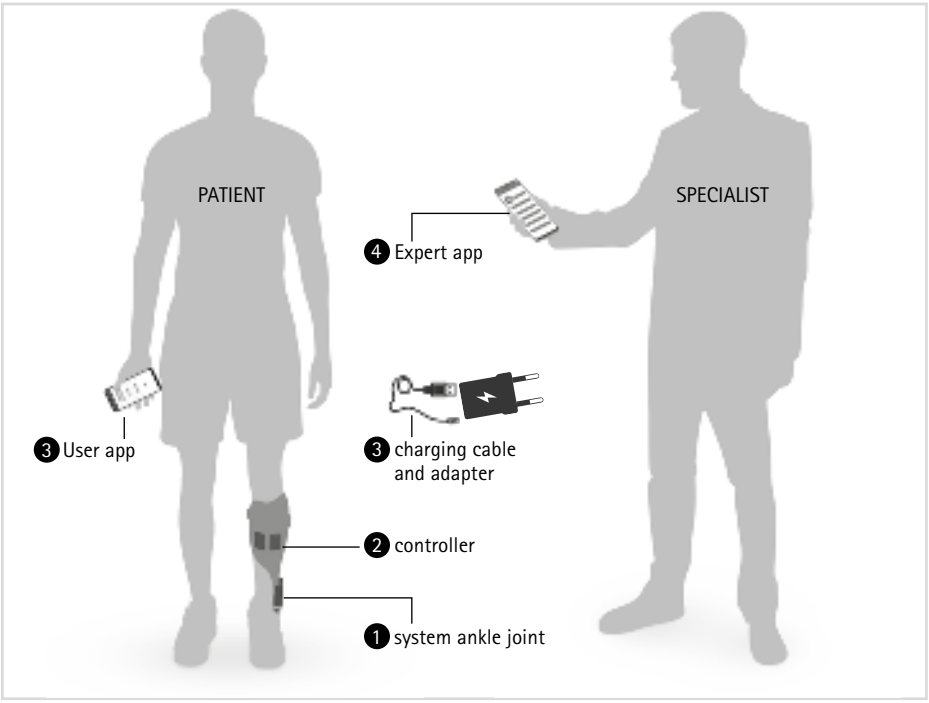


fig. 2

* The Bluetooth® word mark and logos are registered trademarks of Bluetooth SIG, Inc. and any use of such marks by FIOR & GENTZ is under license.

You have received the following system components in addition to your orthosis (fig. 3):

Item	Art. No.	Description	Unit	Quantity
1	ET0710-01	charging cable	pce.	1
2	ET0780-01	adapter	pce.	1

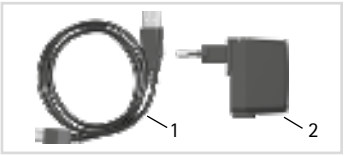


fig. 3

3.1 Joint Functions

The **NEURO HiSWING R+** is a microprocessor-controlled, automatic system ankle joint and provides the following joint functions:

- Zero mode for resetting the lower leg-to-plumb line angle to the basic position, e.g. for walking uphill and downhill
- Relax mode for situations in which you want to use the orthosis as a free moving orthosis, e.g. to relax the foot while sitting
- Stair mode for adjusting the lower leg-to-plumb line angle when climbing stairs
- alternative function with control button for situations in which the ankle joint angle needs to be adjusted manually and the **User** app is not available

The essential performance features of the automatic electronic system joint are to activate and deactivate the adjustment of the ankle joint angle according to the selection in the **User** app and to open the valves in the automatic modes at the right time.

If electromagnetic interference occurs, the automatic ankle joint system does not function as described in these instructions for use. Read the safety instructions before using the ankle joint system to avoid problems.

3.2 Modes

The automatic ankle joint system is equipped with the Zero, Relax and Stair mode. If none of these modes is active, the controller is in standby and is ready for a possible activation of a mode. The system joint can then be used normally and improves the patient's stability while walking and standing with the help of the spring units used.

