

# Instructions for Use for Orthotists or Qualified/ Trained Experts System Knee Joint

EN



NEURO HiTRONIC

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## 1. Information

These instructions for use are addressed to orthotists or qualified/trained experts 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

 <b>DANGER</b>	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
 <b>WARNING</b>	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
 <b>CAUTION</b>	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
<b>NOTICE</b>	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 orthotist or qualified/trained expert and/or the patient is established.

### 2.2 All Instructions for the Safe Handling of the **NEURO HiTRONIC** System Knee 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 Sustained 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 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 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 water splashing on all sides.

**⚠ WARNING**

**Risk of Falling Due to Loosened Screws**

Mount the cover plate 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 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 Improper Shoe/Wrong Shoe Pitch**

Advise the patient to wear a shoe to which the orthosis is adjusted in order to avoid joint dysfunction in Auto mode.

**⚠ WARNING**

**Risk of Falling Due to Improper Handling of the Orthosis**

Make sure that the patient is able to handle their orthosis. Recommend a physiotherapeutic gait re-education, if necessary, and explain to them the system joint's particularities.

**⚠ WARNING**

**Risk of Injury Due to Improper Handling of the Controller or Remote Control**

Use the controller and the remote control 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 or the remote control.

## **WARNING**

### **Risk of Injury Due to Improper Handling of the System Joint**

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. Please inform the patient of this risk.

## **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 our website or contact Technical Support.

## *NOTICE*

### **Limitation of the Joint Function Due to Improper Processing**

Errors in processing can impair the joint function. Pay particular attention to:

- correctly connect 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. 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 Controller Due to Improper Handling**

Use the controller as described in these instructions for use. In particular, please ensure that the controller:

- is used only with the provided charging cable and power supply unit, and
- is only used at ambient temperatures from -10°C to +40°C.



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.

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### 3. Use

#### 3.1 Intended Use

The **NEURO HiTRONIC** knee joint system with component set, including system knee joint and controller, is exclusively for use for orthotic fittings of the lower extremity. The system joint provides stance phase control and is only allowed to be used for producing 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 knee joint system is equipped with Bluetooth® technology. With the **Expert** app you can adjust orthoses that are equipped with the **NEURO HiTRONIC** system knee joint.

#### 3.2 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 central, peripheral, spinal or neuromuscular paralyses, structurally conditioned deformities/malfunctions, 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.

#### 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, for example after amputations of leg segments.

#### 3.4 Qualification

The system joint must only be handled by an orthotist or a qualified/trained expert.

#### 3.5 Application

All **FIOR & GENTZ** system joints were developed for everyday life activities such as standing and walking. Extreme loads connected to activities like running, climbing and parachuting are 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 HiTRONIC** system knee joint can be fitted with system ankle joints from our product range.

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 HiTRONIC** is a microprocessor-controlled, automatic system knee joint and provides four joint functions:

- basic function at delivery status in Auto mode
- alternative function in Lock mode
- alternative function in Free mode
- alternative function in permanent unlocking

The essential performance features of the automatic electronic system joint are to remain unlocked in Free mode and locked in Lock mode, as well as to lock or unlock at the right moment in Auto mode.

The system knee joint is preassembled in a physiological joint angle of 5°. It can be brought into a knee flexion position of 0° or 10° by exchanging system components. To do so, replace the 5° flexion stop disc with a 0° or 10° flexion stop disc, and the 5° extension stop with a 0° or 10° extension stop.

### 4.1 Safe Handling of the Joint Functions



#### Standing Up From a Seated Position

Before the patient stands up, the **NEURO HiTRONIC** system knee joint must be set to Free mode. Once standing securely, the mode can be switched to Auto or Lock mode.

#### Stance Phase Control

The system joint ensures the infinitely variable stance phase in a knee angle of 0° (5°) to 45°. Stance phase control occurs between 45° and 50° contingent upon the load. If the load limit is exceeded, an overload protection takes effect. It is comparable to an electric fuse. If the overload protection is triggered, this may result in deformation of the roll holder and possibly its fracture. In such a case, the roll unit must be exchanged.

## 4.2 Basic Function in Auto Mode

The controller has motion sensors that detect the movement and position of the lower leg. The controller ensures that the hydraulic functional unit locks/unlocks the system joint in the respective gait phases.

### Stance

When the patient is standing with the orthosis (fig. 1) or when they do not finish their step in stance phase, the **NEURO HiTRONIC** system knee joint locks, as no movement is registered.

### Gait

When walking, the system joint locks/unlocks as follows: the system joint is locked in the direction of flexion from mid swing to mid stance. In the gait phases from terminal stance to initial swing, the system joint is unlocked and is therefore free moving (fig. 2).

The time when locking/unlocking occurs can be fine adjusted with the **Expert app**.



Fig. 1

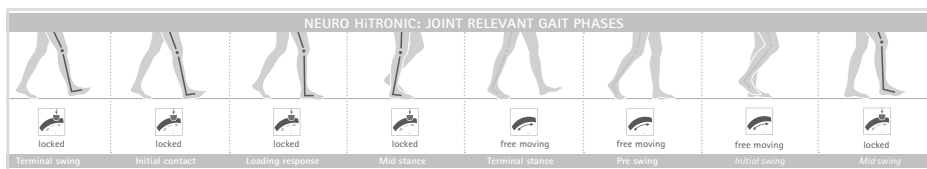


Fig. 2



If, contrary to expectations, weight is put on the leg with orthosis in the free moving phases, the system joint does not lock.


## 4.3 Alternative Function in Lock Mode

In Lock mode, the **NEURO HiTRONIC** is a locked system knee joint that is permanently mechanically locked in a determined extension position.

## 4.4 Alternative Function in Free Mode

In Free mode, the **NEURO HiTRONIC** system knee joint is an unlocked joint that provides motion control. It is free moving up to a determined extension position. When the patient is standing with the orthosis, the stance phase control is not achieved mechanically but by means of the integrated posterior offset (fig. 3) and the remaining function of the patient's knee and hip extension muscles.

