Alere Afinion™
AS100 Analyzer

US

REF 1115175

CE

1116416 Rev. A 2015/04

Dear Customer,

Congratulations on the purchase of your Alere Afinion™ AS100 Analyzer.

Upon arrival of your Alere Afinion™ AS100 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 AS100 Analyzer. The recorded information will be of great value if and when a question is reported, or the desire to add a new Alere Afinion™ test to your Analyzer arises.

Serial number

SN _____ (see label on the underside of the Analyzer or on the transport container)
NOTE! The Analyzer must be turned off when the label on the underside is read.

Software records

	Date	Software version*	Alere 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 10).

Notes

Technical Support

Call 1.866.216.9505

Alere Afinion™ AS100 Analyzer System

Intended use

Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC) is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Alere Afinion™ Test Cartridges. The ADCC is a small device for automatic transfer of data, including patient and control assay results, from the Alere Afinion™ Analyzer to a laboratory information system or another electronic journal system. Alere Afinion™ AS100 Analyzer System, consisting of Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC), Alere Afinion™ Test Cartridges and Alere Afinion™ Controls is for in vitro diagnostic use only.

CLIA Statements

Waived Alere Afinion™ tests

Alere 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 Alere Afinion™ test or Alere Afinion™ AS100 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 the European IVD directive

The Alere Afinion™ AS100 Analyzer meets all provisions in the European directive 98/79/EC on In Vitro Diagnostic Medical Devices and is CE marked accordingly.

Safety standards

Alere Afinion™ AS100 Analyzer has been tested and found to be in conformity with IEC, UL, CAN/CSA-C22.2: 61010-1 (Safety requirements for electrical equipment for measurement, control, and laboratory use), IEC 61010-2-081:2001 + A1 and IEC 61010-2-101:2002 (Particular requirements for in vitro diagnostic (IVD) medical equipment).

EMC standards

Alere Afinion™ AS100 Analyzer has been tested and found to be in conformity with EN 61326-1:2006 (Electrical equipment for measurement, control, and laboratory use – EMC requirements) and EN 61326-2-6:2006 (In vitro diagnostic (IVD) medical equipment) and CFR 47 Telecommunications, Chapter I- FCC Part 15 – Radio Frequency Devices – Subpart B: unintentional radiators.

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ISO 9001 and ISO 13485 certified company

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About this User Manual

This User Manual will guide you through installation, operation and maintenance of your Alere Afinion™ AS100 Analyzer. The User Manual also explains how the Analyzer works, describes the quality assurance system and assists you in troubleshooting.

For analyzing patient samples or controls, please also read the test specific information given in the Package Inserts found in the Alere Afinion™ test kits. The Quick Guides highlight the main steps of the test procedures and contains information on proper quality control routines.

It is recommended that you become familiar with the user instructions before you start operating the Alere Afinion™ AS100 Analyzer.

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


Operator's handling


Warnings and precautions


References to the Package Inserts and Quick Guides for the specific Alere 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 Alere Afinion™ AS100 package unit includes:

- Alere Afinion™ AS100 Analyzer
- Power cable
- Power cord adapter, 24 volt power supply
- Quick Guides for the available Alere Afinion™ tests
- User Manual
- Installation video (CD-ROM)

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 Alere Afinion™ AS100 Analyzer

Figure 1 shows the main exterior parts of the Alere Afinion™ AS100 Analyzer.

