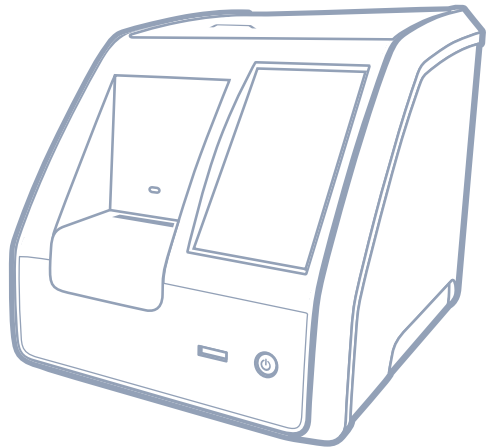




IVD

# AFIAS-3



AFIAS-3

The information contained herein is subject to change without prior notice.

Boditech Med Inc. shall not be liable for any technical and editorial errors or omissions contained herein.

Additionally, any malfunction in elements including the optical sensor assembly, the system board and the drive train should be consulted with and serviced by Boditech Med Inc. Any unauthorized operations on elements not suggested in this document will void the existing warranty.

Any serious incident that has occurred in relation to this product shall be informed to Boditech Med Inc. and your competent authority.

*For technical assistance, contact:*

**Boditech Med Inc.'s Technical Services**

Tel: +(82)-33-243-1400, E-mail: TS@boditech.co.kr



**Boditech Med Inc.**

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,  
Gang-won-do, 24398, Republic of Korea

Tel: +(82)-33-243-1400 / Fax: +(82)-33-243-9373

www.boditech.co.kr



**Obelis s.a**

Bd. Général Wahis 53, 1030 Brussels, Belgium

Tel: +(32)-2-732-59-54

Fax: +(32)-2-732-60-03

E-Mail : mail@obelis.net



**The actual contents of the display could differ, depending on the specification and customer requirements.**

## Table of Contents

<b>1. General warnings and important instructions</b>	<b>3</b>
<b>2. Principle of operation</b>	<b>8</b>
<b>3. Commercial package contents</b>	<b>9</b>
<b>4. Specifications</b>	<b>10</b>
<b>5. Operation and functional elements</b>	<b>12</b>
<b>6. Installation</b>	<b>14</b>
<b>7. Running tests on AFIAS-3</b>	<b>18</b>
<b>8. Auxiliary features</b>	<b>30</b>
<b>9. Configuring AFIAS-3</b>	<b>42</b>
<b>10. Maintenance, servicing and disposal</b>	<b>68</b>
<b>11. Troubleshooting</b>	<b>72</b>
<b>12. Warranty</b>	<b>76</b>

# 1. General warnings and important instructions

## Graphic symbols

The following list explains various symbols, which the user will find in this operation manual as well as in package inserts and on labels of AFIAS-3 products.

Symbol	Description
	Manufacturer
	Consult instructions for use
	For <i>in vitro</i> diagnostic use
	CE conformity marking
	Separate collection for electrical and electronic equipment
<b>Biohazard.</b>	
	To warn of a biological hazard. Taking care to avoid exposure to a biological hazard.
<b>Biological risks</b>	
	To indicate a reference to substances that may be hazardous to men, animals, plants, or the environment based on biological activity (for example, holding a virus).
	USB memory
	Temperature limitation
	Humidity limitation
	Direct current
	Alternating current



On (Power)



Off (Power)



Serial number



**LASER radiation.**

Do not stare into beam.



**Caution**

Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. This symbol is essentially a cautionary symbol and is used to highlight the fact that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.



Indicates a hazardous situation, which if not avoided, could result in injury to the operator or a bystander (e.g. electrical shock or UV exposure).



**Danger!**

Improper use or careless handling of AFIAS-3 may cause electrocution, burns, fire and other hazards. To reduce the risk of electric shock:

- Use only the power cord provided with AFIAS-3.
- Never try to disassemble AFIAS-3 as it does not have any operator-serviceable components.
- Do not allow AFIAS-3 to come in contact with water or any liquid in any manner.
- Only occasional cleaning of cartridge holder and exterior by wiping with a soft cloth is recommended. Unplug AFIAS-3 from external power source before cleaning.
- Disconnect the power cord during an extended period of non-use and/or storage.



### **Laser Radiation**

AFIAS-3 has an internal laser module. It can cause some risks due to laser radiation. To protect these risks, please keep the followings.

- Do not alter or disassemble the AFIAS-3. Unauthorized alternation and disassembly can cause exposure to laser radiation. When operating the AFIAS-3, please keep and follow the instructions in this operation manual.
- There is no need to use specific eyes protective gears because it is impossible to see laser beam during the normal use.
- Do not open the holder cover during a test. If you look internal laser beam by using a microscope or telescope, it may cause some risks.
- The exteriors of the AFIAS-3 protect users from laser beam. Do not open the exteriors.
- It is impossible to adjust the laser power except the manufacturer.



### **Biological risk**

Patient samples and used AFIAS cartridges must be treated as potentially infectious substances. To reduce the risk of any biohazard,

- Used cartridges should be disposed of in accordance with local regulations as applicable to the disposal of bio-hazardous materials.
- At the end of its useful life, AFIAS-3 could be sent back to Boditech Med Inc. for recycling or proper disposal. Alternatively, it should be disposed of in accordance with relevant local regulations.
- To reduce the risk of any biohazard or chemicals, wear protective gloves. Do not touch or use test cartridges and holder cover with bare hands.



**Caution**

AFIAS-3 is designed for countertop operation under laboratory conditions.

To reduce the risk of damage to AFIAS-3:

- Handle AFIAS-3 gently with care to prevent damages to its internal components.
- Keep AFIAS-3 in a dust-free place.
- Do not expose AFIAS-3 to an environment with high humidity, direct sunlight and/or extreme temperature.
- Do not place anything on top of AFIAS-3.
- Use only the accessories provided with AFIAS-3, cartridge(s) and ID chip(s) supplied by Boditech Med. Inc.
- Unless otherwise instructed specifically, do not insert anything into any opening, socket or drawer provided in AFIAS-3.
- During transportation and/or storage, keep AFIAS-3 dry in temperature range of -20 ~ 60 °C (-4 ~ 140 °F) in an upright position and protect it from mechanical shocks.
- Before moving to another location, remove tips from the tip box.

**Failure to follow these precautions will invalidate the warranty.**

To reduce the risk of obtaining misleading or erroneous results with AFIAS tests:

- Ensure that AFIAS-3 is in proper working condition before performing the test.
- AFIAS test setup should be arranged in an operational environment having temperature 15 ~ 35 °C (59 ~ 95 °F) and humidity ~70%.
- Use AFIAS cartridges that have been stored recommended storage conditions only.
- Expired cartridges must not be used for tests.
- Before performing any AFIAS tests, ensure that the test name as well as the lot number printed on the 'AFIAS ID chip' agree with those on the 'AFIAS cartridge'.
- Do not remove the cartridge from its blister packing until prior to performing the test and allow it to reach the room temperature by leaving it in the room for 30 minutes or longer.
- Before performing any AFIAS tests, read the package insert of the test completely and

follow the instructions carefully.

**Failure to follow these precautions may yield misleading or erroneous results with the AFIAS-3 test.**



## 2. Principle of operation

### Intended use

AFIAS-3 is an analyzer intended for use in conjunction with fluorescence immunoassay (FIA) kits for quantitative, semi-quantitative and qualitative measurements of various analytes. For *in vitro* diagnostic use only.

### Intended user

AFIAS-3 should be operated by healthcare professionals or trained medical technologists (professional use only).

### Principle

AFIAS-3 is a fluorescence and europium nanoparticle scanning system for use with various AFIAS tests based on antigen-antibody reactions and the fluorescence technology (fluorophores or nanoparticles). AFIAS-3 uses a semiconductor diode laser as the excitation light source for illuminating the sample-loaded AFIAS cartridge(s) inserted in its cartridge slot(s); thereby triggering fluorescence emission from the fluorochrome-labeled complexes of analyte accumulated at the test line on the cartridge membrane. Fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of scattered and fluorescent light. The Intensity of fluorescence is scanned and converted into an electric signal which is correlated with the concentration of target analytes in the sample.

The on-board microprocessor computes the concentration of the analyte in the test sample based on proprietary software. Computed and converted test result is displayed on the display screen of the AFIAS-3.

AFIAS-3 tests are *in vitro* diagnostic tests intended for screening, monitoring and/or routine physical examination in centralized laboratories of hospitals and physician clinics.



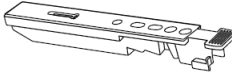



### 3. Commercial package contents

AFIAS-3 and its accessories are provided in a single box. For proper operation, users must be familiar with the technical terms and use of each of them.

Users must ensure that following items are included the package. If any item(s) were found missing, please contact your sales representative or Boditech Med Inc.'s customer care representative at +(82)-33-243-1400 in the Republic of Korea.

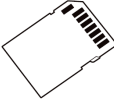


#### Basic contents

1. AFIAS-3 (1 EA)
2. Operation manual (1 EA)
3. Set of AFIAS-3 system check cartridge and a system check ID chip (1 EA)
4. Power cord (1 EA)
5. Thermal printer paper roll (1 EA)

1	2	3a	3b
			
4	5		
			

## Optional contents

1. AFIAS OS SD card (Inserted in the instrument) (1 EA)
2. Barcode scanner
3. USB keyboard (86 keys)

1	2	3
		

## 4. Specifications

### Physical features

□ Dimensions	276 mm (W) x 365 mm (D) x 313 mm (H)
□ Weight	9.3 kg
□ Power supply	100-240 V AC, 50 / 60 Hz, 2.5-1.0 A
□ Data output	LCD / Internal printer / RS-232 port

### Environmental requirements

□ Operation temperature	15 ~ 35 °C (59 ~ 95 °F)
□ Storage temperature	-20 ~ 60 °C (-4 ~ 140 °F)
□ Humidity	Maximum 70 %
□ Location	Dry, clean, flat and horizontal surface in an indoor setting away from direct sunlight, mechanical vibration and magnetic field

