

Abionic SA
EPFL Innovation Park B
CH-1015 Lausanne
SWITZERLAND

info@abionic.com
<http://www.abionic.com>

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USER MANUAL

abioSCOPE

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Print History

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EU 1.0	April 2015	New document

Warranty

The information contained in this document is subject to change without notice.

Abionic makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Abionic shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

This product may contain remanufactured parts equivalent to new in performance or parts that have had incidental use.

Warnings

The abioSCOPE uses laser components. The device casing must not be opened except by the manufacturer or an authorised specialist. Unauthorised opening of the casing and breaking of the security seal will render the guarantee invalid with immediate effect.

Electrical Shock Hazard



Do not remove system covers. To avoid electrical shock, use only supplied mains cord set and power leads and connect only to properly earthed main power outlets.

Explosion Hazard



Do not operate the system in the presence of flammable substances or anaesthetics.

Radio Frequency Communications Equipment Hazard



The use of portable and mobile RF communications equipment in close proximity can affect the operation of medical equipment.

CE marking

This system fulfils the essential requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices as per Annex I with the conformity assessment route described in Annex III.

This Manual

This document provides the information needed to setup and operate the abioSCOPE product from Abionic SA.

Intended Audience

This abioSCOPE User Manual is intended to assist physicians, medical staff and biomedical engineers who may operate the abioSCOPE system.

If You Need Assistance

If you have questions regarding either the use of the abioSCOPE or the information contained in the accompanying documentation, please contact Abionic SA Customer Support at service@abionic.com.

On no account should the user attempt to open the device casing. The abioSCOPE uses laser components. The device casing must not be opened except by the manufacturer or an authorised specialist. Unauthorised opening of the casing and breaking of the security seal will render the guarantee invalid with immediate effect.

Safety symbols

Symbol	Description	Explanation
	Note	A NOTE provides additional or special information to assist operation. Disregarding a NOTE may cause inconvenience but will not result in personal injury or damage to equipment.
	Protective gloves	Always wear protective gloves when handling components of the abioSCOPE or abioKIT- α , because of biological risk.
	Laser beam	The abioSCOPE is fitted with a class 1 laser which has the risk of causing permanent eye injury. Never open the housing to look into the laser.
	Biological hazard	Indicates the presence of hazardous substances that may be infectious. The test is performed with human whole blood, plasma or serum which may carry a risk of transmitting infectious agents.
	Warning	A WARNING is provided in a procedure whenever electrical or mechanical damage may occur. Failure to heed a WARNING may result in some form of damage to the equipment or personal injury.

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1 Introduction

Intended use

The abioSCOPE is a biomedical device that measures specific Immunoglobulin-E (IgE) levels in blood and provides a support for clinical diagnosis of IgE-mediated allergic disorders. abioSCOPE *in vitro* tests (abioKIT- α) are designed to deliver quantitative information about patients' allergen sensitization at the point-of-care.

Protective gloves



Always wear protective gloves when performing tests with the abioSCOPE.

Warning



The abioSCOPE is intended to provide information to medical doctors who are wholly responsible for the interpretation of the test results and for their subsequent decisions.

abioSCOPE Warranty

The abioSCOPE uses laser and high voltage components. The device casing must not be opened except by the manufacturer or an authorised specialist. Unauthorised opening of the casing and breaking of the security seal will render the guarantee invalid with immediate effect.

abioSCOPE features

- Measurement of specific IgE concentrations displayed on a high-resolution touchscreen;
- Allergy test reports are saved on an SD-card in a format that can be opened with any Internet browser.

abioSCOPE cleaning

abioSCOPE cleaning consists in periodically disinfecting the abioSCOPE tray and the abioDISC surfaces with isopropyl alcohol.

There is no obligation to disinfect the other parts of the system. However, in order to ensure the correct functionality of the touchscreen, it is recommended to clean and disinfect the abioSCOPE surfaces regularly with a standard disinfectant.

Warning



Do not steam sterilize or steam clean as this will damage the device which is not resistant to moisture or heat.

International conformity

The abioSCOPE complies with the following standards and harmonized documents:

- IEC 61010-1:2001, Safety requirements for electrical equipment IVD;
- IEC 61010-2-101, Safety requirements: particular requirements for in vitro diagnostic (IVD) medical equipment;
- IEC 60825-1:2014, Safety of laser products;
- EN 61326-1:2013, Electrical equipment for measurement, control and laboratory use – EMC requirements;
- IEC 61326-1:2012, Electrical equipment for measurement, control and laboratory use – EMC requirements;
- EN 61326-2-6:2013, EMC requirements: particular requirements - In vitro diagnostic (IVD) medical equipment;
- IEC 61326-2-6:2012, EMC requirements: particular requirements - In vitro diagnostic (IVD) medical equipment;
- EN 301 489-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;
- EN 301 489-3, Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;
- IEC 62304:2006, Medical device software – software life cycle processes;
- ISO 15223-1:2012, Symbols for use in the labeling of medical devices;
- EN 1041:2008, Information supplied by the manufacturer of medical devices.

The product also complies with the EEC directive 98/79/EC (in vitro diagnostic medical devices

October 27th, 1998) and has received the CE-Marking 

The product has been developed, produced and tested within a Quality Management System according to ISO 9001:2008 and ISO 13485:2003 and annex II section 3 of directive 93/42/EEC.

The medical device is classified as active diagnostic device in class I according to the annex IX and fulfils the essential requirements according to annex I of directive 93/42/EEC.

Operating conditions

Main power supply: 110-240V, 50-60 Hz

Current rating: 1.7A

Operating temperature: 18°C – 25°C / Relative humidity: 20% – 80%

Warning	
	To avoid the risk of electric shock, this equipment must only be connected to a mains electricity supply fitted with a protective earth. Only use the provided power supply (100-240 VAC @50Hz).

