



AFINION™ 2

REF 1116554, 1116663

US User Manual



1116752 Rev. A 2018/09

Dear Customer,

Congratulations on the purchase of your Afinion™ 2 Analyzer.

Upon arrival of your Afinion 2 Analyzer we recommend that the serial number along with the software version be recorded in the table provided below. The additional rows in the table are to be utilized if a software upgrade is performed on your Afinion 2 Analyzer. The recorded information will be of great value if and when a question is reported, or the desire to add a new Afinion Test to your analyzer arises.

Serial number

SN

(for serial number (SN), see label on the rear side of the analyzer or on the transport container)

Software records

	Date	Software version*	Afinion™ Tests available
Upon receipt			
1. SW upgrade			
2. SW upgrade			
3. SW upgrade			
4. SW upgrade			
5. SW upgrade			

* See start-up menu when you power on the analyzer (see “How to power on the analyzer”, page 11).

Notes

Technical Support

Call 1.866.216.9505

Intended use of the AFINION™ 2 System

Afinion 2 System, consisting of the Afinion 2 Analyzer and the Afinion Test Cartridges, is for *in vitro* diagnostic use only. Afinion 2 Analyzer is a compact multi-assay analyzer for point-of-care testing and is designed to analyze the Afinion Test Cartridges.

CLIA Statements - Waived Afinion™ Tests

Afinion HbA1c is waived under the Clinical Laboratory Improvement Amendment of 1988 (CLIA'88). A CLIA Certificate of Waiver is needed to perform testing in a waived setting.

If the laboratory does not have a Certificate of Waiver, the Application for Certification (Form CMS-116), can be obtained at <https://www.cms.gov/cmsforms/downloads/cms116.pdf>.

The form should be mailed to the address of the local State Agency of the State in which the laboratory resides (https://www.cms.gov/CLIA/12_State_Agency_&_Regional_Office_CLIA_Contacts.asp).

If the laboratory modifies the Afinion Test or Afinion 2 Analyzer system instructions, the test no longer meets the requirements for waived categorization. A modified test is considered to be highly complex and is subject to all applicable CLIA requirements.

Conformity to directives and standards

European IVD directive and RoHS 2 directive (CE marking)

The Afinion 2 Analyzer meets all provisions in the Directive 98/79/EC on *in vitro* diagnostic (IVD) medical devices and in the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2).

North American product safety standards (CNUS mark)

The Afinion 2 Analyzer has been tested and found to be in conformity with North American safety standards. See list of safety standards below.

Safety standards

The Afinion 2 Analyzer has been tested and found to be in conformity with standards for Safety requirements for electrical equipment for measurement, control, and laboratory use (IEC 61010-1:2010, UL 61010-1:2012, CAN/CSA-C22.2: 61010-1 -12) and standard for Particular requirements for *in vitro* diagnostic (IVD) medical equipment (IEC 61010-2-101:2015).

EMC standards

The Afinion 2 Analyzer has been tested and found to be in conformity with standards for Electrical equipment for measurement, control, and laboratory use – EMC requirements (EN 61326-1:2013, EN 61326-2-6:2006, EN 61326-2-6:2013 and CFR 47 Telecommunications, Chapter I- FCC Part 15 – Radio Frequency Devices – Subpart B: unintentional radiators).

Table of contents

Introduction	About this user manual	7
	Examining the package contents	7
Analyzer System Description	Description of the AFINION™ 2 Analyzer	8
	Description of the Afinion™ Test Cartridge	8
	How the AFINION™ 2 System works	9
	Internal process control	9
	The analyzer self-test	9
	The fail-safe mechanisms	9
	External process control	9
	Patients ID	9
	Operator ID	9
	Quality Control lockout	9
	Calibration	9
Getting Started	Installing your analyzer	10
	Connecting power supply	10
	Connecting additional equipment	10
	Connectivity	10
	How to power ON the analyzer	11
	How to power OFF the analyzer	11
	How to operate the analyzer	11
Configuration	The AFINION™ 2 menus	12
	Setting the configuration	13
	Patient ID configuration	13
	Patient ID enable/disable	13
	Operator configuration	14
	Operator ID enable/disable	14
	Operator login expiration	14
	Operator list management	14
	Choosing language	15
	Adjusting screen/beeper settings	15
	Setting date and time	15
	QC lockout configuration	16
	General settings	17
	Erase all contents and configuration	17
	Analyzer network settings	17
	Connectivity settings	18
Quality Control	Why quality control testing?	19
	Choosing control material	19
	Handling and testing controls	19
	Frequency of control testing	19

Table of contents continues on next page

Table of Contents

Testing Procedures	Operating precautions	20
	When operating the analyzer	20
	When handling the test cartridge	20
	Preparing for an AFINION™ 2 Analysis	20
	Collecting a sample	21
	Analysing a patient/control sample	21
	Using the operator ID function	22
	Entering operator ID	22
	Using the patient ID function	22
	Entering patient ID	22
	Using the control ID function	23
	Entering control ID	23
	Using the QC lockout function	23
	QC lockout status	23
	Running controls with enabled QC lockout function	24
	Patient and control results records	25
	View, print and export patient and control results	25
Information Codes and Troubleshooting	When an information code appears	26
	Information codes caused by test-specific limitations	26
	Information codes caused by sample or test cartridge	27
	Information codes and messages caused by analyzer failure	27
	Other information codes	28
	Service information	28
Maintenance	Cleaning and maintenance	29
	Cleaning the exterior	29
	Cleaning the cartridge chamber	29
	Disposal of the analyzer	29
	Software upgrade	29
Warranty		30
Technical Specifications	AFINION™ 2 Analyzer	31
	Additional equipment	31
Gallery of Icons	The touch buttons and their function	32
	Other symbols and signs	34
Symbols and Abbreviations		35

About this user manual

This user manual will guide you through installation, operation and maintenance of your Afinion 2 Analyzer. The user manual also explains how the analyzer works, describes the quality assurance system and assists you in troubleshooting.

For analysing patient samples or controls, please also read the test specific information given in the package inserts following the Afinion Test Kits. The quick reference guides, available from your local Afinion supplier, highlight the main steps of the test procedures.

It is recommended that you become familiar with these user instructions before you start operating the Afinion 2 Analyzer.

Some of the information in this user manual is accompanied with a symbol that points you to the following particulars:



Warnings and precautions



References to the package inserts for the specific Afinion Tests and control kits

Examining the package contents

When unpacking, check the contents against the list below and examine the components for signs of shipping damage.

The Afinion 2 package unit includes:

- Afinion 2 Analyzer
- Power cable
- Power supply, 24 VDC
- User manual
- Quick guides for the available Afinion Tests

If the package unit is found incomplete, please report missing items or shipping damage to your supplier. It is recommended to keep the shipping box in case of later transportation of the analyzer.

Description of the AFINION™ 2 Analyzer

Figure 1 shows the main exterior parts of the Afinion 2 Analyzer.

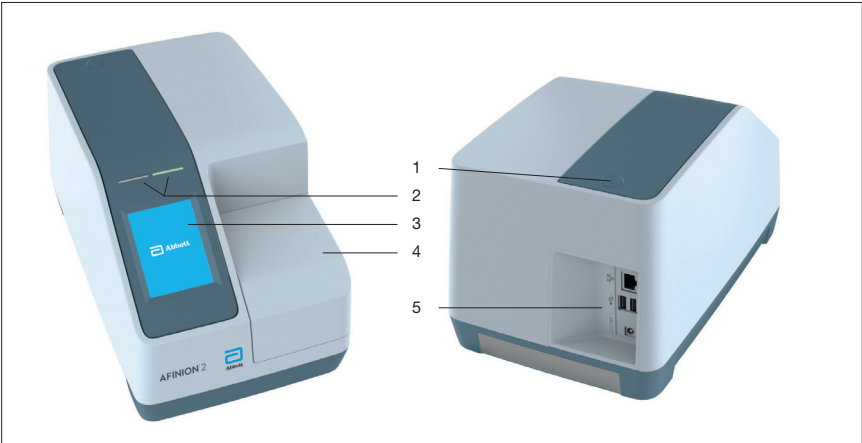



Figure 1

- | | |
|-----------------------|---|
| 1 ON/OFF button: | Turns the power to the analyzer on and off. |
| 2 Red and green LEDs: | Light emitting diodes (LEDs) that indicates whether the analyzer is busy or not. |
| 3 Touch screen: | Allows you to communicate with the analyzer through touch buttons and messages. |
| 4 The lid: | Covers and protects the cartridge chamber. |
| 5 Connectors: | For connecting to mains power supply. Options for printer, barcode reader and/or LIS/HIS/EMR. |

 Do not open the lid manually.

