FIOR & GENTZ

# Instructions for Use for Qualified Specialists in Orthopaedic Technology System Ankle Joint

EN

NEURO HiSWING R+

**Content** **Page**


1. Information 4
2. Safety Instructions 4
   - 2.1 Classification of the Safety Instructions 4
   - 2.2 All Instructions for a Safe Handling of the System Ankle Joint 4
3. Use 8
   - 3.1 Intended Use 8
   - 3.2 Indication 8
   - 3.3 Contraindication 8
   - 3.4 Qualification 8
   - 3.5 Application 8
   - 3.6 Combination Possibilities with Other System Joints 9
4. Joint Functions 9
   - 4.1 Modes 10
     - 4.1.1 Zero Mode 10
     - 4.1.2 Relax Mode 11
     - 4.1.3 Stair Mode 11
     - 4.1.4 Alternative Function with Control Button 11
5. NEURO HiSWING R+ Ankle Joint System 12
6. Scope of Delivery of the System Ankle Joint 14
7. Load 15
8. Tools for Assembling the System Joint 15
9. Functional Unit 15
10. Mounting the System Joint 16
    - 10.1 Demounting the Functional Unit 16
    - 10.2 Mounting the Functional Unit 17
    - 10.3 Mounting the System Stirrup 17
    - 10.4 Checking the Free Movement 18
    - 10.5 Mounting the Spring Unit 18
    - 10.6 Checking the Control Button 19
    - 10.7 Securing the Screws 19
11. Adjustment Options on the Orthosis 19
    - 11.1 Setting or Adjusting the Orthosis Alignment 20
    - 11.2 Expanding the Range of Motion 20
    - 11.3 Exchanging the Spring Unit 20
    - 11.4 Reading the Joint Angles 21
12. Notes on the Production of the Orthosis 21
    - 12.1 Connecting to the System Side Bar/System Anchor 21
    - 12.2 Grinding the Orthosis Parts 21
13. Controller 22
    - 13.1 Cable Connection for the Controller and Functional Unit 22
    - 13.2 Manual Mode Change 23
14. Putting into Operation 23
    - 14.1 Putting the Expert App into Operation 23
    - 14.2 Connection of Controller and Expert App 23
15. Checking the Connection between Controller and User App 24
16. Checking the Mode and Battery Status 24
    - 16.1 Indication of Mode and Battery Status on the Controller 24
    - 16.2 Indication of the Battery Status in the App 25
17. Adjustment Options with the Expert App 25
    - 17.1 Selecting a Mode 25
    - 17.2 Menu 25

17.2.1 Pairing (Putting the Controller Into Operation) 25
17.2.1.1 Calibrate 25
17.2.1.2 Basic Position 25
17.2.2 General Settings 25
17.2.2.1 Mode Change 26
17.2.2.2 Sound 26
17.2.3 System Ankle Joint Settings 26
17.2.3.1 Gestures 26
17.2.3.2 Gestures via Smartwatch 26
17.2.3.3 Angle for Stair Mode 26
17.2.4 Step Counter 26
17.2.5 Battery Health 27
17.2.6 Cable Test 27
17.2.7 Controller Update 27
18. Energy-Saving Modes 27
19. Advice on Optimal Orthosis Functionality 27
19.1 Bluetooth® Connection 27
19.2 System Ankle Joint 28
19.3 Controller 28
20. Maintenance 28
20.1 Documentation of Maintenance in the Orthosis Service Passport 30
20.2 Checking the Battery Health 30
20.3 Functional Check of the Ankle Joint System 30
20.4 Repair of the Functional Unit 30
20.5 Replacing the Sliding Washers 31
20.6 Dirt Removal 31
21. Period of Use 31
22. Storage 32
23. Spare Parts 32
23.1 Exploded View Drawing NEURO HiSWING R+ 32
23.2 Spare Parts for the NEURO HiSWING R+ System Ankle Joint 33
23.3 Spring Units 34
24. Disposal 34
25. Technical Data 35
25.1 Ambient Conditions 35
26. Signs and Symbols 37
27. CE Conformity 38
28. Legal Information 38
29. Electromagnetic Compatibility 39
29.1 Electromagnetic Environment 39
29.2 Electromagnetic Emissions for all Devices and Systems 39
29.3 Electromagnetic Immunity for all Devices and Systems 40
29.4 Electromagnetic Immunity for Non-Life-Supporting Devices and Systems 41
29.5 Electromagnetic Immunity to Proximity Magnetic Fields 42
29.6 Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product NEURO HiSWING R+ for Non-Life-Supporting Devices and Systems 42
29.7 Test Specifications for the Immunity of Enclosures Against Wireless RF Telecommunication Equipment 43
29.8 USA: FCC Regulatory Compliance Statement 44
29.9 Canada: ISED Regulatory Compliance Statement 44
30. Information for the Treatment Documentation 45
31. Handing Over the Orthosis 46

## 1. Information

These instructions for use are addressed to qualified specialists in orthopaedic technology and do not contain any notes about dangers which are obvious to them. To achieve maximum safety, please instruct the patient and/or care team in the use and maintenance of the product.

## 2. Safety Instructions

### 2.1 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.

### 2.2 All Instructions for a Safe Handling of the System Ankle Joint

**⚠ DANGER**

**Potential Traffic Accident Due to Limited Driving Ability**
Advise the patient to gather information about all safety and security issues before driving a motor vehicle with orthosis. The patient should be able to drive a motor vehicle safely.

**⚠ 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. Use suitable sliding washers according to the information in these instructions for use.

**⚠ WARNING**

**Risk of Falling Due to Improper Processing**
Process the system joint according to the information in these instructions for use. Deviating processing and modifications of the system joint require the written consent of the manufacturer.

## ⚠ WARNING

**Risk of Falling Due to Permanent Higher Load**
If patient data has changed (e.g. due to weight gain, growth or increased activity), recalculate the expected load on the system joint, plan the treatment again and, if necessary, produce a new orthosis.

## ⚠ WARNING

**Risk of Falling Due to Improper Heel Height**
Determine with the patient a maximum heel height of the shoes to be worn with the orthosis.

## ⚠ WARNING

**Risk of Falling Due to Incorrectly Selected System Components**
Make sure that the system joint and the system components are not overloaded and are functionally adapted to the requirements and needs of the patient in order to avoid joint dysfunction.

## ⚠ WARNING

**Risk of Falling Due to Loose Functional Unit**
Mount the functional unit to the system joint according to the assembly instructions in these instructions for use. Secure the screws with the specified torque and the corresponding adhesive and make sure that no sliding washers are damaged in the process.

## ⚠ WARNING

**Risk of Falling Due to Use of the Orthosis without a Shoe**
If the patient wants to wear the orthosis without a shoe, attach a fixation that holds the foot piece against the foot. Additionally, place a slip-resistant rubber sole under the sole of the foot piece.

## ⚠ WARNING

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

## ⚠ WARNING

**Risk of Falling Due to Improper Handling**
Inform the patient about the correct use of the system joint and the **integrated electronics**, especially with regard to excessive mechanical load (e.g. due to sports, increased activity level or weight gain), and on not immersing the system joint in water. The electronic system components are only protected from splashing water on all sides. Also inform the patient that the system joint may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the system joint and the orthosis by the patient that goes beyond the tasks described in the instructions for use for patients is not permitted.

