en-US

Qiona®

Ablation Irrigation Pump

Instruction for use

IMPORTANT

READ THIS DOCUMENT CAREFULLY BEFORE USE.

RETAIN IT FOR FUTURE REFERENCE.

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Table of Contents

1 General Safety Instructions

1.1 Explanation of safety symbols used

In the present technical manual, important information is highlighted using visual symbols. These notes are necessary conditions for eliminating hazards to patients and operating personnel as well as for avoiding damage to or malfunctioning of the device.

1.1.1 Symbols in the technical manual

Caution

Information or help

1.1.2 Symbols on the device

Follow instructions for use

Alternating current

Return and disposal as per the WEEE Directive

Equipotentiality

Date of manufacture
YYYY-MM-DD

Foot switch connection (***Qiona***® Foot Switch)

RF current sensor connection (***Qiona***® AutoFlow Sensor)

Defibrillator-proof type CF applied part

Compliant with ANSI/AAMI ES 60601-1
CAN/CSA 22.2 No. 60601-1-08

The product is compliant with Brazilian INMETRO Ordinance No. 54 dated 1 February 2016 and certified accordingly.

1.1.3 Symbols on the display

	Alarm, general
	Bell cancel, temporarily
	Alarm system clear
	Setup menu
	Patient symbol
	LOW flow rate
	HIGH flow rate
	Maximum flow rate in rinse function
	Infusion bottle/container level indicator
	Infusion bottle/container change confirmation button
	Normal overpressure detection active
	Sensitive overpressure detection active
	Remote control via Qubic RF high-frequency unit
	Scroll through Setup menu
	Exit Setup menu

1.1.4 Symbols on the keypad

UP

DOWN

Rinse

Start-stop key

1.1.5 Symbols on the sales packaging

Consult instructions for use

Catalog number

Batch code

Serial number with year and month of manufacture [YYMM1234]

Packaging unit

Use-by date [YYYY-MM-DD]

Sterilized using ethylene oxide

Single sterile barrier system

Double sterile barrier system

Single sterile barrier system with protective packaging outside

Single sterile barrier system with protective packaging inside

Do not re-use

General Safety Instructions

	Do not resterilise
	Do not use if packaging is damaged
	Defibrillator-proof type CF applied part
TC	Thermal element/Thermocouple
	Keep dry
	Manufacturer
	Sales partner
	Total length
	Caution
	Temperature limit
	Humidity, limitation
	Stacking limit, do not store more than 3 packs high
	Manufacturing date YYYY-MM-DD
MD	Medical devices
UDI	Unique identifier of a medical device
℞ ONLY	Attention: Under US Federal law, this device may be only sold to a physician or ordered by a physician.

For more information about the symbols used, please visit our homepage:
www.moeller-medical.com/glossary-symbols

1.2 Explanation of the presentation conventions used

Various fonts are used in this technical manual for better orientation.

Font	Use
Bold and italics	Buttons in instructions.
Italics	Device options, buttons as well as reference to sections and sub-sections in the running text.

1.3 Responsibility of the manufacturer

The manufacturer can only consider itself responsible for the safety, reliability and usability of the devices, if:

- assembly, upgrades, readjustments, changes, or repairs are solely carried out by persons who were authorized for this by the manufacturer.
- the electrical installation at the location where the devices are being used complies with the relevant requirements and regulations (e.g., VDE 0100, VDE 0107 or IEC specifications).
- the devices are used in accordance with the instructions for use and the country-specific regulations and national deviations are observed.
- the conditions specified in the technical data are complied with.

Any use other than that described in this operator manual is not in accordance with the intended use and leads to exclusion of warranty and manufacturer liability.
The manufacturer will accept device returns in accordance with the German Electrical and Electronic Equipment Act (ElektroG).

1.4 Operator's duty of care

The operator is responsible for the proper operation of the medical device. Based on the Medical Devices Operator Ordinance, the user is subject to extensive obligations and responsibility as part of the user's activities when handling medical devices.
The use of the ***Qiona***® ablation irrigation pump requires precise knowledge and compliance with the instructions of this manual, which is supplied as part of the product. Keep this technical manual in a safe place to use it along with the ablation irrigation pump. The present technical manual is not a substitute for the instruction to be provided to the operator/user by a medical device consultant authorized by the manufacturer. The device may only be operated by persons who have the required training or knowledge and experience. Clinical application may only take place following instruction by qualified personnel.

The ***Qiona***® ablation irrigation pump is subject to special precautionary measures about electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC-related information contained in this manual.
If this device does not function properly due to a malfunction, it must no longer be operated and must be evaluated by the Technical Service department.

Use of device parts that do not conform to the manufacturer's original design may impair performance and safety of the device.
All work requiring the use of tools must be carried out by the Technical Service department of the manufacturer or the manufacturer's authorized representative.

The occurrence of all serious incidents relating to the device must be reported to the manufacturer and to the competent authority of the member state where the user and/or the patient is domiciled.

1.5 Warnings

- No modification of the device is permitted.
- Liquids must not penetrate parts of the device that carry voltage.
- When cleaning, ensure that no cleaning agent flows into the connector sockets.
- Disconnect the power cord before cleaning.
- Replace all types of connection cables, even if the cables only have minor damage, and take precautions not to roll over the cables.
- Keep the cables away from heat sources. Doing so will help prevent the insulation from melting, which can lead to fire or electric shock.
- Do not force the plugs into the connector ports.
- When disconnecting plugs, do not pull on the cable. Release the lock of the plug to disconnect.

- Do not expose the devices to intense heat or fire.
- Do not expose the devices to hard impacts.
- Immediately disconnect the devices from the electrical power supply if heat, fumes or smoke occur.
- The line voltage must correspond to the specifications on the type plate affixed on the rear side of the device.
- Only use the device with power supplies that are equipped with PE conductors.
- Do not spray cleaning agents into the connector sockets or the air bubble sensor.
- Do not use a portable multiple socket outlet when combined with more devices.

Also observe the safety instructions in the technical manuals of devices (ablation catheter, generator) that are operated together with the ***Qiona***®.

1.6 Additional equipment not related to the product

Additional equipment that is not included in the package contents of the device and is connected to the analogue and digital interfaces of the device must have proof that they are compliant with the relevant EN specifications (e.g., EN 60601 for medical electrical equipment). Further, all configurations must fulfil the currently valid version of the system requirements in accordance with the IEC 60601-1 +A1:2012 standard. Anyone who connects additional devices is a system configurator and is therefore responsible for ensuring that the currently valid version of the system requirements in accordance with the IEC 60601-1 + A1:2012 standard is complied with.

Use of parts that do not conform to the manufacturer's original design may impair the performance, safety, and EMC behaviour.

1.7 Single use

The reuse of items meant for single use carries the potential risk of infection for the patient or the user. Contaminated items may lead to injury, illness, or death of the patient. Cleaning, disinfection, and sterilization may adversely affect critical material properties and product parameters to such an extent that it leads to failure of the item.

Dispose of the used single-use items in accordance with your hygiene regulations.

1.8 Statement on DEHP

The ***Qiona***® tube product family does not contain any bis(2-ethylhexyl) phthalates (DEHP).

1.9 Potential equalization conductor

It is important to limit the differences in potential between the various parts of a system within the patient environment. The quality of the connection plays an essential role in limiting this potential difference in a system of PE conductors. It is therefore important to prevent an interruption in the protective measures in each part of the system. In the event of a fault in a PE conductor connection of a device within the patient environment, this potential difference can occur on the housing of the device and cause a hazard for the operator and patient if the operator touches the device and the patient simultaneously.

1.10 Target group (users)

The application of ***Qiona***® is reserved for persons having the required training or knowledge and experience for this.

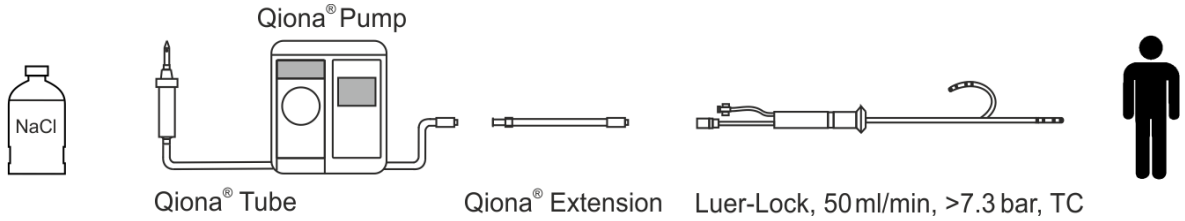
2 Intended Purpose

The ***Qiona***® ablation irrigation pump is used together with a sterile tube set and a container with physiological saline solution for the purpose of cooling the catheter tip during the ablation procedure. The ablation therapy with cooling is a special case of the ablation therapy applied to particularly sensitive areas. During ablation therapy, a defective cardiac conduction system in the inner wall of the heart can be destroyed by heating the tissue with a high frequency current. The ***Qiona***® ablation irrigation pump is used in cardiac catheter laboratories in a clinical environment and is constantly monitored by the user during the application. The permitted application of the ***Qiona***® is **only** as an ablation irrigation pump.

The ***Qiona***® has a total of two output ranges. During the entire ablation procedure, a small amount of physiological saline solution is pumped into the blood circulation system of a patient using the adjustable ***Qiona***® LOW flow function to keep the catheter lumen open, and thus prevent coagulation and blockage at the catheter opening. While using high-frequency current for ablation of cardiac conduction in the myocardial tissue, the ***Qiona***® switches over, automatically or by manual operation, to a more intensive HIGH flow rate so that cooling of the catheter tip can be achieved.

For venting the tube set with the connected ablation catheter, the ***Qiona***® also has a rinse function, in which the maximum flow rate (circa 50 ml/min) of the ablation irrigation pump is available.

