

Quo-Test



User Manual

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Quo-Test User Manual

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Section 1 Safety Precautions

Basic safety precautions must always be taken, including all those listed below.

Danger - Misuse of electrical equipment can cause electrocution, burns, fire and other hazards.

Close supervision is necessary when the system is used, on, or near children, or vulnerable persons.

Read the following instructions before using the system

- 1) Connect the analyzer to the mains supply. The mains outlet must have an earth connection.
- 2) If the system is not going to be used for an extended period of time, unplug the analyzer from the mains supply.
- 3) **Do not** place the system in liquid, or put it where it could fall into liquid. If the equipment becomes wet, unplug from the mains supply before touching it.
- 4) Use the system only for the purpose described in this User Manual.
- 5) **Do not** use accessories which are not supplied or recommended by the manufacturer.
- 6) **Do not** use the system if it is not working properly or if it has suffered any damage, for example;
 - a) damage to the flexible supply cord or its plug.
 - b) damage caused by dropping the system.
 - c) damage caused by dropping the system into liquid or splashing liquid on to it.
- 7) **Do not** let the equipment or the flexible cords come into contact with surfaces which are too hot to touch.
- 8) **Do not** block air openings or place the system on a soft surface. Keep air openings free from debris.
- 9) **Do not** place anything on top of the system.
- 10) **Do not** drop or put anything into any opening in the equipment, unless instructed by this User Manual.
- 11) **Do not** use the system where aerosol sprays are used, or where oxygen is administered.
- 12) **Do not** use the system out of doors.
- 13) **Do not** use the system in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation of the analyzer. An evaluation of the electromagnetic environment should be undertaken before using the system.

General Information

IVD Please read these instructions in full before performing a test

The Quo-Test Analyzer is for *in vitro* diagnostic use only.

The Quo-Test Analyzer is for use at the point of care.

Only Quo-Test Cartridges can be used with the Quo-Test Analyzer.

Unpacking

Unpack the system and check that the following components are present in the pack. If there is anything missing contact your local distributor or customer support.

- Quo-Test Analyzer
- Barcode Scanner
- Mains Power Cable
- Power Supply
- User Manual

It is recommended to keep the packaging to transport your analyzer. If the optional printer has been purchased, it will be delivered in a separate box.



Warnings and Precautions

- There are no user serviceable parts inside the analyzer. Call your local distributor or customer support if you have any problems that are not resolved by following the **Troubleshooting Guide and Error Messages** section of this User Manual.
- Place the system on a clean, dry, flat and level surface away from direct sunlight in a room with a temperature range of 18 to 30 °C (64 to 86 °F). An analyzer which has been stored at a temperature above or below the working temperature will take longer to exit the Analyzer Warm Up screen when the system is first powered on.
- Place the system away from draughts, or other sources that may cause sudden changes in temperature e.g. air flow from air conditioning units.
- The system must be within easy reach of a mains supply outlet with a protective earth connection.
- The system has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may need to take measures to mitigate the interference.
- Ensure that the analyzer and cartridges have reached room temperature before using the system.
- The analyzer must be used in accordance with the instructions stated in this User Manual.
- Used cartridges must be treated and disposed of as clinical waste.

Intended Use

The Quo-Test A1C System is intended for the *in vitro* quantitative determination of glycosylated hemoglobin (HbA1c) in whole blood obtained from a finger prick or venous whole blood sample collected into EDTA tubes.

The Quo-Test A1C System is indicated in the management and treatment of diabetes mellitus and for monitoring long term glycemic control in patients diagnosed with diabetes.

The Quo-Test A1C System is designed for professional use only.

Quo-Test Quality Controls are intended to check the correct operation of the Quo-Test A1C System.

Quo-Test System Description

The Quo-Test A1C System consists of the Quo-Test Analyzer, Quo-Test A1C Test Cartridges, Quo-Test A1C Control Kit and Thermal Label Printer (optional). Quo-Test A1C Test Cartridges can only be run on the Quo-Test Analyzer. Figure 1 shows the main parts of the analyzer.