## ⚠ WARNING

**Risk of Falling Due to Improper Handling**
Instruct the patient not to put any weight on the orthosis in Relax mode (e.g. when walking, running or riding a bicycle) and to change the lower leg-to-plumb line angle slowly and with little effort.

## ⚠ WARNING

**Risk of Falling Due to Unintentional Performing of the Gesture**
The use of gestures reduces the safety when using the orthosis. Only activate the gesture for activating Zero mode if your patient is physically fit so that they do not fall if the gesture is performed unintentionally.

## ⚠ 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 29.6).

## ⚠ WARNING

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

## ⚠ WARNING

**Damage to the Anatomical Joint Due to Incorrect Position of the Joint's Mechanical Pivot Point**
Determine the joint's mechanical pivot points correctly in order to avoid a permanent incorrect load on the anatomical joint. Please refer to the online tutorials on the FIOR & GENTZ website or contact Technical Support.

## ⚠ WARNING

**Breakage of the System Joint Due to Lack of System Anchor**
Use a system anchor when producing the orthosis in order to ensure a secure integration of the system joint into the laminate. The system joint can break if it is integrated without a system anchor.

## ⚠ 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 controller is a sensitive electronic device with an integrated lithium-polymer battery. Pay particular attention to:
- not wearing the orthosis during the battery charging process,
- avoiding contact with strong heat or fire,
- not charging the controller under direct sunlight, and
- not opening the controller.

## *NOTICE*

**Limitation of the Joint Function Due to Improper Processing**
Errors in processing can impair the joint function. Pay particular attention to:
- correctly connecting the system side bar/system anchor with the system case in accordance with the production technique;
- not tempering the orthosis when the functional unit and controller are mounted,
- greasing the joint components only **slightly** and
- adhering to the maintenance intervals.

## *NOTICE*

**Limitation of the Joint Function Due to Improper Dirt Removal**
Inform the patient on how to properly remove dirt from the orthosis and the system joint.

## *NOTICE*

**Limitation of the Joint Function Due to Lack of Maintenance**
Respect the specified maintenance intervals in order to avoid joint dysfunction. Also inform the patient about the maintenance appointments to be respected. Enter the next maintenance appointment in the orthosis service passport of the patient.

## *NOTICE*

**Damage to the System Joint Due to Improper Handling of the Functional Unit**
Do not open the functional unit. Do not remove any screws that are sealed with blind plugs labelled "SEAL" or any safety screws.

ⓘ Advise the patient to contact the manufacturer in case of problems with the system joint and potentially occurring allergic reactions. You can find the manufacturer's contact data on the back page of these instructions for use.

# 3. Use

## 3.1 Intended Use

The **NEURO HiSWING R+** ankle joint system must be used exclusively for the orthotic treatment 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. The system joint may only be used for one fitting and must not be reused.

The ankle joint system is equipped with **Bluetooth®** technology. With the **Expert** app, you can adjust orthoses that are equipped with the **NEURO HiSWING R+** system ankle joint.

## 3.2 Indication

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

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. An evaluation regarding the safe handling of the orthosis by the patient must be carried out.

fig. 1

All system ankle joints can also be used in complement to a 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. 2

Furthermore, all system ankle joints can be used for the treatment of patients with peripheral arterial disease (PAD). For this purpose, the orthosis produced for the patient by a qualified specialist in orthopaedic technology (custom-made product) is combined with a foot orthotic. Further information can be found in the **PAD Guide** (see QR code, fig. 2).

## 3.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 3.2, 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.

## 3.4 Qualification

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

## 3.5 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, parachuting and football, is excluded. The system joint can be used at temperatures of -10°C to +40°C.

## 3.6 Combination Possibilities with Other System Joints

The **NEURO HiSWING R+** system ankle joint can be combined with system knee joints from the FIOR & GENTZ product range. The **NEURO CLASSIC free moving** can be used as supporting joint.

We recommend that you use the Orthosis Configurator when selecting all system components for your orthosis and follow the recommendations of the configuration result.

# 4. 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 the patient wants to use the orthosis as a free moving orthosis while they are resting, 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.

Due to the mounted system components, the system ankle joint also has the following functions:

| System Component | Function |
|---|---|
| spring units | **dorsal (posterior spring unit):**<br>- integrated dorsiflexion assist<br>- controlled lowering of the foot during loading response |
| | **ventral (anterior spring unit):**<br>- increased energy return during heel lift to support push off |
| | **dorsal and ventral:**<br>- dynamically bringing the patient from a bent into an upright position as well as improving the patient's stability while walking and standing by balancing the body |
| control button | - modification of the ankle joint angle by the patient, e.g. when the **User** app is not available<br>- increase of the range of motion by 34° |

## 4.1 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 a mode has been activated. Load should be taken off the spring units of the system ankle joint while the lightning bolt is displayed filled in. As soon as the spring units are free of load within this time, the hydraulic valves open and the lower leg-to-plumb line angle can be adjusted. During angle adjustment, only the outline of the lightning bolt is displayed. If no mode is activated, no lightning bolt is displayed.

If the patient has missed the time to take the load off the spring units, they can tilt their 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, a mode change can only be carried out when standing still. The patient must wait half a second before activating the mode with the app.

### 4.1.1 Zero Mode

Zero mode allows the patient 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. The patient proceeds as follows:

1 The patient stops or stands up.
2 They 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 The patient keeps the foot on the floor, but takes some weight off the lower leg and tilts it forwards and/or backwards until the background of the slider lights up green.

The patient remains 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.

Zero mode should be used in the following situations:

- for standing or walking on an incline or slope to facilitate walking uphill (the lower leg can be tilted forwards so that the inclination of the lower leg corresponds to the set angle in relation to the plumb line in the basic position) and to increase stability when walking downhill (the lower leg can be tilted backwards so that the inclination of the lower leg corresponds to the set angle in relation to the plumb line in the basic position)
- after the orthosis has been used for walking uphill or downhill and the patient is standing and walking on level ground again
- after the orthosis has been in Relax mode and the patient wants to use it again for standing or walking
- after the patient has used Stair mode
- after every shoe change
- for wearing the orthosis without a shoe

### 4.1.2 Relax Mode

In Relax mode, the system ankle joint is free moving and the patient can freely adjust the lower leg-to-plumb line angle to relax the foot while sitting.

Relax mode is suitable for resting, but not for walking or riding a bicycle.

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

### 4.1.3 Stair Mode

With the Stair mode, the patient can adjust the orthosis alignment to the physiological ankle joint angle when climbing stairs before proceeding up or down the stairs. They activate the Stair mode with the **User** app and move their foot in the direction of dorsiflexion until the angle adjustment is completed. After climbing stairs, Zero mode must be activated 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 the patient can ascend or descend the stairs.

### 4.1.4 Alternative Function with Control Button

The alternative function describes the adjustment of the ankle joint angle by the patient using the control button (fig. 3) on the system joint when the **User** app is not available. If this is pressed and held, the ankle joint angle can be changed manually and separately in both directions.

fig. 3

## 5. NEURO HiSWING R+ Ankle Joint System

The ankle joint system is equipped with Bluetooth technology* and consists of the following components (fig. 4):

❶ **system ankle joint**

❷ **controller**

❸ **charging cable with power supply unit** and **User** app for the patient

❹ **Expert** app for qualified specialists in orthopaedic technology

The system ankle joint and the controller are built into the patient's orthosis. In order to put the orthosis into operation and adjust it, you need the **Expert** app. The app must be activated once using the code generator for the **Expert** app on the FIOR & GENTZ website. The patient needs the **User** app to operate the orthosis.