Configuration of ***Qiona***® – from the infusion container to the patient:



Configuration of **Qiona**®*, from the infusion container to the patient*

2.1 Indications for cooled ablation

The ***Qiona***® is an irrigation pump (cooling medium: only NaCl solution 0.9%) for cooled high frequency catheter ablation (HF ablation) of symptomatic tachycardia or cardiac rhythm disturbances. It is used in combination with the ***Qiona***® Tube Set incl. Extension tube system, an RF generator, and compatible ablation catheters with irrigation systems for intracardiac application. The ablation catheters must have a Luer-lock connector (female) in accordance with EN 1707:1996 to connect to the ***Qiona***® Tube Set, and have a thermocouple for temperature monitoring, allow a flow rate of up to 50 ml/min, and withstand a maximum pump delivery pressure of 7.3 bar. In addition, the connected ablation catheter should have a lower working pressure, less than 1.5 bar at 1 ml/min and less than 3.3 bar at 35 ml/min (normal overpressure detection) or 3.2 bar at 50 ml/min (sensitive overpressure detection) (see diagram in Section 5.3.2.2 Pressure – overpressure detection). The specifications of the ablation catheter can be found in its technical manual or can be obtained from the manufacturer. If the specification of the ablation catheter is unclear, do not use it.

2.2 Contraindications

Absolute contraindications

- Active systemic infection
- Sepsis
- Hypercoagulability
- Verified atrial/ventricular thrombus
- Decompensated heart insufficiency

Relative contraindications

- Anomalies in vein selected for catheter insertion
- Leg vein or pelvic axis thrombosis
- Patients with artificial heart valves

2.3 Complications

- Death
- Cerebrovascular stroke
- Valvular damage
- Myocardial infarction
- Embolism, such as pulmonary embolism
- Severe rhythm disturbances
- Life-threatening ventricular arrhythmias
- Bradycardia
- Decompensation of a previously existing cardiac/kidney insufficiency
- Hypotension
- Vasovagal reaction
- Vein thrombosis
- Injury to the endocardium
- Endocarditis
- Fever
- General systemic infections

2.4 Key features

The key ***Qiona***® features are as follows: detection of air bubbles within the tube set through air bubble sensor, tube internal pressure monitoring by means of the pressure sensor on the tube set, and redundant monitoring of the air bubble sensor through an additional monitoring device.

2.5 Combination with other products

The ***Qiona***® ablation irrigation pump may only be used together with the applied "***Qiona***® Tube Set incl. Extension" part.
The "***Qiona***® Tube Set incl. Extension" (REF: 365775) may only be connected to cooled ablation catheters. The ablation catheters must have a Luer-lock connector (female) in accordance with EN 1707:1996 to connect to the ***Qiona***® Tube Set, and have a thermocouple for temperature monitoring, which must always be used when operating ***Qiona***®, must allow a flow rate of up to 50 ml/min, and withstand a maximum pump delivery pressure of 7.3 bar. In addition, the connected ablation catheter should have a lower working pressure, less than 1.5 bar at 1 ml/min and less than 3.3 bar at 35 ml/min (normal overpressure detection) or 3.2 bar at 50 ml/min (sensitive overpressure detection) (see diagram in Section 5.3.2.2 Pressure – overpressure detection). The specifications of the ablation catheter can be found in its technical manual or can be obtained from the manufacturer. If the specification of the ablation catheter is unclear, do not use it.
Furthermore, optional accessories that can be connected to the ***Qiona***® include:

- "***Qiona***® Foot Switch" (foot switch with REF: 406937) and
- "***Qiona***® AutoFlow Sensor" (RF current sensor with REF: 406936).

Combination with the Qubic RF high-frequency unit is also possible:

- Qubic RF high-frequency unit by BIOTRONIK
- VK-119 (connection cable)

2.6 Patient population and residual risk

There are no restrictions about the patient population. The device can be used on all age groups, all patient and health conditions, and all ethnic groups. The patient does not operate the device.
Residual risk for patients primarily arises due to selection of ablation parameters that may be unsuitable for the patient or due to other mistakes in application.

3 Product Description

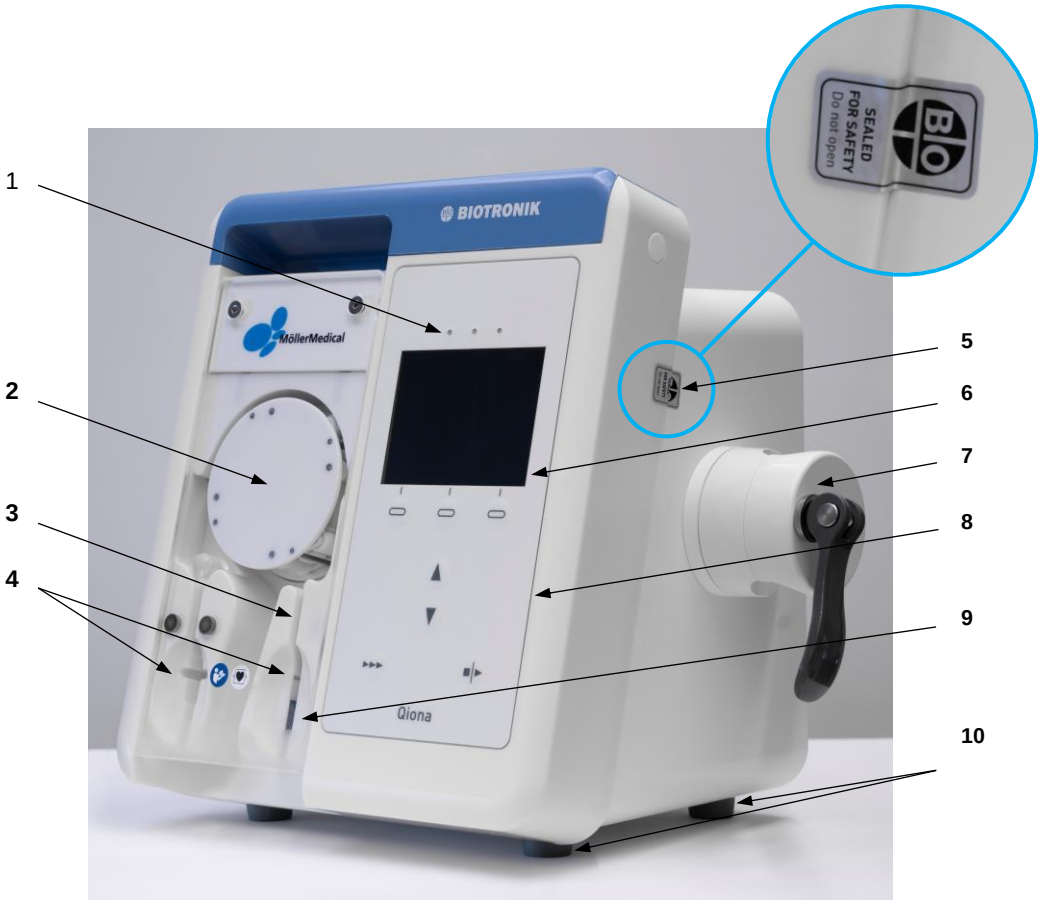


Figure 1
Front view of the **Qiona**® *ablation irrigation pump*

1 3 LEDs for information indication (yellow)
2 Pump rotor
3 Pressure sensor
4 Irreversible tube set attachment
5 Safety Seal
6 Display
7 Pole mount
8 Keypad
9 Air bubble sensor
10 Supporting feet

The ***Qiona***® is turned on and off by means of the ON/OFF switch located at the rear. All functions can be performed via the embossed soft keys on the keypad.

3.1 Keypad and display layout

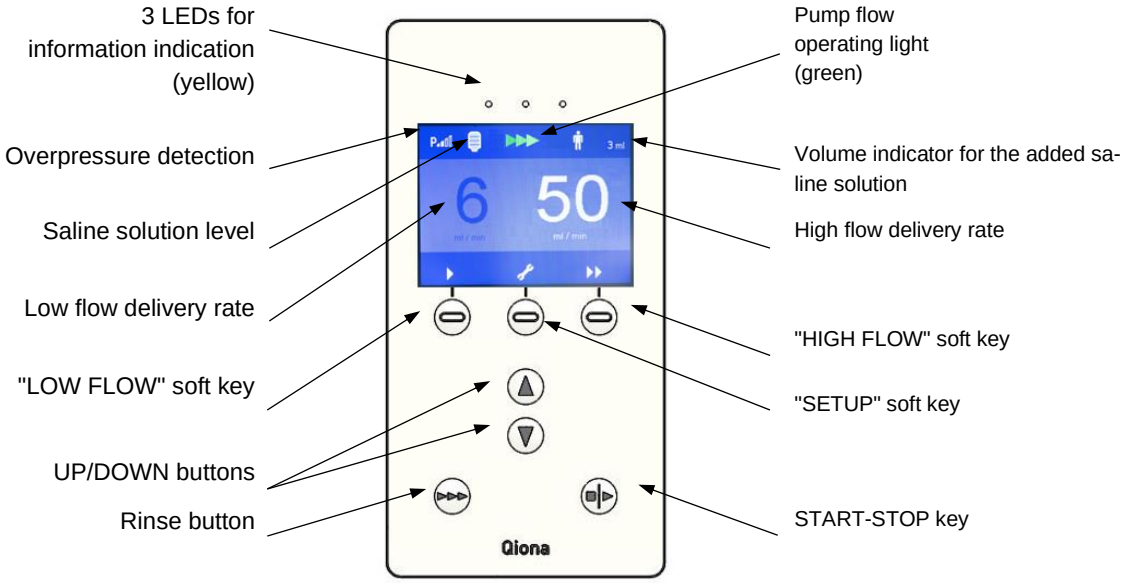


Figure 2

*View of the keypad of the **Qiona**® ablation irrigation pump*

3.2 Connection options on the rear side of the housing

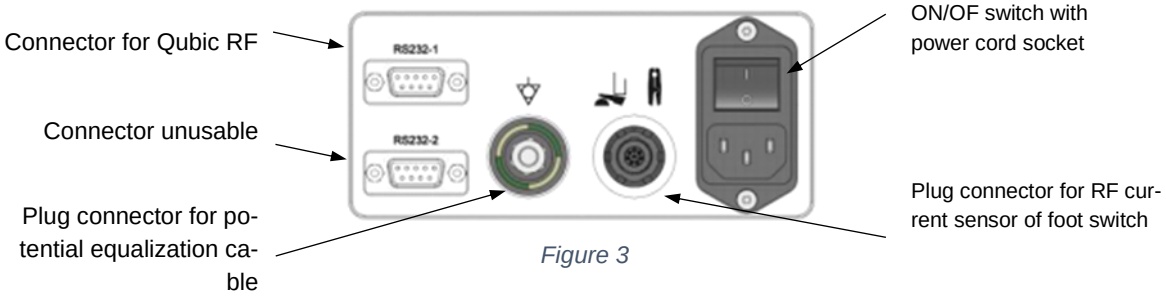


Figure 3

*Rear view of the **Qiona**® ablation irrigation pump with connectors*

4 Installation and Start-Up

Ensure that the packaging box has been delivered to you undamaged. Report transport damage immediately to the shipping company. Inspect all products for damage. Do not use damaged products. Contact your supplier immediately.