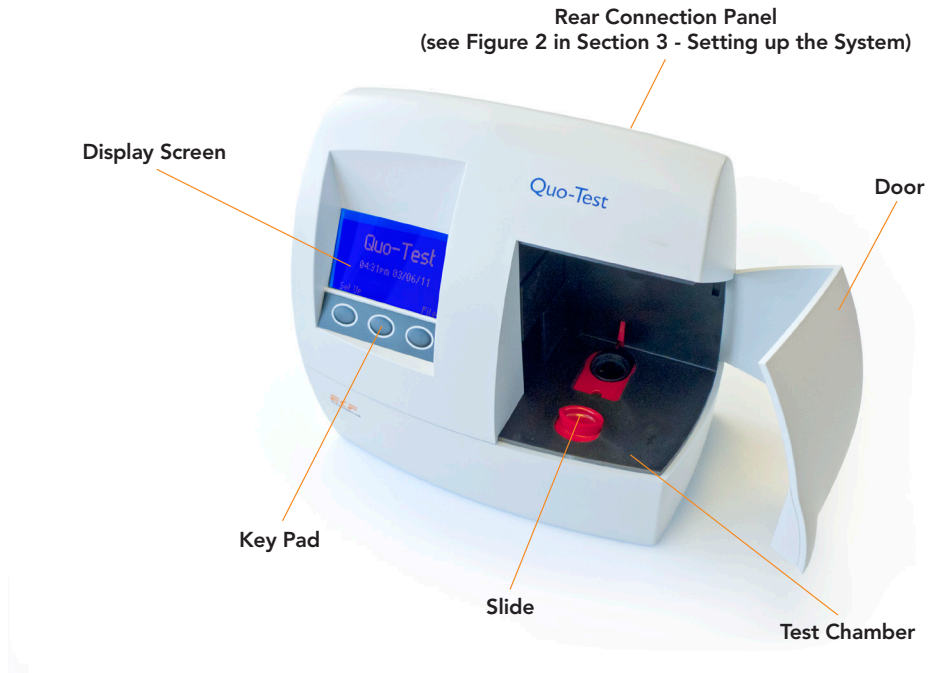


Figure 1: The Quo-Test Analyzer

Read the Instructions For Use that come with the Test Cartridges. Refer to the Instructions For Use on how to prepare and perform the test. The Quo-Test Analyzer will provide on screen instructions at each stage of performing the test. At the end of the test the result is displayed on the screen, stored in the analyzer memory and can be printed on to a label with the optional printer.

The Quo-Test Analyzer is calibrated by the manufacturer and there are no user-serviceable parts.

The analyzer performs optical, electronic and mechanical checks on the test cartridge throughout the test procedure and if a problem is detected the analyzer stops the test and an error message is displayed on the screen. If this happens, then consult the **Troubleshooting Guide and Error Messages** section of this User Manual.

Measurement Principle

The arrangement of the two light sources and associated detectors allows the Quo-Test Analyzer to be used as a dual channel spectrophotometer / fluorimeter. This allows the Quo-Test Analyzer to be used either to measure changes in optical density as used in Immunospectrometric assays or changes in light transmission from specific fluorophores as they interact with analytes of interest e.g. HbA1c.

Section 3 Setting up the System

Connect the barcode scanner and the printer (optional) to the analyzer by pushing the cables into the connectors on the rear panel. Make sure the printer and barcode scanner are connected to the correct ports as shown in Figure 2 below. If the printer is no longer required, disconnect it from the analyzer.

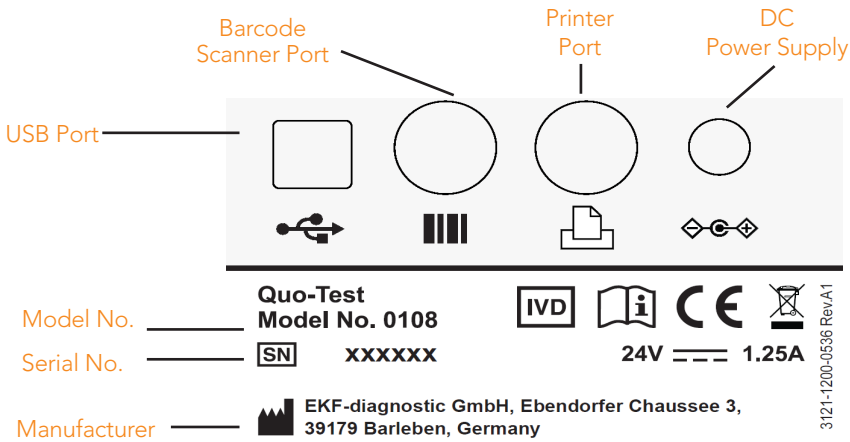
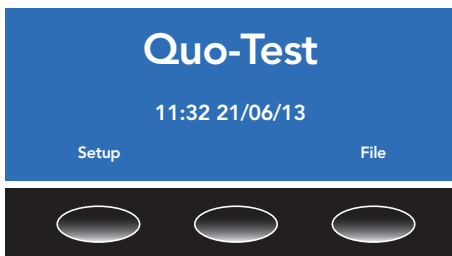


Figure 2: Connection panel on the rear of the analyzer.

Connect the power supply to the analyzer and plug the supply cord into the mains supply (100-240v AC 50-60Hz). Ensure that the supply has a protective earth connection.

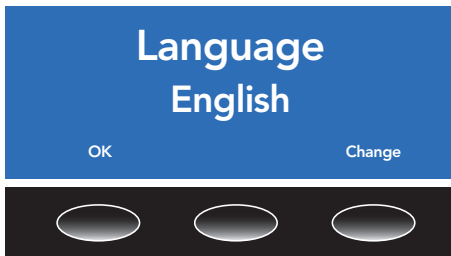


Once the analyzer has warmed up the screen will show the Quo-Test logo, this is the home screen. The keypad under the blue screen has three buttons. The text on the screen immediately above each button shows the function of that button. If there is no text above a button, then it has no function. The functions of the buttons change, depending on which screen is displayed.

When the analyzer is first switched on, you must set the local language, time, date, ID options and reported units before you perform a test. You only need to do this once.

