

Afinion™ AS100 Analyzer

User Manual

REF 1115175

CE

afinion™
POINT OF CARE CENTER



Dear Customer,

Congratulations on the purchase of your Afinion™ AS100 Analyzer.

Upon arrival of your 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 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*	Afinion™ tests available
Upon receipt			
1. SW upgrade			
2. SW upgrade			
3. SW upgrade			
4. SW upgrade			
5. SW upgrade			

* See display when you switch on the Analyzer (see "Automatic start-up procedure", page 13).

Notes

Technical Support

Call 1-877-4-Afinion or 1-877-423-4646. E-mail: techsupport@us.axis-shield.com

Afinion™ AS100 Analyzer System

Intended use

The Afinion™ AS100 Analyzer System consists of the Afinion™ AS100 Analyzer and the Afinion™ Test Cartridges. The Afinion™ Analyzer System is designed for point-of-care testing and is for *in vitro* diagnostic use only.

CLIA Statements

Waived Afinion™ tests

This User Manual is valid for the Afinion™ tests waived under the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88). A CLIA Certificate is needed to perform testing in a waived setting. If the laboratory modifies the Afinion™ test or Afinion™ AS100 Analyzer 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 IVD directive

The 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

The Afinion™ AS100 Analyzer is tested and conforms to the safety standards IEC/EN 61010-1, IEC/EN 61010-2-081 and IEC/EN 61010-2-101, and to the EMC standard IEC/EN 61326.

Axis-Shield PoC AS

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ISO 9001 and ISO 13485 certified company

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Intended use of the Afinion™ AS100 Analyzer System

Afinion™ AS100 Analyzer System, consisting of the Afinion™ AS100 Analyzer and the Afinion™ Test Cartridges, is for *in vitro* diagnostic use only.

Afinion™ AS100 is a compact multi-assay analyzer for point-of-care testing. It is designed to analyze the Afinion™ Test Cartridges. The Afinion™ Analyzer System is easy to use, rapid and gives reliable and accurate results.

About this User Manual

This User Manual will guide you through installation, operation and maintenance of your 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 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 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 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™ AS100 package unit includes:

- Afinion™ AS100 Analyzer
- Power cable
- Power cord adapter; 24 volt power supply
- Quick Guides for the available 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.

ANALYZER SYSTEM DESCRIPTION

Description of the Afinion™ AS100 Analyzer

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

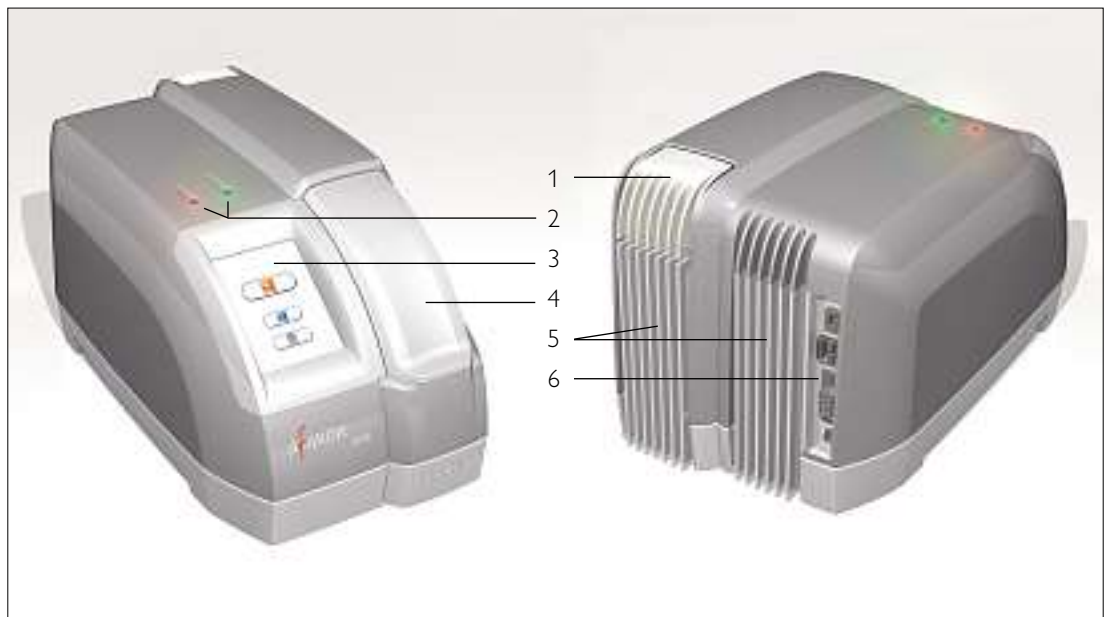


Figure 1

- | | |
|-----------------------|--|
| 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: | For connecting to power cord adapter. Options for printer, barcode reader and/or PC connections. |