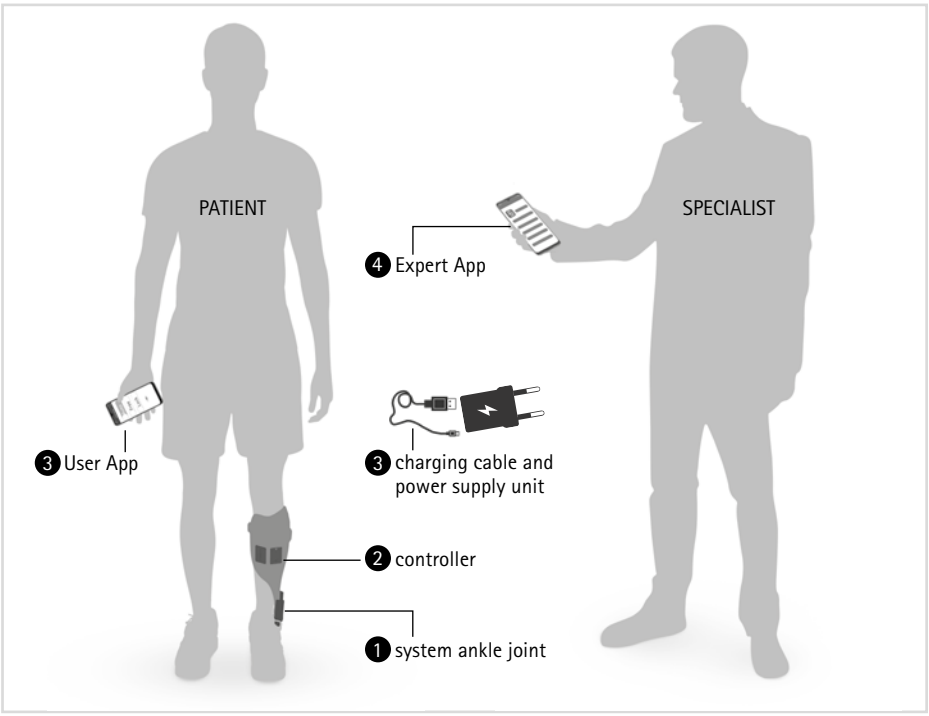



fig. 4

* 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.

In order to produce an orthosis with the **NEURO HiSWING R+,** you need a controller set and a connection cable set in addition to the system ankle joint. Even if you want to combine the system ankle joint with an automatic system knee joint from the FIOR & GENTZ product range in a KAFO, you only need one controller.

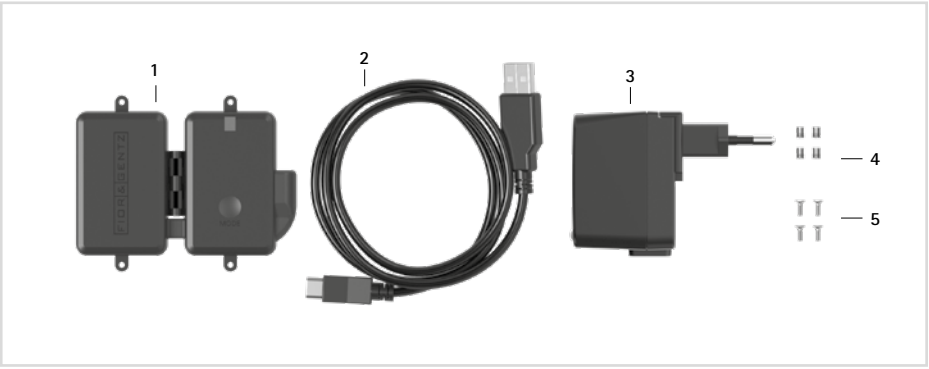



fig. 5

| Controller Set (SL3860-S) | | | | |
|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity Unilateral |
| 1 | ET3860 | controller with Bluetooth with lithium-polymer battery | pce. | 1 |
| 2 | ET0710-01 | charging cable for controller, 1m | pce. | 1 |
| 3 | ET0780-01 | power supply unit incl. primary adapters for Europe, USA/ Japan, Great Britain, Australia | pce. | 1 |
| 4 | VE0831-A3 | thread insert | pce. | 4 |
| 5 | SC1302-L06 | countersunk flat head screw, cross recessed H | pce. | 4 |

Please note that the charging cable and power supply unit are not part of the medical device.

| Connection Cable Set NEURO HiSWING R+ (SH8860-K) | | | | |
|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity Unilateral |
| w/o fig. | ET0711-03 | connection cable for functional unit NEURO HiSWING R+, 510mm | pce. | 1 |
| w/o fig. | ET0971-1 | lamination dummy for cable length compensation | pce. | 1 |
| w/o fig. | SH0985-11 | lamination dummy for connection cable, 390mm | pce. | 1 |

| Connection Cable Set NEURO HiSWING R+, NEURO HiTRONIC (SL3860-K/4) | | | | |
|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity Unilateral |
| w/o fig. | ET0713-02 | connection cable for functional unit NEURO HiTRONIC and NEURO HiSWING R+, 660mm | pce. | 1 |
| w/o fig. | ET0972-3 | lamination dummy for connection cable for functional unit | pce. | 1 |
| w/o fig. | ET0971-1 | lamination dummy for cable length compensation | pce. | 3 |
| w/o fig. | SH0985-15 | lamination dummy for connection cable for NEURO HiSWING R+ functional unit, 270mm | pce. | 1 |
| w/o fig. | SH0985-16 | lamination dummy for connection cable for controller, 140mm | pce. | 1 |
| w/o fig. | SL0935-17 | lamination dummy for connection cable for NEURO HiTRONIC functional unit, 190mm | pce. | 1 |

| Connection Cable Set NEURO HiSWING R+, NEURO TRONIC (SK3860-K/4) | | | | |
|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity Unilateral |
| w/o fig. | ET0714-02 | connection cable for functional unit NEURO TRONIC and NEURO HiSWING R+, 660mm | pce. | 1 |
| w/o fig. | ET0972-3 | lamination dummy for connection cable for functional unit | pce. | 1 |
| w/o fig. | ET0971-1 | lamination dummy for cable length compensation | pce. | 3 |
| w/o fig. | SH0985-15 | lamination dummy for connection cable for NEURO HiSWING R+ functional unit, 270mm | pce. | 1 |
| w/o fig. | SH0985-16 | lamination dummy for connection cable for controller, 140mm | pce. | 1 |
| w/o fig. | SK0935-11 | lamination dummy for connection cable for NEURO TRONIC functional unit, 250mm | pce. | 1 |

You can find more information on special work steps that must be observed when producing an orthosis with the **NEURO HiSWING R+** system ankle joint, such as the placement of dummies as well as the specifics of reinforcement, in the corresponding online tutorial (see QR code, fig. 6) on the FIOR & GENTZ website.

fig. 6

## 6. Scope of Delivery of the System Ankle Joint

| Description | Quantity |
|---|---|
| **NEURO HiSWING R+** system ankle joint (fig. 9) | 1 |
| cover plate pressing aid (fig. 7) | 1 |
| assembly/lamination dummy (fig. 8) | 1 |
| orthosis joint grease, 3g (without figure) | 1 |

fig. 7

fig. 8

fig. 9

## 7. Load

The actual load on the system joints is based on the relevant patient data and the choice of shoes. When selecting the system joint, the maximum heel height of the shoes that the patient wants to wear with the orthosis must be taken into account after consultation with the patient. The load and the appropriate system components can be determined by using the Orthosis Configurator. We recommend that you use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique. You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

## 8. Tools for Assembling the System Joint

| Tool | System Width | |
|---|---|---|
| | 20mm | 24mm |
| T8 hexalobular screwdriver/bit | x | x |
| T10 hexalobular screwdriver/bit | x | - |
| T15 hexalobular screwdriver/bit | - | x |
| T30 hexalobular screwdriver/bit | x | x |
| torque screwdriver, 1–6Nm | x | x |
| twist drill, 3.2mm | x | x |
| PH0 cross-recessed screwdriver | x | x |
| pliers | x | x |

fig. 10

## 9. Functional Unit

The functional unit includes the hydraulic system with hydraulic oil. The functional unit is delivered fully assembled. The functional unit may not be opened. Do not remove any screws that are sealed with blind plugs labelled "SEAL" or any safety screws, as this will invalidate the warranty (fig. 10). The sealed screws may only be removed when the functional unit is disposed of.