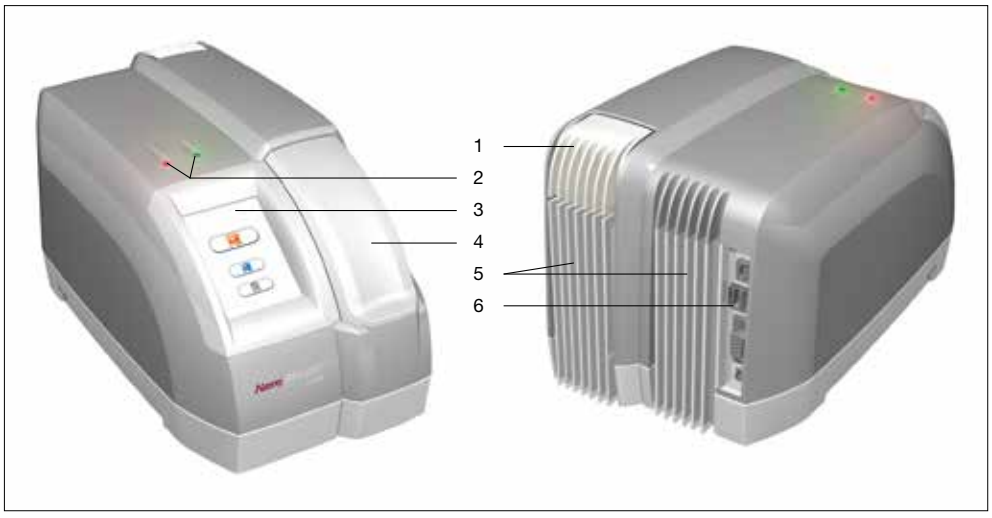


Figure 1

1	ON/OFF button:	Turns the power to the Analyzer on and off.
2	Red and green LEDs:	Light emitting diodes (LEDs) that indicate whether the Analyzer is busy or not.
3	Touch screen:	Allows you to communicate with the Analyzer through touch icons and messages.
4	The lid:	Covers and protects the cartridge chamber.
5	Cooling ribs:	Facilitate temperature control.
6	Connectors:	Connection to power cord adapter USB port- Options for printer, barcode reader, export of patient and control record to USB flash and SW upgrade. RS232- Connectivity options to EMR and/or HIS/LIS systems through the Alere Afinion™ Data Connectivity Converter (ADCC).

⚠ Do not open the lid manually.

Description of the Alere Afinion™ Test Cartridge

The Alere 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 and the sampling device labels have a unique color for each test. The Test Cartridges are separately packed in foil pouches to protect the chemicals 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 re-used.

Figure 2 illustrates an Alere Afinion™ Test Cartridge with its functional parts:

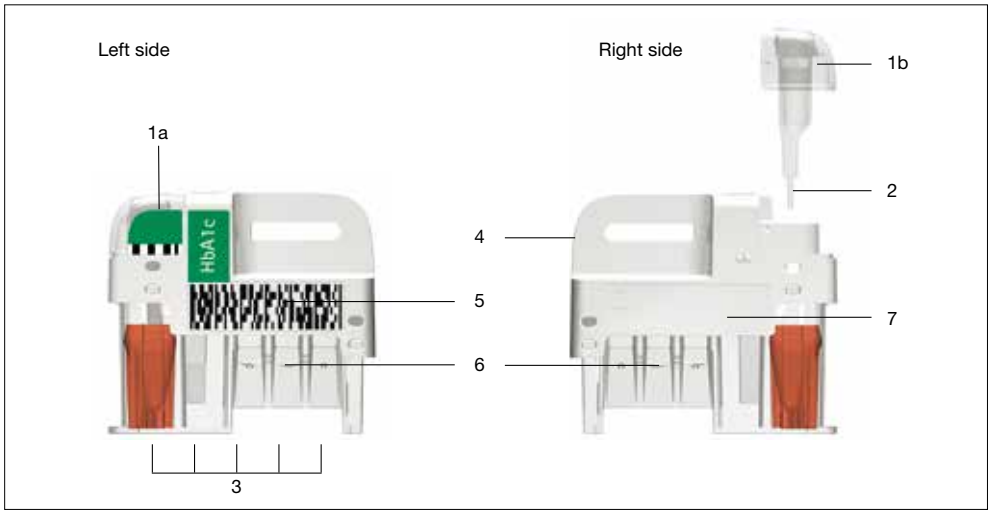


Figure 2

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:	Contains 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 labeled sample identification.

How the Alere Afinion™ AS100 Analyzer System works

The Alere Afinion™ AS100 Analyzer 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. The calibration data for the actual lot are read, which then initiates the processing of the Test Cartridge. The sample and reagents are automatically transferred between the wells. An integrated camera monitors the entire process. Light-emitting diodes (LEDs) illuminate the reaction area, which can be either a colored 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 27).

