



# The abioSCOPE®


## User Manual



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# USER MANUAL

## abioSCOPE

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### ***Print History***

| Version | Publication Date | Reason for Revision / Issue   |
|---------|------------------|---|
| 1.0     | 10 October 2019  | First approved version  |
| 1.1     | 8 November 2019  | Essential requirements now assigned to the appropriate directive 98/79/EC |

|     |                  |   |
|-----|------------------|---|
| 1.2 | 05 December 2019 | <p>Addition of compatibility with norm IEC 60601-1-2</p> <p>Addition of the functionality to display a QR-code containing the test results</p> <p>Addition of settings for: regional settings, software updates and factory reset</p>   |
| 1.3 | 17 December 2019 | Electrical safety norms IEC/EN/UL/ CAN/CSA 61010-2-101 updated to their most recent edition   |
| 1.4 | 14 January 2020  | Addition of warning regarding electromagnetic compatibility   |
| 1.5 | 27 April 2020    | Update of display screens   |
| 2.0 | 9 July 2020      | <p>Addition of Quality Control screens and corresponding troubleshooting</p> <p>Addition of audio settings, display settings, power setting, quality settings</p> <p>Update of IT settings and corresponding troubleshooting</p> <p>Addition of user management and user login</p> <p>Update of the test results archive with new functionalities</p> |
| 2.1 | 18 January 2021  | <p>Addition of the additional warning for vibration detection</p> <p>Addition of the possibility to display the PSP score</p>   |

|     |                 |   |
|-----|-----------------|---|
| 2.2 | 16 August 2021  | <p>Reference to IVDR</p> <p>Errors display updates</p> <p>Addition of patient data input field names customization</p> <p>Addition of the option to assign an item to sample ID in the code reader custom mode</p> <p>Radio Frequency Communications Equipment Warning moved to the section "Location of Intended Use"</p> <p>Pre-analysis procedure now refers to the IVD CAPSULE package insert</p> |
| 2.3 | 9 November 2021 | <p>Addition of new customization possibilities of the measurement data input</p> <p>Addition of error 010-20 ("Tray blocked").</p>  |
| 2.4 | 03 March 2022   | <p>Addition of the explanation of the NRTL certification mark.</p> <p>Addition of the rated power in the operating conditions.</p> <p>Operating maximum altitude increased from 2000 m to 4000 m</p>  |
| 2.5 | 25 May 2022     | <p>CE marking with reference to EU regulation 2017/746 on in vitro medical devices (IVDR)</p>   |

## 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 authorized specialist. Unauthorized 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 anesthetics.   |

## CE marking

The product also complies with the EU regulation 2017/746 on in vitro medical devices (IVDR) and has received the CE-Marking as class A with EC conformity declaration according to annex IX, chapter I of said regulation.

## ***This Manual***

This document provides the information needed to setup and operate the abioSCOPE product from Abionic SA. This user manual is the instructions for use of the abioSCOPE with reference number P01.0007.

## ***Intended Audience***

This abioSCOPE User Manual is intended to assist healthcare specialists (ex. biologists, physicians, medical staff and biomedical engineers) who may operate the abioSCOPE system.

## ***Operator training***






A training of the operator must be accomplished prior to initial use of the abioSCOPE and the IVD CAPSULE.

## ***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](mailto: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 authorized specialist. Unauthorized 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 without powder when handling components of the abioSCOPE or IVD CAPSULE, because of biological risk and/or particle contamination of the abioSCOPE or IVD CAPSULE. |
|    | 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.        |



# Content

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|   |           |
|---|-----------|
| <i>Print History</i> .....  | 2         |
| <i>Warranty</i> .....   | 5         |
| <i>Warnings</i> .....   | 5         |
| <i>CE marking</i> .....   | 5         |
| <i>This Manual</i> .....  | 6         |
| <b>1 INTRODUCTION</b> .....   | <b>10</b> |
| <i>Intended use</i> .....   | 10        |
| <i>abioSCOPE Warranty</i> .....                                       | 11        |
| <i>abioSCOPE features</i> .....                                       | 11        |
| <i>abioSCOPE cleaning</i> .....                                       | 11        |
| <i>International conformity</i> .....                                 | 12        |
| <i>Operating conditions</i> .....                                     | 14        |
| <i>Locations of intended use</i> .....                                | 14        |
| <i>Laser information</i> .....  | 15        |
| <i>Radiofrequency transmitter information</i> .....                   | 16        |
| <b>2 SYSTEM COMPONENTS</b> .....                                      | <b>17</b> |
| <i>About the System's Components</i> .....                            | 17        |
| <i>Locating the abioSCOPE Serial Number</i> .....                     | 19        |
| <i>Turning on your abioSCOPE</i> .....                                | 19        |
| <b>3 INSTRUCTION OF USE</b> .....                                     | <b>20</b> |
| <i>Principle of detection</i> .....                                   | 20        |
| <i>Pre-analysis procedure</i> .....                                   | 21        |
| <i>Device start-up</i> .....  | 22        |
| <i>Analysis procedure</i> .....                                       | 25        |
| <b>4 POST ANALYSIS PROCEDURE</b> .....                                | <b>30</b> |
| <b>5 ABIOSCOPE CONFIGURATION AND ADDITIONAL FUNCTIONALITIES</b> ..... | <b>31</b> |
| <i>Quality control</i> .....  | 32        |
| <i>Test configuration</i> .....                                       | 43        |
| <i>User management</i> .....  | 46        |
| <i>Healthcare unit</i> .....  | 53        |
| <i>Device settings</i> .....  | 54        |
| <i>Device status</i> .....  | 70        |
| <b>6 TEST RESULTS ARCHIVE</b> .....                                   | <b>72</b> |
| <i>Results archive on abioSCOPE</i> .....                             | 72        |
| <i>Results archive on computer</i> .....                              | 78        |
| <b>7 TROUBLESHOOTING</b> .....  | <b>82</b> |
| <i>E001-008. Problem of electrical supply</i> .....                   | 82        |

|  |            |
|--|------------|
| <i>E004-002. Device damaged.....</i>                             | <i>83</i>  |
| <i>E004-004. Device under vibrations.....</i>                    | <i>84</i>  |
| <i>E009-01 Incorrect type of test .....</i>                      | <i>86</i>  |
| <i>E009-05. Internal memory full .....</i>                       | <i>87</i>  |
| <i>E009-06. Internal storage memory is corrupt.....</i>          | <i>88</i>  |
| <i>E009-07. Capsule data inaccessible.....</i>                   | <i>89</i>  |
| <i>E009-10. Touchscreen is not responding.....</i>               | <i>90</i>  |
| <i>E009-11. Tray is not opening .....</i>                        | <i>91</i>  |
| <i>E009-12. Tray is blocked.....</i>                             | <i>92</i>  |
| <i>E009-13. Capsule data invalid .....</i>                       | <i>93</i>  |
| <i>E009-14. Test failed.....</i>                                 | <i>94</i>  |
| <i>E009-15. Configuration capsule data inaccessible.....</i>     | <i>95</i>  |
| <i>E009-16. Configuration capsule data invalid .....</i>         | <i>96</i>  |
| <i>E009-18. Software error .....</i>                             | <i>97</i>  |
| <i>E009-19. Language pack invalid.....</i>                       | <i>98</i>  |
| <i>E009-20. Firmware file invalid .....</i>                      | <i>99</i>  |
| <i>E009-21. Firmware update unsuccessful.....</i>                | <i>100</i> |
| <i>E009-22. Factory reset unsuccessful .....</i>                 | <i>101</i> |
| <i>E009-25. abioSCOPE Control capsule expired.....</i>           | <i>102</i> |
| <i>E009-26. Network connectivity lost.....</i>                   | <i>103</i> |
| <i>E010-07. Outside of operating conditions.....</i>             | <i>104</i> |
| <i>E010-08. Capsule ID error .....</i>                           | <i>105</i> |
| <i>E010-09. Capsule missing.....</i>                             | <i>106</i> |
| <i>E010-10. Capsule is expired .....</i>                         | <i>107</i> |
| <i>E010-16. Critically outside of operating conditions .....</i> | <i>108</i> |
| <i>E010-17. Internal IVD CAPSULE control incorrect.....</i>      | <i>109</i> |
| <i>E010-18. abioSCOPE control capsule incorrect .....</i>        | <i>110</i> |
| <i>E010-20. Tray blocked.....</i>                                | <i>111</i> |
| <i>E014-01. Initialization test unsuccessful .....</i>           | <i>112</i> |
| <i>E014-02. abioSCOPE control failed .....</i>                   | <i>113</i> |
| <i>E014-03. Internal IVD CAPSULE control failed .....</i>        | <i>114</i> |
| <i>E014-04. abioSCOPE control invalid .....</i>                  | <i>115</i> |
| <i>E014-05. Internal IVD CAPSULE control invalid.....</i>        | <i>116</i> |

# 1 Introduction

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## Intended use

The abioSCOPE is a table top diagnostic device that measures analytes in biological samples, using test-specific capsules (IVD CAPSULE) intended for use with this instrument.

### Protective gloves



Always wear protective gloves without powder when performing tests with the abioSCOPE.

### Warning



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

### Warning



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

### Warning



Users shall report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority where they are established.

## ***abioSCOPE Warranty***

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


## ***abioSCOPE features***

- Measurement of IVD CAPSULEs (in-vitro diagnostic tests) and display of qualitative, semi-quantitative or quantitative results on a high-resolution touchscreen;
- Test results of all the performed tests can be displayed on the device.
- Display of a QR-code containing the test results for the transfer to the mobile application abioGUIDE or a QR-reader for further treatment of the data.

## ***abioSCOPE cleaning***

abioSCOPE cleaning consists in periodically disinfecting the abioSCOPE tray 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 61010-1:2010 and IEC 61010-1-2010/AMD2016, Safety requirements for electrical equipment for measurement, control and laboratory use
- EN 61010-1:2010/A1:2019, Safety requirements for electrical equipment for measurement, control and laboratory use
- UL 61010-1:2012/R:2018-11, Safety requirements for electrical equipment for measurement, control and laboratory use
- CAN/CSA C22.2 No. 61010-1-2012//A1:2018-11, Safety requirements for electrical equipment for measurement, control and laboratory use
- IEC 61010-2-101:2018, Safety requirements: particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61010-2-101:2019, Safety requirements: particular requirements for in vitro diagnostic (IVD) medical equipment
- UL 61010-2-101:2019, Safety requirements: particular requirements for in vitro diagnostic (IVD) medical equipment
- CAN/CSA C22.2 No. 61010-2-101:2019, Safety requirements: particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 60825-1:2014, Safety of laser products
- EN 60825-1:2014, Safety of laser products
- CAN/CSA-E60825-1:2015, Safety of laser products
- EN 61326-1:2013, 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
- EN 61000-3-2:2014, Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current  $\leq 16$  A per phase)
- EN 61000-3-3:2013, Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current  $\leq 16$  A per phase and not subject to conditional connection
- EN 301 489-1 V2.2.0 (2017-03), Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;
- EN 301 489-3 V2.1.1 (2017-03), Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;

- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;

Emission group 1 class B according to CISPR 32 /EN 55032;

Immunity level complying with "Professional healthcare facility environment" in IEC 60601-1-2:2014;


- EN 62304:2006+AMD1:2015, Medical device software – software life cycle processes;
- EN ISO 15223-1:2016, Symbols for use in the labelling of medical devices;

The product also complies with the EU regulation 2017/746 on in vitro medical devices (IVDR) and has received the CE-Marking  as class A with EC conformity declaration according to annex IX, chapter I of said regulation.


The product has been developed, produced and tested within a Quality Management System according to ISO 13485:2016.

The in vitro diagnostic medical device fulfils the essential requirements according to annex I of EU regulation 2017/746.



The  symbol is adopted by the European Council to represent waste electrical and electronic equipment in the Waste Electrical and Electronic Equipment Directive.



The  mark on the label is the NRTL certification mark. It may or may not be present on the label (every abioSCOPE has this certification, whether it is present on the label or not).

## ***Operating conditions***

Indoor use only

Max. altitude: 4'000 m


Main power supply: 100-240V (+/- 10% max. variations), 50-60 Hz

Power rating: 65W

Operating temperature: 18°C – 28°C / Relative humidity: 20% – 80%

Pollution degree 2


In order to maintain the device performance with regard to the electromagnetic compatibility the device must be kept within the operating conditions indicated in the user manual. Other than this, no specific maintenance is needed to maintain the electromagnetic compatibility of the device during its lifetime.

| <b>Warning</b>  |  |
|---|--|
|  | To avoid the risk of electric shock, this equipment must only be connected to a main electricity supply fitted with a protective earth.<br>Only use the provided power cord. |


## ***Locations of intended use***

The following locations are suitable for the device intended use:

- Physician offices
- Pharmacies
- Analysis laboratories
- Hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near high frequency surgical equipment and outside the radio frequency shielded room of an medical electrical system for magnetic resonance imaging)

| <b>Warning</b>  |   |
|---|---|
|  | The device stores medical patient data and it is thus needed to prevent unauthorized physical and remote access to the device |

In case the device is used in an environment with stronger electromagnetic disturbances than commonly expected from the locations above, the precision of the test results could be lower than described in the corresponding IVD CAPSULE product insert.


| Radio Frequency Communications Equipment Hazard                                   |  |
|---|--|
|  | <p>Portable radiofrequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the abioSCOPE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> |

## 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 < 5mW, Class 3B. The abioSCOPE should not be opened under any circumstances.

| Laser beam  |   |
|---|---|
|  | <p>Do not use the abioSCOPE without the device housing due to harmful light intensity causing permanent eye injury.</p> |

The following label is located on the abioSCOPE housing:

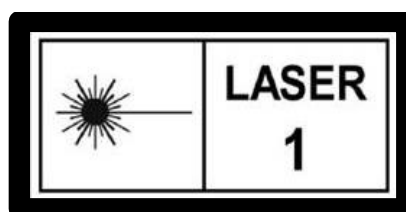


Figure 1.1: abioSCOPE laser class 1 warning label



The following label is located inside the abioSCOPE:



Figure 1.2: abioSCOPE laser class 3B warning label

### ***Radiofrequency transmitter information***

The abioSCOPE includes a radiofrequency transmitter to identify the IVD capsules when inside the device. This radiofrequency transmitter works at the frequency of 13.56MHz with an amplitude-shift keying (ASK) modulation. The effective radiated power is 0.22 mW.

## 2 System Components

---

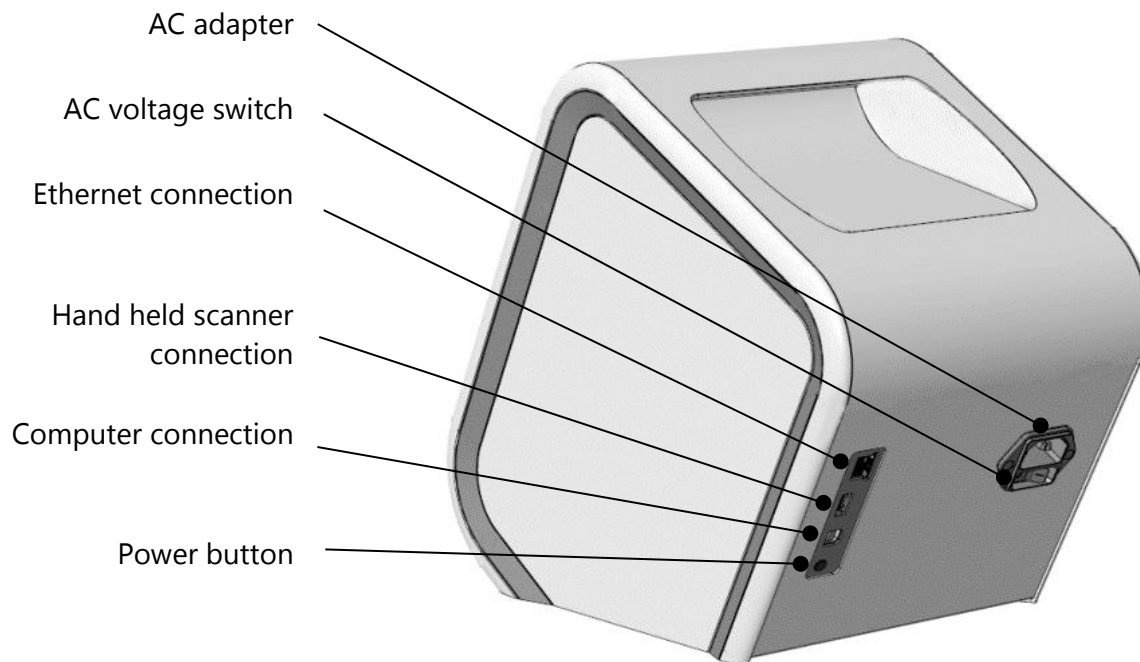
### **About the System's Components**

The abioSCOPE is a diagnostic device that provides rapid medical diagnostic test results. Operating the abioSCOPE does not require extensive training and can be used by any Healthcare professional.

The abioSCOPE is composed of a fully automated fluorescence microscope, a tray, onto which is placed a single-use disposable IVD CAPSULE. The abioSCOPE is operated through the high-resolution touchscreen. Following the preparation of the IVD CAPSULE, it is placed in the tray of the device. In a few minutes the results are then presented on the touch screen and saved onto the internal memory of the abioSCOPE.


Detailed descriptions and functional specifications of each assay (the "IVD CAPSULE") are provided with its product insert.






If you use another power cord than the one provided with the device, do not use cables longer than 5 meters.

A hand-held scanner can be connected to the USB port shown in the picture above. The hand-held scanner has to be programmed to emulate a regular RS232-based COM port

| Warning   |   |
|---|---|
|  | <p>WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.</p> |

| Warning   |  |
|---|--|
|  | <p>Only use hand-held scanners that are CE marked.</p> |

**Warning**



Do not spill liquid on the tray or tray cover. In case this should happen, clean it with a disinfectant and dry it before using the device again.

**Warning**



The tray is a moving part. Be careful not to trap your fingers when the tray is moving.

### ***Locating the abioSCOPE Serial Number***

The system serial number is printed on a label at the back of the device. Unauthorized 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 the mains (AC source between 100 and 240V at 50 or 60Hz). 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. Then turn the AC voltage switch ON.

To turn the abioSCOPE on or off, use the small power button situated on the rear side of the system.

## ***3 Instruction of Use***

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### ***Principle of detection***

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

The abioSCOPE system is designed to enable automated workflow. Only a few and simple operational steps are required.

The biological specimen, typically a patient's venous serum or capillary whole blood sample is diluted with a solution composed of fluorescently labelled biomolecules.

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. A fluorescence signal is emitted from the biosensors upon excitation of these molecular complexes and analyzed in the abioSCOPE. The amplitude of this fluorescent signal is proportional to the analyte concentration in the patient sample.

Due to the innovative technology that comprises the nanofluidic biosensor, washing and cleaning steps are eliminated and incubation times greatly decreased.

### ***Pre-analysis procedure***

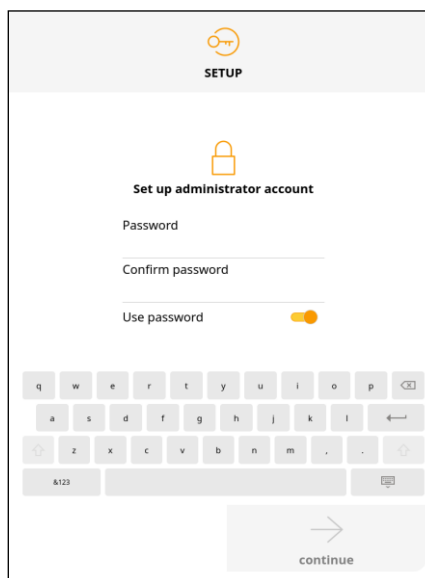
The abioSCOPE is to be used with IVD CAPSULE in vitro diagnostic test kits only. Only material from the IVD CAPSULE kit must be used for the preparation. The pre-analysis procedure is described in the package insert (IFU) provided with each IVD CAPSULE kit; the user is invited to carefully read these user instructions. In summary, the principle is always to collect the patient sample (blood, saliva,...), mix it with a reagent and then deposit it in the capsule of the IVD CAPSULE kit.

### ***Device start-up***

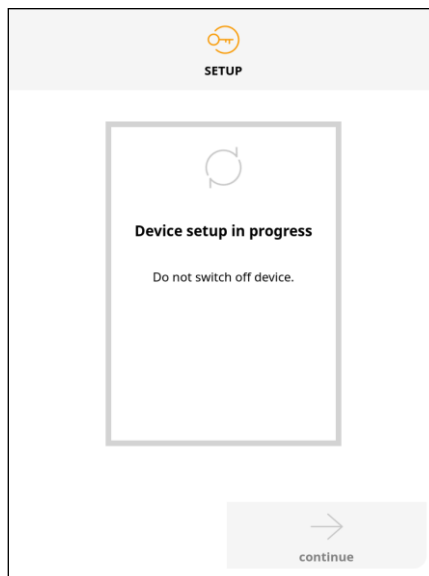
Turn the abioSCOPE on. First a splash screen will be displayed while the device starts up:



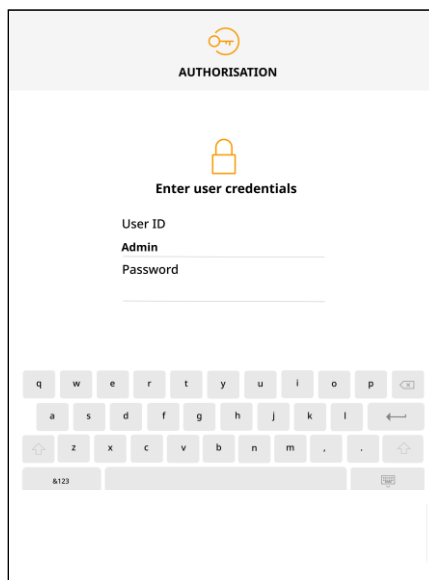
During the first start-up of the device only, the following screen will be displayed:



This screen is used for setting up the administrator account password. Please enter the desired password. This password shall be at least 8 characters long. There is also the possibility not to use a password. Then touch "continue" and the following screen will be displayed:



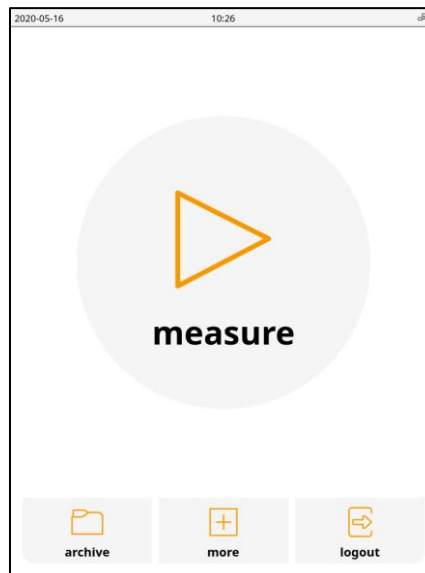
When finished, the login screen will be displayed. This is also the screen that is displayed after the splash screen for every device start-up after the first one:



Please enter your credentials there (user ID and password if applicable).



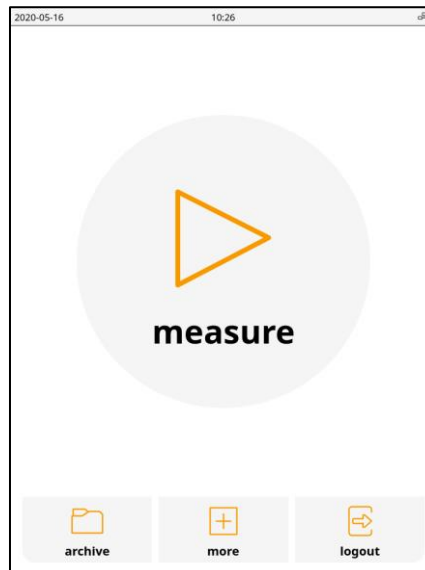
After having entered the appropriate credentials, the welcome screen will then appear. It invites you to choose between starting a test, consulting the test archive, configuring the abioSCOPE and logging out:



Touching "logout" will go back to the previous screen. The other options are described below.

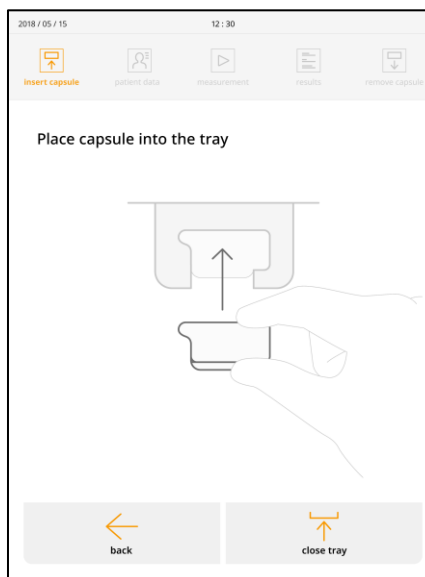
## ***Analysis procedure***

**1.**



Touch "measure" (see step 2), "archive" (see chapter "4" and printing the results) or "more" (see chapter 6, abioSCOPE configuration).

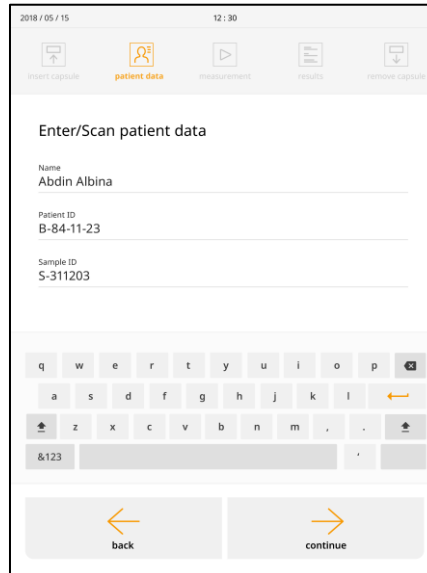
**2.**



The tray opens. Place the capsule into the tray and make sure that the capsule is correctly set in the tray. Never use a defective capsule (e.g. one that is leaking or cracked etc.).


After placing the capsule close the tray by touching “close tray” on the screen. Be careful not to trap your fingers when closing the tray.