Laser information

The laser is located inside the abioSCOPE and the beam is not accessible from outside. As the beam used inside the abioSCOPE is harmful to eyes, do not attempt to open or disassemble the housing.

Refer servicing of the abioSCOPE to qualified personnel only.

The abioSCOPE integrates two Class 3B lasers, which emit laser radiation in the red. Internal laser radiation: Wave lengths 635nm and 780nm, Output power < 35mW, Class 3B. The abioSCOPE should not be opened under any circumstances.

Laser beam	
	Do not use the abioSCOPE without the device housing due to harmful light intensity causing permanent eye injury.

The following label is located on the abioSCOPE housing:

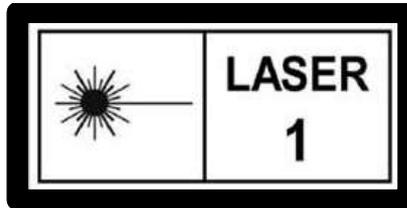


Figure 1.1: abioSCOPE laser class 1 warning label

The following label is located inside the abioSCOPE:

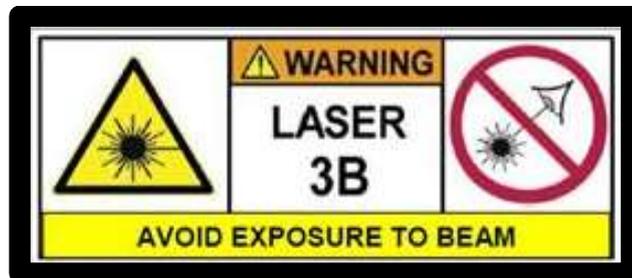
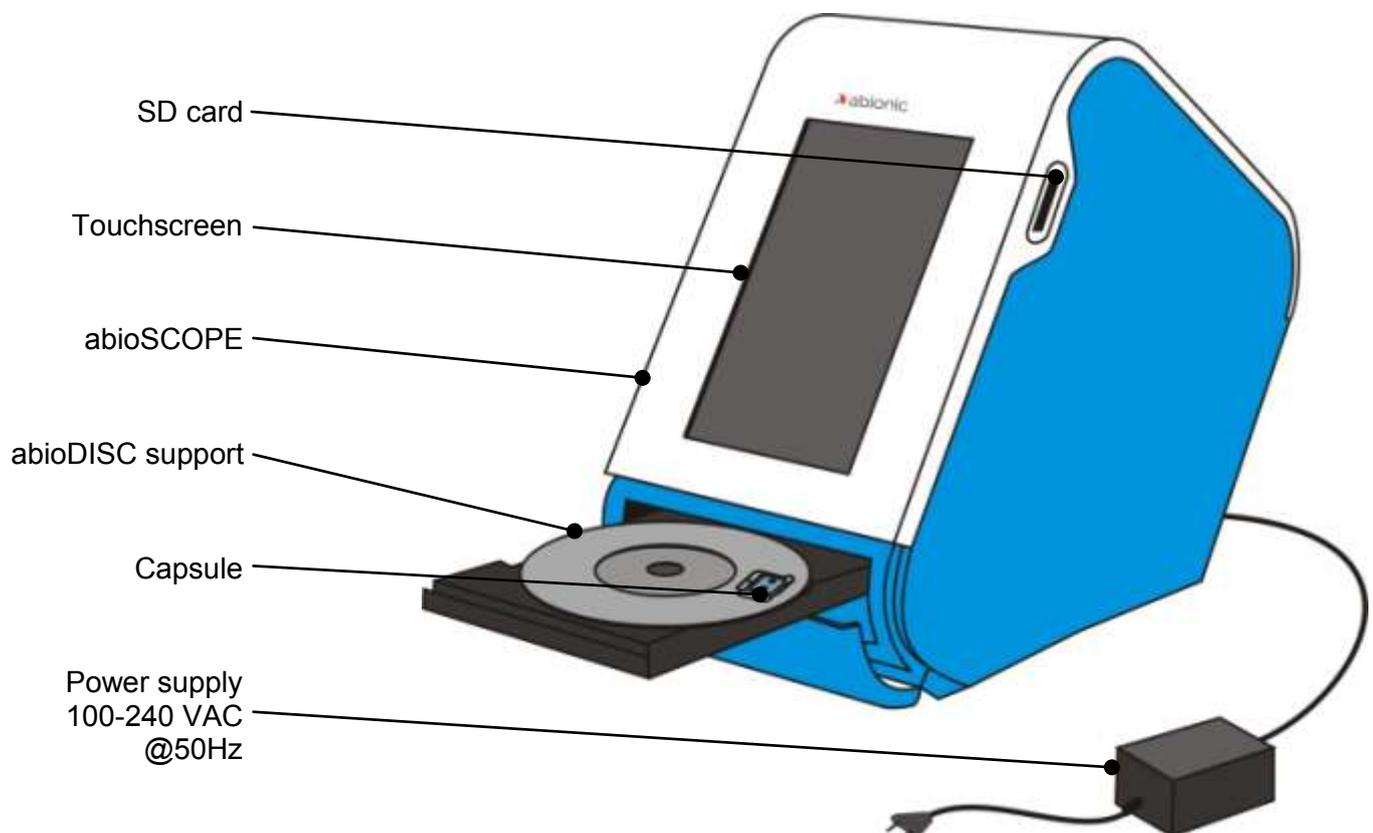