Description of the Afinion™ Test Cartridge

The Afinion Test Cartridge is unique for each analyte to be measured, as the reagent composition, reagent volumes and the integrated devices are test specific. The test cartridge label has a colour unique for the test. The test cartridges are separately packed in foil pouches to protect the reagents and plastic devices from light, dirt and humidity. A single test cartridge contains all necessary reagents for one test and is ready to use. An integrated sampling device is used for collection of the patient sample or control. The test cartridge cannot be reused. Figure 2 illustrates an Afinion Test Cartridge with its functional parts:

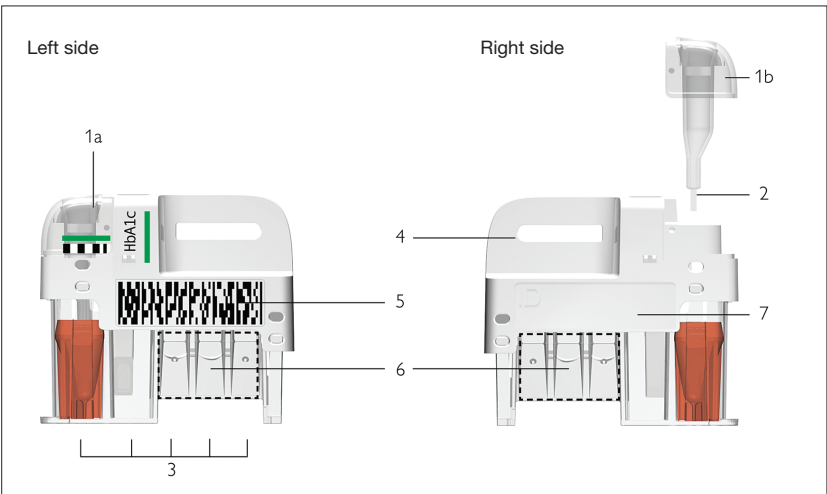


Figure 2

- | | |
|-------------------------|---|
| 1 Sampling device: | For collection of patient sample or control (1a - closed position, 1b - lifted position). |
| 2 Capillary: | Capillary to be filled with sample material. |
| 3 Reaction wells: | Contain all necessary reagents for one test. |
| 4 Handle: | For correct finger grip. |
| 5 Barcode label: | Contains assay and lot-specific information for the analyzer. |
| 6 Optical reading area: | Area for transmission measurement. |
| 7 ID area: | Space for written or labelled sample identification. |

How the AFINION™ 2 System works

The Afinion 2 System uses different chemical and mechanical assay methods combined with advanced, computerized processing and measuring technology.

A test cartridge with patient sample or control is placed in the cartridge chamber of the analyzer. By manually closing the lid, the test cartridge is transported into the analysis compartment of the analyzer. Test and lot-specific information is obtained from the barcode label (Figure 2). When the test cartridge enters the analyzer, the integrated camera reads the barcode which then initiates the processing of the test cartridge. The sample and reagents are automatically transferred between the wells. An internal camera monitors the entire process. Light-emitting diodes (LEDs) illuminate the reaction area, which can be either a coloured membrane or a reaction well. The camera detects the reflected or transmitted light, which is converted to a test result and displayed on the touch screen. When the user accepts the result, the lid covering the cartridge chamber opens automatically and the used test cartridge can be removed and discarded. The analyzer is then ready for the next run.

Internal process control

The analyzer self-test

A self-test is performed during start-up of the analyzer to ensure that the instrument is operating according to established specifications. The self-test validates:

- Hardware and software integrity
- Test cartridge transport system
- Liquid transport system
- Camera vision system

If the self-test fails at any point, the red LED will start flashing and an information code will be displayed on the touch screen (see “Information codes and troubleshooting”, page 26-28).

When the analyzer is powered on for a longer period, it will automatically restart once a day to ensure that a self-test is done regularly. This procedure does not interrupt any analysis of the test cartridge.

The fail-safe mechanisms

Fail-safe mechanisms are included to secure safe processing. The integrated camera inspects the test cartridges initially before the process starts and during the assay. If defects are detected (e.g. broken capillary, the cartridge is used past its expiry date), the test cartridge is rejected and an information code is displayed. During processing vital functions and components (e.g. pumps, heater) are supervised. When problems are detected by the built-in safety mechanism, the process will be aborted and an information code will be displayed.

External process control

Patient ID

The Afinion 2 patient ID functionality will, if configured, allow up to four patient ID fields to be entered. The patient ID will be stored with each patient test result in the result records.

Operator ID

The Afinion 2 operator functionality will, if configured, require the operators to login before testing. The functionality may also prevent unauthorized operators to login, perform tests and configuration. The operator ID will be stored with each test result in the result records.

Quality Control lockout

The Afinion 2 QC lockout function allows you to configure the instrument to automatically enforce your local required frequency of control testing. If the required control test has not been performed or the control result is outside the acceptable range, the instrument will disable patient testing for this assay. For manufacturer recommendations (see “Frequency of control testing” page 19).

For more information regarding these functionalities, see “Configuration” page 12–18.

Calibration

The Afinion 2 Analyzer has been manufactured to deliver reliable and accurate results. During manufacturing, the analyzers are calibrated against a reference system. This procedure has been established to ensure that all analyzers operate within identical tolerance limits.

Test specific calibration data are established for each lot of test cartridges and then stored in the barcode label (Figure 2). When the test cartridge enters the analyzer, the integrated camera reads the barcode. The calibration data for the actual lot are transferred to the instrument and used for calculating the results. Calibration by the operator is thus not required.

Installing your analyzer

Place your Afinion 2 Analyzer on a dry, clean, stable and horizontal surface. Make sure that the analyzer is located with sufficient surrounding airspace, at least 5 inches on each side. Placement of Afinion 2 Analyzer should allow easy disconnection from the wall outlet at any time. Acclimate the analyzer to ambient operating temperature (15-32°C, 59-89°F) before use.



The analyzer might be impaired by:

- Condensing humidity and water
- Heat and large temperature variations
- Direct sunlight

- Vibrations (e.g. from centrifuges and dishwashers)
- Electromagnetic radiation
- Movement of the analyzer during processing of a test cartridge

Connecting power supply

- Connect the power cable to the power supply.
- Insert the plug from the power supply into the power socket (Figure 3) in the back of the analyzer.
- Plug in the power supply to a wall outlet.



Only use the power supply and cable supplied with Afinion 2 Analyzer. Any other power supplies or cables can damage the analyzer and may cause possible hazards.



Figure 3

- 1 Ethernet port for connection to LIS/HIS/EMR systems. Use shielded cable.
- 2 USB-A connectors for printer, USB flash and barcode reader.
- 3 Power input for power supply connection

Connecting additional equipment

Optional equipment, not provided with your Afinion 2 Analyzer are:

- External barcode reader – for reading barcoded sample or operator identification.
- Printer – for optional print out of test results.

For additional information regarding barcode reader and printer specifications, please contact your local Afinion 2 supplier.



Connecting the equipment should be done while the analyzer is powered off.



All equipment connected to the USB and/or Ethernet ports must have double or reinforced insulation from mains to prevent the risk of electric shock.




Connectivity

Afinion 2 Analyzer can reliably transfer test information to an information system. Use the Ethernet cable to interface the Afinion 2 Analyzer to an information system. Afinion 2 Analyzer automatically transfers patient and control results to a connected LIS/HIS/EMR system via TCP/IP networking using the protocols POCT1-A, HL7, ASTM 1381-85 (low level) or ASTM 1394-97 (high level), selectable by configuration. ASTM and HL7 protocols support the transfer of patient and QC results. POCT1-A protocol supports in addition functions such as device lockout and operator list management. Operator configuration allows for protection of connectivity settings. When operator configuration is set to operator ID with verification, the configuration of connectivity will only be available for operators at supervisor level. For relevant information, see chapter "Operator configuration", page 14.

When you export data that contains patient information, it is your responsibility to comply with your local regulations on protection of personal health information.

Afinion 2 Analyzer POCT1-A, ASTM and HL7 communication protocols are available at www.alere.com or by contacting your local Afinion 2 supplier.

How to power ON the analyzer

- 1  Power on the analyzer by pressing the ON/OFF button (Figure 1). An automatic start-up procedure will be initiated. Please wait. Do not open the lid manually.
- 2  The automatic start-up procedure will be initiated shortly after the analyzer has been powered on. The red light on the top of the analyzer will turn on, indicating that the analyzer is busy. The analyzer is ready for use when the start-up menu is displayed and the green indicator light turns on.
- 3  **Start-up menu**
The analyzer's software version (SW X.XX) will appear in the upper left corner of the Start-up menu screen. The temperature displayed in the Start-up menu is the operating analyzer temperature. Make sure that the operating temperature is within the recommended range for your Afinion Test (see the package insert for the Afinion Test).
If the analyzer fails during the start-up procedure, an information code will appear referring to a message given in the section "Information codes and troubleshooting", page 26-28.

How to power OFF the analyzer

Switch off the analyzer by pressing the ON/OFF button (Figure 1). The analyzer should be powered off after the end of a working day.



The analyzer can only be powered off when the cartridge chamber is empty and the lid is closed. If the ON/OFF button is pressed and the lid is open, the message "Close lid" will appear on the screen.

How to operate the analyzer

The Afinion 2 Analyzer has two main user interfaces, the touch screen and the cartridge chamber. The analyzer is easily operated using the touch buttons that appear on the screen. When a button is touched, its function will be activated. Text messages that appear on the screen will help guide you through the testing procedure. The functions of the touch buttons are explained in the section "Gallery of icons", page 32-34.

The other main operative part of the Afinion 2 Analyzer is the cartridge chamber. The cartridge chamber is designed to receive the test cartridge in one orientation only. The lid must be manually closed, but opens automatically. When a new test cartridge is placed in the chamber, manually closing the lid will initiate the analysis. When the analysis is complete the lid will open automatically. The lid protects the cartridge chamber from dust, dirt, light and humidity during processing and when the analyzer is not in use.