## 10. Mounting the System Joint

The system joint is delivered fully assembled. All functions are checked beforehand. In order to mount the system joint to the orthosis and for maintenance, you must first demount the functional unit from the system joint. To ensure an optimal functioning, follow the assembly instructions below. Secure all screws with the torque specified in paragraph 10.7.

You can find more information on the assembly in the online tutorial **Joint Assembly NEURO HiSWING R+** (see QR code, fig. 11) on the FIOR & GENTZ website.

fig. 11

The hydraulic system of the functional unit must not be opened. Refer to the exploded view drawings (figs. 41–42) to see which system components of the system joint may be demounted. The screws of the hydraulics marked in fig. 10 must not be loosened.

Only use the FIOR & GENTZ orthosis joint grease to grease the system components.

### 10.1 Demounting the Functional Unit

1 Unscrew both countersunk flat head screws.
2 Screw the pressing screw into the thread of the first screw (S1, fig. 16). The pressing screw must not be screwed in completely (fig. 12).
3 Push the joint's upper part and the functional unit apart by exerting force on them as illustrated (arrows in fig. 12). This can be achieved by using a vice or by controlled knocks (e.g. with a soft-faced hammer).
4 Remove the pressing screw.

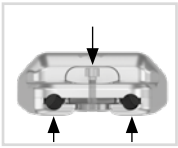


fig. 12

## 10.2 Mounting the Functional Unit

Make sure not to damage the sliding washer during assembly. Jammed sliding washer particles can cause lateral play in the system joint.

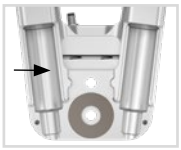


fig. 13

1 Before the assembly, clean the thread of the bearing nut and of the joint's upper part as well as the bores of the functional unit with LOCTITE® 7063 Super Clean. Allow the threads to air-dry for 10 minutes.
2 Apply spray adhesive on one side of a sliding washer and adhere it to the functional unit (fig. 13).
3 Grease the other side **slightly** with orthosis joint grease.
4 Grease the lateral contact surfaces of the joint's upper part to the functional unit with orthosis joint grease (fig. 14).

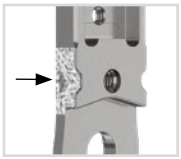


fig. 14

5 Mount the functional unit by pressing it with the pressing screw and the washer (fig. 15).
6 Remove pressing screw and washer.
7 Screw in the first countersunk flat head screw (S1; fig. 16).
8 Make sure that there is no opening left between the functional unit and the joint's upper part (fig. 17).

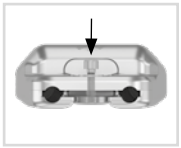


fig. 15

## 10.3 Mounting the System Stirrup

1 Grease the sliding surfaces of the bearing nut as well as the contact surfaces of the system stirrup between system stirrup and spring units with orthosis joint grease.

fig. 16

Greasing the contact surfaces of the system stirrup is important in order to prevent wear of the system stirrup.

fig. 17

2 Grease the second sliding washer **slightly** on both sides and place it on the system stirrup (fig. 18).
3 Slide the system stirrup from below between the functional unit and the joint's upper part. Make sure that the sliding washer points in direction of the joint's upper part and remains in the correct position.

fig. 18

fig. 19

4 Place the bearing nut into the intended hollow on the joint's upper part. The bearing nut must be fully inserted in the hollow (fig. 19).
5 Screw in the second countersunk flat head screw (axle screw, S2; fig. 20).

fig. 20

## 10.4 Checking the Free Movement

Tighten the screws for the functional unit with the appropriate torque (see paragraph 10.7). Check if the system joint moves freely. If the system joint runs with lateral play, mount the next thicker sliding washer. If it does not move freely (it is jammed), mount the next thinner sliding washer.

## 10.5 Mounting the Spring Unit

1 Loosen the screws on the back of the functional unit and remove both spring unit covers (fig. 21).
2 Loosen the screws on top of the spring ducts and remove the adjusting screw covers (fig. 22). The adjusting screws (2) are now visible.
3 Unscrew the adjusting screws as far as they will go.
4 Assemble the O-ring dampers (4) and the sliding bushings (5) with the plungers (3; fig. 23). Make sure that the sliding bushing is correctly positioned on the plunger (fig. 24).
5 Put the coil springs (6) on them.
6 Insert the spring units (7) including the plungers (3) and the assembled system components (4, 5 , 6; fig. 23) completely and centred into the spring ducts (fig. 25). When inserting, press the plunger from below with your thumb for the 24mm system width (3; fig. 23).
7 Screw the adjusting screws back in. The adjusting screws must be screwed in far enough to ensure that there is no more play in ap direction. The spring units must not be compressed.
8 Press and hold the control button on the system joint and check the hydraulics by adjusting the ankle joint angle.
Once you have connected the controller and paired it with the **Expert** app (see paragraphs 13 and 14), check the hydraulics in Zero or Relax mode. If the hydraulics are disturbed (lack of movement in the hydraulics), loosen the adjusting screws slightly.
9 Replace the spring unit covers on the back of the functional unit and the adjusting screw covers on the spring ducts and tighten the screws.

fig. 21

fig. 22

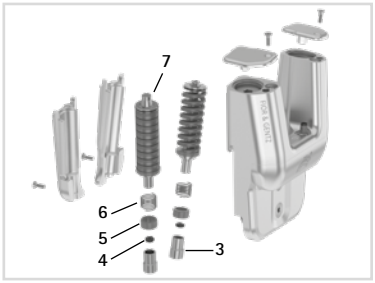



fig. 23

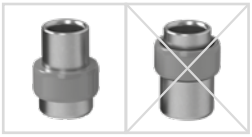


fig. 24

fig. 25

## 10.6 Checking the Control Button

After mounting the spring units, check the function of the control button.

1 Press and hold the control button.
2 Move the system joint in ap direction and check if the ankle joint angle can be changed.
3 Release the control button and check if the new ankle joint angle is secured and remains in place.

## 10.7 Securing the Screws

The screws are secured after the orthosis has been produced and tried on and before it is handed over to the patient.