For training purposes when changing modes, a lightning bolt appears in the top right-hand corner of the app immediately after you have activated a mode. While the lightning bolt is displayed filled in, the load should be taken off the spring units of the system ankle joint. As soon as the spring units are free of load within this time, the hydraulic valves open and you can adjust the lower leg-to-plumb line angle. During angle adjustment, only the outline of the lightning bolt is displayed. If no mode is activated, no lightning bolt is displayed.

If you have missed the time to take the load off the spring units, you can tilt your lower leg forwards and backwards. The lightning bolt is then displayed again filled in for the period in which the load should be taken off the spring units.

In the default setting, you can only switch modes when standing still. You must wait half a second before activating the mode with the app.

If the orthosis is exposed to strong shocks, vibrations or fluctuations in air pressure, a safety mechanism is activated. Angle adjustment is not possible at this point. Press the control button on the system joint once (fig. 7) so that the orthosis can be used normally again.

For safety reasons, it is not possible to change the lower leg-to-plumb line angle of the orthosis when one of the spring units is loaded. Take the load off the spring unit by moving slightly in the other direction (fig. 4) and try again in the **User** app.

fig. 4

3.2.1 Zero Mode

Zero mode allows you to reset the orthosis alignment to the basic position set by a qualified specialist in orthopaedic technology. The angle of the lower leg in relation to the plumb line is set to the same angle that the qualified specialist in orthopaedic technology defined as the basic position when the orthosis was handed over. Proceed as follows:

1 Stand still or stand up.
2 Move the Zero slider in the **User** app to the right.
3 The background of the slider lights up red if the inclination of the lower leg does not correspond to the basic position.
4 Keep your foot on the floor, relieve your lower leg slightly and tilt it forwards and backwards until the background of the slider lights up green. Remain in this position briefly until the background of the slider no longer lights up. The inclination of the lower leg now corresponds to the angle determined by the qualified specialist in orthopaedic technology when setting the basic position.

Use Zero mode in the following situations:

- for standing or walking on an incline or slope to make walking uphill easier and to increase stability when walking downhill
- after you have used the orthosis to walk uphill or downhill and are standing and walking on level ground again
- after the orthosis has been in Relax mode and you want to use it again for standing or walking
- after you have used Stair mode
- after every shoe change
- for wearing the orthosis without a shoe

The prerequisite for wearing the orthosis without a shoe is that the orthosis has been appropriately prepared by a qualified specialist in orthopaedic technology, particularly regarding a fixation for your foot on the foot piece of the orthosis and a slip-resistant sole (fig. 5).

fig. 5

3.2.2 Relax Mode

In Relax mode, the system ankle joint is free moving and you can freely adjust the lower leg-to-plumb line angle to relax the foot while sitting (fig. 6) or to put on or take off the orthosis.

fig. 6

If the automatic system ankle joint has been combined with an automatic system knee joint, Relax mode is not available.

3.2.3 Stair Mode

With the Stair mode, you can adjust the orthosis alignment to the physiological ankle joint angle when climbing stairs before proceeding up or down the stairs. Activate Stair mode with the **User** app and tilt your lower leg forward until the angle adjustment is completed. After climbing stairs, you must activate the Zero mode to return the lower leg-to-plumb line angle to the basic position.

A qualified specialist in orthopaedic technology defines the lower leg-to-plumb line angle for Stair mode in the **Expert** app. When this preset angle is reached in Stair mode, the hydraulic valves close and you can ascend or descend the stairs.

fig. 7

3.2.4 Alternative Function with Control Button

The alternative function describes the adjustment of the ankle joint angle using the control button (fig. 7) on the system joint when the **User** app is not available. If you press and hold the control button, the ankle joint angle can be changed manually and separately in both directions.

fig. 8

3.3 **User** App

You can set the mode on your orthosis with the **User** app. Make sure that you are standing securely when changing the mode of your orthosis.

You can operate the orthosis with the free app (fig. 8) via your smartphone/tablet or your Apple Watch* (fig. 9). Minimum requirements are Bluetooth 4.0 and Android 6.0 or iOS 12.

fig. 9

The orthosis can only be operated with the **User** app to which it is currently connected. Other apps have no influence on your orthosis.

