



Qubic Connect

Device for data transmission from the cardiac catheter laboratory

Technical Manual

R_x

only

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1 About this Technical Manual

Objective

This technical manual provides information on how to use Qubic Connect. Among others, the following topics are explained:

- Device startup
- Device handling
- Disposal
- Transportation

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 the technical manual.
2. Keep the technical manual for future reference.

Conventions

Identification of Safety Warnings

The following symbol draws attention to potential safety risks:



Follow all safety warnings indicated by this symbol to avoid possible serious or fatal injury or damage to the system.

Safety warnings are also indicated by a signal word.

Signal word	Meaning
Attention	Non-compliance leads to a potentially dangerous situation that can cause minor injuries and/or material damage .

Typographical Conventions

The following typographical conventions are used in this technical manual:

Instructions

The individual steps of an instruction are numbered. Prerequisites, intermediate results, and results may be specified.

Prerequisite

This is a prerequisite.

1. Step
2. Step

Intermediate result

3. Step

Result

This is the result.

Elements	Description and appearance
Cross references	Cross references are indicated using "see" or "see also".
Highlights	Text that needs to be highlighted is shown in bold .
Notes	Useful information is indicated using the word Note .

Figures

Figures that show the product or the user interface are used for illustration. The details shown in the figure may differ from that of the delivered product or your software version.

Gender

If personal designations are used only in the male or female form for reasons of better readability, this expressly includes all other gender identities.

2 Device Description

Intended Purpose

The Qubic Connect is designed for downloading data from medical products or devices used in an EP lab and uploading the data to the BIOTRONIK Cloud Services. The Qubic Connect device is designed for stationary and mobile usage.

Intended Conditions of Use

Application environment

The Qubic Connect may be used anywhere within the specified temperature, pressure, and humidity ranges (see Operating Conditions).

The Qubic Connect is typically placed in the control room of an EP lab on the office desk, for example.

3 Safety

Conditions for Operation

Transport and Storage

If the package is damaged, please contact BIOTRONIK immediately. Do not put the device into operation.

The ambient conditions for shipping and storage are:

Temperature	+ 0°C (32°F) ... + 50°C (122°F)
Relative humidity	30% ... 75%, no condensation
Atmospheric pressure	700 ... 1060 hPa

Operating Conditions

Attention

After transporting the equipment from a cold location to a warm location, condensation may form, particularly on metal parts of the device, and damage the electronics.

- After transport, wait approximately 2 h until the device has reached room temperature and the condensation has dried up before using the system.

The ambient conditions for operation are:

Temperature	+ 0°C (32°F) ... + 40°C (104°F)
Relative humidity	30% ... 75%, no condensation
Atmospheric pressure	700 ... 1060 hPa

Power Supply

Qubic Connect is operated via an external power supply brick (12 V DC/5 A) in a medical room outside the patient environment Qubic Connect is not connected to the AC voltage supply.

The external power supply brick must meet the requirements of IEC 62368-1.

Cable and Plug Connections

- Replace any cable that shows even slight damage.
- Ensure that the contacts of all connector ports and connectors are clean. Dirty contacts can lead to signal distortions.
- Ensure that there is no condensation on the plugs or in the connector ports. If condensation is present, dry it before use.
- Do not force the plugs into the connector ports. Do not pull on the cable when disconnecting the plugs. Rather, release the lock on the plug.

Maintenance, Care, and Disposal

General information

Note the following points before cleaning and disinfecting:

- Unplug Qubic Connect from the power supply brick before cleaning and disinfecting.
- Let cleaning and disinfection agents evaporate before operating the device.
- Do not use any strong and abrasive cleaning agents or organic solvents such as ether or benzine, as they corrode the surface of the device.

Cleaning and Disinfecting

Clean the device with a damp cloth and a mild soap solution. 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
 - Aerodesin 2000
 - Isopropyl (70%)
 - Ethanol (85%)
- Hydrogen peroxide-based disinfectant
 - 2 percent ready-to-use solution with Terralin PAA
- Quaternary compound-based disinfectant
 - 2 percent ready-to-use solution with Terralin protect

Test before Each Use

A short test of the device and the approved accessories should be performed prior to each use. It includes a visual inspection and a simple function test.

- Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
- Inspect cables and connection areas to ensure proper insulation, no breaks, etc.

Qubic Connect runs automatic self-tests on a regular basis. If the self-test fails, the device displays a notification for the user (see Troubleshooting).