1 Loosen the screws for the functional unit (fig. 20) after checking the free movement and remove them from the functional unit.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screws.
3 Secure the screws for the functional unit (fig. 20) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

| Screws for Functional Unit | System Width | |
|---|---|---|
| | 20mm | 24mm |
| pressing screw of the cover plate pressing aid | 6Nm | 6Nm |
| countersunk flat head screw with hexalobular socket (S1) | 6Nm | 6Nm |
| countersunk flat head screw with hexalobular socket (axle screw, S2) | 6Nm | 6Nm |

The screws of the functional unit are not secured with the necessary torque at delivery. You can also find information on the torque in the openings of the functional unit.

# 11. Adjustment Options on the Orthosis

The orthosis can be individually adapted to the patient's needs with adjustable system ankle joints. The adjustments described in the paragraphs 11.1 to 11.4 do not influence each other and can be changed separately.

Mind the correct adjustment of the dorsiflexion stop when mounting the system ankle joint. It is decisive for the entire alignment of the orthosis. You can find more information on this in the online tutorial **AFO Alignment Guidelines** (see QR code, fig. 26) on the FIOR & GENTZ website.

fig. 26

## 11.1 Setting or Adjusting the Orthosis Alignment

With the app, the lower leg-to-plumb line angle can be continuously adjusted by up to 17° in both directions. Alternatively, the control button on the system joint can also be used for this purpose. Make all adjustments to the orthosis on the workbench and not on the patient's leg. For this purpose, proceed as follows:

1 Place the orthosis in the shoe.
2 Press and hold the control button or use the app and bring the orthosis into the desired position (fig. 27).
3 If you have used the control button, secure the system joint by releasing the control button.

fig. 27

## 11.2 Expanding the Range of Motion

The range of motion of the system joint can be increased by 34° using the app. Note that the spring units are not active in this setting.

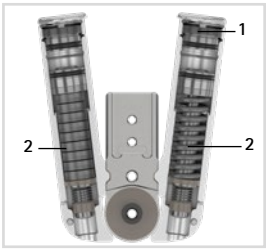



fig. 28

This setting is only suitable for adjusting the lower leg-to-plumb line angle, sitting as well as putting on and taking off the orthosis and must not be used for walking, running or riding a bicycle. The orthosis does not provide the patient with the necessary security as its function is disabled in this setting. Furthermore, this can cause damage to the hydraulics of the system joint.

## 11.3 Exchanging the Spring Unit

The spring force can be changed with spring units (2; fig. 28) in different strengths. Insert a spring unit into the spring duct that corresponds with the required spring force. There are five spring units with spring forces ranging from normal to extra strong (fig. 29). Note that the spring unit determines the maximum possible range of motion of the secured system joint.

In order to replace the spring unit, the adjusting screw (1; fig. 28) must be loosened. After inserting the new spring unit, the adjusting screw must be screwed in again until the spring unit is mounted without play.

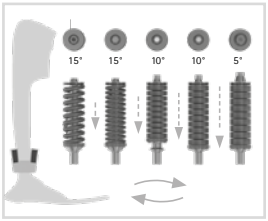



fig. 29

## 11.4 Reading the Joint Angles

There are markings (fig. 30) on all system ankle joints and system stirrups which indicate the angle of the system components to each other. This allows you to check the individual normal posture (the orthosis' basic alignment), record the joint angle and compare later deviations. The joint angle in the individual normal posture must not be outside the degree markings.

The distances between the degree markings can be seen in the following table.

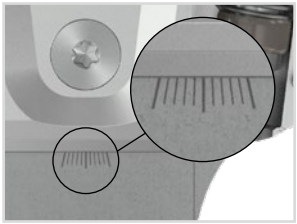


fig. 30

| Degree Marking | | |
|---|---|---|
| System Width | 20mm | 24mm |
| Degree | 2° | 2° |

# 12. Notes on the Production of the Orthosis

## 12.1 Connecting to the System Side Bar/System Anchor

The system side bar/system anchor must be connected to the system joint by adhering and screwing or screwing and wrapping in accordance with the production technique provided in the planning (fig. 31–33).

You can find more information in the **Instructions for Use for Qualified Specialists in Orthopaedic Technology System Side Bars and System Anchors** (see QR code, fig. 34).

fig. 31

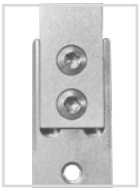


fig. 32

fig. 33

## 12.2 Grinding the Orthosis Parts

After tempering the orthosis parts, grind the laminate edges. Be careful not to grind the lateral surfaces of the joint's upper part. This can damage the fit between the joint's upper part and the cover plate, which can lead to mechanical noises.

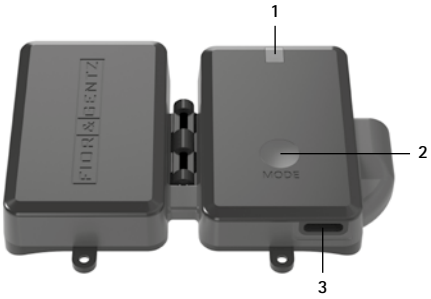
You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

fig. 34

## 13. Controller

The controller is mounted to the orthosis. It receives adjustments from the **Expert** app and commands from the **User** app, registers the patient's movements and controls the **NEURO HiSWING R+** system ankle joint.

When producing the orthosis, ensure that the controller is positioned so that the charging port is at the bottom.

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

For more information on mounting the controller to the orthosis, refer to the online tutorials on the FIOR & GENTZ website.

### 13.1 Cable Connection for the Controller and Functional Unit

Only tighten the knurled threaded bushings by hand. Do not use pliers to tighten the threaded bushings.

Before you mount the controller to the orthosis, you must establish a connection to the functional unit of the system ankle joint via a connection cable.

fig. 35

1 Plug the connection cable into the port on the functional unit and tighten the knurled threaded bushing by hand.
2 Insert the connection cable into the port on the controller (fig. 35) and tighten the knurled threaded bushing by hand. A small gap remains visible.
3 Secure the controller to the orthosis shell using the accompanying countersunk flat head screws.

## 13.2 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 the patient is travelling by plane, as the app's Bluetooth connection may not be used during take-off, final approach and landing. The app can usually be used during the flight and after landing.

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+**.

# 14. Putting into Operation

## 14.1 Putting the **Expert** App into Operation

Download the app with your smartphone/tablet. Minimum requirements are Bluetooth 4.0 and Android 6.0 or iOS 12. Activate the app once using the code generator for the **Expert** app on the FIOR & GENTZ website. This way, we ensure that patients cannot access the **Expert** app and change the orthosis' settings.

fig. 36

Carry out regular updates for your mobile device and enable automatic updates. Make sure that your **Expert** 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.

## 14.2 Connection of Controller and **Expert** App

In order to adjust an orthosis with the app, Bluetooth must be permanently activated and the app must be opened in the foreground. Use the app menu and select the menu item **Pairing**. Follow the additional instructions in the app. The controller can communicate with the **Expert** and the **User** app simultaneously. If there is an active connection to an app, the blue LED on the controller flashes permanently. If you want to adjust the orthosis with the **Expert** or **User** app on a different mobile device, you must first close the app that is currently connected to the controller.

## 15. 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 indicate 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.

## 16. Checking the Mode and Battery Status

### 16.1 Indication of Mode and Battery Status on the Controller

The mode and battery status of the controller are displayed 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 the 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, the mode in which the orthosis is currently operating in can be selected so that the mode is not changed involuntarily. 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 in the app settings until the next charge.

### 16.2 Indication of the Battery Status in the App

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

## 17. Adjustment Options with the Expert App

### 17.1 Selecting a Mode

The available modes (Zero, Relax and Stair mode) can be selected using the app. Zero mode can additionally be activated using gestures (see paragraph 17.2.3.1). You will find further information in the app.

