

Instructions for Use for Patients Automatic Electronic System Knee Joints

EN

These instructions for use are valid from version:
Bluetooth Steuereinheit/Controller/Besturingseenheid/Styreenheten V3.00.46
Steuereinheit/Controller/Besturingseenheid/Styreenheten V2.80



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Instructions for Use for Patients Automatic Electronic System Knee Joints

Dear Patient,

You have received an individually produced orthosis with a high quality FIOR & GENTZ automatic electronic system knee joint from your orthotist or a qualified/trained expert. This knee joint system is also available with Bluetooth® technology.

1. Safety Instructions

1.1 Classification of the Safety Instructions

 DANGER	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
 WARNING	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
 CAUTION	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
<i>NOTICE</i>	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.

1.2 All Instructions for Your Safety

DANGER

Potential Traffic Accident Due to Limited Driving Ability

Gather information about all issues concerning safety and security and potential dangers, e.g. unintentional locking of the system joint, before driving a motor vehicle with orthosis.

DANGER

Danger to Life Due to Improper Handling of the Charger

When using the charger, please respect the information of the manufacturer in order to avoid short circuits and surges. The corresponding instructions for use are included with the remote control/the remote control set.

WARNING

Risk of Falling Due to Loosely Attached Cover Plate

Do not secure screws for the system joint on your own. Consult your orthotist or a qualified/trained expert about the maintenance intervals to be respected.

WARNING

Risk of Falling Due to Improper Handling

Have your orthotist or a qualified/trained expert inform you about the correct use of the system joint.

- Avoid contact with moisture and water.
- In Auto mode, always make the first step with the leg with orthosis.
- Disable the permanent unlock function if you no longer wish to use it.
- When changing the mode with the orthosis, make sure to stand safely.

WARNING

Risk of Falling Due to Improper Shoe/Wrong Shoe Pitch

Wear a shoe to which your orthosis is adjusted in order to avoid joint dysfunction.

WARNING

Risk of Falling Due to Orthosis Adjustments

If you notice any changes on the orthosis (e.g. loosely attached joint components or changed spring forces), immediately contact your orthotist or a qualified/trained expert.

WARNING

Risk of Falling Due to Improper Cleaning

In order to avoid a failure of the lock function, clean the orthosis and the system joint as described in these instructions for use. Do not grease the system joint on your own. If necessary, consult your orthotist or a qualified/trained expert.

WARNING

Risk of Falling Due to Walking Incorrectly with Orthosis

Consult your orthotist or a trained/qualified expert about the correct use of your orthosis and the particularities of the system joint. If necessary, we recommend a physiotherapeutic gait re-education.

WARNING

Risk of Falling Due to Improper Maintenance

In order to avoid failure of the joint function and the electronics, have your orthosis checked only by your orthotist or a qualified/trained expert.

WARNING

Risk of Falling Due to Damages to the Orthosis

Avoid damage to your orthosis and to the integrated electronics (e. g. due to shocks, knocks and fall). If your orthosis is still damaged, switch it to Lock mode and contact your orthotist or a qualified/trained expert as soon as possible.

WARNING

Risk of Injury Due to Improper Handling of the Batteries

In order not to damage the batteries being used and, therefore, not to cause failure of electronics, avoid improper handling of the batteries:

- strong heat (e.g. fire),
- knocks and shocks as well as
- contact with high humidity and water.

CAUTION

Threat to Environment Due to Improper Disposal of the Batteries

Never dispose of batteries with the residual waste so that toxic substances are not released into the environment. Dispose the batteries properly.

NOTICE

Limitation of Joint Function Due to Electrostatic/Magnetic Field

Please note that, while using the orthosis, an electromagnetic and magnetic field (e.g. MRI) can lead to joint dysfunction.

NOTICE

Damages to Batteries Due to Improper Handling

Note the information in these instructions for use to avoid shortening the life of the batteries and disturbing the joint function.

NOTICE

Damages to Controller and Remote Control Due to Improper Handling

Ensure the correct use in order to avoid joint dysfunction.

Avoid:

- to open the controller and the remote control as well as
- using them in areas where radio waves are forbidden (e.g. in planes, hospitals).

Ask the responsible staff on-site about using the controller and remote control.

