

TwistDx

Twista™

Manual



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Copyright Information

User Manual Twista™

Document Version 0.7 / March 2011

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Printed in Germany

Qiagen GmbH
Jacques-Schiesser-Strasse 3
D-78333 Stockach
Germany

Tel: +49 (0) 7771-9166-0
Fax: +49 (0) 7771-9166-18
Email: sales-qjc@qiagen.com
Website: www.qiagen.com

Qiagen GmbH is certified according to ISO 9001 and EN 13485 and is thus equipped for usual regulatory requirements.

The following document describes the Twista™



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1 Introduction

1.1 General

The isothermal DNA amplification process, for example Recombinase Polymerase Amplification (RPA), operates at a constant temperature. Isothermal DNA/RNA amplification enables a new generation of DNA tests for a broad spectrum of end-users through a reduction in the need for hardware and sample manipulation.

Most isothermal methods lack either the necessary scalability, sensitivity, rapid time to result, or specificity. Complete solutions, including hardware are required to support and sustain the RPA process, especially for point-of-care and field applications.

The Twista™ offers powerful solutions for a range of applications including:

- Tests performed in clinical chemistry
- Isothermal and end-point Nucleic Acid Amplification and Testing including RPA
- End-point PCR read out
- ELISA–Tests / Immunodiagnosics
- Colorimetric and Fluorescence Bacteriological Tests / Cell-Cultures
- Colorimetric and Fluorescence Environmental Tests / Water Analysis
- DNA and Protein Quantification (Fluorescence)
- Many other Tests in Tube Format with or without Thermal Control

Operating the test close to the sample source saves time and costs. It also reduces the risks of sample contamination, sample degradation due to incorrect or prolonged storage and sample mis-identification can, therefore, decrease the incidence of false-positive and false-negative results.

The Twista™ provides sensitive, accurate and specific results, as well as rapid turnaround. The stand-alone device provides operational and physical robustness at an affordable cost.

Due to its mobility, the Twista™ requires no sample storage or transportation, because clinical samples can be processed directly, most of the trouble of sample preparation can be avoided.

1.2 Intended Use of the Device

The Twista™ is a device for the analysis of fluorescence and colorimetric tests. It should only be used according to the safety precautions outlined in chapter 1.4. The Twista™ should only be used with specified test materials by trained qualified personnel. The mobile device has to be powered by the specified power pack or with the specified external power supply. The data resulting from measurements can be transferred to a PC via USB port, using the software provided. The Twista™ may be used in the laboratory, or in the field, provided that all the environmental and operating conditions are met.

Note:

For your own safety do not operate the Twista™ without tubes inserted. With the exception of sample mixing, do not open the tube lid while measurement is in progress. Only authorized persons are allowed to service or disassemble the device.

1.3 Main Features of the Reader

- **Quantitative:** excellent repeatability, long term stability and the powerful controller provide reliable test results.
- **Highly Sensitive:** the award winning confocal detector used for measurements provides unmatched sensitivity.
- **Easy to Use:** the complete analysis (data collection, evaluation, display and storage of raw and result data) can be initiated via a single button operation.
- **Portable:** the Twista™ provides all the necessary requirements of a portable device. It is small, lightweight and can be operated as a stand-alone device. The device can be optionally operated by a Li-Ion rechargeable power pack.
- **Connectivity:** easy connection and transfer of data to a PC via USB is available. User-friendly software allows quick and easy processing of data.

1.4 Safety Precautions

Operating Location:

The location of the Twista™ should be preferably on a desk or stable surface with enough surrounding space in order to provide convenient access to the device. In case of an emergency, or under abnormal operating conditions, the location should provide, at any time, enough space to allow the easy disconnection of the device.

Power Pack:

The Twista™ can be powered by a Li-Ion rechargeable power pack without external power supply. The power pack must be periodically recharged by connecting the external power supply.

Ambient Temperature:

The use of the Twista™ in environments prone to large changes in temperature can cause measurement values to deviate from real values. Calibrate under similar conditions beforehand. Please take the environmental conditions into account when trouble shooting.

Ambient Light:

The Twista™ is a highly sensitive and precise optical device. It has internal correction for normal levels of ambient light, yet highly intense light falling into the tube holder can cause serious interference with the measurement and must be avoided.

Vibration:

Twista™ is a highly sensitive and precise optical device and thus must be used on a stable and level surface. The results can be influenced by vibrations, for example, if the device is used close to vibrating machinery.

Dirty Environment:

If you plan to use the Twista™ in a working environment prone to dust and dirt, you will need to clean the device regularly. For cleaning, use a damp cloth. For more persistent stains, it is also possible to clean the surface with a cloth moistened with pure alcohol (isopropanol or ethanol). Avoid the use of aggressive solvents such as acetone.