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

If no error message appears, the device is ready to be used.

Maintenance

Qubic Connect is intended for continuous operation. When correctly in-use, ongoing maintenance is typically not required.

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 unsound 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). Return devices that are no longer in use to BIOTRONIK.

4 Device Handling

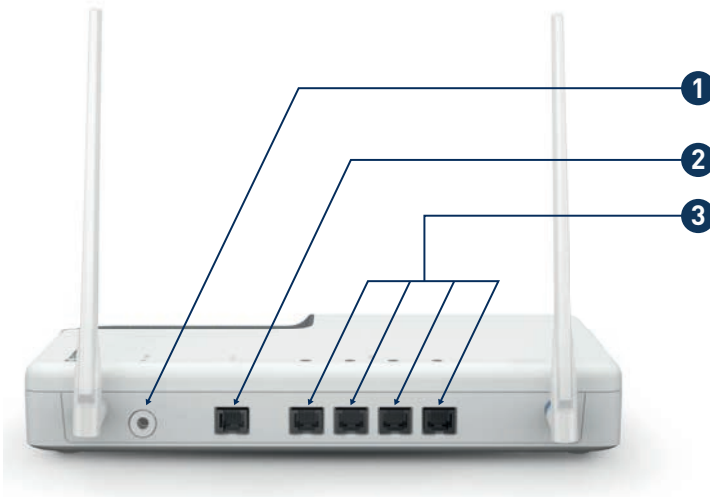
Device Overview

Front View



Item	Description
1	QR code <ul style="list-style-type: none">• For connecting with BIOTRONIK support.
2	Indicator LED BIOCLOUD <ul style="list-style-type: none">• Shows the data transfer to the BIOTRONIK Cloud. Storage of the data received from the Qubic Connect device and provision of the data.
3	Indicator LED MOBILE <ul style="list-style-type: none">• Shows whether the device has an LTE connection.
4	Indicator LED WIFI <ul style="list-style-type: none">• Shows whether the device has a WIFI connection.
5	Indicator LED LAN <ul style="list-style-type: none">• Shows whether the device has a LAN connection.
6	Indicator LED A, B, C, D <ul style="list-style-type: none">• Shows the connection to an EP device. Currently, only the AcQMap system is intended to be used.
7	Stand <ul style="list-style-type: none">• Enables to stand the device in an upright position.
8	Two antennas <ul style="list-style-type: none">• To improve the signal quality of the cellular phone network.







Rear View of Device






Item	Description
1	Power supply port <ul style="list-style-type: none">For connecting the external power supply brick
2	WAN port <ul style="list-style-type: none">Enables internet access via an Ethernet connection
3	Four LAN Ethernet ports <ul style="list-style-type: none">For connection to an EP device. Currently, only the AcQMap system is intended to be connected using the VK-118 cable.To connect to the Qubic Connect GUI using a laptop or PC.

Symbols on the Device




Explanation of symbols






Symbol	Meaning
	Power supply connection symbol
	Symbol for the WAN Ethernet connection
	Symbols for the Ethernet connections of the EP devices
	Manufacturing date
	Manufacturer
	Serial number

Symbol	Meaning
	CE mark
	Global Trade Item Number
	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.

LED Symbols and Display Status

The Qubic Connect LED symbols are displayed in green and yellow.

Symbol on the device	Explanation	LED display solid green	LED display flashing green	LED display solid yellow	LED display flashing yellow
	LED display Bio Cloud	Data transfer to BIOTRON IK cloud running	Device is establishing the connection to the BIOTRON IK Cloud Service	Data upload not possible	Device is establishing the connection to the BIOTRON IK Cloud Service
	LED display Mobile	Connection to BIOTRON IK Cloud Service via cellular phone network	Setting up the LTE connection to the BIOTRON IK Cloud Service	n/a	n/a
	LED display WIFI	Connection to the BIOTRON IK Cloud Service via WLAN of the hospital IT infrastructure	Setting up the WLAN connection to the BIOTRON IK Cloud Service	n/a	n/a

Symbol on the device	Explanation	LED display solid green	LED display flashing green	LED display solid yellow	LED display flashing yellow
	LED display WAN	Connection to the BIOTRON IK Cloud Service via Ethernet of the hospital IT infrastructure	Setting up the Ethernet (WAN) for the BIOTRON IK Cloud Service	n/a	n/a
	LED display devices	Connection with the AcQMap system	Data transfer to/from the AcQMap system	Data transfer to/from the AcQMap system not possible	Connection to the AcQMap system in progress
	LED display devices	n/a	n/a	n/a	n/a
	LED display devices	n/a	n/a	n/a	n/a
	LED display devices	n/a	n/a	n/a	n/a

Setting up the Device

General

Qubic Connect can be wall mounted, stood upright using a stand, and placed on a table.