2. Application

The FIOR & GENTZ automatic electronic system knee joints are exclusively for use for orthotic fittings of the lower extremity. They must be handled by orthotists or qualified/trained experts. 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 following automatic electronic system knee joints are part of the FIOR & GENTZ product range:



NEURO TRONIC

3. Introduction

The knee joint system is also available with **Bluetooth®** technology* and consists of the following articles (fig. 1):

- ① system knee joint
- ② controller
- ③ remote control for the patient including microprocessor-controlled quick charger or USB charging cable and User app
- ④ multi-purpose device for the orthotist or qualified/trained expert and Expert app

The system knee joint and the controller are mounted to your orthosis. The orthotist or qualified/trained expert uses the multi-purpose device to adjust the orthosis. You need the remote control to operate the orthosis. In addition, you can also use the User app.

i In order to operate or adjust the orthosis via an app, the orthosis has to be equipped with a controller with Bluetooth.

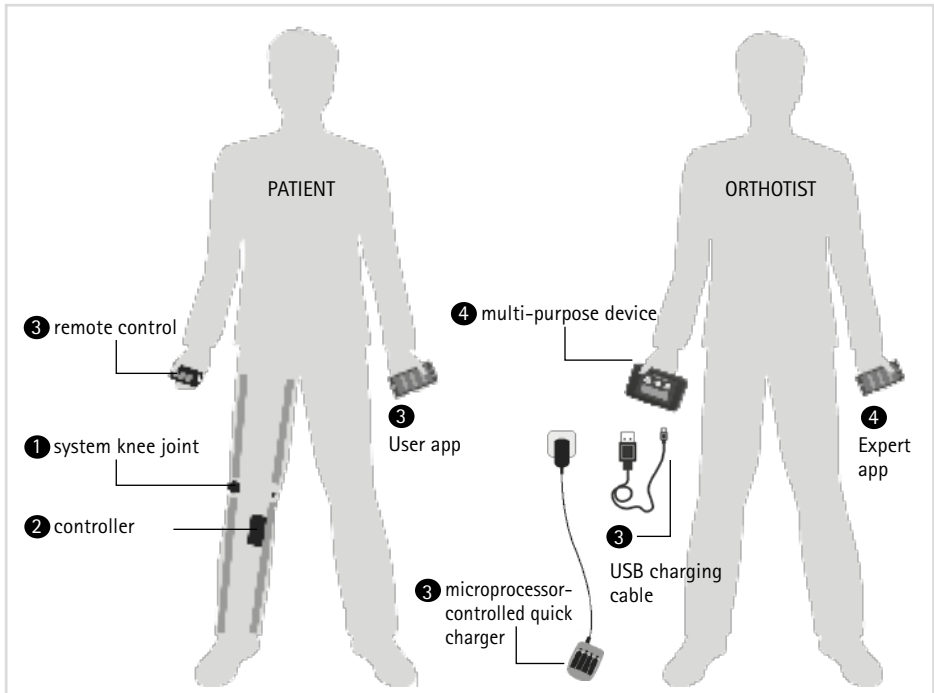


fig. 1

* 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.

4. Your Orthosis

The remote control set with or without Bluetooth for the controller with exchangeable batteries includes the following system components (fig. 2):



fig. 2

Item	Art. No.	Description	Unit	Quantity	
				One Leg	Both Legs
1	ET0890	battery box	piece	1	1
2	PR4000	lanyard FIOR Et GENTZ	piece	1	1
3	ET0850	microprocessor-controlled quick charger including plug-in adapter, USB charging cable and 12V car adaptor	piece	1	1
4	ET3800-P	remote control	piece	1	2
w/o fig.	ET3840-P	remote control with Bluetooth	piece	1	2
5	ET0810-AA2	2 pce. AA NiMH batteries with number stickers	set	3	6
w/o fig.	PA0800-ET	number stickers to mark rechargeable batteries	set	1	1
w/o fig.	HE3800-SK/L	letter sticker L for remote control, left leg	piece	-	1
w/o fig.	HE3800-SK/R	letter sticker R for remote control, right leg	piece	-	1



If a controller with exchangeable batteries is mounted to your orthosis, make sure that you have sufficient number stickers.