### Optical components

□ Light source	Laser diode
□ Detector	Silicon photo diode

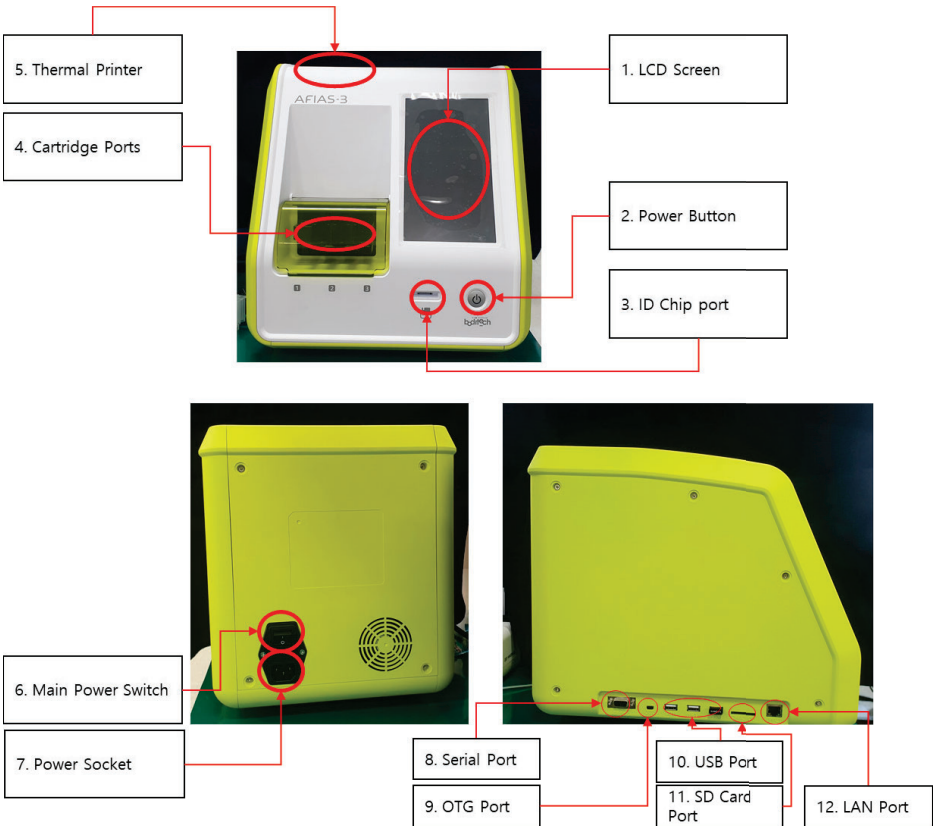
### Other components

□ Interface	RS-232	1 port
	USB / OTG	3 ports / 1 port*
	LAN	1 port
	SD card slot	1 port
□ Display	LCD (800x480 graphic LCD, touch-screen module)	

\* These ports may come disabled by the manufacturer.

**AFIAS-3 complies with the EMC requirements according to EN 61326-2-6.**  
**AFIAS-3 complies with the safety requirements according to IEC 61010-1 and IEC 61010-2-101.**

## 5. Operation and functional elements



No.	Description
① LCD screen	For entering all information regarding the test. Displays test result and message alerts.
② Power button	For switching AFIAS-3 'On' or entering it in 'Sleep Mode'
③ ID chip port	For inserting 'AFIAS-3 ID chip'
④ Cartridge ports	Accommodates cartridge holders

---

⑤ Thermal printer	Print-out of test result
⑥ Main power switch	For switching AFIAS-3 on/off
⑦ Power socket	For connecting the power cable
⑧ Serial port	For connecting to a PC *
⑨ OTG port	For connecting to a PC *
⑩ USB port	For connecting barcode scanner / keyboard
⑪ SD card port	For upgrading software *
⑫ LAN port	For connecting LAN/internet cable *

---

\* These may come disabled by the manufacturer.

---

### Function key



#### Power Button

If you press this button momentarily, AFIAS-3 will enter/exit 'Sleep mode' and the LCD screen will be turned off/on. If you press this button for more than 4 seconds, "Power off" pop-up window will be displayed. To shut AFIAS-3 down, please tap "OK".

---

## 6. Installation



**Important**

Before using AFIAS-3, read the warnings and precautions described previously in 'Clause 1: General warnings and important instructions' of this manual.

---

### **Power supply:**

AFIAS-3 will work on the common power line (i.e. 100-240 V AC, 50~60 Hz, 2.5-1.0A). If you are uncertain of your power line specifications, consult your utility manager.

### **Operational environment:**

AFIAS-3 should be placed on a dry, clean, flat, and horizontal surface in an in-door setting away from direct sunlight, mechanical vibration and any source of electromagnetic radiation (e.g. power transformers). Room temperature of the chamber must be maintained in the range of 15~35 °C (59~95 °F).

### **Installation procedure:**

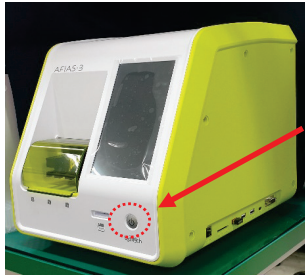
Remove the contents from the package and inspect the contents for any physical damage and/or missing item(s).

Proceed as follows:

1. Connect power cable by inserting the plug into the power socket provided at the rear of AFIAS-3.
2. Turn on the main power switch located adjacent to the power socket.



3. Connect the power cord to external power outlet and press the power button on the front façade of AFIAS-3.



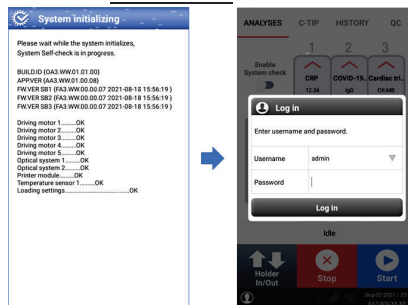


- Up on pressing the power button, AFIAS-3 will display the logo while it simultaneously executes a series of system initialization and self-checking routines; upon successful completion, the printer print-outs "System OK!". The "log in" window then follows.



During system initialization, AFIAS-3 will display each test items and the test results will be displayed. After finishing this step, AFIAS-3 will display the mode selection window. If a user does not select a test mode within 10 seconds, the test mode is set to "General mode" by default. Then AFIAS-3 will display the log-in window. If there is any problem, an error message is displayed. If a user taps the "Proceed" button, AFIAS-3 will be ready for testing.

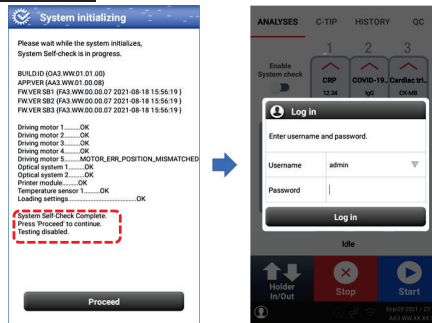
<No error>



### <Minor error>: Available use test function



### <Critical error>: Not available use test function



5. Open the protective cover of cartridge bay before inserting ID chip(s) of the AFIAS test(s) you wish to perform.



## 7. Running tests on AFIAS-3

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Before performing any AFIAS tests, please read the package insert carefully for other details of the test procedure.

---



Before performing any AFIAS tests, ensure that **test names as well as lot number printed on the 'AFIAS ID chip' exactly match with those on the 'AFIAS cartridge'** Otherwise AFIAS-3 will display an error message "Insert ID chip".

---



AFIAS cartridges and Boditech Control(s) or Calibrator(s) must have been stored under recommended storage conditions and must not have passed the respective expiration date otherwise, the test may yield misleading/erroneous results.

---



If scanning of cartridge is terminated abruptly or any problem occurs, relevant error code or an alert message will be displayed. Refer to 'Clause 11: Troubleshooting' for probable cause(s) and remedial/corrective measure(s) for the error code or message alert displayed.

---

## 7.1. Test setup:

- For performing an AFIAS test, following items in addition to AFIAS-3 in a test-ready mode are required.
- AFIAS XXX ID chip(s)
- AFIAS XXX cartridge(s)
- Patient Sample(s) or Boditech XXX Control(s) or Calibrator(s)

*(Note. XXX represents name of the AFIAS test being performed. AFIAS-3 can simultaneously perform up to 3 tests of the same or different types)*

- Match the test name as well as lot number printed on the 'AFIAS ID chip' with those of the 'AFIAS cartridge' before removing the cartridge from its blister packing.
- Allow patient sample(s), control(s) or calibrator(s) and the cartridge(s) to attain room temperature for about 30 minutes before using for the test.



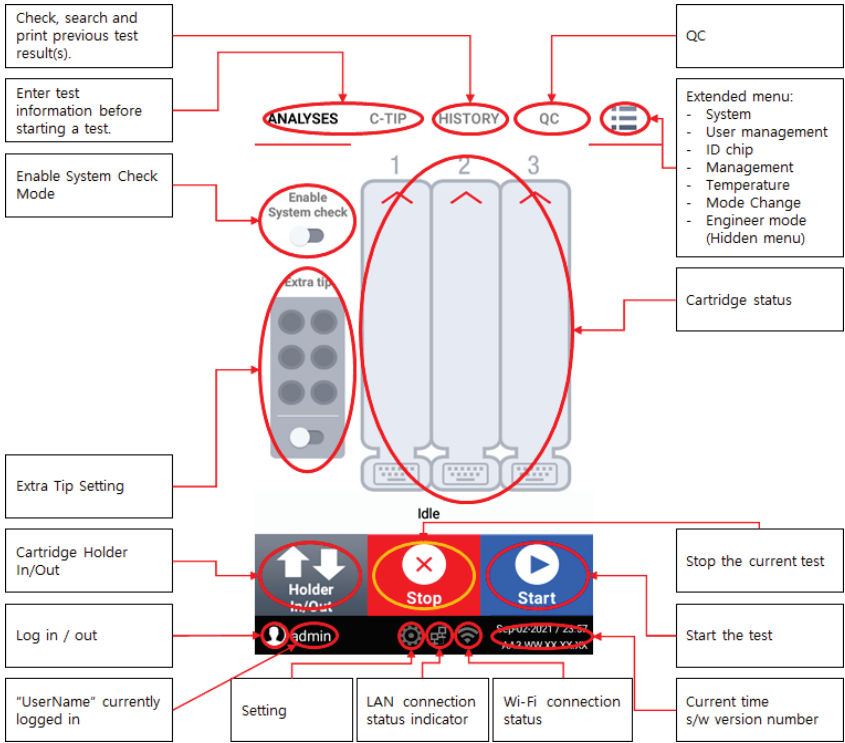
## 7.2. Logging in and entering required information:

- As described in 'Clause 6: Installation', test-ready AFIAS-3 displays the "Log in" window.

**7.2.1** Enter user name and password. The default 'user name' and 'password' are "admin" and "0000" respectively. You can change the password for 'admin' and also add other user(s). Please refer to 'Clause 9.2: User management' for further details.

Upon successful log in, the main menu will be displayed.