Carry out regular updates for your mobile device and enable automatic updates. Make sure that your **User** app and the operating system of your mobile device are always working with the latest version. If the manufacturer of your mobile device no longer offers updates to fix bugs or security gaps, it is advisable to switch to a newer device.

* Apple Watch is a trademark of Apple Inc., registered in the U.S. and other countries.

3.3.1 Pairing

In this menu item of the **User** app, you can establish a connection between the controller of your orthosis and the **User** app. To do so, follow the instructions in the app.

3.3.2 Step Counter

The app gives you access to the step counter, which counts all steps you take with the leg with orthosis. If you would like to know how many steps you have taken in total (with both legs), double the value.

3.3.3 Sound

In the sound settings, you can adjust the volume of the signal tones or switch them off.

3.3.4 Gestures

With this menu item, you can switch on and change the gesture for activating Zero mode. It allows you to activate Zero mode without using the app. You can select one or more gestures. It is possible that not all gestures are suitable for you. Check which gestures you can perform and activate these. The following gestures are available for selection:

- foot rotation (external and internal foot rotation)
- sole tap (tapping the sole of the foot on the ground)
- toe tap (tapping the tip of the toes on the ground)

Zero mode can only be activated by gesture when standing still. Wait half a second before activating the mode with a gesture. For training purposes, there is a circle in the top left-hand corner of the app that lights up green as soon as you have waited half a second and the controller is ready for activation of Zero mode by gesture.

3.4 Controller

The controller is mounted to your orthosis. It receives commands from the app, registers your movements and controls the system ankle joint.

Controller with Integrated Lithium-Polymer Battery	Item	Description
	1	multicolour LED for battery charging, mode and Bluetooth connection
	2	MODE button
	3	charging port

3.5 Manual Mode Change

A MODE button is built into the controller, which can be used to change the mode of the orthosis without the app.

Depending on the mode that is already selected, it can be switched in the following order by pressing briefly: Zero, Relax and standby. This button is particularly important if you are travelling by plane, as the app's Bluetooth connection may not be used during take-off, final approach and landing. You can generally use the app during the flight and after landing. For further information, please contact the flight crew.

The MODE button can only be used as long as the battery is not fully discharged. When the battery is fully discharged, adjustment is only possible using the control button.

If an automatic system knee joint has been combined with the **NEURO HiSWING R+** system ankle joint and both are connected to the same controller, the mode for the system knee joint can be changed by briefly pressing the MODE button. If the MODE button is pressed down for longer, the controller switches between Zero and standby for the **NEURO HiSWING R+**.

4. Connection between Controller and App

A qualified specialist in orthopaedic technology establishes the connection between the controller and the app. However, you can also establish the connection yourself if you switch to another mobile device.

In order to operate the controller with the **User** app, use the app menu and select the desired menu item to connect. Follow the additional instructions in the app. In order to operate the orthosis via the app, Bluetooth must be permanently switched on and the app must be open in the foreground.

4.1 Controlling Two Orthoses

If you wear two orthoses with automatic ankle or knee joint systems from FIOR & GENTZ, you have the option of switching modes separately or simultaneously for the controllers of both orthoses using the same **User** app.

5. Checking the Connection between Controller and User App

In order to operate the orthosis via the app, Bluetooth must be permanently switched on and the app must be open in the foreground.

The controller gives signals in order to inform you about the connection status of the app and the controller. The blue LED on the controller indicates that the app and the controller communicate.

For safety reasons, only one **User** app can be connected to the controller. Existing connections are disconnected when a new **User** app is connected.

6. Checking the Mode and Battery Status

6.1 Indication of Mode and Battery Status on the Controller

You can see the mode and battery status of the controller in the app. Furthermore, the LED battery level indicator displays the following light signals for the battery status:

Light Signal	Meaning
colour: yellow, green, red (depending on battery status)	The controller is in Zero mode.
signal duration: ■	
colour: yellow, green, red (depending on battery status)	The controller is in Relax mode.
signal duration: ■ ■	
colour: yellow, green, red (depending on battery status)	The controller is in Stair Mode or connected to the **NEURO HiSWING R+** system ankle joint and an automatic system knee joint and the **NEURO HiSWING R+** is in Zero or Stair mode.
signal duration: ■ ■ ■	
–	The controller is in standby.

