Operating instructions

Qiona® **Ablation irrigation pump**





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General safety instructions

Explanation of safety symbols used

In the present operating instructions visual symbols are used to highlight important instructions. These references are prerequisites for preventing hazards to patients and operating personnel, as well as for avoiding damages or malfunctioning of the device.

Symbols used in the operating instructions:



Symbols appearing on the device:

	Applied part CF (defibrillation-proof)
(E ₁₂₇₅	Conformity with Medical Device Directive EEC 93/42
\sim	Alternating voltage
X	Return and disposal according to WEEE Directive
	Foot switch connection (Qiona [®] Foot Switch)
A	RF current sensor connection (Qiona® AutoFlow Sensor)
Δ	Equipotential cable connection

Symbols appearing on the ablation irrigation pump:

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\bigtriangleup	Alarm signal
\bowtie	Alarm signal deactivation "AUDIO PAUSE"
·Z	Alarm signal reset
L.	Setup menu
İ	Patient symbol

Qiona[®]

General safety instructions

	LOW flow rate
	HIGH flow rate
	Maximum flow rate in rinse function
	Infusion bottle/container level indicator
	Infusion bottle/container change confirmation button
Patt	Normal overpressure detection active
Padd	Sensitive overpressure detection active
ΎΞ	Scroll through Setup Menu
	Exit Setup Menu
Symbols appearing or	n the packaging:
ĺĺ	Observe operating instructions
REF	Order Number
LOT	Lot Number
SN	Serial Number
++	Unit quantity in packaging
	Expiration date
STERILE EO	Sterilised with ethylene oxide
(Single use
STERNIZE	Do not resterilise
	Do not use if packaging is damaged
Ť	Store in a dry place
	Manufacturer
	Distributor
k >	Overall length

General safety instructions

A thorough knowledge and observance of the present operating instructions provided as an integral part of the product are a prerequisite for using the **Qiona**[®] ablation irrigation pump. Store the ablation irrigation pump operating instructions carefully. The present operating instructions do not replace instructions given to the operator/user by the manufacturer's authorized medical device consultant. The device must be used only by persons who have the required training or knowledge and experience.



The performance, safety and electromagnetic compatibility of the device may be affected by the use of non-original parts.

Manufacturer's liability

The manufacturer is responsible for the safety, reliability and serviceability of the device in the following cases:

Assembly, upgrades, adjustments, changes or repairs performed only by persons authorized by the manufacturer. The electrical installation of the medicinally used room must comply with the appropriate regulations (i. e. VDE 0100, VDE 0107 or IEC regulation) and the device must be used according to the operating manual. In addition, country-specific regulations and national deviations must be complied with. The manufacturer undertakes to accept returned old devices according to the Electronic Equipment Act.

Operator's obligations

The owner of the device must accept responsibility for the proper operation of the medical device. In terms of the regulations relating to operators of medical devices, the user is subject to comprehensive obligations, as well as responsibilities concerning his/her activities when handling medical devices. Only qualified personnel is permitted to use the *Qiona*[®] ablation irrigation pump. The present operating manual does not replace the instructions provided to the user by the device owner. A clinical application may only take place following instruction by qualified personnel.

Use the device only on a mains power supply fitted with a protective grounding conductor. The mains voltage must conform with the indications provided on the identification plate on the back of the device. Liquids must not penetrate parts of the device which carry electrical voltage. Do not spray cleaning agents in the connector socket or air bubble sensor. Disconnect the device plug before cleaning. All connecting cables must be replaced in the event when minor damages are detected and must not be rolled over. Plugs must not be forcefully pushed into sockets. When removing plugs, do not pull on the cable but rather loosen the push-pull locking or screwing mechanism where needed.

Furthermore, observe the safety instructions in the operating manuals of devices (ablation catheters, generators) which are operated together with the *Qiona*[®].



General safety instructions

Additional accessories

Additional accessories that are beyond the scope of delivery of the present device and are connected to the analog and digital interfaces of the device must be proven to comply with the relevant EN specifications (e.g. EN 60601 for electrical medical devices). In addition, all configurations must be in accordance with the current valid version of the EN 60601-1 standard. Operators installing additional devices are required to configure these and are, therefore, responsible for ensuring that these devices comply with the current version of the aforementioned EN 60601-1 standard.

Equipotential cable

It is important to limit potential variances between the different parts of a system within the patient's environment. In limiting this potential variance by using a system of protective grounding conductors, the quality of the connection is of utmost importance. It is, therefore, essential to avoid a failure in the protective measures in each part of the system. In the event of a fault in a protective grounding conductor connection in one of the devices within the patient's environment, this potential variance can present itself in the casing of the device and constitute a danger to the user and patient if the user touches the device and the patient simultaneously.

Single-use

Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.

Statement regarding DEHP and BPA

The Qiona[®] Tube product family does not contain Bis(2-ethyhexyl) phthalate (DEHP) and Bisphenol A (BPA)."

