FIOR & GENTZ

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

EN

NEURO TRONIC

NEURO TRONIC

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## 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 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 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 Processing**
Always mount the system knee joint to an orthosis with a system ankle joint in order to avoid joint dysfunction. This also applies in case of anatomical stiffening in the ankle joint.

## ⚠ 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 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 Improper Greasing of the System Joint**
Only use the orthosis joint grease from the FIOR & GENTZ product range to grease the system joint. Grease the axle bore of the toothed ring and the sliding surfaces of the bearing nut of the joint axis **with just one drop** of orthosis joint grease.

## ⚠ 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 knee 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 about 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 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 Falling Due to Unintentional Performing of the Gesture**
The use of gestures reduces the safety when using the orthosis. Only activate the gesture for sitting down in Auto mode if your patient is physically fit so that they do not fall if the gesture is performed unintentionally. Also advise them to be particularly careful when lifting heavier objects, as this movement could unintentionally trigger a gesture.

## ⚠ WARNING

**Risk of Falling Due to Unintentional Locking of the System Joint**
Advise the patient to use the alternative function in permanent unlocking for activities where the system joint must remain unlocked by all means (e.g. when walking down stairs, driving a car or riding a bicycle).

## ⚠ WARNING

**Risk of Falling Due to Electromagnetic Interference**
Do not use the knee joint system in close proximity to or stacked with other portable RF communication devices in order to avoid impairing the function of the knee joint system. If such use is necessary, observe the knee 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 knee joint system to avoid impairing the function of the knee joint system. If use at a distance of less than 30cm is necessary, observe the knee 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 26.6).

## ⚠ 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 knee joint system.

## ⚠ 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 part, in which clothing or skin could get caught. Please inform the patient of this risk.

## *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 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.

# 3. Use

## 3.1 Intended Use

The **NEURO TRONIC** knee joint system, including system knee joint and controller, must be used exclusively for the orthotic treatment 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 TRONIC** system knee 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.

## 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 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 TRONIC** system knee joint must be combined with a system ankle joint from the FIOR & GENTZ product range. The **NEURO VARIO** system knee joint can be used as a 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 TRONIC** is a microprocessor-controlled, automatic system knee joint that provides four joint functions:

- basic function in 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 at an angle of 5°, corresponding to a physiological knee joint angle. By exchanging the 5° joint's upper part for a 0° or a 10° joint's upper part, the joint angle can be changed by 5° in the direction of flexion or extension.

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

## 4.1 Basic Function in Auto Mode

The controller of the orthosis has motion sensors which detect the movement and position of the lower leg. Thus, the controller can lock/unlock 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 system knee joint locks, as no movement is registered.

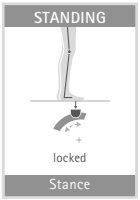


fig. 1

**Gait**

When walking, the system joint locks/unlocks as follows: the system joint is locked in the direction of flexion from terminal swing to mid stance (fig. 2). The solenoid shuts off and the coil spring pushes the plunger upwards, which causes the locking pawl to mesh into the toothing of the toothed ring (fig. 3).

In the gait phases from terminal stance to mid swing, the system joint is unlocked and is therefore free moving (fig. 2). The solenoid turns on and generates an electromagnetic field, which causes the plunger to retract magnetically against the spring force, while gravity causes the locking pawl to fall downwards from the toothing of the toothed ring (fig. 4).

The locking/unlocking moment can be fine adjusted with the **Expert** app.

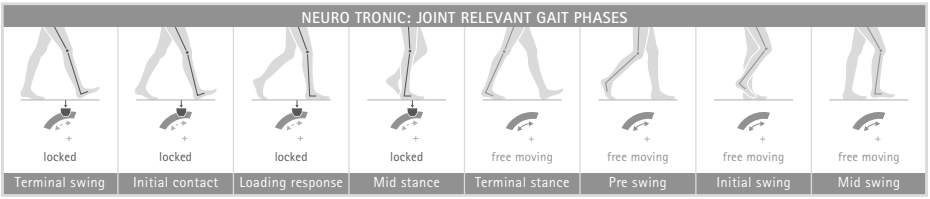


fig. 2

In the free moving phases terminal stance and pre swing, the system knee joint is not secured electronically in order to prepare the knee flexion for pre swing:
- In terminal stance, securing against knee flexion takes place via the levering back extension moment of the forefoot lever.
- If, contrary to expectations, weight is put on the leg with orthosis in pre swing when the step is interrupted in this phase, the system joint will not lock. Explain this situation to the patient and, if necessary, train with them.

If one of the free moving phases initial swing or mid swing is unexpectedly interrupted, the system joint will lock safely.