## 4.5 Alternative Function in Permanent Unlocking

The **NEURO HiTRONIC** system knee joint can be permanently unlocked mechanically with a rotary switch, for example for activities such as driving a car or riding a bicycle. In this mode it is guaranteed that the system knee joint will not lock unintentionally. To do so, take a seat and unlock the system joint manually using the rotary switch below the system joint, by pressing in the rotary switch and turning it in the direction of the  symbol.


In order to save energy, you can then press the Lock button with the remote control/**User** app. The system knee joint remains unlocked even if you select another mode (e.g. Auto) with the remote control/app. In order to change the system joint's mode again with the remote control/app, turn the rotary switch in the direction of the  symbol (fig. 4).



Fig. 3

## 5. Rotary Switch

There is a rotary switch below the system joint (fig. 4). The three symbols show what happens if the rotary switch is turned in their respective direction. The arrows below show how the rotary switch should be controlled in order to select a symbol.




Symbol	Action	Meaning
	Turn the rotary switch in the direction of the symbol	The system joint is operated from the remote control/app.
	Turn the rotary switch in the centre and press in	The system joint is unlocked as long as the rotary switch is pressed in. As soon as it is released, the system joint will be operated once again from the remote control/app.
	Press in the rotary switch and turn it in the direction of the symbol	The system joint is now in permanent unlocking (see paragraph 4.5).



Fig. 4

## 6. NEURO HiTRONIC Knee Joint System

The knee joint system is equipped with **Bluetooth®** technology\* and consists of the following components (fig. 5):

- ❶ system knee joint
- ❷ controller
- ❸ remote control for the patient including charging cable with adapter and User app
- ❹ Expert app for the orthotist or qualified/trained experts

The system knee 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 has to be unlocked once from the login area in the FIOR & GENTZ website. The patient needs the remote control to use the orthosis. In addition, the **User** app can also be used.

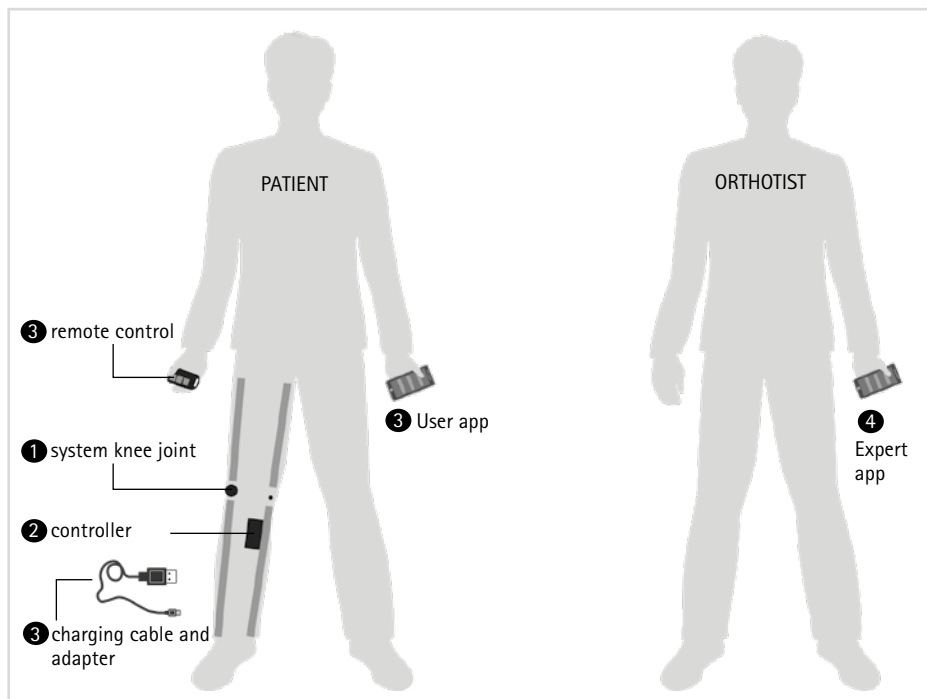


Fig. 5

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

For the production of a KAFO with **NEURO HiTRONIC** you need, in addition to the system knee joint, a component set consisting of a controller set, a remote control set, a maintenance set and a cloth bag for orthoses, as well as a tool set. The lamination dummy for the controller included in the tool set is reusable.

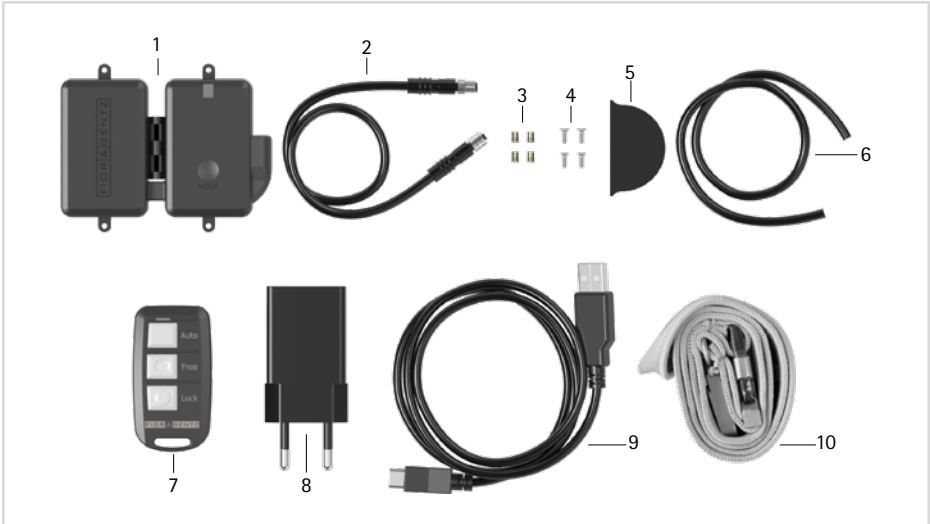


Fig. 6

Controller Set (SL3850-S)				
Item	Article Number	Description	Unit	Quantity Unilateral
1	ET3850	controller with lithium-polymer battery	pce.	1
2	ET0711-01	connection cable for functional unit, 300mm	pce.	1
3	VE0831-A3	thread insert	pce.	4
4	SC1302-L06	countersunk flat head screw, cross recessed H	pce.	4
5	ET0971-1	lamination dummy for cable length compensation	pce.	1
6	SL0935-11	lamination dummy for connection cable, 190mm	pce.	1