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 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 Afinion™ Test Cartridge with its functional parts:

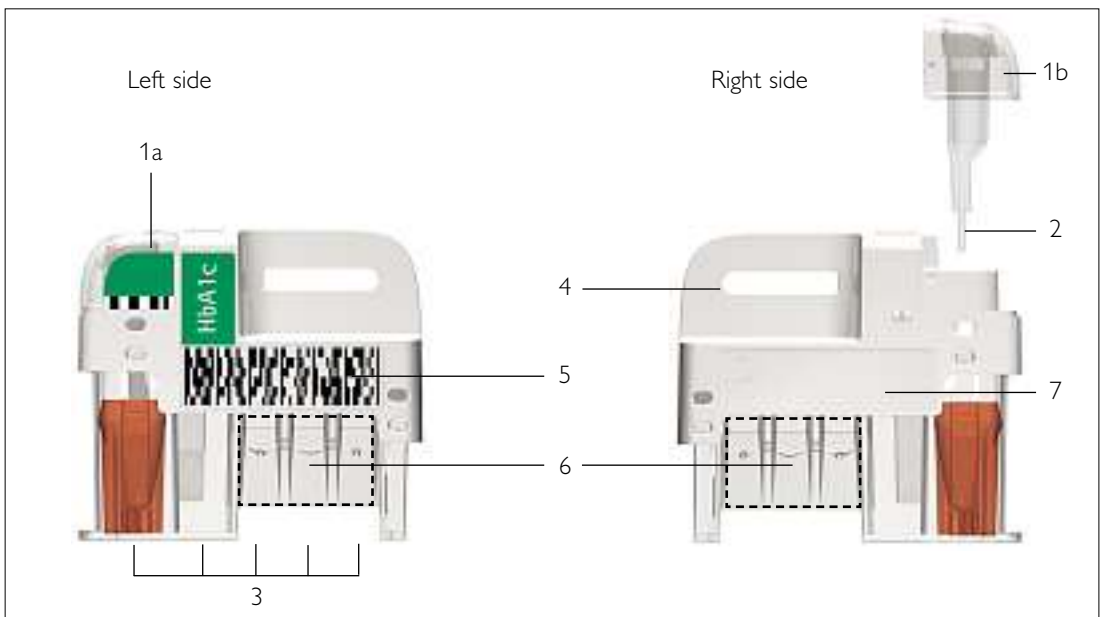


Figure 2

- | | |
|-------------------------|--|
| 1 Sampling device: | For collection of patient sample or control.
1a - closed position
1b - lifted position |
| 2 Capillary: | Glass 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. |

ANALYZER SYSTEM DESCRIPTION

How to operate the Analyzer

The Afinion™ AS100 Analyzer has two main user interfaces, the touch screen and the cartridge chamber. The Analyzer is easily operated using the icons that appear on the screen. Only the icons you need to use at each operative step are displayed. When an icon is touched, it will turn grey and its function will be activated. Text messages that appear on the screen will help guide you through the testing procedure. The functions of the icons are explained in the “Gallery of icons”, page 10.

The other main operative part of the 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 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 3

- 1 Text message
- 2 Icons
- 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 free and ready for use. A flashing green light indicates completion of an analysis.

Sound signals

A short beep indicates completion of an analysis. Two beeps indicate an information or error message.

How the Afinion™ AS100 Analyzer System works

The 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, which then initiates the processing of the Test Cartridge. The sample and reagents are automatically transferred between the wells. A monochrome solid-state camera monitors the entire process. When the assay is completed, light-emitting diodes (LEDs) illuminate the final 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 29). If the Analyzer is unable to use the display, only the red LED will be flashing.

When the Analyzer is switched on for a longer period, it will automatically restart once a day to ensure that a self-test is done regularly. This procedure will not interrupt any Test Cartridge measurements.

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. If defects are detected (e.g. broken capillary, the cartridge is used past its expiration 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.

Calibration

The 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. 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 results. Calibration by the operator is thus not required.

The icons and their function

Touching an icon on the screen will activate the function of this icon. All the icons that may appear during operation of the Afinion™ AS100 Analyzer are explained below by their function.


