Purpose

Purpose

The **Qiona**[®] ablation irrigation pump is used in conjunction with a tube set and a container with physiological saline solution for the purpose of cooling the catheter tip during ablation procedures. Ablation therapy with cooling is a special intervention applied to particularly sensible areas. During ablation therapy, a defective cardiac conduction system in the inner heart wall can be destroyed by heating the tissue by using a high frequency current. The **Qiona**[®] ablation irrigation pump is used in cardiac catheterization laboratories under clinical conditions and its function does not correspond with that of an infusion pump since it is not designed for the administration of medication.

Qiona[®] has two overall operation modes. During the entire ablation procedure, a small quantity of physiological saline solution is pumped into the patient's blood circulation system by means of the adjustable LOW Flow function of **Qiona**[®]. This function is used to keep the catheter lumen open and, therefore, prevent coagulation and blockage of the catheter opening. When using the high frequency current for the ablation of the cardiac conduction system in the heart muscle tissue, **Qiona**[®] switches automatically or by manual control to a higher HIGH Flow rate in order to cool the catheter tip.

The **Qiona**[®] ablation irrigation pump has a rinse function in order to flush the tube set with the connected ablation catheter and can utilize its maximum flow rate (approx. 50 ml/min) for this purpose.



Figure: Layout of the Qiona® from infusion container to patient

Indications for cooled ablation

Qiona[®] is a special ablation irrigation pump used for cooled high frequency catheter ablation (HF ablation) of symptomatic tachycardia or heart rhythm disorders. It has to be used in combination with a tube system (Qiona[®] Tube Set incl. Extension), cooled ablation catheters manufactured by VascoMed (named "Flux") or TactiCath[®] ablaction catherers by Endosense and ablation generators. The device is designed for a therapy procedure with a curative purpose. Catheter ablation is recommended for established indications such as ablation of continuous supraventricular and idiopathic ventricular tachyardia. Additionally, the devices are for use with new indications such as atrial fibrillation and ventricular fibrillation, as well as the application of special ablation techniques such as epicardial ablation. Ablation of ventricular tachycardia arising from structural heart disease as well as ablative severing of the atrio-ventricular nodes in the case of therapy-resistant tachycardiac atrial fibrillation are forms of palliative therapies.



Purpose

Contraindications

Absolute contraindications

- Active systemic infection
- Sepsis
- Hypercoagulation
- 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 cardiac valves

Complications

- Death
- Stroke
- Cardiac valve damage
- Cardiac infarct
- Embolism, such as lung embolism
- Severe rhythm disorders
- Life-threatening ventricular arrhythmia
- Bradycardia
- Sinus arrest
- AV blockage
- Need for pacemaker implantation
- Supraventricular tachycardia
- Asystole
- Decompensation of a previously existing cardiac/kidney insufficiency
- Hypotension
- Vasovagal reaction
- Vein thrombosis
- Coronary sinus perforation
- Damage to the endocardium and perforation of the heart
- Pulmonary vein stenosis
- Stenosis of the superior vena cava
- Atrio-esophageal fistula
- Pericardial effusion
- Pericardial tamponade
- Hemothorax in the event of puncture of the vena subclavia

Purpose

- Pneumothorax in the event of puncture of the vena subclavia
- Damage and perforation of nerves, arteries and/or veins
- Pseudoaneurysm in groin area due to application of catheter technique
- Arterio-venous fistula
- Endocarditis
- Pericarditis
- Fever
- Burns
- General systemic infections

Combination with other products



The **Qiona**[®] ablation irrigation pump may only be used together with the Qiona[®] Tube Set incl. Extension (REF: 365775)

The Qiona[®] Tube Set incl. Extension may only be connected to cooled ablation catheters named "Flux" from the company VascoMed with their various curve configurations and, where applicable, with the gold tip, or with TactiCath[®] ablation catheters by Endosense. The body of these ablation catheters has a lumen through which the cooling fluid can be pumped to the catheter tip, via a temperature monitoring element which must always be used in applications with **Qiona[®]**.

Furthermore, optional accessories that can be connected to the ${\it Qiona}^{\rm @}$ include:

- The Qiona[®] Foot Switch (REF: 365773) and
- The Qiona® AutoFlow Sensor (REF: 365774).

Patient population & residual risk

There are no restrictions with regard to the patient population. The device can be used on any age group, patients with any health condition and all ethnic groups. The patient does not operate the device.

Residual risk for patients lies primarily in the selection of ablation parameters which may be unsuitable for the patient or other incorrect applications.



Product description

Product description



Figure: Front view of the *Qiona*[®] ablation irrigation pump

The **Qiona**[®] is turned on and off by means of the ON/OFF switch located at the back. All functions are performed via the embossed soft keys on the key pad.

Key pad and display layout



Figure: View of the key pad for the *Qiona*[®] ablation irrigation pump

Connection options on the rear side



Figure: View of the back of the *Qiona*[®] with connections

Installation and startup

Installation and startup



Ensure that the packaging is delivered undamaged. Inspect the **Qiona**[®] ablation irrigation pump for any damage prior to use. In the event that the product has defects, it should not be used and the supplier must be informed accordingly.