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 or 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 and 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 Alere Afinion™ 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 Alere Afinion™ operator functionality will, if configured, require the operators to login before testing. The functionality may also prevent un-authorized 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 Alere Afinion™ 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 18). For more information regarding these functionalities (see “Setting the configuration” page 13).

Calibration

The Alere Afinion™ AS100 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 Alere Afinion™ AS100 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. Acclimate the Analyzer to ambient operating temperature (15-32°C, 59-89°F).

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 (e.g.from mobile phones)
- Movement of the Analyzer during processing of a Test Cartridge

Connecting power supply

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

Always use the correct supply voltage. The power supply voltage must match the information quoted in the section “Technical specifications”, page 32.

Figure 3

1 Not in use
2 USB-A connectors for printer, USB flash and/or barcode reader
3 RS-232 port for connection to HIS or LIS systems.
4 Power input for power supply connection

Connecting additional equipment

Optional equipment, not provided with your Alere Afinion™ AS100 Analyzer are:

- External barcode reader – for reading barcoded sample or operator identification.
- Printer – for optional print out of test results.
- Alere Afinion™ Data Connectivity Converter - For data transfer to HIS or LIS systems (see “Additional equipment”, page 32).

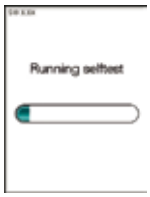
For additional information regarding the barcode reader, printer, and connection to HIS or LIS systems, please contact your local Alere Afinion™ supplier.

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

How to power ON the Analyzer

1 

Power on the Analyzer by pressing the ON/OFF button (Figure1). 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 Alere Afinion™ test (see the Package Insert for the Alere Afinion™ test).
If the Analyzer fails during the start-up procedure, an information code will appear referring to a message given in the "Information codes and troubleshooting", page 27–29.

How to power OFF the Analyzer

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

Please note:

- When the power is turned off, a closing down procedure is initiated. The cartridge carriage will move to a safe position and the display will be active a few seconds while the Analyzer shuts down. The Analyzer can be powered off, or the power supply disconnected, without loss of stored results.
- 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 Alere Afinion™ AS100 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 “Gallery of icons”, page 33–35.

The other main operative part of the Alere Afinion™ AS100 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 lid in open position
4 The cartridge chamber with a Test Cartridge

Screen saver

The screen saver will turn on after 3 minutes, if the touch screen is not in use. To re-activate, 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 Alere Afinion™ Menus

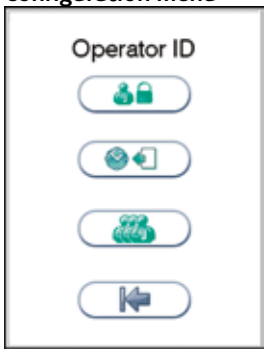
Start-up menu

Main menu

Configuration menu

Patient ID configuration menu

Operator configuration menu



QC lockout configuration menu

Language settings

Date/Time Menu

Screen and beeper volume menu

Setting the configuration

Before using your Alere Afinion™ AS100 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

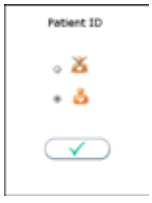
Select an item for configuration (see following pages).

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 verified is enabled, instrument 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 management”, bottom of the page).

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 analysis of the test is complete.
Touch [ ] to confirm and return to previous view.

Operator management

Touch [ ] in operator configuration menu to enter operator list.

1

Touch [ ] to add new operator.
Touch desired operator ID and touch [ ] to delete or [ ] to edit the highlighted operator.

2

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.

3

Configure the operator level:

Select whether this operator will be a user or supervisor.

1) User

2) Supervisor

Configure tests accessible by checking the appropriate test boxes for this operator.

Check off 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 500 operator IDs.

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

Copy operator list

It is possible to copy operator lists between instruments using a USB flash drive. Insert USB flash in instrument USB port. Touch to export operator list from instrument to USB flash. Move USB to new instrument and touch to import operator list. Any existing operator list on the instrument will be deleted.