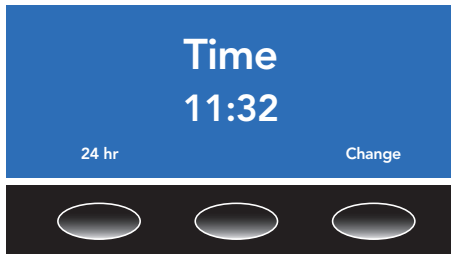
The analyzer should be switched off at the mains supply or unplugged when not required for long periods. Otherwise the analyzer should be left on, but must be powered down and restarted once a week, to perform the self-check procedure. Ensure that the analyzer is displaying the home screen before powering the system down.

Press the button labelled Setup to start the setup process.



Setting the Language

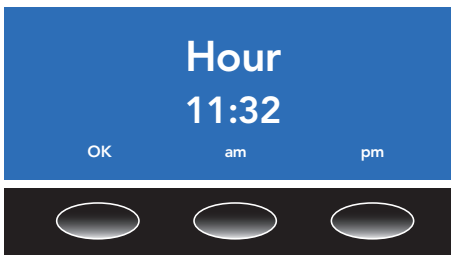
The default language for the analyzer is English. To change to a different language, press the **Change** button and use the **up/down** arrow buttons to select the required language from the list. Press the **OK** button to confirm the selection.



Setting the Time

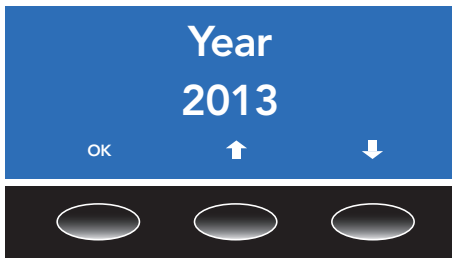
The analyzer has a clock that keeps track of the date and time. Whenever a test is performed, the result is recorded in the analyzer memory with the date and time that it was run. Choose Change on the time screen to set the time.

Choose either the **24 hr** or **12 hr** clock by pressing one of the buttons. Set the hours and minutes by using the **up/down** arrow buttons. Press **OK** when correct.



If the **12 hr** clock is selected, then set either am or pm. Press **OK** to confirm the settings.

The time will then be displayed. Either press the **OK** button to move on to setting the date, see next section, or press the Change button to go back to setting the time.



Setting the Date

To set the date, use the **up/down** arrow and **OK** buttons to set the year, month and day as required. Press the **OK** button to save the selection.

Choose the date format, either **dd/mm/yy** or **mm/dd/yy**. Press the **OK** button to save the selection. The date will then be displayed.

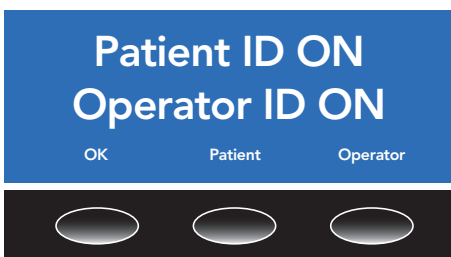
Either press the **OK** button to move on to setting the ID options, see next section, or press **Change** to go back to setting the date.

Note: The analyzer will automatically adjust the time and date for leap years.

Setting the Identification (ID) Options

The Quo-Test Analyzer allows for operator and patient identification (ID) to be entered via the supplied barcode scanner. This feature allows recording of the ID of the person who ran the test and the person who was tested in the analyzer memory and on the result print-out (if the optional printer is attached). These features can be switched on or off. The operator has the option to skip the ID entry when analysing a cartridge if the feature is turned on. Having the operator and patient ID stored or printed with the test result, will aid identification of the result at a later date.

Barcode lengths up to 18 characters in Code 128, Code 39, NW7/Codabar and 2 of 5 Interleaved formats are supported. It is strongly recommend that users do not use 2 of 5 interleaved as this format carries a risk of character substitution. Attempting to scan a barcode in excess of 18 characters will result in the code being shortened to 18 digits.



Users must verify that the Patient or Operator ID scanned matches the one displayed on the Quo-Test.

Press the **Patient** and **Operator** buttons to switch these features on. Press the buttons again to switch the features off. Finally, press **OK** to move on to setting the reported units.

Calibration

The Quo-Test A1C System is certified by the NGSP and IFCC.

The Quo-Test Analyzer and A1C Test Cartridges have been calibrated using samples provided by the European Reference Laboratory via the NGSP network.

Results obtained using the Quo-Test A1C System are traceable to the IFCC reference method.

Reported Units

The Quo-Test A1C assay reports results in up to two user selectable units: % DCCT, mmol/mol IFCC, % JDS, eAG mg/dl or eAG mmol/l.

$$\text{mmol/mol IFCC} = (\% \text{ DCCT} - 2.15) \times 10.929$$

$$\% \text{ JDS} = (0.09274 \times \text{mmol/mol IFCC}) + 1.724$$

$$\text{eAG mg/dl} = (28.7 \times \% \text{ DCCT}) - 46.7$$

$$\text{eAG mmol/l} = (1.59 \times \% \text{ DCCT}) - 2.59$$

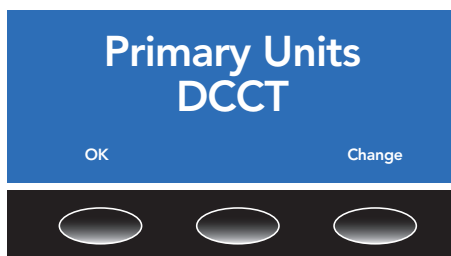
eAG values are based on a correlation study linking % DCCT to the patient's average glucose concentration, resulting in published formula to derive the eAG.

