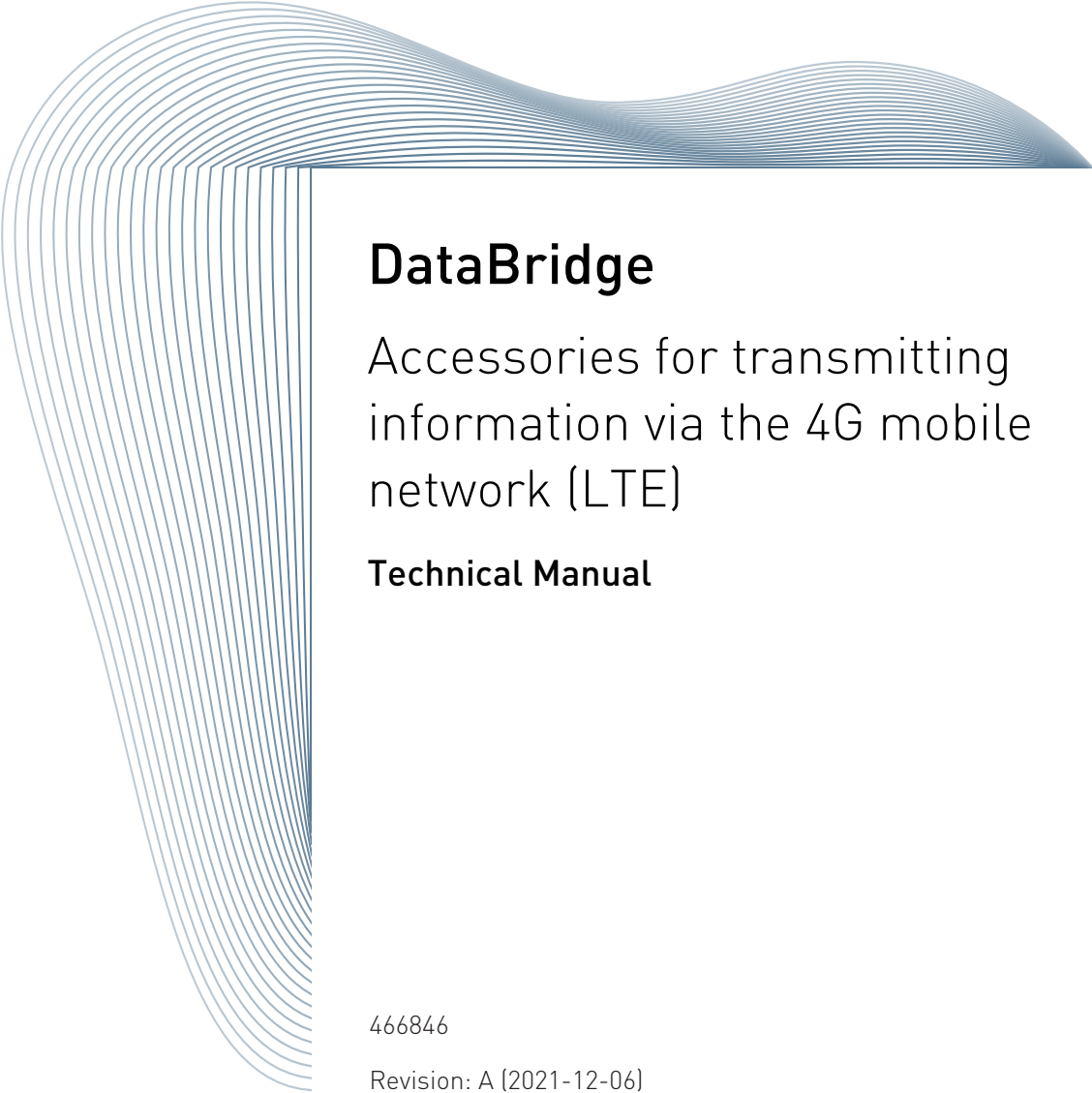




DataBridge

Accessories for transmitting
information via the 4G mobile
network (LTE)

Technical Manual

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1 About the Device

General Description

DataBridge is connected to the BIOTRONIK Renamic programmer. If the Renamic is equipped with a certificate for communication with BIOTRONIK, information is transmitted via the 4G mobile network (LTE) using DataBridge. The information can be transmitted from the programmer to BIOTRONIK and vice versa.