Choosing language

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

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.

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 setting.

1

Touch to enter date setting.
Touch to enter time setting.

2

Enter today's date or time.
Touch to confirm and return to the previous view.

Adjusting screen/beeper volume settings

Touch [ ] in the configuration menu to enter the screen/beeper volume settings.

The screen contrast can be adjusted.

Touch [ ] to enter the screen contrast setting.
Touch [ ] to enter the screen alignment setting.
Touch [ ] to enter the beeper volume setting.

Screen contrast setting

Adjust the screen contrast by touching [−] or [+]
Touch [✓] to confirm and return to previous view.

Screen alignment setting

Tap the cross-hair object (+) in the upper left corner using a blunt pencil to be precise. Repeat for the object appearing in the lower right corner and in the center of the screen. The previous screen view will automatically return.

Beeper volume setting

Adjust the beeper volume by touching [−] or [+]
Touch [✓] to confirm and return to the previous view.

General settings menu

Touch [ ] in the configuration menu to enter the general settings menu.

Touch [ ] to erase all content and configurations.
All data will be permanently erased.

QC lockout configuration

The QC lockout function is disabled as a default setting by the manufacturer.
Touch in the configuration menu to enter the QC lockout setting 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.

1

Select assay type

Touch the arrow in the window to open the drop down menu to select the assay type.

Touch the assay to select.

2

QC lockout

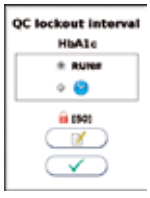
Select to disable the QC lockout function. No QC runs will be required for this assay

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 control, both control level C I **AND** C II, to reset the QC lockout interval.

Touch to confirm and return to the previous view.

3



QC lockout interval

Select RUN# 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.

4

Control lot database

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

The Alere Afinion™ Control Data is a numeric data string which contains all lot spesific data:

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

The Alere Afinion™ Control Data and its accompanying barcode is found in the Alere Afinion™ Control kit package insert. If the Alere 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 Alere 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).

Touch to delete selected lot number from the control lot database. 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.

Why quality control testing?

Quality control testing should be done to confirm that your Alere Afinion™ AS100 Analyzer System is working properly and providing reliable results. Only when controls are used routinely and the values are within the acceptable ranges can accurate results for patient samples be assured.

Choosing control material

Controls recommended by manufacturer should be used for quality control of your the Alere Afinion™ AS100 Analyzer System. These control kits contain control materials with established acceptable ranges for the Alere Afinion™ AS100 Analyzer 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 19–26.

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 outside the acceptable limits, make sure that:
- The control vial has not passed its expiry date.
- The control vial has not passed its open vial expiry date.
- The control vial and Alere 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 re-test 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. Re-test 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

Controls should be analyzed:
- When starting up an Alere Afinion™ AS100 Analyzer for the first time.
- With each new shipment of Alere Afinion™ test kits.
- With each new lot of Alere Afinion™ test kits.
- Users with a low frequency of testing should analyze controls at least every 30 days.
- When training new operators in correct use of the Alere Afinion™ AS100 Analyzer.
- Anytime an unexpected test result is obtained.
- After software upgrade of the Alere Afinion™ AS100 Analyzer.

The controls should always be analyzed if an unexpected test result is obtained (see the Alere 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 trouble-shooting” section, page 27–29.
- Do not move the Analyzer when a Test Cartridge is being processed.

When handling the Test Cartridge

- Do not use Test Cartridges after the expiry 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 re-use any part of the Test Cartridge.

Consult the Package Insert that comes with each Alere Afinion™ test kit for assay specific information.

Preparing for an Alere Afinion™ analysis

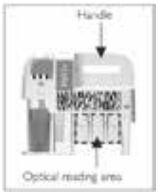
- Allow the Alere Afinion™ Test Cartridges to reach the recommended operating temperature before use.
- Power on your Alere Afinion™ Analyzer so it is ready for the day’s first analysis.
- Enter the operator ID (optional). See procedure on page 22.
- The patient ID, control ID or Alere Afinion™ Control Data can be entered before or during processing of the Test Cartridge in the Analyzer. See procedures on page 21–25.