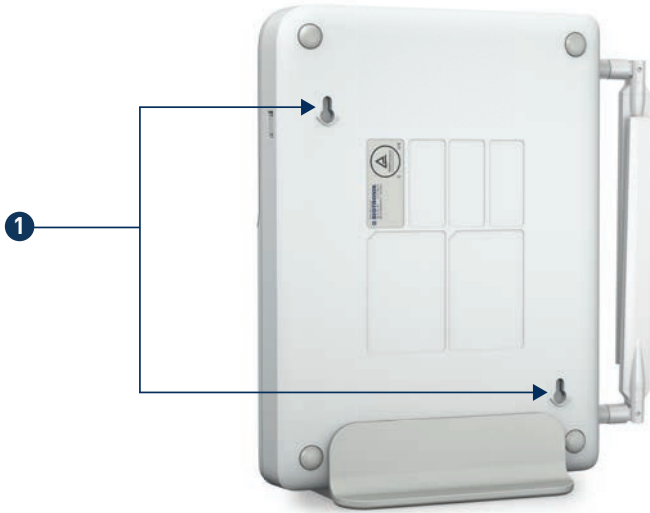
Standing the Device Upright

The device can be placed upright using a stand.



1. Place the Qubic Connect on a flat, dry surface using the stand.
2. Make sure to place the device upright in the holder.

Mounting the Device on the Wall



Item	Description
------	-------------

1	Mounting holes
---	----------------

There are two mounting holes for screws on the underside of the housing to attach the Qubic Connect to the wall.

1. Please use suitable screws such as the universal chipboard screw 3.5 with countersunk head (diameter 7 mm).

Placing the Device on the Table



1. Place the device on a stable table to prevent it from falling.
2. Do not place any objects on the device so that the LED display remains visible.

Connections and Cables

Basic notes for cables and connections

- Do not force the plugs into the connector ports.
- Do not pull on the cable when disconnecting the plugs. If necessary, release the lock on the plug.

Connecting the Power Supply Brick

Qubic Connect is powered via the provided power supply brick and power cord. Only use the power supply brick supplied with the product.

The port for the power supply brick is located on the rear side.



Prerequisite

Before connecting, ensure that the power supply conditions are met (see Power Supply).

1. Connect the external power supply brick to the AC power supply via the power cord.
2. Connect the DC output of the external power supply brick to the power supply port of the Qubic Connect.
3. To disconnect Qubic Connect from the electrical power supply, pull out the external power supply brick from the power supply port.

Connecting the Device

Note

Qubic Connect does not have an on/off switch. The device is put into operation when it is connected to the electrical power supply.

1. Connect the device to the electrical power supply (see Connecting the Power Supply Brick).

Result

The LED display BIOcloud first flashes yellow.

The LED is solid yellow or green. The device is ready for use.

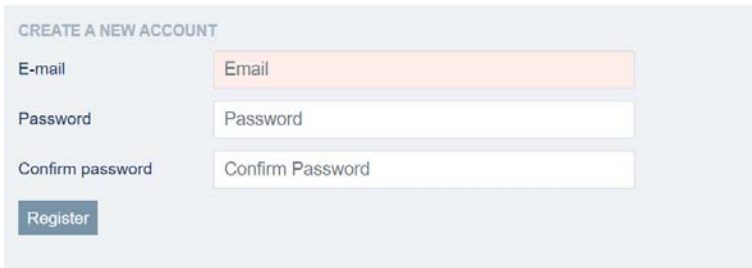
Activating Qubic Connect Service

In the Qubic Connect web front end, you can configure the system, activate the Home Monitoring Service, and troubleshoot.

Prerequisite

Qubic Connect is connected to the electrical power supply.

1. Connect the Ethernet cable VK-118 to the Ethernet port on the Qubic Connect and connect it to a computer or laptop.
2. To enable access to the Qubic Connect GUI, open a browser. Qubic Connect was tested with the Edge browser and with Mozilla Firefox.
3. Enter the URL in the browser.
4. Create a new account and enter an e-mail address and a password into the text fields.
5. Select the **Register** button to register.