### 3.



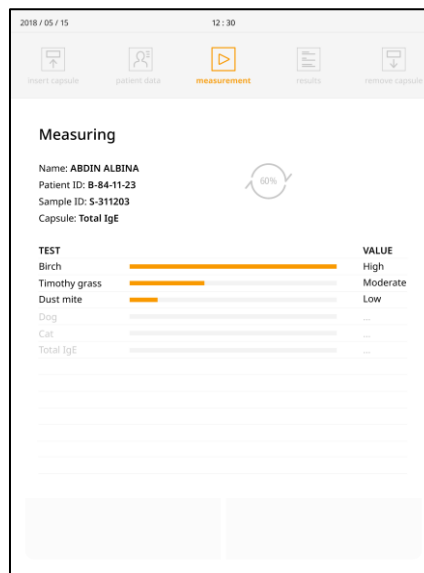
The next screen requires the user to input patient and sample information for identification and documentation purposes.

Select fields by touching the relevant white area. Enter the information using the keyboard or another input device connected.

| Warning   |  |
|---|--|
|  | <p>Always check carefully that the data entered on this screen is correct.</p> |

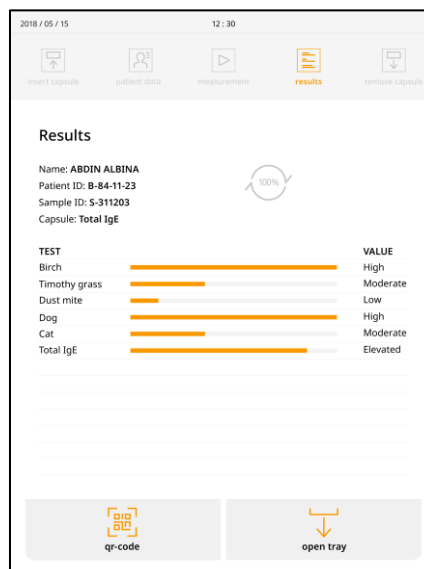
When finished touch “continue”. It is possible to go back to the previous step by touching “back”.

4.



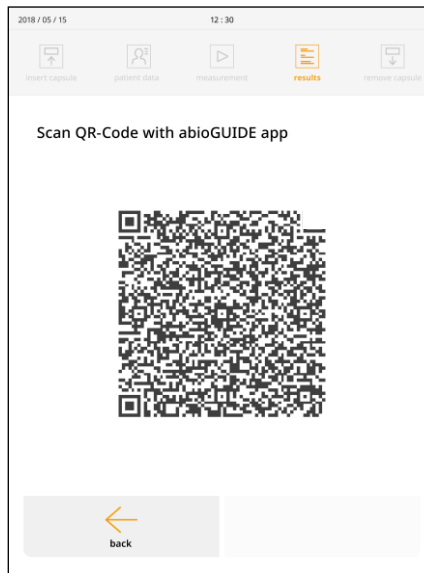
The measurement will now be displayed with a circle progress bar. The time taken for a measurement depends on the specific test. For multiple tests the results are sequentially displayed.

5.




At the end of the test sequence, the entire results are displayed and recorded onto the internal memory. By touching "qr code" a code will be displayed for retrieving results with the abioGUIDE application (see step 6). Touch "open tray" to retrieve the used capsule (see step 7).

6.



Touch "back" to return to the results screen (screen 5).

| Warning   |  |
|---|--|
|  | Only use smartphones and tablets that are CE marked. |

7.



Remove the capsule. Touch “close tray” to go back to the welcome screen (screen 1).

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

8.



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



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

## 4 Post analysis procedure





Test results are displayed on the touch screen. The results must only be interpreted by a Healthcare Professional in conjunction with other data; e. g., results of other tests, clinical impressions and symptoms and patient history.

Abionic's diagnostic tests provide qualitative results as positive or negative, semi-quantitative results with different classes or quantitative results displaying a concentration in corresponding units depending on the IVD CAPSULE test. The following table gives an example of how semi-quantitative and quantitative test results are displayed on the abioSCOPE. Information on concentration ranges or class levels specific to the IVD CAPSULE test is found in each product insert (notice).

Examples of semi-quantitative test results:

| Displayed color bar   | Level    | Concentration [ng/ml] |
|---|----------|-----------------------|
|   | Low      | < 60                  |
|  | Moderate | 60 – 240              |
|  | Elevated | > 240                 |

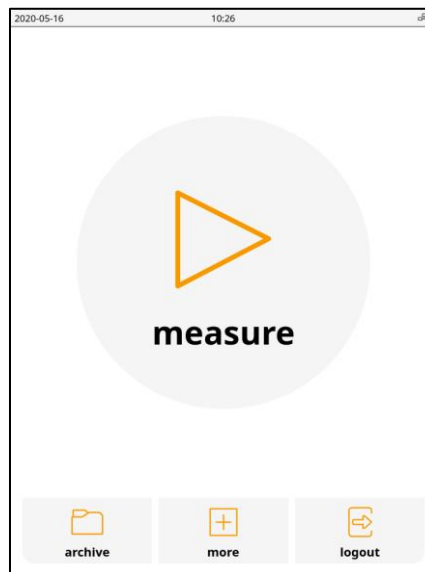
Examples of quantitative test results:

| Concentration [ng/ml] | Displayed color bar  |
|-----------------------|--|
| < 8.4                 |  |
| 14.8                  |   |
| 87                    |   |
| 233                   |  |
| 361                   |  |

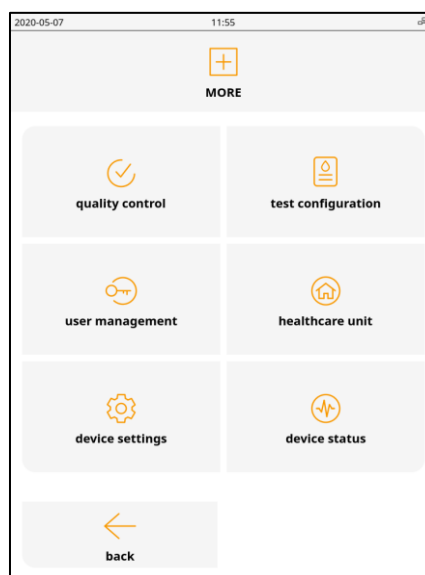
For the quantitative test results the color bar is not necessarily displayed. It depends on the application. Details are always indicated in the product insert of the IVD CAPSULE.

## 5 *abioSCOPE configuration and additional functionalities*

To configure the abioSCOPE turn the abioSCOPE on. The welcome screen will appear.



Touch “more” on the Home screen and the following screen appears:

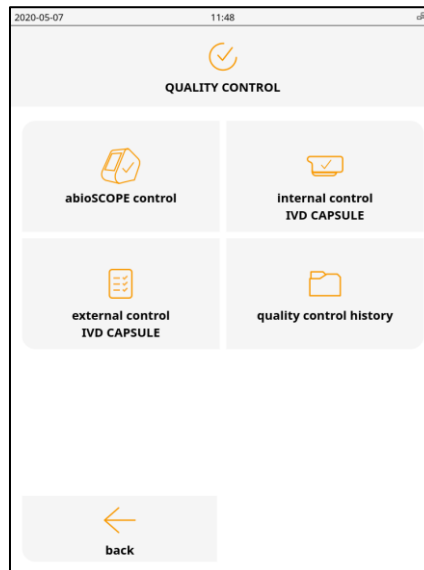


Then, press one of the different buttons to continue.



## Quality control

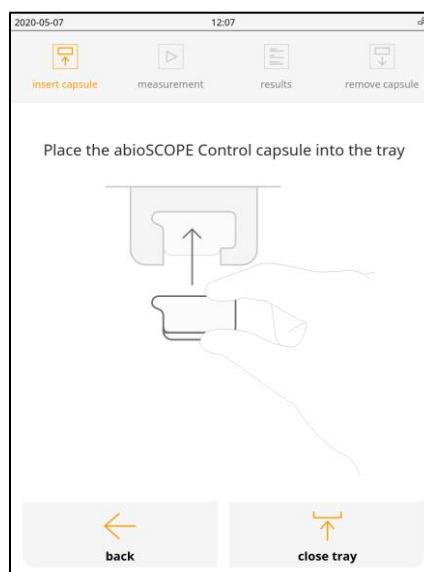
To perform the different types of quality control and to list the quality controls already performed on the device, press "quality control":



Then press on the button corresponding to the desired function.

### abioSCOPE control

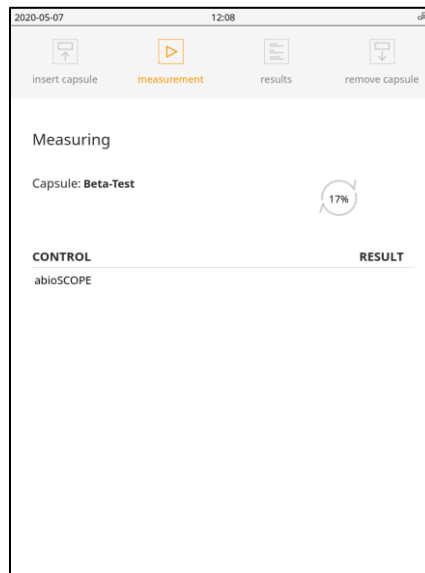
This quality control checks the device capsule measurement functionality. It uses a control capsule (manufactured by Abionic) that is different from the standard IVD CAPSULE. By pressing "abioSCOPE control" the following screen is displayed:



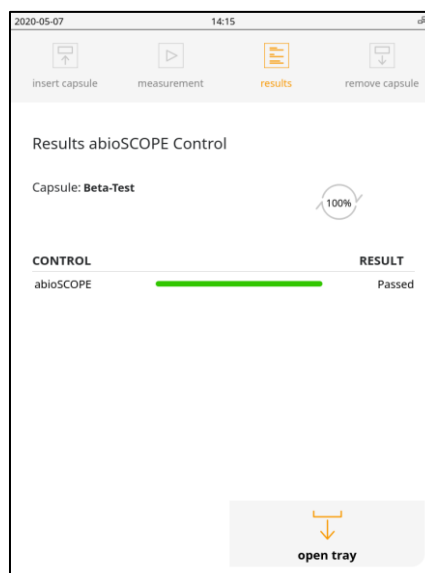
The tray opens. Place the abioSCOPE Control capsule into the tray and make sure that the capsule is correctly set in the tray.

After placing the capsule, close the tray by touching "close tray" on the screen. Be careful not to trap your fingers when closing the tray.

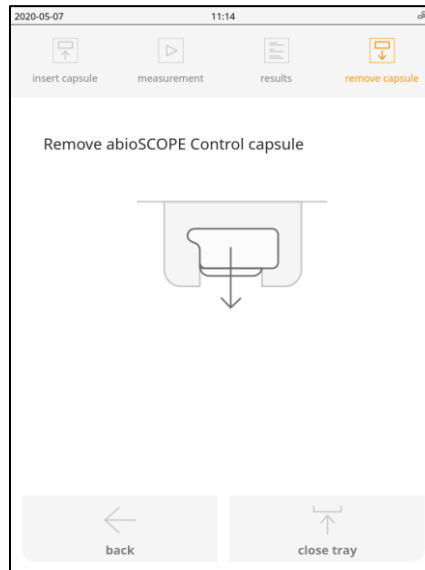
The abioSCOPE control will now start and a circle progress bar will be displayed:



When finished, the test result is displayed:



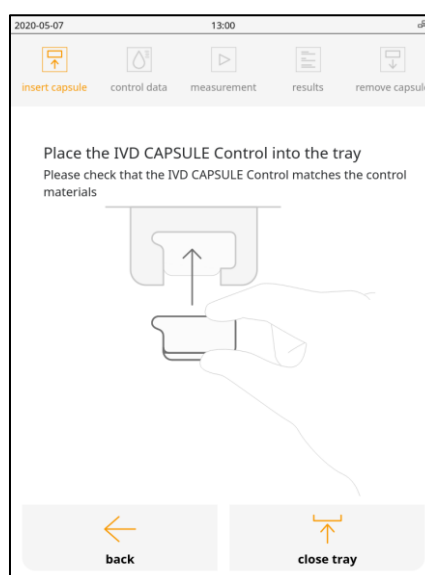
Touch “open tray” to open the tray and retrieve the abioSCOPE control capsule. The screen changes to the following:



Then touch “close tray” to close the tray and go back to the configuration start screen. You can also touch “back” to display the control result.

### ***IVD CAPSULE internal control***

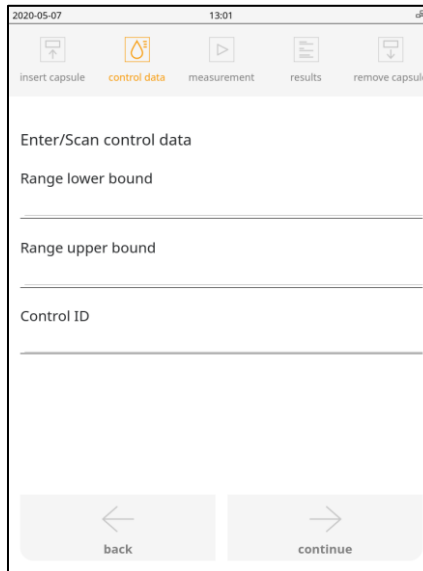
This quality control checks a specific test using a control kit including a standard IVD CAPSULE and a control mix sample. The control kit is manufactured by Abionic. By pressing “IVD CAPSULE internal control” the following screen is displayed:



The tray opens. Place the capsule filled with the sample into the tray and make sure that the capsule is correctly set in the tray.

After placing the capsule close the tray by touching "close tray" on the screen. Be careful not to trap your fingers when closing the tray.


The following screen is then displayed:



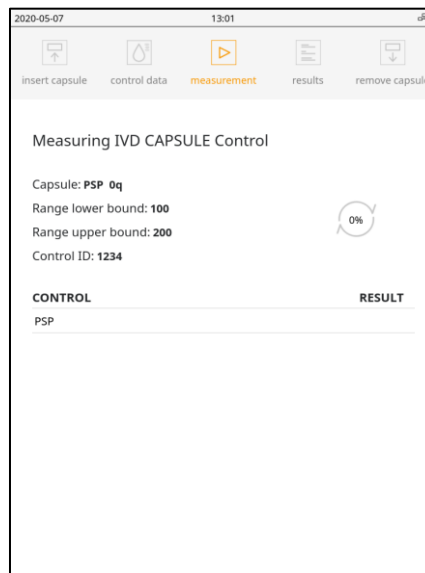
The next screen requires the user to input the control range lower and upper bounds and a control ID.

The control range lower and upper bounds are provided in the kit.

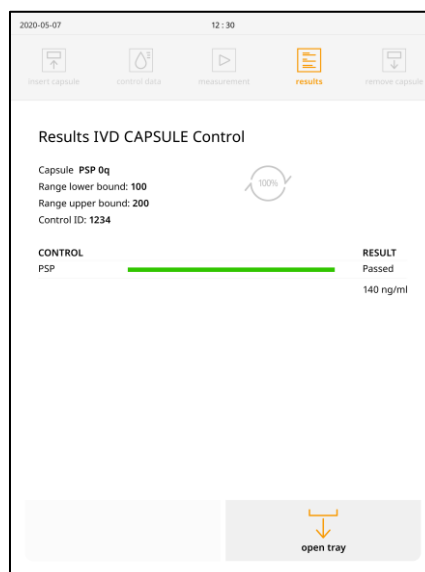
Select fields by touching the relevant white area. Enter the information using the keyboard or another input device connected.

| Warning   |  |
|---|--|
|  | <p>Always check carefully that the data entered on this screen is correct.</p> |

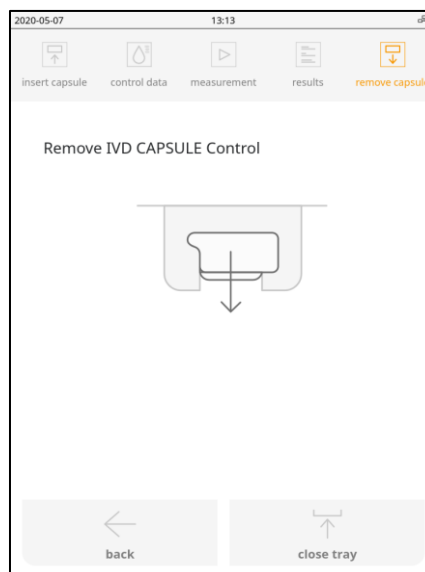
Press “continue” and the IVD CAPSULE internal control will then start and a circle progress bar will be displayed:



When finished, the test result is displayed:



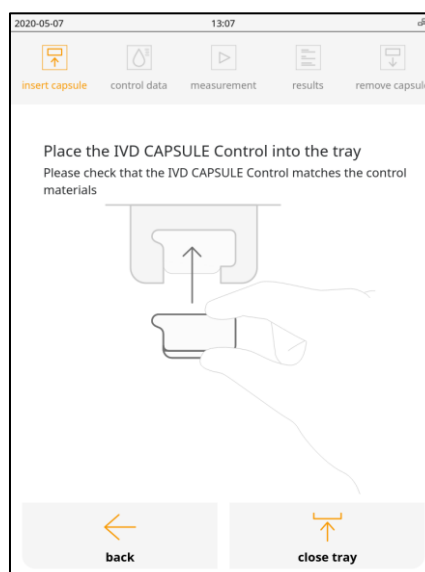
Touch "open tray" to open the tray and retrieve the control capsule. The screen changes to the following:



Then touch "close tray" to close the tray and go back to the configuration start screen. You can also touch "back" to display the control result.

### ***IVD CAPSULE external control***

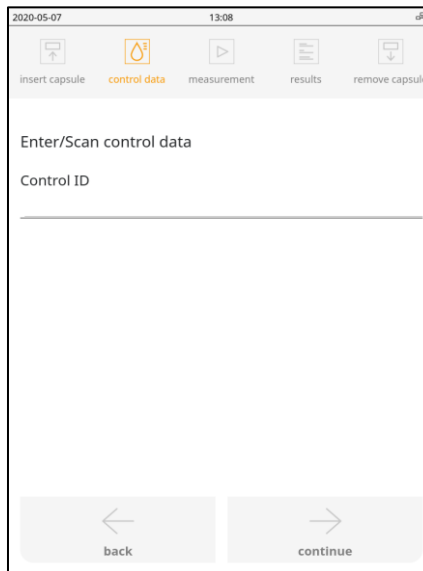
This quality control checks a specific test using a standard IVD CAPSULE and a control sample provided by external source. By pressing "IVD CAPSULE external control" the following screen is displayed:



The tray opens. Place the capsule filled with the sample into the tray and make sure that the capsule is correctly set in the tray.


After placing the capsule close the tray by touching “close tray” on the screen. Be careful not to trap your fingers when closing the tray.

The following screen is then displayed:

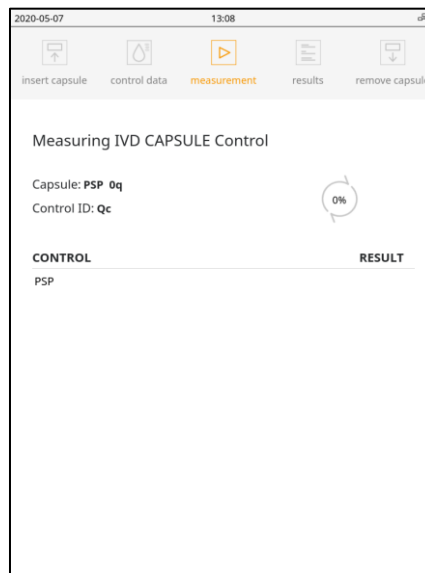


The next screen requires the user to input a control ID.

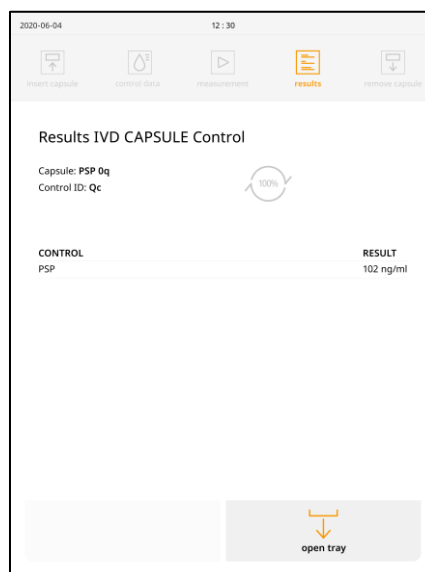
Select the field by touching the relevant white area. Enter the information using the keyboard or another input device connected.

| Warning   |  |
|---|--|
|  | <p>Always check carefully that the data entered on this screen is correct.</p> |

Press “continue” and the IVD CAPSULE external control will then start and a circle progress bar will be displayed:

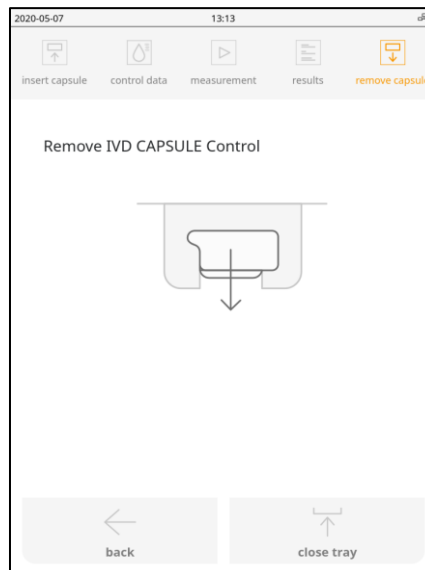


When finished, the test result is displayed:





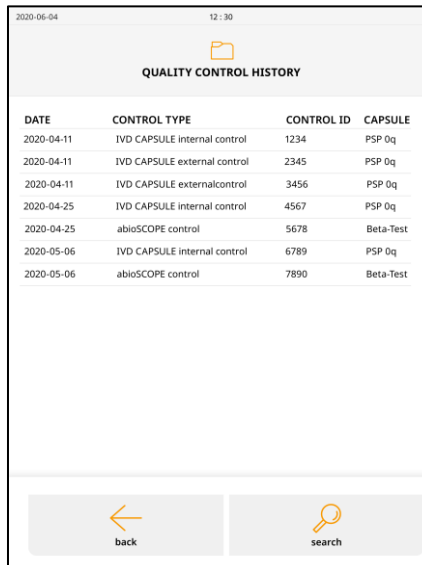
Touch "open tray" to open the tray and retrieve the control capsule. The screen changes to the following:



Then touch "close tray" to close the tray and go back to the configuration start screen. You can also touch "back" to display the control result.

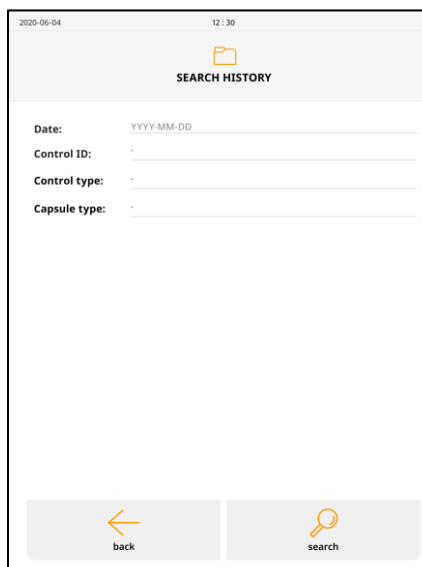
### Quality control history

To consult the quality controls previously made on this abioSCOPE, touch “quality control history”:



| DATE       | CONTROL TYPE                 | CONTROL ID | CAPSULE   |
|------------|------------------------------|------------|-----------|
| 2020-04-11 | IVD CAPSULE internal control | 1234       | PSP 0q    |
| 2020-04-11 | IVD CAPSULE external control | 2345       | PSP 0q    |
| 2020-04-11 | IVD CAPSULE externalcontrol  | 3456       | PSP 0q    |
| 2020-04-25 | IVD CAPSULE internal control | 4567       | PSP 0q    |
| 2020-04-25 | abioSCOPE control            | 5678       | Beta-Test |
| 2020-05-06 | IVD CAPSULE internal control | 6789       | PSP 0q    |
| 2020-05-06 | abioSCOPE control            | 7890       | Beta-Test |

To search the results archive, touch “search”. There you can search by date, control ID, control type and capsule type:

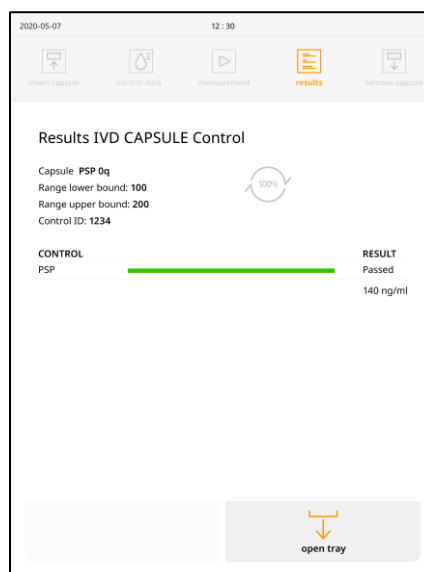


**Date:**   
**Control ID:**   
**Control type:**   
**Capsule type:**

Touch “search” to initiate the search and display the search result:



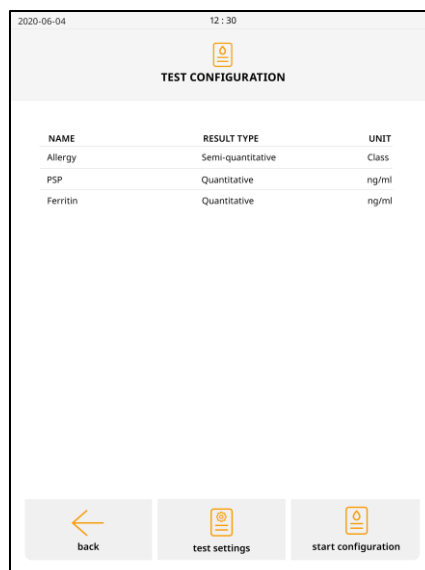
Touching a previous control will display the details of the results of this control, for instance for the abioSCOPE control:



Touch “back” to return to the quality control history.