Do not expose the Twista™ to direct sunlight



Protect the device from high humidity and contact with liquids



Do not expose the device to excessive heat



Do not expose the device to strong electromagnetic radiation



Use the specified rechargeable power pack only

The Twista™ can be used under the following conditions:

Temperature range:	+10°C to +45°C
Relative Humidity:	less than 70%
Air Pressure:	300 to 1060hPa
Maximum Altitude:	2000m



Figure 1: Twista (Lid opened)

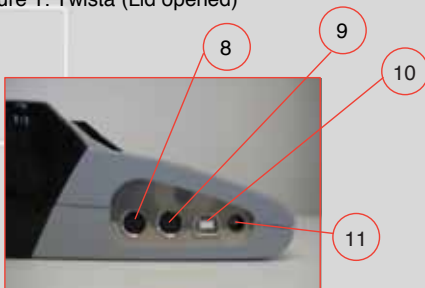


Figure 2: Connectivity Features

2 Getting to know the Twista™

2.1 Overview

- 1 Display
- 2 ENTER Button
- 3 BACK Button
- 4 FORWARD Button
- 5 UP Button
- 6 DOWN Button
- 7 Tube Holder for 8 Tubes
- 8 Printer I/O Port
- 9 Scanner I/O Port
- 10 USB Port
- 11 Power Port



Fig. 3: Connecting the Power Pack

2.2 Contents of the Kit

- Twista™
- CD with Twista™ Studio Software and Manual
- Power Supply
- USB cable

2.3 Optional Accessories

- Power Pack
- Molded Case

2.4 Installation

Power Supply Options:

- a) External Power: connect external power supply to power port.
- b) Power Pack: add the Power Pack at the bottom of the device as shown left. Align the captive screws in the Power Pack with the base of the Twista™ and tighten the screws to secure the Power Pack. Note that the external power supply lead (1) is connected to the Power Pack; the Power Pack lead is connected to the Twista™'s power port (2).

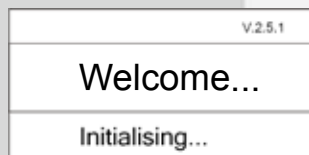


Fig. 4: Initialisation Screen

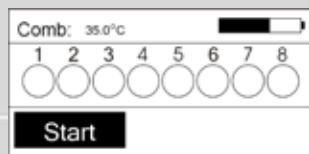


Fig. 5: Start Screen

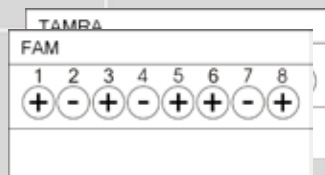


Fig. 6: Individual Channel Data Screens

3 Using the Twista™ in Stand-Alone mode

3.1 Switching on the Twista™

Press the Enter button (see section 2.1 above). The Twista™ will start, showing an initialization screen. When the Twista™ has initialized, the Start screen appears and the Twista™ is ready to run a test.

3.2 Start Screen

Press the Enter button to start the test. The Twista™ will set the temperature, progress is shown on the screen. When the temperature is reached, each tube is measured in turn for the duration of the test. As the test proceeds, a symbol will be displayed for each sample tube as: ? (Invalid), empty (Unknown), + (positive) or – (negative). To stop the test, press the Enter button.

3.3 Viewing Individual Channel Data

Press the Forward or Back button until the individual channel data screen is identified. Individual channel data is displayed for each tube as: ? (Invalid), empty (Unknown), + (positive) or – (negative).

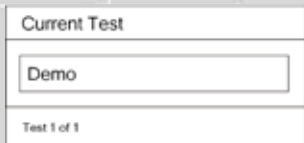


Fig. 7: Current Test Setup Screen

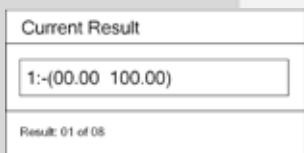


Fig. 8: Current Result Screen

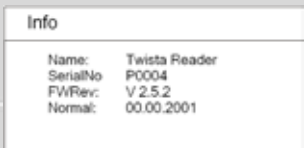


Fig. 9: Info Screen

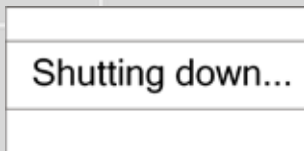


Fig. 10: Shutdown Screen

Press the Forward or Back button until the Current Test Setup screen is displayed. The desired test setup can be selected from any which are resident in memory using the Up and Down buttons.

3.5 Viewing Current Result

Press the Forward or Back button until the Current Result screen is displayed. The desired result set can be selected from any which are resident in memory using the Up and Down buttons.