Icon	Name	Function
	Patient sample mode	Select patient sample mode.
	Control mode	Select control mode.
	Patient ID	Enter patient ID.
	Control ID	Enter control ID.
	Patient records	View patient result records.
	Control records	View control result records.
	Main menu	Enter main menu (operator ID, patient records, control records and configuration menu).
	Operator ID	Enter operator ID.
	Settings	Enter configuration menu (language, patient ID on/off, date/time and screen/beeper).
	Language	Enter language selection.
	Patient ID on/off	Enable/disable patient ID function.
	Date/Time	Enter date/time settings (date and time).
	Exit	Exit current menu and return to previous screen view.
	Date	Enter date setting.
	Time	Enter time setting.
	Screen/Beeper	Enter screen and beeper settings (screen contrast, screen adjustment and beeper volume).
	Screen contrast	Enter screen contrast setting.
	Screen alignment	Enter screen alignment function.
	Beeper volume	Enter beeper volume setting.
	Accept	Accept (a setting or a test result).
	Print	Print result on connected printer.
	ON	Disable patient ID function (turns OFF when touched).
	OFF	Enable patient ID function (turns ON when touched).

Table continued on next page.

Icon	Name	Function
	Enter	Enter and return to previous view.
	Backspace	Delete previous character.
	Increase	Increase contrast/volume.
	Decrease	Decrease contrast/volume.
	Scroll up	View next result in the patient or control records.
	Scroll down	View previous result in the patient or control records.


Other symbols and signs

Other symbols, signs and abbreviations that may appear during operation of the Afinion™ AS100 Analyzer are explained below. These symbols or signs are only informative and cannot be activated like the icons.

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 specific information or an error message (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.
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 24:00h.
LOT#	Lot number	Abbreviation used in the patient and control records for the lot number of the Test Cartridge.

GETTING STARTED

Locating your Analyzer

 Place your 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) 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 (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 4) 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 34.

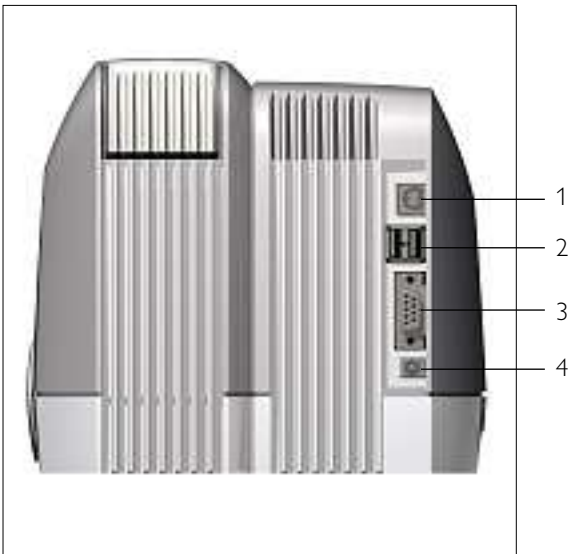


Figure 4

- 1 Not in use
- 2 USB-A connectors for printer and/or barcode reader
- 3 RS-232 port for PC
- 4 Power input for power supply connection

Connecting additional equipment

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

- External barcode reader – for reading barcoded sample or operator identification.
- Printer – for optional print out of test results.
- PC – for data transfer to HIS or LIS systems.

For additional information regarding the recommended barcode reader, printer, and PC connection please call 1-877-4-Afinion (1-877-423-4646) or email techsupport@us.axis-shield.com. See figure 4 for correct connection of the external equipment.



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

How to switch ON the Analyzer



Switch 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.

Automatic start-up procedure



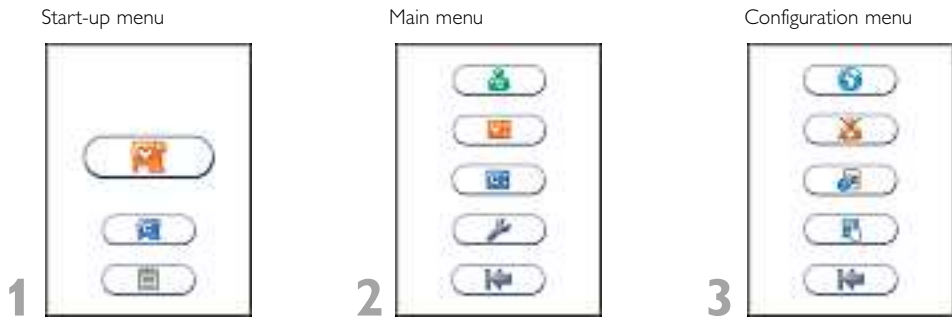
The automatic start-up procedure will be initiated shortly after the Analyzer has been switched on. The Analyzer's software version (X.XX) will appear in the upper left corner of the screen and a self-test will run for approximately 4 minutes. The red light on the top of the Analyzer will turn on, indicating 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.

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 29.

Setting the configuration

Before using your Afinion™ AS100 Analyzer you should set the configuration according to your needs. To enter the configuration menu, do the following:

Entering configuration menu



Touch  to enter main menu.