4.1 Unpacking the device and inspecting the package contents

The ***Qiona***® is delivered in 1 cardboard package. While unpacking, make sure that no part remains in the package.

The ***Qiona***® package contents include:

• ***Qiona***® ablation irrigation pump	REF 406935
• ***Qiona***® power cord EU Type F, 3 m	REF 412488
• ***Qiona***® technical manual "German"	REF 406939
• ***Qiona***® technical manual "English"	REF 406940
• ***Qiona***® Pole Adapter Set	REF 377184

It is recommended not to dispose of the package and preserve it for reuse when any product service is required.

Safety seals:
To prevent unauthorized changes inside the devices, the Qiona pump is provided with tamper-proof safety seals. If a safety seal is damaged, please contact Möller Medical.

4.2 Suitable operating environment

The ***Qiona***® is suitable for environments in the following areas:

Professional health care facilities with specific requirements:

hospitals/clinics (emergency rooms, patients' rooms, intensive care units, operating rooms, except in the vicinity of active facilities of HF surgery equipment or outside the HF shielded room for magnetic resonance imaging, first aid facilities).

The ***Qiona***® is not permitted for use on aircrafts or in military areas. The appropriate EMC requirements for these environments have not been tested.

4.3 Installation and start-up

Before starting up the ***Qiona***®, it must be reprocessed in accordance with the hygiene regulations (see *Section 7.1*).

Always remember:

- Handling any of the devices requires precise knowledge and observance of the instructions of this technical manual.
- Only qualified personnel are permitted to use the device.
- Do not use a portable multiple socket outlet when combined with more devices.
- When installing the ***Qiona***®, make sure that it can be easily switched off using the ON/OFF switch and disconnected from the power supply by disconnecting the power cord.

Basic note for cables and connections:

- Connect the devices according to the manufacturer's instructions. Do not use any intermediate devices (e.g., adapters).
- Do not connect the system to the customer's Ethernet LAN.

Consult the Quick Start Guide of your Qubic RF for the System Wiring.

Harm from damaged device

Malfunctions of the device may lead to an undesired behavior, harming the patient.

- Visually inspect the device before each use and carry out a simple function test by switching the device on. An internal function test is performed automatically. If no error message appears, no errors were found and the device can be used.
- Check the displays (e.g., display of lettering and the language), observe the functioning of the device, and check that functioning for plausibility.

Test before each use

A short test of the device and the approved accessories should be performed prior to each use. This test consists of the following visual inspections and a simple function test:

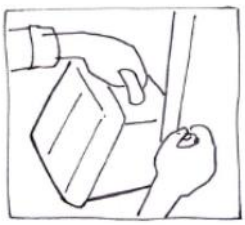
- Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
- Inspect cables and connection areas to ensure proper insulation, no breaks, etc.
- Inspect the foot switch and its actuators for freedom of movement, damage and harmful contamination.
- Inspect the labeling for legibility.
- Perform a simple electrical function test by switching on the device. An internal function test is performed automatically. If no error message appears, no errors were found and the device can be used.

Inspect the displays (e.g., display of characters and language).

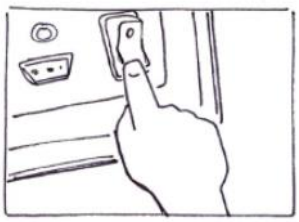
For more information, see *Section 5* "*Application and Operation*".

5 Application and Operation

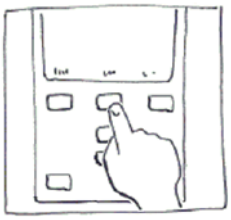
Overview of main operating functions



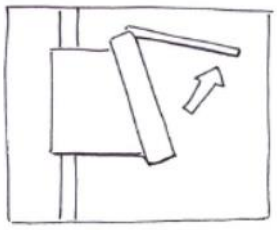
5.1 Unpacking and connecting the ***Qiona***®



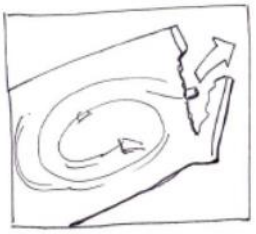
5.2 Switching on ***Qiona***®



5.3 Presetting and setup

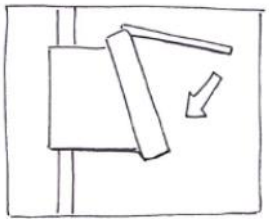


5.4 Opening the front panel

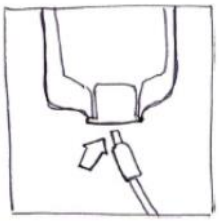


5.5 Taking out the ***Qiona***® Tube Set incl. Extension

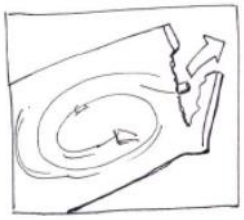
5.6 Inserting the ***Qiona***® Tube



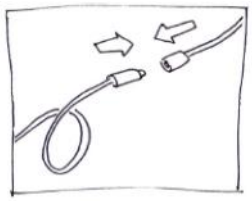
5.7 Closing the front panel



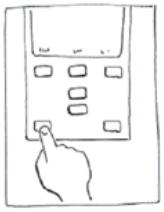
5.8 Connecting the infusion container or infusion bottle



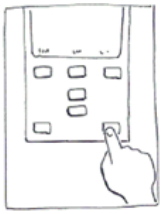
5.9 Taking out the ***Qiona***® Extension



5.10 Connecting the ablation catheter



5.11 Performing rinsing process



5.12 Starting application

Figure 4

Overview of the application and operation of **Qiona**®

5.1 Unpacking and connecting the Qiona®

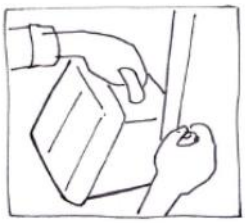


Figure 5

- Remove the ***Qiona***® from the package.
- Place the ***Qiona***® in a suitable, stable place, or attach it to any common infusion stand. If the pole diameter of the infusion stand is too small, use the ***Qiona***® Pole Adapter Set to balance.
- First connect the ***Qiona***® power cord and then connect it to a socket with a PE conductor. Pay attention to the voltage values specified on the type plate.
- If you want to use an RF current sensor (***Qiona***® AutoFlow Sensor) or a foot switch (***Qiona***® Foot Switch) as ***Qiona***® accessory, you can connect the accessory to the appropriately marked plug connector at the rear of the device housing.
- Place the ON/OFF switch at the rear of the ***Qiona***® in position I.
- The device is now ready for use.

5.2 Switching on Qiona

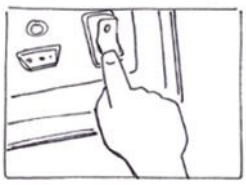


Figure 6

- Place the ***ON/OFF switch*** at the rear of the ***Qiona***® in position I.

The device is now ready for use.
The ***Qiona***® performs a self-test.

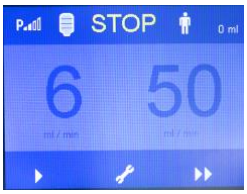


Figure 7

After the self-test, the display always shows the pump status to be in "STOP" mode. The settings for the HIGH flow and LOW flow of the last application are shown on the display. The settings of the previous application are always automatically carried over to the new application. In "STOP" mode, you can start the pump immediately, create the settings in Setup menu, or preset the flow rates.

You have the following options to choose from:

- Keep all settings unchanged, go to *Section 5.4*.
- Change the settings of the application, go to *Section 5.3.1*.
- Change the settings in the Setup menu, go to *Section 5.3.2*.

5.3 Presetting and setup

5.3.1 Presettings

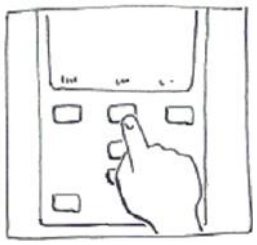


Figure 8

- Use the soft keys in STOP mode to switch between LOW flow and HIGH flow.
- Set the values using the ***UP*** and ***DOWN buttons***. The settable value is highlighted. The changed values are immediately accepted without additional confirmation. If the UP/DOWN buttons are not pressed within two seconds, the highlighted value will become inactive again.

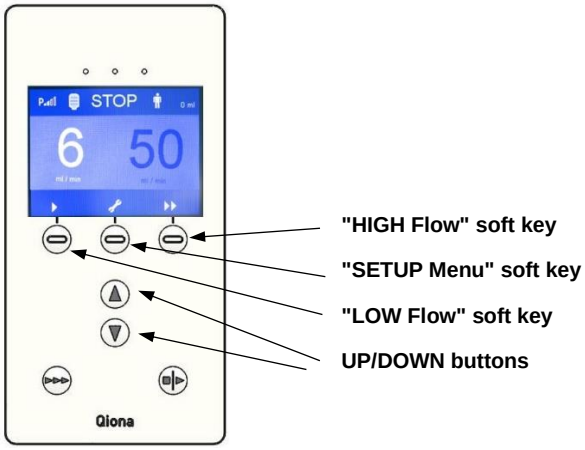


Figure 9

5.3.2 Setup menu

- Press the "***Setup*** (wrench)" soft key. You will enter the "Pump Setup" menu. This function is only available before or after an application. The soft key is blocked during an application.
- Set all the required ***Qiona***® operating parameters in the "Pump Setup"(STOP) operating mode. You can use the "***Scroll***" soft key to go to individual menu items.