### 7.2.2 Details of the information/main menu displayed on the screen are as follows:



<p>7.2.3</p>	<p>✓ <b>General mode</b></p> <ul style="list-style-type: none"> <li>▪ <b>'Entering test information'</b></li> </ul> <p>Tap the section shown with a red-dotted circle on the right to enter the patient ID and select a sample type.</p>	
<p>7.2.4</p>	<ul style="list-style-type: none"> <li>▪ Enter patient ID using the keyboard on the LCD. You can also enter the patient ID with an USB keyboard if connected.</li> <li>▪ Select a sample type by tapping the designated tab.</li> <li>▪ Tap "Apply" to confirm the provided information.</li> </ul>	
<p>7.2.5</p>	<ul style="list-style-type: none"> <li>▪ Tap "Start" to start a test.</li> <li>▪ A new window will pop-up. Check and confirm patient ID and sample type for each test you want to perform.</li> <li>▪ Prepare the test cartridge following steps shown in the next Clause. If ready, tap the "Confirm start" icon.</li> <li>▪ To cancel the test, tap "Cancel start".</li> </ul>	

<p>7.2.6</p>	<p>✓ <b>C-tip mode</b></p> <ul style="list-style-type: none"><li>▪ Insert a test cartridge into a slot, and an ID chip into the ID chip port.</li><li>▪ Insert a sample-loaded C-tip into the tip hole.</li><li>▪ Tap "Start" to enter patient information.</li></ul> <p><b>Note.</b> "Start" button on the right bottom of the screen is disabled when "C-tip" mode is selected.</p>	
<p>7.2.7</p>	<ul style="list-style-type: none"><li>▪ Enter the patient ID using the keyboard on the LCD. You can also enter the patient ID with an USB keyboard if connected.</li><li>▪ Tap "Confirm start" to verify the provided information and start the test.</li></ul>	
<p>7.2.8</p>	<ul style="list-style-type: none"><li>▪ The item name is displayed in the top of the slot and the PID on the bottom of the slot.</li><li>▪ After mixing and loading process are completed, the remaining reaction time is displayed.</li><li>▪ To cancel the test, tap "Stop".</li></ul> <p><b>Note.</b> "Stop" button marked with "1" on the right diagram is used to stop the only 1 test. If you want to stop all tests, tap "Stop" button marked with "2".</p>	

<p>7.2.9</p>	<ul style="list-style-type: none"><li>When the test is completed, AFIAS-3 displays the test result under the item name.</li></ul>	
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➤ *Note. To perform additional test while the intended bay is in use, press 'Start' button when it gets activated.*

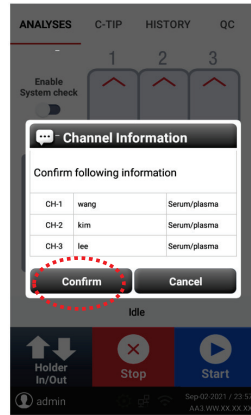


### 7.3. Inserting Sample-loaded cartridge and Obtaining Test Result:

<p>7.3.1</p>	<ul style="list-style-type: none"><li>▪ With a 'AFIAS PCT ID chip' in the ID chip port, proceed as follows to run a AFIAS PCT test on a clinical sample:</li><li>▪ Load recommended volume of the test sample into the 'Sample Well' of a 'AFIAS PCT cartridge'.</li></ul> <p><b>Note.</b> Refer to the package insert of the AFIAS test for details.</p>	
<p>7.3.2</p>	<ul style="list-style-type: none"><li>▪ After inserting the test cartridge into the specific cartridge holder, place a 'Pipette Tip' (with its broad end facing upwards) into the 'Tip slot' of the test cartridge.</li><li>▪ While inserting the cartridge, the sample well should be oriented outward from AFIAS-3.</li></ul> <p><b>Note.</b> Push it gently with your thumb or index finger; all the way into the cartridge holder until it comes to a stop. Avoid applying excessive force; otherwise it may result in mechanical failure of the system.</p>	

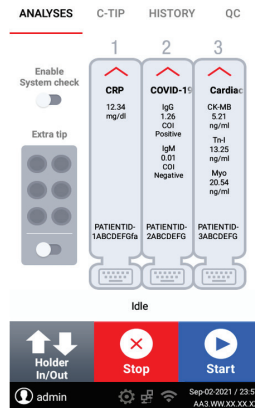
7.3.3

- To proceed with the test, tap "Confirm".
- To cancel the test, tap "Cancel".



7.3.4

- The system automatically scans the barcode and checks the pipette tip.
  - Test names (i.e. AFIAS test cartridges) inserted in respective cartridge holders are also displayed on the screen.
  - The system will start the test automatically.
  - During the test, the system displays the status as "In progress" below the screen display columns corresponding to the bay. Bay is accommodating three test cartridge holders.
  - Time (Minutes: Seconds) remaining to compete the test for each cartridge is also displayed under the test name in the respective screen display columns.
  - Upon completion of the test, the result is displayed under the test name in the respective screen display column.
- The system also displays completion of the test run as 'Test completed' below the screen display columns corresponding to the bay.



<p>7.3.5</p>	<ul style="list-style-type: none"> <li>▪ If a 'Pipette Tip' is not in the 'tip slot' of the test cartridge, the system will display 'Error! ...No Pipette tip' upon starting the test.</li> </ul> <p>The user should insert a 'Pipet tip' into the 'tip slot' to start the test by following steps according to 7.2.3.</p>	
<p>7.3.6</p>	<ul style="list-style-type: none"> <li>▪ If the user attempts to initiate the test without selecting a sample type, the system will display 'Select sample type'.</li> </ul> <p>The user should select an appropriate sample type as described in step 7.2.4.</p>	
<p>7.3.7</p>	<ul style="list-style-type: none"> <li>▪ If the test starts without a test cartridge in any of the cartridge holder, the system will display 'Error! ...Insert test cartridge'.</li> </ul> <p>Users should restart the run as described in steps as per 7.2.3.</p>	

<p><b>7.3.8</b></p>	<ul style="list-style-type: none"> <li>▪ The built-in printer automatically prints out each test result.</li> <li>▪ AFIAS-3 can save up to 5,000 test results in its internal memory.</li> </ul> <p>(Refer to Clause 8.2 for details of retrieval/printing of stored test results.)</p>	
<p><b>7.3.9</b></p>	<p>Clause 7.3 is only for "General mode". If you run the test in the "C-tip mode", please follow the steps listed below.</p> <p>① <b>Collect finger blood using a C-tip that comes with the AFIAS test cartridge box.</b></p> <p><b>Follow step 7.2.6 ~ 7.2.9 to proceed the test.</b></p>	



Before performing any AFIAS test, ensure that name of the test as well as lot number mentioned on the 'ID chip' must match with that of the 'AFIAS cartridge'.



'AFIAS cartridge' having a lot number mismatching with that of the 'ID chip' will lead to display of the error alert 'Insert ID chip'.




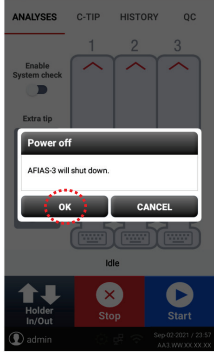


After AFIAS test is successfully performed; the used cartridge should be disposed of in accordance with local regulations regarding the disposal of bio-hazardous materials.



If you press the power button during the test, the display will be turned off. However, the test run will proceed on normally without affecting the test result.

### 7.4. Shutting AFIAS-3 down:

<p>7.4.1</p>	<ul style="list-style-type: none"><li>Before turning off AFIAS-3, make sure that ID chip and cartridge(s) have been removed from ID chip port and cartridge holder(s) respectively.</li></ul>	
<p>7.4.2</p>	<ul style="list-style-type: none"><li>Close the protective cover of bay.</li></ul>	
<p>7.4.3</p>	<ul style="list-style-type: none"><li>Press the 'Power Button' for more than 4 seconds.</li></ul>	
<p>7.4.4</p>	<ul style="list-style-type: none"><li>'Power off' menu will be displayed.</li><li>Tap 'OK' to shut down AFIAS-3.</li></ul>	

<p>7.4.5</p>	<ul style="list-style-type: none"> <li>▪ "Power off" will be executed.</li> <li>▪ AFIAS-3 will shut down.</li> </ul>	
<p>7.4.6</p>	<ul style="list-style-type: none"> <li>▪ Turn off the main power switch located on the rear side of AFIAS-3.</li> </ul>	
<p>7.4.7</p>	<ul style="list-style-type: none"> <li>▪ If you do not intend to use the system for an extended period, unplug AFIAS-3 power cord from the external power outlet is highly recommended.</li> </ul>	
<p>7.4.8</p>	<ul style="list-style-type: none"> <li>▪ Remove the power cable from the 'Power Socket'.</li> </ul>	

## 8. Auxiliary features

For ensuring efficient and reliable performance as well as proper recording and reporting of test results, AFIAS-3 provides following auxiliary features.

### 8.1 System check, Calibration and QC

#### 8.2 Retrieval/Printing/LIS of stored test results

### 8.1. System check, Calibration and QC

#### ▪ System check

- To perform a system check, a user needs to use specific system check cartridge and a system check ID chip.
- AFIAS-3 measures intensity of fluorescence and compares that result with pre-set value to inspect if the measured signal agrees with pre-set values.
- AFIAS-3 repeats measurement several times to ensure stable performance of a fluorescence system when checking the system.

#### ▪ The system check is needed as below.

- When AFIAS-3 is installed initially.
- When AFIAS-3 is moved to another place and install it again.
- When some errors are generated.
- When a test result is considered abnormal or differs from the reference value.

▪ **Calibration**

- The master calibration curve for cartridges is stored in the ID chip included in the cartridge box and no separate calibration process is required for the new reagent.
- Calibration curves stored in the ID chip may not be valid for all test environments. In this case, it is required to carry out the calibration process.
- A dedicated calibrator and a test cartridge are required for calibration.

▪ **The calibration is needed as below.**


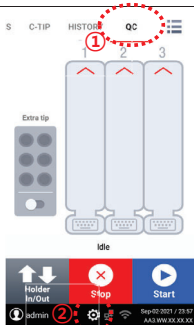
- When the QC test results are out of range.
  - When the test results are suspected to be abnormal.
- ※ AFIAS test system is designed for point of care, emergency, and small-volume testing. Therefore, a regular calibration is not required/recommended.

▪ **QC (Quality control)**



- To perform QC, a user needs to use specific quality control reagent which is supplied by the manufacturer on demand.

▪ **The QC is needed as below.**

- When a test lot is changed.
- When a test result is considered abnormal or differs from the reference value.
- When a test result is not consistent with symptoms.
- For teaching or learning the system.