Objective

In this technical manual, you will find information on how to use DataBridge. Topics such as start-up, cleaning and disinfection, disposal and transport, among other things, are explained.

This technical manual does not contain any information on the Renamic programmer or its functions. For a description of these functions, refer to the technical manuals of the programmer and the associated software of the programmer. You will also find information in the technical manual of the programmer arising from its use, such as operating environments or use with high-frequency surgical instruments.

Intended Purpose

DataBridge provides capabilities for cellular communication between the Renamic programmer and cellular mobile networks.

Indications, Contraindications, and Expected Clinical Benefit

DataBridge is used exclusively for the transmission of information via mobile networks. Therefore, it has no indications, no contraindications, and no expected clinical benefit.

Residual Risk

The risk analysis carried out by the manufacturer's Risk Management team has determined that the residual risk is at the lowest possible level. Prerequisites for this are the intended use of a device that has been serviced and inspected according to the manufacturer's specifications by qualified medical staff and the compliance with the safety-relevant instructions in this technical manual.

Intended user

The use of the device and the technical manual are intended for trained and experienced physicians, hospital technicians and nursing staff, general practitioners, as well as sales representatives of BIOTRONIK, who are familiar with the following topics:

- Use of implantable pacemakers, ICDs, or implantable cardiac monitors (ICMs)
- Risks and possible contraindications accompanying the use of these systems
- Experience with programmers for implantable devices

The user of the programmer performs:

- Follow-up and emergency follow-up
- Implantation support with post-implantation follow-up

BIOTRONIK offers user trainings for specific target groups. Current information on training and education opportunities can be requested from: education.training@biotronik.com

Product identification

Each product is identified by a so-called unique device identification (UDI), which contains product-specific information. In addition, a basic identifier called B-UDI-DI (basic – unique device identification – device identifier) is assigned to several products.

The B-UDI-DI is: 4035479BUDI00052Q5

Using this B-UDI-DI, it will be possible to search the European Database on Medical Devices (EUDAMED) for additional information on the product.

Reporting of Serious Incidents

Report any serious incident that has occurred with the device to the manufacturer and to the competent authority.

The competent authority can be found at: <https://ec.europa.eu>

2 Safety during Use

Safety Messages



WARNING

Safety information

The installation and use of the device are subject to special operating conditions and possible complications and risks.

- Pay careful attention to all the safety information in this section and in the entire technical manual.



WARNING

Function impairment due to damage

Mechanical impact, for example dropping the unit – even from a height of just 5 cm if unpackaged – can permanently impair the function of the device.

- Do not use the device if it shows visible damage.

Technical Manuals

Technical manuals are either included in hard copy form in the storage package or available in digital form on the internet: <https://manuals.biotronik.com>.

1. Consult all relevant technical manuals.
2. Keep the technical manuals for future reference.

To ensure safe operation, in addition to this technical manual, please also consult the following technical manuals:

- Technical manuals for the programmer and its accessories
- Technical manuals for the programmer's software
- Technical manuals for other devices, such as external monitors

Liquids

- Never use a damp or wet device.
- Protect the device from accidental ingress of fluids (e.g., infusion fluids).
- Protect the device from condensation.

Changes not permitted

Only the manufacturer BIOTRONIK or a party expressly authorized by the manufacturer may perform corrective maintenance, enhancements, or modifications to the device.

Using in combination with high-frequency devices

The device is protected against damage when using it in conjunction with high-frequency surgical instruments. Even though this protection was tested, its effectiveness depends on the strength, wave shape, and transmission path of the induced current.

- Perform a test after any application with HF surgical equipment, see Test before Each Use [Page 5].

Current Software Version

The function of the device depends on the correct software version of the Renamic programmer.

1. Make sure that the current software version is installed on Renamic.
At least PSW software version 2201 or higher must be installed on it. The device does not work with older software versions.

Software is available for download on the internet at software.biotronik.com, or by contacting BIOTRONIK.