In standby, the battery status is not indicated by a light signal. It can be viewed in the app.

In combination with an automatic knee joint system, the light signal only indicates the battery status and not the mode if at least one of the system joints is active.

The controller emits the following sound signals for battery status when the battery is almost empty:

Sound Signal	Signal Duration							Cause	Meaning
	■ ■ 0.5 sec.	break 1 sec.	■ ■ 0.5 sec.	break 1 min.	■ ■ 0.5 sec.	break 1 sec.	■ ■ 0.5 sec.		The battery is almost empty. Depending on the battery health, it takes a few hours to fully discharge the battery.

Due to the importance of a properly functioning orthosis, this signal sounds every minute. This period can be extended to ten minutes by activating one of the three mode buttons in the app. To do this, select the mode in which your orthosis is currently operating so that you do not inadvertently change modes. After ten minutes, the pause can always be extended by another ten minutes by pressing the mode button again. If no mode button is pressed, the signal will sound every minute. The sound signals for the battery status can be turned off until the next charge through the **User** app settings.

6.2 Indication of the Battery Status in the App

You can see the battery status of the controller(s) at any time in the app.

7. Energy-Saving Modes

Your orthosis has three different energy-saving modes:

- If the orthosis is not moved in Zero, Relax or Stair mode for more than **two hours**, the orthosis switches into standby automatically. Energy is saved in standby.
- If the orthosis is not moved for more than **30 minutes** in standby, it will automatically switch into Sleep mode. In Sleep mode, the orthosis consumes very little energy. The controller is no longer receiving signals from the app. To switch back into standby, move the orthosis slightly. The LED on the controller then lights up briefly.
- If the orthosis is not moved for more than **three days**, it switches automatically into Deep Sleep mode. In Deep Sleep mode, the controller consumes no energy and no longer receives signals from the app. In order to put the orthosis back into operation, press the MODE button on the controller or connect the charging cable.

8. Handling of the Controller Battery

The controller has a long service life and battery lifespan. Do not try to disassemble the controller as the battery is a fixed part of the controller.

8.1 Charging the Lithium-Polymer Battery

You can charge the battery using the charging cable and adapter included in the scope of delivery via a common household power socket. Always charge the battery fully and respect the general conditions of use and storage.

If the period of use of the orthosis considerably shortens despite fully charged batteries, contact a qualified specialist in orthopaedic technology.

9. Advice on Using Your Orthosis

9.1 Bluetooth Connection

The connection quality depends on how interference-free your environment is.

9.2 Malfunction Due to External Impact

If possible, avoid causing serious damage to your orthosis, e.g. through shocks, impacts or falls, as these can lead to impairment of individual system components and, in the worst case, to failure of the orthosis. If you notice any damage to the orthosis, only use it in standby and consult a qualified specialist in orthopaedic technology.

The orthosis automatically switches into standby in the event of a joint malfunction. Thus, it enables stability during stance and reduces the risk of falling.

If you would like to completely turn off the orthosis for safety reasons, press and hold the MODE button for approx. 17 seconds. This will cause a short beep to sound. After 6–10 seconds a longer beep will sound, and after an additional 10 seconds an extra long beep will sound. The orthosis will then switch into Deep Sleep mode (complete power interruption). If you would like to use the orthosis again, turn it back on by pressing the MODE button or by plugging in the charging cable.