<p>8.1.1</p>	<ul style="list-style-type: none"> <li>▪ To run a QC, you need to activate this function.</li> <li>▪ Select the 'Cal/QC' tap.</li> <li>▪ To activate 'Cal/QC' function, please tap the setting icon  .</li> </ul>	
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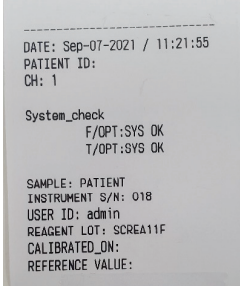
<p>8.1.2</p>	<ul style="list-style-type: none"> <li>Select the 'Control registration' menu to register a control.</li> </ul>	
<p>8.1.3</p>	<ul style="list-style-type: none"> <li>Tap the  icon to register a control.</li> </ul>	
<p>8.1.4</p>	<ul style="list-style-type: none"> <li>An 'Add control' window will pop-up.</li> <li>Enter the lot number of the calibrator, item name, mean value, low value, high value and expiration date.</li> </ul> <p><b>Note.</b> The expiration date is set as YY-MM. The actual date will be set as the last day of the selected month. For example, if you set expiration date as 2017-12, the expiration date will be 2017-12-31.</p> <p>To apply this information, tap the 'OK' button.</p>	
<p>8.1.5</p>	<ul style="list-style-type: none"> <li>If you want to delete a registered control, select a control what you want to delete.</li> <li>Tap the  icon to delete a registered control.</li> <li>Tap the 'OK' button for confirmation.</li> </ul>	

<p><b>8.1.6</b></p>	<ul style="list-style-type: none"><li>▪ To run a QC, please prepare a test cartridge what you want to test.</li><li>▪ Dispense a calibrator and control into the sample well of the cartridge.</li><li>▪ Insert each cartridge into each slot and insert a tip.</li></ul>	
<p><b>8.1.7</b></p>	<ul style="list-style-type: none"><li>▪ Tap each key board icon to select a control information for each slot.</li></ul>	

<p><b>8.1.8</b></p>	<ul style="list-style-type: none"> <li>▪ When you tap the key board icon for QC 1' slot, the 'QC-1 information' window will pop-up.</li> <li>▪ You can select items and lot numbers you want to select by tapping the triangular icon.</li> <li>▪ To apply the change, tap the 'Apply' button.</li> </ul>													
<p><b>8.1.9</b></p>	<ul style="list-style-type: none"> <li>▪ When all calibrators and controls are selected, each lot numbers will be displayed in each slots.</li> </ul>													
<p><b>8.1.10</b></p>	<ul style="list-style-type: none"> <li>▪ To start QC, tap the 'Start' button.</li> <li>▪ A 'Channel Information' window will pop-up.</li> <li>▪ Check the lot number and the item name.</li> <li>▪ To confirm the selected information and start calibration and QC, tap the 'Confirm' button.</li> </ul>	<table border="1" data-bbox="718 1129 918 1225"> <thead> <tr> <th>CH</th> <th>Control ID</th> <th>Item Name</th> </tr> </thead> <tbody> <tr> <td>CH-1</td> <td>CRP_1</td> <td>CRP</td> </tr> <tr> <td>CH-2</td> <td>CRP_2</td> <td>CRP</td> </tr> <tr> <td>CH-3</td> <td></td> <td></td> </tr> </tbody> </table>	CH	Control ID	Item Name	CH-1	CRP_1	CRP	CH-2	CRP_2	CRP	CH-3		
CH	Control ID	Item Name												
CH-1	CRP_1	CRP												
CH-2	CRP_2	CRP												
CH-3														

<p><b>8.1.11</b></p>	<ul style="list-style-type: none"> <li>When the test starts, AFIAS-3 will check item names and lot numbers.</li> <li>The name of items will be displayed, and the test status will be displayed as 'In progress'.</li> <li>During the test, the remaining times are displayed under item names.</li> </ul>	
<p><b>8.1.12</b></p>	<ul style="list-style-type: none"> <li>When the test is completed, the test result is displayed under the item name.</li> <li>AFIAS-3 generates a buzzer signal and each slot opens.</li> <li>The test results are saved in the internal memory and printed automatically.</li> </ul>	

<p><b>8.1.13</b></p> <ul style="list-style-type: none"><li>▪ Select the 'Analysis' tab to check the system.</li><li>▪ Enable system check must be activated for system check.</li></ul> <p><i>Note. The check box is released at the time of initial shipment of the product, and the check box is also released at power on/off.</i></p>		<p>① ANALYSES C-TIP HISTORY QC</p> <p>② Enable System check</p> <p>Extra tip</p> <p>1 2 3</p> <p>Idle</p> <p>Holder In/Out Stop Start</p> <p>admin Sep-02-2021 / 23:57 AA3 WW XX XX XX</p>
<p><b>8.1.14</b></p> <ul style="list-style-type: none"><li>▪ Insert the system check cartridge and system check ID chip into AFIAS-3. (Do not put a separate reagent into the system check cartridge.)</li><li>▪ Touch the "Start" icon.</li><li>▪ Check the displayed information and touch the 'Confirm' button to confirm the start of the system check.</li></ul>		<p>ANALYSES C-TIP HISTORY QC</p> <p>Enable System check</p> <p>System Check</p> <p>Are you sure you want to perform the system check cartridge?</p> <p>Confirm Cancel</p> <p>Idle</p> <p>Holder In/Out Stop Start</p> <p>admin Sep-02-2021 / 23:57 AA3 WW XX XX XX</p>
<p><b>8.1.15</b></p> <ul style="list-style-type: none"><li>▪ During system check, 'In progress' will be displayed</li><li>▪ When the system check is completed, 'SYS OK' and 'Test completed' will be displayed.</li></ul>		<p>ANALYSES C-TIP HISTORY QC</p> <p>Enable System check</p> <p>Extra tip</p> <p>System_chi</p> <p>F-OPT SYS OK</p> <p>T-OPT SYS OK</p> <p>1 2 3</p> <p>Test completed</p> <p>Holder In/Out Stop Start</p> <p>admin Sep-02-2021 / 23:57 AA3 WW XX XX XX</p>

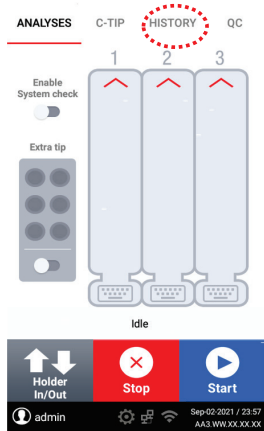
<p><b>8.1.16</b></p>	<ul style="list-style-type: none"><li>▪ The result of the system check will be printed.</li></ul>	 <pre>DATE: Sep-07-2021 / 11:21:55 PATIENT ID: CH: 1  System_check   F/OPT:SYS OK   T/OPT:SYS OK  SAMPLE: PATIENT INSTRUMENT S/N: 018 USER ID: admin REAGENT LOT: SCREA11F CALIBRATED_ON: REFERENCE VALUE:</pre>
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### 8.2. Retrieval/Printing/LIS of stored test results:

8.2.1

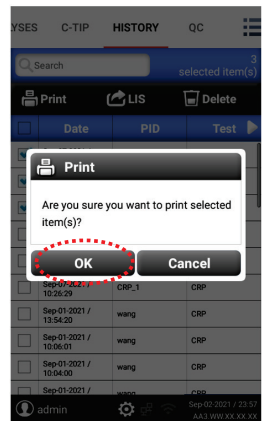
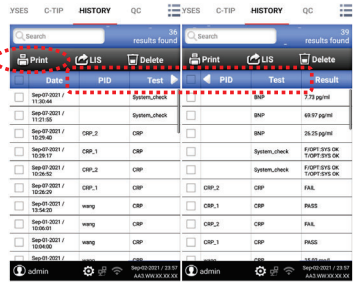
- AFIAS-3 can save up to 5,000 test results in its internal memory.
- To print out stored test result(s), tap 'History'.

**Note.** Stored test results cannot be printed if a test is in progress.



8.2.2

- Upon tapping "History", a chronological log of stored test results is displayed in a reverse order.
- Select the test result(s) you want to print.
- One can select up to 5,000 test results.
- Tap 'Print' to print out the selected test result(s).
- A new window will pop up. Tap "OK" to confirm printing action.
- If you do not want to print out the selected test results, tap 'Cancel'.

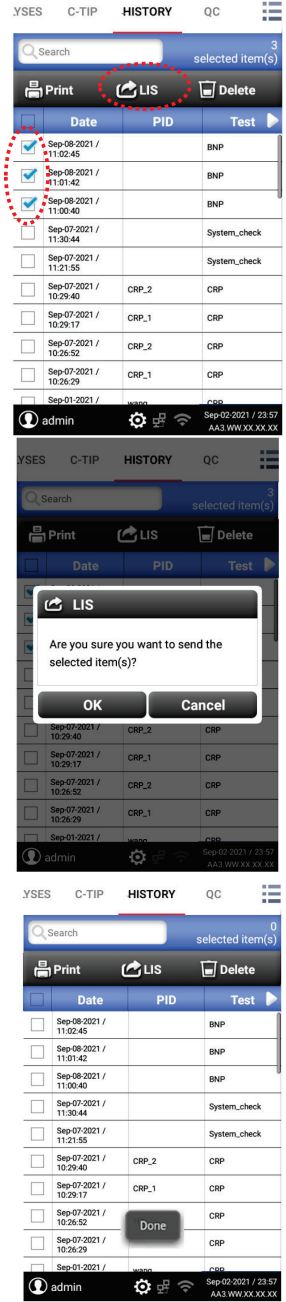


8.2.3

- Select the test result(s) you want to send via LIS.
- It is possible to select up to 5,000 test results.
- Tap 'LIS' to send the selected test result(s) by LIS.
- A new window will pop up. Tap "OK" to confirm sending action.
- If you do not intend to send the selected test results, tap 'Cancel'.
- LIS procedure is completed, AFIAS-3 will display "Done".

**Note.** LIS format is as follow.

Patient Name	Patient ID	Date	Time	Test Name	Result
...	...	...	...	BNP	...
...	...	...	...	BNP	...
...	...	...	...	BNP	...
...	...	...	...	System_check	...
...	...	...	...	System_check	...
...	...	...	...	CRP_2	CRP
...	...	...	...	CRP_1	CRP
...	...	...	...	CRP_2	CRP
...	...	...	...	CRP_1	CRP
...	...	...	...	CRP	...