Transport and storage instructions

Temperature	-10° C to +50° C
Humidity	less than 90% rel. humidity
Weight with packaging:	approx. 6 kg
Dimensions of the <i>Qiona[®]</i> with packaging:	Width x Height x Depth: 450 mm x 400 mm x 475 mm

Unpacking the device and inspecting delivery

The *Qiona*[®] is delivered in a cardboard package. When unpacking the *Qiona*[®], make sure that all of the parts are removed from the package.

The *Qiona*[®] is delivered with the following parts:

- **Qiona[®]** ablation irrigation pump,
- Three-pole mains cable Type F,
- Operating instructions in German,
- Operating instructions in English,
- Qiona[®] Tube Set incl. Extension, and
- Qiona[®] Pole Adapter Set

It is advisable not to dispose of the packaging and to use it again for any service required.

Startup

First, remove the *Qiona***[®]** from its packaging and place it in a suitable stable place.

The *Qiona*[®] can be installed:

- in a suitable place, or
- on the current infusion stand. Ensure that it is firmly fitted onto the infusion stand.

Connect the mains cable to the back of the *Qiona*[®] casing and insert into a socket with a protective grounding conductor. Observe the voltage indicated on the identification plate. The *Qiona*[®] can be operated by turning on the ON/OFF switch. The *Qiona*[®] must be positioned so as to ensure that the ON/OFF switch can easily be operated to turn it off.

Refer to chapter "Application and Operation" in order to startup and operate the **Qiona**[®].

Overview of primary operating functions



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

1 Unpacking and connecting the Qiona[®]



Remove the **Qiona**[®] from its packaging and connect it either to the infusion stand or position it on a suitable level surface. In the event that the pole diameter is too small, use the Qiona[®] Pole Adapter Set to compensate. Connect the mains cable firstly to the **Qiona[®]** and then into a socket. If you wish to use a RF current sensor (Qiona[®] AutoFlow Sensor) or foot switch (Qiona[®] Foot Switch) as accessories to the **Qiona[®]**, you can connect an accessory to the back of the device casing into the appropriately marked plug connector.

2 Turn on the Qiona[®]



Place the ON/OFF switch at the back of the device in the ON position (I) in order to begin operating the *Qiona*[®]. The *Qiona*[®] will perform a self-test.



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 automatically carried over into the new application. While in "Stop" mode, the pump can immediately be started, settings entered into the Setup menu or flow rates preset.

The following three options are available:

- Keep all settings and go to Point 4.
- Change application settings and go to Point 3.1.
- Change settings in the Setup menu and go to Point 3.2.

3 Pre-setting and Setup

3.1 Pre-setting



Use the soft key buttons in "Stop" mode to switch between LOW Flow and HIGH-Flow and the UP and DOWN buttons to adjust the values (see Stop mode illustration on next page). The adjusted value is highlighted.





The changed values are automatically accepted without the need for confirmation. If the UP/DOWN buttons are not pressed within two seconds, the highlighted value will become inactive again.

Figure: Stop mode

3.2 Setup Menu

The "Pump Setup" menu is accessed by pressing the "Setup (wrench)" soft key button. This function is only available before or after an application. The button is locked during an application. The user can set all required operating parameters of the **Qiona[®]** in the "Pump Setup" (STOP) operating mode. The individual menu items can be selected by using the "Scroll" soft key button.



Each value changed is automatically accepted without requiring confirmation. The values of the previous application, with the exception of the dispensed cooling fluid quantity, are saved.

DISPLAY	*	85 [.] % 80 %	CLEAR PRESSURE	∳& P	0 · [ml] #dd	
SERVICE			SIZE	•	500 [ml]	
CLEAR	₩ £i	0 [ml]	ALARM AT	۰	off	Soft key button
PRESSURE	Р	DDae	DELAY	•	off	"EXIT"
5	١Ē		5	I.		Soft key button "SCROLL"

Figure: Overview of setting options in the *Qiona[®]* Setup Menu

3.2.1 Clear

By using the UP or DOWN buttons, this function resets the current volume indicator to zero (similarly when switching the **Qiona**[®] on or off).

3.2.2 Overpressure detection

This function sets the overpressure sensitivity of the *Qiona***[®]**. Two options are available:

The sensitive overpressure detection function indicated with the Paul symbol should be selected for ablation catheters which work with a relatively low operating pressure due to a relatively large flush tube diameter. This setting is recommended for "Flux" cooled ablation catheters by VascoMed. The HIGH flow mode can be set to a maximum of 50 ml/min.

• The normal overpressure detection system (default value) indicated with the End symbol should be selected, in contrast, for ablation catheters with small flush tube diameters and, therefore, higher operating pressures. This setting is recommended for "TactiCath[®]" cooled ablation catheters by Endosense. The HIGH flow mode can be set to a maximum of 35 ml/min.

3.2.3 Size

This function establishes the volume of the infusion bottle or container.