## 4.2 Alternative Function in Lock Mode

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

fig. 3

fig. 4

## 4.3 Alternative Function in Free Mode

In Free mode, the **NEURO TRONIC** system knee joint is unlocked and free moving up to a defined extension position. When the patient is standing with the orthosis, the stance phase control is achieved by means of the integrated posterior offset (fig. 5) and the patient's remaining function of the knee and hip extension muscles.

fig. 5

## 4.4 Alternative Function in Permanent Unlocking

The **NEURO TRONIC** system knee joint can be permanently unlocked mechanically with a lever. For activities where the system joint must remain unlocked by all means (e.g. when walking down stairs, driving a car or riding a bicycle), the permanent unlocking must be used. This mode guarantees that the system knee joint does not lock unintentionally e.g. due to an empty battery or shocks. To do so, unlock the system joint manually with the lever by setting it to the symbol.

In order to save energy, you can then press the Lock button with the remote control/**User** app. The system knee joint also remains unlocked if you select another mode (e.g. Auto) with the remote control/app since the lever blocks the locking pawl, which, therefore, cannot mesh into the toothing (fig. 6). In order to change the system joint's mode again with the remote control/app, set the lever to the symbol (fig. 5).

fig. 6

## 5. NEURO TRONIC Knee Joint System

The knee joint system is equipped with Bluetooth technology* and consists of the following components (fig. 7):

1. **system knee joint**
2. **controller**
3. **remote control** for the patient including **charging cable with power supply unit** and **User** app
4. **Expert** app for qualified specialists in orthopaedic technology

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 must be activated once using the code generator for the **Expert** app on the FIOR & GENTZ website. The patient needs the remote control to operate the orthosis. As a complement, the **User** app can be used.

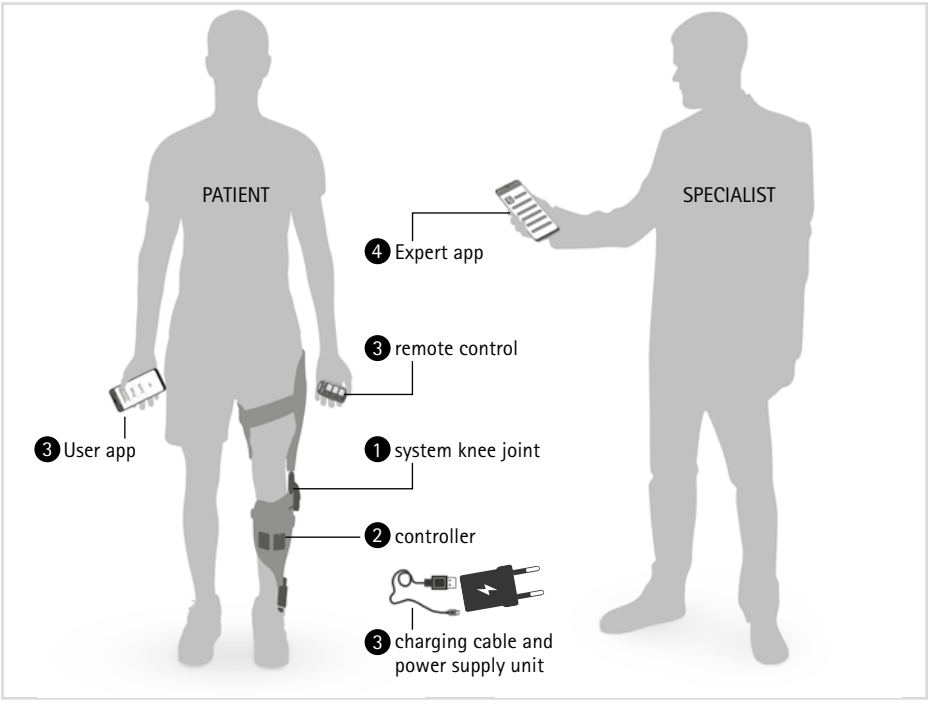



fig. 7

* 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.

For the production of a KAFO with the **NEURO TRONIC** you need, in addition to the system knee joint, a controller set, a remote control set and a connection cable set. Please note that you must order the lamination dummy for the controller and the lamination dummy for the wye junction of the solenoid connection cable separately. These can be used multiple times.

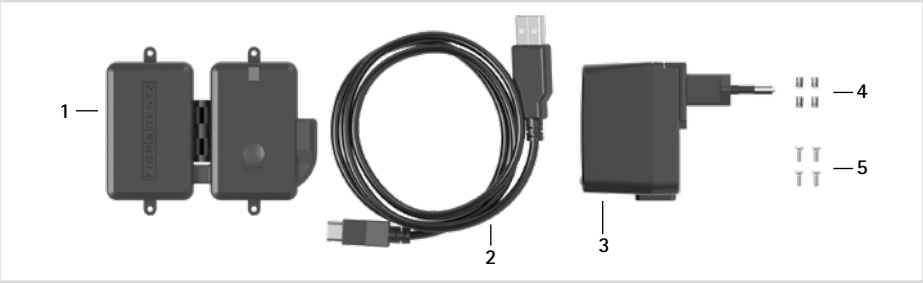



fig. 8

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

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

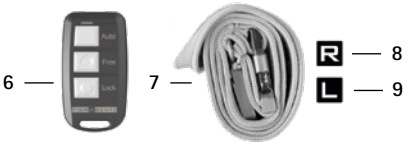



fig. 9

| Remote Control Set (SL3860-P) | | | | | |
|---|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity | |
| | | | | Unilateral | Bilateral |
| 6 | ET3840-P | remote control with Bluetooth for the patient | pce. | 1 | 1 |
| 7 | PR4000 | lanyard FIOR & GENTZ | pce. | 1 | 1 |
| 8 | HE3800-SK/R | letter sticker R for remote control, right leg | pce. | 1 | 1 |
| 9 | HE3800-SK/L | letter sticker L for remote control, left leg | pce. | 1 | 1 |