<p><b>8.2.4</b></p> <ul style="list-style-type: none"> <li>▪ If you want to search specific test result(s), tap "Search" and enter the search key word (e.g. patient ID, test name)</li> <li>▪ Tap the search icon </li> <li>▪ Search results will be displayed.</li> </ul>		<p>YES C-TIP HISTORY QC</p> <p>Search selected item(s) 0</p> <p>Print LIS Delete</p> <table border="1"> <thead> <tr> <th>Date</th> <th>PID</th> <th>Test</th> </tr> </thead> <tbody> <tr><td>Sep-08-2021 / 11:02:45</td><td></td><td>BNP</td></tr> <tr><td>Sep-08-2021 / 11:01:42</td><td></td><td>BNP</td></tr> <tr><td>Sep-08-2021 / 11:00:40</td><td></td><td>BNP</td></tr> <tr><td>Sep-07-2021 / 11:30:44</td><td></td><td>System_check</td></tr> <tr><td>Sep-07-2021 / 11:21:55</td><td></td><td>System_check</td></tr> <tr><td>Sep-07-2021 / 10:29:40</td><td>CRP_2</td><td>CRP</td></tr> <tr><td>Sep-07-2021 / 10:29:17</td><td>CRP_1</td><td>CRP</td></tr> <tr><td>Sep-07-2021 / 10:26:52</td><td>CRP_2</td><td>CRP</td></tr> <tr><td>Sep-07-2021 / 10:26:29</td><td>CRP_1</td><td>CRP</td></tr> </tbody> </table> <p>admin Sep-02-2021 / 23:07 AA3 WW XX XX XX</p>	Date	PID	Test	Sep-08-2021 / 11:02:45		BNP	Sep-08-2021 / 11:01:42		BNP	Sep-08-2021 / 11:00:40		BNP	Sep-07-2021 / 11:30:44		System_check	Sep-07-2021 / 11:21:55		System_check	Sep-07-2021 / 10:29:40	CRP_2	CRP	Sep-07-2021 / 10:29:17	CRP_1	CRP	Sep-07-2021 / 10:26:52	CRP_2	CRP	Sep-07-2021 / 10:26:29	CRP_1	CRP
Date	PID	Test																														
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Sep-07-2021 / 10:26:29	CRP_1	CRP																														
<p><b>8.2.5</b></p> <ul style="list-style-type: none"> <li>▪ If you just want to browse stored test result(s) without printing, tap the field displaying the test result of your interest.</li> <li>▪ A new window will pop-up, displaying details including the patient ID, test name, test result, date &amp; time of the test, lot number and expiry date of test reagents etc.</li> </ul>		<p>YES C-TIP HISTORY QC</p> <p>Result details</p> <p>PID wang</p> <p>Test CRP</p> <p>Result 15.02 mg/L</p> <p>Date &amp; Time Sep-01-2021 / 13:54:20</p> <p>Lot No CRRDB29F</p> <p>Exp.date 2022.12.25</p> <p>Channel 1</p> <p>Sample type Serum/plasma</p> <p>OK</p> <p>admin Sep-02-2021 / 23:57 AA3 WW XX XX XX</p>																														

	<ul style="list-style-type: none"> <li>In case of HbA1c test result, AFIAS-3 will display test result in NGSP(%) and IFCC(mmol/mol) units simultaneously.</li> </ul>	
<p><b>8.2.6</b></p>	<ul style="list-style-type: none"> <li>Print-out generated by the built-in printer contains the test result along with other information as shown.</li> <li>The print out will also contain reference values/interval for the specific patient population if information regarding the same has been previously provided by the laboratory.</li> <li>In order to edit the reference value, refer to 9.1.16 and 9.1.17.</li> </ul>	

## 9. Configuring AFIAS-3

Following settings and/or parameters of AFIAS-3 can be adjusted, upgraded or modified without prior notices.

### 9.1. Configuring System Operation

- **Setting/configuring one or more of the following:**
  - Date
  - Time
  - Date format
  - Ethernet
  - LIS
  - Language
  - Set print options
  - Set default sample type
- **Setting/configuring miscellaneous operational parameters**
  - SW update
  - Test menu
  - Device information

### 9.2. User management

### 9.3. ID chip management

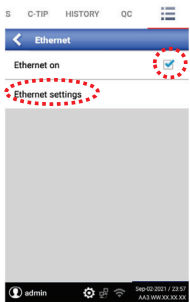
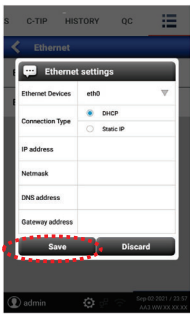

### 9.4. Temperature


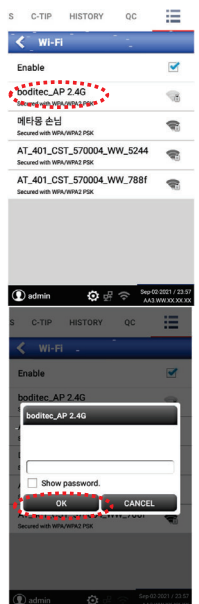
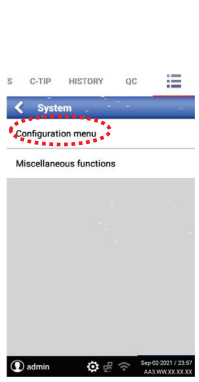
## 9.1 System configuration

<p>9.1.1</p>	<ul style="list-style-type: none"><li>▪ <b>Setting the 'Date':</b></li><li>① Tap the 'Configuration menu'.</li><li>② Tap the 'Set date' menu.</li></ul>	<p>S C-TIP HISTORY QC</p> <p>&lt; System</p> <p>Configuration menu</p> <p>Miscellaneous functions</p> <p>admin</p> <p>S C-TIP HISTORY QC</p> <p>&lt; Configuration menu</p> <p>Set date</p> <p>Set time</p> <p>Set date &amp; time format</p> <p>Network configuration</p> <p>LIS settings</p> <p>Select language - English (United States)</p> <p>Set print options</p> <p>Set default sample type</p> <p>admin</p>
<p>9.1.2</p>	<ul style="list-style-type: none"><li>▪ Tap the button(s) to set the desired month, date and year.</li><li>▪ To effect the changed date, tap 'Set'.</li></ul>	<p>2021</p> <p>Wed, Dec 15</p> <p>&lt; December 2021 &gt;</p> <p>S M T W T F S</p> <p>1 2 3 4</p> <p>5 6 7 8 9 10 11</p> <p>12 13 14 15 16 17 18</p> <p>19 20 21 22 23 24 25</p> <p>26 27 28 29 30 31</p> <p>CANCEL OK</p>
<p>9.1.3</p>	<ul style="list-style-type: none"><li>▪ <b>Setting the 'Time':</b></li><li>① Tap the 'Configuration menu'.</li></ul>	<p>S C-TIP HISTORY QC</p> <p>&lt; System</p> <p>Configuration menu</p> <p>Miscellaneous functions</p> <p>admin</p>

	<p>② Tap the 'Set time' menu.</p>	<p>The screenshot shows the 'Configuration menu' with options: Set date, Set time (circled in red), Set date &amp; time format, Network configuration, LIS settings, Select language - English (United States), Set print options, and Set default sample type. The status bar at the bottom shows 'admin', signal strength, Wi-Fi, and battery level.</p>
<p>9.1.4</p>	<ul style="list-style-type: none"> <li>▪ Tap the button(s) to set the hour and minutes.</li> <li>▪ You can set the time as 'AM' or 'PM' by tapping the adjacent tab.</li> <li>▪ To effect changed time, tap 'Set'.</li> </ul>	<p>The screenshot shows a digital clock displaying '11:34 AM'. Below the clock is a circular analog-style time picker with '11' selected. At the bottom, there are 'CANCEL' and 'Set' buttons, with 'Set' circled in red. The status bar at the bottom shows 'admin', signal strength, Wi-Fi, and battery level.</p>
<p>9.1.5</p>	<p>▪ <b>Setting the date format</b></p> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Set date format' menu.</p>	<p>The first screenshot shows the 'System' menu with 'Configuration menu' circled in red. Below it is a 'Miscellaneous functions' section. The second screenshot shows the 'Configuration menu' with 'Set date &amp; time format' circled in red. The status bar at the bottom of both screenshots shows 'admin', signal strength, Wi-Fi, and battery level.</p>

<p><b>9.1.6</b></p>	<ul style="list-style-type: none"><li>▪ Check/tap the blank box corresponding to the date format you want to select.</li><li>▪ If you want to cancel changing the date format, tap 'Cancel'.</li></ul>	
<p><b>9.1.7</b></p>	<ul style="list-style-type: none"><li>▪ <b>Ethernet configuration:</b> For connecting AFIAS-3 to the local area network.</li></ul> <ol style="list-style-type: none"><li>① Tap the 'Configuration menu'.</li><li>② Tap the 'Ethernet configuration' menu.</li><li>③ Tap the 'Ethernet' menu.</li></ol>	

	<p>④ Tap the 'Ethernet settings' menu.</p>	 A screenshot of the 'Ethernet' settings page. At the top, there are tabs for 'S', 'C-TIP', 'HISTORY', and 'QC'. Below the title bar, there is a back arrow and the word 'Ethernet'. Underneath, it says 'Ethernet on' with a toggle switch. A red dashed circle highlights the 'Ethernet settings' option.
<p>9.1.8</p>	<ul style="list-style-type: none"><li>▪ "Configure ethernet devices" window will pop-up.</li><li>▪ 'Ethernet Devices' is 'eth0' and 'Connection Type' is 'DHCP' by default.</li><li>▪ Select 'Ethernet Devices' as 'eth0' from the options available in the drop down box</li><li>▪ Select 'DHCP' as the 'Connection Type'.</li><li>▪ Tap 'Save' to effect the configuration.</li></ul>	 A screenshot of the 'Ethernet settings' configuration form. It shows fields for 'Ethernet Devices' (set to eth0), 'Connection Type' (set to DHCP), 'IP address', 'Netmask', 'DNS address', and 'Gateway address'. At the bottom, there are 'Save' and 'Discard' buttons. A red dashed circle highlights the 'Save' button.
<p>9.1.9</p>	<ul style="list-style-type: none"><li>▪ <b>Wi-Fi configuration:</b> For connecting AFIAS-3 to the Wi-Fi Network.</li></ul> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Ethernet configuration' menu.</p>	 Two screenshots. The top one shows the 'System' settings page with a red dashed circle around the 'Configuration menu' option. The bottom one shows the 'Configuration menu' page with a red dashed circle around the 'Network configuration' option.

	<p>③ Tap the 'Wi-Fi' menu.</p>	
<p>9.1.10</p>	<ul style="list-style-type: none"><li>▪ Mount the Wi-Fi dongle on the equipment and check 'Enable'.</li><li>▪ Select the Wi-Fi AP you want and enter your password.</li><li>▪ Touch the 'Ok' button to try Wi-Fi connection.</li></ul>	
<p>9.1.11</p>	<p>▪ <b>LIS configuration:</b></p> <p>For sending test results from AFIAS-3 to the LIS server via local area network or RS232C.</p> <p>① Tap the 'Configuration menu'.</p>	



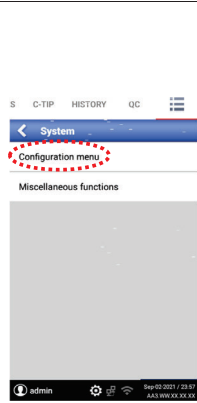
- ② Tap the 'LIS configuration' menu.
- ③ To send test results by LIS after finishing tests, select 'On' in the 'Send' item. In the opposite case, select "Off".
- ④ Please select a data format desired.
- ⑤ Please select an interface you want to use. In case of 'Network', only HL7 protocol is available. The protocol item will be changed to 'HL7' automatically. The server field is available only when 'Network' is selected. You can enter a server IO or PORT in the server field.
- ⑥ To apply setting, tap the 'Save' button.



**9.1.12**

▪ **Setting the language:**

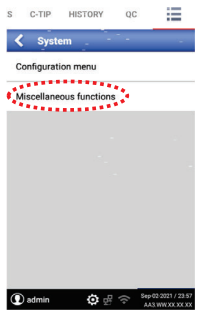
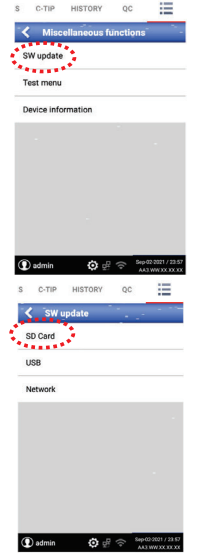
- ① Tap the 'Configuration menu'.