- Range of values: off 5000 ml
- Increment in change of volume: 250 ml
- Default value: off



In the case that the volume is adjusted to 0 ml, the text "Off" appears instead of the figure together with a unit of measure. The indication of infusion volume is deactivated during the application.

3.2.4 Alarm at

This function activates an alarm signal when the set residual volume of the container is reached. The residual volume indication is expressed in percentage.

- Range of values: off 50 %
- Increment in change of residual volume indicator: 5 %
- Default value: off



In the case that the volume is adjusted to 0 ml ("off" displayed), this parameter is deactivated and is no longer visible to the user. As soon as the setting is > 0 ml, the parameter will once again be visible.

3.2.5 HIGH Flow – Time delay

A time delay can be set with this function. When the **Qiona**[®] flow is switched from HIGH Flow to LOW Flow, the system will remain in HIGH Flow mode for the period of the time delay set.

- Range of values: 0 s 15 s
- Increment: 1 s
- Default value: 3 s



In the case of a time delay of 0 s, the text "Off" will appear instead of the figure together with the unit of measure and the time delay will be deactivated.

3.2.6 Display brightness

This function is used to adjust the display brightness.

- Range of values: 10 % 100 %
- Increment: 5 %
- Default value: 50 %



The display brightness is limited to a minimum value so as to guarantee the operability of the *Qiona*[®] at any setting.



3.2.7 Display contrast

This function is used to adjust the display contrast.

- Range of values: 10 % 100 %
- Increment: 5 %
- Default value: 50 %

3.2.8 Service

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

3.2.9 Exit Setup menu

When the "EXIT" soft key button is pressed, the device changes to "Stop" mode.

4 Open front panel



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

5 Unpack the Qiona[®] Tube Set incl. Extension



A Qiona[®] Tube Set incl. Extension is included in the packaging of each new **Qiona[®]**. Unpack this set and open only the outer packaging.

6 Insert the Qiona[®] Tube



Remove the Qiona[®] Tube from its packaging and insert the tube into the **Qiona[®]**. The Qiona[®] Tube has two pump adapters (Adapter 1 and Adapter 2). Insert Adapter 1 (the adapter which is closest to the drop chamber) into the **Qiona[®]**. Each adapter entry point of the **Qiona[®]** is designed so that an incorrect fitting is not possible. Once you have fitted Adapter 1, hold Adapter 2 in your hand and insert the tube over the rotor into the **Qiona[®]**. Press the tube behind the motor downwards with your left index finger (see illustration above). At the same time, using your right hand in which you hold Adapter 2, pull the tube

through the right slit in the Adapter 2 entry point. Ensure that the tube is inserted as firmly as possible into the slit.

If the tube does not fit firmly enough in the air bubble sensor intake point, faulty readings will be taken by the air bubble sensor. In this case, insert the filled tube set once again. Ensure that you pull it sufficiently firmly into the air bubble sensor intake so that the sensor LED lights up green.

7 Close front panel



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

8 Connect infusion container or infusion bottle



Hold the drop chamber by hand and remove the protective cap. Connect the drop chamber to the infusion pouch or infusion bottle containing the relevant fluid. Ensure that the drop chamber is always free and hangs down perpendicularly in order to avoid air bubbles.

9 Remove the Qiona[®] Extension

Remove the **Qiona**[®] Extension from the sterile packaging.



10 Connect ablation catheter



Remove the protective cap of the Luer connector and execute a sterile tube connection between the *Qiona*[®] Tube and the *Qiona*[®] Extension, as well as the ablation catheter.



The **Qiona**[®] may only be connected to cooled ablation catheters with their various curve configurations and to gold tip catheter versions where applicable, such as the Flux catheters by VascoMed or TactiCath[®] by Endosense. Ensure that the Luer connections are always closed and the temperature monitor of the HF generator is activated.



11 Perform rinsing



Rinsing or flushing of the entire tube system with the connected ablation catheter is of utmost importance. The RINSE button must be held permanently pressed. The indicator display changes to Rinse mode (Fig. A on next page). As long as the RINSE button is pressed, the pump will function on maximum capacity of 50 ml/min in order to flush the tube set and ablation catheter.

It is the user's responsibility to continue the rinse process until it is certain that no air remains in the tube system and catheter.

The air bubble sensor is deactivated during rinsing in order to avoid any alarm signal. The green LED of the air bubble sensor indicates that there are no air bubbles within the range of the sensor and that the tube set is firmly fitted into the air bubble sensor inlet point. In the event that the air bubble sensor LED does not turn green after the tube set has been bled 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 inlet point until the sensor LED lights up green.



The pressure monitoring sensor is active during rinsing. In the event of overpressure, an optical and acoustic alarm is activated and the pump stops immediately.

If the RINSE button is released the rinse process is ended and the pump changes once again to Stop mode (Fig. B).

START/STOP button

RINSE button

Figure A: Key pad

Figure B: Stop mode

12 Start application

The application is started by using the START/STOP button.







