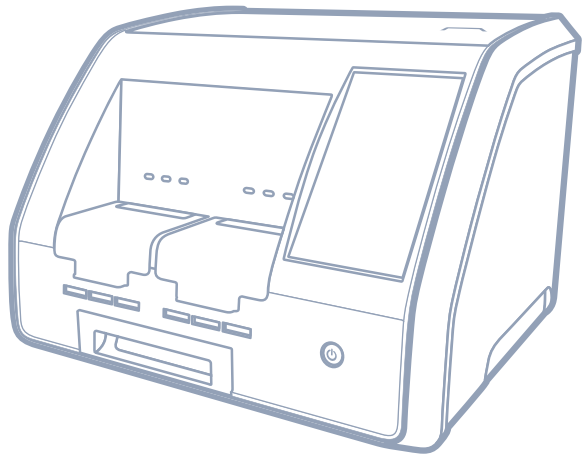




IVD

# AFIAS-6



AFIAS-6



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>11</b>
<b>5. Operational and functional elements</b>	<b>13</b>
<b>6. Installation</b>	<b>15</b>
<b>7. Running tests on AFIAS-6</b>	<b>20</b>
<b>8. Auxiliary features</b>	<b>33</b>
<b>9. Configuring AFIAS-6</b>	<b>51</b>
<b>10. Maintenance, servicing and disposal</b>	<b>86</b>
<b>11. Troubleshooting</b>	<b>94</b>
<b>12. Warranty</b>	<b>98</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-6 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)

---

**SN** Serial number

---



**LASER Radiation**

Do not stare at the 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-6 may cause electrocution, burns, fire and other hazards. To reduce the risk of electric shock.

- Use only the power cord provided with AFIAS-6.
- Never try to disassemble AFIAS-6 as it does not have any operator-serviceable components.
- Do not allow AFIAS-6 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-6 from external power source before cleaning.
- Disconnect the power cord during an extended period of non-use and/or storage.



### Laser Radiation

AFIAS-6 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-6. Unauthorized alteration and disassembly can cause exposure to laser radiation. When operating the AFIAS-6, 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-6 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-6 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.

**Always dispose of biological waste in accordance with relevant local regulations.**



**Caution**

AFIAS-6 is designed for countertop operation under laboratory conditions.

To reduce the risk of damage to AFIAS-6:

- Handle AFIAS-6 gently with care to prevent damages to its internal components.
- Keep AFIAS-6 in a dust-free place.
- Do not expose AFIAS-6 to an environment with high humidity, direct sunlight and/or extreme temperature.
- Do not place anything on top of AFIAS-6.
- Use only the accessories provided with AFIAS-6, 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-6.
- During transportation and/or storage, keep AFIAS-6 dry in temperature range of 20 ~ 60 °C 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-6 is in proper working condition before performing the test.
- AFIAS test setup should be arranged in an operational environment, having a temperature of 15 ~ 35 °C (59 ~ 95 °F).
- Use AFIAS cartridges that have been stored in recommended storage conditions only.
- Expired cartridges must not be used.
- 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 testing and allow it to stand at room temperature for at least 30 minutes.
- Before performing any AFIAS tests, read the entire package insert of the test thoroughly and carefully follow the instructions.

**Failure to follow these precautions may yield misleading or erroneous results with the AFIAS-6 test.**

## 2. Principle of operation

### Intended use

AFIAS-6 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-6 should be operated by healthcare professionals or trained medical technologists (professional use only).

### Principle

AFIAS-6 is a fluorescence and europium nanoparticle scanning system for use with various AFIAS tests based on antigen-antibody reactions and fluorescence technology (fluorophores or nanoparticles). AFIAS-6 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. 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-6.

AFIAS-6 tests are *in vitro* diagnostic tests intended for screening, monitoring and/or routine physical examination.



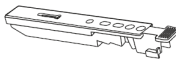

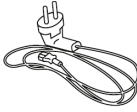

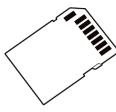
### 3. Commercial package contents

AFIAS-6 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 component.

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.

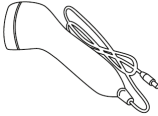


#### Basic contents

1. 1 AFIAS-6
2. 1 Operation manual
3. 1 Set of AFIAS-6 system check cartridge and a system check ID chip
4. 1 Power cord
5. 1 Thermal printer paper roll
6. 1 AFIAS OS SD card (inserted in the instrument)

1	2	3a	3b
			
4	5	6	
			

**Optional contents**

- 7. Barcode scanner
- 8. USB keyboard (86 keys)
- 9. Washing cartridge (6 ea / box)

7	8	9
		



## 4. Specifications

### Physical Features

❑ Dimensions	420 mm (L) x 336 mm (W) x 293 mm (H)
❑ Weight	15.1 kg
❑ Power supply	100-240 V AC, 50~60 Hz, 1.8 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