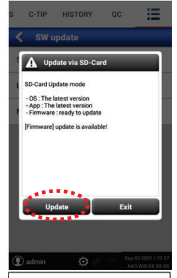
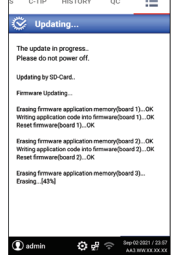
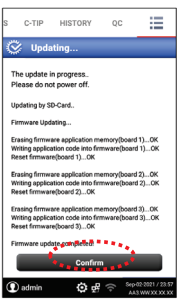



	<p>② Tap the 'Select language' menu.</p>	
<p>9.1.13</p>	<p>① You can select language. The default language is English.</p> <ul style="list-style-type: none"> <li>▪ You can select the users in English or a compound sentence.</li> <li>▪ Default language is English.If a compound sentence that appears, select the language changes to the compound sentence.</li> </ul>	
<p>9.1.14</p>	<p>▪ <b>Turning the printer on / off:</b></p> <p>① Tap the 'Configuration menu'.</p> <p>② The 'Set Printer options' menu.</p>	

<p><b>9.1.15</b></p>	<ul style="list-style-type: none"> <li>▪ 'To turn the printer on, check/tap the blank box of the 'Printer on' menu.</li> <li>▪ To turn the printer off, uncheck/tap the blank box of the 'Printer on' menu.</li> </ul>																					
<p><b>9.1.16</b></p>	<ul style="list-style-type: none"> <li>▪ When the blank box of the 'Print including the reference value' menu is checked, test results are printed including the reference value.</li> </ul>																					
<p><b>9.1.17</b></p>	<ul style="list-style-type: none"> <li>▪ <b>Edit reference values:</b> <ol style="list-style-type: none"> <li>① If you choose the 'Edit reference value', you can find the reference value information.</li> <li>② Reference values can be edited when you select each item. Values are entered on pop-up windows.</li> </ol> </li> </ul>	<table border="1" data-bbox="784 1125 974 1401"> <thead> <tr> <th>Item</th> <th>Ref. value</th> </tr> </thead> <tbody> <tr><td>PEA</td><td></td></tr> <tr><td>APP</td><td></td></tr> <tr><td>CEA</td><td></td></tr> <tr><td>MAU</td><td></td></tr> <tr><td>HbA1C</td><td></td></tr> <tr><td>GSP</td><td>10</td></tr> <tr><td>PCT</td><td></td></tr> <tr><td>TN-I</td><td></td></tr> <tr><td>D-Dimer</td><td></td></tr> </tbody> </table>	Item	Ref. value	PEA		APP		CEA		MAU		HbA1C		GSP	10	PCT		TN-I		D-Dimer	
Item	Ref. value																					
PEA																						
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CEA																						
MAU																						
HbA1C																						
GSP	10																					
PCT																						
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D-Dimer																						

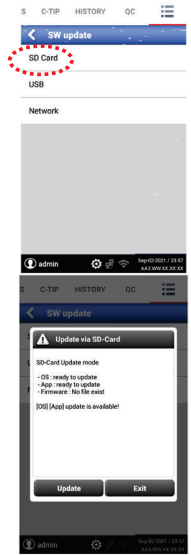
	<p>③ If you choose an item that you want to edit, a new window will pop-up for editing the reference value.</p>	
<p>9.1.18</p>	<ul style="list-style-type: none"> <li>▪ <b>Set default sample type</b></li> </ul> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Set default sample type' menu.</p> <p>③ Select the sample type.</p>	
<p>9.1.19</p>	<ul style="list-style-type: none"> <li>▪ 'Once you choose the 'Set default sample type' menu, a new window will pop up.</li> <li>▪ When you choose a sample type under 'set default sample type' menu, the sample type you chose will be automatically selected under the general mode test.</li> </ul>	

<p>9.1.20</p>	<p>▪ <b>Updating Software:</b></p> <p><i>Note.</i> This function should be handled only by the 'administrator', a trained engineer or manufacturer's authorized representative. Incorrect or unwarranted use of this function can cause serious problems in system operations.</p> <p>▪ If you insert the Upgrade SD card and tap the 'SD/USB' menu, then the program will automatically determine if an upgrade is needed. When an upgrade is needed, it will start upgrading.</p> <p><i>Note.</i> If you want to update S/W via a network, you can tap 'Network' menu. Please refer to 9.1.24.</p>	
<p>9.1.21</p>	<p>▪ <b>Updating firmware via a SD card:</b></p> <ol style="list-style-type: none"><li>① Tap the 'Miscellaneous functions' menu.</li><li>② Tap the 'SW update' menu.</li><li>③ Tap the 'SD Card' menu.</li></ol>	

	<p>④ 'Update via SD-Card' window will pop up.</p> <p>⑤ Tap the 'Update' menu after confirming the information in the pop-up box.</p> <p>⑥ If you insert a SD card with updated version of firmware, it will start to update automatically.</p> <p>⑦ If you tap the 'Confirm' menu, it will automatically reboot.</p> <p>⑧ Update will be completed after rebooting.</p> <p><i>Note.</i> You can check whether the firmware update is successful or not by accessing the 'Device information' menu as described in Step 9.1.29.</p>	  
<p><b>9.1.22</b></p>	<p><b>Updating the android operating system via SD card</b></p> <p>: To update the 'Android OS', insert the 'Upgrade SD Card' (provided by the manufacturer or its authorized service representative) into the 'SD card port'.</p> <p>① Tap the 'Miscellaneous functions' menu.</p> <p>② Tap the 'SW update' menu.</p> <p>③ Tap the 'SD Card' menu.</p>	

- ④ 'Update via SD-Card' window will pop-up.
- ⑤ Tap the 'Update' menu after confirming the information in the pop-up box.
  - i. If you insert a SD card with updated version of android OS, it will start to update automatically.
  - ii. If you tap the 'Confirm' menu, it will automatically reboot.
  - iii. Update will be completed after rebooting.

- ⑥ Then "SW update" screen will be presented. To finish android OS updating, it takes about 4 minutes.



	<p>⑦ When android OS updating is completed, AFIAS-3 will reboot automatically.</p> <p><b>Note.</b> You can check if the android OS update is successful by accessing the 'Device information' menu as described in Step 9.1.31.</p>	
<p>9.1.23</p>	<p>▪ <b>Updating the application via a SD card:</b></p> <p>: To update the 'Application', insert the 'Upgrade SD Card' (provided by the manufacturer or its authorized service representative) into the 'SD card port'.</p> <ol style="list-style-type: none"><li>① Tap the 'Miscellaneous functions' menu.</li><li>② Tap the 'SW update' menu.</li><li>③ Tap the 'SD Card' menu.</li></ol>	



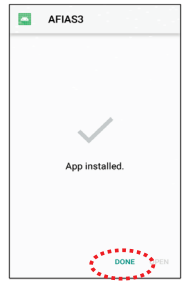
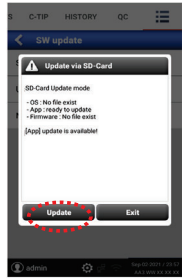
④ 'Update via SD-Card' window will pop-up.

⑤ Tap the 'Update' menu after confirming the information in the pop-up box.

- i. If you insert a SD card with updated version of application, it will start to update automatically.
- ii. If you tap the 'Done' menu, it will automatically reboot.
- iii. Update will be completed after rebooting.

**Note.** You can check if the application update is successful by accessing the 'Device information' menu as described in Step 9.1.31.

**Note.** If the SD card contains the latest android OS version, 1. firmware and 2. OS will start updating in this order. android OS includes application, so application update is not needed.



**9.1.24**

**Updating Software through a network**

: To update software via a network, AFIAS-3 should be connected to network(e.g. LAN cable connection is needed.) and insert a 'SD card' (provided by the manufacturer or its authorized service representative) into the 'SD card port'.

- ① Tap the 'Network' menu.
- ② If the AFIAS-3 is not registered, 'Device Registration' window will be displayed.



- ③ Tap the 'Register now' button to register the device.

**Note.** If you tap the 'Later' button, the update function will be disabled.

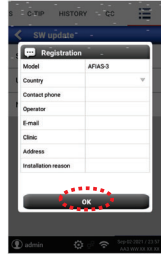
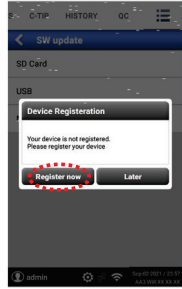
- ④ Enter registration information and tap the 'OK' button. Then tap the 'Network' menu again(refer to Step 1 of Clause 9.1.24.).

- ⑤ AFIAS-3 displays 'Update via Network' window and you can check the available updates.

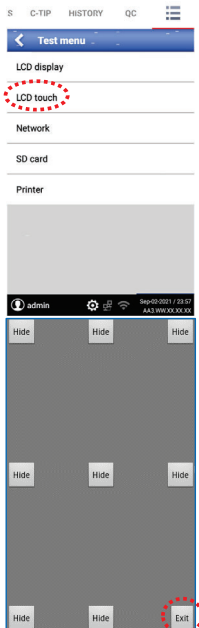
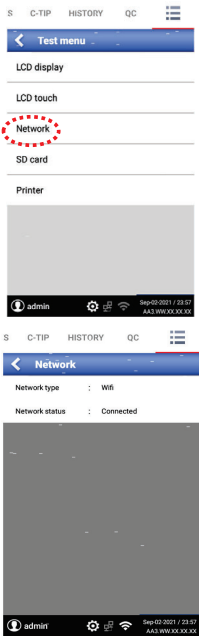
- ⑥ Tap the 'Download' button to proceed to update.

- ⑦ AFIAS-3 displays 'Download update' window and the downloading progress is displayed.

- ⑧ When the download is completed, AFIAS-3 performs the updating automatically.



