EP // External devices // **Technical Manual**

Qubic Force

Device for visualization of contact force of the catheter tip on the cardiac wall

ACUTUS™
MEDICAL

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1 Introduction

About the Device

General description

Qubic Force is used with the AcQBlate® FORCE ablation catheter, a compatible radiofrequency (RF) generator, and an external monitor. Qubic Force is a device for visualization of the contact force of the ablation catheter tip on the cardiac wall during an electrophysiological study in cardiac catheter laboratories with or without cardiac radiofrequency (RF) ablation. An external monitor is placed in a position easily visible to the user and connected to the Qubic Force. The contact force is displayed which allows the user to monitor the contact force of the ablation catheter tip on the cardiac wall, establish proper contact on the cardiac wall, and influence lesion formation.

Intended medical use

The relevant cardiology association guidelines do not contain a medical indication for the visualization of the contact force of the catheter tip on the cardiac wall and therefore contain no indication for the use of Qubic Force.

Qubic Force is not required to perform an electrophysiological study in cardiac catheter laboratories with or without cardiac radiofrequency ablation, but this device does provide important information to the user, for example for the assessment of lesion formation and optimization of ablation parameters.

Contraindications

There are no specific contraindications for the use of Qubic Force. For information on contraindications for the ablation catheter and the RF generator, please consult their technical manuals.

Patient group

Use of Qubic Force is indicated for all patients subjected to a therapeutic electrophysiological study. For studies using Qubic Force, there are no restrictions in terms of the age, sex, weight, state of health, nationality, or condition of the patient.

Compatible RF generators

The following RF generators are compatible with Qubic Force:
- BIOTRONIK: Qubic RF
- Stockert: EP-Shuttle
- Biosense Webster: SMARTABLATE™ HF Generator (manufacturer: Stockert)
- St. Jude Medical: IBI-1500 T11
- Medtronic: Atakr II
- Osykpa: HAT 300 Smart

About this Technical Manual

Objective

This technical manual provides all the safety information required to use the device.

The following topics are covered in this manual:
- Device startup
- Device handling
- Using the software

Target group

This technical manual is intended for cardiologists, electrophysiologists and cardiac surgeons possessing knowledge in the following areas:
- Catheterization procedures
- Procedures for ablating the intracardiac stimulation and conduction systems

This technical manual is also intended for clinical and technical assistants possessing expertise in handling devices in cardiac catheter laboratories. Additional required expertise is:
- Basic medical knowledge of the examination method employed
- Ability to work with a PC
- Ability to use software-controlled medical devices

Other Technical Manuals

The following additional technical manuals must be followed to ensure the safe and correct use of the device:
- Technical manuals for other system components in the cardiac catheter laboratory, not supplied with the Qubic Force (e.g., AcQBlate® FORCE ablation catheter, RF generator, lab monitoring system, and external monitor)
- Technical manuals for the intended catheters, indifferent electrodes, patient cables, and adapters
- Technical manuals for other designated accessories

2 Safety during Use

Required Expertise

Required expertise

Qubic Force is intended for use by cardiologists, electrophysiologists, cardiac surgeons, and clinical and technical assistants specialized in handling devices in cardiac catheter laboratories and trained in handling the Qubic Force. In addition to having basic medical knowledge, the user must be thoroughly familiar with the electrophysiology of the heart, catheterization procedures, and the method of ablating the intracardiac stimulation and conduction system.

Only trained and qualified medical personnel with this knowledge can properly operate the device.

Note: Please note that in principle there is a risk of cardiac wall perforation during a cardiac radio frequency ablation and that this cannot entirely be excluded despite the use of Qubic Force. Therefore, take any measures to minimize this risk as much as possible.

Electromagnetic Interference

Possible electromagnetic interference

This device is protected against electromagnetic interference and electro- static discharges in the specialized environment of a cardiac catheter laboratory containing high-frequency surgical instruments and X-Ray devices. At the same time, the emitted interference is reduced to a minimum.

The device thus fulfills the requirements of EN 60601-1-2 as they apply to CISPR 11 class A in relation to both interference emitted and resistance to interference. The following norms do not apply here:

- IEC 61000-3-2
  Harmonic distortion (harmonic currents in the mains supply)
- IEC 61000-3-3
  Voltage fluctuations and flicker in the mains supply

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

Section of IEC 60601-1-2:2014	Test	Test level
7.1	EN 55011 (CISPR 11) Conducted interference emissions	• Group 1 • Class A
	EN 55011 (CISPR 11) Radiated emissions	
8.9	IEC 61000-4-2 Electrostatic discharge (ESD)	• ±8 kV contact discharge • ±15 kV air discharge
8.9 / 8.10	IEC 61000-4-3 Electromagnetic fields	• Modulation: 1 kHz • 3 V/m, 80 MHz – 2.7 GHz • Limits for RF communication equipment per Table 9 in IEC 60601-1-2 (9-28 V/m)
8.9	IEC 61000-4-4 Transient conducted surge voltages (EFT, bursts)	• ± 2kV mains supply • ± 1kV signal line
	IEC 61000-4-5 Surge voltage waves on supply lines	• ± 2 kV common mode • ± 1 kV common mode
	IEC 61000-4-6 Conducted radio- frequency interference	• Modulation: 1 kHz • 3 V • 6 V in ISM bands
	IEC 61000-4-8 Power frequency magnetic fields	• 30 A/m • 50/60 Hz
	IEC 61000-4-11 Voltage fluctuations and interruptions in supply voltage	

Even when, as pointed out above, the device complies with the requirements of EN 60601-1-2, strong electromagnetic disturbances may occur in the immediate vicinity of electrical motors, high-voltage power lines, PCs, monitors and other – perhaps defective – electrical devices which may cause the Tare key to be triggered unintentionally and may sometimes impair the functioning of the device.

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

- The values displayed for contact force and application angle are set to zero with the AcQBlate® FORCE ablation catheter connected, as long as the Tare key has not been pressed.
- The device displays other inexplicable behavior.