Setup Location

- Only operate the device in rooms that fulfill the following conditions:
 - Suitable for medical purposes
 - No danger of explosion
- Place the device on a flat, dry surface.
- The device should be placed in a manner that does not allow it to slip, even while the cable is connected, and so that it is protected against liquids and moisture. Also, ensure that the patient only comes into contact with the applied parts, namely the programming head, ECG cable, and patient cable for the PSA on the programmer.
- Make sure that you can easily connect and disconnect the USB connector.
- To avoid interference, place the device at least 30 cm away from other radio equipment.
- Do not touch any exposed plug connections such as USB ports and the patient at the same time.

Test before Each Use

A short test should be performed prior to each use of the device. This includes a visual inspection:

1. Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
2. Inspect the cables (for insulation, fractures, etc.) and cable connection areas.
3. Perform a simple electrical function test: With the device connected, switch on the Renamic programmer.

If you find any damage or failures, please contact BIOTRONIK.

Connecting

The function of the device can only be used with the BIOTRONIK Renamic programmer. Ensure the following conditions are met:

- The Renamic must be equipped with a certificate for communication with BIOTRONIK. This is ensured for devices that are already equipped with a UMTS module. You can tell whether the Renamic is equipped with a UMTS module by the "UMTS" identification on the backside of the Renamic.
- To avoid interference in communication, do not connect the device to the Renamic during implantation or follow-ups.
- DataBridge must be connected to the Renamic USB port.
- Only one DataBridge may be connected to a Renamic.
- Do not touch any exposed plug connections such as USB ports and the patient at the same time.

Cleaning and Disinfection

Clean the device with a damp cloth and a mild soap solution with a pH value between 4 and 10.

For disinfecting, use an alcohol-based, hydrogen peroxide-based, or quaternary compound-based disinfectant. The disinfection of the device was tested using the following agents:

- Alcohol-based disinfectant
 - Mixture of 70% isopropyl and 30% water
 - Mixture of 85% ethanol and 15% water
 - Aerodesin 2000 (manufactured by Lysoform Dr. Hans Rosemann GmbH)
- Hydrogen peroxide-based disinfectant
 - 2-percent solution for use with terralin® PAA (manufactured by Schülke & Mayr GmbH)
- Quaternary compound-based disinfectant
 - 2-percent solution for use with terralin® protect (manufactured by Schülke & Mayr GmbH)

Sterilization

The device is non-sterile and must not be sterilized. Follow the instructions on cleaning and disinfecting.

Disposal

The symbol on the type plate, a crossed out garbage can, indicates that the device must be disposed of in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2).

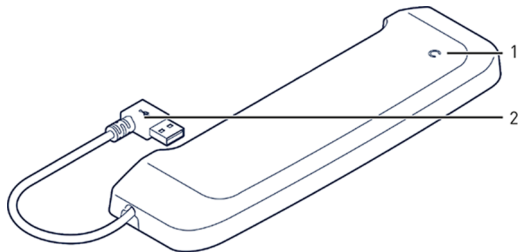
Disposal of this device in an environmentally unfriendly manner will result in environmental pollution, as this device contains materials that must be disposed of in accordance with environmental protection regulations (e.g., WEEE, RoHS, REACH). Dispose of the used product in an environmentally sound manner and according to the applicable country-specific directives. Return products that are no longer in use to BIOTRONIK.



3 Start-up

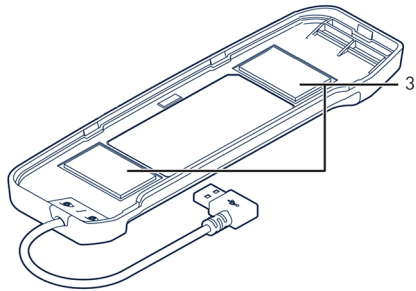
Device Overview

View from the top



1	On/Off light indicator (Lights up only when the device is connected and the Renamic is switched on.)
2	USB connector

View from the bottom



3	Hook and loop fasteners to attach to the Renamic for transportation
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Symbols on the Device

	Manufacturer
	Medical device
	Serial number
	Manufacturing date
	Unique device identifier
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.

	CE mark
IP30	• Protection against the ingress of solid foreign bodies with a ≥ 2.5 mm diameter • No protection against ingress of water
	Regulatory compliance mark (RCM)

Connecting the Device

Prerequisite

- The Renamic is equipped with a certificate for communication with BIOTRONIK.
 - No other DataBridge is connected to the Renamic.
 - The Renamic is not being used for an implantation or follow-up at the time of connecting it.
1. Check that at least PSW software version 2201 or higher is installed on the Renamic. If an older software is installed, you must update and install the latest software.
 2. Switch off the Renamic.
 3. Connect the USB connector of the device to the Renamic USB port.
 4. Switch on the Renamic.