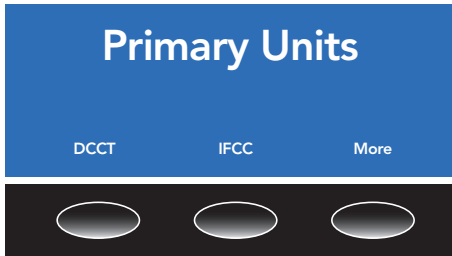


eAG values may differ significantly from a patient's glucose level measured at the same time.

The Quo-Test Analyzer allows the user to select dual reporting (two different measurement units can be displayed) or single reporting. Users should refer to national guidance when setting up reported units.

% DCCT is the default primary unit, to change the primary reported unit press **Change**



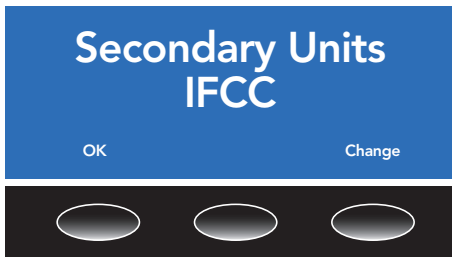


The first screen allows you to select **DCCT (%)**, **IFCC (mmol/mol)** or select **More** to see additional units.



If you select **More**, **JDS (%)** or **More** are the options. If you select **More** you are returned to the first menu screen.

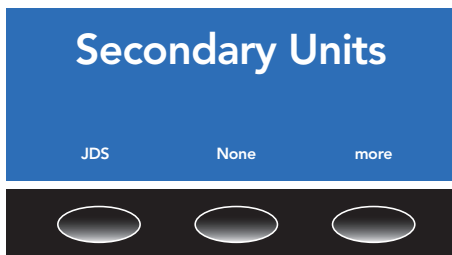
Once a Primary reportable unit is selected you can select a Secondary Reportable unit to 'Dual Report'.



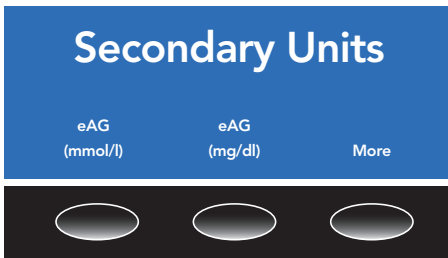
IFCC (mmol/mol) is the default secondary reportable unit. To select an alternative secondary unit or switch off dual reporting select **Change**.



The first screen allows you to select **DCCT (%)**, **IFCC (mmol/mol)** or select **More** to see additional units.



If you select **More**, **JDS (%)**, **None** or **More** are the options. Selecting **None** switches off dual reporting. Selecting **More** will forward you to the eAG options.



eAG can be reported in either mmol/l or mg/dl to match the units used to report glucose measurements locally.

Selecting **More** will return you to the first secondary units screen.

Once a secondary unit (or none) has been selected, then setup is complete and the analyzer is ready to run a test.

Note: Changing the secondary reported unit will also change the secondary reported units on previously run samples held in the memory of the analyzer, as these are calculated each time they are displayed. Changing the primary reported unit will not alter the primary units reported on previously run samples.

Functional Checking

Each time the Quo-Test Analyzer is switched on it performs a series of functional checks of the system and optics. The analyzer must be powered off and powered on at least once a week to allow the analyzer to perform the internal self-checks.

Refer to the **Troubleshooting Guide and Error Messages** section of this User Manual to diagnose any problems, if they occur.

Correct operation of the system may be confirmed by running Quo-Test A1C Control samples.

To run a control, read the Instructions For Use supplied with your Quo-Test A1C Control Kit in combination with the Running a Quality Control section of this User Manual.

Section 4 Running a Test



Please read the Instructions For Use supplied with your Test Cartridges.

Always use protective gloves when handling blood samples.

Preparing to Run a Test

Step 1

When the Quo-Test Analyzer displays the home screen with '**Quo-Test**', the time and date, the analyzer is ready to run a test.



Step 2

Before using a new lot of test cartridges, scan the calibration barcode that is printed on the inner flap of the carton, indicated by the **CAL** symbol.

Place the barcode scanner over the calibration barcode and press the barcode scanner button until you hear a beep. The analyzer will confirm that the data has been accepted, along with displaying the lot number and expiry date.



Step 3

Remove a pouched cartridge from the carton and place it next to the analyzer. Allow at least 40 minutes for it to equilibrate to the analyzer's environmental temperature before use, even if previously stored at room temperature. When ready to perform the analysis, carefully open the pouch and remove the Test Cartridge. Check the indicator color of the silica gel (see test Instructions For Use).

Do not handle the lower part of the cartridge containing the liquid.