Remote Control Set (SK3850-P)				
Item	Article Number	Description	Unit	Quantity Unilateral
7	ET3840-P	remote control	pce.	1
8	ET0780	adapter	pce.	1
9	ET0710-01	charging cable	pce.	1
10	PR4000	lanyard FIOR & GENTZ	pce.	1

**i** Please note that the charging cable and adapter are not a part of the medical device.

Maintenance Set (SL3005-6M)*				
Item	Article Number	Description	Unit	Quantity Unilateral
w/o fig.	GS2411-***	sliding washer	pce.	1
w/o fig.	SC1404-L10	countersunk flat head screw with hexalobular socket	pce.	1
w/o fig.	SC1405-L14	countersunk flat head screw with hexalobular socket	pce.	1
w/o fig.	SC1406-L14	countersunk flat head screw with hexalobular socket (axle screw)	pce.	1
w/o fig.	SL0355-01	guide piece	pce.	1
w/o fig.	SL0355-11	roll unit	pce.	1
w/o fig.	SL0355-12	air filter	pce.	1

\* The maintenance set for the first maintenance after 6 months is included in the scope of delivery of the component set.

Tool Set (SL3005-WZ)				
Item	Article Number	Description	Unit	Quantity Unilateral
w/o fig.	WZ5018-0612	6.5mm double open-end wrench	pce.	1
w/o fig.	WZ5602-A13	13mm socket wrench insert, 1/4"	pce.	1
w/o fig.	WE3055-SL	adapter for socket wrench insert	pce.	1
w/o fig.	WZ5611-I20	hexagon key wrench, 2mm	pce.	1
w/o fig.	SL0935-1	shaping dummy	pce.	1
w/o fig.	ET0935	lamination dummy for controller, two parts	pce.	1

## 7. Scope of Delivery of the System Knee Joint

Description	Quantity
NEURO HITRONIC system knee joint (fig. 7)	1
assembly/lamination dummy (fig. 8)	1
orthosis joint grease, 3g (w/o fig.)	1
AGOMET® F330, 5g (fig. 9)	1



Fig. 7



Fig. 8

## 8. Load Capacity

The load capacity results from the relevant patient data and 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.



Fig. 9

## 9. Tools for Assembling the System Joint

Tool	System Width 20 mm
T8 hexalobular screwdriver/bit	x
T20 hexalobular screwdriver/bit	x
torque screwdriver 1–6Nm	x
slotted screwdriver 3–4 mm blade width	x
6.5 mm with double open-end wrench	x
13 mm socket wrench insert, 1/4"	x
adaptor for socket wrench insert	x
hexagon key wrench, 2 mm	x
twist drill, 3.2 mm	x
PH0 cross-recessed screwdriver	x

## 10. 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. Turn the plunger guide ring (fig. 21) only when the functional unit is mounted onto the lower part of the joint. Do not remove any of the screws that are sealed with blind plugs with the inscription "SEAL" (fig. 10), as the warranty will otherwise expire. The sealed screws may only be removed when the functional unit is disposed of.

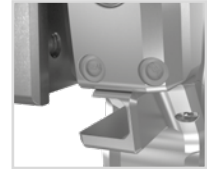


Fig. 10

## 11. Assembly of the System Joint

The system joint is delivered fully assembled. All functions are checked beforehand. You have to partly disassemble the system joint for mounting onto the orthosis and for maintenance. To ensure an optimal function, follow the assembly sequence below. Secure all screws with the torque specified in paragraph 11.6.



Fig. 11



The functional unit must not be opened.



Fig. 12



When mounting the system joint, mind the correct basic alignment of the orthosis as it is essential for the later function of the orthosis.

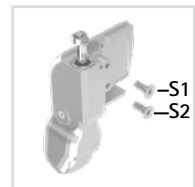


Fig. 13

### 11.1 Preparation of the Joint's Upper Part

- 1 Place the flexion stop disc on the joint's upper part (fig. 11).

## 11.2 Preparation of the Joint's Lower Part

- 1 Before assembly, use LOCTITE® 7063 Super Clean to clean the threads of the joint's lower part and of the bearing nut. Allow the threads to air-dry for at least 10 minutes.
- 2 Insert the extension stop and the extension stop damper into the joint's lower part (fig. 12).
- 3 Loosen the screws (S1 and S2) on the back of the functional unit (fig. 13).
- 4 Place the functional unit on the lower part of the joint (fig. 14).



Fig. 14

## 11.3 Preparation of the Cover Plate

- 1 Insert the guide piece in the cover plate (fig. 15).
- 2 Apply spray adhesive on one side of a sliding washer and adhere it to the cover plate (fig. 15).
- 3 Lightly grease the other side with orthosis joint grease.



Fig. 15



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

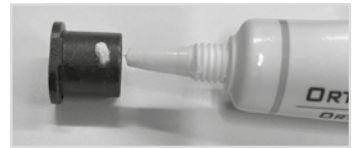


Fig. 16

## 11.4 Assembly of the System Joint

- 1 Grease the axle bore and the sliding surfaces of the bearing nut **with a drop** of orthosis joint grease (fig. 16).
- 2 Place the bearing nut in the lower part of the joint (fig. 17).
- 3 **Lightly** grease the second sliding washer on both sides with orthosis joint grease and place it in the joint's lower part above the bearing nut.
- 4 Attach the joint's upper part with the flexion stop disc to the joint's lower part above the bearing nut (fig. 19). Should the functional unit's plunger protrude too far, set the rotary switch to "Free" and press in the plunger until the joint's upper part fits. Next, you must adjust the plunger guide ring (see step 10).
- 5 Mount the cover plate and screw in the first countersunk flat head screw (axle screw, S3) (fig. 20).
- 6 Screw in the second countersunk flat head screw (S4) (fig. 20).
- 7 Twist the screws for the functional unit into the joint's lower part from behind, in order to screw it together with the functional unit (fig. 14).
- 8 Press the rotary switch (fig. 4) in order to permanently unlock the system joint.
- 9 Carefully unscrew the S5 screw (fig. 21) using the hexagon key wrench (fig. 22).
- 10 Adjust the plunger guide ring (fig. 21) of the functional unit using a flat-head



Fig. 17



Fig. 18

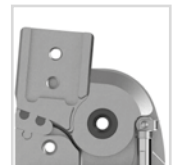


Fig. 19



Fig. 20

screwdriver. When the upper part has made slight contact with the extension stop dampers, a minimum distance should be created between the roll unit and the flexion stop disc. If the plunger guide ring has been unscrewed too much, the system joint will not unlock. If screwed in too far, some play will arise when the system joint is locked.