9.3 Restrictive Use

The system ankle joint has been tested for electromagnetic compatibility in accordance with the IEC 60601-1 standard for medical electrical devices. That means the orthosis works in an electromagnetic environment without introducing intolerable electromagnetic disturbances to other devices in that environment. Nevertheless, similar to smartphones, pay attention to whether or under what conditions you are allowed to use your orthosis in specially designated areas, because the integrated electronics use radio waves (Bluetooth) and can be affected by these as well. In specially designated areas (fig. 10), ask the responsible staff on site if you can use the orthosis without restrictions. If you are not allowed to use the app, change the mode using the MODE button (see paragraph 3.5) or, if needed, take the orthosis off.

fig. 10

10. Maintenance

Ask a qualified specialist in orthopaedic technology to maintain the system joint of your orthosis **regularly**. When the orthosis is handed over to you, you receive an orthosis service passport. Bring this orthosis service passport to each follow-up and let a qualified specialist in orthopaedic technology enter the next maintenance appointment. For your own safety, respect the maintenance appointments. Never carry out maintenance work or other adjustments and repairs yourself. In the case of children and people with cognitive impairments, we would like to remind you as parents or care team to regularly check the orthosis and the system joint for signs of wear. If you notice any changes, immediately contact a qualified specialist in orthopaedic technology.

10.1 Dirt Removal

Remove dirt from the system joint on a regular basis. Use a dry cloth and clean the system joint only superficially. Then, remove visible dust and lint from the mechanics by using tweezers. Check the orthosis in straight and flexed position.

11. Storage

We recommend not storing the system joint in a damp environment.

12. Advice on Optimal Orthosis Functionality

If problems occur with your orthosis, you can display a troubleshooting code in the **User** app. You can then send this code to a qualified specialist in orthopaedic technology so that the error can be corrected more quickly. You can find the code for troubleshooting in the app under the menu item "Information".

12.1 System Ankle Joint

Problem	Cause	Action
The system joint switches unintentionally into standby.	The battery is empty.	Charge the battery.

12.2 Controller

Problem	Cause	Further Action
When the MODE button is pressed, the LEDs do not light up.	The battery is not charged.	Charge the battery. If the problem remains, contact a qualified specialist in orthopaedic technology.
No devices are found during connection of the controller and the **User** app.	The controller was not in connecting mode.	Within 30 seconds of pressing the MODE button, establish a connection between the **User** app and controller (see paragraph 4). Check whether the LEDs light up (see paragraph 6) or whether a short and a longer beep tone can be heard. If the problem remains, contact a qualified specialist in orthopaedic technology.

13. Disposal

If you no longer need the orthosis, please return it to a qualified specialist in orthopaedic technology. The product must not be disposed of with the residual waste (fig. 11). If you have a defective controller, please also return it to a qualified specialist in orthopaedic technology.

fig. 11

14. Technical Data

NEURO HiSWING R+	
period of use	unlimited, excluding wear parts
protection type	IP44
operating mode	continuous operation

14.1 Ambient Conditions

Operation	
ambient temperature	-10°C – +40°C
	+5°C – +40°C when charging the battery, no exposure to direct sunlight
relative air humidity	0% – 95%, non-condensing air humidity
air pressure	1060mbar – 700mbar

Transport	
ambient temperature	-25°C – +60°C
relative air humidity	without original packing: max. 95%, non-condensing air humidity with original packing: max. 95%
air pressure	1060mbar – 700mbar

Storage	
ambient temperature	+5°C – +40°C, no exposure to direct sunlight
relative air humidity	max. 95%, non-condensing air humidity
air pressure	1060mbar – 700mbar

Data Transmission	
remote technology	Bluetooth Low Energy (BLE4.2)
working range	min. 2m
operating frequency	2.4GHz
frequency range	2400MHz – 2483.5MHz
nominal channel bandwidth	2MHz, 40 channels
modulation	GFSK
data rate (OTA)	1Mbps
output power	3.7dBm/2.344mW (less than 20mW)
maximum output power (EIRP)	4dBm

Adapter with Charging Cable (not Part of the Medical Device)	
article number	ET0780-01
manufacturer's designation	FW8002.1MUSB/05
ambient temperature in operation	0°C – +45°C
ambient temperature in storage	-40°C – +70°C
relative air humidity	10% – 90%rH
input voltage	100V – 240V
input frequency	50Hz – 60Hz
power	6W
output voltage	5V
output current	1400mA
Charging Cable (not Part of the Medical Device)	
article number	ET0710-01
length	1m

Controller Battery	
type	lithium-polymer battery
capacity	5Wh
operating time at room temperature	Relax mode: 12 hours min.
behaviour of the system ankle joint during the charging process	The system ankle joint has no function.