### 17.2 Menu

In the menu you can set various adjustments for the orthosis. Follow the instructions in the app.

#### 17.2.1 Pairing (Putting the Controller Into Operation)

In order to establish a connection between the controller and the app, use the app's menu and select the required menu item for a connection with one or two controller(s). Follow the additional instructions in the app.

The **Expert** app automatically tries to recognise which system joints are connected to the controller. Follow the instructions in the app to confirm the connected automatic system ankle joint and/or system knee joint or select it manually.

##### 17.2.1.1 Calibrate

In order for the motion sensors in the controller to detect the position of the lower leg, you have to calibrate the orthosis for a first functional test before fitting. Then, repeat the calibration process. Have the patient wear the orthosis when you calibrate again. Follow the instructions in the app.

##### 17.2.1.2 Basic Position

Bring the leg with orthosis into the basic position and confirm this with the app. From now on, the controller will help the patient to return the orthosis to this basic position when Zero mode is activated. The controller monitors the lower leg-to-plumb line angle and closes the hydraulic valves as soon as the preset angle is reached. To do this, the controller sends a signal to the app so that the patient can see whether they have reached the saved basic position.

#### 17.2.2 General Settings

In this menu item you can make adjustments to the orthosis. To do so, follow the instructions in the app.

#### 17.2.2.1 Mode Change

With this menu item you can adapt the sensitivity of the controller for a mode change, in order to enable a mode change via app even when in motion. Usually, the patient changes the mode while at standstill. Changing the mode while the patient is in motion can endanger the patient's safety. If the patient nevertheless wants to change the mode while in motion, follow the instructions in the app.

#### 17.2.2.2 Sound

After the controller has registered an executed gesture (see paragraph 17.2.3.1), a signal tone sounds. After Zero mode, which was activated by a gesture, has been completed, another signal tone sounds. In the sound settings, you can set the volume of the signal tone for activating Zero mode by gesture for training purposes for the patient or switch off the signal tone.

### 17.2.3 System Ankle Joint Settings

#### 17.2.3.1 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 your patient. Check which gestures they 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. The patient must wait half a second before activating the mode by gesture. For training purposes, there is a circle in the top left-hand corner of the app that lights up green as soon as the patient has waited half a second and the controller is ready for activation of Zero mode by gesture.

#### 17.2.3.2 Gestures via Smartwatch

If the patient has an Apple Watch* or a Samsung** Watch, they can alternatively activate Zero mode with the gestures via smartwatch. You can find further information under **Gestures via Smartwatch** on the FIOR & GENTZ website (see QR code, fig. 37).

fig. 37

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

Minimum requirements for using the gestures via smartwatch are Apple Watch Series 4, Apple Watch SE (1st generation) or Apple Watch Ultra (1st generation) as well as Samsung Galaxy Watch 4.

#### 17.2.3.3 Angle for Stair Mode

In this menu item, you can adjust the specified lower leg-to-plumb line angle (0°-15° in the direction of dorsiflexion) for Stair mode (see paragraph 4.1.3). At 0°, the mode is switched off.

### 17.2.4 Step Counter

The controller counts all the steps taken with the leg wearing the orthosis. Double the value for the total number of steps taken with both legs.

### 17.2.5 Battery Health

Through this menu item you can check the battery health. It can be “good”, “average” or “poor”. Depending on the battery health, the time until the next required charge may vary. With poor battery health, the controller must be replaced (see paragraph 20.2).

### 17.2.6 Cable Test

With this test, you can check the cable connection to the functional unit on the orthosis. For this test, put the orthosis on a workbench. Select the menu item **Cable Test** and follow the instructions in the app. You will then receive the results of the cable test for the functional unit.

When you start the cable test, the **NEURO HiSWING R+** controller automatically switches to standby.

### 17.2.7 Controller Update

When updating the app, the controller update is downloaded at the same time, if available. In the app, you can update the desired controller by following the instructions in the app.

Always keep all controllers in use up to date.

The ankle joint system must not be actively used during the update.

## 18. Energy-Saving Modes

The 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** or the MODE button is pressed for about **20 seconds**, 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.

## 19. Advice on Optimal Orthosis Functionality

If problems occur with the orthosis, you can display a support code. You can then send this code to Technical Support so that the error can be corrected more quickly. You can find the support code in the app under the menu item “Information”.

### 19.1 Bluetooth® Connection

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

## 19.2 System Ankle Joint

| Problem | Cause | Action |
|---|---|---|
| The lower leg-to-plumb line angle of the system joint cannot be adjusted. | A spring unit is loaded by the patient's body weight while it should be released hydraulically. | The patient must take the weight off the leg with orthosis or move the lower leg in the other direction. |
| | The spring units are precompressed and the hydraulics are blocked. | Unscrew the adjusting screws slightly. |
| | A spring unit remains compressed even though it should be released hydraulically. | Press the control button on the system joint once. |
| | The orthosis is exposed to strong shocks, vibrations or fluctuations in air pressure. | Press the MODE button on the controller once so that the orthosis can be used normally again. |
| The system joint does not function as expected. | The controller is adjusted for a different automatic system joint. | Select the **NEURO HiSWING R+** system ankle joint in the menu of the **Expert** app. |

## 19.3 Controller

| Problem | Further Action |
|---|---|
| When the MODE button is pressed, the LEDs do not light up. | Charge the battery. If the problem remains, contact Technical Support. |
| No devices are found during connection of the controller and the app. | Establish a connection between the app and controller within **30 seconds**. Check whether the LEDs light up or whether a short and a longer beep tone can be heard. If the problem remains, contact Technical Support. |

# 20. Maintenance

Check the system joint regularly for wear and functionality. In particular, check the joint components listed in the following table for the possible problems described and, if necessary, take the appropriate measures. Also check the functionality after every maintenance carried out. It must be possible to move the system joint without problems or unusual noises. Make sure that there is no lateral play and no play around the axis.

| System Component | Potential Problem | Measure | Recommended Inspection/ Potential Replacement | Latest Replacement |
|---|---|---|---|---|
| spring unit | wear | replacing spring unit | every 6 months | every 18 months |
| | radial move of disc springs | realigning disc springs with pliers | every 6 months | every 18 months |
| | noise of spring unit | greasing spring unit with spray oil (article no. FT3000-15) | every 6 months | every 18 months |
| O-ring for securing the spring unit | wear | replacing O-ring | every 6 months | every 18 months |
| coil spring** | wear | replacing coil spring | every 6 months | every 18 months |

| System Component | Potential Problem | Measure | Recommended Inspection/ Potential Replacement | Latest Replacement |
|---|---|---|---|---|
| sliding bushing (spring unit)** | wear | replacing sliding bushing | every 6 months | every 18 months |
| sliding bushing (system stirrup) | wear | replacing sliding bushing | every 6 months | every 18 months |
| O-ring damper** | wear | replacing O-ring damper | every 6 months | every 18 months |
| sliding washer | wear | replacing sliding washer, see paragraph 20.5 | every 6 months | every 18 months |
| countersunk flat head screw with hexalobular socket** | wear | replacing countersunk flat head screw | every 6 months | every 36 months |
| bearing nut | wear | replacing bearing nut | every 6 months | every 36 months |
| functional unit | wear or loss of function | replacing functional unit, see paragraph 20.4 | every 6 months | every 36 months |
| plunger** | wear | replacing plunger | every 6 months | every 36 months |
| controller | outdated software | updating software | every 6 months | every 36 months |
| | poor battery health | replacing controller | every 6 months | every 36 months |
| system stirrup | wear or breakage | replacing system stirrup | every 6 months | every 48 months |
| connection cable | damage | replacing connection cable | every 6 months | if required |
| software for mobile devices (operating system, **Expert** app, **User** app) | security gaps in the software | updating software | every 6 months | if required |

* depending on the assessment of the distributor of the custom-made product regarding the patient's usage behaviour
** is part of the functional unit

Clean the thread of the bearing nut and of the joint's upper part as well as the bores of the functional unit with LOCTITE® 7063 Super Clean at every maintenance. Allow the threads to air-dry for 10 minutes.