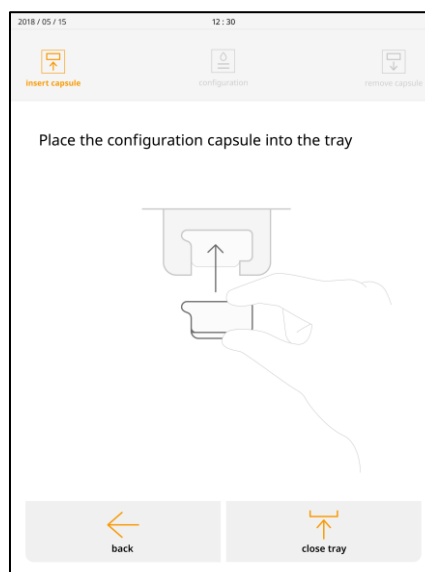
## Test configuration

To display the tests currently configured in the device press "test configuration":



The different configured tests are listed, together with the type of result (either quantitative or semi-quantitative; note: in this screen a qualitative test is considered as a special case of semi-quantitative test with only two classes, positive and negative) and the unit ("class" for semi-quantitative result type, or unit for quantitative results, for instance "ng/ml").

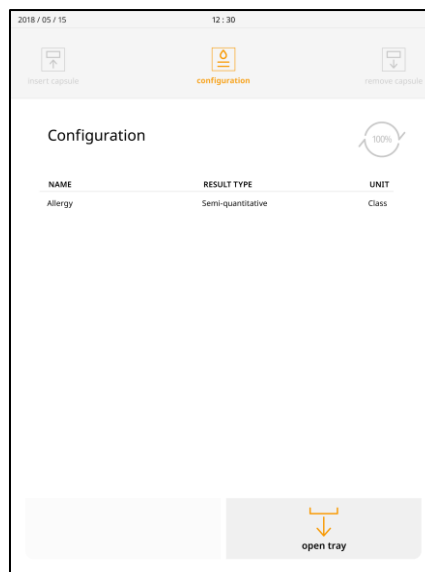
To configure a new type of test in the device, please contact Abionic to receive the corresponding configuration capsule. Then press "start configuration":



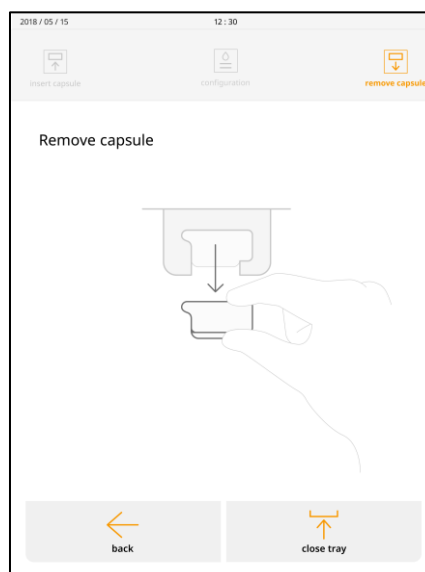
The tray opens. Place the configuration capsule into the tray and make sure that the capsule is correctly set in the tray.

After placing the capsule close the tray by touching "close tray" on the screen. Be careful not to trap your fingers when closing the tray.

The configuration will now start and a circle progress bar will be displayed. Only a few seconds are needed to complete it. When finished, the new configuration is displayed:

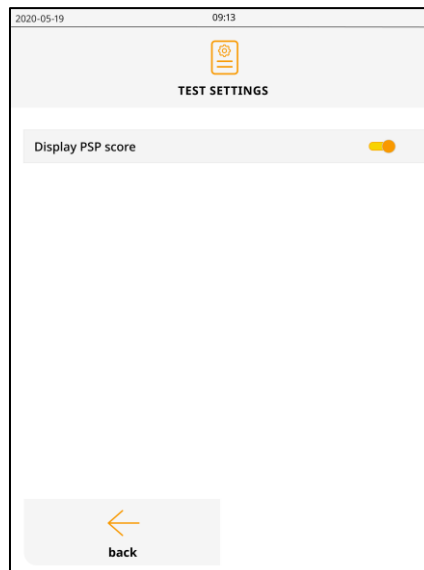


Touch "open tray" to open the tray and retrieve the configuration capsule. The screen changes to the following:

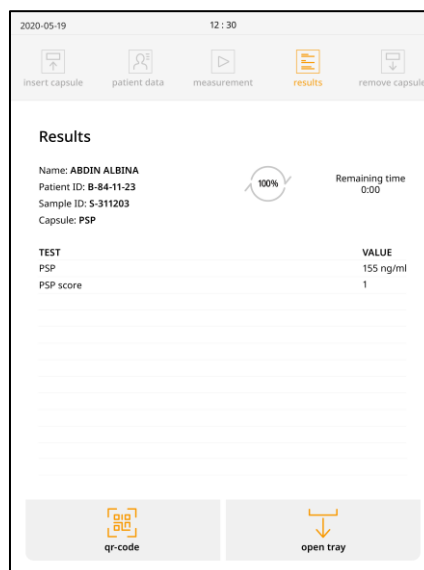


Then touch "close tray" to close the tray and go back to the configuration start screen. You can also touch "back" to display the configuration result.

On the test configuration screen, there is the possibility to change settings related to the tests by touching “test settings”:

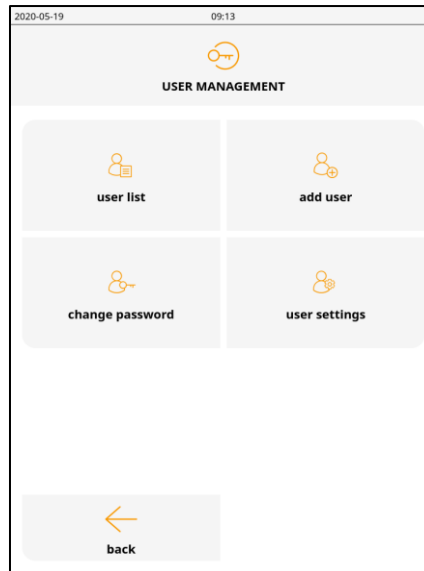


With the PSP score activated, it is displayed below the PSP concentration on the result screen:



## ***User management***

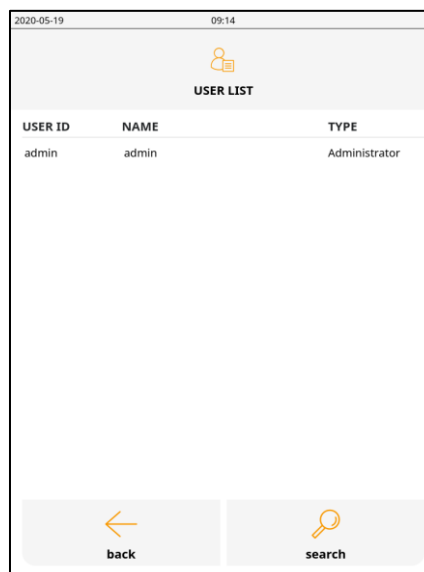
To manage the different users, press “user management”:



Then press on the button corresponding to the desired function.

### ***User list***

To display the list of users, touch “user list”. The following screen is then displayed (here is an example):

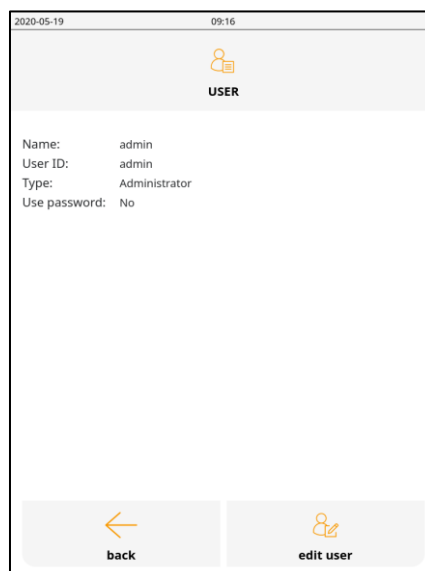


For each user, the list contains the user ID, the name and the type:

- User ID: used on the login screen
- Name: name of the user (not used to login)
- Type: The type of user defines what kind of actions that user can perform. The different types of users are "Operator", "Supervisor", "IT Operator" and "Administrator"
  - Operators can
    - Execute capsule tests
    - Execute and view quality controls
    - Execute and view test configurations
  - Supervisors can
    - Perform the same operations as an operator
    - Handle user management and sets user rights
    - Access to and modify archived results.
    - Perform non-IT configuration operations.
  - IT Administrators can
    - Perform IT configuration operations.
  - Administrators can
    - Perform every task

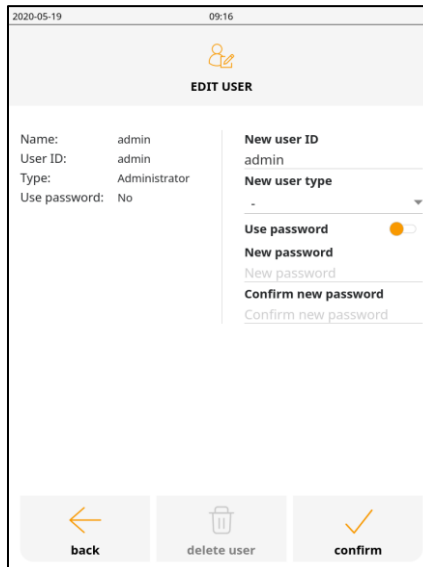
To go back to user management press "back". It is then possible to display the details of a user by pressing on its line or to search specific users by pressing "search".

Touching the line of a user will display the user as in the following screen:





It is then possible to edit the user information by touching “edit user”:



2020-05-19 09:16

**EDIT USER**

Name: admin  
User ID: admin  
Type: Administrator  
Use password: No

New user ID  
admin

New user type  
-

Use password ☒

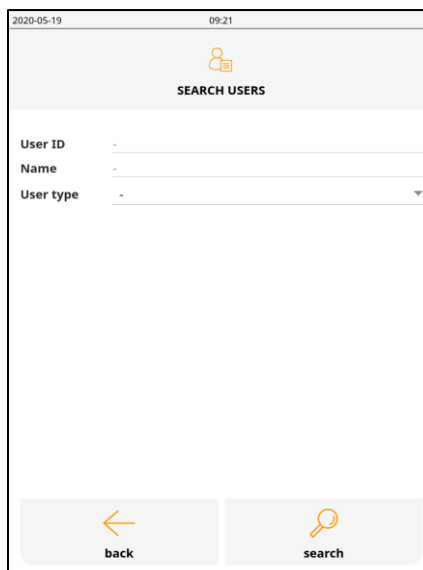
New password  
New password

Confirm new password  
Confirm new password

back delete user confirm

From there, the user ID, user type and password can be changed. It is also possible to delete the user (except the first administrator user). Touching “confirm” will update the user while pressing “back” will cancel the changes.

Back on the user list screen, touching “search” will display the following screen:



2020-05-19 09:21

**SEARCH USERS**

User ID  
-

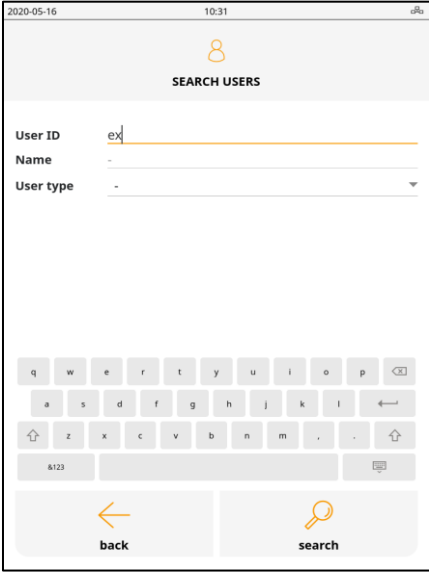
Name  
-

User type  
-

back search

Then it is possible to search by user ID, name and user type.

For user ID and name the virtual keyboard is used:



2020-05-16 10:31

SEARCH USERS

User ID ex

Name -

User type -

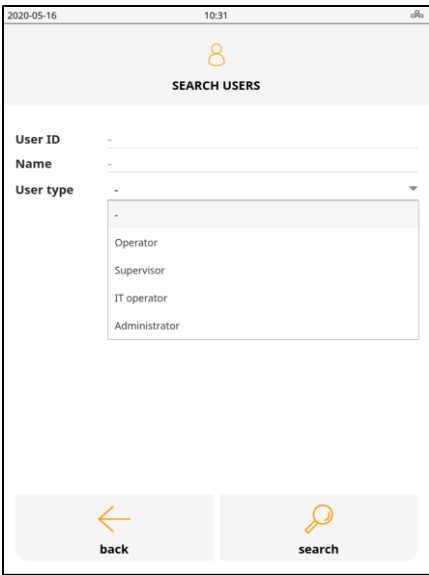
q w e r t y u i o p

a s d f g h j k l

z x c v b n m , .

back search

For user type a drop-down list is used:



2020-05-16 10:31

SEARCH USERS

User ID -

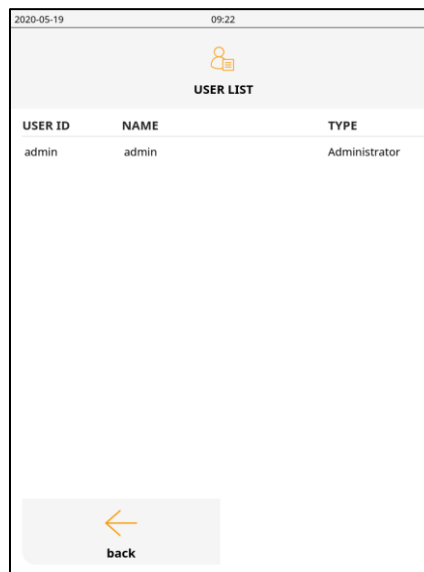
Name -

User type -

- Operator
- Supervisor
- IT operator
- Administrator

back search

When ready, press search to display the list of users that correspond to the search criteria:



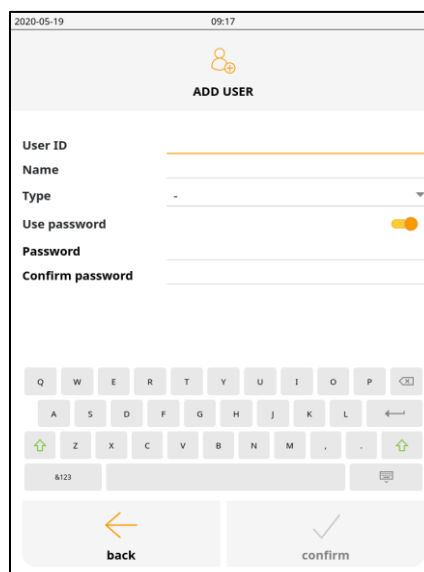
The screenshot shows a mobile application interface titled "USER LIST". At the top, there is a status bar with the date "2020-05-19" and time "09:22". Below the status bar is a header with a user icon and the title "USER LIST". The main content area displays a table with three columns: "USER ID", "NAME", and "TYPE". The table contains one row with the values "admin", "admin", and "Administrator". At the bottom of the screen, there is a "back" button with a left-pointing arrow.

| USER ID | NAME  | TYPE          |
|---------|-------|---------------|
| admin   | admin | Administrator |

Press back to return to the full user list.

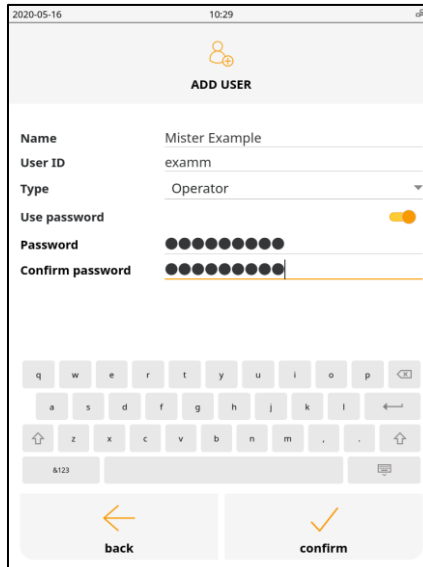
### **Add user**

By touching "add user" new users can be created:



The screenshot shows a mobile application interface titled "ADD USER". At the top, there is a status bar with the date "2020-05-19" and time "09:17". Below the status bar is a header with a user icon and the title "ADD USER". The main content area contains several input fields: "User ID", "Name", "Type" (a dropdown menu), "Use password" (a toggle switch), "Password", and "Confirm password". At the bottom of the screen, there are two buttons: "back" with a left-pointing arrow and "confirm" with a checkmark. A virtual keyboard is visible at the bottom of the screen.

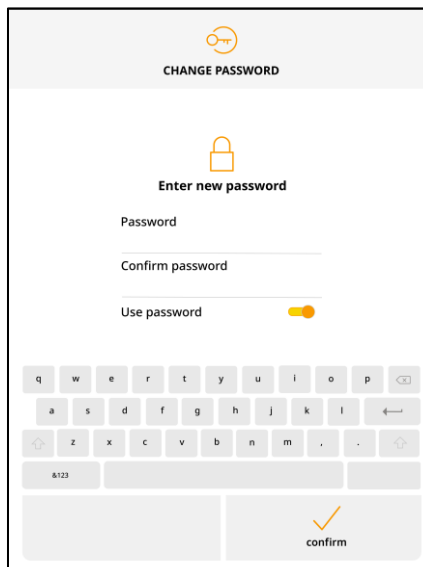
Below is an example of the creation of a new user:



Touching “confirm” will create the new user while pressing “back” will cancel this user creation.

### ***Change password***

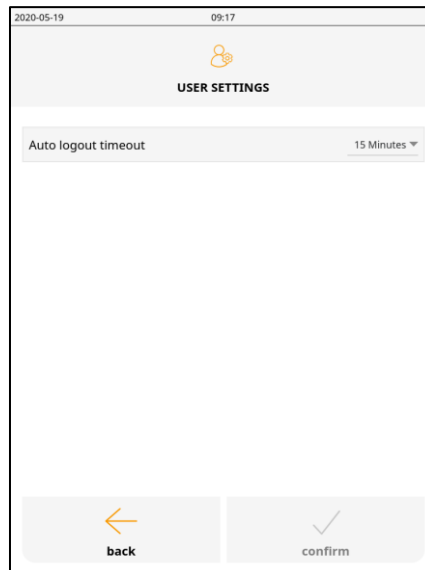
By touching “change password”, it is possible to change its own password:



Touching “confirm” will update the password while pressing “back” will cancel the changes.

### ***User settings***

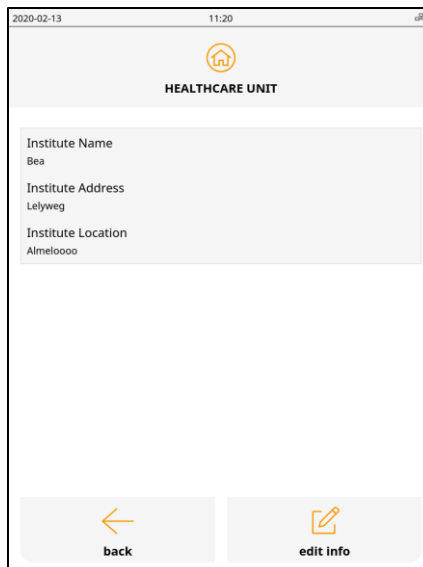
The user settings can be accessed by touching “user settings”




The automatic logout time can be changed on this screen (same value for every user). Touching “confirm” will update the password while pressing “back” will cancel the changes.

## Healthcare unit

It is possible to register the details of the healthcare unit information by touching "healthcare unit":





2020-02-13 11:20

 **HEALTHCARE UNIT**

Institute Name  
Bea

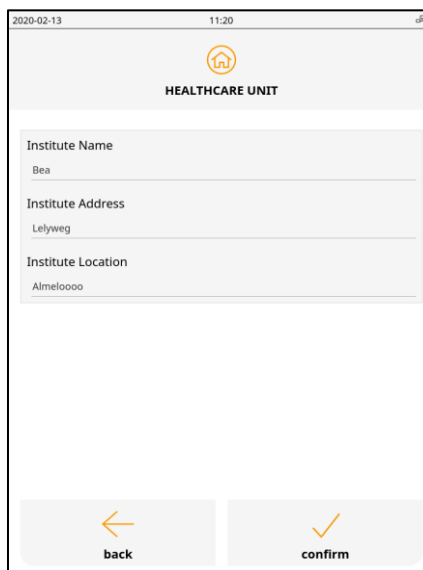
Institute Address  
Lelyweg

Institute Location  
Almeloooo


 back  edit info

This information will appear in the results file that is stored on the internal memory.

By touching "edit info" the healthcare unit information can be added or be modified:





2020-02-13 11:20

 **HEALTHCARE UNIT**

Institute Name  
Bea

Institute Address  
Lelyweg

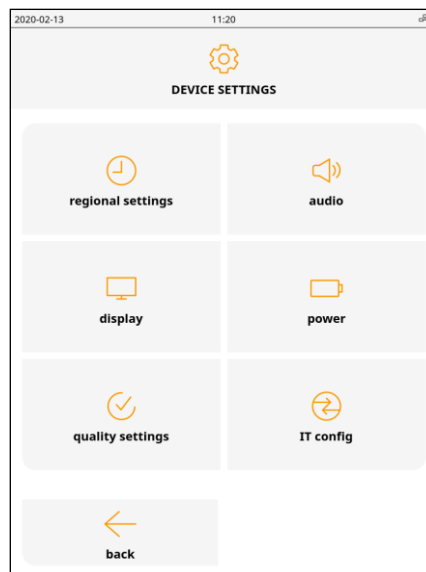
Institute Location  
Almeloooo

 back  confirm

Select the appropriate field by touching the corresponding white area, enter the information using the keyboard and touch "confirm" when finished. This information will remain in the system until changed.

## Device settings

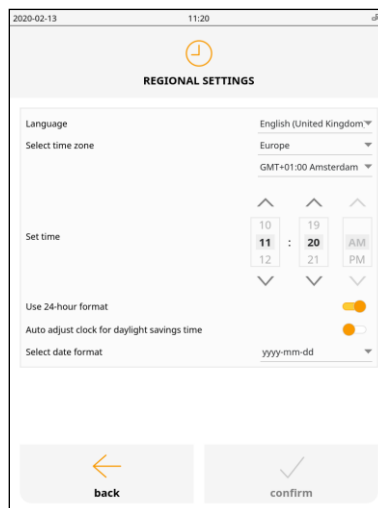
It is possible to change the device settings by touching "device settings":



Touch the corresponding button to access their settings.

## Regional settings

It is possible to change the regional settings by touching "regional settings":

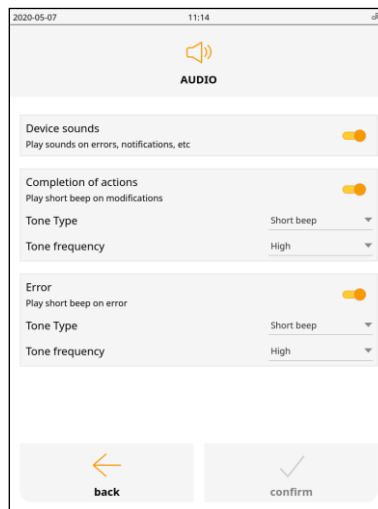


From there, the language, country, time zone, hour, hour format (12h/24h), daylight saving time and date format can be changed.

Touch "confirm" to apply the changes or "back" to cancel; the device settings menu is then displayed.

## Audio

The audio settings can be changed by touching “audio”:



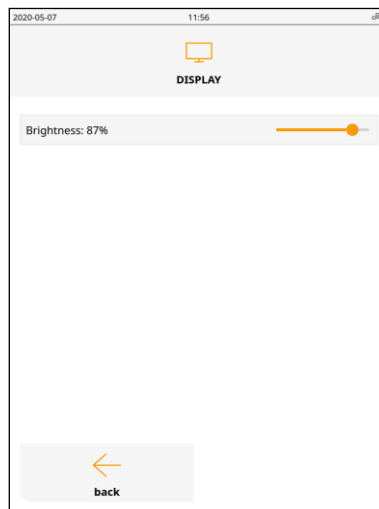
The device audio notifications can be enabled and disabled altogether with the first option. Then, the audio notification of the completion of actions (for instance the completion of a capsule measurement) and errors can be enabled or disabled independently. Also, the duration and tone of the audio notification can be set for both.

Touch “confirm” to apply the changes or “back” to cancel; the device settings menu is then displayed.



## ***Display***

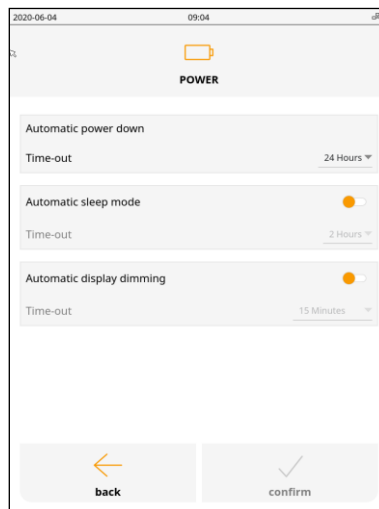
The display settings can be changed by touching “display”:



The display brightness can be set here by changing the slider control.

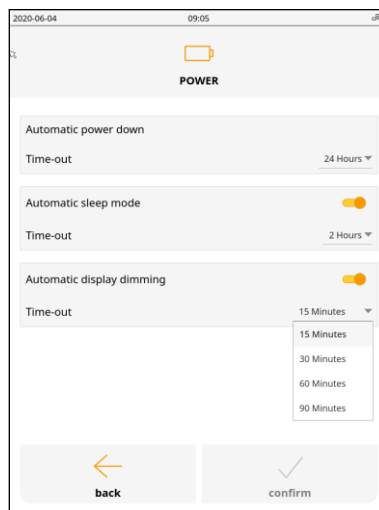
## Power

The power saving settings can be changed by touching "power":



The following power saving options can be individually enabled and the time to trigger them can be selected:

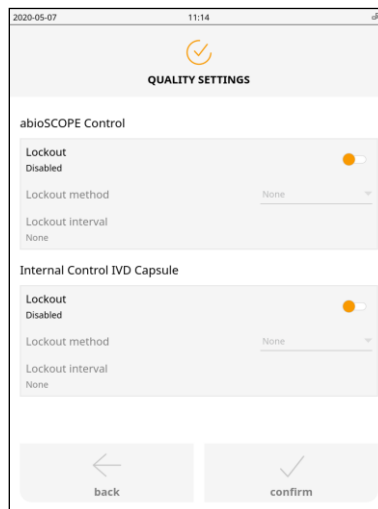
- Time to display dimming (display brightness set to 25%)
- Time to device sleep state (turn off the display backlight)
- Time to automatic power down



Touch "confirm" to apply the changes or "back" to cancel; the device settings menu is then displayed.