Touch  to enter configuration menu.

Select an item for configuration (see following pages).

The following items can be set from the configuration menu:

- Language
- Patient ID on/off
- Date and time
- Screen contrast, screen alignment and beeper volume

To set these items, please comply with the following instructions.


Choosing language

The default setting by the manufacturer is English. Other languages are available.



Touch  to enter language selection.

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

Touch  to accept and return to the configuration menu.

Disabling or enabling patient ID function

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 (ON), the patient ID must be entered for each Test Cartridge to be analyzed.

If the patient ID function is disabled (OFF), a run number will automatically replace the patient ID and be displayed in the upper left corner of the screen. This numbering is reset every 24hrs; each day at 00:00h.

Disabling the patient ID function:

Configuration menu

- 1 Touch to enter patient ID on/off option.
- 2 Touch to disable the patient ID function.
- 3 Touch to accept and return to the configuration menu.

Enabling the patient ID function:

Configuration menu

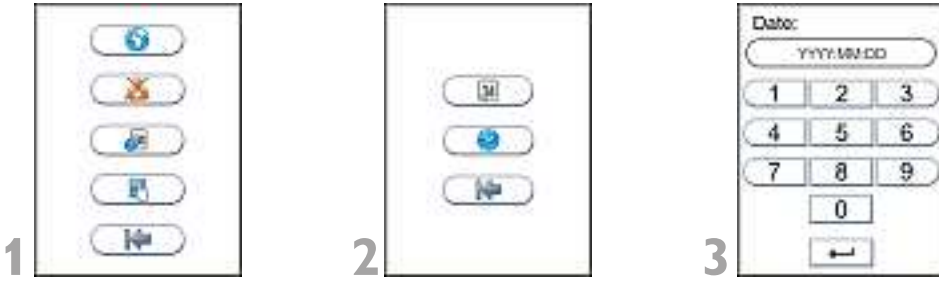
- 1 Touch to enter patient ID on/off option.
- 2 Touch to enable the patient ID function.
- 3 Touch to accept and return to the configuration menu.

GETTING STARTED

Setting date


The correct date should always be set because the date and time for the analysis 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).

Configuration menu



Touch  to enter date/time settings.

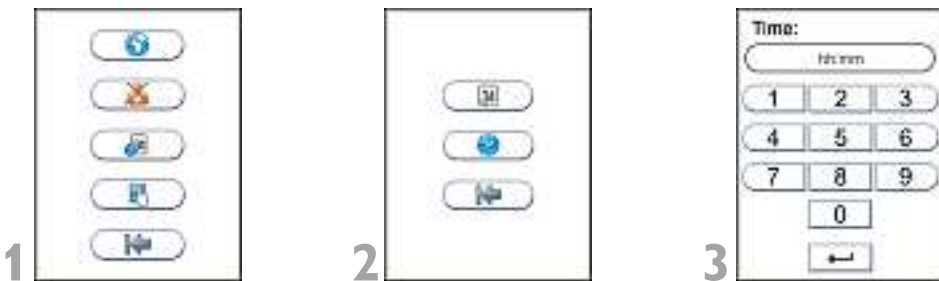
Touch  to enter date setting.

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

Setting time


The correct time should always be set because the date and time for the analysis are stored and displayed in the patient and control records. The time format is hh:mm, where hh is the hour from 00 to 23 and mm is minutes from 00 to 59.

Configuration menu



Touch  to enter date/time settings.

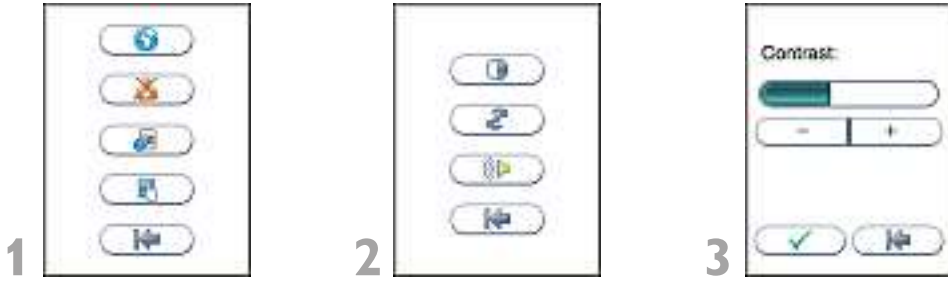
Touch  to enter time setting.

Enter time.
Touch  to confirm and return to previous view.

Adjusting screen contrast

The screen contrast can be adjusted.

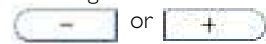
Configuration menu




Touch  to enter screen/beeper settings.