- 11 Screw in the S5 screw (fig. 21) slightly with the hexagon key wrench until the plunger guide ring no longer moves (fig. 22).

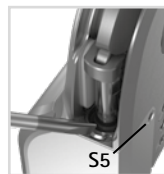


Fig. 21

## 11.5 Checking the System Joint's Free Movement

Secure the screws for the functional unit and the cover plate with the appropriate torque (see paragraph 11.6). 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.

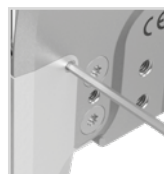


Fig. 22

## 11.6 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 cover plate (fig. 20) after checking the system joint's free movement again, and remove them from the cover plate.
- 2 Apply a small drop of LOCTITE® 243 medium strength to the threads of the screws.
- 1 Secure the screws for the functional unit and the cover plate (fig. 13 and 20) using the torque that is appropriate for the system width.
- 2 Let the adhesive harden (final strength after approx. 24 hours).


Screws for the Functional Unit and Cover Plate	System Width 20mm
countersunk flat head screws for the functional unit (S1 and S2)	3Nm
countersunk flat head screw for the cover plate (axle screw, S3)	4Nm
countersunk flat head screw for the cover plate (S4)	4Nm



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

12. Controller

The controller is delivered with the component set and is mounted onto the orthosis. It receives adjustments from the Expert app and commands from the remote control/User app, registers the patient's movements and controls the NEURO HiTRONIC system knee joint.

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



For more information on mounting the controller on the orthosis, refer to our online tutorials on our website [www.fior-gentz.com](http://www.fior-gentz.com).

## 12.1 Cable Connection for the Controller and Functional Unit

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

- 1 Insert the connecting cable into the functional unit port (fig. 23) and tighten the knurled threaded bushing.
- 2 Place the cable cover over the connecting point and affix it using the accompanying countersunk flat head screw (fig. 24).
- 3 Insert the connecting cable into the controller port (fig. 25) and tighten the knurled threaded bushing.
- 4 Secure the controller to the orthosis shell using the accompanying countersunk flat head screws.



Fig. 23



Fig. 24

## 13. Checking the Orthosis' Basic Alignment

Make sure that there is proper basic alignment before putting the orthosis into operation. You can then make further adjustments to the orthosis using the **Expert App**. You can find additional information on a proper orthosis alignment in the online tutorials, in the "Handing Over the Orthosis" section on our website, or on our YouTube channel.

### On the Workbench

Regardless of the plantar flexion, automatic system knee joints require a systematic adjustment of the dorsiflexion stop for an optimal function of the orthosis. The dorsiflexion stop determines the moment the system knee joint unlocks during mid stance. Furthermore, it affects the extension moment which is applied to the orthosis and the system knee joint, respectively. This is necessary to unlock the system knee joint.

Fix the foot piece of the orthosis firmly in the patient's shoe and put the orthosis on the workbench.

The dorsiflexion stop of the system ankle joint must be adjusted in such a way that the line of gravity passes through the middle of the femoral shell and runs vertically downwards in front of the system ankle joint and between the ankle's pivot point and the rolling-off line.

### Statically on the Patient

For checking the correct static alignment of the orthosis, the patient must wear the orthosis and stand upright with parallel feet. When viewed from the side, the line of gravity must run from the body's centre of gravity vertically downwards in front of the system ankle joint and between the ankle's pivot point and the rolling-off line. The course of the line of gravity at knee height results from the individual normal posture. Wearing the orthosis leads to deformation of soft tissue. This deformation causes the line of gravity to shift forward. Please consider this by readjusting the dorsiflexion stop, if necessary.

If the dorsiflexion stop is adjusted correctly, a lever between forefoot and lower leg is formed (activation of the forefoot lever) which brings the patient into a stable balance (they are able to balance themselves) and applies the necessary knee extension moment.



Fig. 25

## Dynamically on the Patient

For checking the correct dynamic alignment of the orthosis, the patient must wear the orthosis and walk a few steps with it. The dorsiflexion stop must be adjusted in such a way that a heel lift can clearly be seen in terminal stance. The consequence is a lever between forefoot and lower leg which brings the patient into a stable balance and applies the necessary knee extension moment. If the heel does not lift, you must reduce the system ankle joint's range of motion in dorsiflexion.

## 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 10. Unlock the app once from the login area in the FIOR & GENTZ website. This way, we ensure that patients cannot access the **Expert App** and change the orthosis' settings.

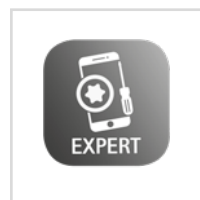


Fig. 26

### 14.2 Connection between Controller and Remote Control

In order to connect the remote control with the controller, proceed as follows:

- 1 Press the MODE button on the controller. First, a short beep is emitted. Press and hold the button until a second, longer beep is emitted after about 6–10 seconds.
- 2 Press the Auto and Lock buttons on the remote control at the same time for about four seconds. The LED blinks orange.



The orthosis can only be controlled by the one remote control or app to which it is currently connected. Other remote controls/apps have no influence on the orthosis.

If the connection to the controller has been successful, the LED on the remote control will blink green. If establishing the connection has failed, it blinks red.