Do not use the cartridge if condensation is present.



Collecting the Sample

Step 4

The Quo-Test can be used with either venous whole blood collected with EDTA or with a finger prick blood sample.

For fringer prick sample collection, the patient's finger must be warm, dry and clean, including being free of substances such as hand cream. Use a single use lancet (not provided) on the patient's finger to get a droplet of blood about the same width as the Blood Collector.



For venous samples previously collected into EDTA tubes, ensure that the sample is thoroughly mixed and use standard equipment to place a droplet of blood, approximately 10 to 20 μ l, onto a non-metallic and non-absorbant surface such as Parafilm® M.

Do not attempt to sample directly from the tube.

Note: Parafilm® M is a trademark of Pechiney Plastics Packaging.

Step 5

Lightly touch the pointed tip of the Blood collector to the top surface of the droplet of blood, as per the image.

The blood will be taken up by the collector.

The blood must completely fill the slot.

Note: avoid taking up air bubbles and excess sample on the outside of the tip of the Blood collector.

Do not wipe excess blood from the collector.



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Step 6

place the Blood collector into the free cavity on the top of the Test cartridge, making sure that the Blood collector is flush with the top of the Test cartridge and is not sticking out.

Note: Do not push the Blood collector into the Test cartridge, as this may cause an error message to be displayed instead of a result. **Refer to the Troubleshooting Guide and Error Messages** section of this User manual for further details.



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Running a Test

Step 7

After the Test cartridge is prepared, open the door of the analyzer and place the cartridge into the test chamber, making sure that the Test cartridge is firmly seated. The Test cartridge must be inserted into the analyzer within 1 minute of the blood sample being collected.



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Step 8

Pull the red slide towards the front of the analyzer and close the door. The test will start automatically.

You will be prompted to scan the Operator and Patient ID, if these features have been activated.

Note: If the analyzer displays “Scan Lot ***** Data Card” then scan the calibration barcode (see Step 2).



Step 9

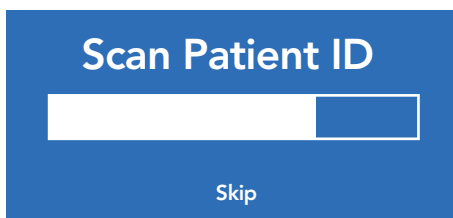
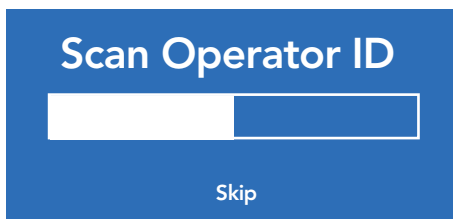
When the test has finished the result will be displayed on the screen and printed on the (optional) printer, if connected.

Open the door and push the red slide towards the rear of the analyzer. Remove the used cartridge and dispose of it as clinical waste.

Upon closing the analyzer door, the display will return to the home screen and the analyzer will be ready to run another sample.

Note: See Section 4 - **Retrieving a Result from the Analyzer Memory**





Scanning Operator and Patient ID

If the Operator and/or Patient ID features are enabled (see section 3), when the analyzer door is closed to start the test the screen will request that the user scans the Operator and/or Patient ID, depending upon which features have been activated in the analyzer setup.

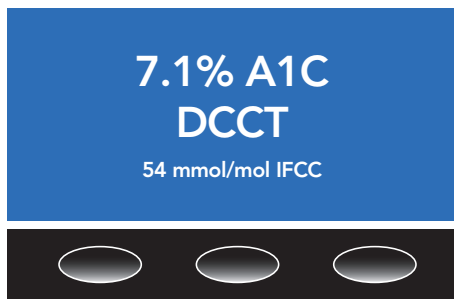
Please note that when using the system in QC mode the system will only request the operator ID to be scanned, as the system automatically uses the Patient ID for the Control Lot number.

When requested to scan the 'ID', place the barcode scanner over the Operator or Patient ID barcode and press the barcode scanner button.

When the analyzer has recorded the barcode a beep will sound and the ID is displayed on the screen. Confirm the displayed ID matches the barcode scanned. If you do not have an Operator or Patient ID barcode label available, press the **Skip** button to exit the screen. The test result will not be displayed until the requested ID's have been scanned or the screens have been exited. If an error occurs, the analyzer will abort the request to scan the Operator and/or Patient ID if not already completed.

The Test Result

When the test is finished, the result will be displayed on the screen in the specified units (Section 3 - **Reported Units**). The image below shows an example of the result of a Quo-Test A1C Test. In this case, the test result was 7.1 % A1C. The letters "DCCT" below the test result show the selected primary reported units of the test at the time it was run. **Important:** make a note of the calibration scheme in order to accurately compare results. Below the main result is a derived result showing the equivalent value in mmol/mol IFCC units.



The result will stay on the screen until the analyzer door is opened. The result is stored in the analyzer memory (see Section 4 - **Retrieving a Result from the Analyzer Memory**). On removal of the used cartridge, the analyzer will be ready to perform another test.

