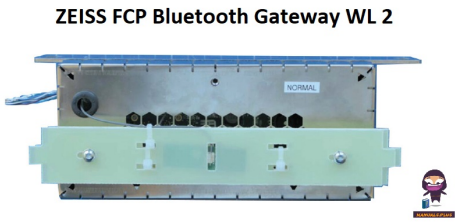
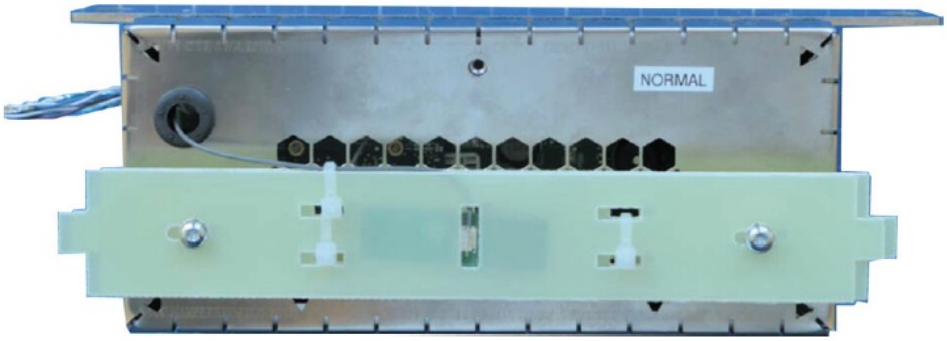


ZEISS FCP Bluetooth Gateway WL 2 Instruction Manual

Contents

ZEISS FCP Bluetooth Gateway WL 2



Notes on the instructions for use

System name
FCP Gateway WL 2 is referred to as “FCP Gateway” in the present Instructions for Use.

Scope of application
The present Instructions for Use apply to FCP Gateway with the following software version:

- **Application**:
  PicAppl-REGGIO_GW.APP.01.02.063.CORE.01.04.000

Purpose and storage of the documentation
These Instructions for Use explain the safety features, functions and the performance parameters of the system. They are a guide for safe operation and specify the measures for maintenance and repair of the system. The correct operation of the system is vital for safe and successful use. Action u Read these Instructions for Use before starting and using the system.

- Keep the Instructions for Use accessible at all times for all users.
- Pass the Instructions for Use on to the next owner of the system.

Questions and comments
Action u If you have any questions or comments concerning these Instructions for Use or the system, please contact ZEISS Service. You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

Conventions in this document
Certain types of information are specially marked in this document for better recognition.

Conventions in all text areas

- This is a list.
- This is a second level list.
- This is a cross-reference: Questions and comments [} 5].
- This is bold type.

- This is software code or program text.
- Names of software dialogs, fields or menus, and software messages are marked by quotation marks:
- “View” menu.
- “Do you want to save the settings?”
- The steps in menu and file paths are separated by slashes:
- “File / Save as”
- “My documents / Documents”
- Keys, buttons, knobs, levers and other operating controls are marked by square brackets:
- [START] key
- [Next] button

Conventions in a course of action
WARNING! This is warning information about hazards that can cause death or severe injuries if not avoided. The warning message names the possible consequences.

- This is a measure with which hazards can be prevented.
- **CAUTION**! This is warning information about hazards that can cause injuries if not avoided. The warning message names the possible consequences.
- This is a measure with which hazards can be prevented.
- **NOTE** This is warning information about hazards that can cause property damage if not avoided.
- The warning message names the possible consequences.
- This is a measure with which hazards can be prevented. Prerequisite þ This is a requirement that must be met before the start of a sequence of actions.

Action

1. This is a command.
2. **CAUTION**! This is a warning message about hazards that can occur during a single action. This is a command. This is the result of a sequence of actions.

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Safety notes

Area of use

1. **Intended use**
   FCP Gateway is intended for performing tests for standard conformity and regulatory conformity.
2. **Normal use**
   FCP Gateway is designed for interfacing the Foot Control Panel (FCP) to provide power and to pass on data transmitted via cable or wirelessly.
3. **Discipline**
   Gateway between two devices

Responsibilities and duties of the operator

Operating personnel
The device may be operated only by properly instructed and trained persons.

- Make sure that the operating personnel are appropriately trained and instructed.
- Make sure that the operating personnel have read and understood the Instructions for Use.
- Keep the Instructions for Use available at all times for the operating personnel.
- To facilitate access for all operating personnel: Request additional copies of the Instructions for Use as required from ZEISS.
- Specify the competencies for handling the device and state who is authorized to perform what tasks.

- Determine the reporting obligations for malfunction and damage and make them known. Notification of the manufacturer and authorities. [} 9]
- Provide the necessary protective clothing.
- Regularly check that the legal regulations applicable in your country with regard to accident prevention and work safety are being complied with.