With a manual start, the *Qiona***[®]** sets the pump to LOW Flow mode. The LOW Flow value is highlighted and the *Qiona***[®]** pumps the volume set. The green running light at the top of the display indicates that the *Qiona***[®]** is functioning.

If a HF signal is detected by the flow sensor already at startup, the *Qiona*[®] changes immediately to HIGH Flow mode.

If the "Size" and "Alarm at" functions in the SETUP menu are activated, a blue bottle appears in the top left corner of the display. The blue bottle indicated the current level in the infusion container or bottle provided that the total volume has been entered correctly in the "Size" Setup menu. The digital value next to the patient symbol indicates the current volume of dispensed saline solution.

Padl 📮	255 ml
9	10

The switch from LOW Flow to HIGH Flow, as well as back to LOW Flow is executed by means of:

- the soft key button on the **Qiona**[®], or
- the optional foot switch (Qiona[®] Foot Switch), or
- the optional RF current sensor (Qiona[®] AutoFlow Sensor).



Switch-over options

Switch-over by means of soft key button:

By using the HIGH Flow soft key button, the flow can be switched from LOW Flow to HIGH Flow. The *Qiona*[®] switches immediately to HIGH Flow mode. The value set is highlighted. Press the LOW Flow soft key button to switch the flow back to LOW.

Switch-over by means of foot switch (Qiona[®] Foot Switch):

By using the optional foot switch which can be connected to the back of the **Qiona**[®], the flow can be switched from LOW to HIGH and back. Press the foot switch button in order for the ablation irrigation pump to immediately switch to the HIGH Flow value entered. The value set is highlighted on the display. When the foot switch is released, the **Qiona**[®] switches back to LOW Flow.

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

The optional RF current sensor which can be connected to the back of the **Qiona**[®] can be used to switch the flow automatically between LOW Flow and HIGH Flow, according to the flow required for the ablation. Clamp the RF current sensor to the connecting cable between the HF generator and ablation catheter. The green LED of the RF current sensor indicates that the system is ready to operate. The **Qiona**[®] switches immediately to the HIGH flow set for as long as the RF current sensor detects a continuous HF signal. A yellow LED indicates that the RF current sensor has detected a HF signal. As soon as the HF signal stops, the flow will either be immediately switched back to LOW or will do so after a time delay if applicable.

Ensure that the RF current sensor is not laid on the floor and is firmly attached to the connecting cable.



Figure: Configuration using the RF current sensor (Qiona[®] AutoFlow Sensor)



The activation threshold of the RF current sensor is shown in the following diagram which indicates 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 from LOW flow to HIGH flow. A further prerequisite is that the ablation generator operates with a frequency of approx. 500 kHz (\pm 10%).

Figure: Activation threshold of the RF current sensor (Qiona[®] AutoFlow Sensor)

Time delay function

A time delay of max. 15 seconds in switching from HIGH flow to LOW flow can be set in the *Qiona*[®] Setup menu.

The time delay is activated when the **Qiona**[®] is switched from HIGH to LOW flow by the RF current sensor signal, foot switch or a manual operation of the key pad. During the time delay, the **Qiona**[®] continues to operate in HIGH flow mode for the period preset in the SETUP menu (max. 15 seconds) and switches automatically to LOW flow after the time delay. However, during the time delay the **Qiona**[®] accepts user commands and executes these. Soft key button commands using the **Qiona**[®] key pad always have priority over RF current sensor or foot switch signals. In the event that the **Qiona**[®] receives a HIGH flow signal from the foot switch or RF current sensor during the time delay, it will immediately switch back to HIGH flow mode. The time delay can be overridden when the soft key button LOW-Flow on the **Qiona**[®] key pad is pressed during this period.

The time delay should be at least 1 to 5 seconds in order to avoid that the **Qiona**[®] switches over for brief periods due to generator transients.

Volume indicator function



In the event that the "Size" and "Alarm at" functions in the SETUP menu are activated, the display will indicate the rinse fluid level. 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 with 100 ml residual volume, the four segments constitute 400 ml. In this case, each segment in the display corresponds to 100 ml.

When the **Qiona**[®] reaches the set rinse fluid residual volume, it activates an optical and acoustic signal. The rinse fluid residual volume is indicated in yellow on the bottle displayed. The signal is in the form of an acoustic sound 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 show a full bottle and the level detector to measure the added rinse fluid. If the button is pressed, the white bottle will disappear.



The drop chamber must be switched over to a new full bottle. During this process, an air bubble may enter the tube system. In this case, the *Qiona*[®] will stop immediately and the application must be interrupted.

When switching the drop chamber over, always ensure that it remains properly filled.



13 End application



The application is ended by means of the START/STOP button and the *Qiona*[®] changes to the "Stop" mode as illustrated.

14 Turn the Qiona[®] off

The *Qiona***[®]** is turned off by using the ON/OFF switch at the back of the device. All values set in the *Qiona***[®]** remain available for the next application.

In the event that the power supply to the *Qiona*[®] is interrupted during an application, a continuous tone will be emitted for at least 2 minutes to sound the alarm signaling the interruption.