Correct operation of the device can be restored with the following miscellaneous measures:

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

If the interference continues, contact Acutus Medical immediately.

⚠ WARNING

Risk of electromagnetic interference through the use of unauthorized accessories

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

- Use only accessories authorized by Acutus Medical

⚠ WARNING

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

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

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

General Safety Warnings

Risks of improper handling

Disregarding the safety warnings can endanger the patient, the staff and the equipment.

Note: Failure to observe the safety warnings voids all damage claims and manufacturer liability.

The following dangers can, for example, arise in the event of improper use:

- Failure of important device functions
- Personal endangerment due to electrical impact

Changes not permitted

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

Replacement parts and accessories

Use only accessories authorized by Acutus Medical. Using any other parts voids liability for any consequences, as well as the product guarantee and warranty.

RF accessories

Use only RF accessories certified according to Standard IEC 60601-2-2.

Defective devices

Do not use defective or damaged devices.

Physician supervision

The device may only be used under the constant supervision of a physician. The patient must be monitored at all times using an external surface ECG with rate control.

Patient observation

Ensure that patients are individually observed over a suitable period of time in order to monitor the compatibility and effectiveness of the electrophysiological therapy.

Emergency equipment

During an examination, keep resuscitation equipment (e.g., cardiac defibrillator, external pacemaker) available and ready for use at all times in order to perform life-supporting measures immediately in the event of an emergency.

Liquids

Never use a damp or wet device. Protect the device from accidental ingression of fluids (e.g. infusion fluids).

If the device becomes wet, immediately unplug and stop using the device. Contact Acutus Medical for testing and, if necessary, repair of the device.

Electrostatic potentials

Ensure that electrostatic potentials between medical staff and patients are balanced. Before handling the device, the electrostatic potential between the physician or medical staff and the patient must be balanced by touching the patient at a point as far away from the catheters or leads as possible.

Leakage currents

Avoid leakage currents between all connected devices. Such leakage currents can cause lethal arrhythmias.

Potential equalization cables must be attached to all connected components, if present.

Before initial commissioning, check and document all device combinations. National and international directives concerning the use of electromedical devices also apply to patient cables.

Touching contacts on cables and catheters

Do not touch the contacts on the patient cable or the catheters. The device has electrical contact with the patient's heart and blood via the implanted catheters. Touching the contacts on the patient cable or catheters could expose the patient's heart to dangerous electrical currents.

Defibrillation

When connected with the approved patient cable, the device is defibrillation protected. However, damage cannot be ruled out in all circumstances.

Following a defibrillation, the recovery time can take up to 10 seconds until the device is ready for use again. Check all functions of the device, following a defibrillation. During defibrillation, do not touch the patient, the device the patient is connected to, or the attached accessories. Otherwise, there is a danger that you may suffer an electrical shock.

Risk of infection

Contaminated devices can lead to infection. Clean and disinfect the device on a regular basis. Refer to the cleaning instructions for all other system components.

Operating Conditions

Storage and transportation

If the packaging is damaged, please contact Acutus Medical immediately. Do not put the device into operation.

The ambient conditions for shipping and storage are:

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

Operating conditions

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

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

⚠ **WARNING**

Risk of electromagnetic interference

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

- Where usage in such a manner is unavoidable, you should monitor this device and the device or devices being used together with it in order to check that they are all working correctly.

⚠ **WARNING**

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

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

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

Only operate the device in rooms that fulfill the following conditions:
- No danger of explosion
- Suitable for medical purposes
- Class I power outlet with protective conductor connection

Place the device in a position protected from spray water. Place the device on a flat, dry surface. Place the device in a position where it cannot slip, even with cables connected, nor be touched by the patient, and so that you can pull the power plug out of the device at any time. Make sure that the ventilation slots remain unobstructed. The device cannot be sterilized and therefore must not be operated in sterile areas.

The ambient conditions for operation are:

Temperature	+10°C ... +40°C
Relative humidity	30% ... 75%, no condensation
Atmospheric pressure	700 ... 1060 hPa
Operation at altitudes	Up to 2000 m AMSL

Power supply

The device is operated via the AC voltage (100 to 240 V at 50 / 60 Hz) of a room used for medical purposes.

⚠ **CAUTION**

Possibility of electric shock

To avoid the risk of electric shock, connect the device only to a power supply fitted with a PE conductor.

The electrical port must fulfill the following conditions:
- The power outlet fulfills at least the requirements of IEC 60364-7- 710:2002 group 2.
- The device cable feeds directly into a permanently installed socket. No portable multiple socket outlets may be used.
- When used in combination with other devices, no portable multiple socket outlets should be used.
- Only power cords which are suitable for medical devices can be used, such as power cords from Acutus Medical or equivalent power cords labeled H05VV 3 x 0.75 mm, H05VV 3 x 1 mm, or SJT AWG18.

To disconnect Qubic Force from the mains supply, pull the power plug out of the device.

Cable and plug connections

⚠ WARNING

Allergic reaction

The cable material may trigger allergic reactions in extremely rare cases.
- Prevent the cable from contacting the skin or wounds.

- Replace any cable that shows even slight damage.
- Lay all cables between the patient and the device, as well as within the measuring apparatus, in such a way that they pose no danger of tripping and that any tensile forces that may occur can be safely buffered.
- Ensure that the contacts of all connector ports and connectors are clean. Soiled contacts can lead to signal distortions, and thus to false diagnoses.
- Ensure that there is no condensation on the plugs or in the connector ports. If condensation is present, dry it before use.
- Do not force the plugs into the connector ports. Do not pull on the cable when disconnecting the plugs. Rather, release the lock on the plug.

Maintenance, Care and Disposal

General information

Note: Note the following points before cleaning and disinfecting:
- Disconnect the power plug before cleaning and disinfecting the device surfaces.
- Let cleaning and disinfection agents evaporate before operating the device.
- Do not use any strong and abrasive cleaning agents or organic solvents such as ether or benzine, as they corrode the surface of the device.