Result

When the Renamic is ready for use after successful start-up, the DataBridge on/off light indicator turns green. On the Renamic user interface, the number **[4]** is displayed in the status bar next to the symbol for the signal strength of the mobile connection.



On/Off light indicator

The on/off light indicator is located on the top side of DataBridge. It is an open circle. The on/off light indicator is only visible and continuously lit green when DataBridge is connected and the Renamic is turned on.

Switching On and Off

The device does not have its own on/off key. When DataBridge is connected to the Renamic, it can only be switched on or off by switching the Renamic on or off.

Switching on

1. Switch on the Renamic.

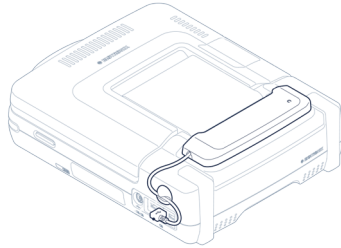
Switching off

1. Switch off the Renamic.
Or
Disconnect the USB connector of the device from the Renamic USB port.

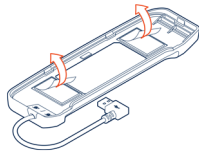
Transportation

On the bottom side of the device there are two hook and loop fasteners with which you can fasten the device to the lid of the power cord compartment of the Renamic. Furthermore, a self-adhesive cable holder is included in the package contents for attaching the USB cable close to the Renamic housing.

These aids enable you to attach the device to the Renamic for transportation so that you can transport DataBridge and the Renamic as one unit.



1. Clean the power cord compartment lid.
Proceed as described in the Renamic technical manual.
2. Position DataBridge over the power cord compartment lid and find a suitable position for the hook and loop fasteners.
3. Peel off the protective films of the hook and loop fasteners.



4. Check the suitable position and attach DataBridge to the lid using the adhesive surfaces.
5. Find a suitable place for the cable holder on the housing side of the Renamic (e.g., above the USB port used).
6. Clean this surface as well.
7. Peel off the protective film from the adhesive surface of the cable holder.



8. Position the cable holder and attach it to the Renamic.
9. Clamp the USB cable into the cable holder. Make sure that the cable is not subjected to tensile stress and that it is as close to the Renamic as possible.

4 Appendix

Technical Data

Category	Design
Dimensions (W x D x H)	320 mm x 160 mm x 50 mm / 12.6" x 6.3" x 1.9"
Weight	190 g / 0.419 lbs
Degree of protection	IP 30
Sterilization	Non-sterile
Longevity	6 years
Operating mode	Continuous operation
Power supply to the device	Operation via the Renamic USB port
On/Off light indicator	Green LED, lit continuously
Disclosure pursuant to Section 33 REACH, Regulation (EC) No. 1907/2006	See: https://www.biotronik.com/material-compliance

Ambient conditions

Category	Operation	Transport and storage
Temperature	+10°C ... +40°C/ +50°F ... +104°F	0°C ... +50°C/ +32°F ... +122°F
Relative humidity	20% ... 75%, non-condensing	
Atmospheric pressure	700 hPa ... 1060 hPa	

Mobile specifications

Category		Design
Max. power of transmission		+23 dBm (Class 3)
Max. data rate		LTE-CAT1
		Download: 10 Mbit/s
		Upload: 5 Mbit/s
Bandwidth		Up to 20 MHz
Modulation	Download	QPSK, 16-QAM, 64-QAM
	Upload	QPSK, 16-QAM

Category		Design
Model	Europe	Telit LE910C1-EU
	North America	Telit LE910C1-NA
	Asia-Pacific	Telit LE910C1-AP
	Latin America	Telit LE910C1-LA
LTE bands in use	Europe	B1 (1,900 MHz), B3 (1,800 MHz), B7 (2,600 MHz), B8 (900 MHz), B20 (800 MHz), B28A (700 MHz)
	North America	B2 (1,900 MHz), B4 (1,700/2,100 MHz), B12 (700 MHz)
	Asia-Pacific	B1 (1,900 MHz), B3 (1,800 MHz), B5 (850 MHz), B28 (700 MHz)
	Latin America	B1 (2,100 MHz), B3 (1,900 MHz), B3 (1,800 MHz), B4 (1,700/2,100 MHz), B7 (2,600 MHz), B28 (700 MHz)

Package Contents

Information about the package contents can be found on the shipping label.