A remote control can also be connected to two controllers:

- 1 Press the MODE button on both controllers. First, a short beep is emitted. Press and hold the button until a second, longer beep is emitted after about 6–10 seconds.
- 2 Press the Auto and Lock buttons on the remote control at the same time for about four seconds. The LEDs light up.

If the connection to both controllers has been successfully established, the LED at the remote control blinks green twice. If the LED at the remote control blinks green only once, the remote control is only connected to one controller. In this case, repeat steps 1– 2. If the connection is unsuccessful, the LED will blink red.

---

## 14.3 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 cannot communicate simultaneously with multiple **Expert** apps. If there is an active connection to the app, the blue LED on the controller will blink permanently. If you want to adjust the orthosis with the **Expert** app on a different mobile device, you must first close the app that is currently connected to the controller.

## 15. Adjustment Options with the Expert App

### 15.1 Selecting a Mode

You can select the available modes AUTO, FREE and LOCK with the app. The mode is active when the respective mode is displayed with a green background.

### 15.2 Signal Function for Training Purposes in Auto Mode

The signal function for training purposes supports the patient acoustically. When the patient exercises walking with the orthosis, the orthosis provides a tone signal if the signal function is on. This signal indicates if the system joint is locked or free moving.

You can select the tone, volume and signal via the settings (see paragraphs 15.3.4.2 to 15.3.4.4). You can switch off the signal tone by setting the volume to 0.

### 15.3 Main Menu

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

#### 15.3.1 Connecting (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.

#### 15.3.2 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 19.2)

### 15.3.3 Cable Connection Test

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



When you start the cable connection test, the orthosis switches automatically into Lock mode and remains in this mode after the test. To change the mode, use the remote control/User app or the Expert app.

#### 15.3.3.1 Result Messages and Further Actions After the Cable Connection Test

The following result messages will be displayed in the app:

Result Message	Meaning	Further Action
system joint is connected	The cable connection from controller to system joint is correct.	-
system joint is not connected	The cable connection from controller to system joint is incorrect.	Check the cable connection from controller to system joint.
short circuit	There is a short circuit in the cable from controller to system joint.	Check the cable connections at the controller and the system joint.
C91: Call technical Support	internal device error	Contact Technical Support.

### 15.3.4 Settings

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

#### 15.3.4.1 Calibration

In order for the motion sensors in the controller to detect the position of the lower leg, 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.

#### 15.3.4.2 Volume

In the sound settings you can set the volume of the signal tone for the signal function, for patient training purposes (see paragraph 15.2). Follow the instructions in the app.

#### 15.3.4.3 Tone Selection

In the sound settings you can set the tone for the signal function, for patient training purposes (see paragraph 15.2). You can select between two frequencies. This way, you can select a different tone for each controller/orthosis when both patient's legs are treated. Follow the instructions in the app.

#### 15.3.4.4 Signal Selection

In the sound settings you can set the type of signal tone for the signal function, for patient training purposes (see paragraph 15.2). Signal type 1 is preset. Follow the instructions in the app.

#### 15.3.4.5 Unlocking in Mid Stance

With this menu item, you can fine adjust the time when the system knee joint unlocks in mid stance. Follow the instructions in the app.

Have the patient practise walking with the orthosis with the adjusted time of unlocking and adapt the settings again, if required.

#### 15.3.4.6 Rotation Safety

Here, you have the option to adjust the orthosis in a way that enables the system knee joint to unlock easier during rotation movements. The rotation safety is preset to 0 and applies to patients with physiological rotation. Patients with unphysiological rotation movements of the leg inwards or outwards may experience problems with unlocking, which is why you can set an easier unlocking in this menu item. Follow the instructions in the app.

In cases in which a rotational movement of the leg makes the unlocking of the system joint difficult, thus impeding a harmonious gait pattern, there is an option to decrease the rotation safety. Please inform yourself of situations in which this might make sense, as well as the process and safety-related aspects, in the **Expert** app.

Inform the patient of the changes that will occur with a decrease in rotation safety. Make sure that the patient confirms in writing, on the back side of the instructions for use, that they have understood this process and the resulting consequences.



Please note that reducing the rotation safety may result in the system joint unlocking too easily, which would make it easier for the patient to fall. Only reduce the rotation safety if absolutely necessary and inform the patient accordingly.

#### 15.3.4.7 Motion Sensitivity

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

#### 15.3.4.8 First Step

With this menu item you can adjust the settings for the first step, to facilitate walking. Usually, the patient is able to start walking with the contralateral leg. During the second step with the selected leg, the system joint is automatically unlocked, which results in a more physiological gait. If the patient feels insecure and takes pathological, slow steps, this setting should be deactivated. We also recommend deactivating this setting for one of the two orthoses for patients where both legs are treated.

### 15.3.5 Step Counter

The controller counts all steps that were taken with the leg with the orthosis, in the different modes (Auto, Free and Lock). The step counter displays the strides taken for each respective mode. The sum of these values represents the total number of strides taken with the leg with the orthosis. Double the value for the total number of strides taken with both legs.

### 15.3.6 Updating the Controller and Remote Control

When updating the app, the controller update and the remote control update, if available, are downloaded simultaneously. In the app you can update the desired controller or remote control, by following the instructions in the app. Updating the remote control was successful if the LED on the remote control blinks green once.

Always update all controllers and remote controls in use.



The knee joint system may not be actively used during the update.

## 16. Connecting to the System Side Bar/System Anchor

The system side bar/system anchor must be connected to the system joint by adhering or screwing and wrapping in accordance with the production technique provided in the planning (fig. 27–29). You will find more detailed information in the **Instructions for Use for Orthotists or Qualified/Trained Experts System Side Bars and System Anchors**. You will find information on the production techniques in the "Online Tutorials" section of our website [www.fior-gentz.com](http://www.fior-gentz.com).



Fig. 27



Fig. 28



Fig. 29

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## 17. Conversion Options for the NEURO HiTRONIC System Knee Joint

The NEURO HiTRONIC system knee joint can be replaced by a NEURO TRONIC system knee joint on the orthosis. To do so, please contact our Technical Support.