Secure the screws for the functional unit with the corresponding torque and LOCTITE® 243 medium strength during every maintenance (see paragraph 10.7). Remove all adhesive residues first.

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 38) on the FIOR & GENTZ website.

fig. 38

## 20.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport from a qualified specialist in orthopaedic technology when the orthosis is handed over (fig. 39). The orthosis must be checked regularly according to the specifications in the maintenance plan in order to maintain its function and to ensure the safety of the patient. The maintenance appointments are noted and confirmed in the orthosis service passport.

fig. 39

## 20.2 Checking the Battery Health

Regularly check the battery health for the controller with the **Expert** app.
In the case of poor battery health or if the patient needs to charge the controller more than once per day, the controller must be replaced. Do not try to disassemble the controller as the battery is a fixed part of the controller.

| Battery Health | Further Action |
|---|---|
| good | There is no need for action. |
| average | There is no need for action. You may need to replace the controller at the next maintenance. |
| poor | Replace the controller. |

Poor battery health does not endanger the patient. It simply points out that the time until the next charge of the controller has been reduced.

## 20.3 Functional Check of the Ankle Joint System

In order to check the function of the ankle joint system, proceed as follows:

1 Check whether the system joint can be moved in Relax mode without any restrictions or unusual noises.
2 Check whether the settings are retained when the controller is in standby and the system joint is loaded in both directions.
3 Move the system joint slightly in ml direction to ensure there is no lateral play.
4 Check the Bluetooth connection, the battery charge and the availability of software updates for the controller.
5 Check whether the control button on the system joint is working. Hold it down and check whether you can change the ankle joint angle. When you release the control button, this new position of the spring units must be secured.

## 20.4 Repair of the Functional Unit

A free repair of the functional unit within 36 months of purchase of the system joint (see invoice date) is included in the FIOR & GENTZ service. You will receive a replacement cover plate for the duration of the repair. To this end, please send us the functional unit, the filled-out claim form and the maintenance logs.

## 20.5 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS2411-**040** is 0.40mm thick). Each thickness has a different marking (fig. 40). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

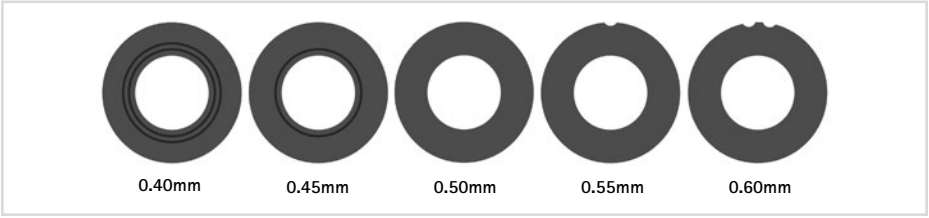



fig. 40

## 20.6 Dirt Removal

Dirt must be removed from the system joint and the controller when necessary and during regular maintenance. For this purpose, disassemble the system joint and demount the controller, and clean the soiled system components with a dry cloth.

The functional unit may not be opened.

# 21. Period of Use

To guarantee a safe use and complete functionality as well as an unlimited period of use of the system joints, you must adhere to the following conditions:

- Adhere to the specified maintenance intervals without interruption and document each maintenance (see paragraph 20).
- Adhere to the determined maintenance conditions (see paragraph 20).
- Check the wear parts, as required, and exchange them at the defined intervals (see paragraph 20).
- Check the adjustment of the system joint during maintenance and correct it if necessary (see paragraph 20).
- Check the functionality of the system joint during maintenance (see paragraph 20).
- The maximum load determined during the planning of the custom-made product shall not be exceeded by changes in the patient data (e.g. due to weight gain, growth or increased activity). If the determined maximum load on the system joint is exceeded, the system joint must no longer be used. When planning the custom-made product, expected changes in patient data need to be taken into account.
- The period of use of the system joints ends with the period of use of the custom-made product (orthosis).
- The multiple use of the system joint in another custom-made product is not allowed (see paragraph 28).

## 22. Storage

It is recommended to store the system joint in its original packaging until the custom-made product is produced. Heed the information regarding storage in paragraph 25.1.

## 23. Spare Parts

### 23.1 Exploded View Drawing **NEURO HiSWING R+**

The functional unit is delivered preassembled. If individual components of the functional unit (fig. 41) have to be exchanged, you can order them as well.

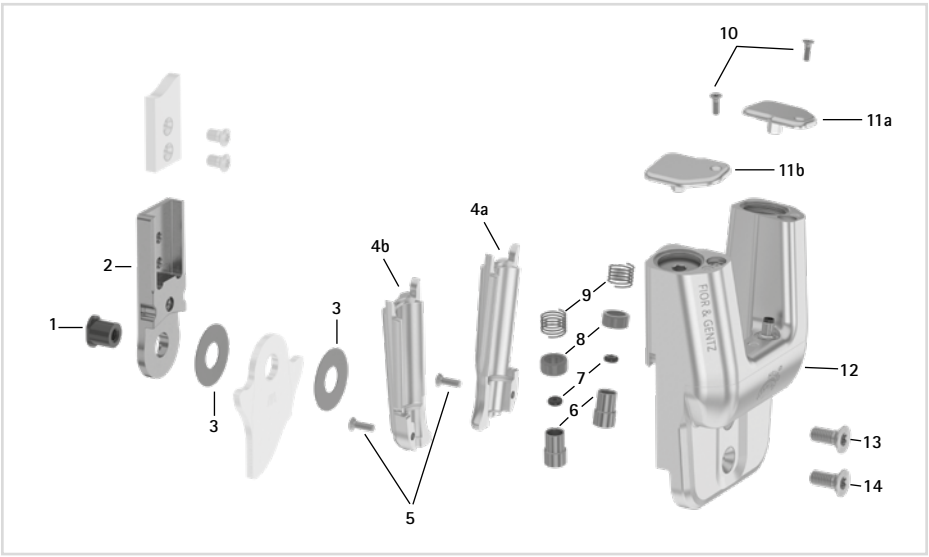



fig. 41

All system stirrups of the system ankle joints are delivered with an integrated sliding bushing.