The remote control set with Bluetooth for the controller with lithium-polymer battery includes the following system components (fig. 3):

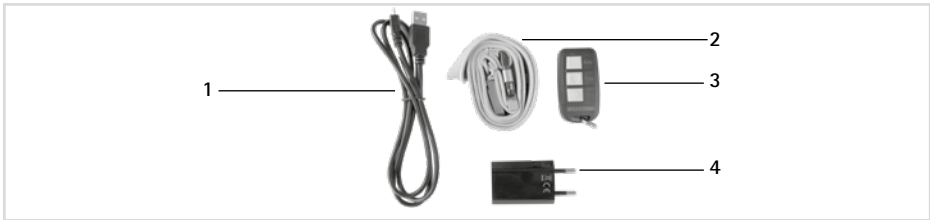


fig. 3

Item	Art. No.	Description	Unit	Quantity	
				One Leg	Both Legs
1	ET0710	USB charging cable	piece	1	2
2	PR4000	lanyard FIOR & GENTZ	piece	1	1
3	ET3840-P	remote control with Bluetooth	piece	1	2
4	ET0780	USB adapter	piece	1	2
w/o fig.	HE3800-SK/L	letter sticker L for remote control, left leg	piece	-	1
w/o fig.	HE3800-SK/R	letter sticker R for remote control, right leg	piece	-	1

4.1 Joint Functions

The system knee joint is an automatic 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

4.1.1 Basic Function in Auto Mode

The controller of the orthosis has motion sensors that detect the movement and position of your lower leg. The controller locks and unlocks the system joint depending on which gait phase you are in.

When are standing with your orthosis (fig. 4) or when you interrupt the step in stance phase, the **NEURO TRONIC** system knee joint locks, as no movement is registered. 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. In the gait phases from terminal stance to swing phase, the system joint is unlocked and is therefore free moving (fig. 5).

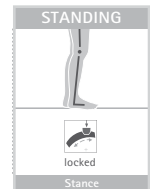


fig. 4

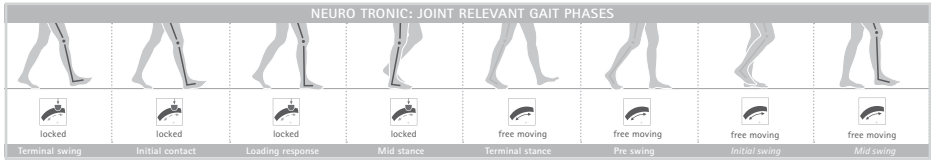


fig. 5



If, contrary to expectations, you put weight on the leg with orthosis during the free moving phases, the system joint will not lock.

4.1.2 Alternative Function in Lock Mode

In Lock mode, the system knee joint is a locked joint that prevents a flexion of the leg. An extension remains possible.

4.1.3 Alternative Function in Free Mode

In Free mode, the system knee joint is an unlocked joint that is free moving up to a determined position.

4.1.4 Alternative Function in Permanent Unlocking

The system knee joint can be permanently unlocked mechanically, for example for activities such as driving a car or bicycle. In this mode, it is guaranteed that the system knee joint does not lock unintentionally. Unlock the system joint manually with the lever by setting it to F. If you then press the lock button on the remote control/ the app, you also save energy.

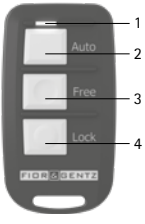
The system knee joint remains unlocked even if you select another mode (e.g. Auto) with the remote control/the app. In order to change the system joint's mode as usual with the remote control/the app, set the lever to the dot (fig. 6).



fig. 6

4.2 The Remote Control

You can select the mode on your orthosis with the remote control. You cannot change the mode while walking. Therefore, make sure that you stand securely when changing the mode of your orthosis. Every time you press a button of the remote control, the LED blinks shortly.

remote control	Item	Description	Meaning
	1	LED	The LED indicates light signals for the selected mode and the battery health.
	2	Auto button	The system joint switches into Auto mode.
	3	Free button	The system joint switches into Free mode.
	4	Lock button	The system joint switches into Lock mode.

Handle the remote control properly. If your remote control does not work as usual, do not try to open it. Consult your orthotist or a qualified/trained expert.