<p>9.1.25</p>	<ul style="list-style-type: none"><li>▪ <b>Configuring the 'Test Menu':</b></li></ul> <p>: In 'Test menu', you can test LCD display, LCD touch, LAN connectivity, SD card and printer connectivity.</p> <ol style="list-style-type: none"><li>① Tap the 'Miscellaneous functions' menu.</li><li>② Tap the 'Test menu'.</li></ol>	<p>The screenshot shows the 'System' menu with 'Miscellaneous functions' circled in red. Below it, the 'Miscellaneous functions' menu is shown with 'Test menu' circled in red.</p>
<p>9.1.26</p>	<ul style="list-style-type: none"><li>▪ To test 'LCD display', tap the 'LCD display' menu.</li><li>▪ AFIAS-3 will display various colors to test LCD display.</li><li>▪ When the test is finished, tap 'Exit'.</li></ul>	<p>The screenshot shows the 'Test menu' with 'LCD display' circled in red. Below the menu, a test pattern is displayed, including a color bar and a circular test pattern. An 'Exit' button is circled in red at the bottom.</p>

<p>9.1.27</p>	<ul style="list-style-type: none"><li>To test 'LCD touch', tap the 'LCD touch' menu.</li><li>AFIAS-3 will display 9 blocks( 8 'Hide' blocks and 1 'Exit' block).</li><li>To test 'LCD touch', tap the 8 'Hide' blocks.</li><li>To complete this test, tap the 'Exit' block.</li></ul>	
<p>9.1.28</p>	<ul style="list-style-type: none"><li>To test the network connectivity, tap the 'Network' menu.</li><li>If the LAN is connected, the network type is displayed as 'Ethernet' and network status is displayed as 'Connected'.</li></ul>	

	<ul style="list-style-type: none"> <li>If the LAN is not connected, network type is displayed as 'None' and network status is displayed as 'Disconnected'.</li> </ul>	
<p>9.1.29</p>	<ul style="list-style-type: none"> <li>To check a SD card, tap the 'SD card' menu.</li> <li>AFIAS-3 will check the SD card inserted in the 'SD card slot'.</li> <li>If SD card has been inserted, screen will display the alert 'SD card mounted'.</li> <li>If SD card has not been inserted or if the SD card has been inserted yet could not be accessed by the system, the screen will display 'No SD card'.</li> </ul>	
<p>9.1.30</p>	<ul style="list-style-type: none"> <li>To test the printer, tap the 'Printer' menu.</li> <li>AFIAS-3 prints out standard texts according to language setting as shown in the pictures herewith.</li> </ul>	<p style="text-align: center;">English format</p>



	<p>③ Following information related to the system will be displayed:</p> <ul style="list-style-type: none"><li>- Build date</li><li>- Build ID</li><li>- Android version</li><li>- Kernel version</li><li>- Application version</li><li>- Firmware version</li><li>- Mac address</li></ul>	<p>The screenshot shows the 'Device information' screen with the following details:</p> <ul style="list-style-type: none"><li><b>BUILD DATE (D0180208)</b></li><li><b>BUILD ID (A43.WW.01.01.00)</b></li><li><b>ANDROID VERSION (8.0.0)</b></li><li><b>KERNEL VERSION (4.9.17)</b></li><li><b>APP VERSION (A43.WW.01.01.00)</b></li><li><b>FW VERSION 181 (FA3.WW.00.00.07.2021-07-22 17:09:47)</b></li><li><b>FW VERSION 182 (FA3.WW.00.00.07.2021-07-22 17:09:47)</b></li><li><b>FW VERSION 183 (FA3.WW.00.00.07.2021-07-22 17:09:47)</b></li><li><b>NETWORK INTERFACE 0</b></li><li><b>MAC ADDRESS (C2:79:3D:00:90:04)</b></li></ul> <p>The bottom status bar shows 'admin', signal strength, Wi-Fi, and battery level at 100%.</p>
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## 9.2 User management

- 'User Management' is available to the 'Administrator' only.
- This function should be used for adding a new user or deleting an existing/registered user.
- The 'Administrator' can register/add up to 100 users.

① Tap the 'User management' menu.

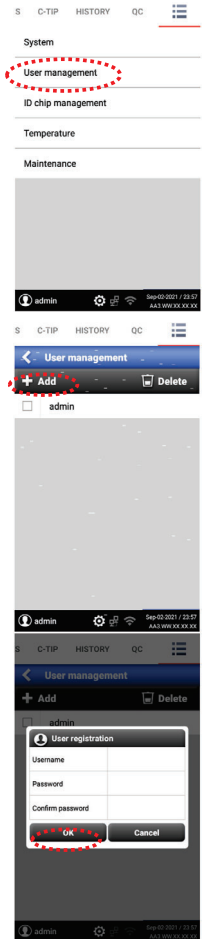
**Note.** If any registered user (xxxx) other than the 'administrator' tries to access the 'User management' menu, AFIAS-3 will display the warning message 'Access denied for xxxx'.

### 9.2.1

- ② Tap the '+' icon to add a user.
- ③ Enter a suitable 'user name' and a 'password'.
- ④ Confirm/re-enter the password.

**Note.** The User name and the password should comprise at least 4 characters each.

- ⑤ Tap 'OK' to add the user with the above user name and the password.
- ⑥ Tap 'Cancel' if you do not intend to proceed.

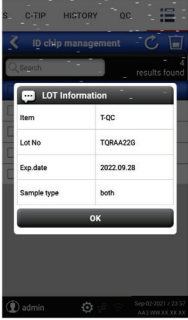

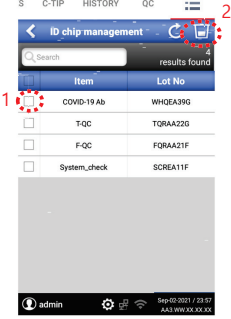




<p><b>9.2.2</b></p>	<ul style="list-style-type: none"><li>▪ To delete an existing/registered user, check/select the blank box corresponding to the 'user name' you want to delete.</li><li>▪ Tap 'Delete'.</li><li>▪ Tap 'OK' to confirm deleting the selected user.</li></ul> <p><i><b>Note.</b> 'Administrator' being the default user name, cannot be deleted or modified.</i></p>	
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### 9.3 ID chip management

<p>9.3.1</p>	<p>When any 'AFIAS Test ID chip' is inserted into the ID chip slot, information derived from the ID chip will be saved in the internal memory of AFIAS-3.</p> <p><b>Note.</b> AFIAS-3 can save ID chip information from up to 500 ID chips.</p> <ul style="list-style-type: none"> <li>By accessing the 'ID chip management' menu, one can search and check relevant ID chip information such as the name of the AFIAS test, Lot number, Expiry date and sample type(s).</li> <li>You can also delete outdated ID chips.</li> <li>Tap the 'ID chip management' menu.</li> </ul>	<p>The screenshot shows the main menu of the AFIAS-3 system. The menu items are: System, User management, ID chip management (highlighted with a red dashed circle), Temperature, and Maintenance. The bottom status bar shows 'admin', signal strength, Wi-Fi, and the date/time 'Sep 02 2021 / 23:57'.</p>										
<p>9.3.2</p>	<ul style="list-style-type: none"> <li>To search ID chip information, tap the 'Search' icon.</li> <li>Enter an appropriate term/keyword (e.g. test name, lot number, sample type etc.) for the information you want to search for and tap 'search'.</li> </ul>	<p>The screenshot shows the 'ID chip management' screen. At the top, there is a search bar with a magnifying glass icon and a 'Search' button. Below the search bar is a table with columns 'Item' and 'Lot No'. The table contains the following data:</p> <table border="1"> <thead> <tr> <th>Item</th> <th>Lot No</th> </tr> </thead> <tbody> <tr> <td>COVID-19 Ab</td> <td>WH0EA39G</td> </tr> <tr> <td>T-QC</td> <td>TORAA22G</td> </tr> <tr> <td>F-QC</td> <td>FR0AA21F</td> </tr> <tr> <td>System_check</td> <td>SCREA11F</td> </tr> </tbody> </table> <p>The search bar is highlighted with a red dashed circle. The bottom status bar shows 'admin', signal strength, Wi-Fi, and the date/time 'Sep 02 2021 / 23:57'.</p>	Item	Lot No	COVID-19 Ab	WH0EA39G	T-QC	TORAA22G	F-QC	FR0AA21F	System_check	SCREA11F
Item	Lot No											
COVID-19 Ab	WH0EA39G											
T-QC	TORAA22G											
F-QC	FR0AA21F											
System_check	SCREA11F											
<p>9.3.3</p>	<ul style="list-style-type: none"> <li>List of the search results will be displayed.</li> <li>To get the ID chip info, tap the test name listed under the column 'Item'.</li> </ul>	<p>This screenshot is identical to the previous one, showing the 'ID chip management' screen with search results. The search bar is highlighted with a red dashed circle. The bottom status bar shows 'admin', signal strength, Wi-Fi, and the date/time 'Sep 02 2021 / 23:57'.</p>										

	<ul style="list-style-type: none"><li>▪ Relevant information (test name/item, lot number, expiry date and sample type) corresponding to the ID chip will be displayed.</li></ul>											
<p>9.3.4</p>	<ul style="list-style-type: none"><li>▪ To delete an ID chip info, select/check the blank box corresponding to the ID chip.</li><li>▪ Tap the  icon.</li><li>▪ Tap 'OK' to confirm deleting the ID chip info.</li></ul>	 <table border="1" data-bbox="737 542 966 646"><thead><tr><th>Item</th><th>Lot No</th></tr></thead><tbody><tr><td><input type="checkbox"/> COVID-19 Ab</td><td>WH0EA990</td></tr><tr><td><input type="checkbox"/> T-QC</td><td>TORAA220</td></tr><tr><td><input type="checkbox"/> F-QC</td><td>FORAA21F</td></tr><tr><td><input type="checkbox"/> System_check</td><td>SCREA11F</td></tr></tbody></table>	Item	Lot No	<input type="checkbox"/> COVID-19 Ab	WH0EA990	<input type="checkbox"/> T-QC	TORAA220	<input type="checkbox"/> F-QC	FORAA21F	<input type="checkbox"/> System_check	SCREA11F
Item	Lot No											
<input type="checkbox"/> COVID-19 Ab	WH0EA990											
<input type="checkbox"/> T-QC	TORAA220											
<input type="checkbox"/> F-QC	FORAA21F											
<input type="checkbox"/> System_check	SCREA11F											

## 9.4 Temperature

- You can access this function to check the operating temperature for each bay.

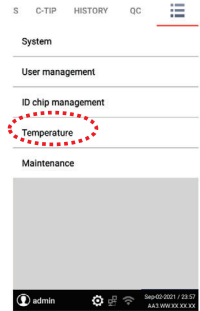
**Note.** *The normal/operational temperature range in the bay is 33-37 °C.*

- Tap the 'Temperature' menu.

### 9.4.1

- Operating temperature of both bays will be displayed.

**Note.** *If 'Incorrect temperature' or 'Error status' shows AFIAS tests will not run till the temperature is brought to the accepted range.*



The screenshot shows the 'Temperature' screen with a table of data:

Unit	Temperature	Status
°C	35.0	●
°F	95.0	●

Legend:  
● - Ok, no errors  
! - Incorrect temperature  
● - Error status

Normal status

The screenshot shows the 'Temperature' screen with a table of data:

Unit	Temperature	Status
°C	30.1	!
°F	86.0	!