Every changed value is accepted directly without additional confirmation. The values of the previous application, with the exception of the dispensed cooling fluid quantity, are saved.

Figure 10

Overview of the setting options in the **Qiona**® *Setup menu*

5.3.2.1 Clear

This function allows you to reset the current volume indicator to "Zero" using the ***UP*** or ***DOWN button*** (similarly when switching the ***Qiona***® on and off).

5.3.2.2 Pressure – overpressure detection

This function allows you to set the sensitivity of the ***Qiona***® overpressure detection. Two options are available:

- Sensitive overpressure detection with the symbol  to be used for ablation catheters, which work with a relatively low working pressure due to a relatively large flush tube diameter. In this setting, the HIGH flow output range of up to a maximum of 50 ml/min is available.
- Normal overpressure detection (default value) with the symbol  to be used for ablation catheters with smaller flush tube diameters and, therefore, higher working pressure. In this setting, the HIGH flow output range of up to a maximum of 35 ml/min is available.

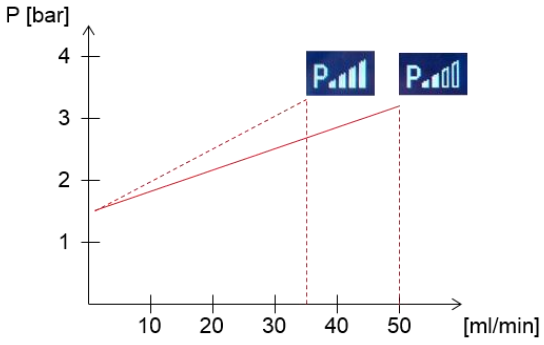


Figure 11

Overview of the setting options for **Qiona**® *overpressure detection*

5.3.2.3 Size

This function defines the volume of the infusion bottles or containers.

- Range of values : off – 5,000 ml
- Step size in change of volume : 250 ml
- Default value : off

If the volume setting is 0 ml, the "off" text appears instead of the figure with the unit of measure. The indication of infusion volume is deactivated during the application.

5.3.2.4 Alarm at

- Range of values : off – 50%
- Step size in change of residual volume indication : 5%
- Default value : off

If the volume setting is 0 ml (display "off"), this parameter will be deactivated and therefore no longer be visible to the user. As soon as the volume setting is > 0 ml, this parameter will be shown on the display again.

5.3.2.5 HIGH flow – delay

You can set an overrun time using this function. When the ***Qiona***® volume flow is switched from HIGH to LOW flow, it remains in HIGH flow mode for the duration programmed as parameters below.

- Range of values : 0 s – 15 s
- Step size : 1 s
- Default value : 3 s

If the overrun time is set to 0 s, the "off" text will appear instead of the figure with the unit of measure and the overrun time will be deactivated.

5.3.2.6 Display brightness

You can set the brightness of the display using this function.

- Range of values : 10% – 100%
- Step size : 5%
- Default value : 50%

The minimum display brightness is limited to a lower value to ensure that the ***Qiona***® remains operable at any setting.

5.3.2.7 Display contrast

You can set the contrast of the display using this function.

- Range of values : 10% – 100%
- Step size : 5%
- Default value : 50%

5.3.2.8 Service

Setup for the Service menu. This function is reserved for use by the manufacturer.

5.3.2.9 Exit Setup menu

On pressing the "***EXIT***" soft key, the device changes to STOP mode.

5.4 Opening the front panel

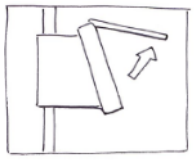
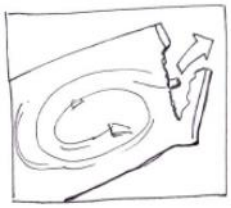


Figure 12

- To open the front panel, reach under the front panel and pull it up until it engages. When the front panel is open, the pump stops.

5.5 Taking out the Qiona® Tube Set incl. Extension



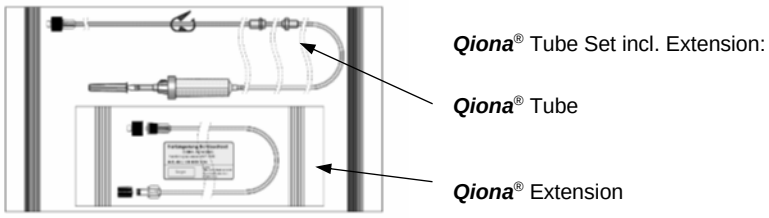


Figure 13
Qiona® *Tube Set incl. Extension*

Open only the **outer** package of the ***Qiona***® Tube Set incl. Extension tube set.

5.6 Inserting the Qiona® Tube

- Insert a new, sterile tube set for each new application in order to prevent patient infection, for example.
- Check the original packed and undamaged tube set for use-by date prior to application.
- Properly remove the tube set from the sterile packaging.

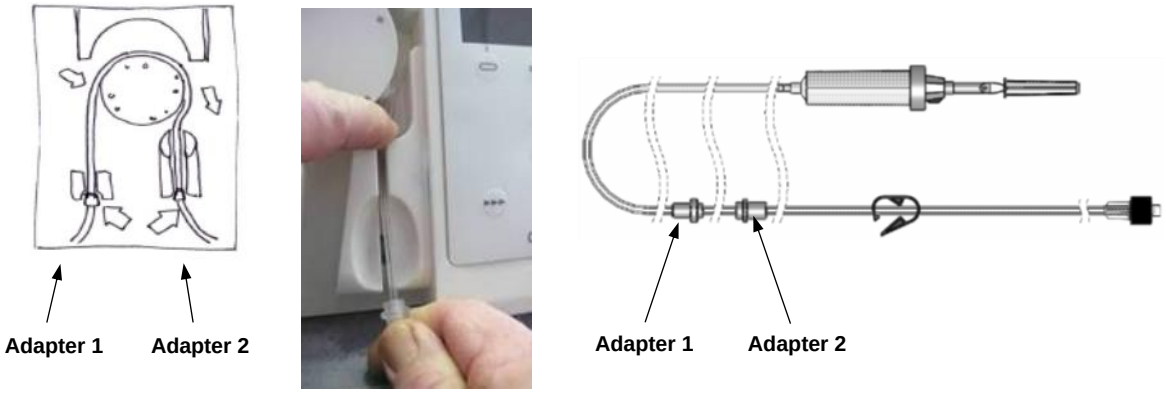


Figure 14
Inserting **Qiona**® *Tube*

1. Insert Adapter 1 (the adapter that is closest to the drip chamber) into the ***Qiona***®.

   The ***Qiona***® adapter entry points are uniquely designed to fit only the proper adapter.

2. Hold Adapter 2 in your right hand and insert the tube over the rotor into the ***Qiona***®. Press the tube behind the rotor, downwards, with your left index finger (see *Figure 14*). At the same time, using your right hand, while holding Adapter 2, pull the tube through the right slit in the Adapter 2 entry point.

   Make sure that the tube is inserted as deeply as possible into the slit. If the tube does not sit deeply enough in the air bubble sensor intake point, the air bubble sensor will signal falsely detected air bubbles. If the sensor falsely indicates the detection of air bubbles, reinsert the already filled tube set. Ensure that the tube is inserted deeply enough into the air bubble sensor intake point that the sensor LED indicator turns green.

5.7 Closing the front panel

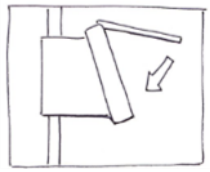


Figure 15

- After inserting the tube into the ablation Irrigation pump, close the front panel.

5.8 Connecting the infusion container or infusion bottle

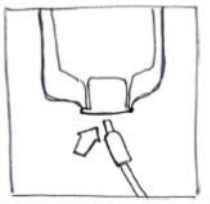


Figure 16

- Hold the drip chamber in your hand and remove the protective cap.
- Pierce the drip chamber into the infusion container or infusion bottle containing the intended liquid.

The drip chamber must always hang freely and vertically to avoid any air bubbles.

5.9 Taking out the Qiona® Extension

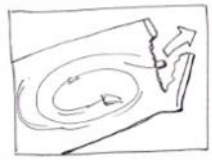


Figure 17

- Remove the "***Qiona***® Extension" tube extension from the sterile packaging.

5.10 Connecting the ablation catheter

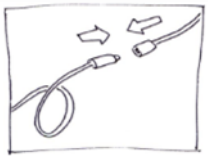


Figure 18

- Remove the protective caps of the Luer connector and establish a sterile tube connection between the pump segment and the applicator.

Only cooled ablation catheters with various curve configurations can be connected to the ***Qiona***®. They must have a Luer-lock connector (female) in accordance with EN 1707:1996 to connect to the ***Qiona***® Tube Set. They must also have a thermocouple for temperature monitoring, which must always be used when operating the ***Qiona***®, allow a flow rate of up to 50 ml/min, and withstand a maximum pump delivery pressure of 7.3 bar. In addition, the connected ablation catheter should have a lower working pressure, less than 1.5 bar at 1 ml/min and less than 3.3 bar at 35 ml/min (normal overpressure detection) or 3.2 bar at 50 ml/min (sensitive overpressure detection) (see diagram in Section 5.3.2.2 Pressure – overpressure detection). The specifications of the ablation catheter can be found in its technical manual or can be obtained from the manufacturer. If the specification of the ablation catheter is unclear, do not use it.

5.11 Performing rinsing process

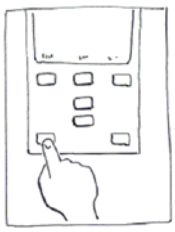


Figure 19

- Keep the ***RINSE button*** pressed continuously to rinse or vent the entire tube system along with the connected ablation catheter.

The display changes to Rinse mode. If the ***RINSE button*** is pressed, the pump will function at maximum capacity of 50 ml/min to vent the tube set as well as the ablation catheter.

- End the rinsing process by releasing the START-STOP key.

The pump changes to Stop mode.

The user must use their judgment to continue the rinsing process until it is certain that there is no air present in the tube system and in the ablation catheter. During the rinsing process, the air bubble sensor is deactivated so that no alarm signal is triggered. The green LED of the air bubble sensor indicates that there are no air bubbles present within the range of the sensor and the tube set is firmly fitted in the intake point of the air bubble sensor.