- The lid must be manually closed, but opens automatically. Do not open the lid manually.
- Use the fingertips only on the touch screen. Do not use pens or other sharp instruments.

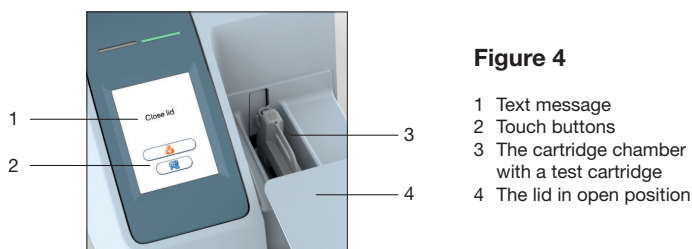


Figure 4

- 1 Text message
- 2 Touch buttons
- 3 The cartridge chamber with a test cartridge
- 4 The lid in open position

Screen saver

The screen saver will turn on after 3 minutes, if the touch screen is not in use. To reactivate, touch the screen.

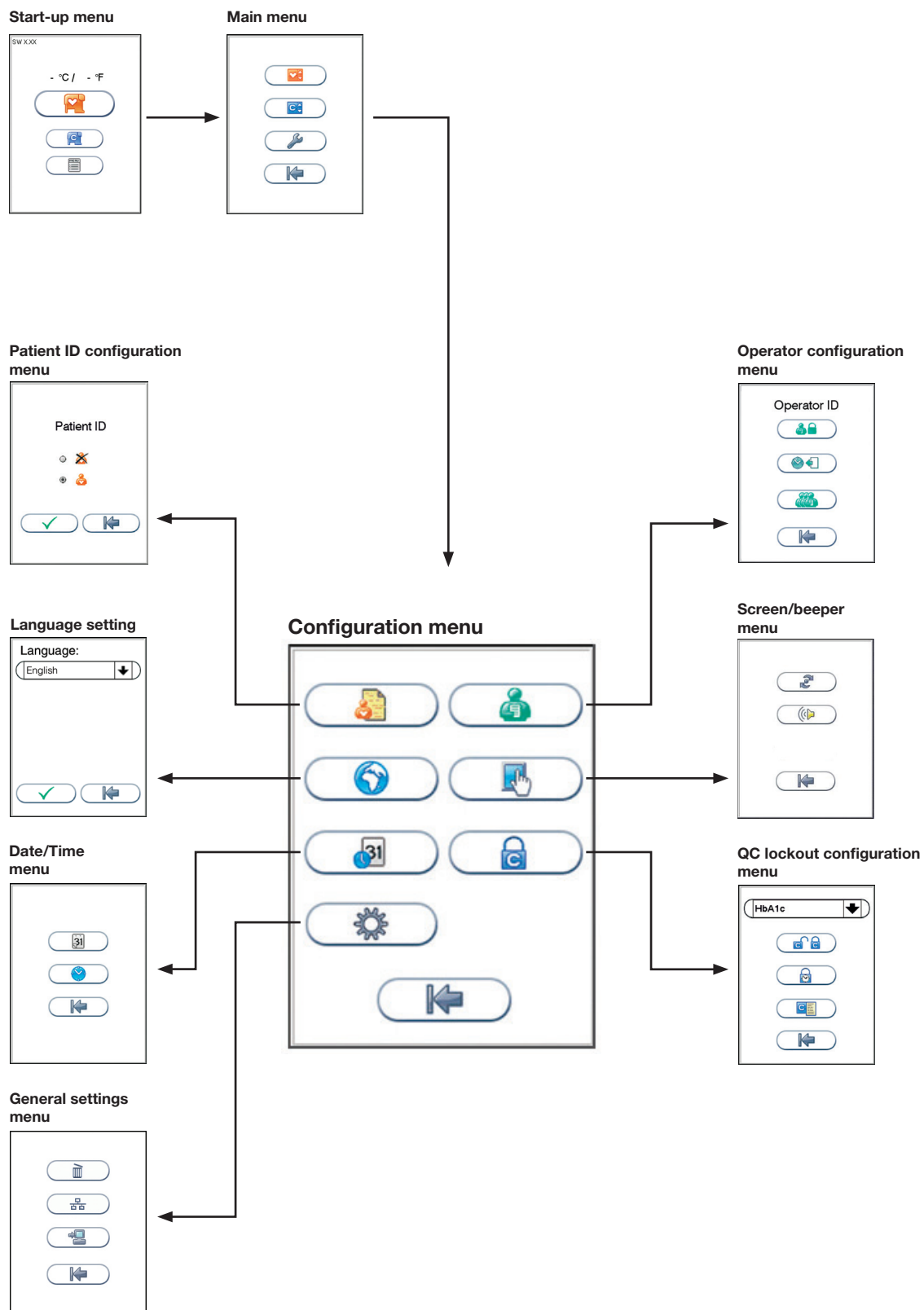
Light signals (the red and green LEDs)

The red diode is illuminated when the analyzer is busy. A flashing red light is seen when an information code is displayed. The green diode is illuminated when the analyzer is ready for use. A flashing green light indicates completion of an analysis.

Sound signals

A short beep indicates completion of an analysis. Two beeps mean that an information code or message is displayed.


The AFINION™ 2 menus




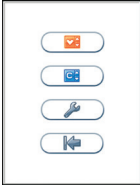
Setting the configuration


Before using your Afinion 2 Analyzer you should set the configuration according to your needs. To enter the Configuration menu, do the following:


- 1



Start-up menu
Touch  to enter Main menu.
- 2



Main menu
Touch  to enter Configuration menu.
- 3




Configuration menu
Select an item for configuration (see following pages).


Patient ID configuration


Patient ID enable/disable


The patient identification (ID) function can be enabled or disabled. The patient ID function is enabled as a default setting by the manufacturer. When the patient ID function is enabled, the patient ID must be entered for each test cartridge to be analyzed. If the patient ID function is disabled, a run number will automatically replace the patient ID and be displayed in the upper left corner of the screen. This numbering is reset each day at midnight.

Touch  in the configuration menu to enter the patient ID on/off option.

- 


Select  to disable the patient ID function.

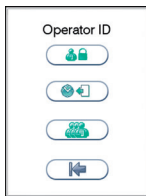
Select  to enable the patient ID function.

Touch  to accept and return to the Configuration menu.

Operator configuration

The operator ID function is disabled as a default setting by the manufacturer.

Touch  in the Configuration menu to enter the Operator configuration menu.





Operator ID enable/disable

Touch  in Operator configuration menu to enable/disable operator ID.




Select  to disable the operator ID function.


Select  to enable operator ID. Any operator ID is accepted.

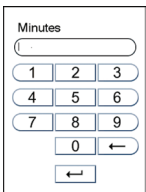
Select  to enable operator ID with verification.

- To enable this function at least one supervisor is required to be present in the operator list.
- When operator ID with verification is enabled, analyzer configuration will only be available to the supervisors.
- To log in, the operator ID entered is required to be present in the operator list. See "Operator list management", page 14.

Touch  to accept and return to the Configuration menu.


Operator login expiration

Touch  in the Operator configuration menu to set automatic logout of the operator.



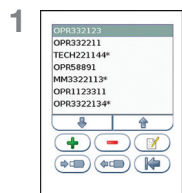
Enter the number of minutes before automatic logout of operator.


The operator will automatically be logged out after the configured number of minutes after ended test.



Touch  to confirm and return to previous view.

Operator list management

Touch  in Operator configuration menu to enter operator list.





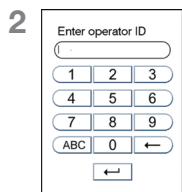
Touch  to add new operator.

Touch desired operator ID and touch  to delete or  to edit the highlighted operator.

Copy operator list

It is possible to copy an existing operator lists between analyzers using a USB flash drive. Insert USB flash in the analyzer USB port.

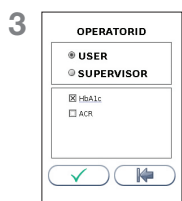
Touch  to export operator list from instrument to USB flash. Move USB to the new analyzer and touch  to import operator list. Any existing operator list on the analyzer will be deleted.



Enter new/edit operator ID

Enter new/edit operator ID and touch  to enter. Both letters and numbers can be entered (maximum 16 characters).

If a barcode reader is connected to the analyzer, a barcoded operator ID can be entered.



Configure the operator level

Select USER to configure user access.

Select SUPERVISOR to configure supervisor access.

Configure tests accessible:

Select the test accessible for this operator.

Touch  to return and edit the operator ID.

Touch  to accept and store new operator in the operator list. The operator list can store 1000 operator IDs.


*Supervisors will be marked with * in the operator list. When analyzer is configured to Operator ID with verification, configuration of the analyzer will only be available to the supervisors.*



Choosing language

Touch  in the Configuration menu to enter the language setting. The default setting by manufacturer is English. Other languages are available.


1

Language:
English










Touch the arrow in the window to view other options. Scroll down until you find the preferred language.


Touch  to accept and return to the Configuration menu.


Adjusting screen/beeper settings

Touch  in the Configuration menu to enter the Screen/beeper menu.






Touch  to enter the Screen alignment setting.



Touch  to enter the Beeper volume setting.






A + sign is shown. Use a blunt pencil and tap the center of the +. Repeat tapping the center of the + each time it is shown. When the process is finished, the previous screen will return.