### Quality settings

The lockout settings for the different types of quality controls can be set by touching “quality settings”:

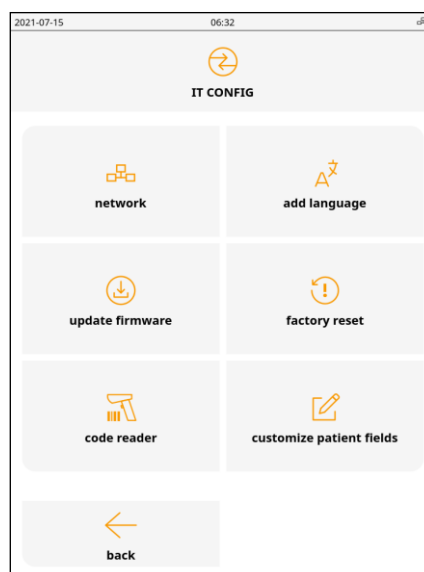


The lockout can be configured independently for the abioSCOPE control and the IVD CAPSULE internal control. First, the lockout can be enabled or disabled. If the lockout is enabled, the lockout method can either use the number of capsule tests or the time interval defined here.

Touch “confirm” to apply the changes or “back” to cancel; the device settings menu is then displayed.

### IT config

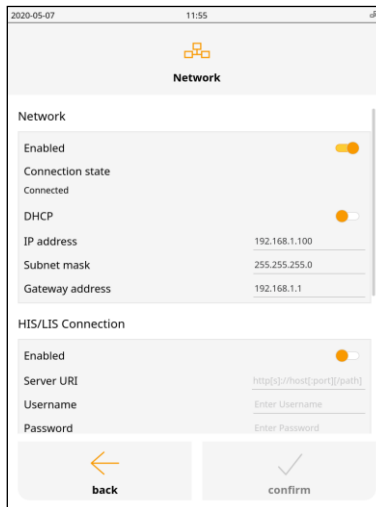
From the device settings display, touch “IT config” to get to the following menu:



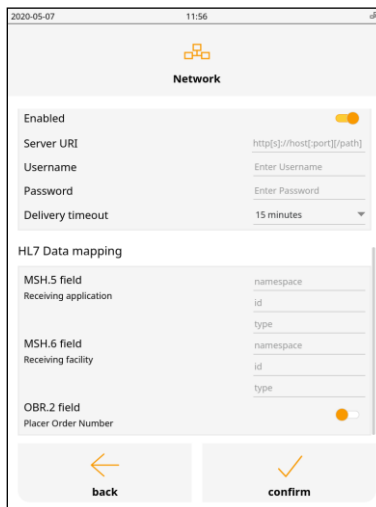
Touch the corresponding button to access their settings.

## Network

The network settings can be set by touching “network”:



The network functionality (using the Ethernet connection) can be enabled or disabled altogether. If enabled the connection status is indicated. Then the DHCP can be enabled or disabled and configured. The HIS (Hospital Information System) / LIS (Laboratory Information System) connection can be enabled or disabled and configured. A scrollbar on the right-hand side of the display is used to access all the settings:

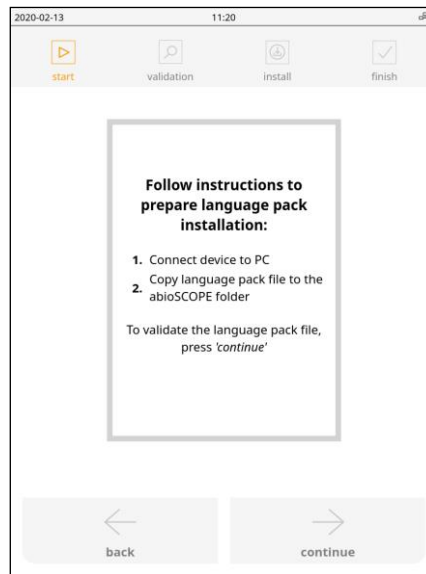


By enabling the OBR.2 field (Placer Order Number), an additional text field named “Order ID” will be present on the input patient and sample data screen.

Touch “confirm” to apply the changes or “back” to cancel; the device IT settings menu is then displayed.

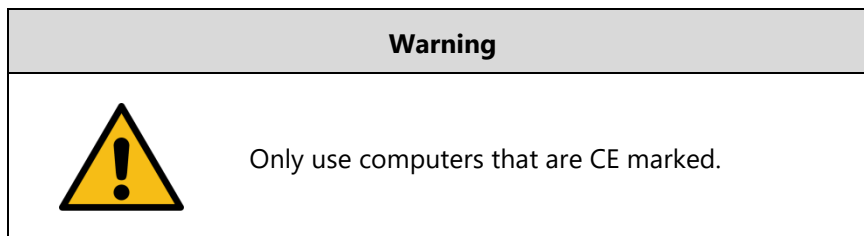
### Add language

It is possible to add another language by importing a language pack provided by Abionic. Touch the "add language" button:

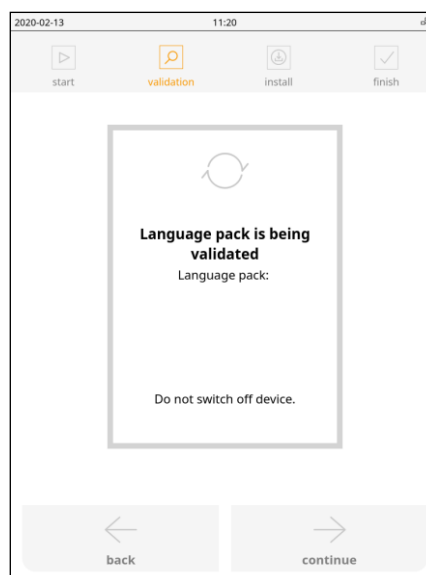


To proceed, follow the instructions on the display:

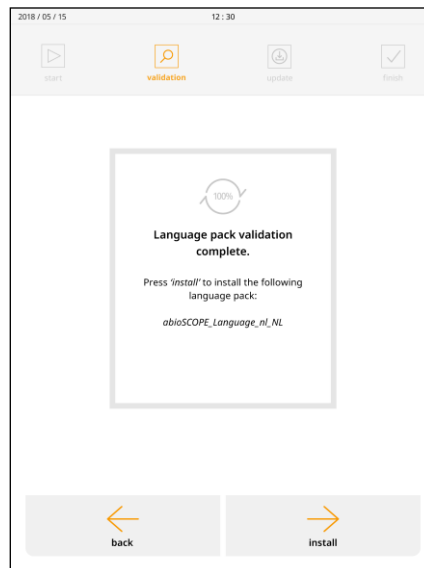
- With a USB cable connect your computer to the abioSCOPE "Computer connection" connector
- Copy the language pack provided by Abionic to the abioSCOPE folder that just appeared



You can then either go back to the previous screen or go on with the process by touching "continue":

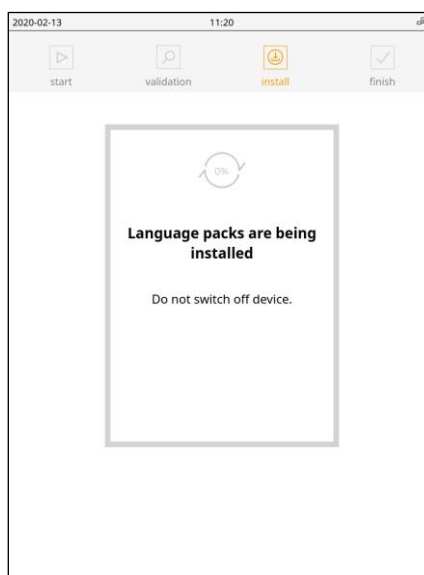


The device validates the language pack and will then display the following if successful:

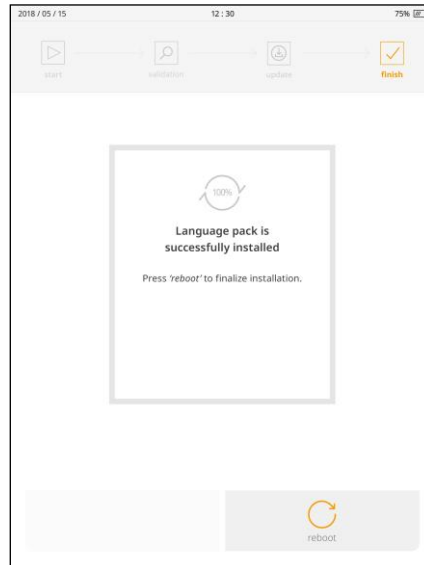


You can then either go back to the previous screen or go on with the process by touching "continue".

The device will proceed with the installation of the language pack:



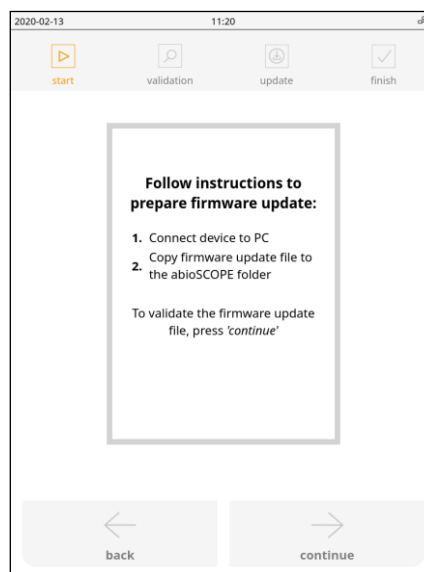
If the installation is finished successfully the following message is displayed:



When finished, touch “reboot” to reboot the device, which is needed to take into account this new language package.

### **Update firmware**

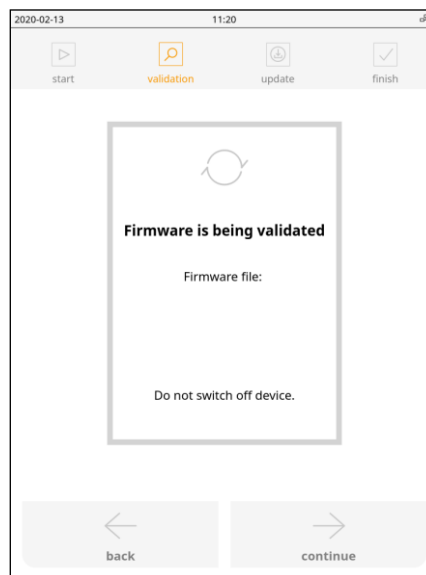
In order to update the firmware, touch the “update firmware” button:



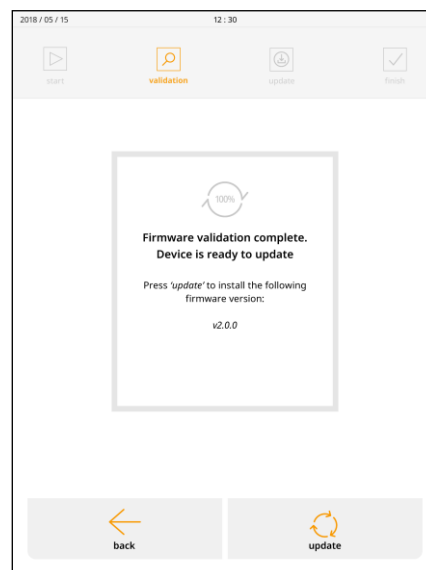
To proceed, follow the instructions on the display:

- With a USB cable connect your computer to the abioSCOPE “Computer connection” connector
- Copy the firmware file provided by Abionic to the abioSCOPE folder that just appeared

You can then either go back to the previous screen or go on with the process by touching “continue”:



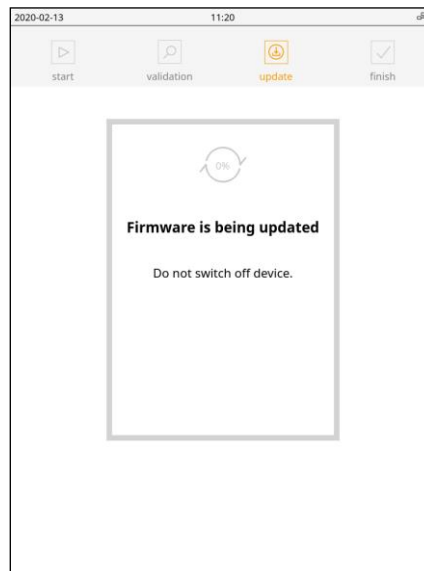
The device validates the firmware and will then display the following if successful:



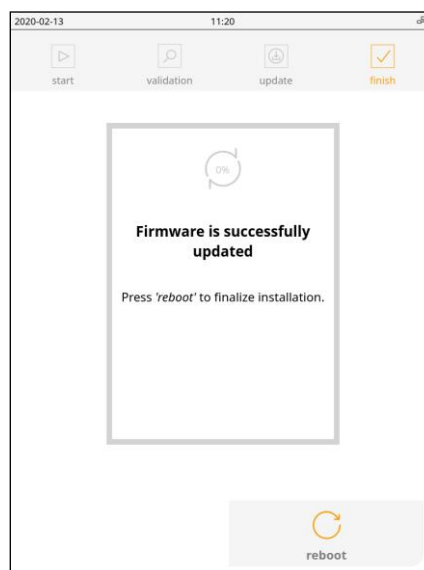


You can then either go back to the previous screen or go on with the process by touching “continue”.

The device will then proceed with the installation of the firmware:



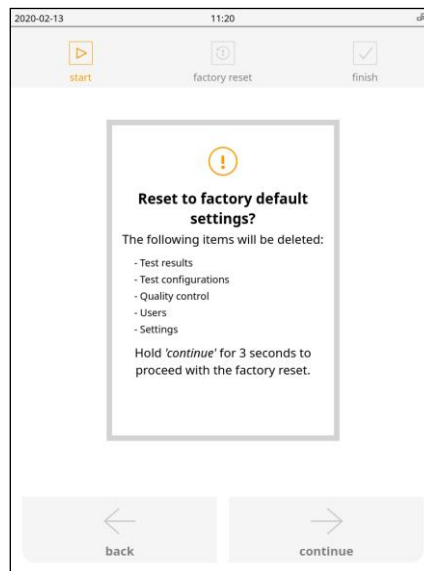
If the installation is finished successfully the following message is displayed:



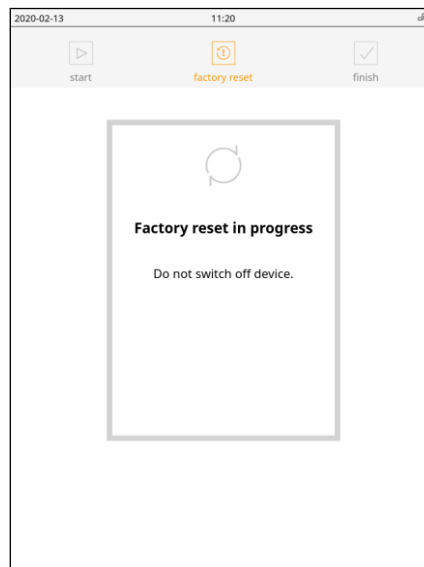
When finished, touch “reboot” to reboot the device, which is needed to take into account this new firmware.

### **Factory reset**

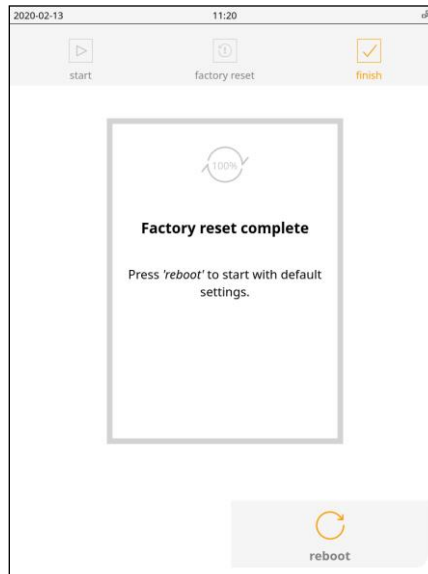
In order to reset the device to factory defaults, touch the “factory reset” button:



You can then either go back to the previous screen or go on with the process by touching “continue” for 3 seconds:



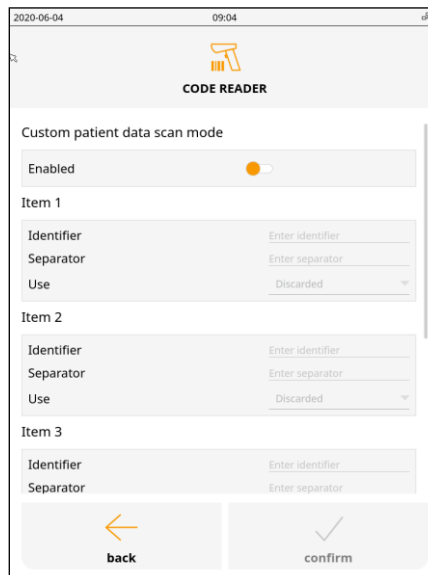
If the factory reset completes successfully the following message is displayed:



When finished, touch "reboot" to reboot the device, which is needed to finalize the factory reset.

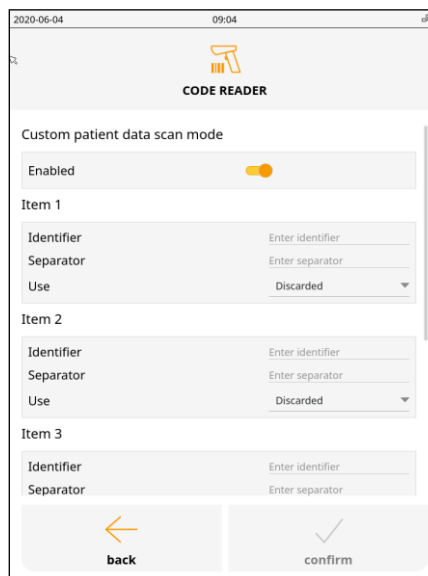
### Code reader

The way the code reader interprets patient data code can be defined by touching “code reader”:



The screenshot shows the 'CODE READER' screen. At the top, the date is 2020-06-04 and the time is 09:04. Below the title bar, there is a toggle switch for 'Custom patient data scan mode' which is currently turned off. Underneath, there are three items (Item 1, Item 2, Item 3). Each item has three input fields: 'Identifier' (with a placeholder 'Enter identifier'), 'Separator' (with a placeholder 'Enter separator'), and 'Use' (with a dropdown menu currently set to 'Discarded'). At the bottom, there are two buttons: 'back' (with a left arrow icon) and 'confirm' (with a checkmark icon).

This only changes the behavior of the patient data screen of capsule measurements (step 3 of the analysis procedure). By default, custom scan mode is deactivated, and the code reader simply appends the data in the text field currently selected. Custom mode can then be activated, and set-up is described below:



This screenshot is identical to the previous one, but the 'Custom patient data scan mode' toggle switch is now turned on (indicated by an orange dot). The rest of the interface, including the three items and the bottom buttons, remains the same.

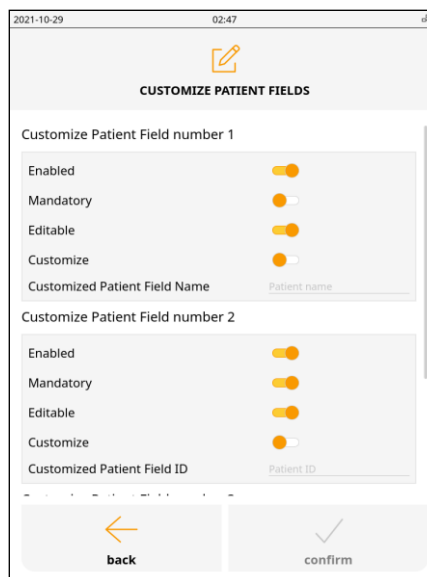
The QR / barcode is treated as sequential items that contain information to be used to fill a text field or be discarded. There can be a maximum of 5 items. An item consists of the following elements:

- Identifier: part of the code that indicates the content of the text that follows but that should not be present in the text fields; can be configured
  - Examples: "ID", "ID:", "ID<space>", "ID:<space>", "Name", nothing
- The content itself (no configuration)
- Separator (up to 3 characters or character code can be configured): used to separate the different information; can be configured
  - Examples: "^", "\*", "|"
  - Exhaustive list of separators using the escape character "\":
    - "\n" (new line)
    - "\r" (carriage return)
    - "\t" (tabulation),
    - "\\" (backslash)
- Use: the text field to fill with the content can be configured between the patient name, the patient ID, the sample ID and none (discard)

### ***Customize measurement data input***

It is possible to customize the three measurement data input fields independently of each other in different ways:

- It is possible to enable or disable an input field (at least one field has to be enabled). A disabled field will not be present on the measurement data input screen.
- It is possible to make a field mandatory or not (at least one field has to be mandatory). A mandatory field has to be filled on the measurement data input screen.
- It is possible to make a field editable in the test archive. An editable field can be changed after the measurement in the test archive by a user with sufficient rights.
- It is possible to customize the data input text headers. By default, the customization for each of the 3 fields is deactivated and the default name written in grey next to "Customize Patient Field Name" is used. By activating the customization of a field, it is then possible to write the content desired.



2021-10-29 02:47

**CUSTOMIZE PATIENT FIELDS**

Customize Patient Field number 1

Enabled ☒

Mandatory ☒

Editable ☒

Customize ☒

Customized Patient Field Name

Customize Patient Field number 2

Enabled ☒

Mandatory ☒

Editable ☒

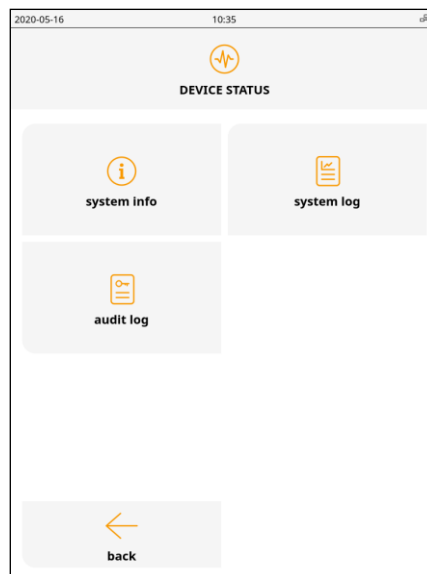
Customize ☒

Customized Patient Field ID

Once every desired field has been customized, touch "confirm" to apply the changes.

## Device status

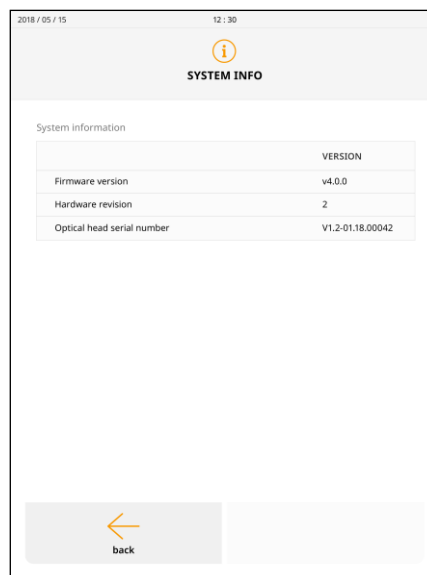
Some options on the device status are accessible by touching "device status":



Touch the corresponding button to access their settings.

## System info

By touching "system info", the user can see the firmware version, the hardware revision and the optical head number:



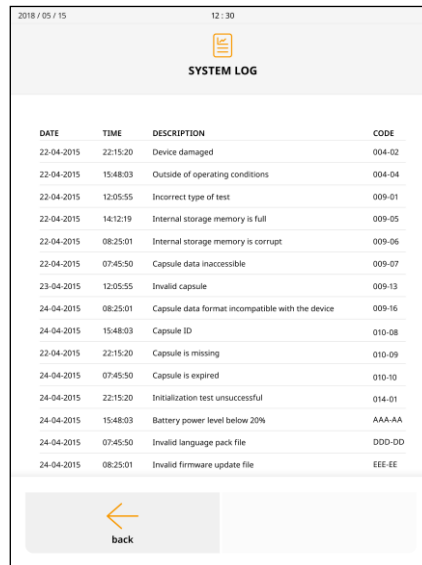
It is also possible to view the firmware version and in addition the license manifest on your computer:

- Power-down the device
- Connect your computer with a USB cable to the abioSCOPE "Computer connection" connector
- Power-up the device.

At the end of the start-up, a new disk will appear on your computer that contains one file with the firmware version and one file with the license manifest.

### System log

By touching “system log”, the user can display a list of system events:

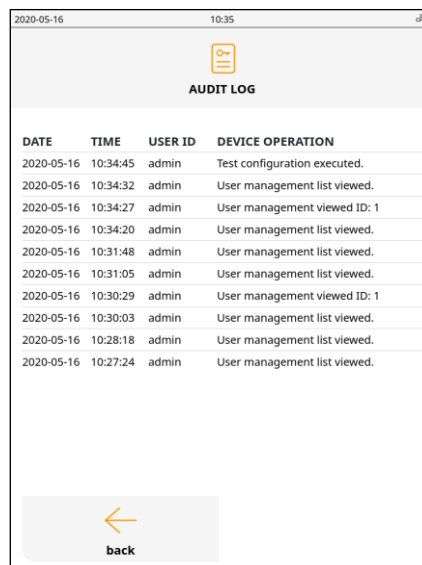


| DATE       | TIME     | DESCRIPTION                                      | CODE   |
|------------|----------|--|--------|
| 22-04-2015 | 22:15:20 | Device damaged                                   | 004-02 |
| 22-04-2015 | 15:48:03 | Outside of operating conditions                  | 004-04 |
| 22-04-2015 | 12:05:55 | Incorrect type of test                           | 009-01 |
| 22-04-2015 | 14:12:19 | Internal storage memory is full                  | 009-05 |
| 22-04-2015 | 08:25:01 | Internal storage memory is corrupt               | 009-06 |
| 22-04-2015 | 07:45:50 | Capsule data inaccessible                        | 009-07 |
| 23-04-2015 | 12:05:55 | Invalid capsule                                  | 009-13 |
| 24-04-2015 | 08:25:01 | Capsule data format incompatible with the device | 009-16 |
| 24-04-2015 | 15:48:03 | Capsule ID                                       | 010-08 |
| 22-04-2015 | 22:15:20 | Capsule is missing                               | 010-09 |
| 24-04-2015 | 07:45:50 | Capsule is expired                               | 010-10 |
| 24-04-2015 | 22:15:20 | Initialization test unsuccessful                 | 014-01 |
| 24-04-2015 | 15:48:03 | Battery power level below 20%                    | AAA-AA |
| 24-04-2015 | 07:45:50 | Invalid language pack file                       | DDD-DD |
| 24-04-2015 | 08:25:01 | Invalid firmware update file                     | EEE-EE |

The system log contains the following information: the date and time of the event, a short description and finally the error code. Every error code is referenced in the troubleshooting part of this manual: please refer to it to get more information on the events.