Electromagnetic Interferences

Possible electromagnetic interference

This device is protected against electromagnetic interference and electrostatic discharges in the special environment in the vicinity of high-frequency surgical instruments. At the same time, the emitted interference is reduced to a minimum. The device thus meets all requirements of IEC 60601-1-2.

The following tests were conducted according to IEC 60601-1-2: 2014:

Section	Test	Test level
7.1	EN 55011 (CISPR 11) Radiated emission	- Group 1 - Class B
8.9	IEC 61000-4-2 Electrostatic discharge (ESD)	± 8 kV contact discharge ± 15 kV air discharge
8.9/8.10	IEC 61000-4-3 Electromagnetic fields	- Modulation: 1 kHz 3 V/m, 80 MHz – 2.7 GHz - Limits for RF communication equipment per Table 9 in IEC 60601-1-2 (9–28 V/m)

Section	Test	Test level
8.9	IEC 61000-4-6 Conducted radiofrequency interference	• Modulation: 1 kHz • 3 V • 6 V in ISM bands
	IEC 61000-4-8 AC frequency magnetic fields	• 30 A/m • 50/60 Hz
8.11	IEC 61000-4-39 Proximity magnetic fields	• Limits according to Table 11 in IEC 60601-1-2 (7.5 – 65 A/m)

However, strong electromagnetic interferences that occur in the close vicinity of electrical motors, power cables, PCs, monitors, or other, possibly defective, electrical devices may compromise the function of the device.

This kind of device malfunction should be considered as a possible cause if the following is observed:

- The device switches on unintentionally.
- The device displays other abnormal behavior.

Correct operation of the device can be restored by the following methods:

- Switch off the interfering electrical device.
- Remove the source of interference from this device.
- Switch this device on and off or break the electrical connection between this device and the source of interference, if this can be done safely.

If the interference continues, contact BIOTRONIK immediately.



Caution

Risk of electromagnetic interference

The use of this device close to or in direct contact with other devices should be avoided, as this may lead to the device operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor this device and the other device(s) being used with it in order to ensure that they are all working correctly.



WARNING

Risk of electromagnetic interference through the use of unauthorized accessories

The use of accessory parts, transducers, or cables not listed by BIOTRONIK, or other than those specified by BIOTRONIK, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to electromagnetic interference. Such effects can lead to the faulty operation of the device.

- Only use accessories authorized by BIOTRONIK.



WARNING

Risk of electromagnetic interference through the use of portable RF communication equipment

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 30 cm (12 inches) from this device, this can result in a reduction in its performance. This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral devices such as antenna cables and external antennae), keep such devices at a distance of at least 30 cm (12 inches) from this device.

Country-Related Information

International Radio Certification

Telemetry information for Australia:



This device is in compliance with the Australian "Radiocommunications Act 1992" and, therefore, it is labeled with the Regulatory Compliance Mark (RCM) in accordance with the requirements for radiocommunication devices.

Telemetry information for Canada:

This device will be registered with Innovation, Science and Economic Development Canada under the following number:

IC: 4708A-DATABRIDGE

Telemetry information for the USA:

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

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note

This equipment 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 can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular type of installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off temporarily and then turning it on again, you may try to correct the interference by one or more of the following measures:

- Changing the orientation or location of the receiving antenna.
- Increasing the distance between the device and receiver.
- Connecting the device to an outlet on a circuit different from that to which the receiver is connected.
- Consulting the distributor or an experienced radio/TV technician for help.

This device will be registered with the Federal Communications Commission under the following number:

FCC ID: QRI-DATABRIDGE

Legend for the Label

Symbol	Meaning
	Medical device
	Manufacturing date
	BIOTRONIK order number
	Serial number
	Unique device identifier
	Temperature limit
	Humidity limit
	Air pressure limit
manuals.biotronik.com 	Follow the instructions for use!
	Contents
	Do not use if packaging is damaged and consult the technical manual
	Manufacturer
	Distributor
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Symbol	Meaning
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
	DataBridge
	Renamic
	Cable holder