3.6 Viewing System Info

Press the Forward or Back button until the Info screen is displayed. The Info contents are:

Name:	Name of the instrument
ID:	Part Number of the instrument
SerialNo:	Serial number of the instrument
FWRev:	Firmware revision
Normal:	Date of instrument normalization

3.7 Switching Off

Press the Enter button and hold for several seconds until the shutdown screen appears. The instrument will switch off.



Figure11: Icon of the Twista™ Studio Software

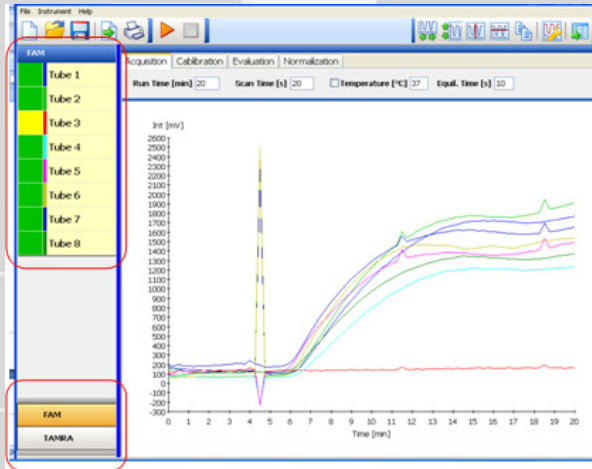


Figure12: Screenshot of Twista™ Studio Software (8 Tubes and 2 Dyes)

4 Using the Twista™ with a Computer

Operating the Twista™ via PC is carried out using the Twista™ Studio Software. This includes setting up and downloading test setups and operating the test under PC control. (Please refer to the Twista™ Software Manual).

5 Trouble Shooting

This section is intended for qualified users with installation and maintenance responsibilities. The instructions are supposed to help users to solve problems and fix errors in the proper operation of the Twista™. Only problems referring to the use of the Twista™ and its specific solutions are described here.

Problem	After turning on the Twista, the display remains black
Cause	POWER ON button was not pressed long enough
Solution	Press the POWER ON button on the key board for more than 1 second
Cause	(The optional) Power Pack is empty
Solution	Charge Power Pack by connecting the external power supply
Problem	Twista™ does not run after pressing start
Cause	Equilibration Time (refer to manual “Twista™ Studio Software”) was defined and has not been reached
Solution	Wait until Equilibration Time has been reached – OR -
Solution	Set Equilibration Time to “0”

Problem	No PC connection
Cause	Cable not inserted into PC and/or reader
Solution	Connect the PC to the reader via USB cable
Cause	USB driver not installed
Solution	Install USB driver (refer to “Twista Studio Software Manual”)
Problem	Measurement results are not displayed constantly in the graph or result table (refer to “Twista Studio Software Manual”)
Cause	The lid was opened during measurement
Solution	Close the lid and start the measurement again
Problem	Twista™ starts beeping during measurement
Cause	The mixing time was defined and the time for mixing has been reached (refer to “Twista™ Studio Software Manual”)
Solution	Open the lid, mix and close the lid again – OR -
Solution	Set the “Remind to mix after”-time to “0” (refer to “Twista™ Studio Software Manual”)

6 Maintenance Notes

This section is intended for qualified users with maintenance responsibility. The instructions should provide the user with the necessary information for proper maintenance and care for the Twista™.

6.1 Charging the Power Pack

The optional Power Pack can be charged with the Twista™ switched on or off by connecting the external power supply lead to the power pack; the power pack lead is connected to the Twista™'s power port.

6.2 Device Calibration

Twista™ is a highly sensitive optical device, but it may be necessary to recalibrate the instrument periodically for optimum results. Please contact your Service partner for details.

6.3 Cleaning the Device

If you use the Twista™ in a working area that is subject to high levels of dirt, you should clean the device regularly. Use a damp cloth to clean the device. If the dirt is persistent, you can also rub the surface of the device with a cloth that has been moistened with pure alcohol (isopropanol or ethanol). Do not use aggressive cleaning agents such as acetone. If the inside of the device is contaminated, please contact the manufacturer.

6.4 Upgrading the Device Software (Firmware)

Upgrading the instrument firmware is performed by the Twista™ Studio software. For up to date information on available firmware, please visit the Qiagen webpage www.qiagen.com

6.5 Disposal of the Sample Tubes

Please refer to the guidelines of the tube supplier.