Figure 1.2: abioSCOPE laser class 3B warning label

2 System Components

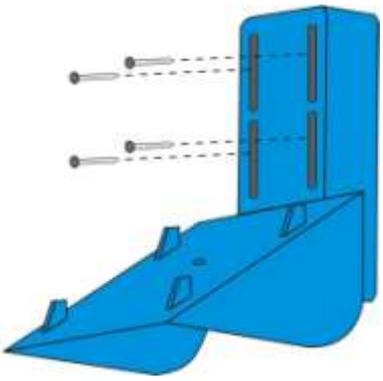
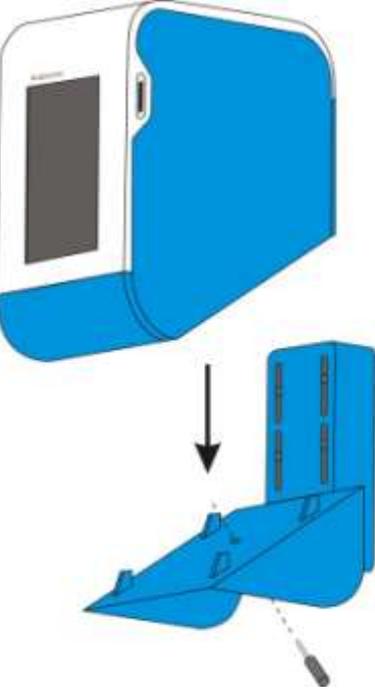
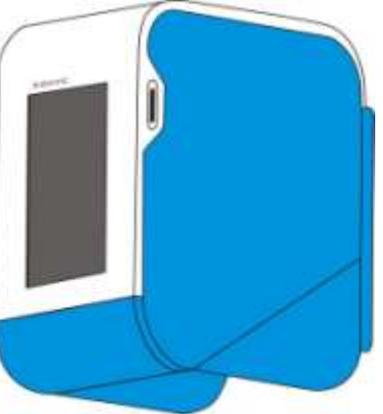
About the System's Components

The abioSCOPE is a biomedical device that provides rapid low-cost allergy diagnosis. abioSCOPE tests are designed to be complementary to skin tests and to offer quantitative *in vitro* allergy analysis at the point-of-care. Abionic technology is user-friendly (users do not need special training) and the device provides to the user a support for clinical diagnosis of IgE-mediated allergic disorders thanks to a clear concise result for up to 10 different allergens per capsule within 20 minutes. Operating the abioSCOPE is straightforward. The patient's blood sample is mixed with a proprietary reagent abioMIX and placed into a special test capsule that contains biosensors capable of quantifying IgE levels. The capsule is placed into an abioDISC mounting plate that is then inserted into the abioSCOPE, in the same way that a DVD is inserted into a player. The results are then presented on a touch screen and saved onto a SD card provided by Abionic which can be read by all standard SD card readers.



Optional: wall support installation

The abioSCOPE may be placed on wall using its dedicated wall support. The following instructions indicate how to mount it properly.

<p>1</p>  <p>Using the screws provided within the kit, fix the support at appropriated height on a wall.</p>	<p>2</p>  <p>Dispose the abioSCOPE reader on the support and immediately fix the reader on its support with the plastic head screw.</p>	<p>3</p>  <p>Connect the wall support power supply to an AC source between 100 and 240V.</p>
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Warning

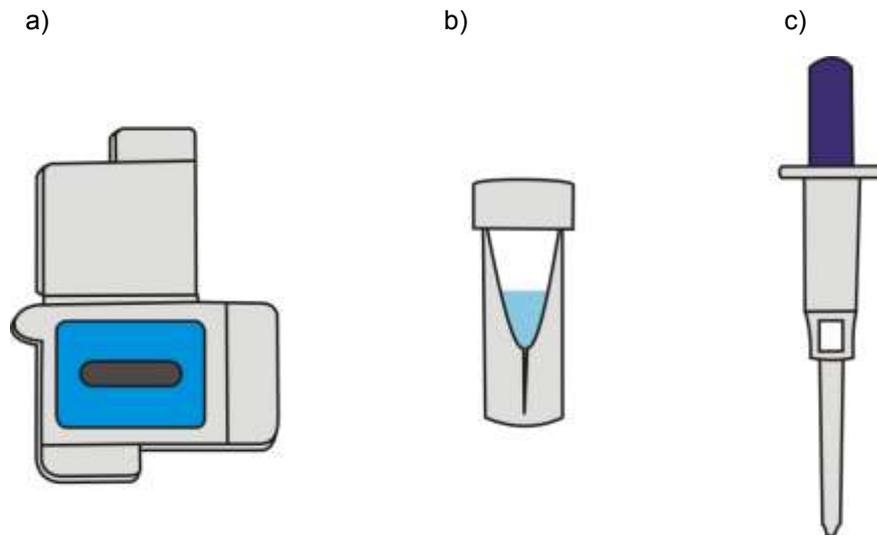


Use only original parts and consumable from Abionic or its agent.

Total & specific IgE diagnostic kit (abioKIT- α) content

Each kit is composed of:

- 1x capsule (a)
- 1x phial of abioMIX reagent (b)
- 1x Point-of-Care (POC) blood collector (c)
- 1x test notice (not depicted)



Warning



Do not use any of the elements for any other purposes than with the abioSCOPE.

Locating the abioSCOPE Serial Number

The system serial number is printed on a label at the bottom side of the device. Unauthorised removal of the label will invalidate your warranty.

Turning on your abioSCOPE

Before starting the abioSCOPE, make sure that the system is properly connected to its dedicated power supply, and that this is properly connected to an AC source between 100 and 240V. The power supply connection is situated on the rear side of the abioSCOPE. Keep the alimentation cable accessible in order to be able to disconnect the abioSCOPE. Also verify that a SD card is correctly inserted into its dedicated slot (situated at the top right side of the abioSCOPE, next to the touchscreen).

To turn the abioSCOPE on or off, use the On/Off switch situated on the rear side of the system.

Restarting the abioSCOPE

In the unlikely event that your system becomes “frozen” or is not working properly, use the following procedure to restart the abioSCOPE:

- Turn the abioSCOPE off by pressing the On/Off button.
- Wait at least 10 seconds.
- Turn the abioSCOPE on by pressing the On/Off button.