If the air bubble sensor LED does not turn green after the tube set has been vented, despite the fact that the tube set does not indicate any air bubbles, pull the filled tube set once again firmly into the air bubble sensor intake point until the sensor LED displays green.

The pressure monitoring sensor is active during the rinsing process. If overpressure is detected, a visual and audible alarm signal is activated, and the pump stops immediately.

If the ***RINSE button*** (see *Figure 20*) is released, the rinsing process is ended and the pump again changes to the Stop mode (see *Figure 21*).

Figure 20

Rinsing process

Figure 21

Stop mode

5.12 Starting application

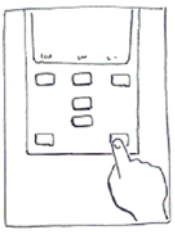


Figure 22

- Start the application by pressing the ***START-STOP key*** once.

Figure 23

With a manual start, the ***Qiona***® switches the pumping process to the LOW flow range. The LOW flow value is highlighted and the ***Qiona***® pumps the set volume. The flashing green arrows at the top of the display indicate the pump flow of the ***Qiona***®.
If power supply to the switched-on ***Qiona***® is interrupted during application, a continuous tone is emitted for at least 2 minutes as an information signal indicating this interruption.
If an HF signal is detected during start-up by the RF current sensor, the ***Qiona***® immediately switches over to the HIGH flow range.

Figure 24

If the "Size" and "Alarm at" functions are set in the Setup menu, a blue bottle will appear on the top left corner of the display. The blue bottle reflects the current fill level of the infusion container or bottle, provided that the total volume has been entered correctly in "Size" in the Setup menu. The digital displayed value next to the Patient symbol shows the current volume indicator of the added saline solution.

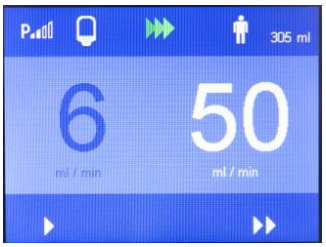


Figure 25

The switch-over from LOW to HIGH flow volume, as well as back to LOW flow, is done by means of:

- the ***Qiona***® soft keys or
- the optional foot switch (***Qiona***® Foot Switch) or
- the optional RF current sensor (***Qiona***® AutoFlow Sensor)

or the optional remote control (Qubic RF).

Switch-over options

Switch-over using soft keys:

By using the "***HIGH Flow***" soft key, the flow can be switched from LOW flow to HIGH flow. The ***Qiona***® will immediately switch to the set HIGH flow. The set value is highlighted. By pressing the "***LOW Flow***" soft key, the flow can be switched back to LOW flow again.

Switch-over by means of remote control:

The ***Qiona***® (REF 406935 and REF 406938) can be controlled remotely by the Qubic RF high-frequency unit. Connect the ***Qiona***® to the Qubic RF high-frequency unit in accordance with *Section 0*.

Switch-over by means of foot switch (***Qiona***® Foot Switch)

By using the optional foot switch, which can be connected to the back side of the ***Qiona***®, flow can be switched from LOW flow to HIGH flow and back again.
When you press the foot switch button, the ablation irrigation pump immediately switches to the set HIGH flow value. The set value is highlighted on the display.
When you release the foot switch, the ***Qiona***® switches back to LOW flow.

Switch-over by means of an RF current sensor (***Qiona***® AutoFlow Sensor):

The optional RF current sensor, which can be connected to the back side of the ***Qiona***®, can be used to automatically switch the flow in the ***Qiona***® from LOW flow to HIGH flow and back again, according to the flow required for the ablation.
Clamp the RF current sensor to the connecting cable between the HF generator and the ablation catheter. The green LED of the RF current sensor indicates that the system is ready for operation. The ***Qiona***® immediately switches to the set HIGH flow for as long as the RF current sensor detects a continuous HF signal. A yellow LED indicates that the RF current sensor has detected an HF signal. As soon as the HF signal stops, the flow will either be immediately switched back to LOW or will do so after the overrun time, if set.
Ensure that the RF current sensor does not lie on the floor and is firmly attached to the connecting cable.

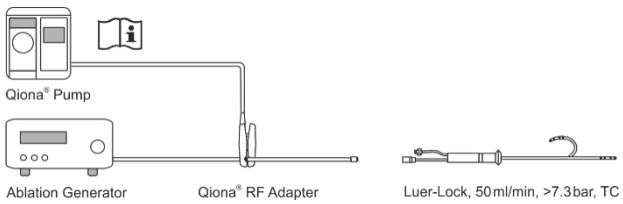


Figure 26
Configuration with the RF current sensor
*(**Qiona**® AutoFlow Sensor)*

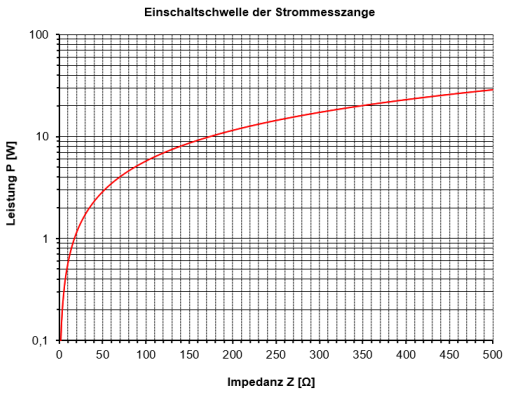


Figure 27
Activation threshold of the RF current sensor
*(**Qiona**® AutoFlow Sensor)*

The activation threshold of the RF current sensor is defined in the above graph.
The graph shows the combinations of impedance Z and performance output P required to ensure a definite activation. Only the combinations above the curve will result in the switch-over from LOW to HIGH flow. A further prerequisite is that the RF generator operates with a frequency of approx. 500 kHz (± 10%).

Overrun time function

An overrun time of max. 15 seconds can be set for the switch-over from HIGH flow to LOW flow in the ***Qiona***® Setup menu.
The overrun time is activated when the ***Qiona***® is switched from HIGH to LOW flow by means of the RF current sensor signal, the foot switch, or a manual operation on the keypad. During the overrun time the ***Qiona***® continues to pump according to the set HIGH flow for a time (max. 15 seconds) preselected in the Setup menu and it automatically switches to LOW flow when this overrun time expires. However, during the overrun time interval, the ***Qiona***® accepts the following user commands and executes them:
Commands issued by pressing the soft keys on the ***Qiona***® keypad always have priority over the RF current sensor signal or the foot switch signal. If the ***Qiona***® receives a signal for HIGH flow from the foot switch or the RF current sensor during the overrun time, it will immediately switch back to HIGH flow mode. To override the overrun time, press the "***LOW Flow***" soft key on the ***Qiona***® keypad during the overrun time period.
The overrun time should be at least 1 to 5 seconds in order to avoid switch-over of the ***Qiona***® for brief periods due to generator transients.

Volume indicator function

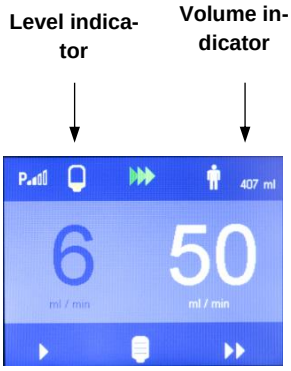


Figure 28

If the "Size" and "Alarm at" functions are activated in the Setup menu, the rinsing fluid level will appear on the display. The four segments of the level indicator each represent a quarter of the bottle volume, less the residual volume.
For example, in the case of a 500 ml bottle and 100 ml residual volume, the four segments constitute a volume of 400 ml. In this case, each segment in the display corresponds to 100 ml.
When the ***Qiona***® reaches the set rinse fluid residual volume, a visual and audible signal is emitted. The rinse fluid residual volume is indicated in yellow on the displayed bottle. The corresponding reminder signal is in the form of an audible tone sequence "a - a".
A new bottle in the form of a soft key button appears simultaneously at the bottom of the display field.
Press this soft key button after replacing the bottle. This will cause the level indicator to be reset to a full bottle and the volume indicator to continue measuring the added rinse fluid. If the button is pressed, the displayed white bottle will again disappear.
To replace the bottle, the drip chamber must be switched over to a new full bottle. During this process, it is possible that an air bubble will enter the tube system. In this case, the ***Qiona***® will immediately stop and the application must be interrupted.
While switching the drip chamber, always ensure that it is still well filled while replacing.

5.13 Connecting Qiona® to Qubic RF high-frequency unit

The ***Qiona***® has a binary RS232-1 interface at the rear for connecting the Qubic RF Generator by BIOTRONIK SE & Co. KG. Using the Qubic RF software, the ***Qiona***® (REF 406935 and REF 406938) can be controlled remotely and the settings, such as flow rate of the cooling fluid in relation to the ablation energy used, can be adjusted from the Qubic RF. The overrun time for the increased flow rate of the cooling fluid can also be set on the high-frequency unit.

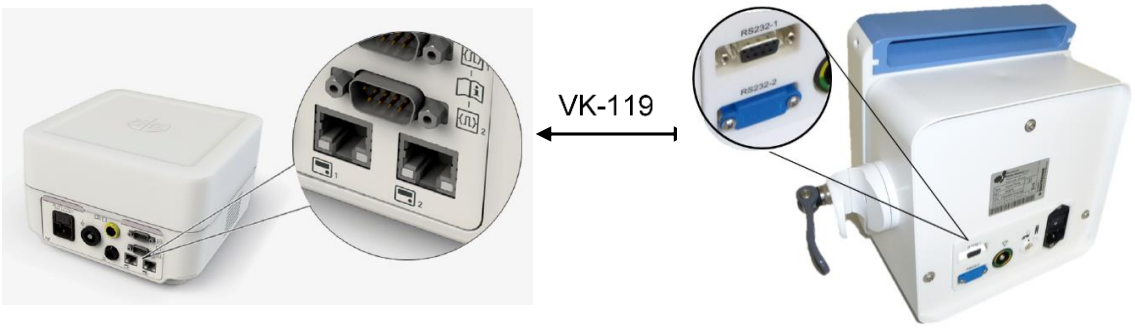


Figure 29

Rear view of the Qubic RF high-frequency unit (left) and the **Qiona**® *with connectors (right)*

To use the ***Qiona***® ablation irrigation pump in combination with the Qubic RF, proceed as follows:

1. Connect the VK-119 data cable to the binary interface 2 (9-pin D-Sub RS-232 connector port) located on the rear of the Qubic RF high-frequency unit. Please consult the technical manual of the Qubic RF for this. Observe the warnings in the chapter 4.3 on connecting the cables.
2. Connect the VK-119 data cable to the binary interface RS232-1 (upper connector port) located on the rear of the ***Qiona***® ablation irrigation pump.
3. Prepare the ***Qiona***® in accordance with *Section 5.1* to *Section 5.12*. At the end of the preparation, it is important to start the ***Qiona***® in the LOW flow output range by pressing the START-STOP key.
4. Take control over the ***Qiona***® by pressing the relevant switch on the control unit of the Qubic RF high-frequency unit. Please consult the technical manual of the Qubic RF for this.