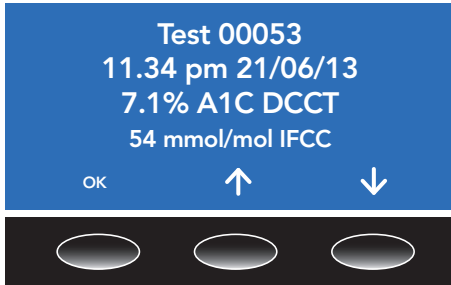
Quo-Test A1C	
Time:	11:34
Date:	21/06/13
Result:	7.1 % A1C DCCT
	54 mmol/mol IFCC
Lot:	020130
Inst ID:	021132
Test ID:	00053
Patient:	xxxxxxxxxxxxxxxx
Operator:	xxxxxxxxxxxxxxxx

Printing the Test Result

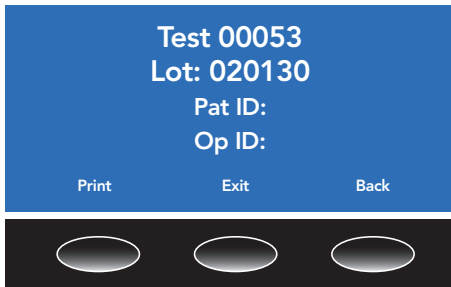
If you have the optional printer connected, the result will be printed when the test has finished. The result is printed onto a self-adhesive label to be kept with the patients' records.

Retrieving a Result from the Analyzer Memory

The results of the most recent 7,000 tests run on the analyzer are recorded in the memory. Only the most recent 1,000 test results can be viewed on the analyzer. Press the **File** button on Quo-Test home screen. The most recently performed test result will be shown on the screen.



The sequential number of the test (in the example below it is Test 53) will be shown together with the time and date the test was started along with the result. If the **OK** button is pressed a second page will be shown which includes the Operator and Patient IDs and the cartridge lot number.



Press the **Print** button for a printed copy of the result, if the optional printer is attached, or press the **Exit** button to return to the home screen. Press the **Back** button to return to the memory file.

The most recent 1,000 test results may be accessed using the **up/down** arrow buttons on the result screen as shown above. To find earlier test results contact your local distributor or customer support.

Note: Changing the secondary reported unit (see Section 3 - **Report Units**) will also change the secondary reported units on previously run samples held in the memory of the analyzer, as these are calculated each time they are displayed. Changing the primary reported unit will not alter the primary units reported on previously run samples.

Running a Quality Control Sample

The Quo-Test A1C Control Kit must be used with Quo-Test A1C Test Cartridges to ensure that the system is operating correctly.

Only Quo-Test A1C Controls should be used with the Quo-Test A1C Test.

Please read the Instructions For Use included with each Quo-Test A1C Control Kit to ensure that the correct procedure is used.

Quality controls should be run:

- With each new lot of Test Cartridges.
- With each new shipment of Test Cartridges.
- At any time there is concern that the result may be wrong, the Test Cartridges may not have been stored correctly, the user is unfamiliar with the test procedure or the user may be performing the test incorrectly.

Use the Quo-Test A1C Control Kit according to the quality standards set by the organisation or laboratory and according to local and national regulations.

If the controls do not give results within the range stated in the Instructions For Use, contact your local distributor or customer support.

The quality control result is stored in the memory of the analyzer. The lot number of the Quo-Test A1C Control Kit used is stored under the Patient ID field.

Section 5 Maintenance



Other than restarting the system once a week to allow the system to perform a self check, no routine maintenance of the Quo-Test Analyzer other than cleaning is required.

- Cleaning may be carried out by wiping the analyzer with a non-abrasive lint free cloth dampened with a mild detergent or with iso-propyl alcohol wipes.
- Disinfection of the system can be performed by wiping the analyzer with a non-abrasive lint free cloth dampened with a non-hypochlorite (bleach) based disinfectant solution such as Virkon® , in-line with local guidance on prevention of infection.
- Always power off the analyzer by unplugging the power supply when performing any cleaning and disinfection operation. Allow all surfaces to fully dry before restoring power.
- Always power off the analyzer on a weekly basis. Leave off for a minimum of 10 seconds, then the analyzer may be powered on in order to perform the internal self-checks. To power off the system, the Quo-Test Analyzer should be in the home screen, then either switch off at the mains supply or disconnect the power cable from the power socket on the back of the analyzer.
- Do not clean or disinfect inside the cartridge test chamber. Contact your local distributor or customer support for advice.
- If you spill liquid inside the the cartridge test chamber, call your local distributor or customer support for advice.
- If the instrument is stored when not in use, ensure that the main cored is not liable to damage or kinking.
- The analyzer is calibrated by the manufacturer and there are no user-serviceable parts.

Note: Virkon® is a trademark of Antec International Limited

Virkon® is a trademark of Antec International Limited.

Section 6 Troubleshooting Guide and Error Messages

Operational Error Messages

To access the log files listing results or error messages please refer to the **Retrieving a Result from the Analyzer Memory** section of this User Manual.