Volume:






Adjust the beeper volume by touching  or .




Touch  to confirm and return to the previous view.


Setting date and time


The correct date and time should always be set because the date and time for the analyses are stored and displayed in the patient and control records. The date format is YYYY:MM:DD, where YYYY is the year, MM is the month (01 to 12), and DD is the day (01 to 31). The time format is hh:mm, where hh is the hour from 00 to 23 and mm is minutes from 00 to 59.

Touch  in the Configuration menu to enter Date/time menu.

1



Touch  to enter Date setting.

Touch  to enter Time setting.

2


Date:
YYYY:MM:DD

123


456

789


0

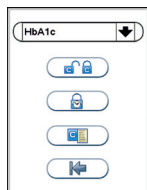


Enter today's date or time.

Touch  to confirm and return to the previous view.

QC lockout configuration

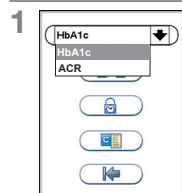
Touch  in the Configuration menu to enter the QC lockout configuration menu.



Touch  to configure QC lockout for the assay selected.

Touch  to configure QC lockout interval.

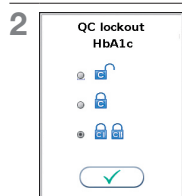
Touch  to view/add/delete stored control lots in the control lot database.



Select assay for QC lockout configuration


Touch the arrow in the window to open the drop down menu.

Touch the assay to select.




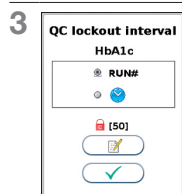
QC lockout

Select  to disable the QC lockout function. No QC runs will be required for this assay.


Select  to enable the QC lockout function. It is required to run ONE passed control, control level C I OR C II, to reset the QC lockout interval.

Select  to enable the QC lockout function. It is required to run TWO passed controls, both control level C I AND C II, to reset the QC lockout interval.

Touch  to confirm and return to the previous view.




QC lockout interval

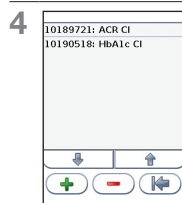
Select  to configure QC lockout interval by number of runs.

Select  to configure QC lockout interval by hours.

Touch  to enter/edit number of runs/hours to QC lockout.

 [xx] displays the number of runs/hours configured in the QC lockout interval.

Touch  to confirm and return to the previous view.



Control lot database

To add a control to the control lot database the Afinion Control Data is required.

The Afinion Control Data is a numeric data string which contains all lot specific data:

- Afinion Control lot number
- Control expiry date
- Control type (assay)
- Acceptable control range
- Control level (C I or C II)
- CRC (check sum to validate the previous data)

The Afinion Control Data and its accompanying barcode is found in the Afinion Control Package Insert. If the Afinion Control Data is not available, contact your local supplier.


Touch  and either manually enter the Control Data or if a barcode reader is connected to the analyzer (recommended), scan the barcode.

The Afinion Control Data may also be entered before, during or after a control run. The control lot will automatically be stored in the database. See page 25.




Select lot number and touch  to delete a control from the list.

When a control lot has reached its expiry date, the control will automatically be deleted from the instrument control database. The control lot database can store 100 control lots.


General settings

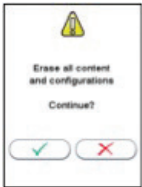
Touch  in the Configuration menu to enter the General settings menu.





- Touch  to erase all content and configurations.
- Touch  to enter Instrument network settings.
- Touch  to enter Connectivity settings.

Erase all contents and configurations

Touch  in General settings menu to erase all contents and configurations.




- Touch  to erase all content and configurations.
- Touch  to cancel and return to General settings menu.

Analyzer network settings

See Table 1 for description of the available analyzer network settings.

Touch  to enter Instrument network settings view.



Touch  to configure the network.






- Enter the IP Address. Touch  to confirm and continue to Gateway.
- Enter the Gateway. Touch  to confirm and continue to Network mask.
- Enter the Network mask. Touch  to confirm and return to Hostname.
- Enter the Hostname. Touch  to confirm and return to Instrument network settings view.
- Touch  to accept and return to the General settings menu.


Table 1 Description of the available analyzer network settings
Consult your network administrator and LIS/HIS/EMR administrator for required network settings.

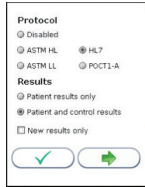
DHCP	DHCP is turned on/off by selecting "DHCP". When using DHCP the instrument's IP address will be assigned by the DHCP Server. No other network settings are necessary. NB! If DHCP is activated, only the hostname setting can be edited.
IP address	Insert fixed IP address [0-255/0-255/0-255/1-254]
Gateway	Insert Gateway [0-255/0-255/0-255/1-254]
Network Mask	Insert Network mask [0-255/0-255/0-255/0-255]
Host name	Insert Host name. Valid characters are [A-Z], [0-9], [-]. The length can be from 1-16 characters

Configuration

Connectivity settings

See Table 2 for description of the available Connectivity settings.

Touch  in General settings to enter Connectivity settings



Protocol
☐ Disabled
☐ ASTM HL
☐ ASTM LL
☐ HL7
☐ POCT1-A
Results
☐ Patient results only
☐ Patient and control results
☐ New results only

Select appropriate communication protocol



- ASTM HL
- ASTM LL
- HL7
- POCT1-A

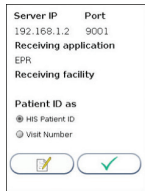
Communication protocol is disabled as default.

Select which results to be transferred to LIS/HIS/EMR by selecting the appropriate button


- Patient results only
- Patient and control results

Select "New results only" and previous obtained results will not be transferred to the LIS/HIS/EMR

Touch  to enter page 2 of the configuration or  to return to the General settings menu



Server IP Port
192.168.1.2 9001
Receiving application
EPR
Receiving facility
Patient ID as
● HIS Patient ID
● Visit Number

Touch  to enter Server IP and Port number, Receiving application (available for ASTM HL, ASTM LL and HL7 only) and Receiving facility (available for HL7 only).

Enter the server IP address: Press  to continue to the Port number setting.

Enter the server port number setting: Touch  to continue to the Receiving application setting or to close the text input.

Enter the Receiving application setting: Press  to continue to the Receiving facility setting or to close the text input.

Use the button to select Patient ID as (available for HL7 only):

- HIS Patient ID
- Visit Number


Touch  to return to the General Settings menu

Table 2 Connectivity settings

Consult your network administrator and LIS/HIS/EMR administrator for required connectivity settings.

Protocol	ASTM HL	ASTM High Level: The communication protocol is based on ASTM E 1394 - 97
	ASTM LL	ASTM Low Level: The communication protocol is based on ASTM E 1381 - 95
	HL7	HL7: The communication protocol is based on HL7 version 2.4
	POCT1-A	POCT1-A: The communication protocol is based on CLSI: POCT01-A2 Point-of-Care Connectivity; Approved Standard – Second Edition
	Disabled	Data connectivity is disabled
Results	Patient results only	Only patient results will be transferred to the LIS/HIS/EMR
	Patient and quality control	Both patient and QC results will be transferred to the LIS/HIS/EMR
Server IP		Insert the IP address of the receiving system [0-255.0-255.0-255.1-254]
Port		[0-65535] (0 = not set)
Receiving Application		(ASTM HL, ASTM LL and HL7 only) Receiving application name (0 – 30 characters)
Receiving Facility		(HL7 only) Receiving facility name (0-30 characters)
Patient ID As	HIS Patient ID	(HL7 only)
	Visit Number	(HL7 only)

For further information about the connectivity settings, see the Afinion 2 data sheets for POCT1-A, ASTM and HL7 which can be obtained at www.Alere.com or through your local Afinion supplier.

Why quality control testing?

Quality control testing should be done to confirm that your Afinion 2 System is working properly and provides reliable results. Accurate results for patient samples can only be assured when controls are used routinely and the values are within the acceptable ranges.

Choosing control material

Controls supplied by Alere Technologies AS are recommended for use with the Afinion 2 System. These control kits contain control materials with established acceptable ranges for the Afinion 2 System.

If you decide to use controls from another supplier, you will need to determine their precision and to establish acceptable control ranges for the Afinion 2 System.

Handling and testing controls



Consult the package insert that comes with each control kit for detailed instructions on handling and storage of the control material.

To run a control, follow the procedure in the section “Testing procedures”, page 20-25.

The measured value should be within the acceptable range stated on the control vial label or in the control package insert. If the control results are within the acceptable ranges, patient samples may be tested and results reported.

If the result obtained for a control is out of range, make sure that:

- The control vial has not passed its expiration date.
- The control vial has not passed the declared stability for opened vials.
- The control vial and Afinion Test Cartridges have been stored according to recommendations.
- There is no evidence of bacterial or fungal contamination of the control vial.

Correct any procedural error and retest the control material. If no procedural errors are detected, it is recommended to examine the laboratory's quality control record to investigate the frequency of control failures. Ensure that there is no trend in out-of-range quality control results. Retest the control material using a new control vial.



Patient results must be declared invalid when controls do not perform as expected. Contact your Technical service representative (1.866.216.9505) for advice before analyzing patient samples.