CREATE A NEW ACCOUNT

E-mail

Password

Confirm password

This takes you to the main menu dialog.

6. To use the Home Monitoring Service, select the **HMSC INFO** dialog.
7. Activate the **Activate Home Monitoring Service Center** button.

Activate Home Monitoring Service Center

8. In the text fields, enter the user group data provided by BIOTRONIK and the registration ID and select the associated country.

Note

Internet access via cellular phone network is enabled by default, and Qubic Connect automatically tests the internet connection.

If the signal strength is poor or there is no internet connection, you have the option to configure the internet connection (see Configuring Internet with WIFI and LAN).

Configuring Connection to the Internet with WIFI and LAN

To configure the internet connection, proceed as follows:

Prerequisite

The system has booted up. Qubic Connect is connected to a laptop or PC via an Ethernet cable and the Qubic Connect GUI is accessible.

1. Activate the **Internet** dialog at the top of the main menu.

The screenshot shows the Qubic Connect main menu with the 'INTERNET' tab selected. The menu includes sections for 'BASIC CONFIGURATION', 'TROUBLE SHOOTING & ADDITIONAL INFO', 'INTERNET / NETWORK STATUS', 'FILE UPLOAD TO BIOTRONIK CLOUD', and 'FILE DOWNLOAD FROM ACQMAP'. The 'INTERNET / NETWORK STATUS' section shows 'Cell' as the active connection, with 'Wi-Fi' and 'LAN' options. The 'BASIC CONFIGURATION' section has buttons for 'Configure internet access', 'Activate Home Monitoring Service Center', and 'Firmware update'.

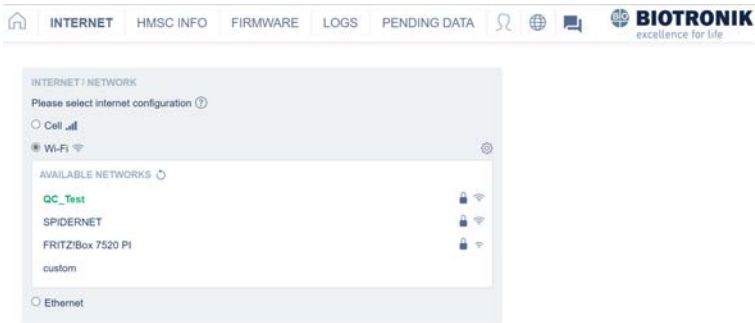
2. From the Basic Configuration menu, select the **Configure internet access** button.

Configure internet access

3. Enable LAN.

The screenshot shows the 'Configure internet access' dialog box. It has a title bar 'INTERNET / NETWORK' and a subtitle 'Please select internet configuration'. There are three radio button options: 'Cell', 'Wi-Fi', and 'Ethernet'. The 'Ethernet' option is selected, indicated by a filled radio button.

4. If you select WIFI, you must first connect to a network.



5. Select the configuration symbol to access the text entry fields for internet settings.



1. Enter the settings assigned by the hospital IT department. To save the entry, select the **Save** button.

Network settings	
IP address configuration	Static
IP address	192.168.188.29
Subnet mask	255.255.255.0
Gateway	192.168.188.1
DNS	Static
Primary DNS	192.168.188.1
Secondary DNS	
<input type="checkbox"/> Proxy	
Port	0
<input type="button" value="Cancel"/> <input type="button" value="Save"/>	

If the internet connection cannot be established, contact the hospital IT department.

Connecting the AcQMap System

The AcQMap system is connected to the Qubic Connect device using the VK-118 Ethernet cable.

The Ethernet ports are located on the back of the device.








Prerequisite



The AcQMap system is booted up and the required apps for the Qubic Connect Service are available on the AcQMap.




1. Connect the AcQMap System to one of the rear panel ports using the VK-118 Ethernet cable.
2. The LED of the selected connection should be green (either flashing or solid).