User and Expert App	
supported operating system	at least Android 6.0 or iOS 12

15. Signs and Symbols

CE labelling according to Regulation (EU) 2017/745 for medical devices

medical device

article number

Do not dispose of electronic devices with household waste. Dispose of the device and accessories at official delivery points for electronic devices.

manufacturer

batch code

serial number

protect from heat

keep dry

temperature limit values for storage/for transportation

air humidity limit values for storage/for transportation

air pressure limit values for storage/for transportation

follow the instructions for use (white on blue background)

single patient – multiple uses

IP44

protection from the ingress of solid foreign bodies (diameter ≥ 1.0mm) and from splashing water on all sides

Unique Device Identifier – product identification number

Controller Type Plate

Input: 5V/1A, Type:
FW8002.1MUSB/05

Made in Germany
FIOR & GENTZ
Dorette-von-Stern-Straße 5
D-21337 Lüneburg

ET3860
ABCDEF-UVXYZ 

IP44 

16. CE Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of Regulation (EU) 2017/745. Therefore, the FIOR & GENTZ products bear the CE marking.

The product satisfies the requirements of the RoHS Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, for limiting the use of specific hazardous substances in electrical and electronic equipment.

17. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply. The warranty expires, for example, if the product is mounted several times. Please note that the product is not supposed to be combined with other components or materials than with those recommended in the configuration result of the FIOR & GENTZ Orthosis Configurator. The combination of the product with products from other manufacturers is not permitted.

The information in these instructions for use is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

18. Electromagnetic Compatibility

Special precautions must be taken for all electronic medical devices as regards electromagnetic compatibility (EMC). This device complies with standard IEC 60601-1-2:2022-01.

- All electronic medical devices must be installed and put into operation in compliance with the EMC-relevant information contained in these instructions for use.
- Portable and mobile RF communication devices may interfere with the performance of electronic medical devices.

The device satisfies all valid and required standards for electromagnetic disturbances.

- It generally has no effect on systems and devices found in its vicinity.
- It is generally not affected by systems and devices found in its vicinity.
- It is not safe to operate the device in the vicinity of high-frequency surgical devices.
- It is recommended that the device not be used in the direct vicinity of other devices.

18.1 Electromagnetic Environment

Operation of the device is allowed in the following electromagnetic environments:

- professional health care facilities (e.g. hospital, etc.)
- health care areas (e.g. use at home, use outdoors)

The patient must ensure that the device is exclusively operated in such environments.

18.2 Electromagnetic Emissions for all Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Emissions

The product **NEURO HiSWING R+** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiSWING R+** must ensure that it is operated exclusively in such an environment.

Interference Measurements	Compliance	Usage Instructions for Electromagnetic Environment
RF emissions according to CISPR 11	group 1	The product **NEURO HiSWING R+** uses RF energy only for its internal function. Therefore, the RF emissions are very low and unlikely to cause any interference in nearby electronic devices.
RF emissions according to CISPR 11	class B	The product **NEURO HiSWING R+** is suitable for use outside of residential facilities. It is also suitable for facilities directly connected to a public low-voltage network that supplies residential buildings.
harmonics according to IEC 61000-3-2	class A	
voltage fluctuations/flicker according to IEC 61000-3-3	complies with requirements	

18.3 Electromagnetic Immunity for all Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiSWING R+** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiSWING R+** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level	Usage Instructions for Electromagnetic Environment
electrostatic discharge (ESD) according to IEC 61000-4-2	± 8kV discharge on contact ± 2kV, ± 4kV, ± 8kV, ± 15kV discharge through air	± 8kV discharge on contact ± 15kV discharge through air	Floors should be made of wood or concrete or be ceramic tiled. If the floor covering is made of synthetic material, the relative humidity must be at least 30%.
electrical fast transients/bursts according to IEC 61000-4-4	± 2kV for power supply lines 100kHz pulse repetition frequency	± 2kV for power supply lines	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
surges according to IEC 61000-4-5	± 0.5kV, ± 1kV line-to-line voltage ± 0.5kV, ± 1kV line-to-ground voltage	± 1kV line-to-line voltage ± 1kV line-to-ground voltage	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
voltage drops, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	0% of U_T for 0.5 cycles and phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 70% of U_T for 25/30 cycles and phase angles of 0° 0% of U_T for 250/300 cycles	0% of U_T for 0.5 cycles and phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 70% of U_T for 25/30 cycles and phase angles of 0° 0% of U_T for 250/300 cycles	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
magnetic field at mains frequency (50, 60Hz) according to IEC 61000-4-8	30A/m	30A/m	The magnetic fields at mains frequency should be equivalent to the typical levels of a commercial or hospital environment.
Note: U_T is the nominal voltage before applying the test levels.			