3 Instruction of Use

Principle of detection

The principle underlying the abioSCOPE allergy detection system is the biomolecular interaction that occurs in the nanofluidic biosensors contained in the capsules.

The patient's serum or blood sample containing immunoglobulin E (IgE) is diluted with a solution composed of fluorescently labeled biomolecules (anti-IgE).

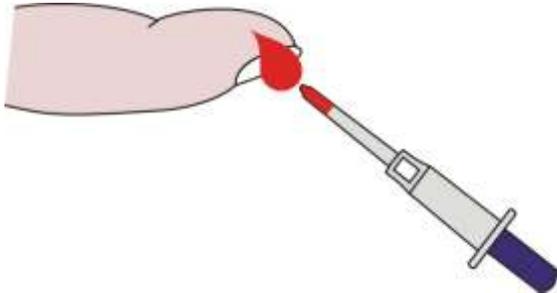
The sample is deposited into a capsule where it fills the biosensors inside through capillary action. Within the biosensors the biomolecules diffuse, interact and form fluorescent molecular complexes.

The immobilized fluorescent complexes are then optically measured by the abioSCOPE reading unit containing a miniaturized fluorescent microscope. The amplitude of the detected fluorescent signal quantifies the patient specific IgE levels, and thus the patient's allergic sensitization. Due to the innovative technology that comprises the nanofluidic biosensor, washing and cleaning steps are eliminated and incubation times greatly decreased.

Pre-analysis procedure

The following procedure describes the abioKIT- α preparation.

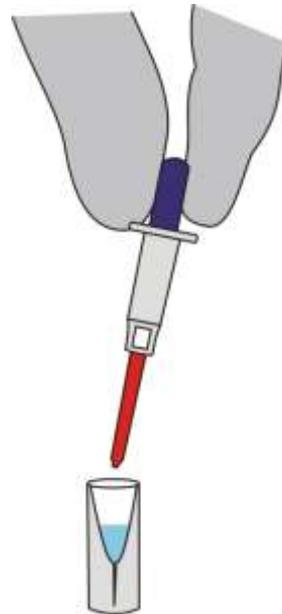
1



Using the provided POC blood collector, take 50 μ l of capillary blood from the patient (if specified “whole blood” on the abioKIT- α package).

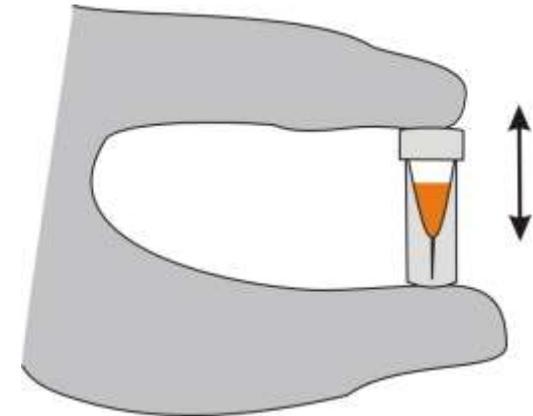
Alternatively, it can also be taken 50 μ l of serum or plasma from the patient.

2



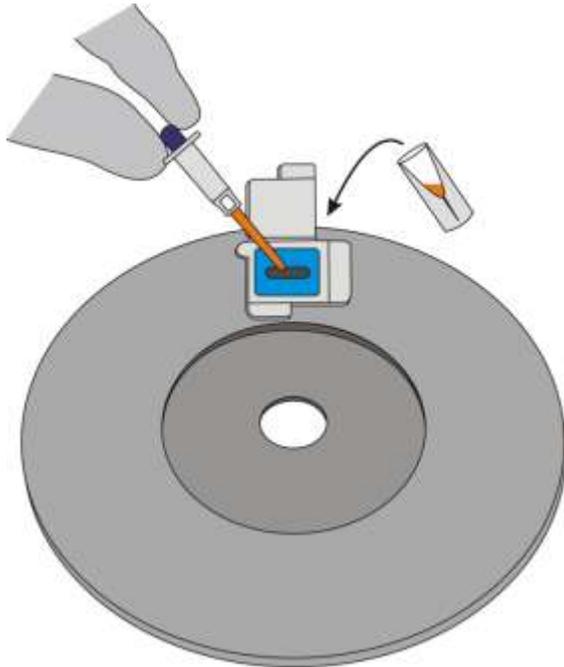
Empty the sample in the POC blood collector in the phial filled with the provided abioMIX solution.

3



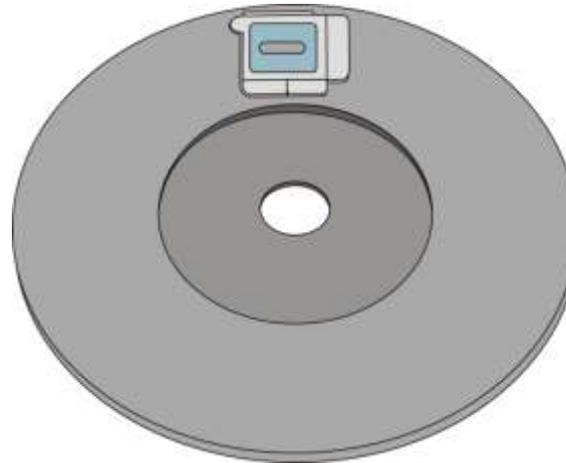
Shake the closed phial with the solution for at least 10 seconds to mix the patient sample and the abioMIX solution. Following, tap the phial several times on a hard surface.

4



Insert the open capsule carefully into the abioDISC. Using the same pipette, extract the solution from the phial using capillary effect and deposit the solution into the central opening in the capsule. In order to prevent spilling, deposit the entire solution slowly to let the liquid penetrate the capsule.