Touch  to enter screen contrast setting.

Adjust screen contrast by touching

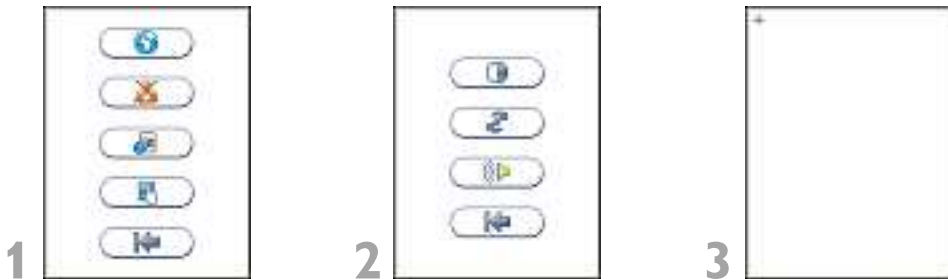


Touch  to accept and return to previous view.

Aligning screen

The screen must be realigned if the buttons do not respond accurately when touched. It is not necessary to align screen as a part of the initial configuration.

Configuration menu



Touch  to enter screen/beeper settings.

Touch  to enter screen alignment function.

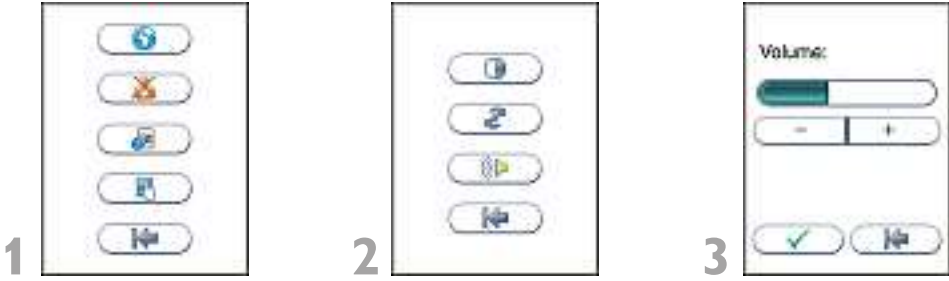
Tap the cross-hair object (+) in the upper left corner using a blunt pencil to be precise. Repeat for the object appearing in the lower right corner and in the center of the screen. The previous screen view will automatically return.

GETTING STARTED

Adjusting beeper volume

One beep means that the test is completed and result displayed. Two beeps means that an information or error code is displayed. The beeper volume can be adjusted. If adjusted to a minimum, no beep will be heard.

Configuration menu




Touch  to enter screen/beeper settings.

Touch  to enter beeper volume setting.

Adjust beeper volume by touching



Touch  to accept and return to previous view.

How to switch OFF the Analyzer

Switch off the Analyzer by pressing the ON/OFF button (Figure 1). The Analyzer should be switched 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 until the Analyzer shuts down. The Analyzer can be switched off, or the power supply disconnected, without loss of stored results.
- The Analyzer can only be switched 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.

Why quality control testing?

Quality control testing should be done to confirm that your 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 Axis-Shield should be used for quality control of your the Afinion™ AS100 Analyzer System. These control kits contain control materials with established acceptable ranges for the 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 20-28.

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 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 customer service representative (1-877-4-Afinion or 1-877-423-4646) for advice before analyzing patient samples.

Frequency of control testing

Controls should be analyzed:

- With each new shipment of Afinion™ test kits.
- With each new lot of 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 Afinion™ AS100 Analyzer.
- Anytime an unexpected test result is obtained.
- After software upgrade of the Afinion™ AS100 Analyzer.

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 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 29.
- Do not move the Analyzer when a Test Cartridge is being processed.
- Do not turn the Analyzer upside down 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 have not been stored in accordance with the recommendations.
- 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 bio-hazardous materials. Use personal protective equipment.
- Do not re-use any part of the Test Cartridge.

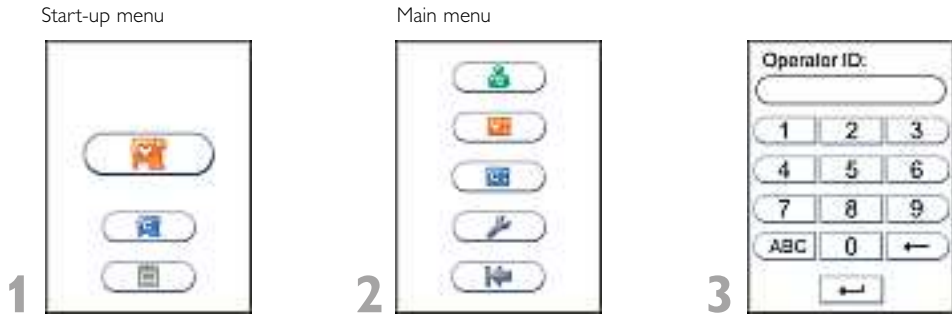



Consult the Package Insert that comes with each Afinion™ test kit for assay specific information.