not in combination with a NEURO HiSWING R+

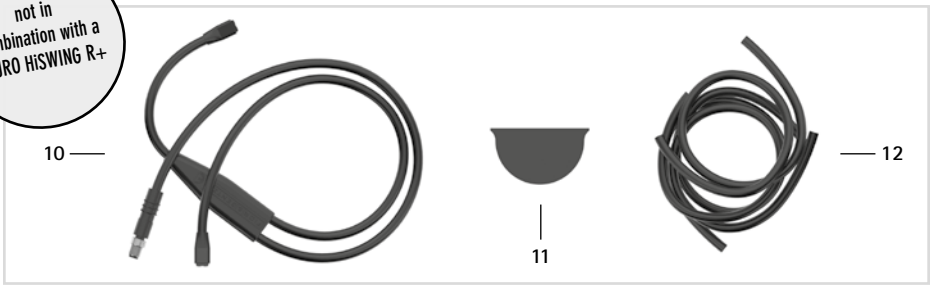



fig. 10

| Connection Cable Sets NEURO TRONIC (unilateral: SK3860-K; bilateral: SK3860-K/2) | | | | | |
|---|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity | |
| | | | | Unilateral | Bilateral |
| 10 | ET0712-00 | connection cable for solenoid, unilateral, 300mm | pce. | 1 | - |
| 10 | ET0712-02 | connection cable for solenoid, bilateral, 420mm | pce. | - | 1 |
| 11 | ET0971-1 | lamination dummy for cable length compensation | pce. | 1 | 3 |
| 12 | SK0935-11 | lamination dummy for solenoid connection cable, 250mm | pce. | 1 | 1 |
| 12 | SK0935-12 | lamination dummy for solenoid connection cable, 170mm | pce. | - | 1 |
| 12 | SK0935-13 | lamination dummy for solenoid connection cable, 85mm | pce. | - | 1 |

only in combination with a NEURO HiSWING R+

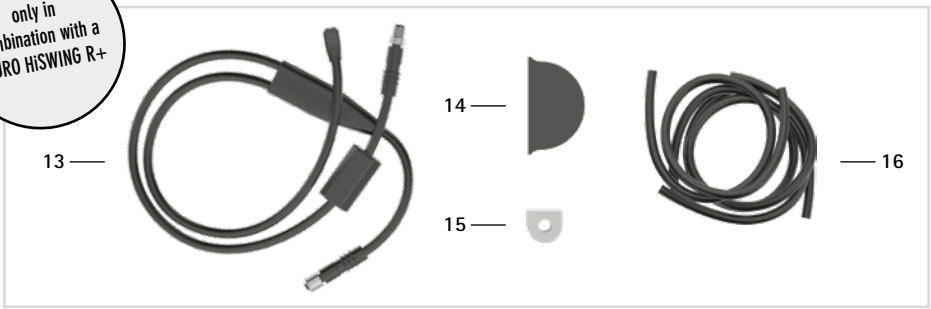



fig. 11

| Connection Cable Set NEURO HiSWING R+, NEURO TRONIC (SK3860-K/4) | | | | |
|---|---|---|---|---|
| Item | Article Number | Description | Unit | Quantity Unilateral |
| 13 | ET0714-02 | connection cable for functional unit NEURO TRONIC and NEURO HiSWING R+, 660mm | pce. | 1 |
| 14 | ET0971-1 | lamination dummy for cable length compensation | pce. | 3 |
| 15 | ET0972-3 | lamination dummy for connection cable for functional unit | pce. | 1 |
| 16 | SH0985-15 | lamination dummy for connection cable for NEURO HiSWING R+ functional unit, 270mm | pce. | 1 |
| 16 | SH0985-16 | lamination dummy for connection cable for controller, 150mm | pce. | 1 |
| 16 | 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 TRONIC** system knee joint, such as the placement of dummies as well as the specifics of reinforcement, in the corresponding online tutorial (see QR code, fig. 12) on the FIOR & GENTZ website.

fig. 12

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

| Description | Quantity |
|---|---|
| **NEURO TRONIC** system knee joint (fig. 13) | 1 |
| assembly/lamination dummy (fig. 14) | 1 |
| orthosis joint grease, 3g (without figure) | 1 |

fig. 13

fig. 14

## 7. Load

The actual load on the system joints is based on the relevant patient data. 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

| Tools | System Width | |
|---|---|---|
| | 16mm | 20mm |
| T8 hexalobular screwdriver/bit | x | x |
| T15 hexalobular screwdriver/bit | x | - |
| T20 hexalobular screwdriver/bit | x | x |
| torque screwdriver, 1–6Nm | x | x |
| twist drill, 3.2mm | x | x |
| PH0 cross-recessed screwdriver | x | x |

## 9. Mounting the System Joint

The system joint is delivered fully assembled. All functions are checked beforehand. You have to disassemble the system joint for mounting it to the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure all screws with the torque specified in paragraph 9.6.