The Qiona[®] Tube Set incl. Extension is designed for single use and must not be reused. Dispose according to hygiene regulations. If the Qiona[®] Extension has not been used, dispose it nevertheless. No provision is made for the reconditioning of the tube set and such action is highly unrecommended.

Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.

Presence of an alarm condition



Figure: Alarm condition display

In the event of an alarm condition, the display indicates the relevant reference (see Alarm System Overview) marked by yellow LEDs. Simultaneously, an acoustic alarm signal with the tone sequence "e - c" is emitted.



The acoustic signal can be turned off for 2 minutes using the soft key button "Audio pause".



By using the soft key button "Alarm Reset", the user confirms that the cause for the alarm has been remedied. The *Qiona*[®] returns to normal settings and the application can be continued.

The **Qiona®** stops immediately in the presence of any alarm condition signal.

Testing alarm functions

If the **Qiona[®]** is turned on at the mains switch, a brief Beep sound is emitted and the yellow LED lights up briefly. A function test is also performed. Another acoustic information signal is emitted and the software version of the Main (FwM) and Watchdog (FwW) controllers are shown temporarily on the display.



With a view to assess risk, the *Qiona*[®] alarm system ensures that in the event of an alarm during proper use of the device, the user can always be informed accordingly by means of optical or acoustic alarm signals (i.e. the user must always be within hearing and/or visual range). The *Qiona*[®] is designed with a technical alarm condition system. The alarm condition priority is set at "Low Priority" for all alarm conditions. The *Qiona*[®] transmits visual and acoustic alarm signals.



Alarm system overview

Technical Alarm Conditions	Alarm limit	Alarm condition delay	Alarm signal emission delay	Alarm Signal	Alarm signal description on display	Audio pause	
Air bubble detected	Air bubble > 2 µl	< 5 ms	<= 250 ms (periodic evaluation of alarm conditions)	acoustic / Visual	× ×	Yes	
Tube overpressure detected	Tube internal pressure > 2.5 bar	< 5 ms	<= 250 ms (periodic assessment of alarm conditions)	Acoustic / Visual		Yes	
<i>Qiona[®] f</i> ront panel open	Front panel > 8° open	< 50 ms	<= 250 ms (periodic evaluation of alarm conditions)	Acoustic / 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)	Acoustic / 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)	Acoustic / Visual		Yes	
Internal safety measures following hardware and software tests		N/A	<= 5 s (periodic evaluation of system test functions)	Acoustic / Visual	△ Exx ▲ ▲ ▲ ▲	Yes	
-double safety- alarm conditior	-double safety- The <i>Qiona[®]</i> should be tested by the Technical Service Center in the event of such an alarm condition.						

Problem fixing

This chapter describes certain problems which may occur in the **Qiona**[®].

Several solutions may be possible for each problem. The solutions proposed should be executed in the order provided until the problem is remedied. When removing or connecting plug connections, with the exception of the tube set, ensure that the *Qiona*[®] is always turned off. In the case that the solutions presented below do not remedy the problem, contact the BIOTRONIK Technical Service Center.

Problem	Solution
Not functional, the display is switched 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 and check the supply cables.
Problem due to humidity penetrating into the plug connector.	Remove mains plug. Allow plug connector to dry.
An overpressure is detected without the presence of an obvious obstruction.	Check whether the recommended overpressure for the ablation catheter used has been selected in the Setup Menu (see 3.2.2).
Green RF current sensor LED does not turn on although it is firmly clamped onto an ablation catheter cable.	Check that the ablation catheter cable is properly gripped and that the RF current sensor is closed.



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



Service

In the event that no solution can be found for the problem, contact the appropriate BIOTRONIK Technical Service Center.



Each time the **Qiona**[®] is returned, a suitable disinfection procedure must be performed to avoid the risk of infection. Consumables must be disposed in accordance with hygiene regulations.



Never open the device when it is connected to the mains power supply. Beware that even when disconnected from the mains, internal parts of the device may still be energized.

Alarm system description

Terms	Definitions	Applicability to the <i>Qiona</i> [®]	Explanation
Alarm condition	Condition of the alarm system once it has determined a possible or real threat.	 Air bubble Overpressure in tube system Front panel not closed Motor jam Foot switch connection broken down RF current sensor connection broken down Technical error 	
Alarm condition delay	Time between occurrence of an alarm condition either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), up to system determination of an existing threat.	No possible setting	
Alarm limit	Limit value used by an alarm system to determine an alarm condition.	 Air bubble > 2 Microliters Internal tube pressure > 2.5 bar Front panel > 8° open No connection to foot switch No connection to Qiona[®] AutoFlow Sensor 	
Alarm OFF	Condition of indefinite duration in which an alarm system or a part of an alarm system does not generate alarm signals.	No setting possible	