7 Technical Specifications

Power	
Power Adapter	Input: AC 100-240V _{AC} , 0.8A, 47-63Hz Output: DC 18V _{DC} , 1.65A
Twista™ Power Port	DC 18V _{DC} , 0.85A
Storage Conditions	
Temperature	-20°C to +70°C
Relative Humidity (non-condensing)	less than 70%
Air Pressure	300 to 1060hPa
Operating Conditions	
Temperature	+10°C to +45°C
Relative Humidity (non-condensing)	less than 70%
Air Pressure	300 to 1060hPa
Protection Category	IP21
Physical Data	
Housing Material	ABS

Dimensions H x W x D	74 x 178 x 188mm (Note 1)
Weight	1kg (Note 2)
Interface	
PC Interface	USB
I/O Input	5V logic
I/O Output	5V logic
Tube Holder	
Tube Type	Maximum 8x 200µl tubes (e.g. manufacturer: Axygen - 8 tubes PN: PCR-0208 - 8 lids PN: PCR-02CP)
Temperature	+35°C to +42°C

Note 1: without power pack

Note 2: without power adapter and without power pack

8 Warranty and Customer Services

For product and service requests, please contact:

Qiagen GmbH
Jacques-Schiesser-Strasse 3
D-78333 Stockach
Germany

Tel: +49 (0) 7771-9166-0
Fax: +49 (0) 7771-9166-18
Email: sales-qlc@qiagen.com
Website: www.qiagen.com



This chapter is intended for qualified users in charge of installation and maintenance. The instructions are meant to make the user familiar with the procedures to follow in a warranty situation.

8.1 Liability for Defects

The warranty period is based on statutory provisions and is usually 24 months. In the case of pre-used equipment, liability for defects and warranty shall be excluded. If instructions given by ESE GmbH with respect to storage, installation and handling of the products are not followed, or if changes are made to the product, parts are replaced or consumable items are used, which do not comply with the original specifications, any warranty rights are forfeited unless the business partner is able to refute any assertion that any of these circumstances

has caused the deficiency. Defects, incorrect deliveries, quantities or transport damage are to be notified without delay by the business partner of ESE GmbH in writing or by fax (in case of defects that can be identified immediately), otherwise within 2 weeks of receipt of the products at the place of destination, by clearly describing the defect. In this respect it is necessary that the business partner properly fulfills his obligations of investigation and notification in accordance with Article 377 of the Commercial Code. ESE GmbH shall be notified of any defects, which cannot be detected within a reasonable time-frame, immediately upon their detection. If the business partner notifies ESE GmbH that the products are defective, ESE GmbH will require return of the defective products to ESE GmbH for repair or replacement at the discretion of ESE GmbH. Transportation of the defective product is to be insured by the business partner of ESE GmbH. If return to factory and rework fails at least twice, or cannot be reasonably expected from ESE GmbH, the business partner has the option to demand a reduction in price or withdraw from the contract. The same shall apply if replacement of the product fails or, cannot be reasonably expected from ESE GmbH. Withdrawal from the contract shall be allowed only if the reduction in value of the product, or reduction in its suitability for use in accordance with the contract is deemed to be significant. In this case, warranty costs will still be applicable.

8.2 Warranty

As a rule, the statutory 24-month manufacturer warranty shall apply for hardware and software products not produced by Qiagen GmbH. Furthermore, warranty for these products will only be provided on condition that the warranty case is recognized and confirmed by the manufacturer or the sub-contractor of Qiagen GmbH. Qiagen GmbH will provide warranty for Twista™ and related products of Qiagen GmbH, including the Twista™ Studio PC software, for at least 24 months. Consumable parts, including rechargeable batteries, will be covered by a specific warranty period. If Qiagen GmbH gives the business partner warranty beyond the warranty period mentioned above, Qiagen GmbH will reserve the right to repair or replace the defective part. The place of fulfillment of this warranty shall be the company address stated below.

If Twista™ is found to be defective despite our rigorous quality control systems, please contact us at the address below:

Qiagen GmbH
Jacques-Schiesser-Strasse 3
D-78333 Stockach
Germany

Tel: +49 (0) 7771-9166-0
Fax: +49 (0) 7771-9166-18
Email: sales-qlc@qiagen.com
Website: www.qiagen.com



Upon receipt of your notification of claim we will promptly send you a RMA form. In addition to the RMA number, this document includes space for you to describe the nature of the problem. The RMA number is for warranty claims and provides transparency in the transaction, allowing us to process the claim as quickly as possible. After filling out the form, please return the form and the defective product, freight collect, to the above address. We will repair or replace the product and return it to you as quickly as possible. Please be aware that it may take several days to process this transaction.



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compliance / accordance
with DIN ISO 9001.

Qiagen GmbH
Jacques-Schiesser-Strasse 3
D-78333 Stockach

Germany

Website: www.qiagen.com
Email: sales-qlc@qiagen.com