Frequency of control testing

It is recommended that controls are analyzed:

- When starting up an Afinion 2 Analyzer for the first time.
- With each new shipment of Afinion Test Kits.
- With each new lot of Afinion Test Kits.
- Anytime an unexpected patient test result is obtained.
- When training new personnel in the correct use of the Afinion 2 System.
- If national or local regulations require more frequent testing of control materials, perform quality control in compliance with the regulations for your facility.
- Users with a low frequency of testing should analyze controls at least every 30 days.

The controls should always be analyzed if an unexpected test result is obtained (see the Afinion Test Package Insert, section Test result reporting). If local, state and/or federal regulations require more frequent testing of control materials, then quality control should be performed in compliance with these regulations. Each laboratory site can benefit from establishing a quality control plan. The laboratory director should determine whether additional testing is appropriate for their laboratory.

Operating precautions

When operating the analyzer:



- Use your fingertip to operate the touch screen. Do not use pens or other objects that may scratch or damage the screen. Exception: If the screen alignment function is required, you will need to use a blunt pencil.
- The lid opens automatically, but must be closed manually. Do not try to open the lid manually.
- The lid protects the cartridge chamber from dust, dirt, light and humidity. Empty the cartridge chamber and keep the lid closed when the analyzer is not in use.
- If an information code appears on the screen during the analysis, please consult the “Information codes and troubleshooting” section, page 26-28.
- Do not move the analyzer when a test cartridge is being processed.

When handling the test cartridge:



- Do not use test cartridges after the expiration date, or if the test cartridges are not stored in accordance with the recommendations.
- Do not touch the test cartridge optical reading area. Hold the test cartridge by the handle. (Figure 2).
- Do not use the test cartridge if the foil pouch, the desiccant bag or the test cartridge itself is damaged.
- The test cartridges must reach recommended operating temperature before use.
- Do not open the foil pouch until just before use. Once opened, the test cartridge has limited stability.
- Handle and dispose the test cartridges and sample collection equipment as potential biohazardous materials. Use gloves.
- Do not reuse any part of the test cartridge.



Consult the package insert that comes with each Afinion Test Kit for assay specific information.

Preparing for an AFINION™ 2 analysis

- Allow the Afinion Test Cartridges to reach the recommended operating temperature before use.
- Power on your Afinion 2 Analyzer so it is ready for the day's first analysis.
- Enter the operator ID (optional). See procedure on page 22.
- The patient ID, control ID or Afinion Control Data can be entered before or during processing of the test cartridge in the analyzer.
See procedures on page 22-25.



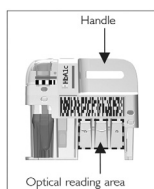
Consult the package insert that comes with each Afinion Test Kit for assay specific information.



1

Open the foil pouch. Grip the handle and remove the test cartridge from the pouch. Discard the desiccant bag and foil pouch in suitable waste containers.

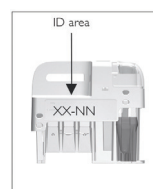
When first opened, the test cartridge has limited stability.



2

Inspect the cartridge. Do not use the test cartridge if it is damaged or if loose desiccant particles are found on the test cartridge.

Use the handle to avoid touching the optical reading area.



3

Mark the test cartridge with the patient or control ID. Use the ID area on the test cartridge. An ID label can also be used.

Do not write on the barcode label or allow it to become wet, dirty or scratched. If an ID label is used, this must fit into the ID area.

If a barcode reader is connected to the analyzer, a barcoded patient ID, control ID or Afinion Control Data can be entered.

Collecting a sample

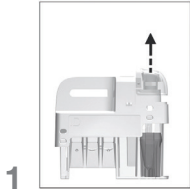


- The patient sample material and control material to be used is specific for each Afinion Test.
- The length of the capillary in the sampling device, and thereby the sample volume, might also vary for the different Afinion Tests.
- The time from filling the capillary until analysing the test cartridge must be as short as possible.
- Do not use the test cartridge if dropped on the bench or floor after the sample has been collected.



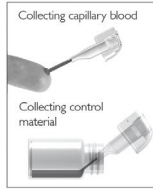
Consult the package insert that comes with each Afinion Test Kit for assay specific information.

Examples:



1 Remove the sampling device from the test cartridge.

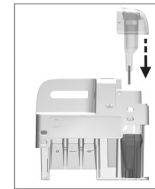
Use the handle to keep the test cartridge steady against the table and pull the sampling device straight up.



2

Fill the capillary; hold the sampling device almost horizontally and bring the tip of the capillary in surface contact with the sample. Make sure that the capillary fills completely. It is not possible to overfill.
Do not wipe off the capillary.

Avoid air bubbles and excess sample on the outside of the capillary.



3



Immediately and carefully replace the sampling device into the test cartridge.

The time from filling the capillary until analysing the test cartridge must be as short as possible.

Analysing a patient/control sample



1

Touch  to enter the patient sample mode.
Touch  to enter the control mode.
The lid opens automatically.



2

Insert the test cartridge with the barcode label facing left.
Be sure that the test cartridge is correctly placed in the cartridge chamber.
A "C" in the upper left corner indicates that the analyzer is in the control mode.







3

Close the lid manually. The analyzer will start processing the test cartridge.
The processing time depends on the test in use.





4

Touch  and enter the patient ID.
Touch  to confirm.
Touch  and enter the control ID or Afinion Control Data.
Touch  to confirm.

Entering the patient ID, control ID or Afinion Control Data will not interrupt the processing.



5

Record the result, then touch  to accept.
If a printer is connected, touch  to print the result.
The lid opens automatically.
The result will be saved in the result records.



6

Remove the used test cartridge from the cartridge chamber and discard it in a suitable waste container.
Insert a new test cartridge or close the lid manually.
Keep the lid closed to protect the cartridge chamber when the analyzer is not in use.

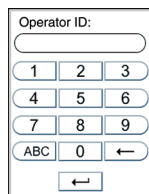



Consult the package insert that comes with each Afinion Test Kit for assay specific information.

Using the operator ID function

Entering operator ID


If enabled, the operator's identification (ID) is required before processing an Afinion Test Cartridge (see "Operator configuration", page 14). Both letters and numbers can be entered (maximum 16 characters). The operator ID will be displayed with the result and stored along with the other specific data for this run (see "Patient and control results records", page 25). If configured to "enabled with verification" the operator ID entered is required to be present in the operator ID list (see "Operator configuration", page 14).

The screen shows a label "Operator ID:" at the top. Below it is a numeric keypad with buttons for digits 1-9, 0, and a backspace arrow. There are also buttons for "ABC" to switch to letter entry and a confirmation arrow at the bottom.

Enter the operator ID by numbers and/or touch  to enter letters. If a barcode reader is connected to the analyzer, a bar coded operator ID can be entered.

Touch  to confirm and return to previous view.

The operator will be automatically logged out according to the configuration (see "Operator configuration" page 14).

The operator may also manually logout by using the operator logout button  displayed in the Start-up menu.

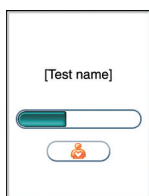
Using the patient ID function



The patient ID function is enabled as a default setting. As long as this function is enabled, the patient ID must be entered for each patient sample to be analyzed. The patient ID function can be disabled (see "Patient ID configuration", page 13).

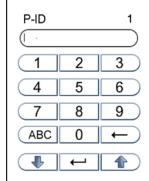
Entering patient ID

It is recommended to enter the patient ID during processing of the test cartridge in the analyzer. Entering the patient ID will not interrupt the processing. It is also possible to enter the patient ID before the processing.

1 Touch  to enter the patient ID option.

The screen shows a label "[Test name]" at the top. Below it is a progress bar. At the bottom, there is a button with a patient ID icon (a person with a plus sign).

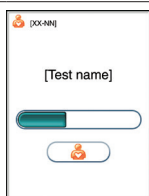
2 It is possible to enter up to four patient ID entries for each patient, P-ID 1 to 4. When enabled, P-ID 1 is required to be entered. Scrolling between the patient IDs is done with the  and .

The screen shows a label "P-ID 1" at the top. Below it is a numeric keypad with buttons for digits 1-9, 0, and a backspace arrow. There are also buttons for "ABC" to switch to letter entry and a confirmation arrow at the bottom. At the very bottom, there are two small buttons with up and down arrows for scrolling between patient IDs.

Enter patient ID by numbers and/or touch  to enter letters (maximum 16 characters). If a barcode reader is connected to the analyzer, a barcoded patient ID can be entered.

Touch  to confirm and return to previous view.

3 The entered P-ID 1 will appear on the screen.
The patient ID touch button will remain in the view and it is possible to make corrections.

The screen shows a label "[Test name]" at the top. Below it is a progress bar. At the bottom, there is a button with a patient ID icon. The icon now includes the text "P-ID 1" next to it.

The P-ID 1 will be stored in the memory and displayed along with the other specific data for this run (see "Patient ID configuration" page 13). Patient ID 2-4 will not be displayed in the result records but will be stored in the memory and appear on printouts and data transferred to data management systems.

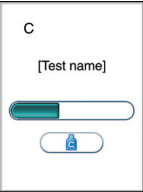

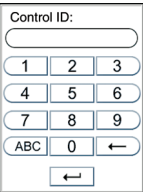


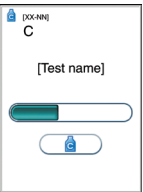
Using the control ID function

In quality control testing, a suitable control ID must always be entered. The lot number of the control material is recommended as a suitable control ID. The control ID function cannot be disabled.