5



Close the capsule by folding over the cover (carefully to avoid spilling the solution).

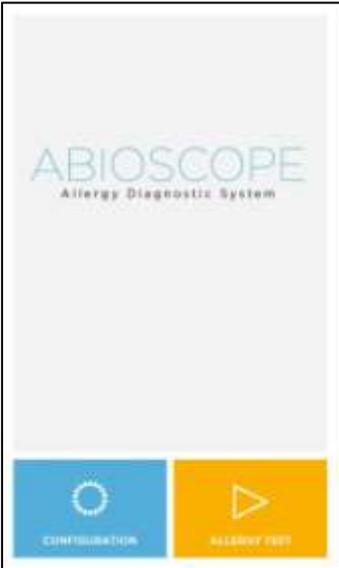
6



When placing the abioDISC in the disc tray, make sure that the capsule is correctly set in the abioDISC, and that the abioDISC is the correct way up as per the above diagram). Never use a defective capsule (e.g. one that is leaking or cracked etc.). Please follow steps 1 to 3 of the analysis procedure in order to open abioSCOPE disc tray.

Analysis procedure

Turn the abioSCOPE on. The welcome screen will appear.

<p>1</p>  <p>The welcome screen invites you to choose between configuring the abioSCOPE and starting a diagnostic test.</p> <p>Touch “ALLERGY TEST” (see step 2) or “CONFIGURATION” (see chapter 6, abioSCOPE configuration).</p>	<p>2</p>  <p>When launching a diagnostic test, the first screen requires the user to input patient and sample information for identification and documentation purposes.</p> <p>Select fields by touching the relevant white area. Enter the information using the keyboard and when finished touch “FORWARD”.</p>	<p>3</p>  <p>Touch “DISC TRAY”, to open the disc tray.</p> <p>The process can be cancelled by touching “BACKWARD”.</p>
--	--	---

4



When placing the abioDISC in the disc tray, make sure that the capsule is correctly set in the abioDISC, and that the abioDISC is the correct way up (as shown in the above diagram).

Never use a defective capsule (e.g. one that is leaking or cracked etc.).

5



After inserting the abioDISC close the disc tray by touching “DISC TRAY” on the screen. **Be careful not to trap your** fingers when closing the tray.

6



Touch “DIAGNOSTIC TEST” to start the testing sequence.

Note you can come back to previous screens by touching “BACKWARD” on the screen.

7



The testing sequence will now start and a circle progress bar will be displayed. It takes approximately 5 minutes to get the measurement completed for 1 test, and approximately 20 minutes to get measurement completed for 10 tests.

8



At the end of the test sequence, the results are displayed and recorded onto the SD card. By touching “QR-CODE” a code will be displayed for retrieving results by the abioGUIDE application (see step 9). Touch “DISC TRAY” to access the abioDISC and retrieve the used capsule (see step 10).

9



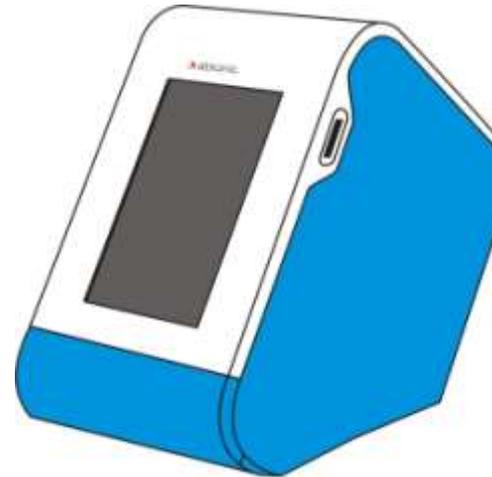
By touching “RESULTS” the user will return to the results screen (screen 8).

10



By touching “HOME” the user will return to the welcome screen (screen 1).

11



Always remove the used capsule and dispose of it in an appropriated biohazard container.

The abioDISC (but not capsules) may be stored in the abioSCOPE drive when not in use.

Control that disc tray is closed and turn the abioSCOPE off.

4 Archiving and printing the results

Post analysis procedure

The quantitative results of the test are displayed on the touch screen and saved onto the SD card. The user can therefore transfer the results to a computer to print or to store them. Abionic's diagnostic tests provide quantitative results on a scale from 3.5 to 500 kU/l. The results should only be interpreted by a physician.

Displayed colour bar	IgE Concentration [kU/l]	IgE Concentration [ng/ml]
	< 3.5	< 8.4
	3.5 – 17.5	8.4 – 42
	17.5 – 50	42 – 120
	50 – 100	120 – 240
	100 – 250	240 – 600
	250 – 500	600 – 1,200
	> 500	> 1,200

Storing and printing results

The results are automatically saved onto the SD card that is compatible with most systems. Please note that once the “HOME” is touched, or the abioSCOPE is turned off, the results are deleted from the abioSCOPE’s memory and are then only available on the SD card.

To transfer, store or print the results, remove the SD card from abioSCOPE and insert it into your computer’s SD card slot. If your computer doesn’t have one, use the USB adapter (in option).

Warning	
	Do not remove SD card after having introduced the patient data. SD card can only be removed once the results are displayed. Otherwise the measurement date may be lost or corrupted.

To start the SD card application on your Web browser, double-click on the file ABIONIC.HTM stored in the SD card.

Note	
	<p>Recommended system requirements:</p> <ul style="list-style-type: none">• At least 1GHz CPU.• At least 256MB of RAM.• Internet Explorer 8, Google Chrome, Firefox (3+), Opera (9+), or Safari (3+).• JavaScript is turned on for the browser• Windows XP, Vista, 7, 8, 10 or later.• Mac OS X 10.4 or later.• Ubuntu 10.4 and Fedora 19+.

Printing results procedure

Insert the SD card into your computer's SD card slot. Double-click on the file ABIONIC.HTM, which will be opened by your Web browser.