Using the operator ID function

Entering operator ID (optional)


If required the operator's identification (ID) can be entered before processing an Afinion™ Test Cartridge. Both letters and numbers can be entered (maximum 16 characters). The operator ID will be stored and displayed in the lower left corner of the screen. The entered operator ID will be memorized and displayed in the patient and control records. The entered operator ID remains in use by the Analyzer until this ID is deleted, a new ID is entered or the Analyzer is switched off.



Touch  to enter the main menu.

Touch  to enter the operator ID option.

Enter operator ID by numbers and/or touch  to enter letters.

Touch  to confirm and return to previous view.

If a barcode reader is connected to the Analyzer, then this can be used to scan a bar-coded operator ID.

Using the patient ID function

The patient ID function is ON 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 "Setting the configuration", page 14).



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. Both letters and numbers can be entered (maximum 16 characters). The patient ID will be stored in the memory and displayed along with the other specific data for this run (see "Viewing result records", page 28).

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



Touch  to enter the patient ID option.

Enter patient ID by numbers and/or touch  to enter letters.
Touch  to confirm and return to previous view.

The entered patient ID will appear on the screen. The patient ID icon will remain in view to allow corrections to be made.

If a barcode reader is connected to the Analyzer, then this can be used to scan a bar-coded patient ID.

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 (see "Viewing result records", page 28).

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



Touch  to enter the control ID option.

Enter control ID by numbers and/or press  to enter letters.

Touch  to confirm and return to previous view.

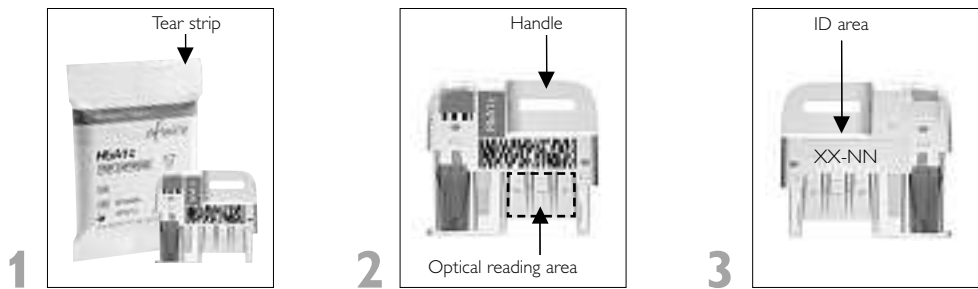
The entered control ID will appear on the screen. The control ID icon will remain in view to allow corrections to be made.

Preparing for an Afinion™ analysis

- ☞
 - Allow the Afinion™ Test Cartridges to reach recommended operating temperature before use.
- ☞
 - Switch on your Afinion™ Analyzer so it is ready for the day's first analysis.
- ☞
 - Enter operator ID (optional). See procedure on page 21.
- ☞
 - The patient ID or control ID can be entered before or during processing of the Test Cartridge in the Analyzer. See procedures on page 22 and 23.



Consult the Afinion™ test Package Insert or Quick Guide for assay specific information.



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.

Once opened, the Test Cartridge has limited stability.

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.

Mark the Test Cartridge with the patient or control ID. Use the ID area on the opposite side of 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.

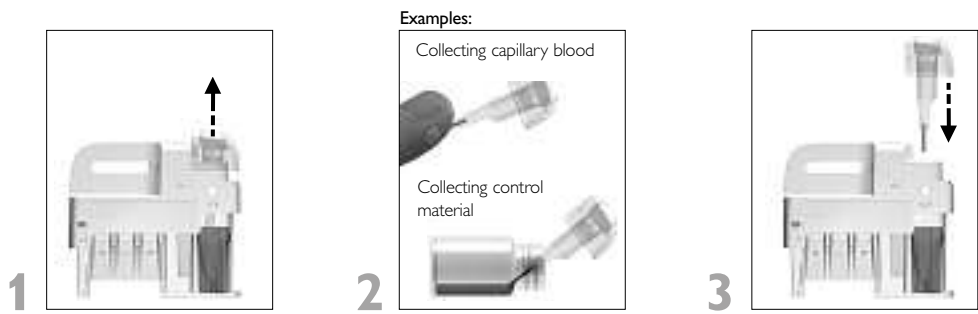
Collecting a specimen with the Test Cartridge



- 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 analyzing the Test Cartridge should 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 Afinion™ test Package Insert or Quick Guide for assay specific information.