Terms	Definitions	Applicability to the <i>Qiona</i> ®	Explanation
Alarm presetting	Set of saved configuration parameters, including selection of algorithms and initial values for using 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 display the existence (or the occurrence) of an alarm condition.	 Optical alarm signal by yellow LED on the key pad Optical alarm signal via display Acoustic alarm signal with a noise pressure level of 55 dB(A) at a distance of 1 meter. 	
Delay in alarm emittance	Time from start of alarm condition to emittance of alarm signal.	No setting possible	
Audio OFF	Condition of indefinite duration during which the alarm system or a part of the alarm system does not generate an acoustic alarm signal.	No setting possible	Refers to all alarm conditions active at the moment the button is pressed.
Audio pause	Condition of specific duration during which the alarm system or a part of the alarm system does not generate an acoustic alarm signal.	2 minutes	Refers to all alarm conditions active at the moment the button is pressed.
De-escalation	Process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	No application	
Escalation	Process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	No application	
Incorrect negative alarm condition	Missing alarm condition, if a valid triggering occurrence in the patient, in the device or in the alarm system has	Double safety measure	



Terms	Definitions	Applicability to the <i>Qiona</i> ®	Explanation
	occurred.		
Incorrect positive alarm condition	Existing alarm condition, if no valid triggering occurrence in the patient, in the device or in the alarm system has occurred.	Results in safe condition of the device.	
Information signal	Every signal, which is not an alarm or reminder signal.	Applies.	
Recurring alarm signal	Alarm signal which continues to emit after its triggering occurrence has been eliminated, until it is stopped with a deliberate operator action.	Applies.	
Non-recurring alarm signal	Alarm signal which automatically stops being emitted once the triggering occurrence 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 or alarm system-related variable.	Applies.	
Alarm reset	Action performed by operator to cancel an alarm signal for which there is no currently associated alarm condition.	Applies.	



Maintenance

Maintenance

Cleaning and disinfection



- No humidity must be allowed to enter into the device.
- Before cleaning and disinfecting the device surfaces, disconnect the mains plug.
- Use lint-free, soft cloths. Clean with a damp cloth, using a mild soap solution or 70% isopropyl alcohol.
- Use a solution of 70% isopropanol and 30% water to disinfect the device. Lysoformin 3000: 2% concentration, allow 15 minutes to take effect. The cleaning and disinfecting solutions must have evaporated before using the device.
- Visual check: The sockets of all connections and cable plugs must be free of all dirt.

Service

Repairs, upgrades or changes to the ablation irrigation pump system may only be performed by BIOTRONIK or a company specifically authorized by the manufacturer. In the latter case, the work performed must be documented, signed and dated. Changes to the device by third parties are not permitted. A technical safety check must be performed at least every 12 months. Use the **Qiona**[®] only if the device is functionally and/or operationally safe. If this is not the case, have it immediately serviced.

Disposal

The present device contains material which must be disposed in accordance with environmental regulations. This device is subject to the European Directive 2002/96/EEC on Waste Electric and Electronic Equipment (WEEE). The identification plate of the device bears the symbol of the crossed through garbage bin.



Return devices which are no longer used to your local BIOTRONIK representative. This ensures that the device is disposed in compliance with the national requirements of the WEEE Directive.

Contact your local BIOTRONIK representative for further information.

Qiona®

Annex

Annex

Technical data

General information:

Order number REF: Dimensions of the **Qiona**[®]:

Weight:

Noise pressure level Minimum operating life:

Electrical connection:

Voltage 100 – 240 VAC (alternating voltage) Frequency Current consumption Safety fuse: Protection class: Degree of protection: Applied part CF (defibrillation-proof)

Transport and storage requirements:

Temperature Humidity Weight with packaging: Dimensions of the *Qiona[®]* with packaging:

Operating conditions:

Temperature Humidity

Specific features:

Delivery rate of the **Qiona®**

Working pressure range Dynamic pressure switch off Air bubble sensor accuracy Output accuracy 363270 Width x Height x Depth: 225 mm x 240 mm x 170 mm approx. 5 kg 56 dB(A) at output of 30 ml/min 8 years

50 – 60 Hz 0.7 – 0.3 A T 3.15 A / 250 V I IP 51 Qiona[®] Tube Set incl. Extension

-10° C to +50° C less than 90% rel. humidity approx. 6 kg Width x Height x Depth: 450 mm x 400 mm x 475 mm

+10° C to +40° C 30 to 75 % rel. humidity

1 ml/min – 50 ml/min (35 ml/min with normal overpressure detection) 0 bar – 3.5 bar approximately 2 bar above working pressure Detection > 2 Microliters -10 % to +20 % of output range end value at 1 to 5 ml/min -5 % to +10 % of output range end value at 5 to 30 ml/min -10 % to +20 % of output range end value at 30 to 50 ml/min

Electromagnetic emission

The **Qiona**[®] is suitable for operation in the specified electromagnetic environment. The customer and/or operator of the **Qiona**[®] must ensure that the device is used in the electromagnetic environment described below.