1



EN  Display the search tool

Last 20 diagnostics generated

Date	Patient ID	Patient Name	Sample ID	Capsule Type
22.04.2015	B-84-11-23	Abdin Albina	S-311203	Capsulse Type 2
22.04.2015	B-82-59-89	Abdullah Alejandra	S-964098	Capsule Type 3
22.04.2015	B-71-73-98	Able Allene	S-107965	Total IgE
22.04.2015	B-84-18-40	Abson Anastasia	S-111812	Capsulse Type 2
22.04.2015	B-91-87-71	Acerno Angila	S-606880	Capsulse Type 2
22.04.2015	B-74-91-27	Affelt Bernard	S-284423	Total IgE
22.04.2015	B-59-70-83	Agee Bethel	S-429145	Capsule Type 3
22.04.2015	B-84-40-35	Aglar Bill	S-107467	Capsule Type 3
22.04.2015	B-26-38-61	Aguillar Breana	S-858754	Total IgE
22.04.2015	B-41-80-95	Aguinaldo Brenda	S-133410	Capsule Type 4
22.04.2015	B-45-17-74	Ahner Buford	S-420989	Capsulse Type 2
22.04.2015	B-20-24-40	Albares Charise	S-793135	Capsule Type 4
22.04.2015	B-14-14-66	Alcalde Chèt	S-998340	Capsule Type 4
22.04.2015	B-71-43-63	Aleizar Clarice	S-708396	Capsulse Type 2
22.04.2015	B-56-46-73	Abbadessa Agripina	S-720555	Total IgE
22.04.2015		Abke Allegra	S-323807	Capsulse Type 2
22.04.2015	B-41-53-18	Aboytes Alton	S-219558	Capsulse Type 2
22.04.2015	B-55-79-62	Abrantes Amalia	S-661666	Total IgE
22.04.2015	B-80-28-79	Aceituno Angelo	S-721065	Capsulse Type 2
22.04.2015	B-36-17-95	Acencio Angelyn	S-848715	Capsule Type 3

The homepage displays you the last 20 results generated by the abioSCOPE. Click on “display the search tool” button to search & find archived results using several available search filters (see screen 2). Click on a specific row to display full details about the result (see screen 3).

2



EN

Search panel

Date Search

Result list

Date	Patient ID	Patient Name	Sample ID	Capsule Type
22.04.2015	B-39-75-60	Adamo	S-294737	Capsule Type 4
22.04.2015	B-51-10-94	Adamo	S-627358	Capsule Type 4
22.04.2015	B-27-28-23	Adamo	S-512042	Total IgE
22.04.2015	B-80-86-97	Adamo	S-123663	Capsule Type 2
22.04.2015	B-78-43-15	Addeo Arturo	S-842573	Capsule Type 3
22.04.2015	B-66-94-52	Addo Ashli	S-226399	Capsule Type 3
22.04.2015	B-81-66-72	Aita Carlos	S-917534	Total IgE
22.04.2015	B-25-20-26	Akmal Cassy	S-501343	Capsule Type 4
22.04.2015	B-88-84-33	Alby Chèryle	S-100251	Capsule Type 4
22.04.2015	B-78-97-72	Alcaraz Chieko	S-975521	Total IgE
22.04.2015	B-27-76-15	Alexanian Clyde	S-549843	Capsule Type 3
22.04.2015	B-73-22-56	Alge Coral	S-435700	Capsule Type 4
22.04.2015	B-53-57-95	Almeter Dee	S-177837	Total IgE
22.04.2015	B-91-79-26	Alsbrook Denisse		Capsule Type 3
22.04.2015	B-51-60-51	Amack Duncan		Capsule Type 4
22.04.2015	B-81-97-39	Amancio Earle		Capsule Type 3
22.04.2015	B-75-60-86	Ameli Elene		Capsule Type 3
22.04.2015	B-14-57-19	Amorin Emanuel		Capsule Type 3
22.04.2015	B-50-41-89	Andradez Ezequiel		Capsule Type 3
22.04.2015	B-85-52-88	Antonopoulos Hailey		Capsule Type 3

← Previous results 2 Next results →

Search for a specific archived result generated by the abioSCOPE using one of the following search filter: date, patient ID, patient name, sample ID or capsule type name. Click on a specific row to display full details about the result (see screen 3).

3



Patient Information
 ID: 123457
 Name: QWER
 Sample information
 ID: ASFG

Test information
 Capsule type: Beta-Test
 Capsule ID: 01.00001
 AbioSCOPE ID: ECHO_debug_BS_
 Control measurements: Passed

Test results: Date: 20.02.2015

Allergy		kU/L	Class
Control	positive	ok	6
Control	negative	ok	0
Birch	rBet v 1	34 kU/L	4
Birch	rBet v 2	1.2 kU/L	1
Timothy	rPhl p 1	1.0 kU/L	1
Olive	rOle e 1	60 kU/L	5
Cat	rFel d 1	0.1 kU/L	0
Dog	rCan f 1	0.4 kU/L	1
Mite	rDer p 1	0.3 kU/L	0
Cattle	nBos d 4	0.6 kU/L	1
Chicken	nGal d 1	0.1 kU/L	0
Peanut	rAra h 1	0.5 kU/L	1



Full details about an abioSCOPE's result are displayed on screen in a new tab. User can print the result as well as using the QR-code to switch to our abioGUIDE mobile application.

5 Test kit and storage

Abionic provides individually packaged abioKIT- α for each diagnostic test, including the capsule, the blood collector and one phial of abioMIX.