MESSAGE OR PROBLEM	DESCRIPTION	RESOLUTION
Analyzer warming up	The analyzer is warming up	Wait for the analyzer to warm up
Screen shows ' Insert New Cartridge ' and ' Close Door ' even when the door has been closed	The door switch in the analyzer may be faulty, or the analyzer may not be able to read the barcode on the cartridge	Check the cartridge barcode label for damage and that the door is properly closed and that there is nothing in the way*
Screen shows ' Pull Slide Forward ' even after the slide has been pulled forward	Either the red slide has not been pulled far enough forward, or it is faulty	Make sure the cartridge is sitting correctly and the red slide is correctly pulled forward. Then close the analyzer door*
Screen shows ' Remove Old Cartridge ' when a new cartridge is inserted.	Either a used cartridge has been inserted or the test cartridge is faulty	Remove cartridge, close the door and allow the system to return to the home screen. Repeat test with a new cartridge.*
Screen shows 'Result Low' or 'Result High' when test completed.	Result is outside the analytical measurement range. Refer to the test kit IFU, linearity and test range for more details.	Repeat the test, if you get a repeat result with the same message and have successfully run control samples then report the result as less than (if Result Low) or greater than (if Result High) the test range limits. Note: a repeat test may report a result close to but within the test range limits, in which case the result can be reported. The patient's clinical history needs careful consideration when interpreting results which are reported close to the test range limits.
Error 01	The analyzer temperature sensor has failed	Contact your local distributor or customer support
Ambient temperature outside analyzer operating range (Error 02)	The temperature of the room is outside the analyzer's working range of 18 to 30°C (64 to 86°F)	Do not turn off the analyzer. Make sure that the room temperature is within 18 to 30°C (64 to 86°F) Once achieved the home screen will be displayed automatically*
Error 03	The analyzer temperature is unstable	Turn off the analyzer, allow it to reach room temperature and turn it on again. Make sure that the analyzer is sited away from draughts*

* If the problem continues, contact your local distributor or customer support.

MESSAGE OR PROBLEM	DESCRIPTION	RESOLUTION
Error 04/05	Part of the optical system has failed	Remove the old cartridge, if present, close the door and allow the analyzer to return to the home screen*
Error 06 / 07	The x- or z-axis motor has failed	Power off the analyzer, wait 10 seconds, and power on again Remove the old cartridge, if present, close the door and allow the analyzer to return to the home screen*
Error 08	The stirrer motor has failed	
Error 09	The internal fan has failed	
Error 10/11	The x- or z-axis motor has jammed	
Error 12	The stirrer motor has jammed	
Error 98	The measurement system has failed	Contact your local distributor or customer support
Error 99	The analyzer memory is full	
Door Opened Assay Abandoned (Error 101)	The analyzer door was opened before the test had finished	Do not open the analyzer door whilst a test is running*
Reagent Out of Range (Error 102 / 103)	The test cartridge is faulty	Remove cartridge and repeat test with a new cartridge*
Too Little Blood (Error 104)	Either the blood sample had a low level of hemoglobin, the blood collector was under filled or the filled blood collector was pushed into the cartridge prior to running the test	Remove cartridge and repeat test with a new cartridge, making sure that the blood collector is filled correctly and that it is carefully placed into the cartridge* (see Section 4 - Running a Test)
Too Much Blood (Error 104)	Either the blood sample had a high level of hemoglobin, or blood collector was overfilled	
Blood Mix Failure (Error 105)	The blood sample did not form a homogenous solution with the buffer	Remove cartridge and repeat test with a new cartridge*
Invalid Result (2)/(1) (Error 106)	A result was not able to be calculated	Remove the cartridge and repeat with a new cartridge*

* If the problem continues, contact your local distributor or customer support.

MESSAGE OR PROBLEM	DESCRIPTION	RESOLUTION
Invalid Result (2)/(1) (Error 107)	A result was not able to be calculated	Remove the cartridge and repeat with a new cartridge. 107 errors are most commonly seen when a cold cartridge is used with the system. Make sure the cartridge has sufficient time to reach the same temperature as the analyzer before use. 107 errors can sometimes occur when the analyzer is working at the bottom of its temperature range and the blood volume/hemoglobin concentration is towards the bottom of the acceptable range. Make sure that the temperature is within the working range of the analyzer and that the collected sample fills the slot on the blood collector*
Invalid Barcode Format (Error 108)	The calibration barcode has not been recognized	Calibration Barcode: re-scan the calibration barcode or scan a barcode from a different carton. Cartridge Lot Barcode: open and close the analyzer door. If the error is still displayed, use a different cartridge*
High Background Fluorescence (Error 110)	The test cartridge is faulty	Remove cartridge and repeat test with a new cartridge*
Curve Fit Fail (Error 112)	A result was not able to be calculated	
Invalid Result (2) (Error 120, 121, 122, 123, 124, 125 or 126)	A result was not able to be calculated	
Mix Motor Stall (Error 128)	Mixer Motor has failed to start during the assay	Remove cartridge, close the door and allow the system to return to the home screen. Repeat the test with a new cartridge*

* If the problem continues, contact your local distributor or customer support.