Measurement of emitted interference	Conformance	Guidelines for the electromagnetic environment
High frequency emitted interference according to CISPR 11	Group 1	The Qiona [®] uses HF energy exclusively for its internal functioning. Therefore, its high frequency emission is minimal and it is improbably that it will disturb nearby electronic devices.
High frequency emitted interference according to CISPR 11	Class B	
Harmonic emittance acc. to IEC 61000-3-2	Not applicable	The Qiona [®] is suitable for use in facilities including living areas and areas that are directly connected to the public power supply that also supplies buildings used for living purposes.
Voltage fluctuation/flicker emittance acc. to IEC 61000-3- 3	Not applicable	



Electromagnetic resistance

Resistance test	IEC 60601 - testing level	Compliance level	Electromagnetic environment / Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should consist of wood or concrete or should be provided with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Rapid transient electrical disturbances/bursts IEC 61000-4-4	±2 kV for power lines ±1 kV for input and output lines	±2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should correspond to the typical environment in businesses or hospitals.
Surge voltages (Surges) IEC 61000-4-5	±1 kV Normal mode voltage ±2 kV Common mode voltage	±1 kV Normal mode voltage ±2 kV Common mode voltage	The quality of the supply voltage should correspond to the typical environment in businesses or hospitals.
Voltage dips, short interruptions and fluctuations of the supply voltage IEC 61000-4-11	< 5 % U _T (> 95 % Dips ofU _T) for 1/2 period 40 % U _T (60 % Dips ofU _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 ofU _T) for 1/2 period 40 % U _T (60 % Dips ofU _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 the typical environment in businesses or hospitals. If the operator of the product requires the device to be used without interruption during a dip in the power supply, it is recommended that the device is connected to an uninterruptible power supply or a battery.
Magnetic field in power supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in the power supply frequency should correspond to the typical values in business and hospital environments.

Note: U_{T} is the AC supply voltage prior to application of the testing level.

Electromagnetic resistance for non-life-supporting devices

Resistance test/Standard	IEC 60601- testing level	Compliance level	Electromagnetic environment / Guidelines		
Derived HF disturbance value acc. to IEC 61000-4-6 Radiated HF- resistance acc. to IEC 61000-4-3	3 V _{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V _{eff} 3 V/m	Portable and mobile radio devices should not be used closer to the Qiona [®] , including cables, than the recommended safety distance, calculated on the basis of the equation applicable for the transmission frequency. Recommended safety distance: $d = 1, 2\sqrt{P}$ $d = 1, 2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2, 3\sqrt{P}$ for 800 MHz to 2.5 GHz with P as nominal transmitter power in Watt (W) acc. to transmitter manufacturer stipulations and d as recommended safety distance in meters (m). According to an on-site ^{a)} examination, the field intensity of stationary radio transmitters ought to be lower than the correlation level ^{b)} . Disturbances may occur in the environment of devices carrying the following symbol.		
Notes: COMMENT 1: The higher frequency range applies at 80 MHz and 800 MHz. COMMENT 2: These guidelines may not be applicable in all cases. The diffusion of nominal electromagnetic factors is influenced by absorption and reflection of buildings, objects and people					

^{a)} The field strength of stationary emitters, such as base stations for cell phones and mobile terrestrial radio systems, amateur radio stations, AM and FM radio and television emitters, cannot be theoretically accurately predicted. To determine the electromagnetic environment in terms of the stationary emitter, a study of the site should be considered. If the measured field strength in which the *Qiona[®]* is used exceeds the compliance level, the *Qiona[®]* should be monitored to ensure that it is working properly. If the device is not performing as expected, additional measures may be necessary, such as changing the direction in which it is facing or moving it to another area.

^{b)} Above the frequency range of 150 kHz to 80 MHz the field strength should be lower than 3 V/m.



Recommended safety distances

Recommended safety distances between portable and mobile HF telecommunications devices and the $\textit{Qiona}^{\texttt{®}}$

The **Qiona**[®] is designed for use in an electromagnetic environment where the high frequency disturbance is controlled. The customer or user of the **Qiona**[®] can help to prevent electromagnetic disturbance by observing the minimum distance between portable and mobile HF telecommunications devices (emitters) and the **Qiona**[®] regardless of the output of the communication device, as indicated below.

Capacity	Safety distance dependent on transmission frequency (m)				
transmitter performance (W)	150 kHz to 80 MHz $d = 1, 2\sqrt{P}$	80 MHz to 800 MHz $d = 1, 2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2, 3\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.37	0.37	0.74		
1	1.2	1.2	2.3		
10	3.7	3.7	7.4		
100	12	12	23		

Accessories

- Qiona[®] Tube Set incl. Extension REF: 365775 Weight: 90 g Overall length Extension: 1.5 m Total length tube: 3 m Length between *Qiona[®]* and catheter adapter: 3 m (1.5 m tube + 1.5 m extension)
- Qiona[®] Foot Switch REF: 365773 Weight: 380 g Cable length: 5 m

- Qiona[®] AutoFlow Sensor REF: 365774 Weight: 200 g Cable length: 4 m
- Qiona[®] Pole Adapter Set REF: 377184 Weight: 25 g





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