4.3 The User App

The app is intended to complement your remote control. It offers the same range of functions.

If your orthosis is equipped with a controller with Bluetooth, you can operate the orthosis either with the remote control with Bluetooth and/or with the free app via your smartphone/tablet (fig. 7) or your Apple Watch* (fig. 8). Minimum requirements are Bluetooth 4.0 and Android 5.0 or iOS 10.



fig. 7

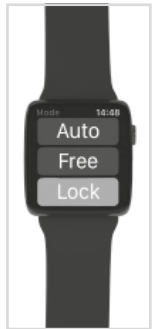


fig. 8



The orthosis can only be operated with remote control or app to which it is currently connected. Other remote controls/apps have no influence on your orthosis.

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

4.3.1 Step Counter

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

4.4 The Controller

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

Controller with Exchangeable Batteries		Item	Description
	1	battery compartment cover	
	2	acoustic signal generator	
	3	LED battery indicator	
	4	LED function indicator	
	5	LED mode indicator	
	6	MODE button	
	7	positive pole	
	8	negative pole	
	9	battery compartment for 2 AA batteries	
Controller with Integrated Lithium-Polymer Battery		Item	Description
	1	cover for Micro-USB port	
	2	LED battery level indicator and LED mode indicator	
	3	LED pairing indicator Bluetooth	
	4	Micro-USB port	
	5	MODE button	

4.5 Manual Mode Change

A MODE switch is built into the controller, which you can use to operate the orthosis manually. On a controller with exchangeable batteries, there is a small opening in the upper part of the battery compartment marked with MODE (fig. 9). Insert a pointed object (e.g. a paper clip) into this opening to set a different mode. On a controller with an integrated lithium-polymer battery, the rectangular MODE switch is located under the cover next to the micro-USB port (fig. 10).



fig. 9

Depending on the mode that is already selected, it can be set in the following order: Auto, Free and Lock. This switch is particularly important if you are travelling by plane, as the remote control/the app must not be used during take-off, final approach and landing. You are allowed to use the remote control/the app during the flight and after landing.

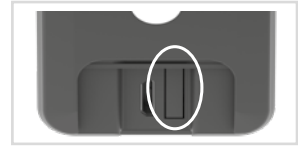


fig. 10



The MODE switch can only be used as long as the batteries are not completely empty. When the batteries are completely discharged, you can only use the Lock mode.

5. Connection between Controller and Remote Control/the App

The connection between the controller and the remote control is established by your orthotist or a qualified/trained expert. If you would like to adjust the controller via the **User app**, you need a controller with Bluetooth. Use the app menu and select the corresponding menu item to establish a connection. Follow the instructions in the app.

5.1 Controlling Two Orthoses

If you are wearing two orthoses with a NEURO TRONIC knee joint system, you can decide to connect the controllers of both orthoses with one or two remote controls. If you activate two remote controls, you can change the modes separately for each controller/orthosis. If you activate only one remote control, the modes of both controllers/orthoses are changed simultaneously. If the orthoses are equipped with controllers with Bluetooth, the modes can be switched separately or at the same time for the two controllers/orthoses with the **User app**.





6. Checking the Connection between Controller and Remote Control





If you have operated the orthosis with the app, you have to close the app in order to operate the orthosis with the remote control.

Due to signals of the controller with battery compartment as well as of the remote control, you will be informed if your remote control is connected with the controller. The LED at the remote control indicates that the remote control and the controller communicate with each other. There are different signals for a connection with one or two controllers.

6.1 Indication of the Connection With one Controller

remote control	Light Signal	Meaning
 <p>One of the three buttons was pressed.</p>	colour: yellow, green, red (depending on battery status)	The remote control is connected with the controller.
	signal duration: ■	
		<ul style="list-style-type: none"> - the orthosis is in Sleep mode (see paragraph 9.2); - the batteries are empty; - the controller has no batteries; - the remote control is too far from the orthosis.
	colour: red	
	signal duration: ■ ■ ■	
		The controller communicates with the remote control.
colour: blue		
signal duration: ■		
		

6.2 Indication of the Connection With Two Controllers

remote control	Light Signal	Meaning
 <p>One of the three buttons was pressed.</p>	colour: yellow, green, red (depending on battery status) signal duration: ■	The remote control is connected with the controllers.
	colour: red signal duration: ■ ■ ■ ■	
	colour: yellow, green, red (depending on battery status) and afterwards red signal duration: ■ . . . ■ ■ ■ ■	Signal for one of the two controllers: - the orthosis is in Sleep mode (see paragraph 9.2); - the batteries are empty; - the controller has no batteries; - the remote control is too far from the orthosis.
	colour: blue signal duration: ■	The controllers communicate with the remote control.
		