Cleaning and disinfecting

- Use lint-free, soft cloths.
- Clean the housing with a damp cloth and mild soap solution or 70% isopropanol.
- Disinfect with alcohol-based agents such as Aerodesin 2000.

Sterilization

- The device is not sterile and cannot be sterilized.

⚠ CAUTION

Infection of the patient from operation of the non-sterile device

Qubic Force is not sterile and cannot be sterilized. If, during the ablation therapy of the patient, the physician operates the device at the same time, infection of the patient can result.

- During ablation therapy, do not operate the device at the same time.

Test before each use

- A 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 functional test:
  - Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
  - Inspect cables and connection areas to ensure proper insulation, the absence of breaks, etc.
  - 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, then no errors were found and the device can be used.
  - Inspect the displays (e.g., display of characters and language).

Inspection

The inspection consists of the regular safety inspection according to medical device standards. This ensures the safety of the device.

- Inspections should be performed:
  - If malfunctions are suspected
  - Once a year
- The inspection can be performed by Acutus Medical.
- The inspection must conform to the manufacturer's specifications. These are available upon request. The specifications list all necessary test steps and the necessary equipment.
- The instructions for performing the inspection are directed at people whose education, knowledge, and experience obtained through practical work provide the basis for proper execution.

Fuse replacement

The fuses are located above the power cord port in a fuse holder.

Step	Action
1	Turn the device off and unplug the power cord.
2	Use a suitable tool to pull the fuse holder out.
3	Replace the old fuses with new ones of the same type.
4	Re-insert the fuse holder. Ensure that it locks securely in place.

Note: Defective fuses can indicate a technical defect in the device. Conduct an inspection after changing fuses and before resuming operation of the device.

Disposal

The symbol on the type plate, a crossed out garbage can, indicates that the device must be disposed of in accordance with the European Directive 2012/ 19/EU on waste electrical and electronic equipment (WEEE 2). If the device is not disposed of in an environmentally friendly manner, it will result in environmental pollution as this device contains materials which must be disposed of in accordance with environmental protection requirements (e.g., WEEE, RoHS, REACH). Return devices that are no longer in use to Acutus Medical.

Disposal of cables

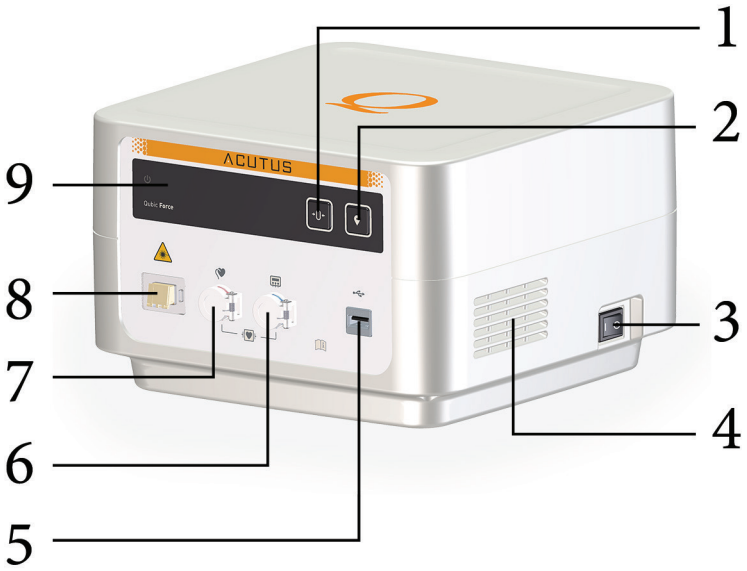
Note: Cables that are to be disposed of must be treated as medical waste, in accordance with environmental regulations, if they have been in contact with blood

Non-contaminated cables must be disposed of in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) or in accordance with the regulations applicable locally.

3 Device Handling

Device Overview

Front view



Explanation of items

Item	Description
1	Tare key • Sets the displayed values for contact force and the angle at which the ablation catheter is applied to the cardiac wall to zero
2	Marker key • Marks the current values in the log file for the current procedure and stores a current screenshot • Transfers the log file for the current procedure and the stored screenshots to a USB flash memory stick
3	On/off key • For switching the device on/off
4	Ventilation slots • To protect the device from overheating
5	USB port • To connect a mouse, keyboard or USB flash memory stick without an independent power supply
6	Redel port for generator • For connecting a compatible RF generator using the corresponding patient cable
7	Redel port for ablation catheter • For connecting the electrical plug of the ablation catheter using patient cable PK-147
8	Optical port for ablation catheter • For connecting the optical plug of the ablation catheter
9	On/off light indicator (LED) • Lights up green when the device is switched on

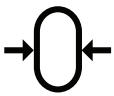
Rear view of device

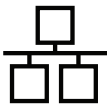
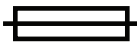
Explanation of items

Item	Description
10	Redel port for expansion • General, analog connection for expansions (No use of this port is planned at present. Consult Acutus Medical.)
11	Ventilation slots • To protect the device from overheating
12	Binary interface 1 (RS-232 port) • General, serial connection for expansions (No use of this port is planned at present. Consult Acutus Medical.)
13	Binary interface 2 (RS-232 port) • General, serial connection for expansions (No use of this port is planned at present. Consult Acutus Medical.)
14	Power cord port and device fuse • For connecting the power cord
15	Ethernet port (not suitable for network connection) • General, digital connection for expansions (No use of this port is planned at present. Consult Acutus Medical.)
16	Monitor port • To connect a monitor

Symbols on the device

Explanation of symbols

Symbol	Description
	On/off light indicator
	Tare
	Marker
	Warning of invisible intense light from an SLED Since this light corresponds to laser class 1, this optical port poses no risk to the user or patient.
	Ablation catheter
	Type CF applied part, defibrillation protected
	USB port
	Radiofrequency unit of the RF generator
	Follow the Instructions for Use

Symbol	Description
	On/off key
	Binary interface 1 or 2
	Monitor port
	Ethernet
	Fuse

Setting up the Device

General

⚠ CAUTION

Functional impairment due to external damage

Mechanical impact can permanently impair the function of an unpackaged system even from a height of 5 cm (roughly 2") or greater.