5 Troubleshooting

There is a QR code on the device that gives you access to BIOTRONIK support. Malfunctions of the Qubic Connect can be recognized by the following behavior of the LED symbol display:

Error possibilities	LED symbol	LED status	Description	Fix
1		Flashing yellow	Device failure	Contact BIOTRONIK support
2	 	Solid yellow illumination Flashing yellow	The device started, but a critical error occurred	Contact BIOTRONIK support
3	 	Flashing yellow Flashing green	BIO Cloud connection is established via LTE. If the signal lasts longer than two minutes, no connection to the BIO Cloud can be established.	Contact BIOTRONIK support

Error possibilities	LED symbol	LED status	Description	Fix
4		Flashing yellow Flashing green	BIO Cloud connection is established via WLAN. If the signal lasts longer than two minutes, no connection to the BIO Cloud can be established.	Contact BIOTRONIK support
5		Flashing yellow Flashing green	BIO Cloud connection is established via LAN. If the signal lasts longer than two minutes, no connection to the BIO Cloud can be established.	Call the hospital IT department to verify that the internet settings are ok. If ok – call BIOTRONIK support.

Error possibilities	LED symbol	LED status	Description	Fix
6		Solid yellow illumination	BIO Cloud connection error during data upload	Contact BIOTRONIK support
7		Flashing yellow Solid yellow illumination	Data transfer to Qubic Connect not possible	Plug in the laptop and access the Qubic Connect GUI. Check if the data could not be retrieved.
8		Solid yellow illumination	Connection with Qubic Connect not possible	Contact BIOTRONIK support

6 Appendix

Technical Data

Physical Characteristics of Communication Unit

Category	Design
Dimensions (W x D x H)	300 mm x 225 mm x 46 mm /
Weight	1.6 kg
Degree of protection	IP30
Operating mode	Continuous operation
Disclosure pursuant to Section 33 REACH, Regulation (EC) No. 1907/2006	See: https://www.biotronik.com/material-compliance

Physical Characteristics of Stand

Category	Design
Dimensions (W x D x H)	175 mm x 106 mm x 50 mm /
Weight	0.3 kg

Longevity

Category	Properties
Longevity	5 years

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	

Radio Interface

Category	Properties
Model	Telit LM940
Frequency LTE	700/800/850/900/1700/1800/1900/2100/2300/2500/2600
Power of transmission	Max. 0.2 W (Class 3)

Mobile Specifications

Category	Design
Max. power of transmission	+max. 0.2 W (Class 3)
Model	Telit LM940

Radio Interface to WiFi Network

Category	Properties			
Frequency band	2.4 GHz ISM Band 802.11b/g/n	5 GHz Unlicensed National Information Infrastructure (U-NII) Band 802.11a/n/ac		
		U-NII-1/2A	U-NII-2C	U-NII-3
Operating frequency [MHz]	2400-2483.5	5150-5350*	5470-5725	5725-5850
Transmitter power FCC region	Max. 30 dBm (1000 mW)	Max. 24 dBm (250 mW)	Max. 24 dBm (250 mW)	Max. 30 dBm (1000 mW)
Transmitter power ETSI region	Max. 20 dBm (100 mW)	Max. 20 dBm (100 mW)	Max. 20 dBm (200 mW)	Max. 14 dBm (25 mW)

*for indoor use only

WAN-Ethernet Interface

Category	Properties
Number of connections	1
Type	Ethernet
Bandwidth	100 Mbit/s

LAN-Ethernet Interface

Category	Properties
Number of connections	4
Type	Ethernet
Bandwidth	100 Mbit/s

Power Supply

Category	Properties
Input voltage	12 V DC/5 A
Type	Coaxial 5.5 x 2.5 socket

Accessories

Item designation	Description	Order no.
NK-41	Power cord US	449306
NK-40	Power cord EU	449305
Ethernet cable VK-118	Length 5 m	397252
Stand QC	Stand	471175
Power supply, 12 V DC 65 W	Power supply brick	473717

Country-Related Information

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 equipment 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 installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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 equipment and receiver.
- Connect the equipment 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.

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

FCC ID: QRI-QCONNECT

Telemetry information for Canada:














This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:








1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

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

IC: 4708A-QRI-QCONNECT

Legend for the Label

Symbol	Meaning
	Manufacturer
	Consult the instructions for use!
	Distributor
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Medical device
	Unique device identification
	Contents
	Qubic Connect
	Ethernet cable
	Power cord
	Power supply brick
	Stand QC
	Air pressure limit

Symbol	Meaning
	Humidity limit
	Temperature limit
	CE mark
	Manufacturing date
	BIOTRONIK order number
	Serial number
	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.

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