18.4 Electromagnetic Immunity for Non-Life-Supporting Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiSWING R+** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiSWING R+** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level	Usage Instructions for Electromagnetic Environment
conducted RF interference according to IEC 61000-4-6	$3V_{rms}$ 150kHz to 80MHz $6V_{rms}$ in ISM bands 150kHz to 80MHz	$3V_{rms}$ 150kHz to 80MHz $6V_{rms}$ in ISM bands 150kHz to 80MHz	Portable and mobile wireless devices should be used at a safety distance from the product **NEURO HiSWING R+** and its lines. The recommended safety distance was calculated using the equation applicable to the transmission frequency. Recommended safety distance: d = 1.2 √P d = 1.2 √P 80MHz to 800MHz d = 2.3 √P 800MHz to 2.7GHz P is the nominal output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). According to an on-site investigation[a], the field strength of stationary radio transmitters should be below the compliance level at all frequencies. Interference may occur in the vicinity of devices marked with the following symbol: 
radiated RF interference according to IEC 61000-4-3	10V/m 80MHz to 2.7GHz 80% AM 1kHz	10V/m 80MHz to 2.7GHz	

Note 1: the higher frequency range applies between 80MHz and 800MHz.
Note 2: these guidelines may not be applicable in all cases. The propagation of electromagnetic factors is affected by absorption and reflection from buildings, objects and people.

[a] The field strength of stationary RF transmitters such as base stations of radio telephones and mobile land radio equipment, amateur radio stations, AM and FM radio and television stations cannot be precisely determined in advance. A site survey is recommended to establish the electromagnetic environment as a result of stationary RF transmitters. If the field strength determined at the site of the product **NEURO HiSWING R+** exceeds the compliance level specified above, the product **NEURO HiSWING R+** has to be monitored with regard to normal operation during use. If unusual performance characteristics are noted, additional measures may be necessary, such as changing the orientation or site of the product **NEURO HiSWING R+**.

18.5 Electromagnetic Immunity to Proximity Magnetic Fields

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity to Proximity Fields in the Frequency Range of 9kHz to 13.56MHz

The product **NEURO HiSWING R+** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiSWING R+** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level
proximity magnetic fields according to IEC 61000-4-39	30kHz[a], CW, 8A/m 134.2kHz, pulse modulation[b] 2.1kHz 65A/m_{rms} 13.56MHz, pulse modulation[b] 50kHz 7.5A/m_{rms}	30kHz[a], CW, 8A/m 134.2kHz, pulse modulation[b] 2.1kHz 65A/m_{rms} 13.56MHz, pulse modulation[b] 50kHz 7.5A/m_{rms}
[a] Applicable only to medical devices and systems intended for use in a home healthcare environment. [b] The carrier must be modulated with a square wave signal with 50% duty cycle.		

18.6 Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product **NEURO HiSWING R+** for Non-Life-Supporting Devices and Systems

Usage Instructions and Manufacturer's Declaration – Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product NEURO HiSWING R+

The product **NEURO HiSWING R+** is designed for operation in an electromagnetic environment where RF interference is monitored. The customer or user of the product **NEURO HiSWING R+** can help prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF communication equipment (transmitters) and the product **NEURO HiSWING R+** , as specified below according to the maximum output of the communication equipment.