Consult the Package Insert that comes with each Alere 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 Alere Afinion™ Control Data can be entered.

Collecting a sample

- The patient sample material and control material to be used are specific for each Alere Afinion™ test.
- The length of the capillary in the sampling device, and thereby the sample volume, might also vary for the different Alere 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 Alere Afinion™ test kit for assay specific information.

Examples:

1	2	3
		
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.*	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.*	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.*

Analyzing a patient/control sample

1

Touch to enter the patient sample mode.

Touch to enter the control mode. A “C” in the upper left corner indicates that the Analyzer is in the control mode.

The lid opens automatically.

If the lid is left open from the previous run and “Insert Cartridge” is displayed, this step is omitted and you can start with step 2.

2

Insert the Test Cartridge with the barcode label facing left.

Be sure that the Test Cartridge is correctly placed in the cartridge chamber.

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 Alere Afinion™ Control Data.

Touch to confirm.

Entering the patient ID, control ID or Alere 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 Alere 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 Alere 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 26).
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).

Enter the operator ID by numbers and/or touch ABC to enter letters. If a barcode reader is connected to the Analyzer, a barcoded 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 and after the processing.

1

Touch to enter the patient ID option.

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 ↑.

Enter patient ID by numbers and/or touch ABC 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 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 print outs 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 and after processing. Both letters and numbers can be entered (maximum 16 characters). The control ID will be displayed in the result records and appear on print outs and data transferred to data management systems.

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 ABC 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 “Configuration of QC lockout” page 17).

QC lockout status

The status of the enabled 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/she 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:

1 

Enabled-unlocked

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

2 

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.

3 

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 lock interval and/or unlock expired assays.

4 

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.

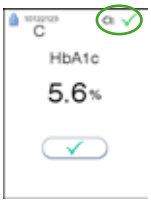
Running controls with enabled QC lockout function

When running controls with the QC lockout function enabled, the Alere Afinion™ Control Data is required to be entered or previously stored in the instrument control lot database (see “QC lockout configuration” page 17).

1) The Alere 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 Alere 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 Alere Afinion™ control database or the Alere 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.

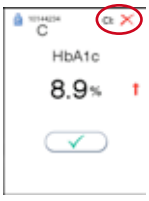


Passed (within the acceptable control range)

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 lock interval is reset according to the QC lockout configuration. The result is stored in the instrument and is sent to the data management system if connected.

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 (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 18).

Patient and control results records

The patient and control results are stored in the memory of the Alere Afinion™ AS100 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 a USB flash (FAT 32 formatted) is inserted into the Alere Afinion™ 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 Alere Afinion™ AS100 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/mo	eAG
2	HbA1c	A50007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130924 08:11	5.2 %		
3	HbA1c	A50007962	10125113	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 08:29	3.1 %		
4	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 08:39	3.3 %		
5	HbA1c	A50007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 09:50	8.2 %		
6	HbA1c	A50007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 10:01	5.1 %		
7	HbA1c	A50007962	10125113	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 11:23	5.3 %		
8	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 12:01	3.8 %		
9	HbA1c	A50007962	10125113	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 13:20	3.3 %		
10	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 13:56	9.2 %		
11	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 14:01	5.1 %		
12	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 14:12	5.2 %		
13	HbA1c	A50007962	10125032	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 15:04	6.1 %		
14	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 15:12	3.3 %		
15	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 15:25	8.2 %		
16	HbA1c	A50007962	10125034	PATIENTID1	PATIENTID2	PATIENTID3	PATIENTID4	OPR0001	20130926 16:20	5.1 %		

Caution

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 Alere Afinion™ AS100 Analyzer refer to specific information 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 re-use 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 Alere Afinion™ supplier (see “Service information” page 29).