As long as the ***Qiona***® is controlled by Qubic RF, all ***Qiona***® indications on the display are greyed out to show the remote-controlled state and the following symbol appears on the ***Qiona***® display:

Figure 30

Symbol on the **Qiona**® *display when remotely controlled by Qubic RF*

After an infusion bottle or an infusion container has been replaced, you can continue by pressing the ***Qiona***® confirmation key. If you want to end the ***Qiona***® remote control mode, this can be done any time by pressing the ***START-STOP key*** on the ***Qiona***®. All other ***Qiona***® operating elements are deactivated in the remote-control mode.
The ***Qiona***® automatically ends the remote-control operating mode when there is an alarm condition present on the ***Qiona***® (see also *Section 6*).

Risk of exceeding the leakage currents when connecting external devices with own power supply or an electrically conductive connection to other devices

- Only connect devices that are compliant with the IEC 60601-1 or IEC 60950 standards to the binary interfaces 1 and 2 (RS-232 port).
- Before starting up for the first time, inspect and document all device combinations according to the IEC 60601-1 standard.
- Perform this inspection at least once per year according to legal requirements.

5.14 Ending application

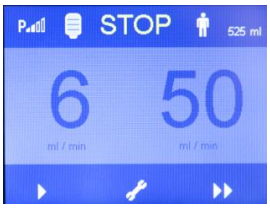


Figure 31

- End the application by pressing the ***START-STOP key*** again.

5.15 Switching off Qiona®

- To switch the ***Qiona***® off, use the ***ON/OFF switch*** at the rear of the device. All set ***Qiona***® values are retained for the next application.
- Dispose of the used single-use tube set in accordance with your hygiene regulations (see also *Section 1.7*).
- Even if you have not used the "***Qiona***® Extension" tube extension, you must still dispose of it.

5.16 Disconnecting Qiona® from the power supply

- Disconnect the power cord from the electrical power outlet and thus disconnect the ***Qiona***® from the power supply.

6 Alarm Signals and Corrective Measures

6.1 Presence of an alarm condition

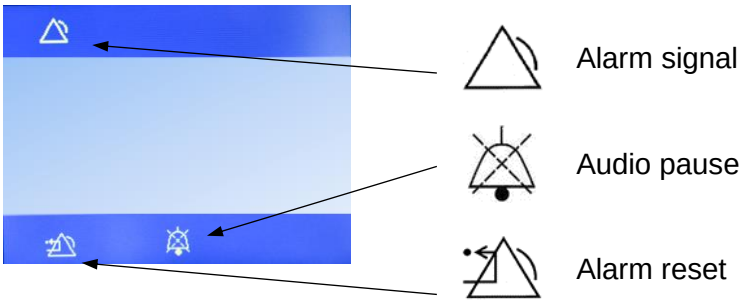


Figure 1
Display layout in an alarm condition

If an alarm condition is present, it will be visible on the display through an appropriate indication (see *Section 0*) and an LED that displays yellow. An audible alarm signal is simultaneously emitted with the tone sequence "e - c".

The audible signal can be turned off for a duration of 2 minutes by pressing the "***Audio pause***" soft key.

By using the "***Alarm reset***" soft key, the user acknowledges that the cause of the generated alarm signal has been rectified. The ***Qiona***® returns to the basic setting, and the application can be continued.

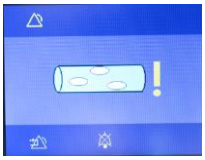
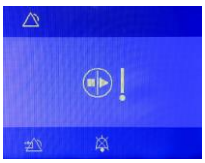
The ***Qiona***® immediately stops when any alarm condition is present.

6.2 Testing the alarm functions

If the ***Qiona***® is turned on at the power switch, a short beep is emitted, and the yellow LEDs briefly light up. Further, a function test is performed. An audible information signal is emitted for this, and the software versions of the main controller (FwM) and the watchdog controller (FwW) are briefly shown on the display.

Based on the risk assessment, the ***Qiona***® alarm concept is designed in such a way that whenever there is an alarm condition during normal use, the user is always reached by visual and audible alarm signals (i.e., the user must always be within the hearing and/or visual range). The ***Qiona***® is designed with a technical alarm condition. The alarm condition priority is set to "Low priority" for all alarm conditions. The ***Qiona***® emits visual and audible alarm signals.

6.3 Alarm system overview

Technical alarm conditions	Alarm limit	Alarm condition delay	Alarm signal emission delay	Alarm signal	Alarm signal description on the display	Audio pause
Air bubble detected	Air bubble > 2 µl	< 5 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Tube overpressure detected	Tube internal pressure > 2.5 bar	< 5 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Front panel of *Qiona*® open	Front panel > 8° open	< 50 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Error in cable connection to foot switch (*Qiona*® Foot Switch)	Cable connection to foot switch interrupted	< 100 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Error in cable connection to RF current sensor (*Qiona*® AutoFlow Sensor)	Cable connection to RF current sensor interrupted	< 100 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Error in the cable connection to Qubic RF high-frequency unit	Serial data line to Qubic RF interrupted	< 600 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Error RF detected and application not yet started	***Qiona*®** in Stop mode during HF energy delivery (only with AutoFlow Sensor)	< 100 ms	<= 250 ms (periodic evaluation of alarm conditions)	Audible/ Visual		Yes
Internal safety measures following hardware and software tests  **-double safety-**	Example: E10 – Communication error Watchdog – Air bubble sensor	Not applicable	<= 5 s (periodic evaluation of system test functions)	Audible/ Visual		Yes

In the event of such an alarm condition, the *Qiona*® must be tested by the Technical Service.

6.4 Troubleshooting

This section shows some of the problems that may occur in connection with ***Qiona***®.
For each problem, several possible solutions are listed. These suggestions should be carried out in the order they are listed until the problem is remedied. When detaching or connecting the plug connections, apart from the tube set, always ensure that the ***Qiona***® is switched off. **If the suggested solutions do not remedy the problem, the defect must be rectified by the BIOTRONIK Service Center.**

Problem	**Solution**
Not functioning, the display is off or the ***Qiona***® does not turn on.	The ***Qiona***® is not connected to the power supply properly. Check the power supply; connect a multiple socket outlet and check the supply lines.
Continuous beep during the application of ***Qiona***®.	Power supply interrupted. Reinsert the power plug into the electrical power outlet.
Problem due to humidity ingress into the plug connection.	Remove the power plug and allow the plug connections to dry out.
After rinsing the tube set, air bubble alarm occurs, even though there are obviously no air bubbles present in the tube set.	Correct the position of the already filled tube set. To do this, open the flap and reinsert the tube set. Ensure that the tube set is inserted deeply enough into the air bubble sensor that the sensor LED indicator turns green.
Overpressure is detected though no obvious obstruction is present.	Check whether the suggested overpressure detection has been selected in the Setup menu for the ablation catheter being used by you (see *Section 5.3.2.2*).
Green LED of the RF current sensor does not turn on, even though it is firmly clamped onto an ablation catheter cable.	Make sure that the ablation catheter cable is fully surrounded, and the RF current sensor is closed.

The ***Qiona***® must not be opened by the user!

6.5 Service

If no solution can be found for a problem, please contact the responsible BIOTRONIK Service Center.
Each time the ***Qiona***® is returned, any possible risk of infection must be eliminated by a suitable disinfection procedure. Consumables must be disposed of in accordance with the hygiene regulations.

Never open the device when it is connected to the electrical power supply. Beware that even when disconnected from the power supply, the internal parts of the device may still be energized.
Warning: This device must not be modified without the permission of the manufacturer!

6.6 Description of the alarm system

Terms	Definitions	Applicability to *Qiona*®	Explanation
Alarm condition	Condition of the alarm system once it has been determined that there is a possible or a real risk.	• Air bubble • Overpressure in the tube system • Front panel not closed • Motor jam • Foot switch connection disrupted • RF current sensor connection disrupted • In case of technical faults/errors, please contact Technical Service	
Alarm condition delay	The time between occurrence of a triggering event either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), until the alarm system determines that an alarm condition exists.	No setting possible	
Alarm limit	Threshold value, which is used by an alarm system to determine an alarm condition.	• Air bubble > 2 micro litres • Tube internal pressure > 2.5 bar • Front panel open > 8° • No connection to the foot switch • No connection to the RF current sensor	
Alarm OFF	Condition of indefinite duration in which an alarm system or a part of an alarm system does not generate any alarm signals.	No setting possible	

Alarm Signals and Corrective Measures

Terms	Definitions	Applicability to *Qiona*®	Explanation
Alarm presetting	A set of saved configuration parameters, including the selection of algorithms and initial values to be used by algorithms, which affect or change the functioning of the alarm system.	No setting possible	
Alarm settings	Alarm system configuration, including but not restricted to: alarm limits, properties of all conditions of alarm activation, and values of parameter variables, which determine the function of the alarm system.	No setting possible	
Alarm signal	Signal type created by the alarm system to indicate the existence (or the occurrence) of an alarm condition.	• Visual alarm signal by yellow LED on the keypad • Visual alarm signal through the display • Audible alarm signal, which has a noise pressure level of 55 dB(A) at 1-meter distance	
Delay in alarm signal emission	Time from the start of the alarm condition to the emission of the alarm signal.	No setting possible	
Audio OFF	Condition of indefinite duration in which an alarm system or a part of the alarm system does not generate any audible alarm signals.	No setting possible	Refers to all alarm conditions that are active at the time when the button is pressed.
Audio pause	Condition of definite duration in which an alarm system or a part of the alarm system does not generate any audible alarm signals.	2 minutes	Refers to all alarm conditions that are active at the time when the button is pressed.
De-escalation	The process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	Does not apply	
Escalation	The process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	Does not apply	
False negative alarm condition	Absence of alarm condition, when a valid triggering event has occurred in the patient, in the device, or in the alarm system.	Double safety	