fig. 42

## 23.2 Spare Parts for the **NEURO HiSWING R+** System Ankle Joint

| Item | Article Number for System Width | | Description |
|---|---|---|---|
| | 20mm | 24mm | |
| 1 | SB1069-L0960 | SB1262-L1400 | bearing nut |
| 2 | SH0815-TI | SF0317-TI | upper part, straight, titanium |
| 2 | SH0835-TI | SF0337-TI | upper part, bent inwards, titanium |
| 2 | SH0835-8/TI | SF0337-8/TI | upper part, bent outwards, titanium |
| 3 | GS2611-* | GS3013-* | sliding washer* |
| 4a | SH0865-2/L | SH0867-2/L | spring unit cover, left rear or right front |
| 4b | SH0865-2/R | SH0867-2/R | spring unit cover, left front or right rear |
| 5 | SC1403-L10 | SC1404-L14 | countersunk flat head screw with hexalobular socket |
| 6 | SH0493-01 | SH0493-01 | plunger |
| 7 | VE3771-012/26 | VE3771-012/26 | O-ring damper |
| 8 | GS1108-500 | GS1108-500 | sliding bushing |
| 9 | FE1027-01 | FE1027-01 | coil spring |
| 10 | SC1403-L08/1 | SC1403-L08/1 | countersunk flat head screw with hexalobular socket |
| 11a | SH0865-3/L | SH0867-3/L | adjusting screw cover, left rear or right front |
| 11b | SH0865-3/R | SH0867-3/R | adjusting screw cover, left front or right rear |
| 12 | - | - | cover plate |
| 13 | SC1416-L14 | SC1416-L20 | countersunk flat head screw with hexalobular socket |
| 14 | SC1416-L14 | SC1416-L20 | countersunk flat head screw with hexalobular socket (axle screw) |
| 4-14 | SH8975-AL | SH8977-AL | functional unit |

| * Sliding Washers | |
|---|---|
| Article Number for System Width | |
| 20mm | 24mm |
| Ø = 24mm | Ø = 30mm |
| GS2611-040 | GS3013-040 |
| GS2611-045 | GS3013-045 |
| GS2611-050 | GS3013-050 |
| GS2611-055 | GS3013-055 |
| GS2611-060 | GS3013-060 |

## 23.3 Spring Units

| Item | Article Number for System Width 20mm | 24mm | Description |
|---|---|---|---|
| 15 | SH5805-15/18 | SH5807-15/12 | spring unit, blue, normal, max. 15° range of motion |
| 15 | SH5805-15/25 | SH5807-15/25 | spring unit, green, medium, max. 15° range of motion |
| 15 | SH5805-10/40 | SH5807-10/53 | spring unit, white, strong, max. 10° range of motion |
| 15 | SH5805-10/60 | SH5807-10/80 | spring unit, yellow, very strong, max. 10° range of motion |
| 15 | SH5805-05/99 | SH5807-05/99 | spring unit, red, extra strong, max. 5° range of motion |
| 15a | VE3771-11/10 | VE3771-140/10 | O-ring for securing the spring unit |

# 24. Disposal

Dispose of the system joint and its individual parts properly. The hydraulic oil contained in the functional unit must be disposed of through the appropriate collection points, observing the local regulations for the disposal of waste oil. Before disposal you must empty the oil from the functional unit. To do so, proceed as follows:

1 Unscrew the three screws on the functional unit and remove the cover (fig. 43).
2 Press the plungers upwards and screw in the adjusting screws as far as they will go so that the oil comes out.

fig. 43

The product must not be disposed of with the residual waste (fig. 44). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

The electronically controlled, automatic **NEURO HiSWING R+** system ankle joint also falls under the area of application of the WEEE (Directive 2012/19/EU) of the European Parliament and the Council of 4 July 2012, regarding old electrical and electronic equipment.

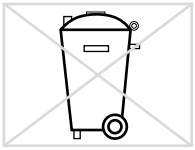


fig. 44

For proper disposal, it is necessary to demount the system joint from the orthosis.

## 25. Technical Data

| NEURO HiSWING R+ | |
|---|---|
| period of use | unlimited, excluding wear parts (see paragraph 20) |
| protection type | IP44 |
| operating mode | continuous operation |

### 25.1 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<br>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 |

| Power Supply Unit 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 (AC) |
| 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 and full battery charge at the end of three years of use | 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 systems | at least Android 6.0 or iOS 12 |
| supported operating systems smartwatch | at least Wear OS 3.0 or watchOS 4.2 |

## 26. 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

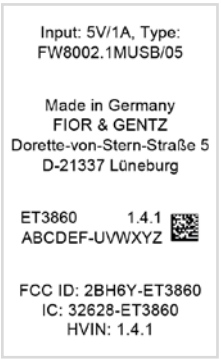
follow the instructions for use (white on blue background)

single patient – multiple uses

**IP44** protection from the ingress of solid foreign bodies (diameter ≥ 1.0mm) and from splashing water on all sides

**UDI** Unique Device Identifier – product identification number

**Controller Type Plate**




## 27. 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.

## 28. 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.

All copy rights, particularly the distribution, copy and translation of these instructions for use or any part of it, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH. Reprints, copies and any other electronic reproduction, even partial, must be authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH.

## 29. 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.

### 29.1 Electromagnetic Environment

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

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

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

### 29.2 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 | |

## 29.3 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<br>± 2kV, ± 4kV, ± 8kV, ± 15kV discharge through air | ± 8kV discharge on contact<br>± 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<br>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<br>± 0.5kV, ± 1kV line-to-ground voltage | ± 1kV line-to-line voltage<br>± 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°<br>70% of $U_T$ for 25/30 cycles and phase angles of 0°<br>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°<br>70% of $U_T$ for 25/30 cycles and phase angles of 0°<br>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. | | | |

## 29.4 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<br>$6V_{rms}$ in ISM bands 150kHz to 80MHz | $3V_{rms}$ 150kHz to 80MHz<br>$6V_{rms}$ 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:<br>$d = 1.2 \sqrt{P}$<br>$d = 1.2 \sqrt{P}$ 80MHz to 800MHz<br>$d = 2.3 \sqrt{P}$ 800MHz to 2.7GHz<br>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.<br><br>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<br>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+.**

## 29.5 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<br>134.2kHz, pulse modulation[b] 2.1kHz 65A/$m_{rms}$<br>13.56MHz, pulse modulation[b] 50kHz 7.5A/$m_{rms}$ | 30kHz[a], CW, 8A/m<br>134.2kHz, pulse modulation[b] 2.1kHz 65A/$m_{rms}$<br>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.<br>[b] The carrier must be modulated with a square wave signal with 50% duty cycle. | | |

## 29.6 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<br>$d = 1.2 \sqrt{P}$ | 80MHz to 800MHz<br>$d = 1.2 \sqrt{P}$ | 800MHz to 2.5GHz<br>$d = 2.3 \sqrt{P}$ |
| 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.<br>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. | | | |

## 29.7 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.

## 29.8 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 device 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 device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device 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 device and receiver.
- Connect the device 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 device.

## 29.9 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)

## 30. Information for the Treatment Documentation

Add these instructions for use to your treatment documentation!

### Patient Data

| | |
|---|---|
| **Name** | |
| **Address** | |
| **Postcode, City** | |
| **Home Telephone** | |
| **Telephone at Work** | |
| **Insurance** | |
| **Insurance No.** | |
| **Attending Physician** | |
| **Diagnosis** | |

## 31. Handing Over the Orthosis

The qualified specialist in orthopaedic technology made sure that the instructions for use for patients as well as the orthosis service passport were also handed over with the orthosis to the patient, parents or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to the patient in detail. The next maintenance appointment was entered in the orthosis service passport. The patient was asked to bring the orthosis service passport along to every maintenance appointment.

**Leg Side**

☐ left ☐ right

**Mounted Sliding Washers**

1. GS _____ - _____

2. GS _____ - _____

PB1050-DE/GB-2026-05

CE

**FIOR & GENTZ**
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