⚠ Do not re-use 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 assay specific limitations

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

Information codes caused by sample or Test Cartridge failure

[#]	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.
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.
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 Alere 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 Alere 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.
	Used sampling device belongs to another Alere Afinion™ test	Repeat the test with a new sample and Test Cartridge. Ensure that the sampling device and Test Cartridge have the same label color.
	Label on sampling device not readable (dirty or damaged)	Repeat the test with a new sample and Test Cartridge. Ensure that the label is clean.
208	Test Cartridge previously used	Repeat the test with a new sample and Test Cartridge.
209	Test Cartridge has passed expiration date	Check expiration date on the Cartridge pouch or box. 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 within recommended operating temperature range (see Package Insert for the Alere Afinion™ test in use).
211	Test Cartridge temperature too high	Repeat the test with a new sample and a new Test Cartridge within recommended operating temperature range (see Package Insert for the Alere Afinion™ test in use, section Test procedure).
212	Test Cartridge not recognized by the Analyzer	The software version required for this test is not installed. 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 (Alere Afinion™ HbA1c)	Consult the Alere Afinion™ HbA1c Package Insert. Repeat the test with a new sample and Test Cartridge.
217	Hemolysed blood sample or poor sample quality (Alere Afinion™ HbA1c)	Consult the Alere 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 or messages caused by Analyzer failure

[#]	Cause	Action to take
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 Alere Afinion™ test in use (see Package Insert). The Analyzer temperature is displayed in the Start-Up menu (see page 13). Repeat the test with a new sample and Test Cartridge.
305	- Printer improperly connected - Malfunction of the printer	Power off the Analyzer, reconnect the printer and restart the Analyzer. If the message persists, see the printer User Manual.

[#]	Cause	Action to take
Touch screen error	Touch screen failure/ Touch screen buttons do not respond accurately	Restart instrument and realign screen. If the problem persists, contact your local Alere Afinion™ distributor.
27 **28** **29**	Start-up procedure failed	Contact your local Alere Afinion™ supplier for assistance.
Self-test error. Analyzer in non-operative mode	Analyzer failure	Restart analyzer. If the problem persists, contact your local Alere Afinion™ supplier.

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 instrument is configured to operator ID verified (see page 14 and 15)
402	Cannot delete last supervisor	At least one supervisor is required in the operator list when the instrument is configured to operator ID verified (see page 14 and 15).
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 configured to required the operator ID entered is required to be present in the operator list. Please contact your supervisor.

[#]	Cause	Action to take
501	The control lot has passed expiry date	Check the expiry date on the control lot package insert or kit box. Repeat the test using a sample for a new control lot.
502	Alere Afinion™ Control Data is not recoginzed and is not stored in control lot database	Re-enter the Alere Afinion™ Control Data (see page 17).
503	Control verificaton aborted.	The Alere Afinion™ Control Data entered was not recognized. 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 500 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:
- Alere Afinion™ AS100 Analyzer serial number (SN) – see page 1
- Software version number – see page 1 or start-up menu
- Alere Afinion™ test type
- Test Cartridge lot number – see foil pouch or kit container
- Control name 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 Alere Afinion™ AS100 Analyzer is required other than cleaning the exterior and cartridge chamber.

Cleaning the exterior

Cleaning the exterior of the Alere Afinion™ AS100 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 instrument, first remove as much as possible of the spilled material with a cloth dampened in the disinfectant (2% glutaraldehyde or 0.5% sodium hypochlorite). The surface of the Analyzer should be exposed to the disinfectant for at least 10 minutes.[1]
- 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 Alere Afinion™ AS100 Analyzer 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 or a disinfectant (2% glutaraldehyde or 0.5% sodium hypochlorite). 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 minutes.[1]
- Wipe off any residual liquid from the cartridge chamber using a new, dry Cleaning Swab.
- Close the lid.
- Plug in the power supply and power on 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 Alere Afinion™ supplier.

Software upgrade

Consult the Alere Afinion™ AS100 Analyzer SW Upgrade Package Insert.