## 18. Advice on Optimal Orthosis Functionality

### 18.1 Bluetooth® Connection

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

### 18.2 Walking with the Orthosis in Auto Mode

The system knee joint unlocks during the first stride. The e-motion algorithm makes it possible for the motion sensors of the controller to unlock the system knee joint at the right moment, when the second step is taken. Therefore, it is not necessary for the patient to become accustomed to always taking the first step using the leg with the orthosis. This leads to a more physiological gait pattern, especially when both legs are treated.

### 18.3 System Knee Joint

Problem	Cause	Action
The system joint does not unlock.	The proximal, dorsal thigh band transfers flexion load when a leg is set back.	Shorten the upper edge of the femoral shell parallel to the gluteal fold, so that the gluteal muscles are unobstructed.
	The controller is adjusted for a <b>NEURO TRONIC</b> system knee joint.	In the <b>Expert</b> app menu, select the <b>NEURO HiTRONIC</b> system knee joint.
	The patient has an abnormal gait.	With the <b>Expert</b> app, change the settings for unlocking in mid stance. The earlier the point in time is chosen, the easier the system joint unlocks. Then, the length of the period of stance phase control is shortened.
	The patient does not reach the dorsiflexion stop due to short steps during heel lift. Thus, the knee extension moment to unlock the system joint cannot be applied.	KAFO with system ankle joint: Adjust the dorsiflexion stop on the system ankle joint in such a way that the forefoot lever causes a knee extension moment.
		KAFO without system ankle joint: The necessary forefoot lever can be applied through the foot piece and/or shoe modifications or adjustments. Produce the foot piece stiffly enough and shift the rolling-off line further forward, if necessary.
	The forefoot lever of the foot piece does not achieve its effect on the knee extension.	Check the orthosis' basic alignment. If the system ankle joint has a dynamic dorsiflexion stop, you might need to insert a stronger spring unit. Also, check the rigidity of the laminate.
	The patient makes non-physiological rotation movements inwards and outwards.	With the <b>Expert</b> app, change the setting for rotation safety.
	The plunger guide ring of the functional unit is unscrewed too far.	Adjust the plunger guide ring for the functional unit with a flat-head screwdriver, so that a small slit can be seen between the roll unit and the flexion stop disc while in extended position.

Problem	Cause	Action
The system joint switches unintentionally into Lock mode.	The battery was not charged.	Charge the battery.
	The orthosis undergoes strong shocks when it is set to Free or Auto mode.	Due to shocks, the magnetic field is interrupted and the orthosis locks automatically. Switch to other mode and then back to the desired.

## 18.4 Remote control

Problem	Further Action
The controller does not respond to pressed buttons on the remote control.	Check whether the controller is still connected to the <b>Expert</b> or <b>User</b> app and whether the patient is standing still with the orthosis. If the problem remains, contact Technical Support.
The LEDs on the controller do not blink when pressing a button on the remote control.	

## 18.5 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.
When connecting the controller with the app, no devices were found.	Establish a connection between the app and controller within <b>30 seconds</b> . Check whether the LEDs light up or whether a short and a longer beep tone can be heard (see paragraph 14.2). If the problem remains, contact Technical Support.

## 19. 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. If you notice any play in the system joint in an ap direction while in Lock mode, adjust the plunger guide ring (see paragraph 11.4, steps 8–11). Make sure that there is no lateral play.

Maintenance Plan				
Joint Component	Potential Problem	Measure	Inspection/ Replacement, If Necessary	Latest Replacement
roll unit	wear	replacing roll unit	every 6 months	every 6 months
air filter	soiling	replacing air filter	every 6 months	every 6 months
guide piece	wear	replacing guide piece	every 6 months	every 6 months
flexion stop disc	wear	replacing flexion stop disc	every 6 months	every 12 months
extension stop damper	wear	replacing extension stop damper	every 6 months	every 18 months
sliding washer	wear	replacing sliding washer, see paragraph 19.5	every 6 months	every 18 months
sliding bushing	wear	replacing sliding bushing	every 6 months	every 18 months
functional unit	loss of function, wear, see paragraph 19.3	replacing functional unit	every 6 months	every 36 months
countersunk flat head screw	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bearing nut	wear	replacing bearing nut	every 6 months	every 36 months
cover plate	wear	replacing cover plate	every 6 months	every 36 months
remote control	outdated software	updating software	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
extension stop	wear	replacing extension stop, see paragraph 11.2	every 6 months	not applicable
connecting cable	damage	replacing connecting cable	every 6 months	not applicable

Use the **maintenance set** for the initial maintenance after 6 months. The maintenance set is included in the scope of delivery of the component set.

Before assembly, use LOCTITE® 7063 Super Clean to clean the threads of the joint's lower part and of the bearing nut. Allow the threads to air-dry for at least 10 minutes.

Secure the screws for the cover plate with the appropriate torque and LOCTITE® 243 medium strength, during every maintenance (see paragraph 11.6). Remove all adhesive residues first.

## 19.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport from their orthotist or qualified/trained expert, when the orthosis is handed over. The orthosis must be checked every 6 months 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. 30

## 19.2 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.

## 19.3 Functional Check of the Functional Unit

In order to check the function of the functional unit, proceed as follows:

- 1 Set the Free mode with the remote control. Try to flex the orthosis. The system joint should be unlocked and the orthosis should be able to move in the direction of flexion.
- 2 Set the Lock mode with the remote control. Try to flex the orthosis. The system joint should be locked and the orthosis should not be able to move in the direction of flexion.
- 3 Set the rotary switch on the system joint to Free. Position the orthosis in such a manner that you can see the plunger. Flex the system joint by 90° and quickly bring it into full extension. If the plunger moves too slowly upwards and loses contact with the flexion stop disc, please contact Technical Support.



Fig. 31

## 19.4 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 functional unit for the duration of the repair. To this end, please send us the functional unit, the filled-out claim form and the maintenance logs.