7. Checking the Connection between Controller and User App







In order to operate the orthosis via the app, Bluetooth must be permanently switched on and the app must be open in the foreground. Use the menu of the app and select the desired menu item to connect to one or two controllers. Follow the instructions in the app.

An orthosis can only be operated with one app at the same time because there is a connection between the controller and the app. Other apps have no influence on the connected orthosis. You can continue to use the remote control instead of the app when the controller is connected to the remote control and is not actively communicating with the app. If there is an active connection to the app, the blue LED on the controller blinks permanently and the controller cannot be operated with the remote control. The app is intended to complement your remote control.

8. Checking the Battery Status







8.1 Indication of Battery Status on the Controller

If your controller has an integrated lithium-polymer battery, you can see the battery status of the controller on the remote control or in the app. Furthermore, the LED battery level indicator indicates the following light signals for the battery status:

Light Signal				
Controller	Colour	Signal Duration	Cause	Meaning
	green	■		The batteries are fully charged.
	yellow	■		The batteries are charging.
	red	■■■■ 0.5 sec.		The battery status is critical.

If your controller has exchangeable batteries, the LEDs on the controller blink briefly when you insert them. If the LEDs do not blink, the batteries are perhaps wrongly inserted or they are fully discharged.

Soon afterwards, the LED battery status indicator on the controller shows one of the following light signals:



Light Signal				
controller	Colour	Signal Duration	Cause	Meaning
	no signal			The batteries in the controller are fully charged.
	orange	■■■ 0.5 sec.		The batteries are 1/3 full. Depending on the battery health, it takes max. 7 hours to fully discharge.
	red	■■■■ 0.5 sec.		The batteries are almost empty. Depending on the battery health, it takes max. 2 hours to fully discharge.

In Auto or Free mode, these battery status light signals are permanently displayed. The LEDs then blink in the corresponding colour every 5 seconds.



In order to save energy, the battery status is not displayed in Lock mode.

Sound signal from the controller for battery status when the batteries are almost completely empty:

Sound Signal	Signal Duration							Cause	Meaning
	■	break	■	break	■	break	■		The batteries are almost empty. Depending on the battery health, it takes max. 2 hours to fully discharge.
	0.5 sec.	1 sec.	0.5 sec.	1 min.	0.5 sec.	1 sec.	0.5 sec.		

Due to the importance of a properly functioning orthosis, this signal sounds every minute. This period can be extended to ten minutes by pressing one of the three mode buttons on the remote control/the app. To do this, select the mode in which your orthosis is currently operating so that you do not inadvertently change modes. After ten minutes, the pause can always be extended by another ten minutes by pressing the mode button again. If no mode button is pressed, the signal will sound every minute.



In case of deviant tone signals, especially while walking, contact your orthotist or a qualified/trained expert as soon as possible.

8.2 Indication of Battery Status on the Remote Control/in the App

If you operate the orthosis via app, you can see the battery status of the controller(s) at any time in the app.

You can also check the status of the batteries in the controller(s) with your remote control. There are different signals for a connection with one or two controllers.

8.2.1 Indication of the Battery Status for a Connection with one Controller

Light Signals at Remote Control:

remote control	Light Signal			Meaning
	LED	Colour	Signal Duration	
<p>One of the three buttons was pressed.</p>		green	■	The batteries in the controller are fully charged.
		yellow	■	The batteries are 1/3 full. Depending on the battery health, it takes max. 7 hours to fully discharge.
		red	■	The batteries are almost empty. Depending on the battery health, it takes max. 2 hours to fully discharge.