You can find more information on the assembly in the online tutorial **Joint Assembly NEURO TRONIC** (see QR code, fig. 15) on the FIOR & GENTZ website.

fig. 15

When mounting the system joint, mind the correct basic alignment of the orthosis as it is essential for the later function of the orthosis. You can find more information on this in the online tutorial **KAFO Alignment Guidelines** (see QR code, fig. 16) on the FIOR & GENTZ website.

fig. 16

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

## 9.1 Mounting the Locking Parts

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

1 Grease the axle bore of the toothed ring and the sliding surfaces of the bearing nut of the joint axis **with a drop** of orthosis joint grease (fig. 17). Make sure that no grease enters the toothing of the locking pawl and the toothed ring.
2 Put the bearing nut for the locking pawl into the opening of the joint's lower part (fig. 18).
3 Mount the locking pawl (fig. 19).
4 Insert the bearing nut for the joint axis into the opening of the joint's lower part (fig. 20).
5 Grease the first sliding washer **slightly** on both sides with orthosis joint grease and place it on the joint's lower part.
6 Place the toothed ring on the front side of the joint's upper part so that it is flush with the joint's upper part. The wavy cut-out has to point in direction of the joint's upper part (fig. 21–22).
7 Mount the joint's upper part (fig. 23). Make sure that the joint's upper part is placed without play.
8 Apply spray adhesive on one side of the second sliding washer and adhere it to the cover plate (fig. 24).
9 Grease the other side **slightly** with orthosis joint grease.

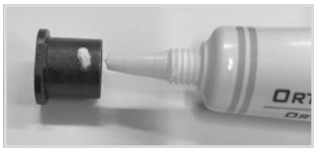


fig. 17

fig. 18

fig. 19

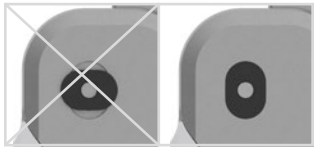


fig. 20

fig. 21

fig. 22

fig. 23

fig. 24

## 9.2 Mounting the Solenoid

1 Place the coil spring (2; fig. 25) onto the plunger (1).
2 Slide the plunger into the solenoid (3).
3 Secure the solenoid by pressing it into the cover plate (fig. 26).

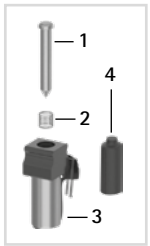



fig. 25

fig. 26

## 9.3 Mounting the Cover Plate

The lever of the cover plate is already premounted. For the following steps, the lever must be set to the symbol.

1 Before the assembly, clean the threads of the bearing nuts with LOCTITE® 7063 Super Clean. Allow the threads to air-dry for 10 minutes.
2 Place the cover plate on the system joint.
3 Screw in the first countersunk flat head screw (axle screw, S1; fig. 27).
4 Screw in the second countersunk flat head screw (S2; fig. 27).

fig. 27

## 9.4 Checking the Free Movement

Tighten the screws for the cover plate with the appropriate torque (see paragraph 9.6). 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.

## 9.5 Mounting the O-Ring Dampers and the Small Cover Plate

1 Bend the system joint, turn it upside down and place the O-ring dampers into the bores (fig. 28).
2 Bring the system joint in extension.
3 Lay the cable for the solenoid (fig. 29).
4 Connect the cable to the solenoid port.
5 Place the end cap (4; fig. 25) over the connection.
6 Mount the small cover plate onto the back of the system joint (fig. 30).

fig. 28

fig. 29

fig. 30

## 9.6 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. 27) after checking the free movement and remove them from the cover plate.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screws.
3 Secure the screws for the cover plate (fig. 27) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

| Screws for Cover Plate | System Width | |
|---|---|---|
| | 16mm | 20mm |
| countersunk flat head screw with hexalobular socket (axle screw, S1) | 4Nm | 4Nm |
| countersunk flat head screw with hexalobular socket (S2) | 3Nm | 4Nm |

The screws for 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.

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

fig. 31

fig. 32

fig. 33

fig. 34

# 11. Conversion Options

The **NEURO TRONIC** system knee joint can be converted into a **NEURO MATIC** system knee joint by exchanging individual system components. You can find more information on this in the online tutorial **Joint Conversion NEURO TRONIC into NEURO MATIC** (see QR code, fig. 35) on the FIOR & GENTZ website.

An orthosis with a **NEURO TRONIC** system knee joint can be converted into an orthosis with a **NEURO HiTRONIC** system knee joint by exchanging the system joint.