- Do not use if the device or the packaging is visibly damaged.
- Contact Acutus Medical for testing and, if necessary, repair of the device.

Qubic Force must be set up in such a way that it can be connected up to the RF generator and to an external monitor. Connect an external monitor with a display screen of at least 10 inches that can display to a resolution of 1024 x 768 pixels. Set up the monitor so that it can be viewed easily by the user and is not positioned any further than 1.5 m from the user during any electro- physiological examination. Depending on the display screen size being used, it may be possible to increase the distance of the user from the monitor with a resolution of 1024 x 768 pixels.

Setting up the device

- Place the device in a position protected from spray water. Place the device on a flat, dry surface. Place the device in a position where it cannot slip, even with cables connected, nor be touched by the patient, and so that you can pull out the power plug on the device at any time. Make sure that the ventilation slots remain unobstructed. The physician must not touch any plug connections such as USB ports and the patient at the same time.

Connections and Cables

Connecting the power cord

The power cord port on the device is designed to accept the power cord. The power cord port is located on the rear side of the device.

Before connecting, ensure that the power supply conditions are met (see Power supply, p. 10).

- Connect the power cord to the power cord port on the device.

Connecting ablation catheters

The AcQBlate® FORCE ablation catheter is connected using the PK-147 cable. The Redel port for the electrical plug of the ablation catheter is marked red and is located on the front of the device. The optical port for the optical plug of the ablation catheter is also located on the front of the device.

- Connect the PK-147 cable to the red Redel port on the device.
- Connect the PK-147 cable to the AcQBlate® FORCE ablation catheter.
- Connect the optical plug on the ablation catheter to the optical port on the device. Refer to the technical manual of the ablation catheter.

Once connected, it may take up to 10 s before the ablation catheter can be used.

The first connection of the AcQBlate® FORCE ablation catheter to Qubic Force is stored and, from this time, the AcQBlate® FORCE ablation catheter can be used for 24 hours. During this time, you can remove the AcQBlate® FORCE ablation catheter from the device, for example.

The values used to obtain contact force and application angle are automatically stored by the device upon first connecting the AcQBlate® FORCE ablation catheter and each time the Qubic Force is started.

Connecting the RF generator

⚠ CAUTION

There is a risk of exceeding the leakage current limits when connecting external devices that have their own power supply as well as a risk of making an electrically conductive connection to other devices.

- Connect to the covered blue Redel port for the RF generator only devices that comply with IEC 60601-2-2 standard and are CF-type applied parts.
- Before initial commissioning, check and document all device combinations according to IEC standard 60601-1.
- Perform this inspection at least once per year according to the legal requirements.

The Redel port on the Qubic Force for the RF generator is marked blue and is located on the front of the device:

- Select the appropriate patient cable for the RF generator that you are using.
- Connect the appropriate patient cable to the Redel port marked in blue on the Qubic Force.
- Connect the appropriate patient cable to the Redel port for the ablation catheter on the RF generator.
- Follow the instructions in the technical manual for the RF generator and for the patient cable that you are using.

The following RF generators are connected using the correct patient cable as indicated below:

RF generator	**Patient cables**
Qubic RF	PK-147
EP-Shuttle	
SMARTABLATE HF Generator	PK-150
IBI-1500 T11	PK-142
Atakr II	PK-112
HAT 300 Smart	PK-111

Note: While the AcQBlate® FORCE ablation catheter and an RF generator are connected to Qubic Force it is always possible to start a cardiac radio frequency ablation, even if there is an error in how the contact force is displayed or if the Qubic Force is switched off.

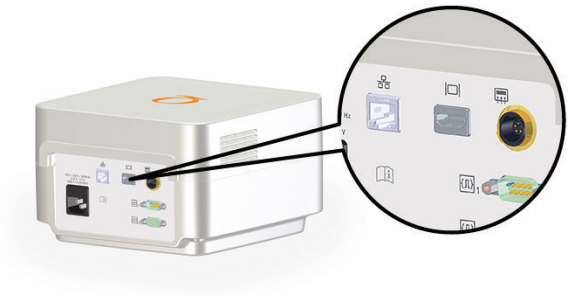
Connecting an external monitor

⚠ CAUTION

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

- Only connect devices that comply with IEC 60601-1 standard or IEC 60950.
- Before initial commissioning, check and document all device combinations according to IEC standard 60601-1.
- Perform this inspection at least once per year according to the legal requirements.

The monitor port is located on the rear side of the device.



- Using the VK-124 cable, connect the external monitor to the monitor port. The device has a monitor port for connecting it to an external monitor with the VK-124 cable. Connect an external monitor with a display screen of at least 10 inches that can display to a resolution of 1024 x 768 pixels. Set up the monitor so that it can be viewed easily by the user and is not positioned any further than 1.5 m from the user during any electrophysiological study. Depending on the display screen size being used, it may be possible to increase the distance of the user from the monitor with a resolution of 1024 x 768 pixels.

Connecting keyboard, mouse or USB stick

⚠ WARNING

Risk of energy being conducted to the patient

If the device and the patient are touched at the same time, electrical energy can be conducted from the device into the patient.

- Never touch the device and the patient at the same time.

The USB port on the device is designed solely for connection of a mouse, a keyboard or a USB flash memory stick (USB flash drive) without an independent power supply. You can connect and disconnect these accessories while the device is still active.

The USB port is located on the front of the device.

- Connect the mouse, keyboard or USB stick to the USB port.

Switching On and Off

Switching the device on and off

The on/off key is located on the right side at the rear of the device.

⚠ WARNING

Risk of energy being conducted to the patient

If the device and the patient are touched at the same time, electrical energy can be conducted from the device into the patient.

- Never touch the device and the patient at the same time.