Safety inspections

- To prevent a decrease in device safety due to aging and wear: Implement regular safety inspections as specified for this device by the applicable national regulations. The safety inspections may only be performed by the manufacturer or qualified personnel.
- Comply with the specified time limits.
- Carry out checks according to the extent specified.

The safety inspections of the device should at least comprise the following points:

- Availability of the Instructions for Use
- Visual inspection of the device and accessories for damage, as well as legibility of the labels
- Leakage current test
- Test of protective ground conductor
- Function and wear test of the brakes
- Function test of all switches, buttons, sockets and indicator lamps of the device

Maintenance and inspection

- To ensure safe operation of the device and reach the expected service life: Comply with the maintenance and inspection intervals specified in these Instructions for Use.

Modifications to the product

- **WARNING**: This device must not be modified without the manufacturer’s approval. If the device is modified, suitable inspections and testing must be completed to ensure that it can still be used safely.

Accessories and additional equipment

- If you want to connect accessories or additional equipment to the device: Contact your ZEISS contact partner. Any additional equipment connected to medical electrical devices must demonstrably comply with the applicable IEC or ISO standards (e.g. IEC 60950 for data processing equipment). In addition, all configurations must meet the normative requirements for medical systems (see IEC 60601-1-1 or Clause 16 of the 3rd edition of IEC 60601-1 respectively). Anyone connecting additional equipment to medical electrical systems is a system configurer and as such responsible for compliance of the system with the standards for systems. Local legislation has priority over the above normative requirements.

Messages to manufacturer and authorities

If a serious incident occurs in connection with this medical device affecting the user, patient or another person, the operator or person responsible must report this incident to the manufacturer or seller of the medical product. In European Union countries, the operator or person responsible must report serious incidents to their responsible authority. In all other countries, the respective country-specific requirements must be followed.

Measures and duties of the operator

Electrical safety

- Always switch off the device before connecting it to or disconnecting it from the power supply, for cleaning its surface, or if it will not be used for a prolonged period of time.
- Only connect the device to a power supply that complies with the values specified on the rating label.
- Do not use multiple sockets!
- Do not use extension cables!
- Do not touch the device if your body is electrostatically charged and the device is not grounded.
- Connect the device via the potential equalization connection (according to IEC 60601-1) to other active devices with the same ground potential or connect it to a protective ground connection.
- Please observe the information on electromagnetic compatibility (EMC). The device contains freely accessible live components. If you remove the housing, you run the risk of electric shock.
- Never open the device!

Environmental conditions

- Make sure that the installation conditions and the operation of the device comply with the surgical requirements:
- Low vibration
- Clean environment
- Avoid extreme mechanical stress
- Do not use power-operated devices included in the delivery package
- in explosive atmospheres,
- at a distance of less than 25 cm from flammable anesthetics or volatile solvents such as alcohol, benzine or similar substances.
- Do not use or store the device in damp rooms. Do not expose the device to water splashes, dripping water or sprayed water.
- Ensure that fluids cannot enter the device.

Symbols and labels

- Note the symbols and labels attached to the device!

Transport

- Only transport the device over long distances (e.g. relocation, return for repair) in its original packaging or special return packaging.
- Please contact your dealer or ZEISS Service for this purpose

Description of the system

System markings

CAUTION! Risk of injury due to illegible labels! Over time, labels can become dirty and thus unidentifiable, making it difficult or impossible for hazards to be recognized or necessary operating instructions to be followed.

- Keep all safety and warning labels and operating instructions in good condition at all times.
- Damaged labels are to be replaced immediately. For replacement labels, contact ZEISS Service or an authorized ZEISS representative.

Labeling on the FCP Gateway

Symbol	Explanation
	Conformity label for FCP Gateway, provides information on standards

Structure of the system

Control elements

The FCP Gateway has no user-operable control interfaces.

Connection panel

The FCP Gateway is a system to convey information and deliver power. It mainly consists of a PCB in a housing that is connected to data (CAN) and power connectors.

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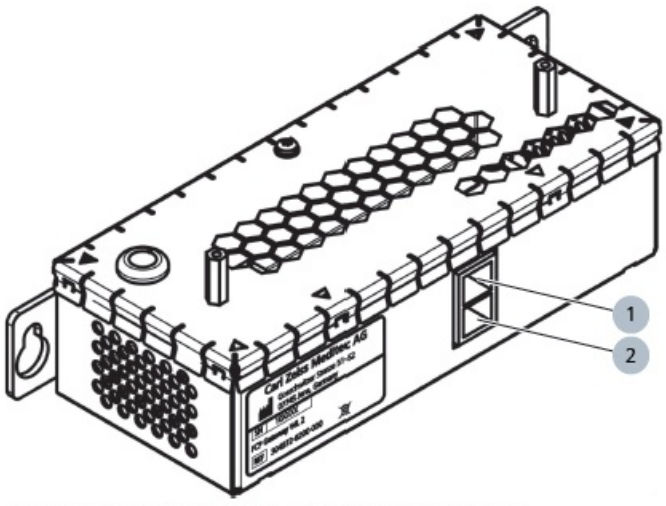