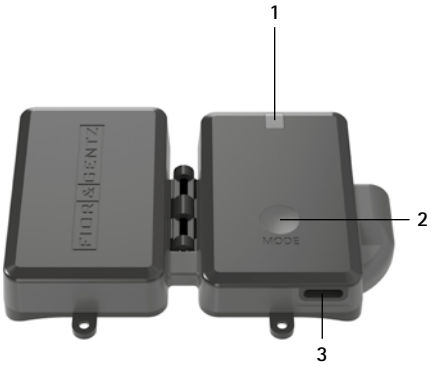
fig. 35

## 12. Controller

The controller is mounted to 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 TRONIC** system knee joint.

The controller can be used for a unilateral as well as a bilateral construction. It automatically recognises whether one or two system knee joints are connected to the controller.

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.

### 12.1 Cable Connection of the Controller

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 solenoid of the system knee joint via a connection cable.

1 Plug the connection cable into the port on the controller (fig. 36).
2 Tighten the knurled threaded bushing of the connection cable by hand.
3 Secure the controller to the orthosis shell using the accompanying countersunk flat head screws.

fig. 36

## 13. Checking the Orthosis' Basic Alignment

Make sure that the orthosis' alignment is correct before putting the orthosis into operation. You can then make further adjustments to the orthosis using the **Expert** app. You can find more information on the correct orthosis' alignment in the online tutorial **Checking the Orthosis' Alignment – Dynamically** (see QR code, fig. 37) and **Checking the Orthosis' Alignment – Statically** (see QR code, fig. 38) on the FIOR & GENTZ website, or on our YouTube channel.

fig. 37

**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 leads to an extension moment which is applied to the orthosis and the system knee joint, which is necessary to unlock the system knee joint.

fig. 38

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 thigh 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 is formed between the forefoot and lower leg (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.

**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

fig. 39

Download the app with your smartphone/tablet. Minimum requirements are Bluetooth 4.0 and Android 6.0 or iOS 12. Unlock the app once from the login area on the FIOR & GENTZ website. This ensures that patients cannot access the **Expert** app and change the orthosis' settings.

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 between Controller and Remote Control

In order to connect the remote control to 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 of 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 blinks green. If establishing the connection has failed, it blinks red.

The 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 buttons until a second, longer beep is emitted after about 6–10 seconds.
2 Press the Auto and Lock buttons of the remote control at the same time for about four seconds. The LEDs light up.

If the connection to both controllers has been successful, the LED on the remote control blinks green twice. If the LED on the remote control blinks green only once, the remote control is only connected to one controller. In this case, repeat steps 1–2. If establishing the connection has failed, the LED blinks 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 Menu

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

### 15.2.1 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.

### 15.2.2 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.

### 15.2.3 Basic Position

Bring the leg with orthosis into the basic position and confirm this with the app. This step is important for performing the gestures (see paragraph 15.2.5.6).

### 15.2.4 General Settings

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

#### 15.2.4.1 Mode Change

With this menu item, you can adapt the mode change settings of the controller, in order to make a mode change possible even while 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.

#### 15.2.4.2 Sound

In the sound settings, you can set the volume, tone and type of signal tone for the signal tones for training purposes or for the signal tones for gestures.

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

With the signal tones for gestures, a signal tone sounds after the controller has registered an executed gesture (see paragraph 15.2.5.6). After the patient has sat down and the system joint is locked again, another signal tone sounds.

For the tone, you can choose between two frequencies. This way, you can select a different tone for each controller/orthosis at a bilateral treatment.

### 15.2.5 System Knee Joint Settings

#### 15.2.5.1 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.

#### 15.2.5.2 Terminal Swing

With this menu item, you can fine adjust the time when the system knee joint locks in terminal swing. Follow the instructions in the app.

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

#### 15.2.5.3 Easier Unlocking

Here, you have the option to adjust the orthosis in a way that enables the system knee joint to unlock easier during rotation movements. This menu item is preset to 0, which applies to patients with a physiological rotation. Patients with unphysiological inward or outward rotation movements of the leg may experience problems with unlocking, making a harmonious gait difficult. In such a case, you can set easier unlocking with this menu item. Follow the instructions in the app. 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 involved in setting an easier unlocking. Make sure that the patient confirms in writing, on the back page of the instructions for use, that they have understood this process and the resulting consequences.

Please note that setting an easier unlocking leads to a reduction in stability, which makes it easier for the patient to fall. Only set an easier unlocking if it is necessary and instruct the patient accordingly.

#### 15.2.5.4 First Step

This menu allows you to adjust the settings for the first step to facilitate walking. In the default setting, the detection of the first step is deactivated. This is the safest setting as the orthosis only unlocks in the second swing phase. For patients who feel very secure walking with their orthosis, the detection of the first step can be activated. In this case, we recommend that the patient makes the first step with the non-orthotically treated leg. During the second step, the controller detects the first swing phase of the treated leg and the system knee joint is automatically unlocked. This enables a physiological gait.

For patients who have both legs treated with orthoses, we recommend activating the detection of the first step for the orthosis with which the patient wants to take the second step. The first step is therefore taken with the orthosis in a locked state, which provides more stability.