Alarm Signals and Corrective Measures

Terms	Definitions	Applicability to *Qiona*®	Explanation
False positive alarm condition	Presence of an alarm condition, when no valid triggering event has occurred in the patient, in the device, or in the alarm system.	Results in safe condition of the device	
Information signal	Every signal which is not an alarm signal or a reminder signal.	Applies	
Recurring alarm signal	Alarm signal which continues to be emitted even after its triggering event no longer exists, until it is stopped by a deliberate user action.	Applies	
Non-recurring alarm signal	Alarm signal which automatically stops being emitted once the associated triggering event no longer exists.	Does not apply	
Physiological alarm condition	Alarm condition originating from a monitored, patient-related variable.	Does not apply	
Technical alarm condition	Alarm condition originating from a monitored, device-related or alarm-system related variable.	Applies	
Alarm reset	Action performed by user to cancel an alarm signal for which there is currently no associated alarm condition.	Applies	

7 Cleaning and Maintenance

7.1 Cleaning and disinfection

- The inside of the equipment must not get wet.
- Disconnect the power plug before cleaning and disinfecting the device surfaces.

- Use a lint-free soft cloth for cleaning. Dampen the lint-free, soft cloth with a mild soap solution or 70% isopropyl alcohol and clean.
- After cleaning, disinfect the surfaces of the devices using a solution of 70% isopropyl alcohol and 30% water. Lysoformin 3000: 2% concentration, allow 15 minutes for it to take effect. The cleaning and disinfecting solutions must have evaporated before the devices are used.

Visual inspection:

Ensure that the ports for all connections and the plugs for the cables to be connected are free of any type of dirt.

7.2 Maintenance

This device must not be modified without the permission of the manufacturer!

Only BIOTRONIK or a company expressly authorized by the manufacturer may perform corrective maintenance, enhancements, or modifications to the ablation irrigation pump system. If an expressly authorized company performs any task, then the work must be documented in a dated and signed report. Modifications to the equipment by unauthorized third parties are not permitted.

7.3 Periodic technical safety checks

Perform technical safety checks on the ***Qiona***® at least every 12 months in accordance with the Medical Devices Operator Ordinance (German: Medizinprodukte-Betreiberverordnung – MPBetreibV). The ***Qiona***® falls under Annex 1 (1.4) of the Medical Devices Operator Ordinance.
If the device is not functionally and/or operationally safe, have it immediately serviced by Device Service.
For technical safety checks, contact the responsible BIOTRONIK Service Center.

7.4 Disposal

These devices contain 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 (WEEE2) applies to these devices. They are marked with the symbol of a crossed-out garbage can on their type plate.

Return devices that are no longer being used to the local BIOTRONIK representative (in reprocessed condition). This ensures that proper disposal will be carried out in accordance with the national implementations of the WEEE directive.
Please contact your BIOTRONIK representative if you have any questions.

8 Appendix

8.1 Mechanical characteristics

General characteristics:

Order numbers	REF 363270, 406935, 406938
Dimensions of ***Qiona***®	Width x height x depth: 225 mm x 240 mm x 170 mm
Weight	Approx. 5 kg
Noise pressure level	56 dB(A) at output of 30 ml/min
Minimum service time	8 years
Electrical connection:	
Voltage	100–240 V AC (AC voltage)
Frequency	50–60 Hz
Current consumption	0.7–0.3 A
Fuse	T 3.15 A / 250 V, not interchangeable, contact Technical Service
Protection class	I
Degree of protection	IP 51
Defibrillator-proof type CF applied part	***Qiona***® Tube Set incl. Extension
Transport and storage requirements:	
Temperature	-10°C to +50°C
Humidity	0% to 90% relative humidity
Weight with package	Approx. 6 kg
Dimensions of ***Qiona***® with package	Width x height x depth: 450 mm x 400 mm x 475 mm

Store the packaged device in a dry place.

A stack of packaged devices may comprise a maximum of 3 packages.

Operating conditions:	
Temperature	+10°C to +40°C
Humidity	30% to 75% relative humidity
Maximum altitude	2,000 m (corresponds to minimum 80 kPa)
Specific characteristics:	
Delivery rate of ***Qiona***®	1 ml/min – 50 ml/min (normal overpressure detection up to a max. 35 ml/min)
Working pressure range	0 bar – 3.5 bar
Dynamic pressure switch off	Approx. 2 bar above working pressure
Air bubble sensor accuracy	Detection > 2 micro litres

Appendix

Output accuracy*	-10% to +20% of the output range end value at 1 to 5 ml/min
	-5% to +10% of the output range end value at 5 to 30 ml/min
	-10% to +20% of the output range end value at 30 to 50 ml/min

*The output accuracies mentioned here are based on the Flux catheter of VascoMed and the TactiCath catheter of St. Jude.

The ***Qiona***® is subject to special precautionary measures with regard to electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the present EMC instructions.

The ***Qiona***® must not be used in an arrangement that places it directly next to or stacks it with other devices.

If it is necessary to operate it close to or stacked with other devices, the ***Qiona***® must be closely observed to check that it is operating properly in this arrangement.

A list of the accessories with which the ***Qiona***® meets the requirements of 6.1 and 6.2 of IEC 60601-1-2 is given in the Accessories appendix.

Operating the ***Qiona***® with additional accessories such as transducers or cables, which are not defined for the intended use with the device, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to interference.

9 Electromagnetic Compatibility

9.1 Electromagnetic emissions

The ***Qiona***® is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the ***Qiona***® should make sure that the ***Qiona***® is used in an electromagnetic environment as described below.

Measurement of emitted interference	**Compliance**	**Guidelines for the electromagnetic environment**
RF interference according to CISPR 11	Group 1	The ***Qiona***® uses RF energy exclusively for its own functioning. Therefore, its high frequency emission is very low, and it is unlikely that it will cause interference in the nearby electronic devices.
RF interference according to CISPR 11	Class B	For areas of application, see *Section 4.2* "Suitable operating environment ".
Emission of harmonic oscillations according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

9.2 Resistance to electromagnetic interference

Resistance test	IEC 60601 – test level	Compliance level	Electromagnetic environment / guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or cement or have ceramic tiles. When the floor consists of a synthetic material, the relative humidity must be at least 30%.
Fast transient electric interference / bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input and output lines	±2 kV for power supply lines ±1 kV for input and output lines	The quality of the supply voltage should correspond to that in a typical business or hospital environment.
Surge voltages (surges) IEC 61000-4-5	±1 kV push-pull voltage ±2 kV common-mode voltage	±1 kV push-pull voltage ±2 kV common-mode voltage	The quality of the supply voltage should correspond to that in a typical business or hospital environment.
Voltage drops, brief interruptions, and fluctuations in the supply voltage IEC 61000-4-11	< 5% U_T (> 95% dips of U_T) for 1/2 period 40% U_T (60% dips of U_T) for 5 periods 70% U_T (30% dips of U_T) for 25 periods < 5% U_T (> 95% dips of U_T) for 5 seconds	< 5% U_T (> 95% dips of U_T) for 1/2 period 40% U_T (60% dips of U_T) for 5 periods 70% U_T (30% dips of U_T) for 25 periods < 5% U_T (> 95% dips of U_T) for 5 seconds	The quality of the supply voltage should correspond to that in a typical business or hospital environment. If the user of the product requires the device to be used without interruption, even during interruptions in power supply, it is recommended that the device be supplied power from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the AC frequency should correspond to that in a typical business or hospital environment.
Comment: U_T is the alternating line voltage before applying the test levels.			

The ***Qiona***® meets all test levels according to IEC 60601-1-2 Edition 4 (Tables 4 to 9).

Electromagnetic Compatibility

The presence of electromagnetic interference may affect the essential performance characteristics of the ***Qiona***®. This is indicated by an information message from the ***Qiona***® and the activation of the peristaltic pump is interrupted.

Portable RF communications equipment (radio equipment) (including accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of the ***Qiona***® parts and wiring designated by the manufacturer. Failure to do so may reduce the performance characteristics of the equipment.

The requirements for aviation, transport, and military were not considered as they were not tested on the system.

9.3 Resistance to electromagnetic interference for non-life supporting devices

<table>
<tr><th>Resistance test/standard</th><th>IEC 60601 – test level</th><th>Compliance level</th><th>Electromagnetic environment / guidelines</th></tr>
<tr><td>Conducted RF interferences according to IEC 61000-4-6</td><td>3 V_{eff}
150 kHz to 30 MHz

6 V_{eff} in ISM and amateur radio frequency bands between 150 kHz and 80 MHz</td><td>3 V_{eff}

6 V_{eff}</td><td rowspan="2">The minimum Qiona® distance from portable and mobile radio devices, including the cables, should correspond to the recommended safe distance that is calculated according to the equation for the suitable transmission frequency.

Recommended safe distance:
$d = 1{,}2\sqrt{P}$ for 80 MHz to 800 MHz
$d = 2{,}3\sqrt{P}$ for 800 MHz to 2.5 GHz
with P as the nominal output of the transmitter in watts (W) according to the information from the transmitter manufacturer, and d as the recommended safe distance in meters (m).
The field strength of stationary transmitting devices should be measured on site [a] and must be lower than the compliance level at all frequencies [b].
Interference can occur in devices that have the following warning sign:
  </td></tr>
<tr><td>Radiated RF interferences according to IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz

Table 9 of IEC 60601-1-2 Ed. 4</td><td>3 V/m
80 MHz to 2.7 GHz

Table 9 of IEC 60601-1-2 Ed. 4</td></tr>
<tr><td colspan="4">Notes:
NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.
NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects, and humans.</td></tr>
<tr><td colspan="4">[a] The field strengths of stationary transmitters, such as base stations for cellular phones and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasts cannot be predicted, theoretically, with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site survey of the electromagnetic phenomenon should be considered. If the measured field strength at the site, where the Qiona® is used exceeds the above-mentioned applicable RF compliance level, the devices should be observed to verify normal functioning. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Qiona® to another site.
[b] Above the frequency range of 150 kHz to 80 MHz, ensure that field strengths are less than 3 V/m.</td></tr>
</table>

9.4 Recommended safe distance

See *Section 9.3 "Resistance to electromagnetic interference for non-life supporting devices*".