Remove the sampling device from the Test Cartridge.

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

Immediately and carefully replace the sampling device into the Test Cartridge.

Use the handle to keep the Test Cartridge steady against the table and pull the sampling device straight up.

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


The time from filling the capillary until analyzing the Test Cartridge should be as short as possible.

Analyzing a patient sample



1



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

If the lid is left open from 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 patient ID. Touch  to confirm.

Entering the patient ID will not interrupt the processing. See detailed procedure on page 22.



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 patient 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 Afinion™ test Package Insert or Quick Guide for assay specific information.

Analyzing a control



1





2



3



Touch  to enter control mode. The lid opens automatically.

If the lid is left open from previous run and "Insert Cartridge" is displayed, touch  then proceed with step 2.

Insert the Test Cartridge with the barcode label facing left.

A "C" in the upper left corner indicates that the Analyzer is in the control mode.

Close the lid manually. The Analyzer will start processing the Cartridge.

The processing time depends on the test in use.



4



5





6



Touch  and enter control ID. Touch  to confirm.

Entering the control ID will not interrupt the processing. See detailed procedure on page 23.

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 control records.

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 Afinion™ test Package Insert for control and assay specific information.

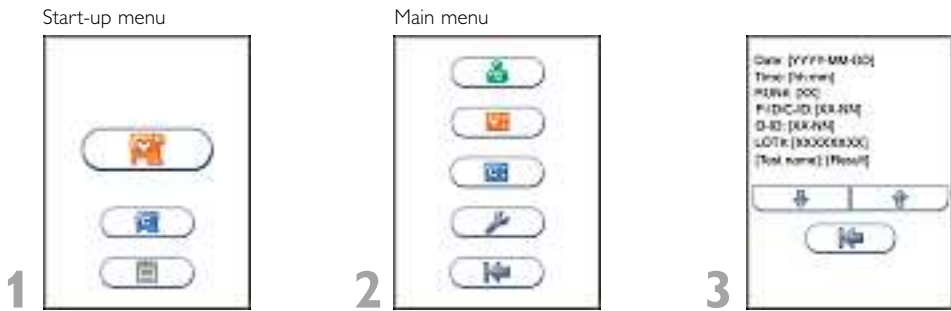
Viewing result records

The patient and control results are stored in the memory of the 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 numbers of Test Cartridge and Test Result.

If a printer is connected, the test results can be printed one by one.

Viewing patient results

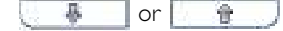


Touch to enter main menu.

Touch to enter patient records.

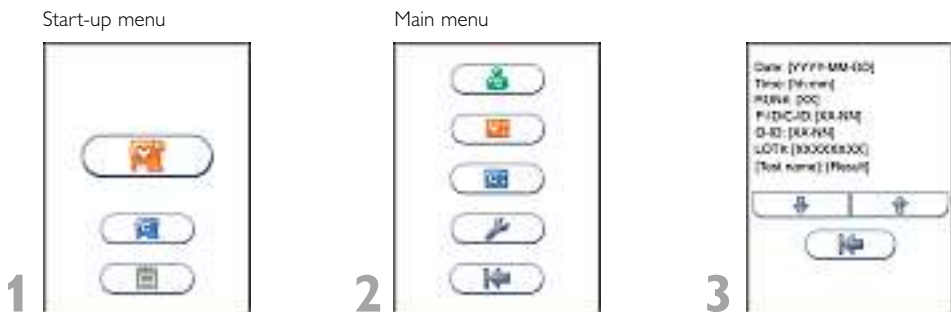
The last patient result is displayed.

To view more results touch



If a printer is connected, touch to print the result.

Viewing control results



Touch to enter main menu.

Touch to enter control records.

The last control result is displayed.

To view more results touch




If a printer is connected, touch to print the result.

When an information code appears

Information codes that might appear during use of the Afinion™ AS100 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 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 Afinion™ supplier (see “Service information” page 31).



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 messages caused by assay specific limitations

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

INFORMATION CODES AND TROUBLESHOOTING

Error messages 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 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 (Afinion™ HbA1c)	Consult the Afinion™ HbA1c 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 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 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 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.

INFORMATION CODES AND TROUBLESHOOTING

[#]	Cause	Action to take
213 214 215	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.
216	Controls are not run after the software upgrade of the Analyzer	Run one Afinion™ Control following the procedure on page 27 "Analyzing a control".