[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 Alere Afinion™ AS100 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 Alere Afinion™ AS100 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 Alere Afinion™ AS100 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 Alere Afinion™ AS100 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 Alere Afinion™ AS100 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 Alere Afinion™ AS100 Analyzer, (iv) operating errors or the disregard of warnings and precautions described in this Alere Afinion™ AS100 Analyzer User Manual; (v) repairs performed to the Alere Afinion™ AS100 Analyzer by any person other than an authorized Alere Technologies AS service representative; (vi) use of the Alere Afinion™ AS100 Analyzer in a manner for which it was not designed, (vii) causes external to the Alere Afinion™ AS100 Analyzer such as, but not limited to, power failure or electric power surges, or (viii) use of the Alere Afinion™ AS100 Analyzer in combination with equipment, components or software not supplied by Alere Technologies AS.

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

Alere Afinion™ AS100 Analyzer

Analyzer	
Size	13,4 x 6,7 x 7,4 in. / 340 x 170 x 190 mm
Weight	11 lbs. / 5 kg
Display	Standard LCD color display with back light and integrated touch panel. Resolution: 240 x 320 pixels. Visible area: 2.3 x 3.0 in. / 58 x 77 mm.
Camera	640 x 480 pixels
Capacity of result records	500 patient results and 500 control results
Capacity of operator list	500 operators
Capacity of control lot database	100 control lots
SW update	via USB flash drive
Communication interface	RS 232C, USB 1.1
Power supply	
Power cord adapter	Separate AC to DC power cord adapter. Double insulated.
Input	100-240 VAC, 50/60 Hz, 42 W
Output	24 VDC ± 5%, 1.75A
Output connector	0.2 x 0.1 in. / 5.5 x 2.5 mm plug. Positive (+) on inner pin.
Adapter standards	IEC/EN-60950/UL 1950 (USA and Europe). EN-60601/UL 2601 (Japan). Approved for in vitro diagnostic medical devices.
Operating conditions	
Temperature	15-32ºC (59-89ºF)
Relative humidity	10-90%, non-condensing
Location	Dry, clean, horizontal surface. Avoid direct sunlight.
Test Cartridge temperature	According to specifications for the Alere Afinion™ test in use.
Storage and transport (in the original container)	
Temperature	-40 to 70ºC (-40 to 158ºF)
Relative humidity	10-93% at 40ºC (104ºF)

Additional equipment

For information regarding recommended barcode reader, printer, The Alere Afinion™ AS100 Analyzer Cleaning Kit, USB flash drive or Alere Afinion™ Data Connectivity Converter, 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 Alere Afinion™ AS100 Analyzer are explained below by their function.

Menu	Touch button	Name	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	Configure patient ID function.
		Operator menu	Configure operator function.
		Language	Enter language selection.
		Screen/Beeper volume menu	Configure screen and beeper volume settings (screen contrast, screen adjustment and beeper volume).
		Date/Time menu	Enter date/time settings (date and time).
		QC lockout menu	Configure QC lockout function.
		General settings	Enter the general settings menu.
Patient ID menu		Patient ID disabled	Patient ID disabled.
		Patient ID enabled	Patient ID enabled and required.
Operator 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.
Universial 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 Alere Afinion™ Test Cartridge
		Operator ID enabled with verification	Operator ID is required to be entered to run an Alere Afinion™ Test Cartridge. The operator ID is verified against the instrument operator list.
Screen/Beeper volume menu		Screen contrast	Enter screen contrast setting.
		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.
QC lockout 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 instrument.
Operator list		Operator list export	Export operator list from instrument to USB flash.
		Operator list import	Import operator list from USB flash to instrument.
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 is 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 Alere Afinion™AS100 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.
	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.

The following symbols and abbreviations are used in the product labelling and instructions for the Alere Afinion™ AS100 Analyzer System.

Symbol/Abbreviation	Explanation
CE	Conformity to the European directive 98/79/EC on in vitro diagnostic medical devices
IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog number
LOT	Lot number
SN	Serial number
TEST CARTRIDGE	Test Cartridge
CONTROL C I	Control C I
CONTROL C II	Control C II
CLEANING KIT	Cleaning kit
	Waste Electrical and Electronic Equipment (WEEE)
	Contents sufficient for "Σ" number of tests
	Expiry date (year-month)
	Storage temperature limitations
	Manufacturer
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Operator's handling
	Warnings and precautions
	Consult the Alere Afinion™ user instructions
	Direct current
	USB port
IOIOI	Serial 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

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