Entering Control ID

It is recommended to enter the control ID during processing of the test cartridge in the analyzer. Entering the control ID will not interrupt the processing. It is also possible to enter the control ID before processing. Both letters and numbers can be entered (maximum 16 characters). The control ID will be stored in the memory and displayed along with the other specific data for this run.

To enter the control ID during processing, do the following:

- 1  Touch  to enter the control ID option.
- 2  Enter control ID by numbers and/or touch  to enter letters.
Touch  to confirm and return to the previous view.
- 3  The entered control ID will appear on the screen.
The control ID touch button will remain in the view and make corrections possible.

Using the QC lockout function

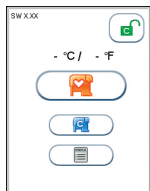
When the QC lockout function is enabled for one or more assays, approved control testing is required within the configured interval. If the interval expires, patient testing for the assay will be locked. A passed control run must be performed according to configuration to reset the interval or to unlock the assay for patient testing. A failed control run will disable patient testing (see "QC lockout configuration", page 16).

QC lockout status


The status of the active QC lockouts is presented with a QC lockout status button (padlock symbol) visible in the Start-up menu. This gives the operator the status of QC lockout before he attempts to run any tests.

The padlock symbol will only be visible if QC lockout function is enabled for one or more assay types.

The padlock symbols used are:




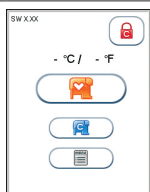
Enabled-unlocked

 All controls are within the configured interval. It is possible to run patient tests for all assays.



Warning-unlocked

 All controls are within the configured interval. When one or more of the assays has 10 % or less of the configured interval remaining the warning icon will be displayed. It is possible to run patient tests for all assays.



Expired-locked

 One or more controls have expired according to the configured interval. Patient testing on the expired assay has been locked.

Touch the QC lockout status button (padlock symbol) in the Start-up menu to enter the QC lockout status view.

Status

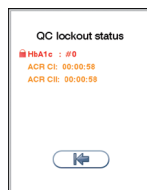
The information is displayed as a list.

Only the assays with QC lockout activated are displayed in this window.

Red text indicates expired assays and orange text indicates assays within warning period.

Control level

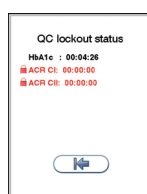
How to reset QC lockout interval and/or unlock expired assays.



If no control level is specified, it is required to run **ONE** passed control, control level C I **OR** C II, to reset the QC lockout interval and unlock the assay for patient testing.

E.g.

HbA1c: #0



If the control level is specified it is required to run **TWO** passed controls, both control level C I **AND** C II, to reset the QC lockout interval and unlock the assay for patient testing.

E.g.

ACR C I: 00.00.00

ACR C II: 00.00.00

Remaining time/runs

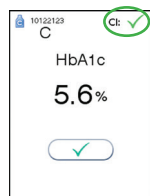
Remaining time (dd:hh:mm) or number of runs for each assay with active QC lockout is shown. dd is the number of days, hh is the number of hours, and mm is the number of minutes until the assay will be locked. # is number of patient tests.

Running controls with enabled QC lockout function

When running controls with the QC lockout function enabled, the Afinion Control Data is required to be entered or previously stored in the instrument control lot database. See "QC lockout configuration", page 16.

- 1) The Afinion Control Data is entered before, during or after the control run. If a barcode scanner is connected (recommended) the control data barcode may be scanned. The control lot will automatically be stored in the instrument control database.
- 2) If the Afinion Control Data is previously stored in the instrument control database, the operator will simply need to enter the 8 digit control lot number before, during or after the control run.

If the instrument is configured to QC lockout and the control lot number is not found in the Afinion Control database or the Afinion Control Data entered is not valid, the instrument will present an option to retry the input or discard the control run result. If discarded, the result will not be stored in the instrument result records.

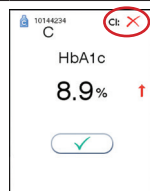


Passed (result within the acceptable control range)

The result of the control is checked against the acceptable ranges for the corresponding lot number.

If the result is within the limits, a pass symbol is displayed on the screen and the QC lockout interval is reset according to the QC lockout configuration.

If QC lockout is configured to require two control levels (C I **and** C II), both levels must pass to reset the lockout interval. Only the interval for the control level used in the test is reset.



Failed (result above or below the acceptable control range)

When a control result is not within the acceptable ranges specified for the control lot, a failed symbol is shown on the screen. The result is stored in the instrument and is sent to the data management system if connected. The QC lockout interval will not be reset.

The arrow symbol will specify whether the result is above or below the acceptable ranges.

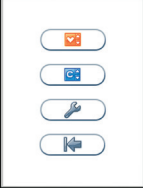
See "Handling and testing controls", page 19.



Patient and control results records

The patient and control results are stored in the memory of the Afinion 2 Analyzer. The last 500 patient results and the last 500 control results are saved in separate records. When exceeding the capacity of 500 results, the oldest result will be deleted. The following parameters are listed for each run: Date and time, run number, patient ID/control ID, operator ID, lot number of test cartridge and the test result.


View, print and export patient and control results




1 Main menu




Touch  to enter patient results.
Touch  to enter control results.

2 The last patient result or control is displayed




To view more results touch  or 
If a printer is connected, touch  to print the result.

Result records may be exported if an USB flash (FAT 32 formatted) is inserted to the Afinion 2 USB port.

Touch  to export the results. The results will be stored on the USB in a .txt file for each assay tested on the Afinion 2 Analyzer. These files may be opened in e.g. Microsoft Excel for further processing.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Test type	Serial number	Cartridge lot no	Patient ID	Patient ID 2	Patient ID 3	Patient ID 4	Operator ID	Test date	% HbA1c	mmol/moleAG	
2	HbA1c	AS0007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130924 08:11	5.2 %		
3	HbA1c	AS0007962	10125113	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 08:29	3.1 %		
4	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 08:39	3.3 %		
5	HbA1c	AS0007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 09:50	8.2 %		
6	HbA1c	AS0007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 10:01	5.1 %		
7	HbA1c	AS0007962	10125113	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 11:23	5.3 %		
8	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 12:01	3.8 %		
9	HbA1c	AS0007962	10125113	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 13:20	3.3 %		
10	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 13:56	9.2 %		
11	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 14:01	5.1 %		
12	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 14:12	5.2 %		
13	HbA1c	AS0007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 15:04	6.1 %		
14	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 15:12	3.3 %		
15	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 15:25	8.2 %		
16	HbA1c	AS0007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 16:20	5.1 %		


 When you export data that contains patient information, it is your responsibility to comply with your local regulations on protection of personal health information.


When an information code appears


Information codes that might appear during use of the Afinion 2 Analyzer refer to specific information or error messages. The code numbers, the possible causes and actions to take are listed below.

If the analyzer detects a problem during processing of a test cartridge, the test will automatically be aborted and the test cartridge will be safely moved to the cartridge chamber. Proceed as follows:


- 1



Record the code number (#) and touch  to accept.
The lid opens automatically.
- 2



Remove the test cartridge.
If the test cartridge is not ejected, restart the analyzer.
Do not reuse the test cartridge.
- 3



Look up the possible cause from the table below, and take actions to solve the problem.
If the problem persists, contact your local Afinion supplier (see "Service information" page 28).

 Do not reuse a test cartridge that has been rejected by the analyzer. Collect a new sample and repeat the test with a new test cartridge.

Information codes caused by test-specific limitations

[#]	Cause	Action to take
103	Hemoglobin too low	Consult the Afinion HbA1c Package Insert.
104	Hemoglobin too high	Consult the Afinion HbA1c Package Insert.
105	HbA1c too low	Consult the Afinion HbA1c Package Insert.
106	HbA1c too high	Consult the Afinion HbA1c Package Insert.
107	Creatine too high	Consult the Afinion ACR Package Insert.
108	Blood in urine	Consult the Afinion ACR Package Insert.