### Audit log

By touching “audit log”, the user can display a list of user operations:



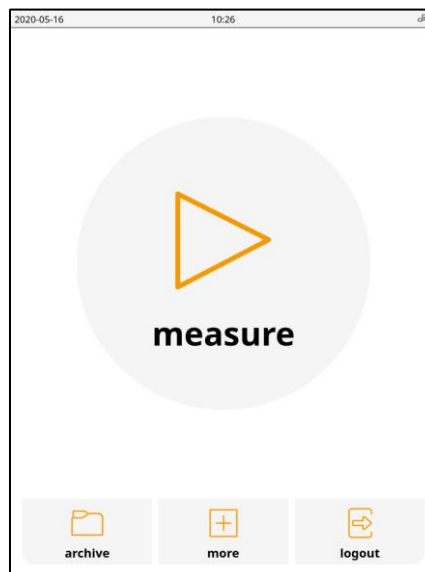
| DATE       | TIME     | USER ID | DEVICE OPERATION             |
|------------|----------|---------|------------------------------|
| 2020-05-16 | 10:34:45 | admin   | Test configuration executed. |
| 2020-05-16 | 10:34:32 | admin   | User management list viewed. |
| 2020-05-16 | 10:34:27 | admin   | User management viewed ID: 1 |
| 2020-05-16 | 10:34:20 | admin   | User management list viewed. |
| 2020-05-16 | 10:31:48 | admin   | User management list viewed. |
| 2020-05-16 | 10:31:05 | admin   | User management list viewed. |
| 2020-05-16 | 10:30:29 | admin   | User management viewed ID: 1 |
| 2020-05-16 | 10:30:03 | admin   | User management list viewed. |
| 2020-05-16 | 10:28:18 | admin   | User management list viewed. |
| 2020-05-16 | 10:27:24 | admin   | User management list viewed. |

The audit log contains the following information: the date and time of the event, the user that performed the operation and the description of the action.



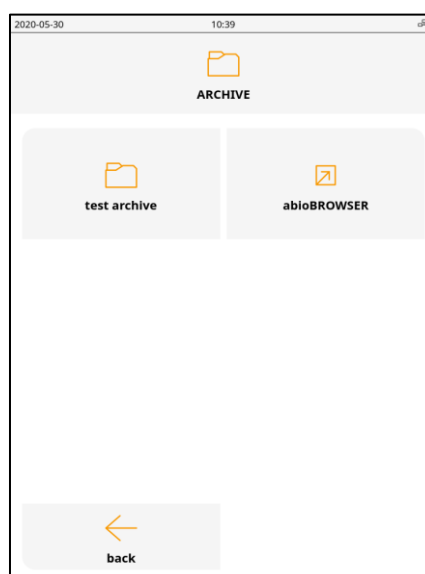
## 6 Test results archive

To consult the test results previously made on this abioSCOPE, turn the abioSCOPE on. The welcome screen will appear.

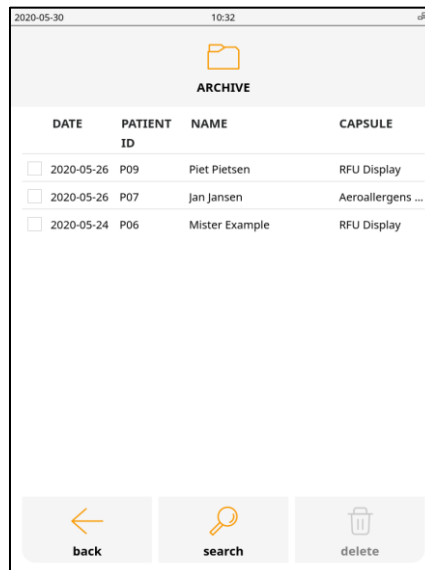


### Results archive on abioSCOPE

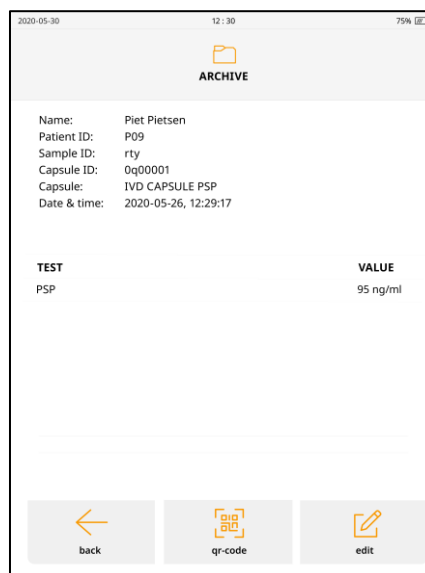
Touch “archive” on the Home screen:



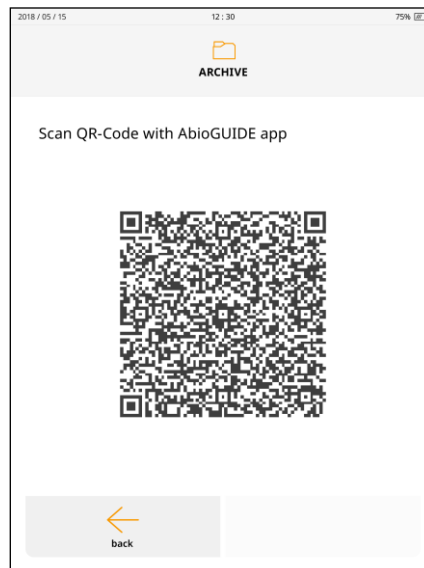
Then touch "test archive":



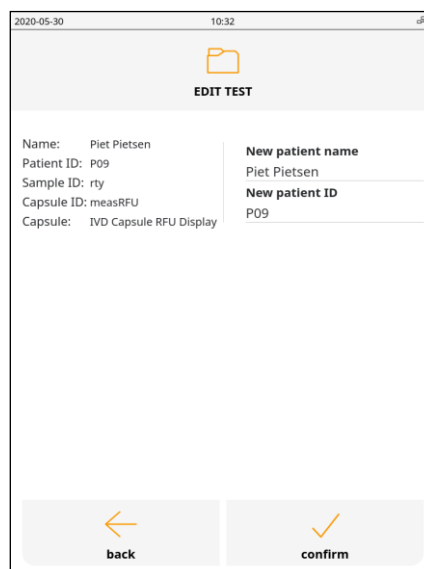
Touching an archived test will display the details of the results of this test:



By touching “qr code” a code will be displayed for retrieving results by the abioGUIDE application:

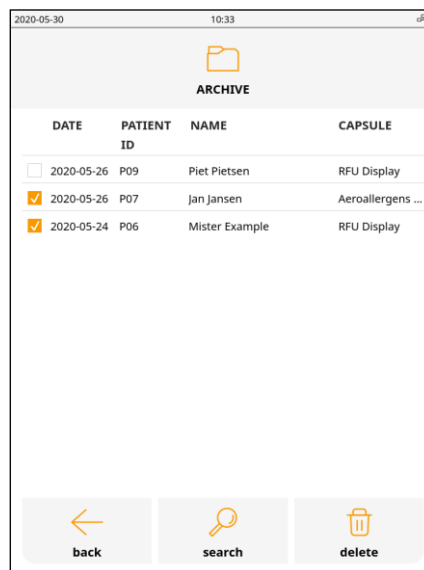


Touch “back” to return to the previous test results screen. Touching edit allows to edit the patient name and ID of a record:



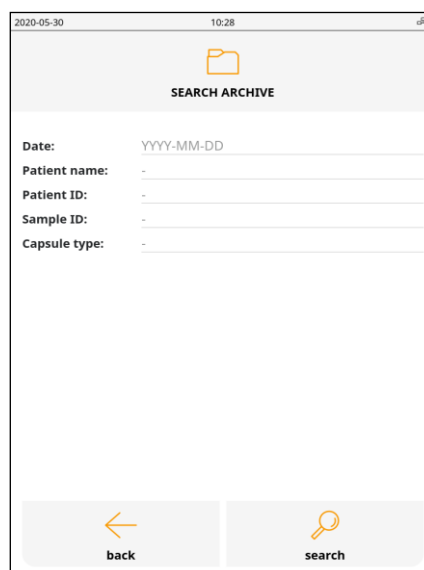
Touch “confirm” to apply the changes or “back” to cancel; test results are then displayed again.

Touch back to go to the whole test archive. There it is possible to select test results to be deleted:

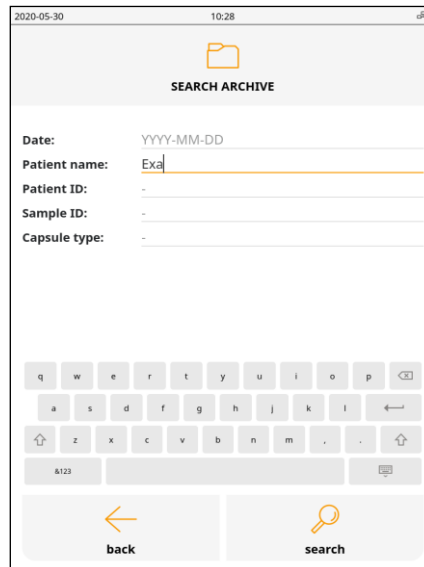


Touch "delete" to delete these results.

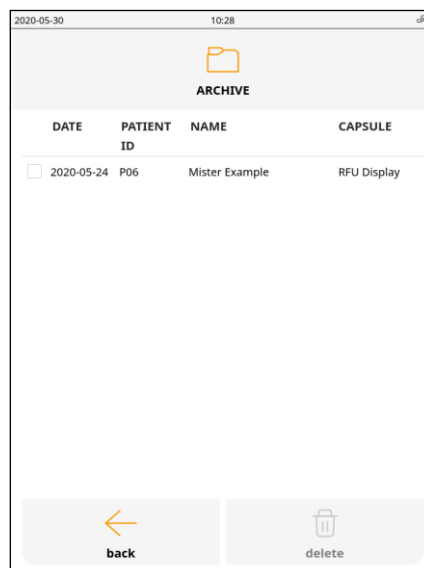
To search the results archive, touch "search":



There you can search by date, patient name, patient ID, sample ID and capsule type:

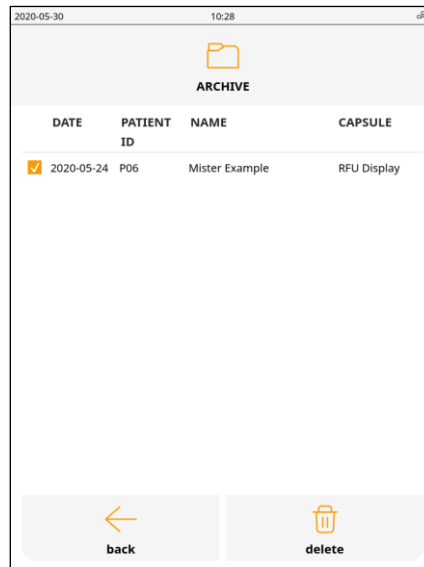


Touch "search" to initiate the search and display the search result:



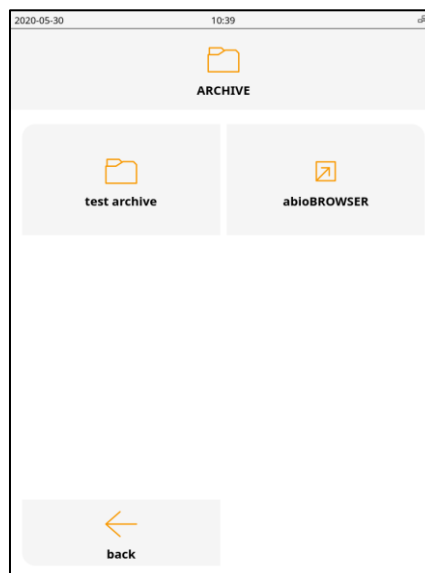
| DATE                                | PATIENT ID | NAME           | CAPSULE     |
|-------------------------------------|------------|----------------|-------------|
| <input type="checkbox"/> 2020-05-24 | P06        | Mister Example | RFU Display |

There you can also select and delete results:



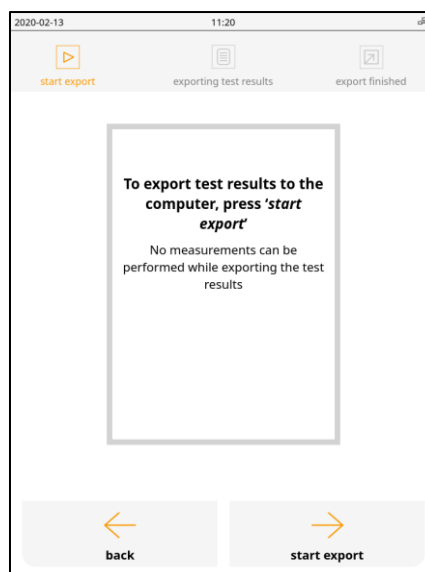
## ***Results archive on computer***

Back to the archive starting screen, it is possible to export the whole archive of results to a computer:

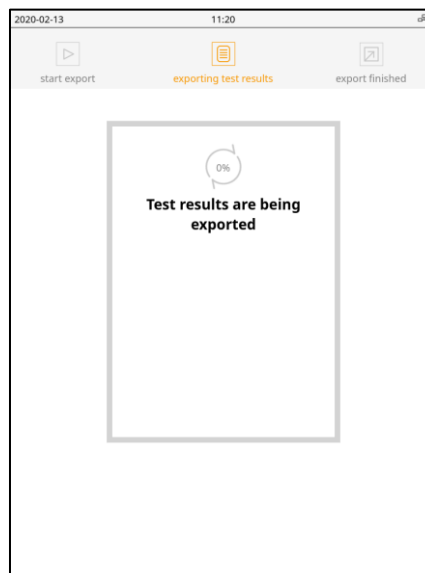


To do this:

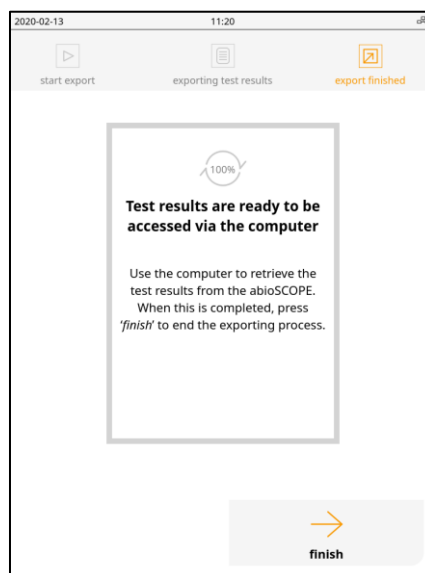
- Connect your computer with a USB cable to the abioSCOPE "Computer connection" connector
- Touch the "abioBROWSER" button (see previous figure). The following information appears on the display:



You can then either go back to the previous screen or start exporting the results by pressing "start export" (please note that no measurements can be performed during this process):




The device will prepare the export and when finished will display the following screen:





In addition, a new drive will pop-up on the computer, where the results of the archive can be accessed. To start the application on the web browser of your computer, double-click on the file abioBROWSER.html on the disk.

**Note**




Recommended requirements:

- Firefox (32+), Google Chrome (40+), Opera (25+), or Safari (9.1+), Edge (12+)
- Windows XP, Vista, 7, 8, 10 or later
- Mac OS X 10.4 or later


Note: in case your browser is not supported, a link to download a suitable web browser will be displayed


The homepage displays the last 20 results generated by the abioSCOPE, which can be changed to 50 or to “all” with the control on the bottom left of the test list. Also, the different pages can be displayed with the page number indicator on the bottom right of the test list. Below is an example:


EN

| <input type="checkbox"/> | TEST NUMBER | DATE                | PATIENT ID          | NAME                          | CAPSULE                 |
|--------------------------|-------------|---------------------|---------------------|-------------------------------|-------------------------|
| <input type="checkbox"/> | ID 0        | 2020-05-27 09:54:48 | J-123               | John Jones                    | PSP 0q                  |
| <input type="checkbox"/> | ID 1        | 2020-05-27 10:03:31 | PX009287756         | Gary Grant                    | Aeroallergens D 0n WB   |
| <input type="checkbox"/> | ID 2        | 2020-05-27 10:15:09 | X010203040506070809 | Frank Fraser                  | IVD Capsule RFU Display |
| <input type="checkbox"/> | ID 3        | 2020-05-27 10:21:59 | Patient ID xxxxxxxx | Max Martin xxxxxxxxxxxxxxxxxx | PSP 0q                  |

20
1

  
 print

  
 Clear all filters


Patient ID:

Name:

Capsule:

Date:


One or more reports can be selected to be printed by clicking on the checkboxes that are on the left of each row. Once the selection is done you can print all the reports by clicking “print”:



EN

2 Measurements selected

| <input type="checkbox"/>            | TEST NUMBER | DATE                | PATIENT ID          | NAME                          | CAPSULE                 |
|-------------------------------------|-------------|---------------------|---------------------|-------------------------------|-------------------------|
| <input type="checkbox"/>            | ID 0        | 2020-05-27 09:54:48 | J-123               | John Jones                    | PSP 0q                  |
| <input checked="" type="checkbox"/> | ID 1        | 2020-05-27 10:03:31 | PX009287756         | Gary Grant                    | Aeroallergens D 0n WB   |
| <input checked="" type="checkbox"/> | ID 2        | 2020-05-27 10:15:09 | X010203040506070809 | Frank Fraser                  | IVD Capsule RFU Display |
| <input type="checkbox"/>            | ID 3        | 2020-05-27 10:21:59 | Patient ID xxxxxxxx | Max Martin xxxxxxxxxxxxxxxxxx | PSP 0q                  |

20
1

  
 print

  
 Clear all filters

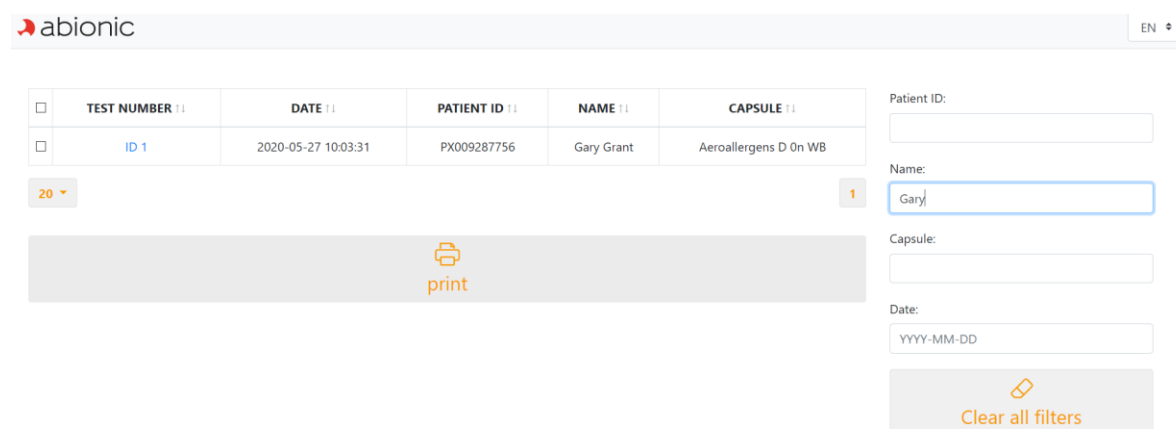
Patient ID:

Name:

Capsule:

Date:

It is possible to filter specific archived test results by using one of the following search filter: patient ID, patient name, capsule type or date. Here is an example:



The screenshot shows the abionic search interface. At the top, there is a search bar with the abionic logo and a language dropdown set to 'EN'. Below the search bar, there is a table with columns: TEST NUMBER, DATE, PATIENT ID, NAME, and CAPSULE. The first row is highlighted with a blue background. To the right of the table, there are input fields for Patient ID, Name, Capsule, and Date. Below the table, there is a 'print' button with a printer icon. To the right of the 'print' button, there is a 'Clear all filters' button with a trash icon.

| TEST NUMBER | DATE                | PATIENT ID  | NAME       | CAPSULE               |
|-------------|---------------------|-------------|------------|-----------------------|
| ID 1        | 2020-05-27 10:03:31 | PX009287756 | Gary Grant | Aeroallergens D 0n WB |

20

print

Patient ID:

Name:

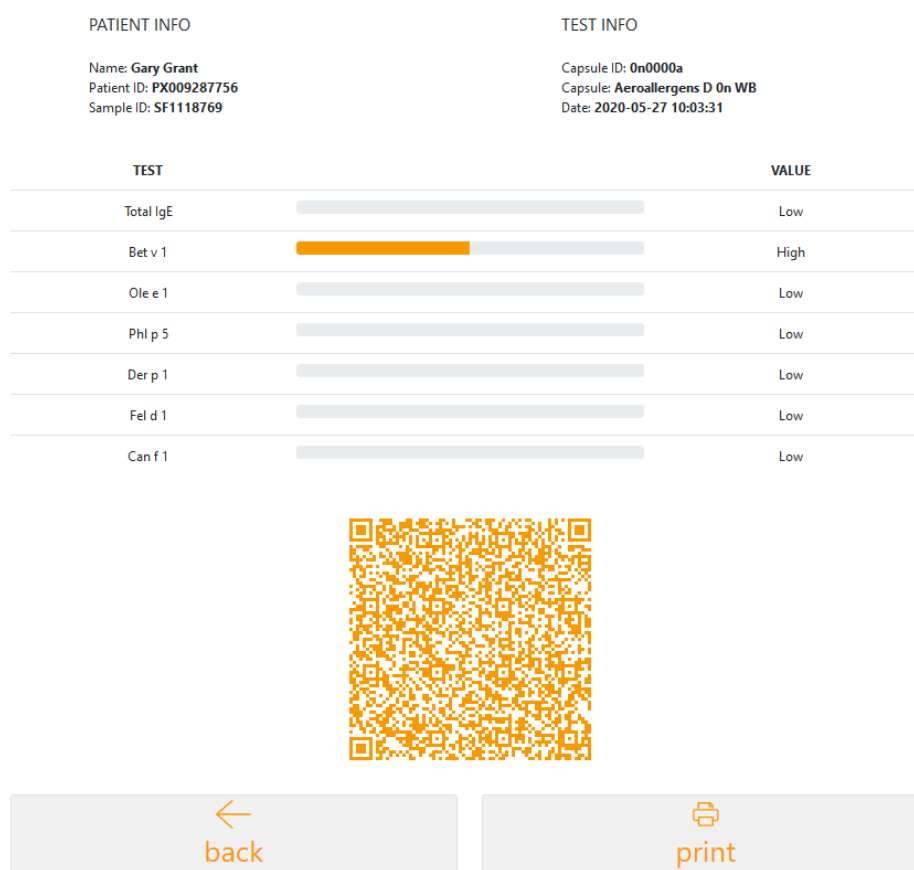
Capsule:

Date:

Clear all filters

The filters can be cleared by clicking on "clear all filters".

Click on a specific row to display full details about the test results:



The screenshot shows the abionic test results interface. At the top, there are two sections: PATIENT INFO and TEST INFO. Below these sections, there is a table with columns: TEST and VALUE. The table contains seven rows of test results. Below the table, there is a QR code. At the bottom, there are two buttons: 'back' and 'print'.

PATIENT INFO

Name: Gary Grant  
Patient ID: PX009287756  
Sample ID: SF1118769

TEST INFO

Capsule ID: 0n0000a  
Capsule: Aeroallergens D 0n WB  
Date: 2020-05-27 10:03:31

| TEST      | VALUE |
|-----------|-------|
| Total IgE | Low   |
| Bet v 1   | High  |
| Ole e 1   | Low   |
| Phl p 5   | Low   |
| Der p 1   | Low   |
| Fel d 1   | Low   |
| Can f 1   | Low   |

back

print

The QR code can be used to transfer the test information to another application. From there it is possible to print the report by clicking on "print" or go back to the listing by clicking on "back".

When finished with the abioBROWSER on the computer, touch "finish" on the abioSCOPE to go back to the archive screen. The additional drive on the computer will also be disconnected.

## **7 Troubleshooting**

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### ***E001-008. 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.

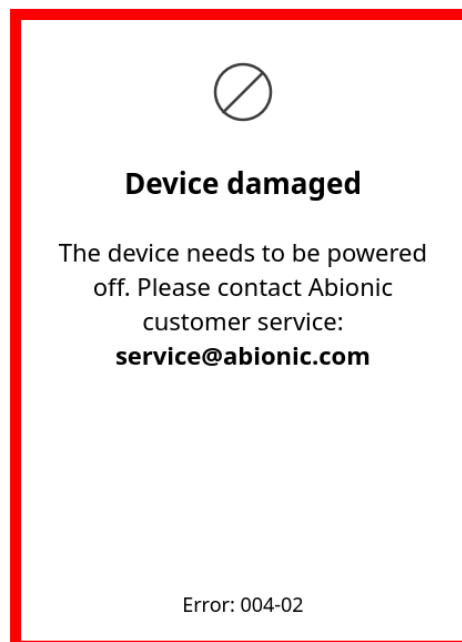
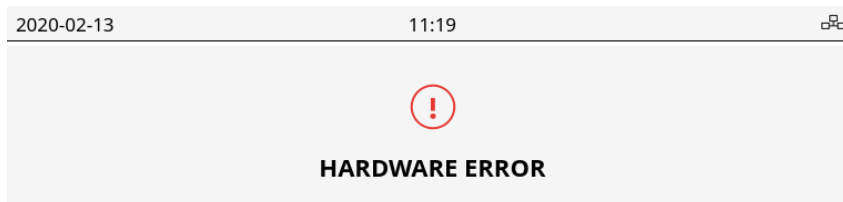
In all cases, check the electrical plug by testing another device on the same plug. If the other device is working properly and not the abioSCOPE, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

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.