For unilateral treatments where the patient feels insecure and takes pathological, slow steps, the detection of the first step should not be activated.

#### 15.2.5.5 Using a Walker

With this menu item, you can optimise the locking/unlocking moment for patients using a walker. This setting should be activated for patients who only use the orthosis with the support of a walker and are under therapeutic supervision. For all other patients, this setting is not suitable.

#### 15.2.5.6 Gestures

With this menu item, you can activate the gesture for sitting down in Auto mode. You have to carry out the first activation. Afterwards, the patient can switch the function off and on themselves. This gesture unlocks the system joint for a short time while in Auto mode so that the patient can sit down. To do so, the patient has to stand still in basic position for one second and then set down the affected leg with the heel and wait for another second. The system joint unlocks and the patient can sit down. The system joint locks as soon as the lower leg is put in a vertical position.

The use of gestures reduces the safety when using the orthosis. Only activate the gesture for sitting down in Auto mode if your patient is physically fit so that they do not fall if the gesture is performed unintentionally.

#### 15.2.5.7 Gestures via Smartwatch

If the patient has an Apple Watch* or a Samsung** Watch, they can alternatively activate sitting down in Auto mode with the gestures via smartwatch. You can find further information under **Gestures via Smartwatch** on the FIOR & GENTZ website (see QR code, fig. 40).

fig. 40

* 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.

### 15.2.6 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.

### 15.2.7 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 17.2).

### 15.2.8 Cable Test

With this test, you can check the cable connection to the solenoid 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 connection test for the solenoid.

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

#### 15.2.8.1 Result Messages and Further Actions After the Cable Test

The following result messages will be displayed in the app:

| Result Message | Meaning | Further Action |
|---|---|---|
| one system joint connected | The cable connection from the controller to the system joint is correct. | - |
| two system joints connected | The cable connections from the controllers to both system joints are correct. | - |
| no system joint connected | The cable connection from the controller to the system joint is incorrect. | Check the cable connection from the controller to the system joint. |
| short circuit | There is a short circuit in the cable from the controller to the system joint. | Check the ports at the controller and the system joint. |
| C91: Call Technical Support | An internal device error has occurred. | Contact Technical Support. |

### 15.2.9 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 must not be actively used during the update.

## 16. 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".

### 16.1 Bluetooth® Connection

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

### 16.2 System Knee Joint

| Problem | Cause | Measure |
|---|---|---|
| The system joint locks unintentionally in a slightly flexed position. | The patient uses strong momentum to extend their leg. If the leg comes into full extension before the heel touches the floor, the lower leg bounces off the stop into a slightly flexed position. Ventrally, an instant before heel strike, you can see an obvious opening between the upper and lower part of the system knee joint. | Recommend gait re-education to achieve a harmonious and natural swing phase. In terminal swing, the heel should be about to touch the ground.<br>Alternatively, the locking of the system joint can be set earlier using the fine adjustment via the app, so that the system joint locks when full extension is reached. |
| The system joint does not unlock. | The proximal, posterior thigh band transfers flexion load when a leg is set back. | Shorten the upper edge of the thigh shell parallel to the gluteal fold, so that the gluteal muscles are unobstructed. |
| | The patient does not reach the dorsiflexion stop during heel lift due to short steps. Thus, the knee extension moment to unlock the system joint cannot be applied. | KAFO with system ankle joint:<br>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:<br>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 knee-extending effect. | 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 unphysiological rotation movements inwards and outwards. | With the **Expert** app, change the setting for an easier unlocking. |

| Problem | Cause | Measure |
|---|---|---|
| The system joint unlocks too late. | The patient does not reach the dorsiflexion stop during heel lift due to short steps. 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 anterior part of the foot piece stiffly enough and shift the rolling-off line further forward, if necessary. |
| | | With the **Expert** 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 system joint switches unintentionally into a locked state. | There is a short circuit in a cable. | Carry out the cable test and change cables if necessary. |
| | 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 another mode and then back to the desired one. |
| The system joint creates a ratching noise in swing phase. | The controller is adjusted for a **NEURO HiTRONIC** system knee joint. | In the **Expert** app menu, select the **NEURO TRONIC** system knee joint. |

## 16.3 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 **Expert** or **User** 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. | |

## 16.4 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 (see paragraph 14.2). If the problem remains, contact Technical Support. |

## 17. 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.

| Joint Component | Potential Problem | Measure | Recommended Inspection, Potential Replacement* | Latest Replacement |
|---|---|---|---|---|
| toothed ring with sliding bushing | wear of the teeth | replacing toothed ring | every 3 months | see table below |
| locking pawl | wear of the teeth | replacing locking pawl | every 3 months | see table below |
| solenoid unit** | soiling | removing dirt from solenoid and plunger, see paragraph 17.4 | every 3 months | every 36 months |
| O-ring damper | wear | replacing O-ring damper | every 6 months | every 18 months |
| sliding washer | wear | replacing sliding washer, see paragraph 17.3 | every 6 months | every 18 months |
| sliding bushing | wear | replacing sliding bushing | 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 | 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 |
| 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
*** included system components can be exchanged separately

Especially the **toothed ring** and the **locking pawl** are subject to greater stress than other system components, which is why you should replace them on a regular basis, regardless of visible signs of wear:

| Activity Level | Point in Time |
|---|---|
| 1 and 2 | every 12 months |
| 3 | every 9 months |
| 4 | every 6 months |

For detailed information on the activity level, refer to the orthotic treatment sheet, our Orthosis Configurator or our online tutorials on the FIOR & GENTZ website.