Note: While the AcQBlate® FORCE ablation catheter and a RF generator are connected to Qubic Force it is always possible to start a cardiac radio frequency ablation, even if there is an error in how the contact force is displayed or if the Qubic Force is switched off.

- To switch the device on or off, press the on/off key.
  After switching on the device, the on/off light indicator on the front left lights up and Qubic Force performs a self-test. After the self-test, the main view appears on the external monitor.
- To disconnect Qubic Force from the mains supply, pull the power plug of the device.

Keys on the Device

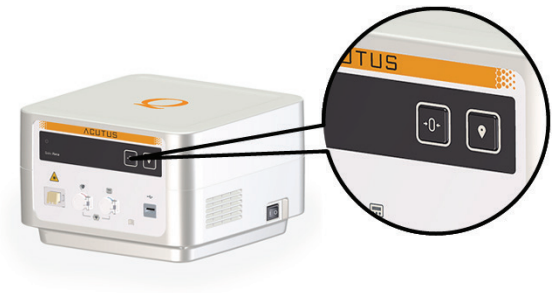
Tare key

Note: In order to prevent incorrect values for the contact force, make sure that no force is acting on the cardiac wall when you press the Tare key.

During insertion and positioning of the AcQBlate® FORCE ablation catheter in the heart, the vectors indicating the values for determination of contact force and the application angle are identified and transmitted to the device. This means that values for contact force and the application angle are already displayed before the actual cardiac radiofrequency ablation is performed. It may be useful to set these values to zero prior to beginning the cardiac radiofrequency ablation so as to better assess the applied contact force and the application angle. The displayed values for the contact force and angle are set to zero using the Tare key.

The device is automatically tared upon first connecting the AcQBlate® FORCE ablation catheter to it and each time the Qubic Force is started. When you disconnect the ablation catheter and then connect it again while the device is still active, the values used to obtain contact force and application angle are not automatically tared again.

The Tare key is located towards the upper right on the front of the device.



- Press the Tare key to set the displayed values for contact force and the angle to zero.

Marker key

A log file for the current procedure is created when an AcQBlate® FORCE ablation catheter is connected. The log stores values including the contact force and the application angle.

The following can be done using the Marker key:

- Mark the current values in the log file for the current procedure and store a screenshot.
- Transfer the log file for the current procedure and all stored screenshots to a connected USB stick.

The log file for the current procedure exists only until another AcQBlate® FORCE ablation catheter is connected. Connecting a new AcQBlate® FORCE ablation catheter overwrites the existing log file for the current procedure.

The Marker key is located on the upper right on the front of the device.

Do the following to mark the current values in the log file for the current procedure and to store a screenshot:

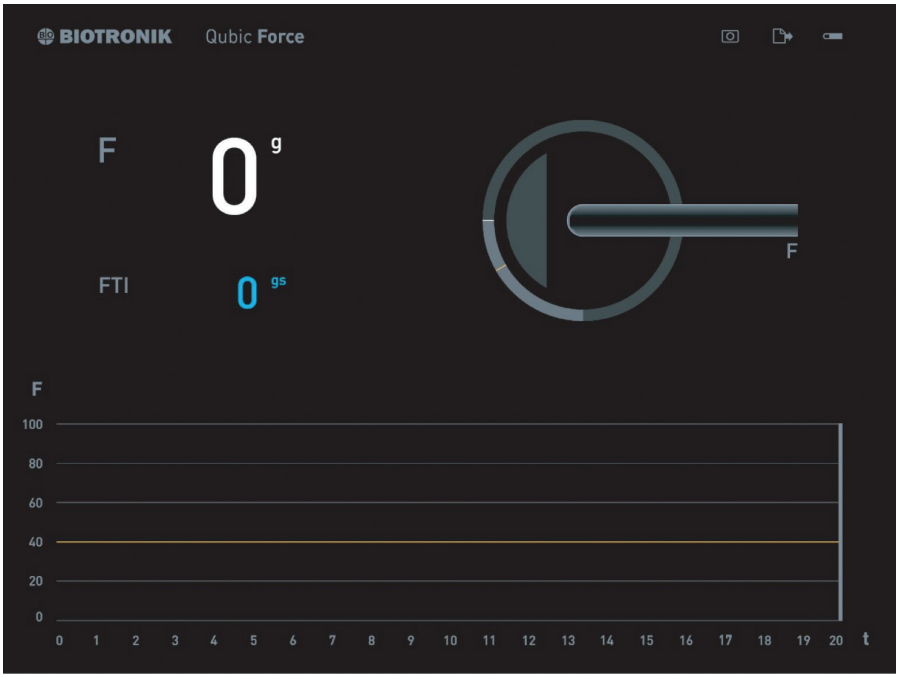
- Press the Marker key for less than 5 seconds.
  The screenshot is backed up to a USB flash memory stick, if connected. Do the following to transfer the log file for the current procedure and all stored screenshots to a connected USB stick:
- Hold the Marker key down for more than 5 seconds.

4 Using the Software

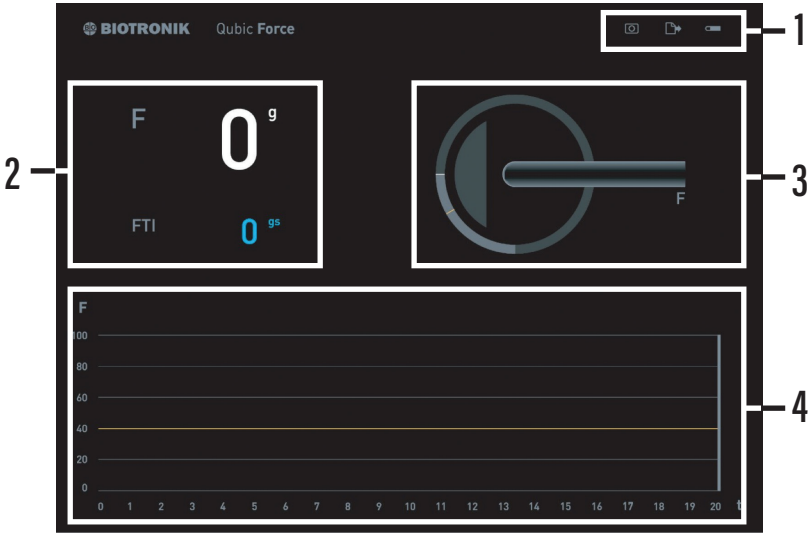
The Main View

General overview

After switching on the device, the on/off light indicator on the front left lights up and Qubic Force performs a self-test. After the self-test, the main view appears on the external monitor.