### ***E004-002. Device damaged***

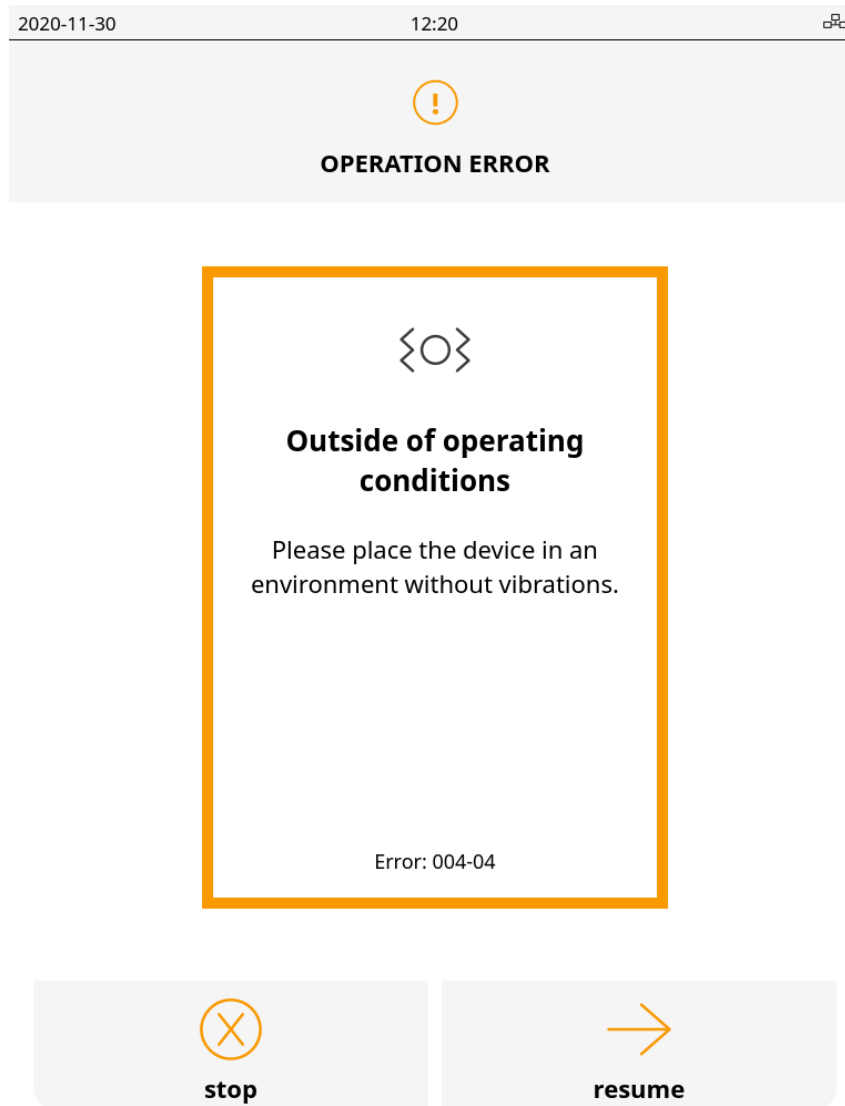
In case the device has been damaged, please do not turn the device on and contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

If the device does not seem damaged and displays the following message, please also contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com):



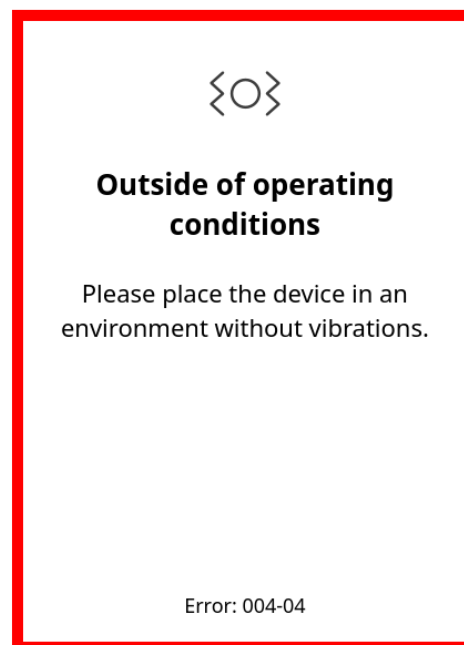
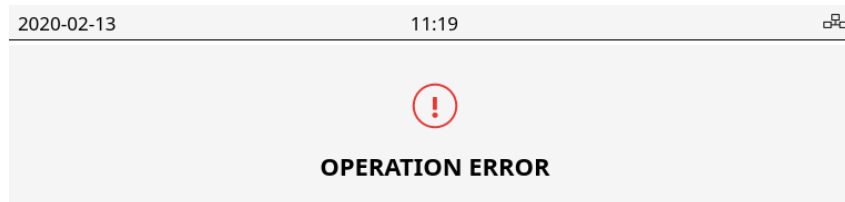
## ***E004-004. Device under vibrations***

In case the device is subject to vibrations, the following message will appear:



It is important to place the device in an environment without vibrations. When the source of vibrations is stopped, you can then resume the measurement by touching "resume" (you have 5 minutes to do so, otherwise the device will automatically get to the next screen). If it is not possible to stop the source of vibrations yet, touch "stop", this will stop the capsule measurement process. In that case it is not possible to resume the measurement using the same capsule. You can then put the device in an environment without vibrations and proceed with a new measurement.

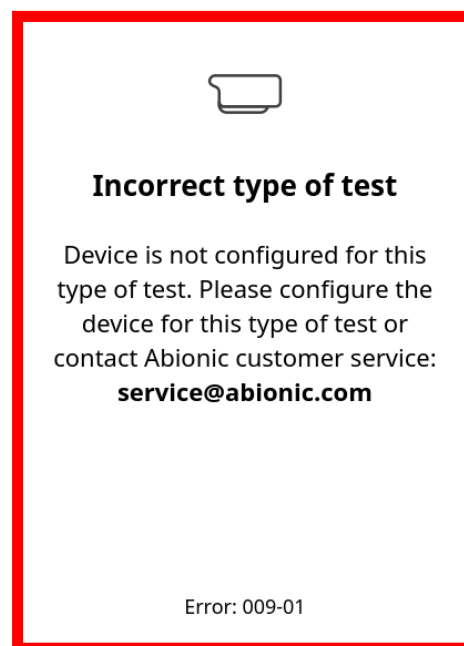
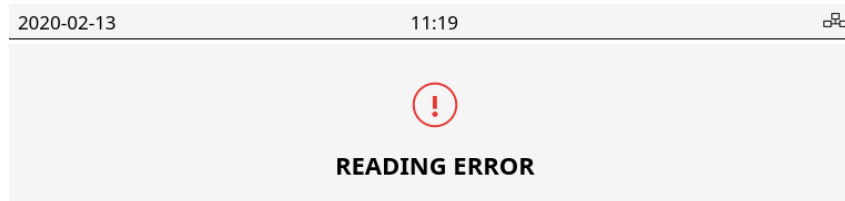
In the case capsule measurement is resumed and vibrations are still present or if 5 minutes have elapsed since the previous screen was displayed without user interaction, the following is displayed



Place the device in an environment without vibrations and start a new measurement.

### ***E009-01 Incorrect type of test***

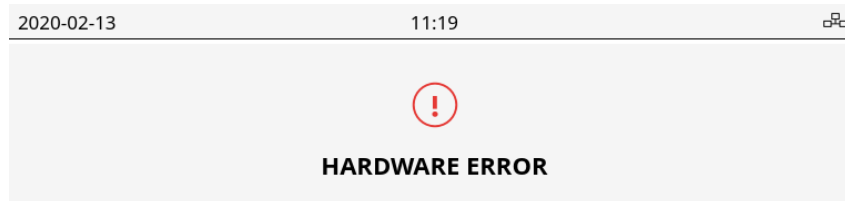
The device has not been calibrated for at least one test (biosensor) in the IVD CAPSULE that is being measured. Such a capsule will trigger the following error:



The abioSCOPE has to be calibrated for each application that an IVD CAPSULE contains.

### ***E009-05. Internal memory full***

During the initialization phase at start up, the system controls the remaining space in the internal memory. If the internal memory is full, the following screen will appear:

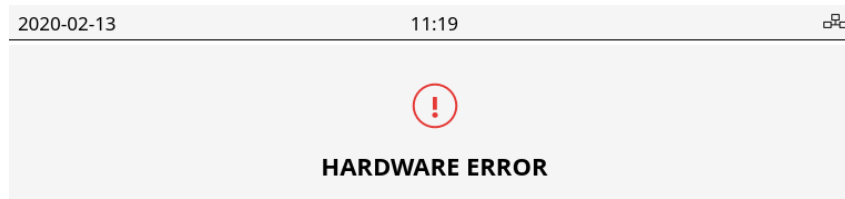


The user must remove older test results or contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).



### ***E009-06. Internal storage memory is corrupt***

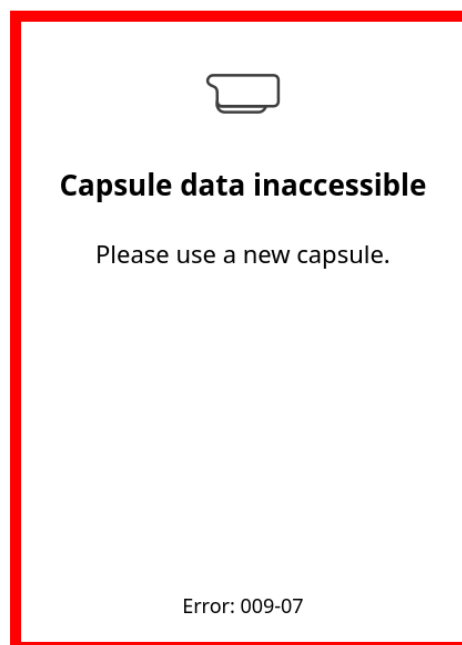
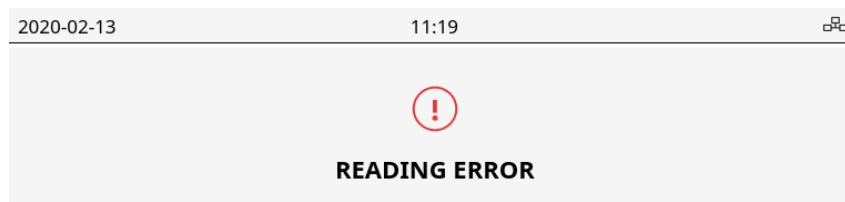
The internal storage memory is inaccessible. The following screen will appear:



The user must contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E009-07. Capsule data inaccessible***

The capsule data can't be read by the abioSCOPE. In that case the following screen appears:



  
**back**

A new capsule has to be used for the test.

### ***E009-10. Touchscreen is not responding***

If the touchscreen does not respond within 10 seconds (except during the measurement time, note that the touchscreen does not respond during measurement time), restart the abioSCOPE: this is done by pressing on the power push-button and holding until the device shuts down and then start it again with the same push-button.

If the abioSCOPE still does 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.

***E009-11. Tray is not opening***

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

If the 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](mailto:service@abionic.com).

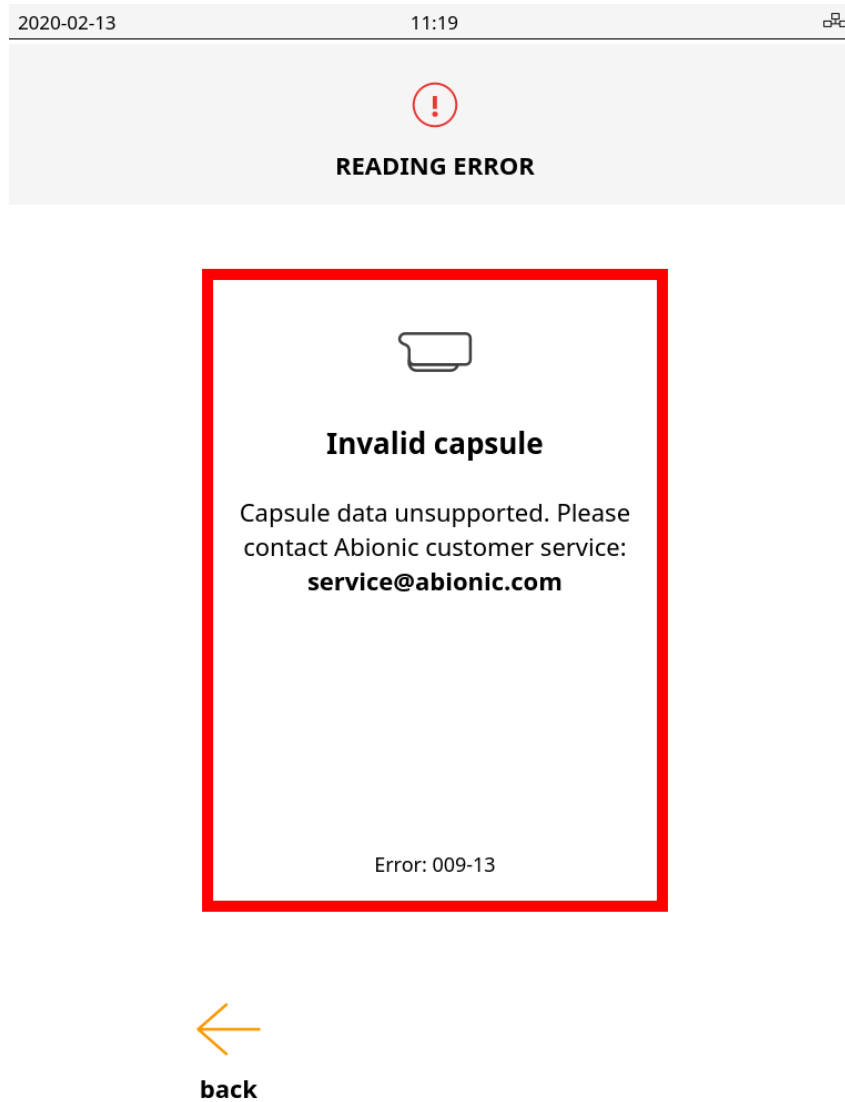
***E009-12. Tray is blocked***

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

If the 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](mailto:service@abionic.com).

### ***E009-13. Capsule data invalid***

In case the format of the capsule data isn't supported by the device software, the following screen appears:




A new capsule has to be used for the test.


## E009-14. Test failed


In case the abioSCOPE can't read the capsule (or a part of it), if the capsule was not filled or if the abioMIX has not been mixed with the patient sample, the results screen will display the test measurement as failed:


2020-06-04


12 : 30


  
insert capsule


  
patient data


  
measurement


  
results


  
remove capsule

### Results

Name:

Piet Pietsen

Patient ID:


P09

Sample ID:


rty


Capsule:

IVD CAPSULE PSP



| TEST | VALUE  |
|------|--------|
| PSP  | failed |

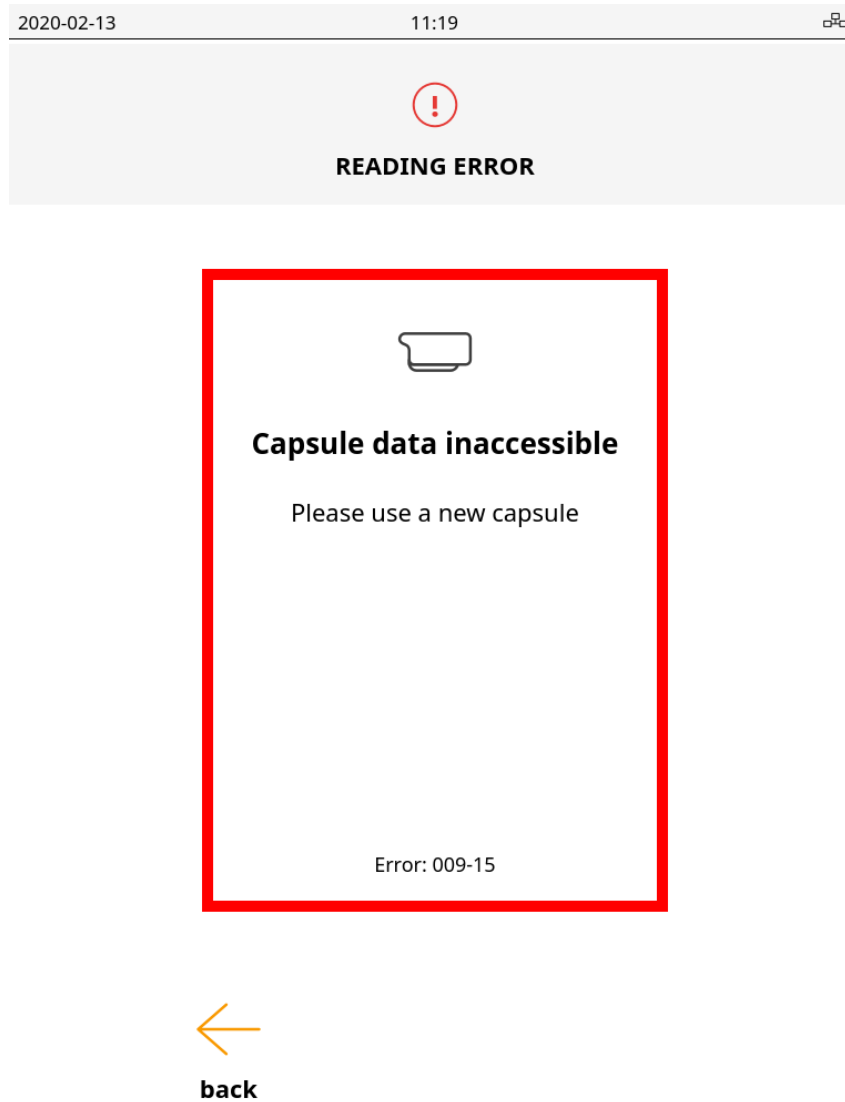

  
qr code


  
open tray

In that case, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E009-15. Configuration capsule data inaccessible***

The configuration capsule data can't be read by the abioSCOPE. In that case the following screen appears:

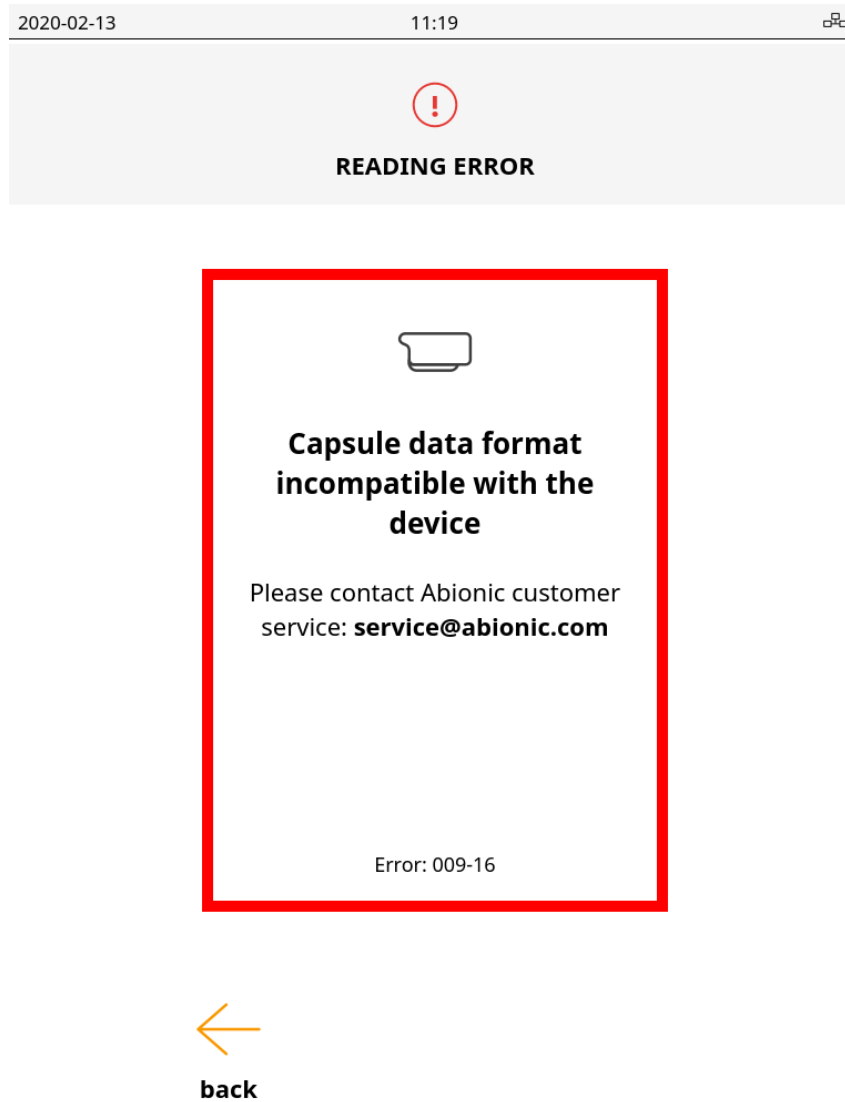


A new capsule has to be used for the configuration.



### ***E009-16. Configuration capsule data invalid***

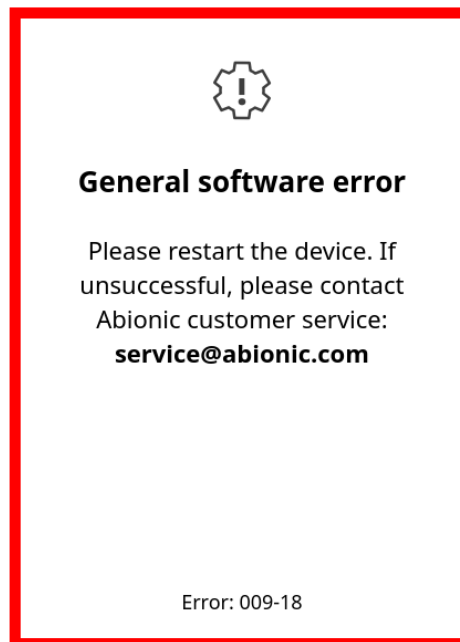
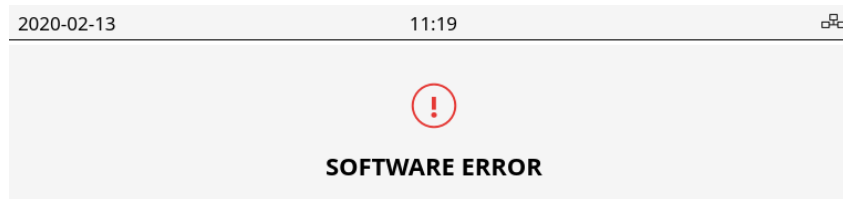
In case the format of the capsule data isn't supported by the device software, the following screen appears:



A new capsule has to be used for the configuration.