Clean the threads of the bearing nuts with LOCTITE® 7063 Super Clean at every maintenance. Allow the threads to air-dry for 10 minutes.

Secure the screws for the cover plate with the torque corresponding to the system width and LOCTITE® 243 medium strength at every maintenance (see paragraph 9.6). Remove all adhesive residues first.

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 41) on the FIOR & GENTZ website.

fig. 41

## 17.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport (fig. 42) from a qualified specialist in orthopaedic technology when the orthosis is handed over. 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. 42

## 17.2 Checking the Battery Health

Regularly check the battery health of 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.

## 17.3 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS1910-**040** is 0.40mm thick). Each thickness has a different marking (fig. 43). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

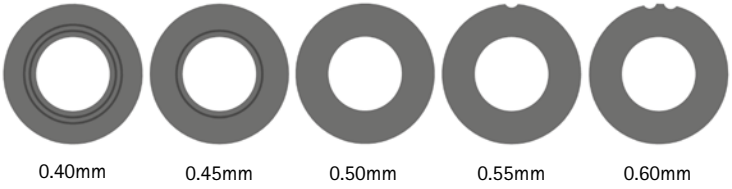



fig. 43

## 17.4 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.

Also remove dirt from the tip of the solenoid plunger (1; fig. 44). Additionally, insert a cotton swab into the solenoid opening (2) in order to remove dirt from the bottom of the opening.

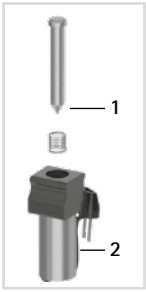



fig. 44

## 18. 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 17).
- Adhere to the determined maintenance conditions (see paragraph 17).
- Check the wear parts, as required, and exchange them at the defined intervals (see paragraph 17).
- Check the adjustment of the system joint during maintenance and correct it if necessary (see paragraph 17).
- Check the functionality of the system joint during maintenance (see paragraph 17).
- 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 25).