Areas of the screen



The Qubic Force screen contains four areas that present information differently:

Item	Explanation
1	Status bar
2	Numerical display
3	Graphic display
4	Trend display

The Status Bar

General overview

The status bar is located at the top right edge. It is visible in the main view and the Settings view.

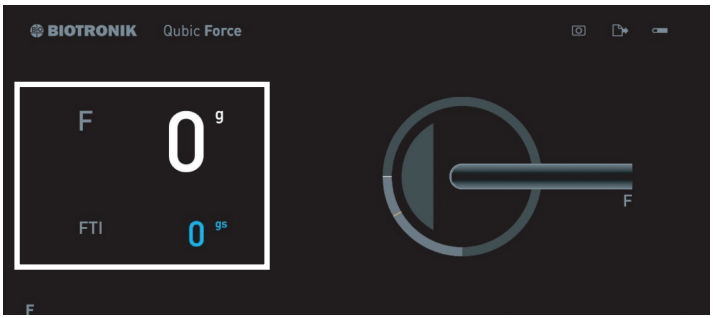
Symbol AcQBlate® FORCE ablation catheter	
	• No AcQBlate® FORCE ablation catheter has been connected.
 	• An AcQBlate® FORCE ablation catheter has been connected, checked successfully, and can be used. • The green marker changes to gray after 10 seconds.
	• An AcQBlate® FORCE ablation catheter has been connected but an error occurred, and it cannot be used. • A connected AcQBlate® FORCE ablation catheter has been removed.

Data export symbol	Marker and screenshot symbol	Explanation
		Have not been used during the current electro-physiological study
		Data has been successfully exported or the screenshot has been stored and the current values marked in the log file for the current procedure. The green marker changes to gray after 10 seconds.
		An error has occurred and the data has not been successfully exported or no screenshot has been stored and the current values have not been marked in the log file for the current procedure.

The Numerical Display

General overview

The numerical display is located in the left main area of the screen.



If an AcQBlate® FORCE ablation catheter is connected, the following current values are shown:

- **F**: The current contact force of the ablation catheter tip on the cardiac wall, in grams (g)
- **FTI**: The current force-time integral in gram seconds (gs)

The force-time integral is calculated from the following formula:

$$FTI: \int_{t1}^{t2} F\,[t]\,*dt$$

- **t1**: Start of radiofrequency ablation
- **t2**: End or duration since start of radiofrequency ablation
- **F**: Current contact force

If there is **no** AcQBlate® FORCE ablation catheter connected, no information will be displayed in this area.

The Graphic Display

General overview

The graphic display is located in the right main area of the screen.

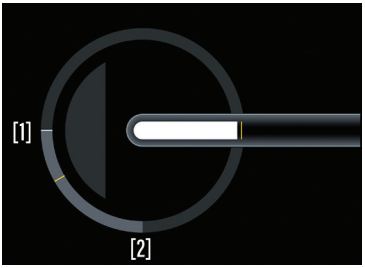
If an AcQBlate® FORCE ablation catheter is connected, the following information is displayed graphically depending on the configuration of the device:

- The angle at which the ablation catheter is applied to the cardiac wall
- The delivery of ablation energy (only if a RF generator is connected to Qubic Force.)
- Exceedance of the set contact force limit
- A possible foreseeable perforation of the cardiac wall because the following values are not within the respective tolerance range:
  - The contact force is **above** the set limit.
  - And the angle at which the ablation catheter is applied to the cardiac wall is **below** the set limit.

The contact force limit (F_{max} = 40 g) is preset in the factory settings. To adjust this value and also set the visual warning limit for the angle at which the ablation catheter is applied to the cardiac wall, a mouse or keyboard must be connected and you have to switch to the Settings view (The Settings View, p. 33).

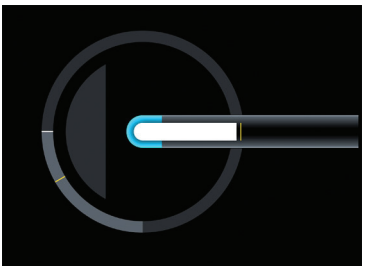
Display of the angle at which the ablation catheter is applied to the cardiac wall

- The white line in the light gray area of the circle moves between 0° (1) and 90° (2). The orange line shows the angle limit.
- The area within the circle symbolizes the cardiac wall and moves according to the angle of the catheter on the cardiac wall.



Display of the delivery of ablation energy

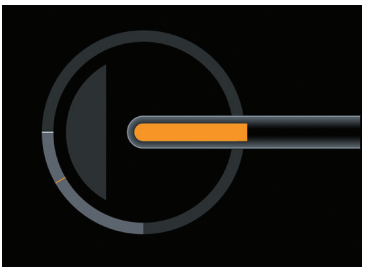
- The catheter tip turns blue.



Display of exceedance of the set contact force limit

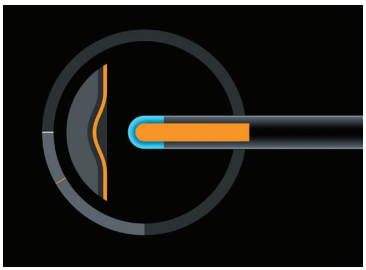
- The white area inside the catheter display turns orange.

In the numerical display on the left side, the value for contact force is also shown in orange.



Indication of possible perforation of the cardiac wall

- The white area inside the catheter display turns orange.
  The display of the cardiac wall turns orange and shows an indentation.