Legend:  
● - Ok, no errors  
! - Incorrect temperature  
● - Error status

Incorrect status

## 10. Maintenance, servicing and disposal

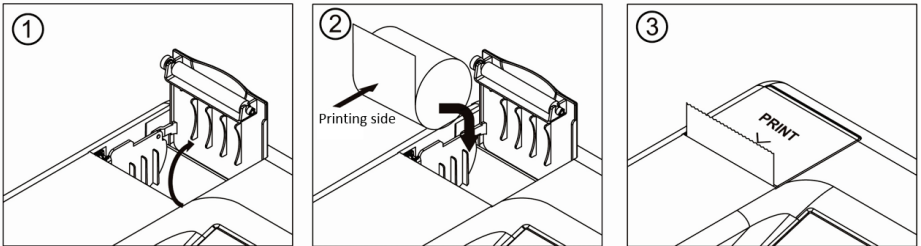
### 10.1. Maintenance:

No maintenance other than the following is required for AFIAS-3:

- Loading paper in the built-in thermal printer
- Emptying the 'Waste tip box' and resetting the 'Waste tip counter'
- Occasional cleaning of cartridge holders and exterior
- Raw data backup for maintenance or service purposes
- Washing the tip adapter

#### Loading paper in the printer

- Open the printer cover as shown in the figure below, insert the paper with correct direction, and take out the paper at least 1 cm.
- Remove the remaining paper, if any.



When the printer cover is closed, built-in printer ejects the printer paper a little for initialization.



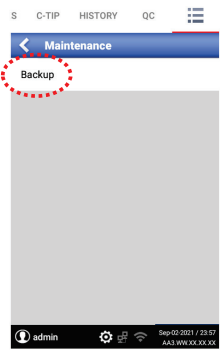
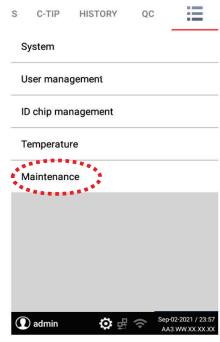
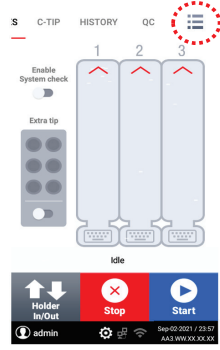
Be careful excessive force when opening or closing the printer cover for preventing malfunction of built-in printer.

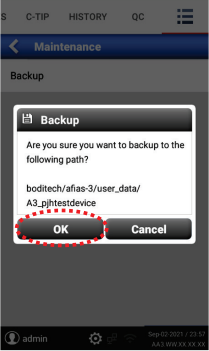
10.1.1

▪ **Raw data backup:**

Test raw data is needed to determine the cause of the problem and solve it in case of a problem.

- ① Touch 'Extension menu' in the upper right corner of the main menu.
  
  
  
  
  
  
  
  
  
  
- ② Touch the 'Maintenance' menu.
  
  
  
  
  
  
  
  
  
  
- ③ Touch the 'Backup' menu.



<p>④ Touch the 'OK' button to confirm the backup progress.</p> <p><b>Note.</b> The backed up data is stored in the <i>bodytech/afias-3/user-data</i> folder on the SD card. This data is encrypted and stored, and can only be checked by the manufacturer.</p>	
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### 10.2. Cleaning:

- It is advised to occasionally clean the cartridge holders and exterior of AFIAS-3 by wiping with a soft cloth slightly dampened with 70 % alcohol or 0.5 % bleaching solution.
- Do not use soap solution or any industrial solvent for cleaning purpose.
- Unplug AFIAS-3 from external power source before cleaning.

### 10.3. Servicing

- AFIAS-3 does not have any operator-serviceable components.
- If any technical servicing or maintenance is required, AFIAS-3 should be sent back to Boditech Med Inc. or its authorized service agents.

### 10.4. Disposal

- If AFIAS-3 is to be disposed of for any reason, the user is advised to observe local regulations as applicable to the disposal of electrical equipment.

#### Important!



At the end of its useful life, AFIAS-3 could be sent back to Boditech Med Inc. for recycling or proper disposal.

Alternatively, it should be disposed of in accordance with local regulations.

## 10.5. Transportation and Storage

- The original shipping container/box should be used to ship or transport AFIAS-3. The same container/box is also recommended for storing AFIAS-3 over an extended period of non-use.



When transporting or storing AFIAS-3, keep it dry in an upright position and protect it from mechanical shocks.

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## 11. Troubleshooting

AFIAS-3 may encounter some operational problems occasionally. The symptoms/error codes displayed, probable causes and recommended remedial/corrective measures for these problems have been listed in the table below.

Symptoms	Probable causes	Recommended remedial/ Corrective measures
Nothing happens; AFIAS-3 does not show any sign of functioning	Power failure	Check whether external power outlet is live.
	Poor connection between the power adapter and the power cable.	Remove the power cable from AFIAS-3 and reconnect firmly.
	Main power Switch is 'Off'.	Turn the main power switch 'on'.
	Faulty power adapter	Call Boditech Med Inc.'s technical services.
'Cartridge Holder' does not protrude out as and when required.	AFIAS-3 is in the 'sleep' mode	Gently press the power button located on the front of AFIAS-3. If the problem persists, contact Boditech Med Inc.'s technical services.
	Mechanical failure	Call Boditech Med Inc.'s technical services.
Clicking noise generated while the cartridge holder(s) protrudes out	Software malfunction	Turn the power 'off' and turn it 'on' again.
	Normal mechanical setting	User's action not required.
'LCD Display' does not function properly.	Electrostatic shock	Connect to a grounded external power outlet. Remove any source of electrostatic charge. Reset the system.

	Electrical circuit failure	Call Boditech Med Inc.'s technical services.
Barcode error! ...Insert the cartridge properly or Barcode module malfunction	AFIAS-3 can't read the barcode of the AFIAS test cartridge on account of the barcode being misprinted or obscured due to presence of blemishes or foreign matter.	Remove any foreign matter obscuring the barcode and continue the test by reinserting the same cartridge. If the error code should persist, repeat the test using a new 'AFIAS test cartridge'.
	Malfunction of the barcode-reading/scanning module.	Call Boditech Med Inc.'s technical services.
Insert printer paper	No paper in the built-in printer.	Load a new paper roll.
Error 25-29	Technical problem with the 'AFIAS test cartridge' or malfunction.	Repeat the test using a new 'AFIAS test cartridge'.
	Malfunction of AFIAS-3.	Call Boditech Med Inc.'s technical services.
Error! ...Insert reagent cartridge	Test run has been initiated without inserting AFIAS test cartridge into the cartridge holder.	Insert sample-loaded 'AFIAS test cartridge' into the cartridge holder before initiating the test run (i.e. before tapping 'Start' on the screen display)
	AFIAS-3 can't identify the 'AFIAS test cartridge' inserted in the cartridge holder.	Call Boditech Med Inc.'s Technical Services.
Error! ...No pipette tip	Test run has been initiated without placing a 'pipette tip' into the 'tip slot' of the AFIAS test cartridge	Place a 'pipette tip' into the 'tip slot' of the sample-loaded 'AFIAS test cartridge' (inserted in the cartridge holder) before initiating the test run

	inserted in the cartridge holder.	(i.e. before tapping 'Start' on the screen display)
	AFIAS-3 can't detect the 'pipette tip' placed into the 'tip slot' of the inserted test cartridge.	Call Boditech Med Inc.'s technical services.
Please wait until the reader reaches recommended temperature	The system temperature is outside the permissible or operational temperature range, Or malfunction of the built-in temperature sensor.	Check the temperature status of the system (Please refer to ' <b>Clause 9.4: Temperature</b> '). If system temperature should lie outside the operational range, wait for about 10 minutes. Proceed with the test(s) after temperature status of the system changes to 'normal'. If the temperature status continues to be out of the range, contact Boditech Med Inc.'s technical services.
Select sample type	The user has attempted to initiate the test run without selecting the sample type.	Select/Enter appropriate sample type on the screen before initiating the test run.
Error! ...Insert ID chip	A system check cartridge is not inserted.	Insert a system check cartridge and do system check.
	The test is performed without an ID chip.	Insert an ID chip and do the test again.
	Lot numbers of the ID chip and test cartridge do not agree	Match lot numbers of the ID chip and the test cartridge and test again.
Error_S1	The System check is not successful. Problems in the optical parts.	Try the system check again. If this error recurs, contact Boditech Med Inc.'s technical services.

The password does not match.	Entered password does not match with the administrator's password.	Enter the correct password (for administrator). If administrator has forgotten his/her password, call Boditech Med Inc.'s technical services for resetting administrator's password.
	Entered password does not match with the registered user's password.	Enter correct password or if the user has forgotten his/her password, reset the password with the help of 'Administrator'.
Built-in printer does not print the test results	Please configure the printer settings to enable. System/Configuration/Set print options/Printer on - enable	Set the printer 'on' by accessing the 'Pinter on/off' menu. (Refer to Clause 9.1.11 ~ 9.1.12).
	Print error	Call Boditech Med Inc.'s technical services.

## 12. Warranty

AFIAS-3 has passed the strict quality assurance and testing procedures.

Boditech Med Inc.'s expressed and implied warranties are conditional upon full observance of Boditech Med Inc.'s published directions with respect to the use of Boditech Med Inc.'s products.

To avail of the warranty service, the consumer must return the defective AFIAS-3 unit or any component thereof; along with proof of purchase to Boditech Med Inc. or the nearest Authorized Service Agent.

### Warranty information

During the warranty period (24 months from the date of purchase), defective or spontaneously malfunctioning AFIAS-3 or its component(s) will be repaired free of cost or may be compensated for in accordance with consumer protection rules and regulations.

The consumer may be charged for repair of AFIAS-3 even during the warranty period in following cases:

- Improper use or misuse
- Consumer's intentional mishandling, abuse or neglect of the product(s)
- Unauthorized repair / replacement of or alteration in any component
- Damages or defects due to fire, pollution, earthquake or other natural disasters.

For after-sales inquiry, please contact:

#### **Boditech Med Inc.**

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,

Gang-won-do, 24398, Republic of Korea

Phone No.: +(82)-33-243-1400 / Fax No.: +(82)-33-243-9373

E-mail: TS@boditech.co.kr / Website: www.boditech.co.kr

## Warranty Card

Thank you for purchasing AFIAS-3.

Please fill in the required information and send a copy of this warranty card within 30 days upon the date of purchase to the above address.

Product name	AFIAS-3
Catalog No.	FPRR040
Serial No.	
Date of manufacture	
Warranty period	24 months from the date of purchase
Date of purchase	Year _____ Month _____ Day _____
Manufacturer	Boditech Med Inc.
Purchase location	



## Respect for life

### **Boditech Med Inc.**



43, Geodudanji 1-gil, Dongnae-myeon,  
Chuncheon-si, Gang-won-do 24398, Korea  
강원도 춘천시 동내면 거두단지 1길 43  
Tel: +82-33-243-1400 Fax: +82-33-243-9373

### **Obelis s.a.**



Bd. Général Wahis 53, 1030 Brussels, Belgium  
Tel: +(32) 2.732.59.54 Fax: +(32) 2.732.60.03  
mail@obelis.net