Nominal Output of the Transmitter [W]	Safety Distance [m] According to Transmission Frequency		
	150kHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters whose maximum nominal output is not specified in the table above, the recommended safety distance d in metres (m) can be determined using the equation in the respective column, where P stands for the maximum nominal output of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: the higher frequency range applies between 80MHz and 800MHz. Note 2: these guidelines may not be applicable in all cases. The propagation of electromagnetic factors is affected by absorption and reflection from buildings, objects and people.			

18.7 Test Specifications for the Immunity of Enclosures Against Wireless RF Telecommunication Equipment

Test Frequency [MHz]	Frequency Band[a] [Mhz]	Radio Service[a]	Modulation[b]	Maximum Output [W]	Distance [m]	Immunity Test Level [V/m]
385	380 to 390	TETRA 400	pulse modulation[b] 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM[c] ± 5kHz deviation 1kHz sine	2	0.3	28
710	704 to 787	LTE band 13, 17	pulse modulation[b] 217Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	pulse modulation[b] 18Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	pulse modulation[b] 217Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	pulse modulation[b] 217Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	pulse modulation[b] 217Hz	0.2	0.3	9
5500						
5785						

Note: if necessary, the distance between the transmitting antenna and the ME device or ME system can be reduced to 1m to achieve the immunity test levels. The 1m test distance is permitted according to IEC 61000-4-3.

[a] For some radio services, only the frequencies for the radio link from the mobile communication device to the base station (uplink) have been included in the table.
[b] The carrier must be modulated with a square wave signal with 50% duty cycle.
[c] As an alternative to frequency modulation (FM), a pulse modulation of 50% at 18Hz can be used, as it does not correspond to the actual modulation, but is the worst case.

18.8 USA: FCC Regulatory Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions for use, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

18.9 Canada: ISED Regulatory Compliance Statement

This device complies with Industry Canada licence-exempt RSS standard(s).

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

RSS-102 Statement:

This equipment complies with Industry Canada radiation exposure limits set forth for an uncontrolled environment.

CAN ICES-003(B)

19. Handing Over the Orthosis

When handing over the orthosis to the patient, parents or care team by the qualified specialist in orthopaedic technology, they also received the instructions for use for patients as well as the orthosis service passport. The functions and handling of the orthosis were explained in detail by means of these instructions for use. Enter the next maintenance appointment in the orthosis service passport.

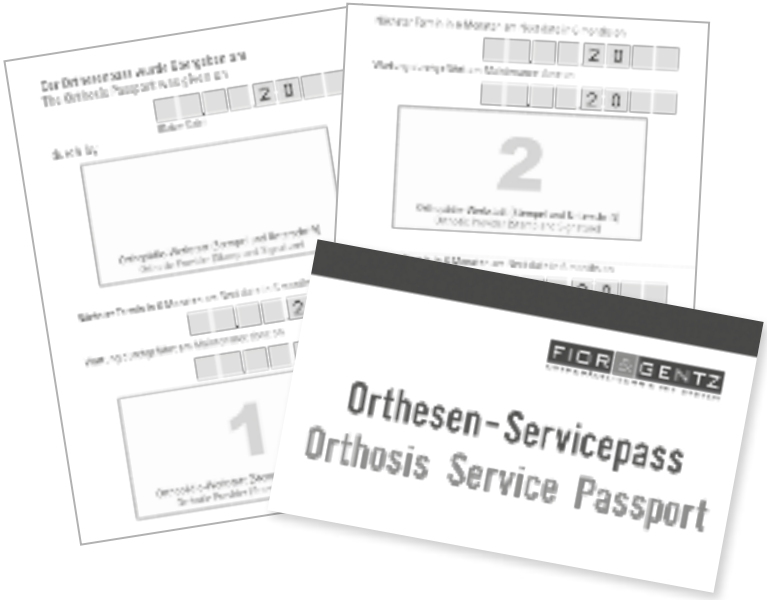
Place, Date

Signature Qualified Specialist in Orthopaedic Technology

FIOR & GENTZ
ORTHOPÄDIETECHNIK MIT SYSTEM

ORTHOSIS SERVICE PASSPORT

Have you not yet received an orthosis service passport?
Ask a qualified specialist in orthopaedic technology!



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