## ***E009-18. Software error***

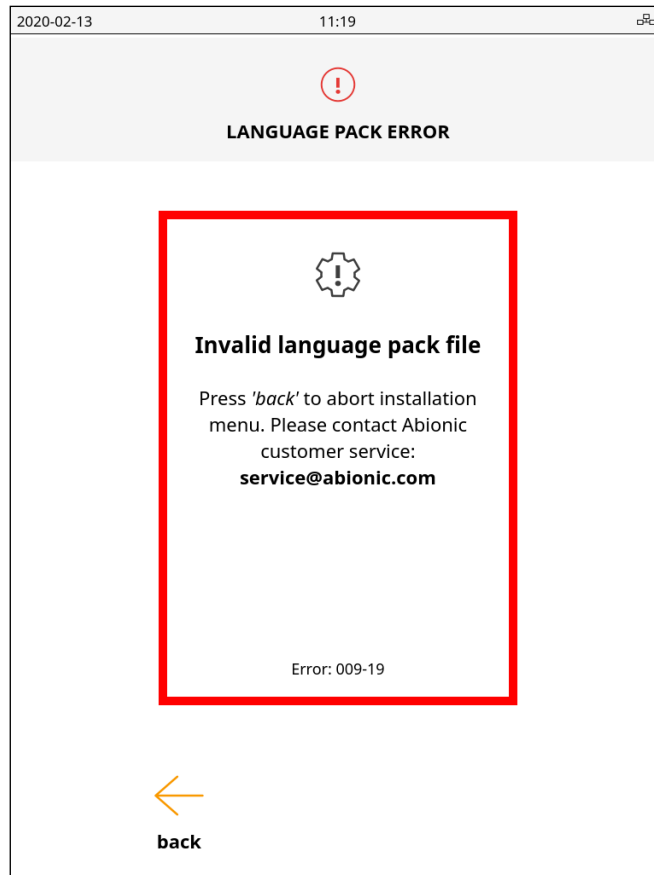
In case the software encounters an unexpected error, the following screen appears:



Please restart the device. If the error is still there, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E009-19. Language pack invalid***

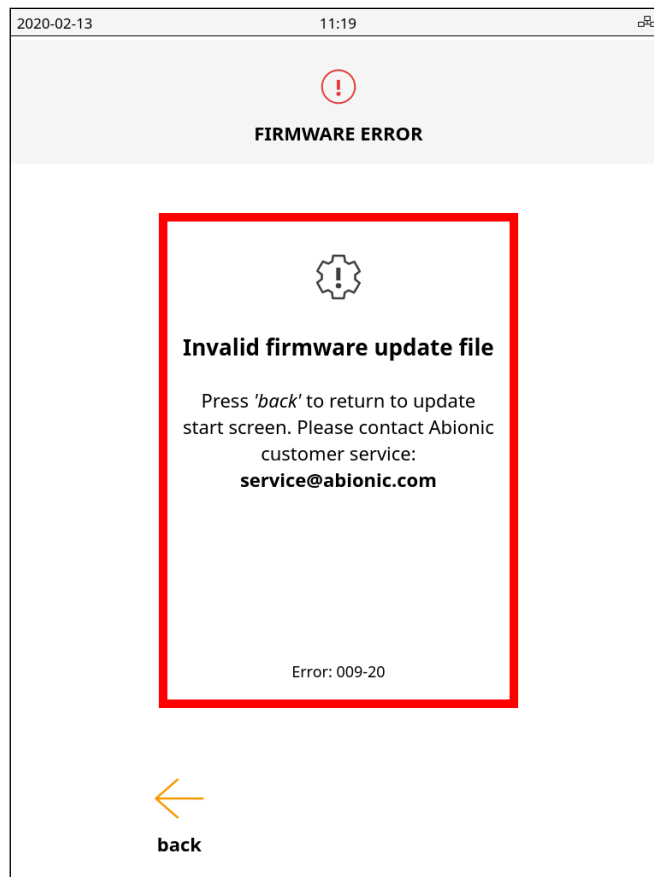
In case the language pack is invalid, the following screen appears during the procedure:



Please touch "back" and contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E009-20. Firmware file invalid***

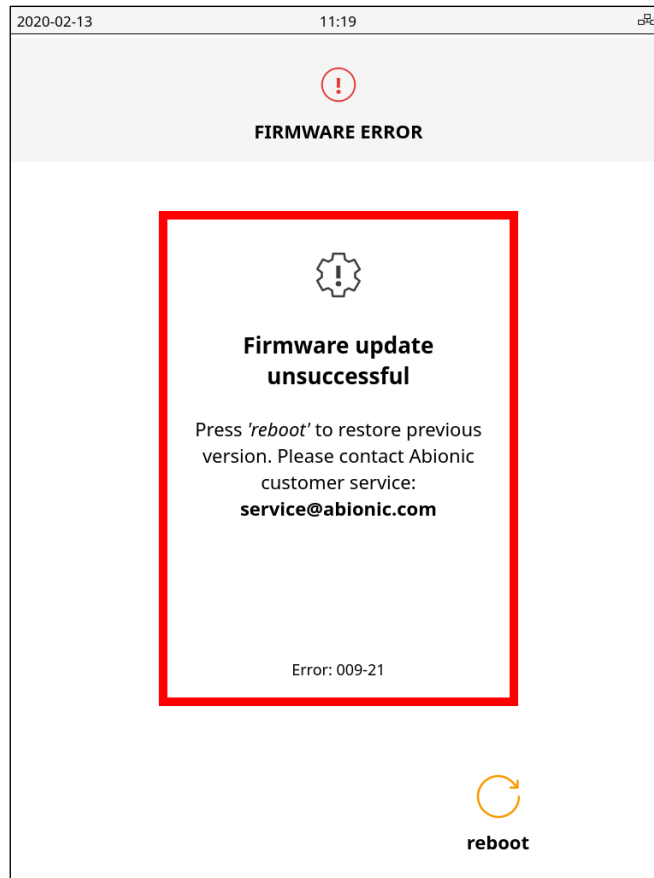
In case the firmware file for update is invalid, the following screen appears during the procedure:



Please touch "back" and contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E009-21. Firmware update unsuccessful***

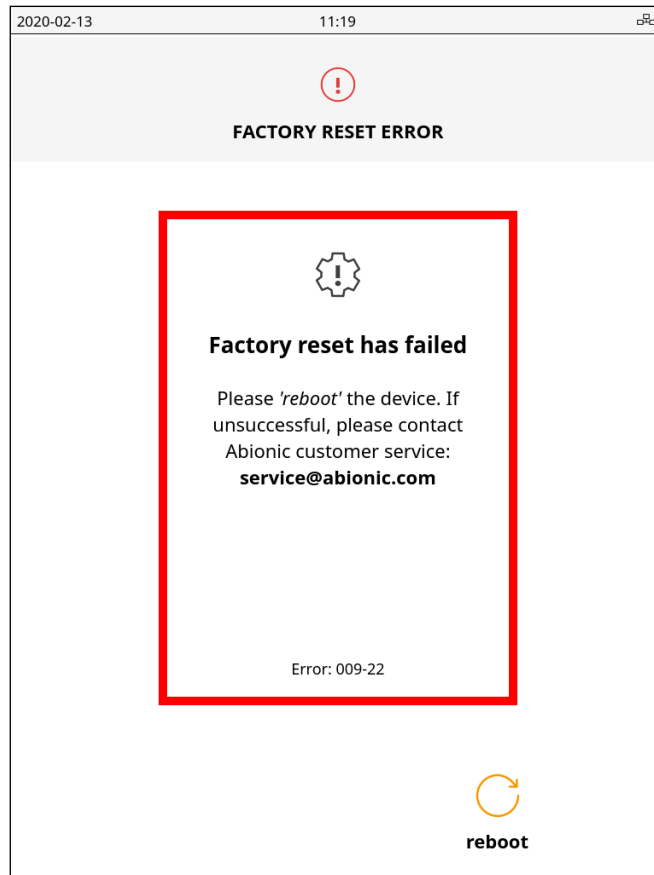
In case the firmware update process fails, the following screen appears during the procedure:



Please touch "reboot" and contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

## ***E009-22. Factory reset unsuccessful***

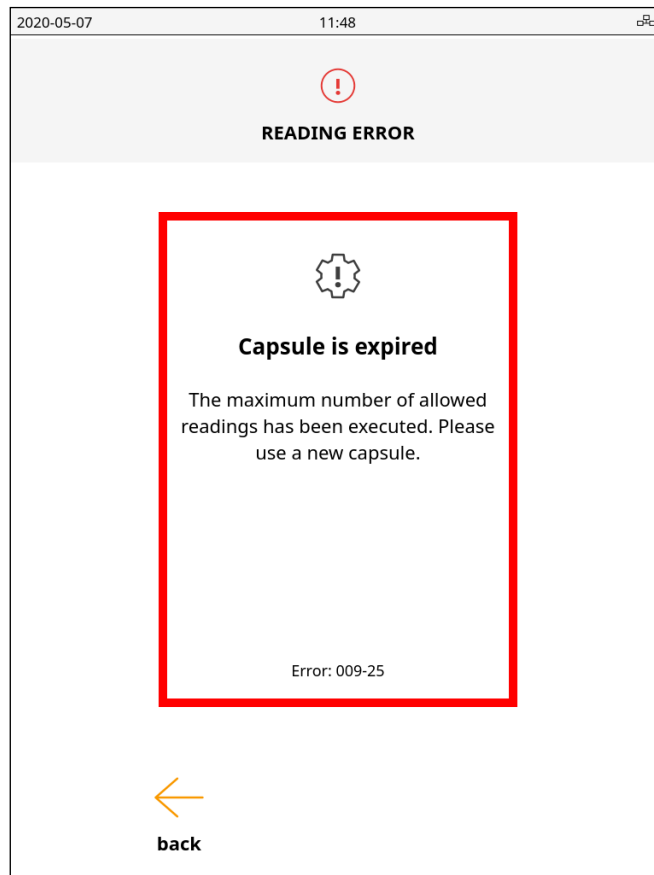
In case the factory reset process fails, the following screen appears during the procedure:



Please touch "reboot" and contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E009-25. abioSCOPE Control capsule expired***

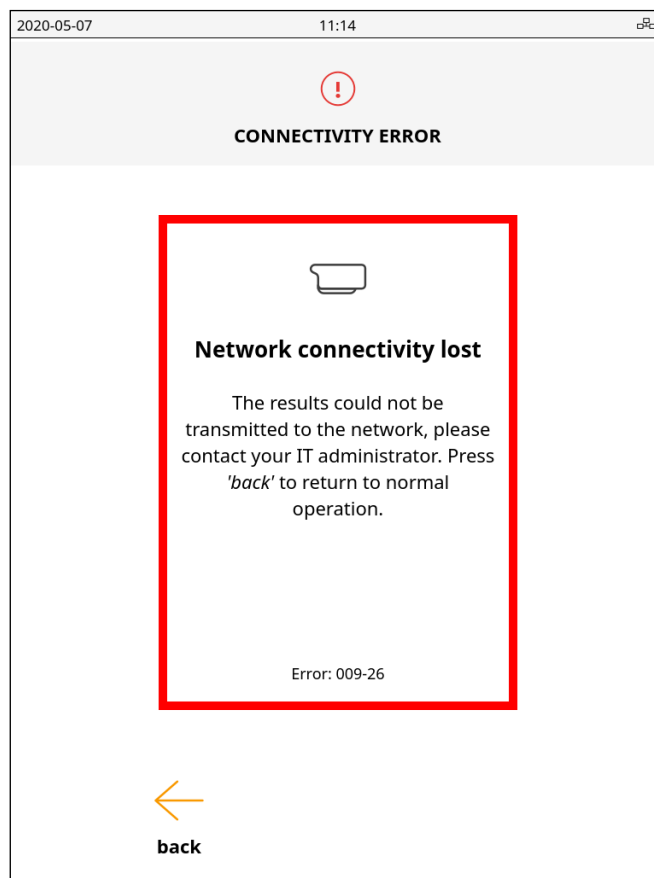
In case the lifetime of the abioSCOPE control capsule is exceeded, the following screen appears after inserting the capsule:



Please touch "back" and use or order a new abioSCOPE control kit.

### ***E009-26. Network connectivity lost***

In case the communication with the HIS/LIS system is configured and test results could not be sent, the following screen appears:

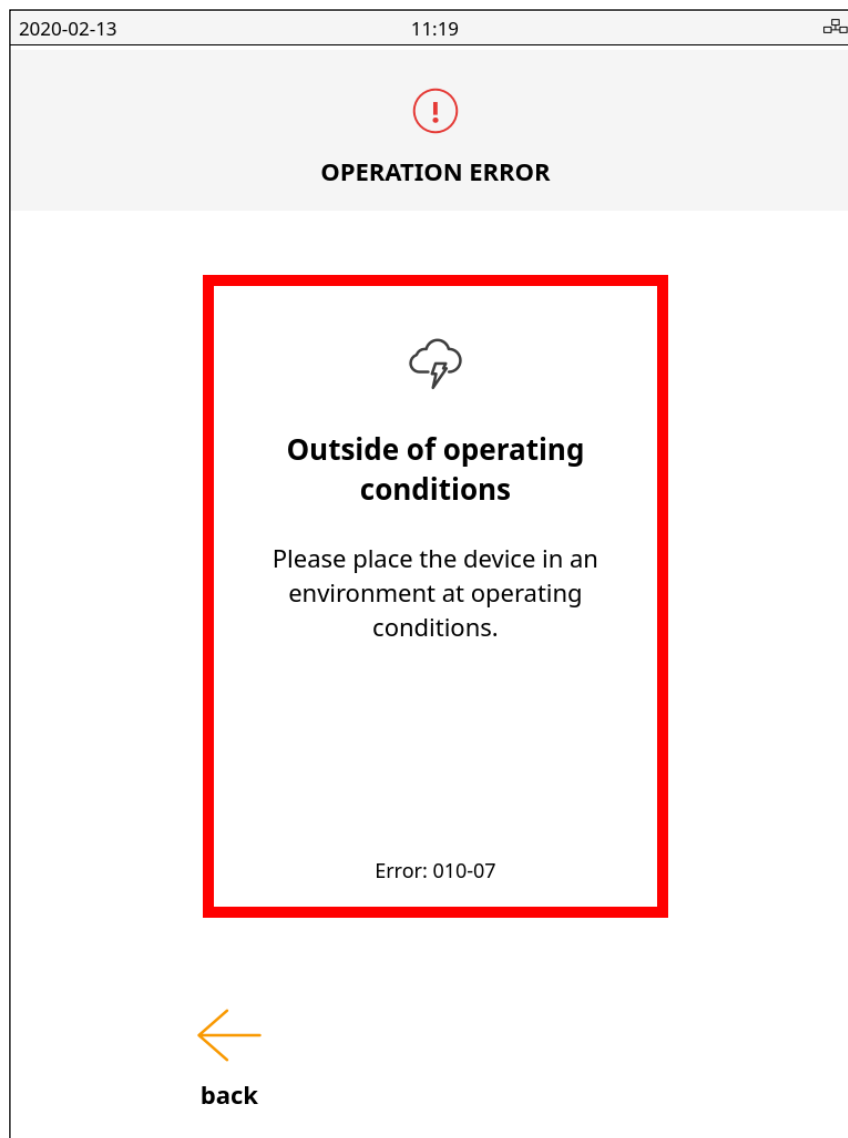


Please touch "back" and contact your IT administrator.



### ***E010-07. Outside of operating conditions***

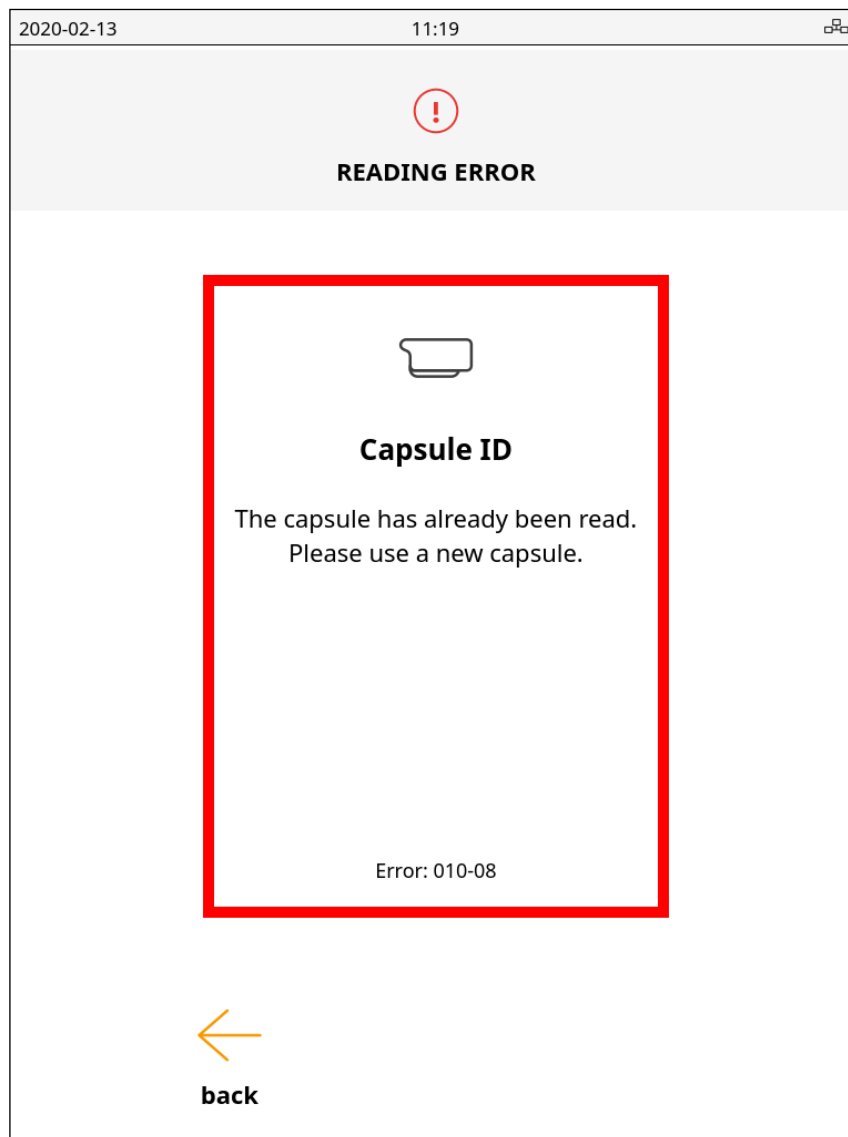
If the device environment is outside of its operating conditions, the following screen will appear:



The device must be put in an environment at operating conditions in order to correctly operate.

### ***E010-08. Capsule ID error***

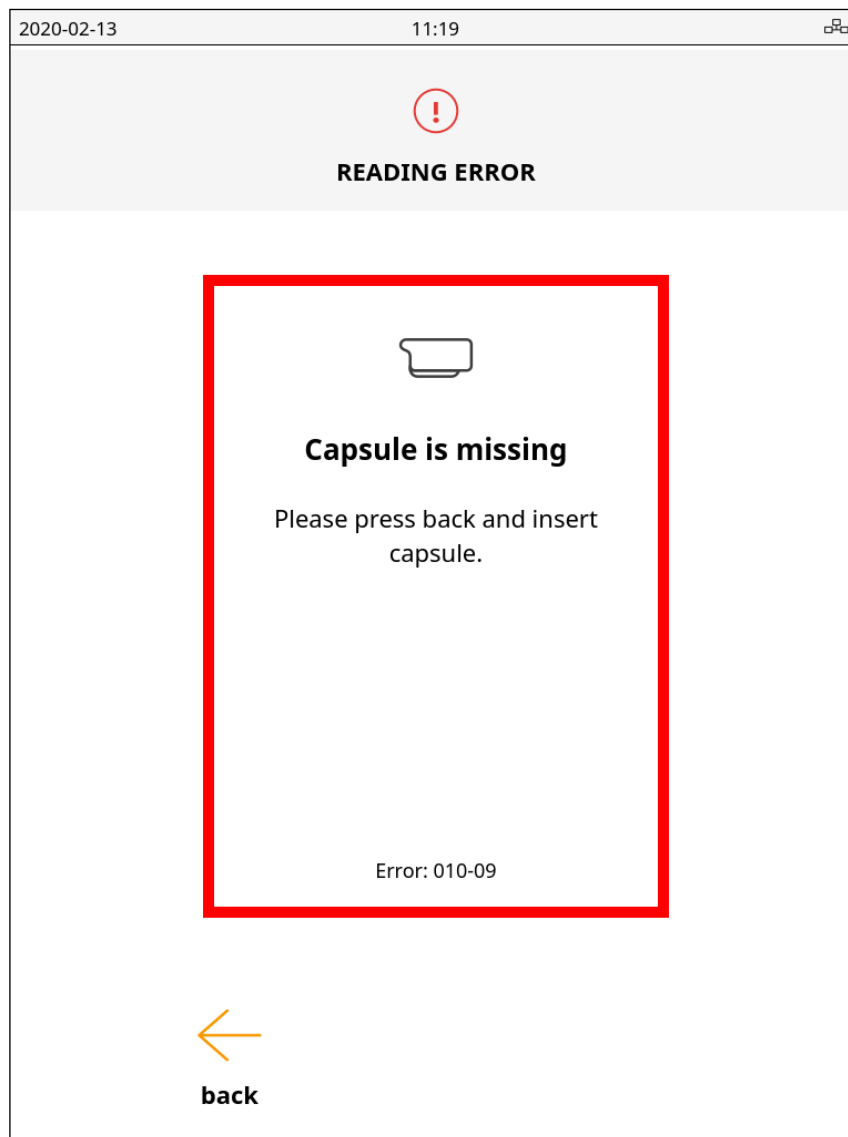
The serial number of the capsule is identified by the abioSCOPE when it is read such as the capsule, i.e. the test, cannot be performed twice in a row. A capsule that has already been read will display the following error:



The capsule that has already been read has to be replaced with a new capsule as instructed by the display.

### ***E010-09. Capsule missing***

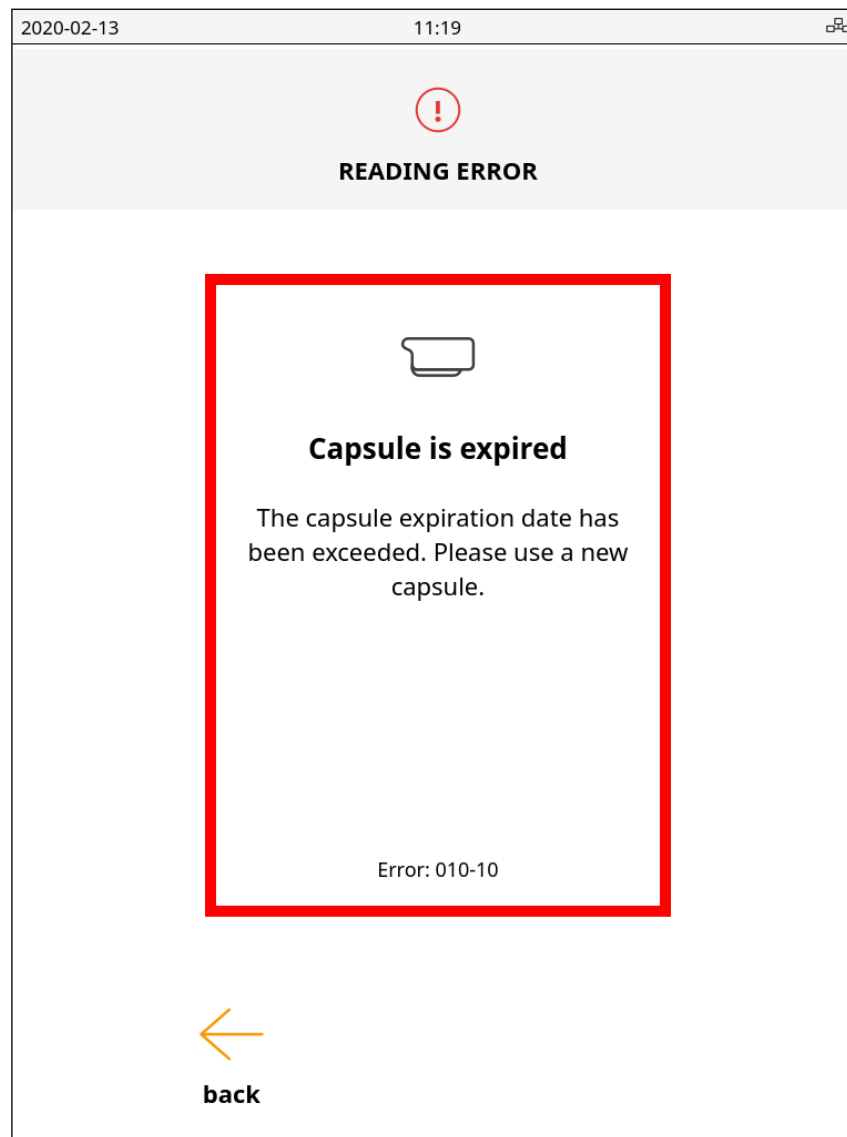
Only certified capsules provided by Abionic must be inserted into the abioSCOPE. Capsules must be new and unused. If a capsule is missing, or if a non-compatible capsule is inserted, the abioSCOPE will detect it and invite the user to insert a new compatible capsule. The following screen will be displayed:



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

### ***E010-10. Capsule is expired***

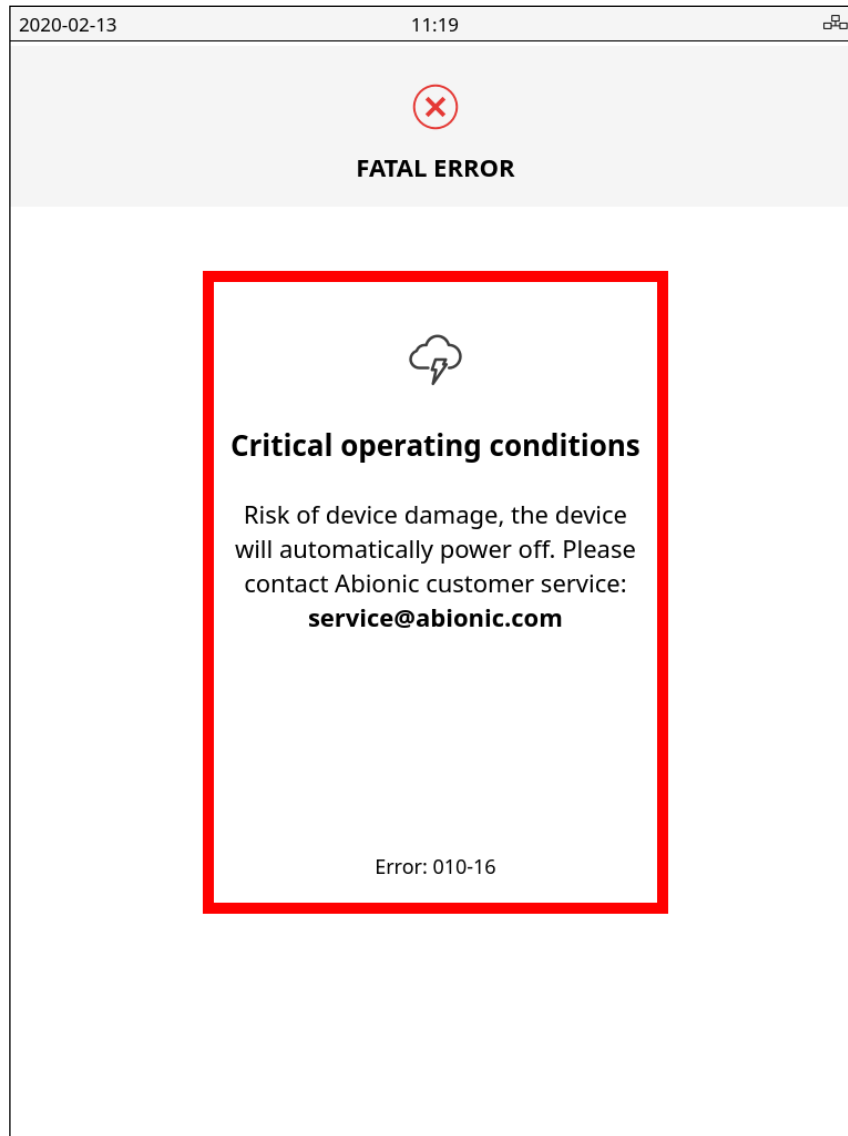
The capsule has an expiration date that has been exceeded. Such a capsule will trigger the following error:



The capsule that has an expiration date that has been exceeded has to be replaced with a new capsule as instructed by the display.