8.2.2 Indication of the Battery Status for a Connection with two Controllers

If your remote control is connected with two controllers, the light signal on the remote control does not apply automatically to both controllers but to that with the lowest battery. The battery status indicator on the controller (see paragraph 8.1) allows you to determine whether the batteries of both controllers are affected or in which orthosis you need to change the batteries.

Example: The LED of the remote control flashes red, after you have pressed one of the three buttons. The LED battery status indicator of the controller of the right orthosis gives no light signal, which means that the battery is full. The LED battery status indicator of the controller of the left orthosis briefly blinks three times red. The batteries in this orthosis should soon be exchanged.

9. Energy Consumption

9.1 Useful Life of Batteries in Different Modes

If two NEURO TRONIC system knee joints are mounted in your orthosis (bilateral construction), the batteries' period of use is shortened compared to a unilateral construction (one NEURO TRONIC system knee joint in your orthosis). The following average battery life was determined at room temperature:

Battery Type	Orthosis	Auto	Free	Lock
exchangeable batteries	unilateral	45 hours	45 hours	over 2 weeks
	bilateral	24 hours	24 hours	
lithium-polymer battery	unilateral	18 hours	42 hours	
	bilateral	8.5 hours	19 hours	

9.2 Energy-Saving Modes

Your orthosis has two different energy-saving modes:

- If the orthosis is not moved in Auto or Free mode for more than **two hours**, the orthosis switches into Lock mode automatically. The Lock mode saves energy. If you press any button on the remote control, the orthosis will change back from Lock mode into Auto or Free mode.
- If the orthosis is not moved in Lock mode for more than **30 minutes**, it switches into Sleep mode automatically. In Sleep mode, the orthosis only consumes very little energy. The controller no longer receives signals from the remote control/the app. To switch back into Lock mode, move the orthosis slightly. Then, the LEDs on the controller blink (see paragraph 8.1).



Switch the orthosis into Lock mode if you do not use it for a longer period of time. It switches into Sleep mode after only 30 minutes and consumes very little energy.

If your orthosis is equipped with a controller with integrated lithium-polymer battery, there is a third energy-saving mode:

- If the orthosis is not moved for more than **72 hours**, it switches into Deep Sleep mode automatically. In Deep Sleep mode, the controller does not consume energy. In order to put the orthosis back into operation, press the MODE button of the controller or connect it to the USB cable.

10. Handling of the Batteries in the Controller

10.1 Conditions of Use and Storage

Respect the following conditions of use and storage:

- Always fully charge the batteries.
- If you store the batteries over a long period of time (e.g. > 12 months), charge them completely beforehand.
- If possible, store and use the batteries at room temperature in a dry and well-ventilated area.
- Do not expose the batteries to temperatures below -20°C or above $+45^{\circ}\text{C}$. Temperatures above $+45^{\circ}\text{C}$ or near freezing point reduce the period of use and the battery lifespan of the batteries. At temperatures below -20°C the batteries become unusable.
- Never store the batteries in places of high temperatures ($> +60^{\circ}\text{C}$), e.g. in a car dashboard during direct sun exposure or next to a heating source.

10.2 Handling of the Exchangeable Batteries

Use AA batteries with a nominal capacity of at least 2500 mAh for the controller. The scope of delivery includes six NiMH batteries. If needed, purchase additional batteries of this type.

Three battery sets (fig. 11) are provided for the controller. Use these as follows (fig. 12):

- Set 1 is located in the controller of the orthosis.
- Set 2 is included in the battery box ready for replacement.
- Meanwhile, set 3 is charging.

If you are using additional batteries, use the provided number stickers from 4 to 9 and 0 to mark the new battery sets. Always use the battery sets in pairs.

Do not transport the batteries loose, but always in the provided battery box (fig. 13) to avoid damage.

10.3 Charging the Exchangeable Batteries

Charge the batteries completely before inserting them in the battery compartment of the controller according to the polarity (+/- symbols). Please read the instructions for use of the microprocessor-controlled quick charger included in the remote control set carefully.

Charge empty batteries as soon as possible. Only use the original charger.