Information codes caused by sample or test cartridge

[#]	Cause	Action to take
201	Insufficient sample volume: - Empty capillary - Air bubble in capillary - Capillary incompletely filled	Repeat the test with a new sample and test cartridge. Ensure that the capillary is completely filled with no air bubbles (see package insert for the Afinion Test in use).
202	Excess sample on the sampling device exterior	Repeat the test with a new sample and test cartridge. Ensure that only the tip of the capillary is in contact with the sample (see package insert for the Afinion Test in use).
203	Wrong sample material	Repeat the test with a new sample and test cartridge. Ensure that proper sample material is used (see package insert for the Afinion Test in use, section "Specimen collection and storage").
204	Coagulated sample	Repeat the test with a new sample and test cartridge. The time from filling the capillary until analyzing the test cartridge should be as short as possible.
	Hemolysed blood sample or poor sample quality	Consult the Afinion Package Insert. Repeat the test with a new sample and test cartridge.
	Test cartridge or analyzer failure	Repeat the test with a new sample and test cartridge. If the problem persists, restart the analyzer and run controls.
205	Capillary cracked or damaged	Repeat the test with a new sample and test cartridge. Inspect the sampling device before use and handle with care.
206	Barcode label not readable (dirty or damaged)	Repeat the test with a new sample and test cartridge. If the problem persists, restart the analyzer and run controls.
207	- No sampling device inserted	Repeat the test with a new sample and test cartridge. Ensure that the correct sampling device is in place and that the sampling device label is clean.
	- Sampling device belongs to another Afinion Test	
	- Label on sampling device not readable (dirty or damaged)	
208	Test cartridge previously used	Repeat the test with a new sample and test cartridge.
209	Test cartridge has passed expiration date	Check expiry date on the foil pouch or kit container. Repeat the test using a new sample and a new test cartridge from another lot.
	The date in the analyzer is incorrectly set	Check the date in the analyzer to make sure it is set correctly. Repeat the test with a new sample and test cartridge.
210	Test cartridge temperature too low	Repeat the test with a new sample and a new test cartridge. Ensure that the operating temperature is within acceptable range (see package insert for the Afinion Test in use).
211	Test cartridge temperature too high	Repeat the test with a new sample and a new test cartridge. Ensure that the operating temperature is within acceptable range (see package insert for the Afinion Test in use).
212	Software upgrade is required to run this test.	Contact your local supplier for assistance.
213 214	Test cartridge or analyzer failure	Repeat the test with a new sample and test cartridge. If the problem persists, restart the analyzer and run controls.
215	Test cartridge or analyzer failure	Repeat the test with a new sample and test cartridge. If the problem persists, restart the analyzer and run controls.
	Hemolysed blood sample or poor sample quality (Afinion HbA1c)	Consult the Afinion HbA1c Package Insert. Repeat the test with a new sample and test cartridge.
217	Hemolysed blood sample or poor sample quality (Afinion HbA1c)	Consult the Afinion HbA1c Package Insert. Repeat the test with a new sample and test cartridge.
218	Condensation detected on cartridge	Run a new test cartridge. Ensure that the cartridge is equilibrated to room temperature before the foil pouch is opened.

Information codes and messages caused by analyzer failure

[#]	Cause	Action to take
27 28 29	Start-up procedure failed	Contact your local supplier for assistance.
Self-test error. Analyzer in non-operative mode	Analyzer failure	Restart analyzer. If the problem persists, contact your local Afinion 2 supplier.
301	Self-test failed	Restart the analyzer.
302	Analyzer failure	Restart the analyzer and run controls. Repeat the test with a new sample and test cartridge.
303	Analyzer temperature is too high	Ensure that the operating temperature is within recommended range (15-32°C, 59-89 °F). Wait until the analyzer has cooled down. Repeat the test with a new sample and test cartridge.
304	Analyzer temperature is too low	Ensure that the operating temperature is within recommended range for the Afinion Test in use (see package insert). The analyzer temperature is displayed in the Start-Up menu (see page 11). Repeat the test with a new sample and test cartridge.

Information Codes and Troubleshooting

[#]	Cause	Action to take
305	Printer improperly connected Malfunction of the printer	Switch off the analyzer, reconnect the printer and restart the analyzer. If the message persists, see the printer user manual.
Touch screen error	Touch screen failure/ Touch screen buttons do not respond accurately	Restart analyzer and realign screen.

Other information codes

[#]	Cause	Action to take
401	No registered supervisors in operator list	At least one supervisor is required in the operator list when the analyzer is configured to operator ID verified, (see page 14).
402	Cannot delete last supervisor	At least one supervisor is required in the operator list when the analyzer is configured to operator ID verified, (see page 14).
403	This assay type is not accessible to the operator	The operator logged in does not have access to run this assay type. Please contact your supervisor.
404	Operator ID is not found in operator list	When Operator ID with verification is enabled, operator ID entered is required to be present in the operator list, (see page 14). Please contact your supervisor.

[#]	Cause	Action to take
501	The control lot has passed expiration date	Check the expiration date on the control lot package insert or kit box. Repeat the test using a sample from a new control lot.
502	Afinion Control Data is not recognised and is not stored in control lot database	Reenter the Afinion Control Data, (see page 16).
503	Control verification aborted.	The Afinion Control Data entered was not recognised. The control test was aborted by the operator. Test result was not stored. Run new control test to reset QC lockout interval.
504	Required control test interval has expired. Patient testing is disabled for this assay.	A passed control run must be performed according to configuration to unlock this assay for patient testing.

[#]	Cause	Action to take
601	Operator list or control lot database is full	The operator list can store 1000 operators and the control lot database can store 100 control lots. Delete an operator or control lot to enter a new item

Service information



The laboratory must notify the manufacturer of this test system of any performance, perceived or validated, that does not meet the performance specifications as outlined in the instructions.

The manufacturer provides a toll free line for technical support: 1.866.216.9505

The toll free number is available for use only in the United States of America.

Before asking for assistance, please record the following information:

- Afinion 2 serial number (SN) – see label on the backside of the analyzer
- Software version number – see Start-up menu.
- Afinion Test type
- Test cartridge or kit lot number – see foil pouch or kit container
- Control identification and lot number – see vial label
- Control results obtained
- Description of the problem with reference to information codes or messages

Cleaning and maintenance

No maintenance of the Afinion 2 Analyzer is required other than cleaning the exterior and cartridge chamber.

Cleaning the exterior

Cleaning the exterior of the Afinion 2 Analyzer should be performed whenever necessary. Most spills and stains can be removed with water or a mild detergent.

- Power off the analyzer. Unplug the power supply when the shut down procedure is completed.
- Clean the outside of the analyzer and the touch display with a clean, lint-free and non-abrasive cloth dampened in water or a mild detergent.
- To disinfect the exterior of the analyzer use a 1:10 solution of household bleach (i.e., 0.5% sodium hypochlorite), 2% glutaraldehyde solution or 70% alcohol solution. The surface of the analyzer should be exposed to the disinfectant for at least 10 minutes.
- Allow the analyzer to air dry.
- Plug in the power supply and power on the analyzer.




- The analyzer must be powered off and unplugged before cleaning.
- Do not use any cleaning liquid or equipment other than those recommended above.
- Do not immerse the analyzer in water or other liquids.

Cleaning the cartridge chamber

The Cleaning Kit (REF 1116048) should always be used for cleaning the cartridge chamber.

The cartridge chamber should be cleaned immediately if materials or liquids are spilled in the cartridge chamber. For regular maintenance (removal of dust particles etc.), the cartridge chamber should be cleaned every 30 days.

- Touch  to open the lid.
- Unplug the power supply.
- Wet a Cleaning Swab with 3 drops of water and gently rinse the cartridge chamber. To disinfect the surface, use a 1:10 solution of household bleach (i.e., 0.5% sodium hypochlorite), 2% glutaraldehyde solution or 70% alcohol solution). Do not soak.
- Carefully remove spills and particles from the cartridge chamber using the moistened swab.
- To disinfect the cartridge chamber, the surface of the chamber should be exposed to the disinfectant for at least 10 minutes¹.
- Wipe off any residual liquid from the cartridge chamber using a new, dry Cleaning Swab.
- Plug in the power supply, and power on the analyzer by pressing the on/off button.
- The lid will close automatically during the self-test. If it doesn't, then close it manually and restart the analyzer.



- The analyzer must be unplugged before cleaning.
- Do not use any cleaning liquid or equipment other than those recommended above.
- Do not allow liquid to drip off the Cleaning Swab into the analyzer. If liquid drips into the analyzer, optics can be destroyed.
- Do not immerse the analyzer in water or other liquids.
- Do not move or tilt the analyzer when cleaning the cartridge chamber.

Disposal of the analyzer



For correct disposal according to the Directive 2012/19/EU (WEEE), contact your local Afinion 2 supplier.

Software upgrade



Consult the Afinion USB Flash Drive Package Insert for software upgrade.

¹ Clinical and Laboratory Standards Institute (CLSI) Guideline M29-A3: "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition". ISBN 1-56-238-567-4

Warranty

Alere Technologies AS warrants solely to the Buyer that the Afinion 2 Analyzer will be free from defects in materials and workmanship, when given normal, proper and intended usage, and will perform in accordance with Alere Technologies AS's specifications for a period of twelve months from the date of delivery.

At its expense, Alere Technologies AS agrees to repair, or at Alere Technologies AS's option, replace with a new or reconditioned unit, any Afinion 2 Analyzer which is under warranty and not performing substantially in accordance with applicable product specifications, provided that the Buyer has given Alere Technologies AS notification of such warranty claim within the warranty period. If Alere Technologies AS is unable after reasonable efforts to repair or replace the Afinion 2 Analyzer not performing substantially in accordance with applicable product specifications, the Buyer's sole remedy shall be the refund of an amount not to exceed the actual purchase price paid by the Buyer for the Afinion 2 Analyzer. All repairs will be done during normal working hours. All replaced parts shall become Alere Technologies AS's property. Alere Technologies AS may require the Buyer to ship the Afinion 2 Analyzer to Alere Technologies AS or elsewhere at Alere Technologies AS's expense, for warranty service to be performed.

Notwithstanding the foregoing, Alere Technologies AS shall have no obligation to make repairs, replacements or corrections which result, in whole or in part, from (i) an act of God or other unforeseen catastrophe, (ii) any error, omission or negligence of the Buyer, (iii) improper or unauthorized use of the Afinion 2 Analyzer, (iv) operating errors or the disregard of warnings and pre-cautions described in this Afinion 2 Analyzer User Manual; (v) repairs performed to the Afinion 2 Analyzer by any person other than an authorized Alere Technologies AS service representative; (vi) use of the Afinion 2 Analyzer in a manner for which it was not designed, (vii) causes external to the Afinion 2 Analyzer such as, but not limited to, power failure or electric power surges, or (viii) use of the Afinion 2 Analyzer in combination with equipment, components or software not supplied by Alere Technologies AS.