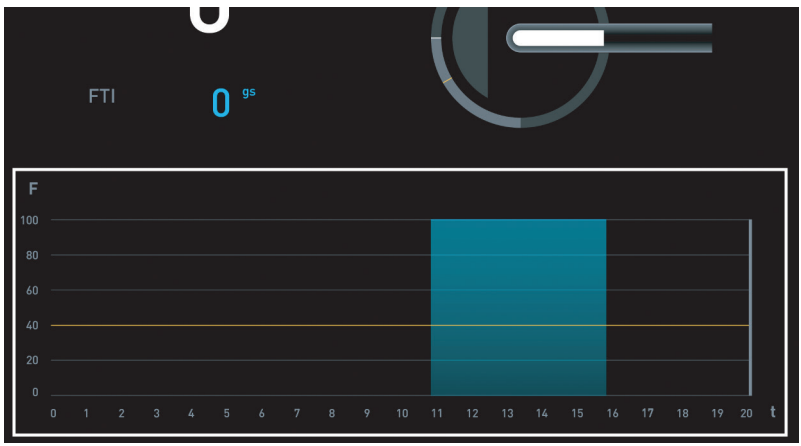


In the numerical display on the left side, the value for contact force is also shown in orange.

The Trend Display

General overview

The trend display is located in the lower area of the screen.



If an AcQBlate® FORCE ablation catheter is connected, the following information is displayed depending on the configuration of the device:

- Contact force over time
  F: Contact force in grams (g)
  t: Time in seconds (s)
- The orange line marks the set contact force limit.
- The blue range highlights the delivery of ablation energy (only if a RF generator is connected to Qubic Force).

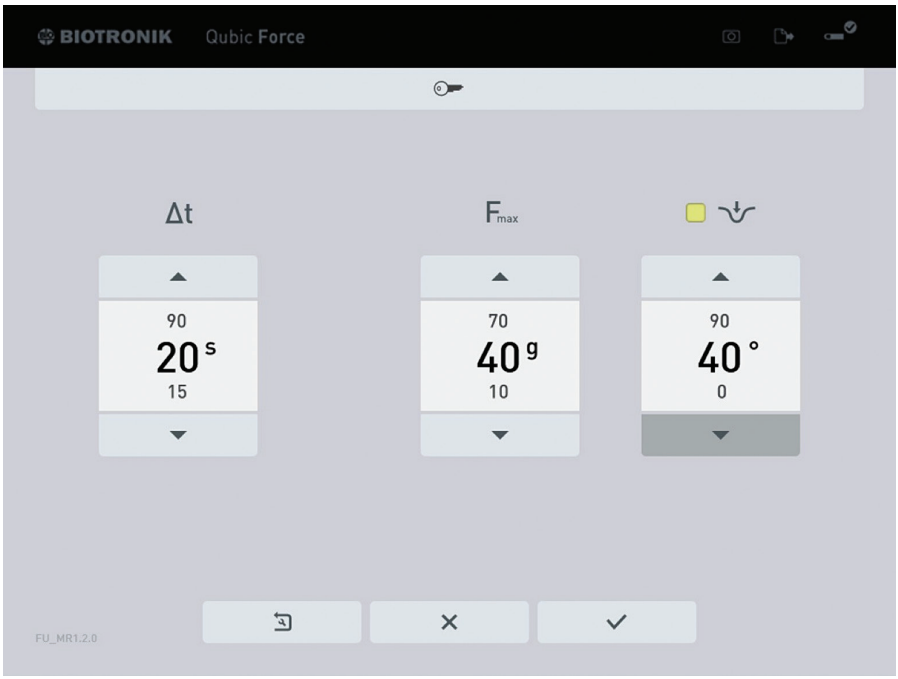
The contact force limit (F_{max} = 40 g) and the duration of the trend display (t = 20 s) are preset in the factory settings. To adjust these values, a mouse or keyboard must be connected and you have to switch to the Settings view (The Settings View, p. 33).

The Settings View

Switching to the Settings view

- Connect a keyboard or mouse to the USB port.
- Press any key.

Overview



You can set the following values in the Settings view:
- **Δt**: Duration of the trend display
- **F_{max}**: Contact force limit
- Limit for the angle at which the ablation catheter can be applied to the cardiac wall
  Setting a limit (0...90°) activates the visual warning for a possible foreseeable perforation of the cardiac wall in the graphic display of the main view. Also, the checkbox lights up green.

Closing the Settings view

- If you have connected a keyboard, there are three ways of closing the Settings view:
  – Press the Esc key.
  – Your changed settings will not be applied.
  – Navigate to the button with the checkmark using the tab key and confirm by pressing the Enter key.
  – Your changed settings will be applied.

  – Navigate to the button with the cross using the tab key and confirm by pressing the Enter key.
  Your changed settings will not be applied.

- If you have connected a mouse, there are two ways of closing the Settings view:
  – Click with the mouse pointer on the button with the checkmark.
  Your changed settings will be applied.

  – Click with the mouse pointer on the button with the cross.
  Your changed settings will not be applied.

The Settings view closes automatically once one of the following actions is performed:
- An AcQBlate® FORCE ablation catheter is connected.
- A key on the device is pressed.

Working with the keyboard

The button that is activated and whose value you can change is surrounded by a frame.

- Switching between the buttons:
  Press the Tab key on the keyboard.
- Activating/confirming a button:
  Press the Enter key on the keyboard.
- Changing the values:
  Press the arrow keys on the keyboard.
- Resetting to factory settings:
  Navigate to the button with the wrench symbol in the arrow using the tab key and confirm by pressing the Enter key.
  – All settings are reset to the factory settings.

  
- The button with the key is intended for internal use only.

Working with a mouse

The button that is activated and whose value you can change is surrounded by a frame.

- Switching between the buttons:
  Click the mouse pointer on the respective arrow key or button.
- Activating/confirming a button:
  Click the mouse pointer on the respective button.
- Changing the values:
  Click the mouse pointer on the respective arrow keys of the button.
- Resetting to factory settings:
  Click the mouse pointer on the button with the wrench symbol in the arrow.
  – All settings are reset to the factory settings.