## 19.5 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. 32). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

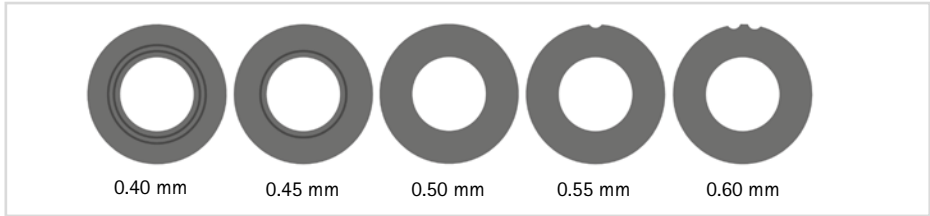


Fig. 32

## 19.6 Replacing the Roll Unit

- 1 Demount the functional unit from the system joint.
- 2 Keep the plunger in place by gripping it from the slot with a 6.5 mm spanner, and loosen the roll unit with a 13 mm socket wrench insert with adapter (fig. 33).
- 3 Replace the roll unit.
- 4 Secure the screws with a torque of 2.5 Nm.
- 5 Remount the functional unit onto the system joint.
- 6 Adjust the plunger guide ring as described in paragraph 11.4.



Fig. 33

## 19.7 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 controller, and clean the soiled system components with a dry cloth.

---

## 20. 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:

- 1 Adhere to the specified maintenance intervals without interruption and document each maintenance (see paragraph 19).
- 2 Adhere to the determined maintenance conditions (see paragraph 19).
- 3 Check the wear parts, as required, and exchange them in the defined intervals (see paragraph 19).
- 4 Check the adjustment of the system joint during maintenance and correct it, if necessary (see paragraph 19).
- 5 Check the functionality of the system joint during maintenance (see paragraph 19).
- 6 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 established maximum load on the system joint is exceeded, the system joint may no longer be used. When planning the custom-made product, expected changes in patient data need to be taken into account.
- 7 The period of use of the system joints ends with the period of use of the custom-made product (orthosis).
- 8 The multiple use of the system joint in another custom-made product is not allowed (see paragraph 27).

## 21. 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 24.1.

22. Spare Parts

22.1 NEURO HiTRONIC Exploded View Drawing

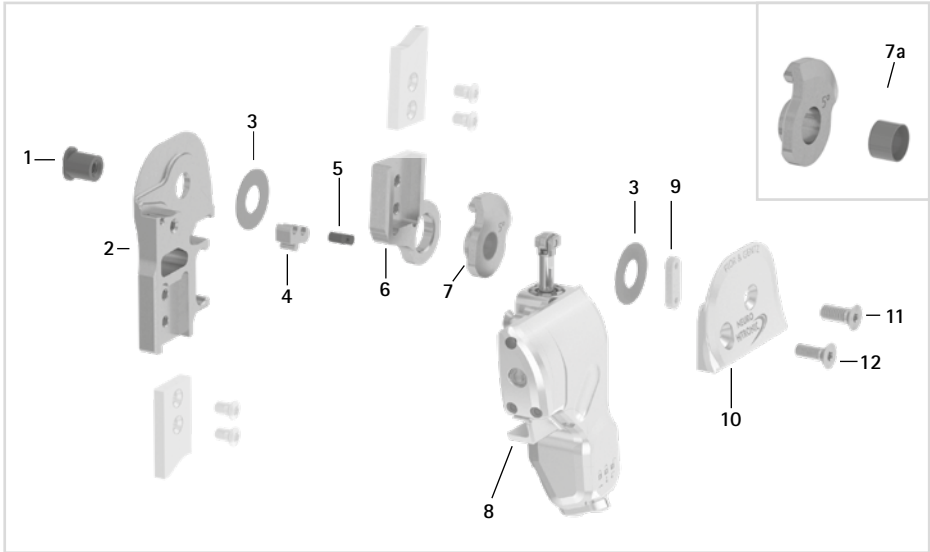


Fig. 34

The functional unit is delivered preassembled. If individual components of the functional unit (fig. 35) have to be exchanged, you can order them as well.

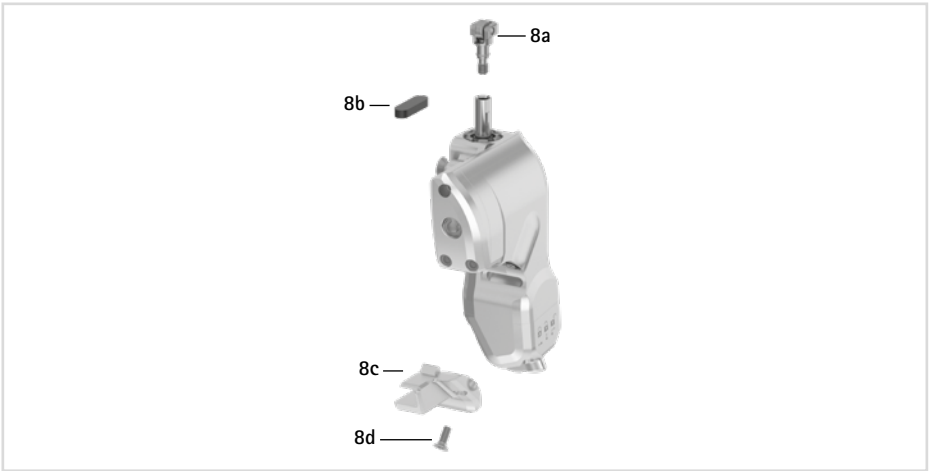


Fig. 35

## 22.2 Spare Parts for the NEURO HiTRONIC System Knee Joint

Item	Article Number for System Width	Description
	20mm	
1	SB1069-L1110	bearing nut
2	SL0315-L/TI	lower part, left lateral, straight, titanium
2	SL0315-R/TI	lower part, right lateral, straight, titanium
3	GS2411-*	sliding washer*
4	SL9005-E005	5° extension stop
5	PN1000-L05/5	extension stop damper
6	SL0305-L/TI	upper part, left lateral, straight, titanium
6	SL0305-R/TI	upper part, right lateral, straight, titanium
7	SL0365-2L	5° flexion stop disc with sliding bushing
7	SL0365-2R	5° flexion stop disc with sliding bushing
7a	BP1211-L077	sliding bushing
8	SL3955-L	functional unit, left lateral
8	SL3955-R	functional unit, right lateral
8a	SL0355-11	roll unit
8b	SL0355-12	air filter
8c	SL0355-16/L	cable cover, left lateral
8c	SL0355-16/R	cable cover, right lateral
8d	SC1403-L08/1	raised countersunk head screw with hexalobular socket
9	SL0355-01	guide piece
10	SL0355-L/AL	cover plate, left lateral
10	SL0355-R/AL	cover plate, right lateral
11	SC1406-L14	countersunk flat head screw with hexalobular socket (axle screw)
12	SC1405-L14	countersunk flat head screw with hexalobular socket