One vial of abioMIX contains 50 μ l of detecting reagent, which corresponds to the quantity for one analysis (one capsule). The abioMIX contains a fluorescently-labelled anti-human IgE antibody at 2 μ g/mL in phosphate buffered saline supplemented with 0.05% (v/v) of polyoxyethylene (20) sorbitan monolaurate (Tween 20, CAS number 005-64-5). The reagent does not contain any preservative and is ready for use. Lot number, recommended storage condition and expiration date are indicated on the label of the tube. The reagent is for in vitro diagnostic use only.

The kit must be stored in a refrigerated area at 2 - 6°C. Based on lifetime tests, the kit's shelf life is estimated at 6 months.

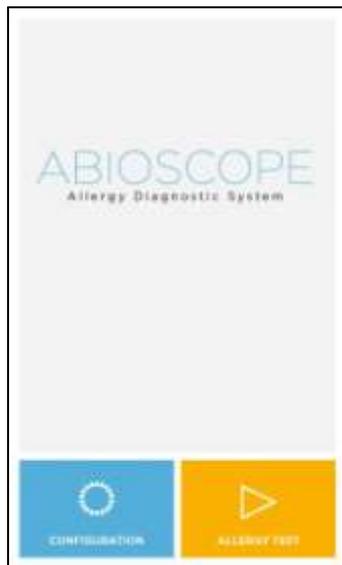
The user is invited to carefully read the user instruction provided with each abioKIT- α .

Biological hazard	
	Once a capsule has been used it must not be reinserted into the abioSCOPE. It should be disposed of in a biohazard container. Be aware that the test is performed with human whole blood, plasma or serum which may carry a risk of transmitting infectious agents.

6 abioSCOPE configuration

Entering the Responsible Physician's and user information

Turn the abioSCOPE on. The welcome screen will appear.



The next step is to register the details of the responsible physician on the abioSCOPE and the name of the person performing the tests. Touch “CONFIGURATION” on the Home screen and the following screen appears:



The physician's office information as well as the person's name performing the test can now be entered. This information will appear in the results file that is stored on the SD card.

Select the appropriated field by touching the corresponding white area, enter the information using the keyboard and touch "DONE" when finished.

This information will remain in the system until changed. For example if there are several people using the system, each user should enter their own name prior to conducting a test. However, the name and address of the responsible physician does not need to be re-entered at each time.

Note	
	There is only one keyboard type (Switzerland, QUERTZ). It only offers capital letters and has no accents.

7 Troubleshooting

E001. Hardware failure at Startup

On starting up, the system enters a short initialization phase that involves the system checking the functionality of the abioSCOPE. If one or several functions do not initialize properly, the system will not be usable and the following error message will appear on screen:

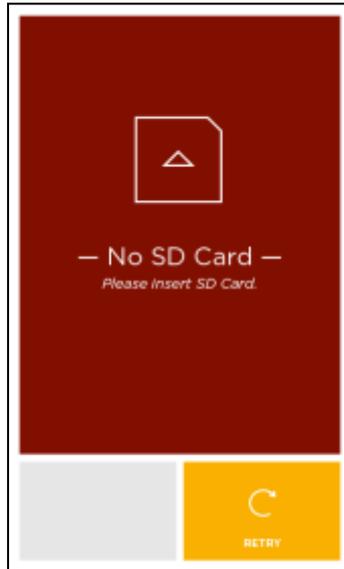


The user should restart the abioSCOPE. If the problem persists, please contact Abionics customer service at service@abionics.com.

E002. No SD Card inserted (missing SD card)

A SD card must be inserted into the abioSCOPE before starting the device.

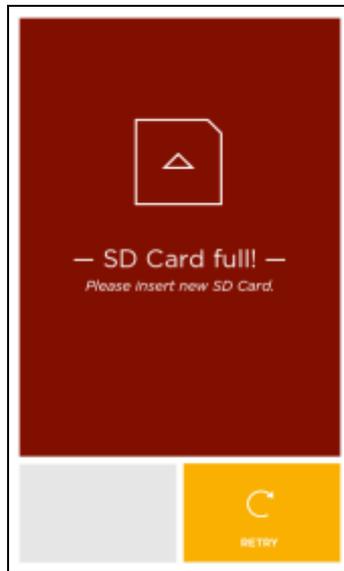
If the SD card is missing during the initialization process, the following screen will invite the user to insert a SD card into the dedicated slot. The abioSCOPE will then immediately continue its initializing process.



If this screen appears when a SD card is present in the abioSCOPE, check that the SD card is correctly inserted by removing it completely and re-inserting it. Check that the SD card is correctly orientated (the metal contacts should not be visible) and that the SD card is the one provided by Abionic (special format). If the problem persists, check whether the SD card is damaged by inserting another one. If the problem persists, then the abioSCOPE could be damaged. Please contact Abionic customer service at service@abionic.com.

E003. SD Card full

During the initialization phase at start up, the system controls the remaining space on the SD card. If the SD card is full, the following screen will appear:



The user must replace the SD card with a new one provided by Abionic. Then, touch “RETRY”.

E004. Touchbutton is not responding (interface software is frozen)

If the touchscreen does not respond within 20 seconds (except during the measurement time), restart the abioSCOPE.

If the abioSCOPE still not responds when the touchscreen is touched several times, then read through the list of possible causes below:

- As for any capacitive touchscreen, users should take care to correctly touch the screen (longer contact time, avoid touching with finger nails etc.).
- Ensure that the user’s gloves are not too thick: the abioSCOPE touchscreen has been designed to be used only with standard medical gloves. Please try wearing thinner gloves.
- Initialization at start-up can cause the touchscreen to block. If this happens, the abioSCOPE should be restarted.

E005. Disc tray is not opening

If the disc tray does not open when “DISC TRAY” is pressed, restart the abioSCOPE.

If the disc tray cannot be opened then the abioSCOPE is probably damaged and should be returned to Abionic: please contact Abionic customer service at service@abionic.com.