Error 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	Wait until the Analyzer has cooled down. Ensure that the operating temperature is within recommended range (15-32°C, 59-89°F). 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 (15-32°C, 59-89°F). Repeat the test with a new sample and Test Cartridge.
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.
ERROR	Touch screen failure	Restart the Analyzer.
27 28 29	Start-up procedure failed	Contact your local supplier for assistance.
Self-test error. Analyzer in non-operative mode	Severe instrument failure	Contact your local supplier for assistance.

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.

Call 1-877-4-Afinion or 1-877-423-4646.

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

E-mail: techsupport@us.axis-shield.com

Before asking for assistance, please record the following information:

- Afinion™ AS100 Analyzer serial number (SN) – see page 1
- Software version number – see page 1
- 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 and error messages

MAINTENANCE AND WARRANTY

Cleaning and maintenance

No maintenance of the Afinion™ AS100 Analyzer is required other than cleaning the exterior and cartridge chamber.

Cleaning the exterior

Cleaning the exterior of the Afinion™ AS100 Analyzer should be performed whenever necessary. Most spills and stains can be removed with water or a mild detergent.



- Switch 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 switch on the Analyzer.




- The Analyzer must be switched 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 Afinion™ AS100 Analyzer Cleaning Kit (REF1115269) 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 switch 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.

¹Clinical 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

Disposal of the Analyzer



For correct disposal according to the Directive 2002/96/EC (WEEE), contact your local Afinion™ supplier.

Software upgrade



Consult the Afinion™ AS100 Analyzer SW Upgrade Package Insert.

Warranty

Axis-Shield warrants solely to the Buyer that the 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 Axis-Shield's specifications for a period of twelve months from the date of delivery.

At its expense, Axis-Shield agrees to repair, or at Axis-Shield's option, replace with a new or reconditioned unit, any Afinion™ AS100 Analyzer which is under warranty and not performing substantially in accordance with applicable product specifications, provided that the Buyer has given Axis-Shield notification of such warranty claim within the warranty period. If Axis-Shield is unable after reasonable efforts to repair or replace the 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 Afinion™ AS100 Analyzer. All repairs will be done during normal working hours. All replaced parts shall become Axis-Shield's property. Axis-Shield may require the Buyer to ship the Afinion™ AS100 Analyzer to Axis-Shield or elsewhere at Axis-Shield's expense, for warranty service to be performed.

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

EXCEPT AS STATED IN THIS SECTION OF THE USER MANUAL, AXIS-SHIELD DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO THE AFINION™ AS100 ANALYZER, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. AXIS-SHIELD'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE AFINION™ AS100 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™ AS100 ANALYZER. IN NO EVENT SHALL AXIS-SHIELD 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™ AS100 ANALYZER. THIS WARRANTY MAY NOT BE TRANSFERRED BY THE BUYER.

The acknowledgement of claims shall be reported to your Axis-Shield Technical Care Specialist at 1-877-4-Afinion or 1-877-423-4646 or by E-mail to techsupport@us.axis-shield.com

TECHNICAL SPECIFICATIONS

Afinion™ AS100 Analyzer






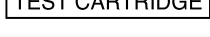
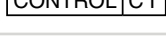
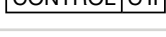
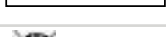










Analyzer	
Size	12.6 x 6.7 x 6.7 in. / 320 x 170 x 170 mm
Weight	11 lbs. / 5 kg
Display	Standard LCD color display with back light and integrated touch panel. Resolution: 240 x 320 pixels. Visible area: 2.3 x 3.0 in. / 58 x 77 mm.
Camera	640 x 480 pixels
Capacity of result records	500 patient results and 500 control results
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 <i>in vitro</i> diagnostic medical devices.
Operating conditions	
Temperature	15-32°C (59-89°F)
Relative humidity	10-90%, non-condensing
Location	Dry, clean, horizontal surface. Avoid direct sunlight.
Test Cartridge temperature	According to specifications for the Afinion™ test 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 (104°F)

Accessories

For information regarding recommended barcode reader and printer please call 1-877-4-Afinion (1-877-423-4646) or email techsupport@us.axis-shield.com.

SYMBOLS AND ABBREVIATIONS

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

Symbol/Abbreviation	Explanation
	Conformity to the European directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
	<i>In Vitro</i> Diagnostic Medical Device
	Catalog number
	Lot number
	Serial number
	Test Cartridge
	Control C I
	Control C II
	Cleaning kit
	Waste Electrical and Electronical Equipment (WEEE)
	Contents are sufficient for one test
	Contents are sufficient for 15 tests
	Expiration date (year-month)
	Storage temperature limitations
	Manufacturer
	Operator's handling
	Warnings and precautions
	Biological risk
	Consult the Afinion™ user instructions
CLIA	Clinical Laboratory Improvement Amendment of 1988
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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ISO 9001 and ISO 13485 certified company