## 22.3 Sliding Washers


* Sliding Washers
Article Number for System Width
20mm
Ø = 24mm
GS2411-040
GS2411-045
GS2411-050
GS2411-055
GS2411-060

## 23. 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:



Fig. 36

- 1 Press in the rotary switch and turn in the direction of the  symbol.
- 2 Slowly unscrew the four screws in the functional unit a little.



Cover the exit point with a cloth as the oil might spurt out.



Fig. 37

- 3 Press the plunger downward so that the oil drains out.
- 4 Unscrew the four screws completely (fig. 36) so that the rest of the oil drains out.

The product must not be disposed of with residual waste (fig. 37). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

The electronically controlled, automatic **NEURO HiTRONIC** system knee 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.



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

## 24. Technical Data

NEURO HiTRONIC	
useful life	unlimited, excluding wear parts (see paragraph 20)
protection type	IP44
operating mode	continuous operation

### 24.1 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
working range	min. 2m
frequency range	2402MHz – 2480MHz
modulation	GFSK
data rate (OTA)	1Mbps
maximum output power (EIRP)	+5dBm

Power Supply Unit with Charging Cable (not Part of the Medical Device)	
article number	ET0780
manufacturer's designation	HNP12-USBV2, HNP07-USBV2
ambient temperature in operation	-10°C – +40°C
ambient temperature in storage	-20°C – +70°C
relative air humidity	10% – 90% rH
input voltage	90V – 264V (AC)
input frequency	47Hz – 63Hz
power	12 W
output voltage	5V (DC)
output current	max. 2.4A
Charging Cable (not Part of the Medical Device)	
article number	ET0710-01

Controller Battery	
type	lithium-polymer battery
operating time at room temperature and full battery charge after 3 years of use	Auto mode: 26 000 strides/Free mode: 24 hours
behaviour of the system knee joint during the charging process	The system knee joint has no function.
User and Expert App	
supported operating system	at least Android 6.0 or iOS 10

## 25. Signs and Symbols



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



medical device



catalogue 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



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



single patient – multiple uses

IP44

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



Unique Device Identifier – product identification number

### Remote Control Type Plate



### Controller Type Plate



---

## 26. 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.

## 27. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply. The manufacturer shall bear liability when the product is used according to the specifications in the instructions for use. The manufacturer shall not be liable for damages caused from non-observance of these instructions for use, especially from improper use or unauthorised alteration of the product. The warranty expires, for example, if the product is mounted several times. The warranty for the functional unit will expire if more than 2 000 000 strides have been taken with the orthosis, if the product was purchased more than 24 months ago or if the screw seals are damaged. Please note that the product may not be combined with components or materials other than those recommended by 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.

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## 28. Electromagnetic Compatibility

Special precautions must be taken for all electronic medical devices as regards electromagnetic compatibility (EMC). This device complies with standard IEC 60601-1-2:2014.

- 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.

### 28.1 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.

### 28.2 Electromagnetic Emissions for all Devices and Systems

#### Usage Instructions and Manufacturer's Declaration – Electromagnetic Emissions

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** 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 <b>NEURO HiTRONIC</b> 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 <b>NEURO HiTRONIC</b> 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	

## 28.3 Electromagnetic Immunity for all Devices and Systems

### Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** 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.

# 28.4 Electromagnetic Immunity for Non-Life-Supporting Devices and Systems

## Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** 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 <sub>rms</sub> 150kHz to 80MHz 6V <sub>rms</sub> in ISM bands 150kHz to 80MHz	3V <sub>rms</sub> 150kHz to 80MHz 6V <sub>rms</sub> in ISM bands 150kHz to 80MHz	Portable and mobile wireless devices should be used at a safety distance from the product <b>NEURO HiTRONIC</b> and its lines. The recommended safety distance was calculated using the equation applicable to the transmission frequency. Recommended safety distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 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 <sup>a</sup> , the field strength of stationary radio transmitters should be below the compliance level at all frequencies.
radiated RF interference according to IEC 61000-4-3	10V/m 80MHz to 2.7GHz 80% AM 1kHz	10V/m 80MHz to 2.7GHz	Interference may occur in the vicinity of devices marked with the following symbol: 

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.

<sup>a</sup> 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 HiTRONIC** exceeds the compliance level specified above, the product **NEURO HiTRONIC** 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 HiTRONIC**.

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## 28.5 Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product **NEURO HiTRONIC** 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 HiTRONIC**

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment where RF interference is monitored. The customer or user of the product **NEURO HiTRONIC** can help prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF communication equipment (transmitters) and the product **NEURO HiTRONIC**, 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.			

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**29. Information for the Treatment Documentation**  
Add these instructions for use to your treatment documentation!

**Patient Data**

Name	
Adress	
Postcode,City	
Home Telephone	
Telephone at Work	
Insurance	
Insurance No.	
Attending Physician	
Diagnosis	

### 30. Handing Over the Orthosis

The orthotist or qualified/trained expert has also handed over the instructions for use for patients as well as the orthosis service passport to you as a patient, parent or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to you in detail. You will find the next maintenance appointment in the orthosis service passport. Bring the orthosis service passport with you to every maintenance appointment.



Place, Date

Signature Patient

Leg Side

- ☐ left  
☐ right

Mounted Sliding Washer

1. GS \_\_\_\_\_ - \_\_\_\_\_  
2. GS \_\_\_\_\_ - \_\_\_\_\_