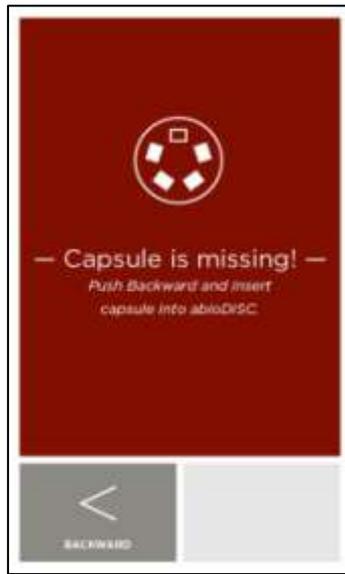
E006. Disc tray is blocked

If the disc tray is partially opened, touch “DISC TRAY” twice to close and open the disc tray correctly. If the disc tray is blocked in its closed position, restart the abioSCOPE.

If the disc tray cannot be opened then the abioSCOPE is probably damaged and should be returned to Abionic: please contact Abionic customer service at service@abionic.com.

E007. Capsule missing

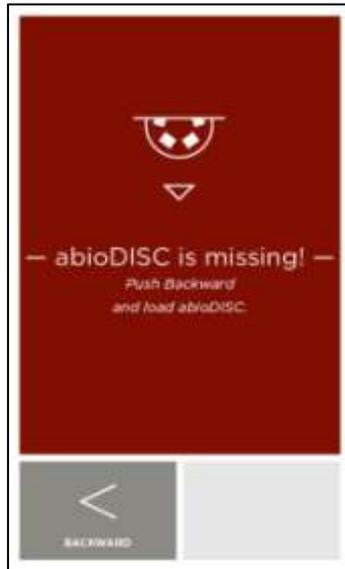
Only certified capsules provided by Abionic should be inserted into the abioSCOPE. Capsules must be new and unused. If a capsule is missing, or if a non-compatible capsule is inserted, the abioSCOPE will detect it and invite the user to insert a new compatible capsule. The following screen will be displayed:



Touch "BACKWARD" and follow the instructions displayed on the screen.

E008. abioDISC missing

Only official disc supports (abioDISC) provided by Abionic should be used with the abioSCOPE. If an abioDISC is missing, or if a non-compatible abioDISC is inserted, the abioSCOPE will detect it. The following screen will be displayed:



Touch “BACKWARD” and follow the instructions displayed on the screen.

Note



The abioSCOPE can only read approved abioDISCs. Do not insert CDs, CD-ROMs, DVDs or any other media into the abioSCOPE.

E009. Progress bar is frozen

If the circle progress bar is frozen in the same position for more than 10 minutes, restart the abioSCOPE.

If a test on a capsule has already been started, the abioSCOPE will ask for a new capsule to insert.

If the progress bar repeatedly freezes at the same point in its progression, please contact Abionic customer service at service@abionic.com.

E010. Hardware failure during measurement

If the abioSCOPE experiences a hardware problem during the measurement phase, the system will stop and the following error message will appear on screen:



Touch “DISC TRAY” and follow the instructions displayed on the screen.

E011. Writing error to a SD card

Just before displaying the results, the abioSCOPE will write the results data to the SD card. If the card is damaged, the system will request that a new card is inserted:



Touch “RETRY” and follow the instructions displayed on the screen.

If the problem persists, insert a new SD card and touch “RETRY”.

E012. Problem of electrical supply

If the electrical supply connector is not fully inserted, the abioSCOPE may not start after pressing the On/Off button. In this case, check the connector as well as the electrical plug.

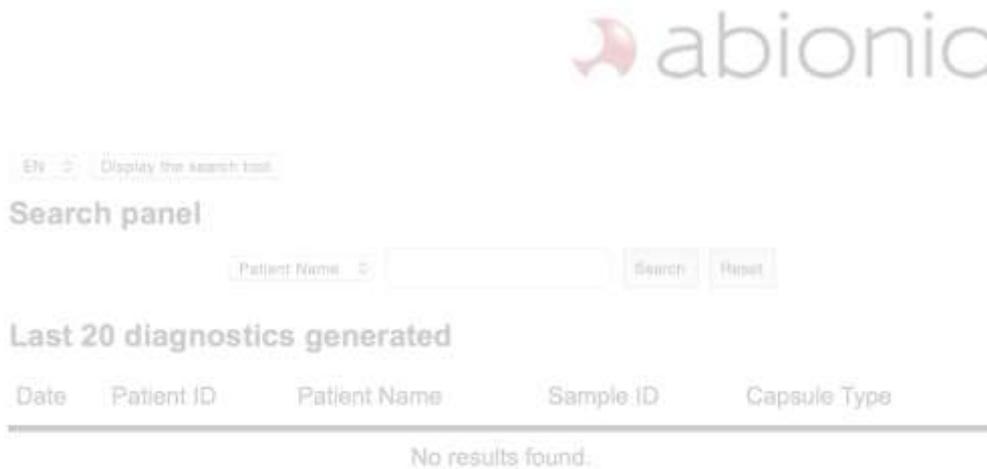
If the abioSCOPE is placed on a wall support, unscrew and remove the abioSCOPE from the wall support. Visually control the electrical pins on the support. Place the abioSCOPE again on its support and secure it with its dedicated screw.

In all cases, check the electrical plug by testing another device on the same plug. If the other device is working properly and not the abioSCOPE, please contact Abionic customer service at service@abionic.com.

In case of a power failure during the measurement, restart the abioSCOPE, remove the used capsule and start the diagnostic test with a new capsule.

E013. Problem using the abioCARD

If the SD card is not correctly inserted in your computer or if the data stored are corrupted, the abioCARD tool will detect it and will display on screen the following error message:



An error occur while starting the application.
Please contact Abionic Customer Service:
service@abionic.com

The user must replace the SD card with a new one provided by Abionic. If the problem persists please contact Abionic customer service at service@abionic.com.