  
- The button with the key is intended for internal use only.

5 Appendix

Technical Data

Physical properties

Property	Design
Dimensions (W x H x D)	230 x 150 x 240 mm
Weight with power cord	4.7 kg (± 300 g)
Housing material	Polyurethane (PUR)

General classification

Property	Design
Medical product classification	Class IIb in compliance with Directive 93/42/EEC (MDD)
Mode of operation	Continuous operation

Longevity

Property	Design
Longevity	5 years

Ambient conditions

Property	Design
Temperature range for operation	+10°C ... +40°C
Temperature range for storage	0°C ... +50°C
Atmospheric pressure for operation	700 ... 1060 hPa
Atmospheric pressure for storage	700 ... 1060 hPa
Relative humidity	30% ... 75%, no condensation
Operation at altitudes	Up to 2000 m

Safety equipment

Property	Design
Applied part classification	CF, defibrillation protected with the specified cables
Degree of protection	IP 30

Power cord port

Property		Design
Supply voltage		100–240 V, ± 10% 50/60 Hz, ± 1 Hz max. 0.2 A-0.47 A/AC
Protection class		I
Fuse type		T 1.6 AH, 250 V
Max. power input	Duration	25 W
	Peak	40 W
Level of efficiency		> 85% (at 230 V/50 Hz)
On/off light indicator		Green LED, lit continuously

Light source

Property	Design
Type	SLED (superluminescent diode)
Laser class	1
Type of radiation	Infrared light
Spectral interval	1510–1590 nm
Radiant flux	< 10 mW

RFID communication

Property	Design
Type	RFID conforming to ISO 15693
Frequency band	13.56 Mhz
Max. power of transmission	200 mW

Measurement accuracy of the contact force system, consisting of AcQBlate® FORCE Catheter and Qubic Force

Measurement accuracy without delivery of ablation energy

Contact force (F)	Measurement accuracy
< 20 g	± 3 g
20 g ≤ F ≤150 g	± 15%

Possible offset during delivery of ablation energy

Contact force (F)	Offset
≤ 80 g	± 10 g

Parameter Values

Parameters of the main view

Parameter	Unit	Range of values	Step size
In the numerical display			
Contact force	Grams (g)	0 – 150 g	1
Force-time integral	Gram seconds (gs)	0 – 9999 gs	1
In the graphic display			
Angle of ablation catheter to cardiac wall	Degrees (°)	0 – 90°	1
In the trend display			
Contact force	Grams (g)	0 – 150 g	–
Time	Seconds (s)	15 – 90 s	1

Parameters in Settings view

Parameter	Factory setting	Unit	Range of values	Step size
Contact force limit	40 g	Grams (g)	10 – 70 g	1
Angle limit for ablation catheter to cardiac wall	Off	Degrees (°)	0 ... 90°, Off	1
Length of time axis in trend display	20 s	Seconds (s)	15 – 90 s	1

Accessories

Accessories

Not all accessory products are available in every country.

Item designation	Description	Order no.
Qubic Force	Device with installed application software	900012
AcQBlate® FORCE Ablation catheter	Variant red: Range 48 mm and length of tip electrode 65 mm	900202
	Variant blue: Range 57 mm and length of tip electrode 75 mm	900203
	Variant green: Range 65 mm and length of tip electrode 85 mm	900204
	Variant black: Range 73 mm and length of tip electrode 95 mm	900205
	Variant cyan: Range 80 mm and length of tip electrode 105 mm	900206

VK-124	Video cable for connecting an external monitor; 5.0 m long	417863
	Video cable for connecting an external monitor; 15 m long	417864
PK-111	Cable for connecting the HAT 300 Smart RF generator	330080
PK-112	Cable for connecting the Atakr II RF generator	330081
PK-142	Cable for connecting the IBI-1500 T11 RF generator	362442
PK-147	Cable for connecting the ACQBlate® FORCE ablation catheter to the Qubic RF generator or EP-Shuttle RF generator ; cable length 2.5 m; sterile	398853
PK-150	Cable for connecting the SmartAblate RF generator	402668
NK-3	Power cord for EU	107526

Item designation	**Description**	**Order no.**
NK-11 (3 m)	Power cord for USA and Japan	128865
NK-16-GB (2 m)	Power cord for the United Kingdom	330705
NK-19-CN (2.5 m)	Power cord for China	339034
NK-21-AU, UY (2.5 m)	Power cord for Australia and Uruguay	339035
NK-22-AR (2.5 m)	Power cord for Argentina	339039
NK-26-CL, IT (2.5 m)	Power cord for Chile and Italy	339043
NK-28-DK (2.5 m)	Power cord for Denmark	339059
NK-25-CH (2.5 m)	Power cord for Switzerland	339042
NK-27-IL (2.5 m)	Power cord for Israel	339044
NK-33-BR (2.5 m)	Power cord for Brazil	378933

Country-Related Information

Canada

- **Industry Canada**
  The device is registered at Innovation, Science and Economic Development Canada under the following identification:
  IC 4708A-QFORCE

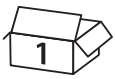
USA

- **Federal Communication Commission**
  The device is registered with the Federal Communications Commission under the following number:
  FCC ID: QRIQFORCE
- Note:
  This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These directives are designed to provide reasonable protection against harmful interference in a commercial installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Legend for the Label

The label icons symbolize the following:

	Date of Manufacture
	Acutus Medical order number
	Serial number
	Temperature limit for storage
	Air pressure limit for storage
	Follow the Instructions for Use

	Quantity of devices
	Keep dry
	CE mark
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EC regarding waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to Acutus Medical.
	Qubic Force
	Patient with inserted diagnostic or ablation catheter
	Manufacturer
	Deadly Risks of Using Non-Approved Chargers and Cables
	European Distributor
	Medical Device
	Authorized representative in the European community
	Humidity Limitation

6 Directories

Index

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