## 19. 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 22.1.

## 20. Spare Parts

### 20.1 Exploded View Drawing **NEURO TRONIC**

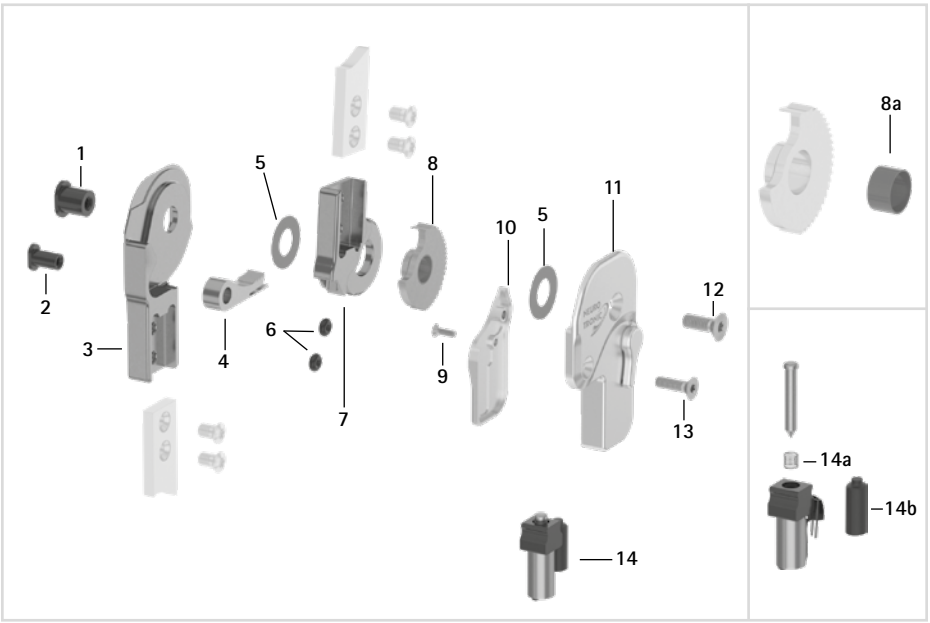



fig. 45

## 20.2 Spare Parts for the **NEURO TRONIC** System Knee Joint

| Item | Article Number for System Width | | Description |
|---|---|---|---|
| | 16mm | 20mm | |
| 1 | SB9669-L0990 | SB1069-L1000 | bearing nut (joint axis) |
| 2 | SB6049-L0990 | SB8559-L1000 | bearing nut (locking pawl) |
| 3 | SK0313-L/TI | SK0315-L/TI | lower part, left lateral or right medial, straight, titanium |
| 3 | SK0313-R/TI | SK0315-R/TI | lower part, left medial or right lateral, straight, titanium |
| 3 | SK0333-L/TI | SK0335-L/TI | lower part, left lateral or right medial, bent inwards, titanium |
| 3 | SK0333-R/TI | SK0335-R/TI | lower part, left medial or right lateral, bent inwards, titanium |
| 3 | SK0333-8L/TI | SK0335-8L/TI | lower part, left lateral or right medial, bent outwards, titanium |
| 3 | SK0333-8R/TI | SK0335-8R/TI | lower part, left medial or right lateral, bent outwards, titanium |
| 4 | SK0373 | SK0375-2 | locking pawl |
| 5 | GS1910-* | GS2411-* | sliding washer* |
| 6 | VE3771-D/012/26 | VE3771-D/012/26 | O-ring damper set |
| 7 | SK0303-2L/TI | SK0305-2L/TI | 5° upper part, left lateral or right medial, straight, titanium |
| 7 | SK0303-2R/TI | SK0305-2R/TI | 5° upper part, left medial or right lateral, straight, titanium |
| 8 | SK0363-2L | SK0365-2L | toothed ring with sliding bushing, left lateral or right medial, titanium |
| 8 | SK0363-2R | SK0365-2R | toothed ring with sliding bushing, left medial or right lateral, titanium |
| 8a | BP1110-L059 | BP1211-L059 | sliding bushing |
| 9 | SC1403-L08/1 | SC1403-L08/1 | countersunk flat head screw with hexalobular socket |
| 10 | SK0343-2L/AL | SK0345-2L/AL | small cover plate, left lateral or right medial, aluminium |
| 10 | SK0343-2R/AL | SK0345-2R/AL | small cover plate, left medial or right lateral, aluminium |
| 11 | SK3893-L | SK3895-L | cover plate with lever, left lateral or right medial |
| 11 | SK3893-R | SK3895-R | cover plate with lever, left medial or right lateral |
| 12 | SC1405-L14 | SC1406-L14 | countersunk flat head screw with hexalobular socket (axle screw) |
| 13 | SC1404-L14 | SC1405-L14 | countersunk flat head screw with hexalobular socket |
| 14 | SK0385 | SK0385 | solenoid unit |
| 14a | FE1508-01 | FE1508-01 | coil spring |
| 14b | ET0723-6/18 | ET0723-6/18 | end cap for connector of the solenoid |
| 9–14 | SK3883-L | SK3885-L | functional unit, left lateral or right medial |
| 9–14 | SK3883-R | SK3885-R | functional unit, left medial or right lateral |

| * Sliding Washers | |
|---|---|
| Article Number for System Width | |
| 16mm | 20mm |
| Ø = 19mm | Ø = 24mm |
| GS1910-040 | GS2411-040 |
| GS1910-045 | GS2411-045 |
| GS1910-050 | GS2411-050 |
| GS1910-055 | GS2411-055 |
| GS1910-060 | GS2411-060 |

## 21. Disposal

Dispose of the system joint and its individual parts properly. The product must not be disposed of with the residual waste (fig. 46). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

The electronically controlled, automatic **NEURO TRONIC** 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.

fig. 46

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

## 22. Technical Data

| NEURO TRONIC | |
|---|---|
| period of use | unlimited, excluding wear parts (see paragraph 17) |
| protection type | IP44 |
| operating mode | continuous operation |

### 22.1 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 | Auto mode: 36 000 strides with unilateral construction/18 000 strides with bilateral construction<br>Free mode: 24 hours with unilateral construction/12 hours with bilateral construction |
| behaviour of the system knee joint during the charging process | The system knee 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 |

## 23. 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

**Remote Control Type Plate**

**Controller Type Plate**

## 24. 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.

## 25. 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 them, 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.

## 26. 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.

### 26.1 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.

### 26.2 Electromagnetic Emissions for all Devices and Systems

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

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

## 26.3 Electromagnetic Immunity for all Devices and Systems

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

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

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

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

The product **NEURO TRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO TRONIC** 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 TRONIC** 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:<br> |
| 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 TRONIC** exceeds the compliance level specified above, the product **NEURO TRONIC** 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 TRONIC**.

## 26.5 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 TRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO TRONIC** 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<br>65A/$m_{rms}$<br>13.56MHz, pulse modulation[b] 50kHz<br>7.5A/$m_{rms}$ | 30kHz[a], CW, 8A/m<br>134.2kHz, pulse modulation[b] 2.1kHz<br>65A/$m_{rms}$<br>13.56MHz, pulse modulation[b] 50kHz<br>7.5A/$m_{rms}$ |

[a] Applicable only to medical devices and systems intended for use in a home healthcare environment.
[b] The carrier must be modulated with a square wave signal with 50% duty cycle.

## 26.6 Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product **NEURO TRONIC** 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 TRONIC**

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

## 26.7 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.

## 26.8 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.

## 26.9 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)

## 27. 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** | |

## 28. 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 _____ - _____

PB2800-DE/GB-2026-04

CE

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