If the period of use of the orthosis considerably shortens, exchange the old batteries for new ones. If the period of use of the orthosis does not improve, contact your orthotist or a qualified/trained expert.



fig. 11

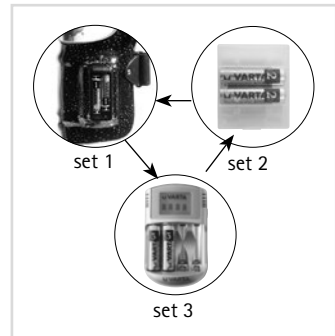


fig. 12



fig. 13



Replace old or defect batteries always as a pair (see paragraph 10.2).

10.4 Handling of the Lithium-Polymer Battery

The controller with lithium-polymer battery has a long period of use and battery lifespan. Do not try to disassemble the controller, as the battery is an integral part of the controller.

10.4.1 Charging the Lithium-Polymer Battery

You can charge the battery using the USB charging cable included in the scope of delivery of the remote control set and the appropriate adapter via a common household socket. Always fully charge the battery and respect the general conditions of use and storage (see paragraph 10.1).

If the period of use of the orthosis considerably shortens despite the fully charged battery, contact your orthotist or a qualified/trained expert.

11. Advices for Using Your Orthosis

11.1 Before Use

Pay attention to the following every time you use the orthosis:

- Switch the orthosis into Free mode to put it on.
- Set the lever to the point so that you can operate the system joint via the remote control/the app.
- Check the battery status of the controller.
- If you have charged the batteries of the controller beforehand, insert them before use.

11.2 Bluetooth Connection

In a knee joint system with Bluetooth, the quality of connection depends on how interference-free your environment is.

11.3 The Proper Shoe

The orthotist or qualified/trained expert adjusts your orthosis when you try it on and make your first steps. Since you have to get used to your new orthosis, the adjusted orthosis should be regularly checked in the first weeks and, if necessary, newly adapted to your need for safety. The orthosis is adjusted to the pair of shoes (shoe pitch) with which you start walking with your orthosis. If you want to wear other shoes, your orthotist or a qualified/trained expert must ensure that the orthosis is also adjusted to these shoes.

11.4 Gait Re-Education

In order to be able to use your orthosis optimally, you should make use of a physiotherapeutic gait re-education.

In gait re-education, the following should be specially trained:

- walking upright, with the upper body slightly bent forward;
- apply as little body weight as possible on orthopaedic devices (such as canes, parallel bars or walkers), since otherwise the physiological gait can be affected.

With gait re-education, you become more secure in using your orthosis, your gait pattern improves and you get used to your orthosis sooner. This is particularly important when a locked orthosis has been used before for many years. Gait re-education can be supported by acoustic signals of the orthosis; ask your orthotist about it. Contact your orthotist or a qualified/trained expert as soon as possible. Be extremely careful when managing

stairs, going on uneven surfaces or uphill/downhill. If you do not feel secure in using your orthosis in Auto mode yet, we recommend selecting Lock mode (see paragraph 4.1.2). Regularly report your experiences with the orthosis during the first weeks to your orthotist or a qualified/trained expert. This is the only way you can get specific advice or help.



The more physiological the gait characteristics become, the better the orthosis can support you.

11.4.1 Walking with the Orthosis in Auto Mode

For safety reasons, the system knee joint remains locked during the first step. When you start walking from a standing position, you should make the first step with the leg with orthosis. The electronics require a stride to switch from standing mode to walking mode in order to avoid disturbed gait or stumbling when starting to walk. Let your physiotherapist also show you in which gait phases the system joint is locked and free moving.

11.5 Malfunction Due to Impacts

The system knee joint is provided with electronic components that react sensitively to very strong shocks. This may lead to the system joint not remaining unlocked during the swing phase, but locked. The orthosis should then work in the previously set mode again. If this is not the case, change the mode with your remote control/app.

In general, try to avoid great damages to your orthosis, e.g. due to shocks or knocks or falls because this may lead to failure of different system components and, in the worst case, of the orthosis. If you notice damage on the orthosis, use it exclusively in Lock mode and contact your orthotist or a qualified/trained expert as soon as possible.



If the joint function is disrupted, the orthosis switches automatically into Lock mode. Thus, it enables stability during stance phase and reduces the risk of falling.