Figure 1: Connection elements of the FCP Gateway

Pos.	Designation	Explanation
1	System connection socket	Exchanges information and receives power from the system
2	FCP connection socket	Exchanges information and transmits power to the FCP

Functional description

FCP Gateway functions

The FCP Gateway serves as interface between the FCP and the system:

- It mediates the data exchange between FCP and system.
- It transmits power from the system to the FCP charging interfaces, i.e. the FCP cable or the system's FCP charging pins.
- The signal transmission between the FCP Gateway and the FCP is handled via cable or wirelessly. Both communication modes allow the user to carry out the same functions via FCP.

Cleaning and disinfection

The FCP Gateway is located inside the system and has no contact to the operator or the patient. Therefore, no cleaning and disinfection is required.

Troubleshooting

Resetting the FCP Gateway

The FCP Gateway is reset when power-cycled. As the power is controlled by the system, no direct intervention is required.

Service information

You can find the ZEISS contact partner for your country on the following website: **www.zeiss.com/med**

Technical specifications

Essential performance features

The system does not have any essential performance features as defined in IEC 60601-1.

Regulatory information

The FCP Gateway meets the requirements of the standards:

- EN 62368-1:2014 + Corr.1:2015 / EN
- 62368-1:2014 + AC:2015 EN 62311:2020
- ETSI EN 301 489-1 V2.2.3
- EN ETSI 301 489-17 V3.2.4
- ETSI EN 300 328 V2.2.2
- FCC – Title 47 CFR Part15
- ICES-003, Issue 7: 2020-10

Canada / USA – IC warnings RSS-Gen & RSS-247 statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. Part 15 Statement gem. FCC 15.19/RSS Gen Issue 3 Sect. 7.1.3 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 harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation of the device.Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Technical data

Electrical data

	Value
Operating Frequency	Bluetooth® BR/EDR 2400 MHz to 2483.5 MHz
Type of transmission	FHSS
Output power	BT classic: Class 2 Output Power (+1.5 dBm typical)
Power Supply	15.0 V DC by external power supply
Voltages	3.3 V (BT Module)
Module(s)	Brand: Microchip Technology, Inc. Model name: GW: BM78SP- P05MC2
Antenna type	GW: External antenna (Laird NanoBlue)
Antenna gain	GW: 2.0 dBi
Radiated power	BDR: 5 dBm EDR: 5 dBm
Modulation	GFSK, Pi/4-DQPSK, 8DPSK
Transmission rate	up to 10 Kbytes/s

Dimensions and weight

	Value
Length	220 mm
Width	120 mm
Height	24 mm
Weight	610 g

Ambient requirements for operation

	Value
Temperature	+10 °C to +40 °C
Rel. humidity (without condensation)	30% to 75%
Maximum operating height	3000 m above N.N.
Air pressure	700 hPa to 1060 hPa

Ambient requirements for transport and storage

	Value
Temperature	-40 °C to +70 °C
Rel. humidity (without condensation)	10% to 90%
Air pressure	500 hPa to 1060 hPa

Accessories and components

FCP Gateway

Designation	Specification	Order no.
FCP Gateway WL 2	N/A	304972-8200-000

Disposal

Safety during disposal
CAUTION! Pollution of the environment Inappropriate disposal may contaminate the environment.

- Do not dispose of the systems along with normal domestic waste.
- Dispose of the system according to the local laws/regulations governing the disposal of electrical and electronic equipment.

Disposal of the system

- Keep packing material in the event of a relocation or repair.
- If you want to dispose of the packing material: Dispose of packing material by sending it for recycling through an acknowledged collection system. The system contains electronic components with integrated batteries.
- Dispose of the system and integrated batteries correctly, in accordance with national legislation. The system specified on the delivery note must not be disposed of via household waste or communal disposal companies

according to the applicable EU guidelines valid at the time the system was placed on the market.

- For more information about the disposal of the system, please contact the ZEISS contact partner in your country. You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med
- If you want to sell on the system or its components: Inform the purchaser that they must dispose of the system according to the regulations valid at that time.

Glossary

- **CAN**
  Controller Area Network
- **FCP**
  Foot Control Panel
- **PCB**
  Printed Circuit Board

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Email: info.meditec@zeiss.com
Internet: www.zeiss.com/med
Specification subject to change without notice
G-30-2285-en – 1.1 – 2024-06-13

Documents / Resources

	ZEISS FCP Bluetooth Gateway WL 2 [pdf] Instruction Manual 304972-8200, 2BF3L304972-8200, 2BF3L3049728200, FCP Bluetooth Gateway WL 2, FCP Gateway WL 2, Bluetooth Gateway WL 2, FCP Gateway, Gateway, WL 2

References

- Medical Solutions made by ZEISS
- User Manual