### ***E010-16. Critically outside of operating conditions***

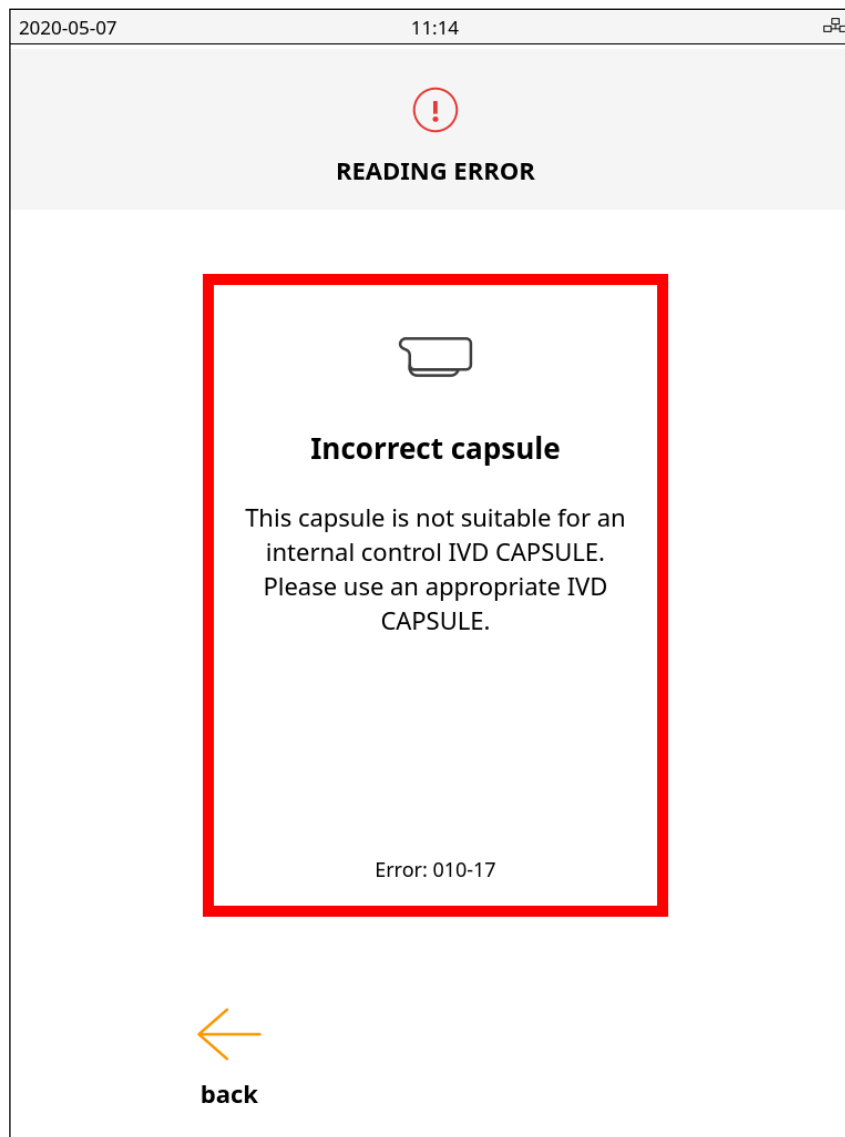
If the device environment (temperature or humidity) is dangerous for the device itself, the following screen will appear:



The device will automatically power off. Before restarting it, put the device in an environment at operating conditions in order to correctly operate.

### ***E010-17. Internal IVD CAPSULE control incorrect***

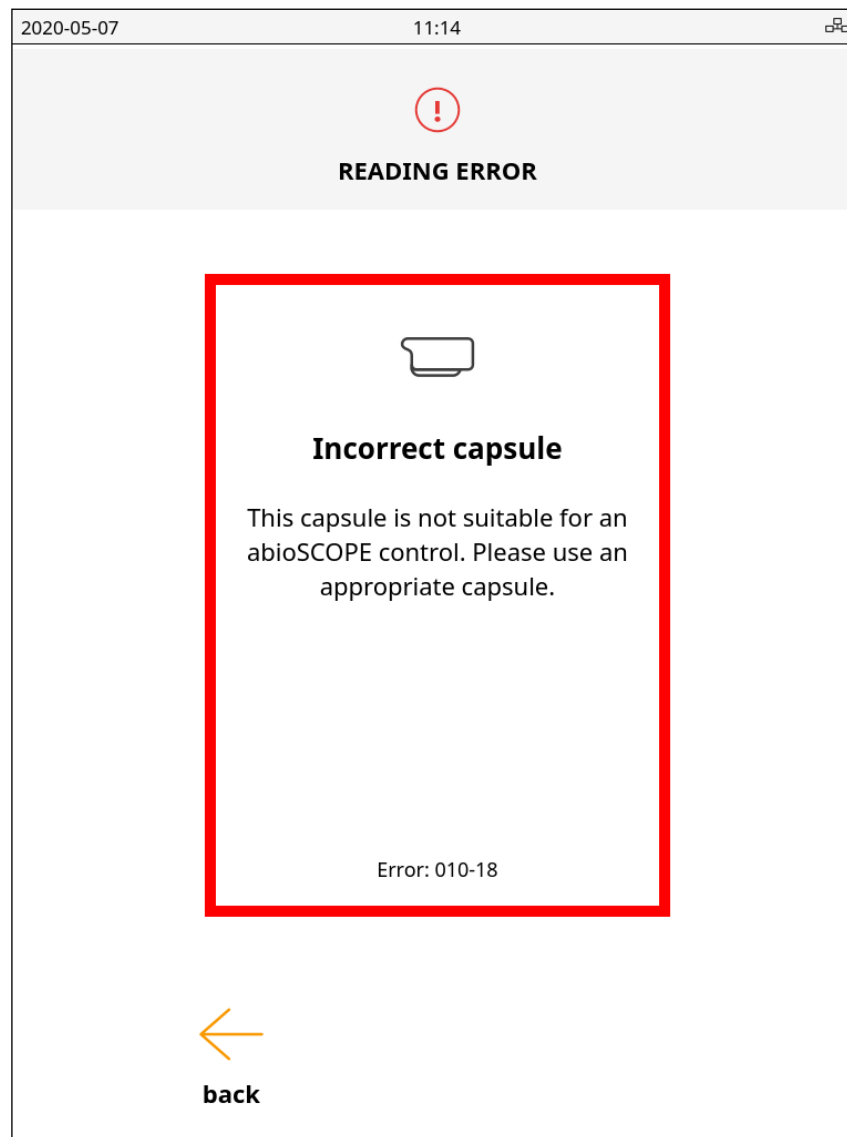
If the capsule inserted in the device for the internal IVD CAPSULE control is not of the correct type, the following screen will appear:



Retrieve the capsule and use a capsule from an internal control IVD CAPSULE kit.

### ***E010-18. abioSCOPE control capsule incorrect***

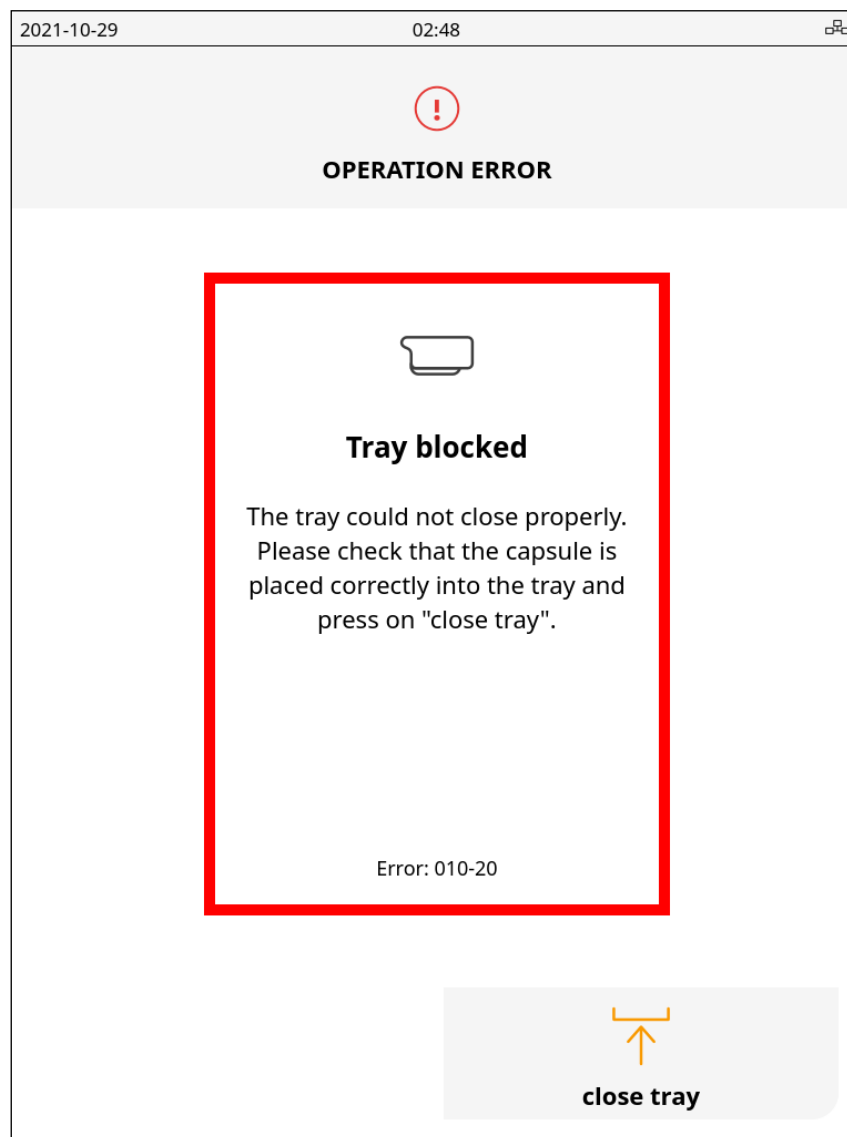
If the capsule inserted in the device for the abioSCOPE control is not of the correct type, the following screen will appear:



Retrieve the capsule and use a capsule from an abioSCOPE control kit.

### ***E010-20. Tray blocked***

If something is blocking the tray when closing (for instance the capsule is not well inserted in the tray), the tray will not be able to close properly. In that case, the tray will reopen, and the following screen will appear:

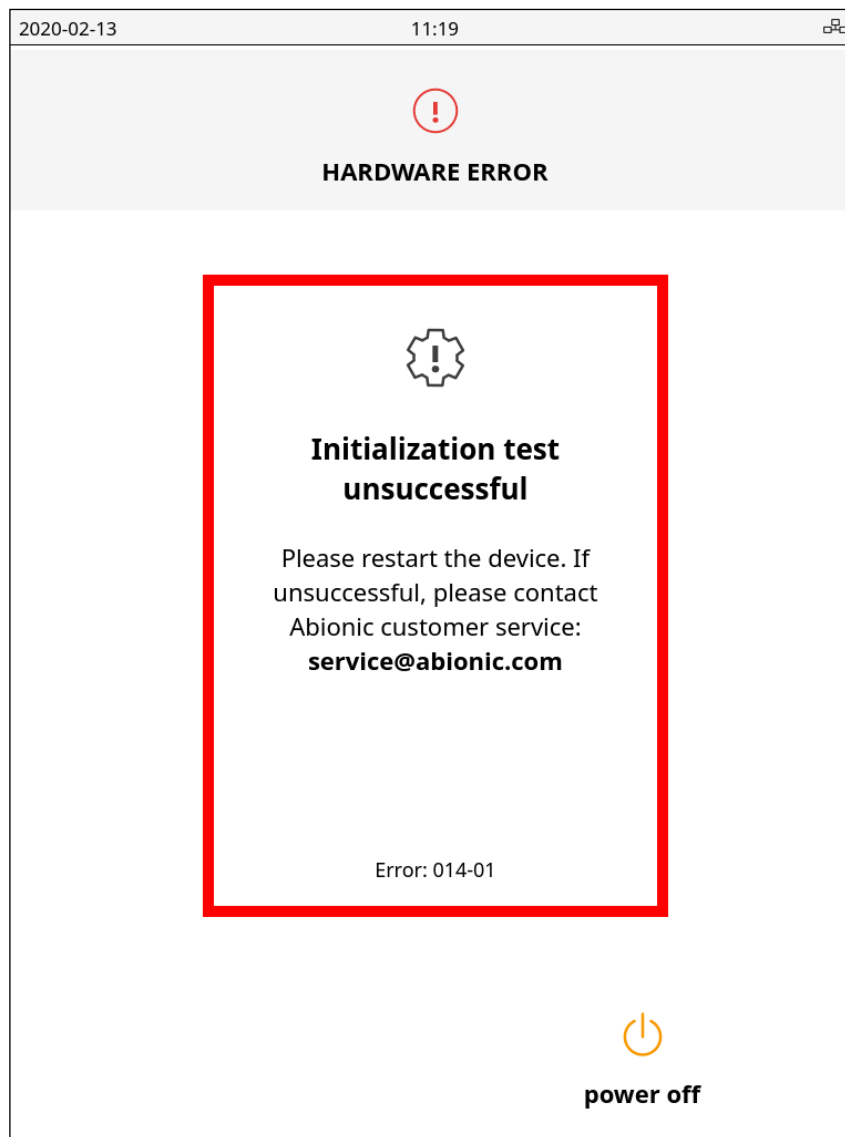


Retrieve the blocking part. In case it is the capsule, please make sure it is well inserted and press on "close tray".



### ***E014-01. Initialization test unsuccessful***

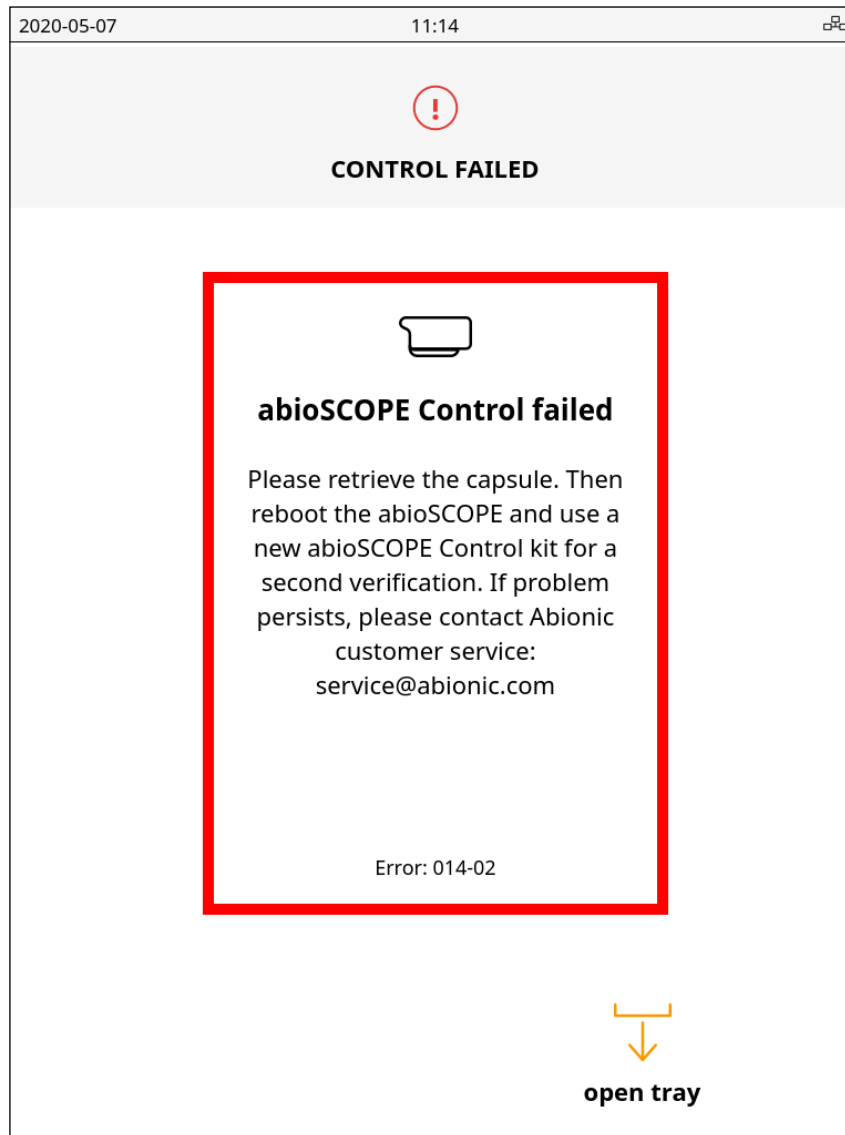
On starting up, the system enters a short initialization phase that involves the system checking the functionality of the abioSCOPE. If one or several functions do not initialize properly, the system will not be usable and the following error message will appear on screen:



Restart the abioSCOPE. If the problem persists, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

## ***E014-02. abioSCOPE control failed***

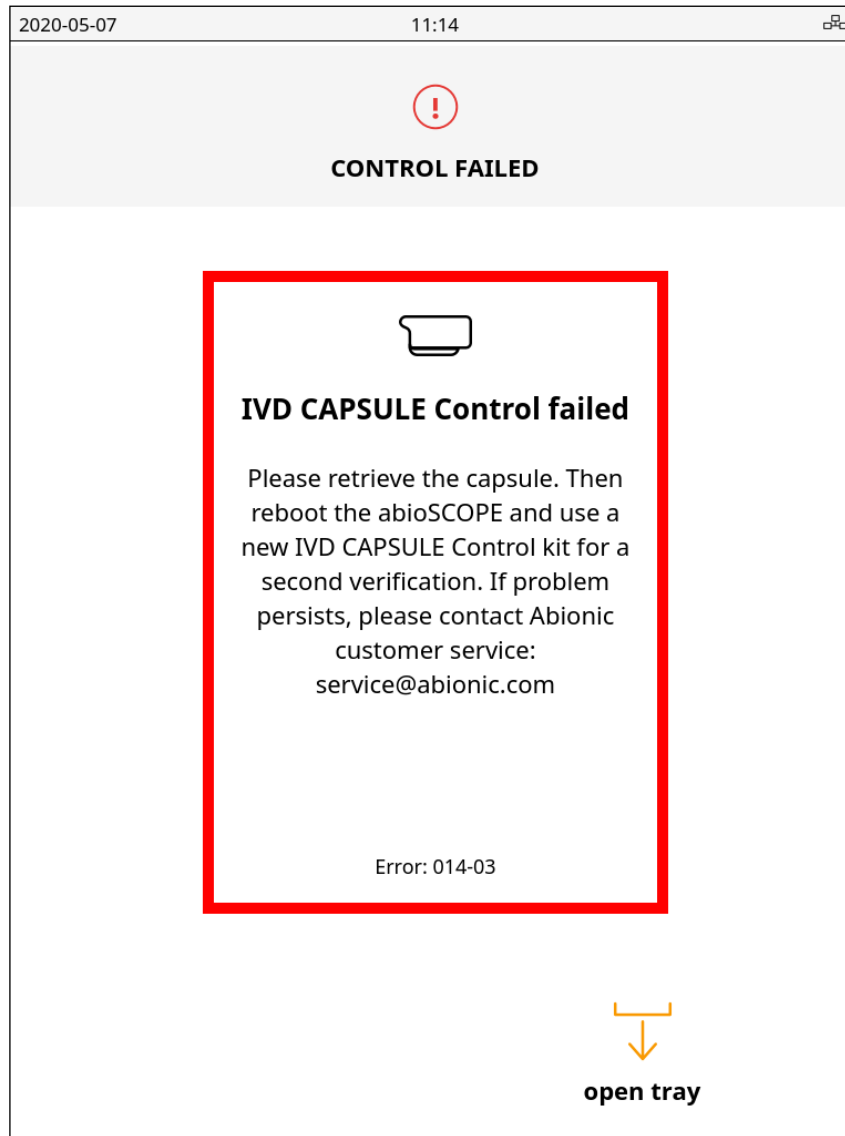
If the result of the abioSCOPE control is failed, the following error message will appear on screen:



Retrieve the capsule, restart the device and use a new abioSCOPE control kit. If this second test is failed, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E014-03. Internal IVD CAPSULE control failed***

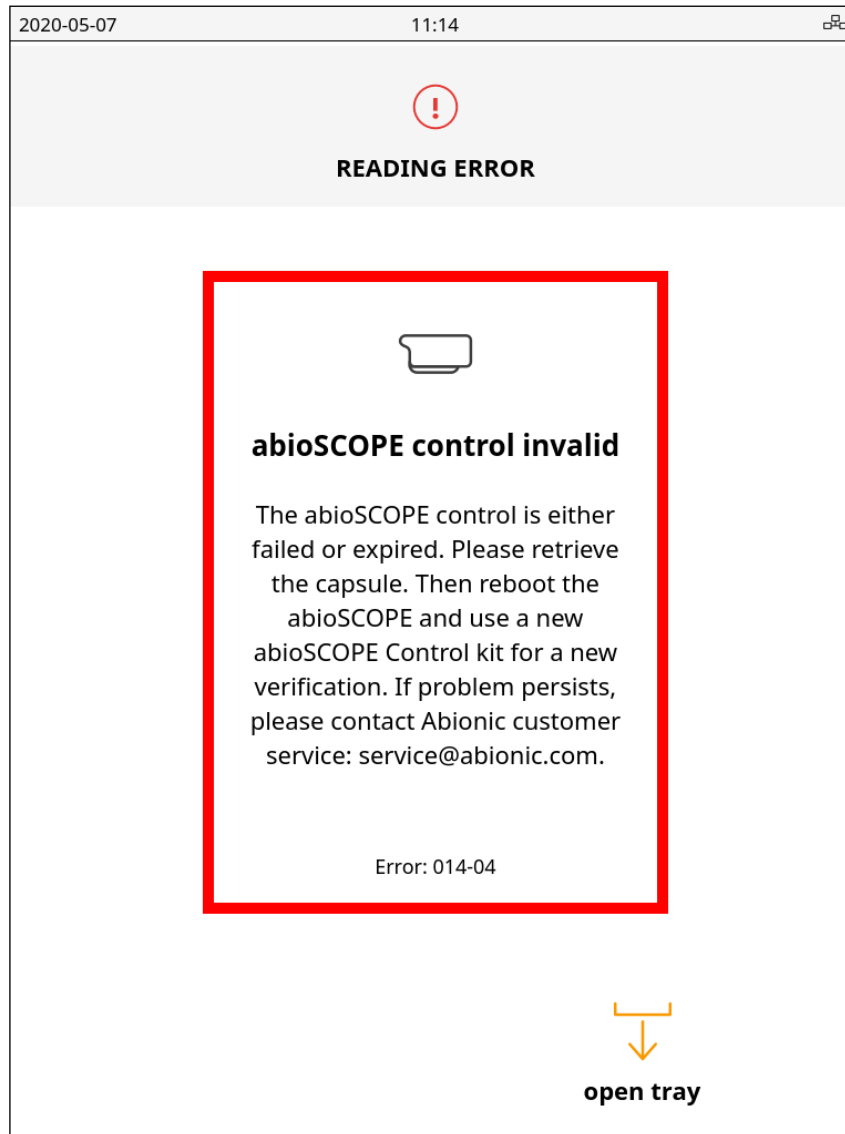
If the result of the internal IVD CAPSULE control is failed, the following error message will appear on screen:



Retrieve the capsule, restart the device and use a new IVD CAPSULE control kit. If this second test is failed, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E014-04. abioSCOPE control invalid***

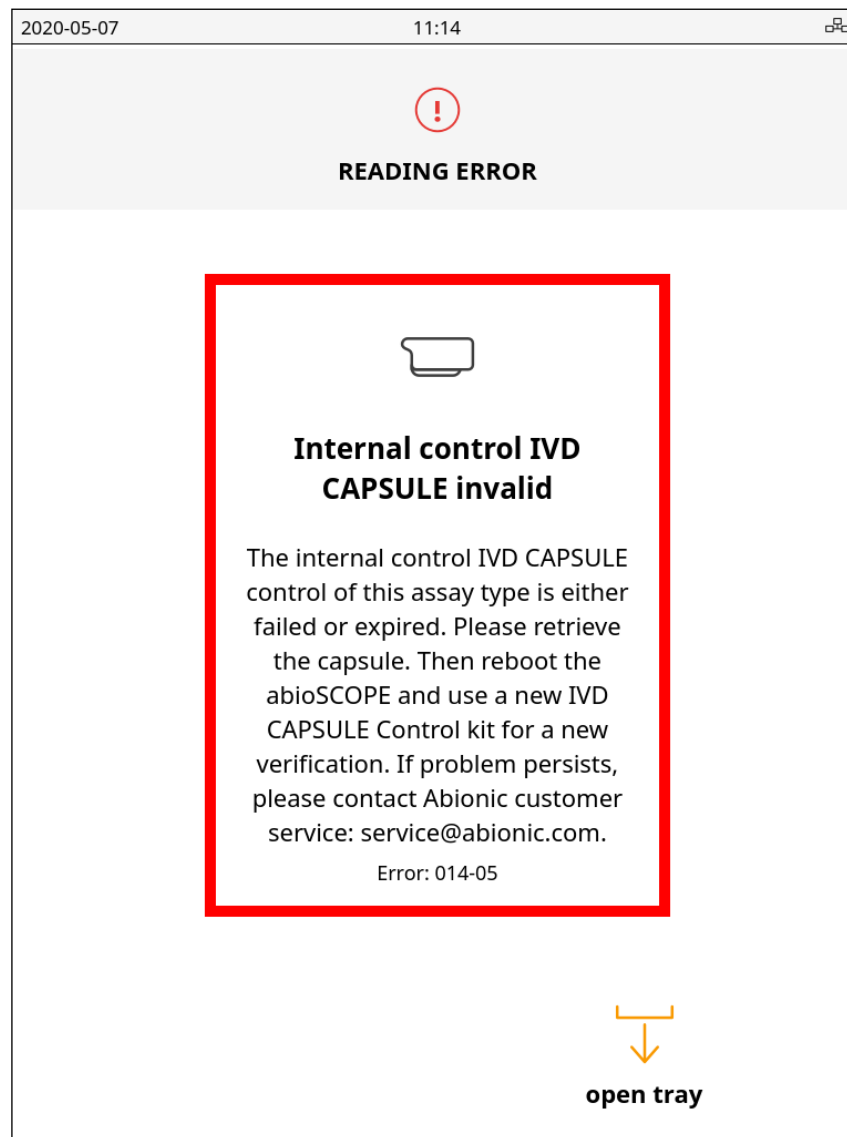
In case the last abioSCOPE control is failed or if it is expired and a capsule measurement is initiated, the following error message will appear on screen:



Retrieve the capsule, restart the device and start an abioSCOPE control. If this fails, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).

### ***E014-05. Internal IVD CAPSULE control invalid***

In case the last internal control IVD CAPSULE of an assay type is failed or if it is expired and a capsule measurement is initiated containing this assay type, the following error message will appear on screen:



Retrieve the capsule, restart the device and start an internal control IVD CAPSULE. If this fails, please contact Abionic customer service at [service@abionic.com](mailto:service@abionic.com).