11.6 Restrictive Use

The system knee joint has been checked for its electromagnetic compatibility by European law. That means the orthosis works in an electromagnetic environment without introducing intolerable electromagnetic disturbances to other devices in that environment. Nevertheless, similar to smartphones, pay attention to whether or how you are allowed to use your orthosis in specially designated areas because the integrated electronics (e.g. Bluetooth) can cause radio waves and can be influenced by these as well. In specially designated areas (fig. 14), ask the responsible staff on-site if you can use the orthosis without restrictions. If you are not allowed to use the remote control/the app, change the mode with the MODE switch (see paragraph 4.5).



fig. 14

12. Cleaning the Orthosis

Clean the orthosis properly and regularly. Clean the orthosis with a damp cloth. Leave out the area around the system joint and the controller and clean them only superficially with a dry cloth. Remove visible dust and lint from the mechanics by using tweezers. Check the orthosis in straight and flexed position. For a smoothly current flow, clean the contacts in the battery compartment and of the batteries occasionally with a rubber.

13. Maintenance of the Orthosis

Ask your orthotist or a qualified/trained expert to check the system joint of your orthosis every **3 months**. Bring these instructions for use to each follow-up and let your orthotist or a qualified/trained expert enter the next appointment in the table on the back. Never carry out maintenance work or other adjustments and repairs yourself. In the case of children and people with cognitive impairments, we would like to point out to you as parents or care team that you must regularly check the orthosis and the system joint for signs of wear. If you notice any changes, immediately contact your orthotist or a qualified/trained expert.

14. Advice on Optimal Orthosis Functionality

If you are using the **User app**, you can display a code for troubleshooting if problems occur with your orthosis. You can then send it to your orthotist or a qualified/trained expert so that the error can be corrected more quickly. You can find the code for troubleshooting in the app under the menu item "Information".

14.1 System Knee Joint

Problem	Cause	Action
The system joint switches unintentionally into Lock mode.	Only applies to a controller with exchangeable batteries: The battery/batteries is/are empty.	Insert a new battery set and/or charge empty batteries.
	Only applies to a controller with exchangeable batteries: The battery/batteries is/are defect.	Insert a new battery set and properly dispose of defect batteries.

14.2 Remote Control

Problem	Cause	Further Action
The controller does not respond to pressed buttons on the remote control.	There is no connection between the User app and the controller or you are moving while pressing the button.	Check if the controller is still connected to the User app. Remain steady while pressing a button. If the problem remains, contact your orthotist or a qualified/trained expert.
The LEDs on the controller do not blink when pressing a button on the remote control.		

14.3 Controller

Problem	Cause	Further Action
Only applies to a controller with exchangeable batteries: The LEDs do not blink when batteries are inserted.	The batteries are inserted incorrectly or are not charged.	Check the polarity and health of the batteries. If the problem remains, contact your orthotist or a qualified/trained expert.
Only applies to a controller with an integrated lithium-polymer battery: The LEDs do not blink when pressing the MODE switch.	The battery is not charged.	Charge the battery completely. If the problem remains, contact your orthotist or a qualified/trained expert.
No devices are found during pairing of the controller and the User app.	There is no connection between the User app and the controller.	Connect the User app with the controller within 30 seconds (see paragraph 5). Check whether the LEDs light up (see paragraph 6.1) or whether a short and a longer beep tone can be heard when the tone signals are switched on. If the problem remains, contact your orthotist or a qualified/trained expert.

15. Disposal

If you no longer need the orthosis, please return it to your orthotist or a qualified/trained expert. The product must not be disposed of with the residual waste (fig. 15). If you have a defect controller with integrated lithium-polymer battery or it is no longer needed, return it to your orthotist or a qualified/trained expert as well. Exchangeable batteries that can no longer be used must be disposed of as hazardous waste in trade (recycling points) or handed in free of charge at collection depots.

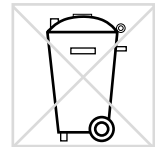


fig. 15

16. Signs and Symbols

Symbols on the Packaging



medical device

17. 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.

18. 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 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 serve as guidelines. Subject to technical modifications.

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Follow-up Appointments

Delivery on	By (Name)	Date/Signature	Next Follow-up

Orthotic Provider (Stamp)

PB2600-PI-2021-05