10 Accessories

- ***Qiona*® Tube Set incl. Extension**

  REF: 365775
  Weight: 90 g
  Overall Extension length: 1.5 m
  Overall Tube length: 3 m
  Length between the ***Qiona***® and the catheter connector:
  3 m (1.5 m Tube + 1.5 m Extension)


- ***Qiona*® Foot Switch ***

  REF: 406937
  Weight: 380 g
  Cable length: 5 m

- **Qiona® AutoFlow Sensor ***

  REF 406936
  Weight: 200 g
  Cable length: 4 m

- ***Qiona*® Pole Adapter Set**

  REF: 377184
  Weight: 25 g

- **VK-119**

  REF: 404966
  Weight: 140 g
  Cable length: 3 m

- **NK-03**

  REF: 107526
  Type F, Germany
  Designation: NK-3/2.5m

- **NK-11**

  REF: 128865
  Type B, USA
  Designation: NK-11/3m

Accessories

- **NK-16**

  REF: 330705
  Type G, Great Britain
  Designation: NK-16/2.0m GB

- **NK-19**

  REF: 339034
  Type I, China
  Designation: NK-19/2.5m CN

- **NK-20**

  REF: 339033
  Type F, Russia
  Designation: NK-20/2.5m HR/RU/SI

- **NK-21**

  REF: 339035
  Type I, Australia
  Designation: NK-21/2.5m AU/UY

- **NK-22**

  REF: 339039
  Type I, Argentina
  Designation: NK-22/2.5m AR

- **NK-23**

  REF: 339040
  Type B, Japan
  Designation: NK-23/2.4m JP

- **NK-24**

  REF: 339041
  Type M, India, South Africa
  Designation: NK-24/2.5m IN/ZA

- **NK-25**

  REF: 339042
  Type J, Switzerland
  Designation: NK-25/2.5m CH

Accessories

- **NK-26**
  REF: 339043
  Type L, Italy, Chile
  Designation: NK-26/2.5m CL/LT

- **NK-27**
  REF: 339044
  Type L, Israel
  Designation: NK-27/2.5m IL

- **NK-28**
  REF: 339059
  Type L, Denmark
  Designation: NK-28/2.5m DK

* Not available in the US.

11 Medizinproduktebuch (§7 MP BetreibV)

Allgemeine Angaben zur Gerätefamilie:

Betreiberadresse (Stempel):

Gerätebezeichnung:

***Qiona*®**

Produkte- / Geräteart:

Ablationskühlmittelpumpe

Standort:

Nummer nach Nomenklatur (DIMDI):

13-192

Kenn-Nr. der benannten Stelle:

0482 (MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)

Zuordnung zu den Anlagen der MPBetreibV:

MP nach Anlage 1	☒ ja
	☐ nein

MP nach Anlage 2	☐ ja
	☒ nein

Hersteller nach §7 MPG:

Möller Medical GmbH
Wasserkuppenstr. 29-31
36043 Fulda, Germany
Tel.: +49 661 94195-0
www.moeller-medical.com

Lieferant / Distributor:

Biotronik SE & Co. KG
Woermannkehre 1
12359 Berlin, Germany
Tel.: +49 30 68905-0
www.biotronik.com

Technische Daten:

☒ Aktives Medizinprodukt ☐ Medizinprodukt mit Messfunktion

Anwendungstyp:CF (IEC 60601-1 + A1:2012): Schutzklasse: I

Zubehör:

☐ ***Qiona*®** Foot Switch	REF: 406937
☐ ***Qiona*®** AutoFlow Sensor	REF: 406936
☐ ***Qiona*®** Tube Set incl. Ext.	REF: 365775
☐ ***Qiona*®** Pole Adapter Set	REF: 377184

Bestehende Verträge (falls vorhanden) zur Durchführung der Sicherheitstechnischen Kontrollen:

Medizinproduktebuch (§7 MP BetreibV)

☒ Sicherheitstechnische Kontrollen	
alle 12 Monate durchzuführen!	
Firma:	

Verantwortlicher des Betreibers:

☐ Beauftragung eines für den Betrieb des Medizinproduktes Verantwortlichen durch den Betreiber.

Am: _____ _____ _____

Datum | Name/Unterschrift des Beauftragten | Tel. -Nr. des Beauftragten

Dokumente:

Aufbewahrungsort der Gebrauchsanweisung:

Einweisung des Verantwortlichen:

☐ **Einweisung der/des vom Betreiber Beauftragten (Anwender) durch den Hersteller/Lieferant**

für baugleiches Medizinprodukt unter Berücksichtigung der Zweckbestimmung, des verwendeten Zubehörs, der Kombination mit anderen Produkten anhand der Gebrauchsanweisung und der sicherheitsbezogenen Informationen.

Am: _____ _____

Datum | Name / Institut / Unterschrift Beauftragter (Anwender)

Am: _____ _____

Datum | Name / Firma / Unterschrift des Einweisenden

Medizinproduktebuch (§7 MP BetreibV)

Gerätebezeichnung:	***Qiona®***
Seriennummer:	

Meldung über Vorkommnisse:

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM):
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Telefon: +49-(0)228-99 307 - 0
Telefax: +49-(0)228-99 307 - 5207

Ursache / Art

Im Medizinproduktebuch sind folgende Vorkommnisse einzutragen:

F - Funktionsstörung
B - Wiederholte gleichartige Bedienungsfehler
Ä - Änderung der Merkmale oder Leistungen
U - Unsachgemäßheit der Kennzeichnung oder der Gebrauchsanweisung

Folgen

Bei einer der hier aufgeführten Folgen muss eine Meldung an das BfArM erfolgen.

zum Tod		**zur schwerwiegenden Verschlechterung des Gesundheitszustandes**	
T	- geführt hat	**V**	- geführt hat
mT	- geführt hätte	**mV**	- geführt hätte

Durchgeführt am Vorgangs-Nr.	**Ursache / Art des Vorkommnisses (F, B, Ä, U) + Gerätenummer!**	**Beschreibung des Vorkommnisses eingeleitete, sicherstellende Maßnahmen** [1]	**Festgestellt von**	**Folge des Vorkommnisses (T, mT, V, mV)**	**Gemeldet an BfArM durch Betreiber oder Anwender** [2]
Datum Uhrzeit Vorg.-Nr.			Name Unterschrift		☐ ja ☐ nein Datum Unterschrift
Datum Uhrzeit Vorg.-Nr.			Name Unterschrift		☐ ja ☐ nein Datum Unterschrift
Datum Uhrzeit Vorg.-Nr.			Name Unterschrift		☐ ja ☐ nein Datum Unterschrift
Datum Uhrzeit Vorg.-Nr.			Name Unterschrift		☐ ja ☐ nein Datum Unterschrift

[1] Als sicherstellende Maßnahme wird die Hinzuziehung eines unabhängigen Sachverständigen empfohlen.

[2] Meldeformular nach DIMDI verwenden.

Medizinproduktebuch (§7 MP BetreibV)

Gerätebezeichnung:	***Qiona®***
Seriennummer:	

Sicherheitsrelevante Erstmesswerte nach IEC 62353			
Schutzleiterwiderstand:	Ω	Ableitstrom vom Anwendungsteil, Ersatzmessung:	µA
Geräteableitstrom, Ersatz:	µA	Ableitstrom vom Anwendungsteil Netz am AW, Direkt:	µA

☐ Funktionsprüfung / Inbetriebnahme am Betriebsort

Am:

Datum _____ Name / Institut / Unterschrift _____

☐ Sicherheitstechnische Kontrollen

Durchgeführt am **Vorgangs-Nr.**	**STK durchgeführt durch**	**Nr. des Prüfprotokolls**	**Ergebnis**			**Nächste Kontrolle MM/JJ**
			Keine Mängel	**Keine sicherheitserheblichen Mängel**	**Wartung/ Instandsetzung erforderlich**	
Datum Vorg.-Nr.	Anschrift Firma / Institution:	Name Durchführender:				
Datum Vorg.-Nr.	Anschrift Firma / Institution:	Name Durchführender:				
Datum Vorg.-Nr.	Anschrift Firma / Institution:	Name Durchführender:				
Datum Vorg.-Nr.	Anschrift Firma / Institution:	Name Durchführender:				
Datum Vorg.-Nr.	Anschrift Firma / Institution:	Name Durchführender:				

Medizinproduktebuch (§7 MP BetreibV)

Gerätebezeichnung:	***Qiona®***
Seriennummer:	

Weitere Instandhaltungsmaßnahmen

Bestehender Instandhaltungsvertrag

I = Inspektion, Feststellung des Ist-Zustands
W = Wartung, Bewahrung des Soll-Zustands
R = Reparatur, Wiederherstellung des Soll- Zustands

Art des Vertrages:	Kosten:	Name und Anschrift der Firma:
Vertragsnummer:	Kündigungsfrist:	
Laufzeit des Vertrages:	Leistungsumfang, Notizen:	

Durchgeführt am Vorgangs-Nr.	**Maßnahme durchgeführt durch**	**Art (I, W, R)**	**Nummer des Serviceberichts**	**Bemerkungen / Maßnahmen**
	Anschrift Firma / Institution:			
Datum		Name Durchführender:		
Vorg.-Nr.				
	Anschrift Firma / Institution:			
Datum		Name Durchführender:		
Vorg.-Nr.				
	Anschrift Firma / Institution:			
Datum		Name Durchführender:		
Vorg.-Nr.				
	Anschrift Firma / Institution:			
Datum		Name Durchführender:		
Vorg.-Nr.				

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