Please contact your local supplier:

Customer support

+49 39203 511 414

support@ekf-diagnostic.de

Section 7 Customer Support

If you cannot resolve your problem by reference to the Troubleshooting Guide, contact your local distributor or customer support on the telephone number or email address listed below for advice and technical assistance. Provide the following information when contacting customer support:

- Analyzer Serial Number (SN) (found on the rear panel label), see Section 3.
- Test Cartridge lot number.
- Quality Control Kit lot number and results, if available.

Reporting Test System Problems

Users should report problems with their Quo-Test Analyzer, its reagents or controls to their local distributor and/or direct to EKF-diagnostic GmbH Customer Support.

Phone: +49 39203 511 414

Email: support@ekf-diagnostic.de

Warranty

EKF-diagnostic GmbH warrants to the original purchaser, for a period of 12 months from the date of invoice, that the Quo-Test Analyzer System is free from defects in materials and workmanship. In the event of failure within the warranty period, EKF-diagnostic GmbH will repair or replace the system, or part thereof, at their discretion, provided it has not been subjected to accident, alteration, misuse or abuse. EKF-diagnostic GmbH shall

not be liable to the purchaser or any third party for any loss, inconvenience, or damage, whether direct, incidental, consequential or otherwise, resulting in any breach of this warranty.



Disposal of the Analyzer

The Quo-Test Analyzer has been designed for a long and fault-free life. However, excessive wear on the mechanisms may result in error conditions and may indicate that the analyzer has reached the end of its useful life.

The analyzer must then be disposed of according to local regulations concerning the disposal of electronic items in general.



The WEEE Directive 2002/96/EC defines the basis for regulations in the EU.

Contact your local distributor or customer support for advice on collection and disposal.

Returning an Analyzer

A signed certificate of decontamination must be completed and a **'Return Authorization Number'** is required from EKF-diagnostic GmbH before returning an analyzer for investigation.

Contact your local distributor to obtain a Return Authorization Number and decontamination certificate. When returning the analyzer, include a copy of the details of the problem along with your contact details, the Return Authorization Number and decontamination certificate.

Return the analyzer in its original packaging with sufficient protective material to protect the analyzer from further damage during transit. Analyzers damaged in transit are not covered by the terms of the warranty.

Ship to your local distributor or directly to:

Customer Support
EKF-diagnostic GmbH

Ebendorfer Chaussee 3

39179 Barleben

Germany

Phone: +49 39203 511 414

Email: support@ekf-diagnostic.de

Upon receipt of the analyzer, it will be investigated and providing it is within warranty and the tamper proof quality control label on the rear of the system is intact, EKF-diagnostic GmbH will promptly repair or replace the analyzer.

Analyzers that have not been maintained in accordance with the operating instructions, which have been misused or abused or which are no longer under warranty will be repaired and returned with a service charge.

Section 8 Technical Specifications

Quo-Test Analyzer

ANALYZER	
Size	205mm(h) x 205mm(w) x 135mm(d)
Weight	1.3kg
Display	Blue LCD backlit monochrome display 128x64 pixels. Visible area 70x39mm
Connections	USB 2.0 (slave), Printer (RS232), Barcode Scanner (PS2)
Data Memory Capacity	7,000 data records
POWER SUPPLY	
Mains Adapter	Separate AC to DC mains adapter
Input	100-240 V AC, 50-60 Hz, 30 W
Output	24 V DC, 1.25A
BATTERY	
Type	CR1225, Lithium, non-rechargeable / non-replaceable. Used to maintain the date, time and memory of the analyzer
BARCODE READER	
Barcode Scanner	T8-W CCD Hand Scanner Part No. 0108-0035
Width of Field	80 mm
Interface	Keyboard PS2
Supported Barcode Formats	Code 128, Code 39, NW7 / Codabar, 2 of 5 interleaved



















OPERATING CONDITIONS	
Temperature	18 to 30 °C (64 to 86 °F) or according to Test Cartridge temperature range
Relative Humidity	10 to 80 %, non condensing
Location	Clean, dry, horizontal surface and away from direct sunlight
STORAGE & TRANSPORT	
Temperature	-20 to 50 °C (-4 to 122 °F)
Relative Humidity	10 to 93 % at 40 °C (104 °F)

Accessories

PRINTER (OPTIONAL)	
Label Printer	Seiko SLP-440 Part No. 0108-0002
New Label Printer	Seiko SLP-650E Part No. 0108-0032 Power supply provided with printer
Paper Type	Thermal Label Rolls SLP-DRL Part No. 0108-0006
Interface	Serial
SHOULDER BAG	
Shoulder Bag	Part No. 0108-0008

Section 9 Packaging Symbols and their Meaning

A number of symbols are used on the Quo-Test Analyzer, Test Cartridges and their packaging. The following table lists the symbols used and their meaning.

SYMBOL	MEANING
	Consult Instructions For Use / User Manual
	<i>In vitro</i> Diagnostic Medical Device
	Batch or Lot Number
	Calibration Barcode
	Product Reference
	Control
	Storage Temperature
	Contents Sufficient for “Σ” Number of Tests
	Expiry Date
	Manufacturer
	Serial Number
	DC Polarity on Rating Label
	Printer Connector
	USB Connector
	Barcode Scanner Connector
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
	Caution
	Conformity to the European Directive 98/79/EC on <i>in vitro</i> Diagnostic Medical Devices