EXCEPT AS STATED IN THIS SECTION OF THE USER MANUAL, ALERE TECHNOLOGIES AS DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO THE AFINION 2 ANALYZER, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALERE TECHNOLOGIES AS'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE AFINION 2 ANALYZER OR ITS USE, WHETHER BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PURCHASE PRICE PAID BY THE BUYER FOR THE AFINION 2 ANALYZER. IN NO EVENT SHALL ALERE TECHNOLOGIES AS BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES, ARISING HEREUNDER OR FROM THE SALE OF THE AFINION 2 ANALYZER. THIS WARRANTY MAY NOT BE TRANSFERRED BY THE BUYER.

The acknowledgement of claims shall be reported to your Technical Care Specialist at 1.866.216.9505

AFINION™ 2 Analyzer















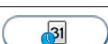














Analyzer	
Size	200 mm W x 186 mm H x 328 mm D
Weight	3.4 kg
Display	Standard LCD colour display with back light and integrated touch panel. Resolution: 240 x 320 pixels. Visible area: 58 x 77 mm.
Camera	640 x 480 pixels
Capacity of result records	500 patient results and 500 control results
Capacity of operator list	1000 operators
Capacity of control lot database	100 control lots
SW update	Via USB flash drive
Communication interface	USB 2.0 High Speed, Ethernet 10/100 Mbps
Power supply	
Power supply	Separate AC to DC power supply. Double insulated.
Input	100-240 VAC, 50-60 Hz
Output	24 VDC \pm 5% , 1.75 A, 42 W
Output connector	0.2 x 0.1 in. / 5.5 x 2.5 mm plug. Positive (+) on inner pin.
Operating conditions	
Temperature	15-32°C (59-89°F)
Relative humidity	10-80%, non-condensing
Altitude	Max 4000 MASL
Location	Dry, clean, horizontal surface. Avoid direct sunlight.
Test cartridge temperature	According to specifications for the Afinion Assay in use.
Storage and transport (in the original container)	
Temperature	-40 to 70°C (-40 to 158°F)
Relative humidity	10-93 % at 40°C

Additional equipment

For information regarding recommended barcode reader, printer, the Afinion Analyzer Cleaning Kit or USB flash drive, please call 1.866.216.9505.

The touch buttons and their function











Touching a button on the screen will activate the function of this button. All the touch buttons that may appear during operation of the Afinion 2 Analyzer are explained below by their function.

Start-up menu		Patient sample mode	Select patient sample mode.
		Control mode	Select control mode.
		Main menu	Enter Main menu (operator ID, patient records, control records and configuration menu).
		QC lockout status	Enabled-unlocked All controls are within the configured interval. It is possible to run patient tests for all assays.
		QC lockout status	Warning-unlocked All controls are within the configured interval. When one or more of the assays has 10 % or less of the configured interval remaining the warning icon will be displayed. It is possible to run patient tests for all assays.
		QC lockout status	Expired-locked One or more controls have expired according to the configured interval. Patient testing on the expired assay has been locked.
		Operator logout button	Manual operator logout button.
Main menu		Patient records	View patient result records. View, print or export patient results.
		Control records	View control result records. View, print or export control results.
		Configuration menu	Enter configuration menu (language, patient ID on/off, date/time and screen/volume).
Configuration menu		Patient ID configuration menu	Configure patient ID function.
		Operator configuration menu	Configure operator function.
		Language setting	Enter language configuration.
		Screen/Volume menu	Configure screen and volume settings (screen contrast, screen adjustment and beeper volume).
		Date/Time menu	Enter date/time settings (date and time).
		QC lockout configuration menu	Configure QC lockout function.
		General settings menu	Enter the general settings menu.
Patient ID configuration menu		Patient ID disabled	Patient ID disabled.
		Patient ID enabled	Patient ID enabled and required.
Operator configuration menu		Operator ID configuration	Configure operator ID function.
		Automatic operator logout	Configure number of minutes before automatic logout of operator.
		Operator list	Manage operator list. View, add, edit and delete operators.
Patient and control records		Print	Print result on connected printer.
		Result records export	Export result records to connected USB flash.
Universal buttons		Patient ID	Enter patient ID.
		Control ID	Enter control ID.
		Enter	Enter and return to previous view.
		Backspace	Delete previous character.
		Increase	Increase contrast/volume.

Menu	Touch button	Name	Function
		Decrease	Decrease contrast/volume.
		Scroll up	View previous
		Scroll down	View next
		Exit	Exit current menu and return to previous screen view.
		Accept	Accept (a setting or a test result).
		Abort	Abort the test result or cancel operation.
		Add button	Add new operator or control lot.
		Delete button	Delete operator or control lot.
		Edit button	Edit QC lockout interval or operator ID.
Operator ID configuration		Operator ID disabled	Operator ID function is disabled.
		Operator ID enabled	Operator ID is required to be entered to run an Afinion Test Cartridge
		Operator ID enabled with verification	Operator ID is required to be entered to run an Afinion Test Cartridge. The operator ID is verified against the analyzer operator list.
Language settings		Language	Enter language configuration.
Screen/Beeper menu		Screen alignment	Enter screen alignment function.
		Beeper volume	Enter beeper volume setting.
Date/Time menu		Date	Enter date setting.
		Time	Enter time setting.
General settings menu		Erase	Erase all content and configurations.
		Instrument network settings	Enter analyzer network settings
		Connectivity settings	Enter connectivity settings
QC lockout configuration menu		QC lockout	Enable/disable QC lockout function.
		QC lockout interval	Configure QC warning and lockout interval.
		Control lot information	View, add or delete control lots stored on analyzer.
Operator list		Operator list export	Export operator list from analyzer to USB flash.
		Operator list import	Import operator list from USB flash to analyzer.
QC lockout		QC lockout disabled	QC lockout is disabled for this test.
		QC lockout enabled	One passed control run of either C I or C II is required to reset QC lockout interval.
		QC lockout enabled	Two passed control runs, C I and C II are required to reset QC lockout interval.
QC lockout interval		Interval by number of patient tests	QC reminder and lockout active after a configured set of patient tests.
		Interval by number of hours	QC reminder and lockout active after a configured set of hours.






















Other symbols and signs








Other symbols, signs and abbreviations that may appear during operation of the Afinion 2 Analyzer are explained below. These symbols or signs are only informative and can not be activated like the buttons.

Symbol	Meaning	Appears when?
	Wait!	Hour-glass icon that appears in the start-up procedure.
	Information code	Icon used along with a code number [#] that corresponds to code specific information messages [#] (see "Information codes and troubleshooting").
	Operator ID	Icon illustrates the operator ID.
	Patient ID	Icon illustrates the patient ID.
	Control ID	Icon illustrates the control ID.
	Connected	The instrument is connected to the LIS/HIS/EMR server. When no symbol, the instrument is not connected to the LIS/HIS/EMR server.
	Quality control pass	Control result is within acceptable range.
	Quality control failed	Control result is outside acceptable range.
	Result is above acceptable range	The displayed control result is above acceptable range.
	Result is below acceptable range	The displayed control result is below acceptable range.
C	Control	The letter C will appear on the screen when the control mode is selected.
O-ID	Operator ID	Abbreviation used in the patient and control records.
P-ID	Patient ID	Abbreviation used in the patient records.
C-ID	Control ID	Abbreviation used in the control records.
RUN#	Run number	Abbreviation used in the patient and control records for the run number of the analysis. This numbering is reset each day at midnight.
LOT#	Lot number	Abbreviation used in the patient and control records for the lot number of the test cartridge.
USER	User	Operator with user privileges.
SUPERVISOR	Supervisor	Operator with supervisor privileges.

Symbols and Abbreviations

The following symbols and abbreviations are used in the product labeling of the Afinion 2 System.

Symbol/Abbreviation	Explanation
	The product conforms to all applicable EC Directives and Regulations
	<i>In vitro</i> diagnostic medical device
	Catalogue number
	Lot number
	Serial number
	Test cartridge
	Control C I
	Control C II
	Cleaning kit
	Waste electrical and electronic equipment (WEEE)
	Biological risks
	Contents sufficient for "n" number of tests
	Expiration date
	Storage temperature limitations
	Manufacturer
	Date of manufacture
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Warnings and precautions
	Consult the Afinion User Instructions

Symbol/Abbreviation	Explanation
	Conformity to the RoHS 2 directive
	Conformity to the technical regulations for EurAsian Conformity Mark
	Conformity to the North American product safety standards
	Direct current
	USB port
	Ethernet port
	Double insulation
LED	Light emitting diode
PC	Personal computer
ID	Identification
HIS	Hospital information system
LIS	Laboratory information system
LCD	Liquid crystal display
AC	Alternating current
DC	Direct current
ASTM	American Society for Testing and Materials
HL7	Health Level Seven
POCT1-A	Point-of-Care Connectivity; approved standard
EMR	Electronic medical record
DHCP	Dynamic host configuration protocol
IP	Internet protocol



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