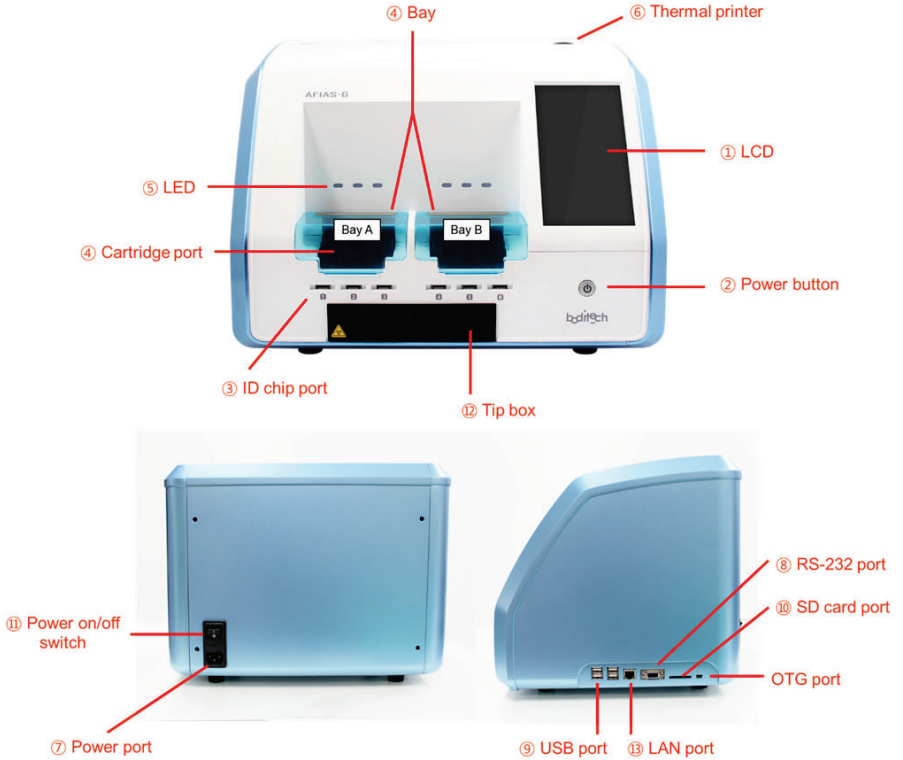
❑ Interface	RS-2321	1 port *
	USB	4 ports
	LAN	1 port *
	SD card slot	1 port *
❑ Display	LCD (800x480 Graphic LCD, Touch-screen module)	

\* These ports may come disabled by the manufacturer.

**AFIAS-6 complies with the EMC requirements according to EN 61326-2-6.**

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

## 5. Operational and functional elements



No.	Description
① LCD screen	For inputting all information regarding the test. Displays test results and message alerts.
② Power button	For switching AFIAS-6 'on' or entering it in 'sleep mode'
③ ID chip ports (1~6)	For inserting 'AFIAS-6 ID chips'
④ Cartridge ports/bays	Accommodates cartridge holders
⑤ LED	Indicators for test status (blue : test in progress / red : error)
⑥ Thermal printer	Prints out test results

⑦ Power socket	For connecting the power cable
⑧ Serial port	For connecting it to a PC *
⑨ USB port	For connecting barcode scanner / keyboard
⑩ SD card port	For upgrading software *
⑪ Main power switch	For switching AFIAS-6 on/off
⑫ Tip box	Collects used pipette tips
⑬ 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-6 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-6 down, please tap 'OK'.

## 6. Installation



**Important**

Before using AFIAS-6, read the warnings and precautions described previously in 'Clause 1: General warnings and important instructions' of this manual.

---

### **Power supply:**

AFIAS-6 will work on the common power line (i.e. 100-240 V AC, 50~60 Hz). If you are uncertain of your power line specifications, consult your utility manager.

### **Operational environment:**

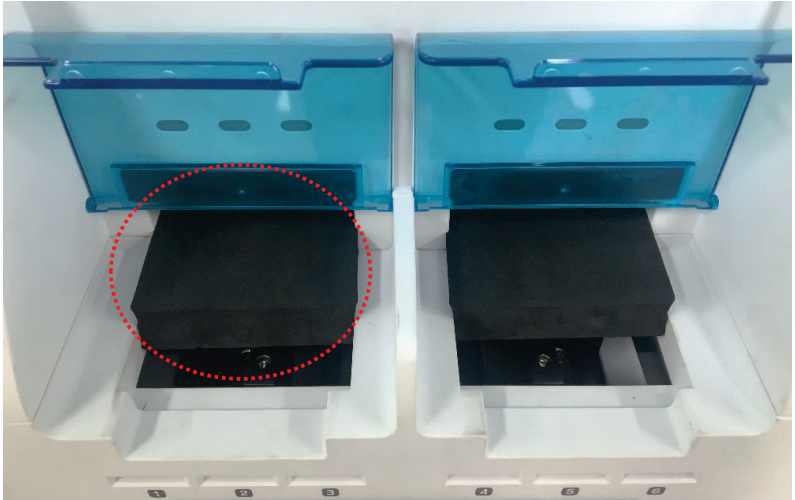
AFIAS-6 should be placed on a dry, clean, flat, and horizontal surface in an indoor setting away from direct sunlight, mechanical vibration and any source of electromagnetic radiation (e.g. power transformers). The temperature of the operational chamber must be maintained in the range of 15~35 °C (59~95 °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. AFIAS-6 is provided with the pump fixing foam.



Please remove the pump fixing foam before power on the AFIAS-6.

2. Connect power cable by inserting the plug into the power socket provided at the rear of AFIAS-6.



3. Turn on the main power switch located adjacent to the power socket.



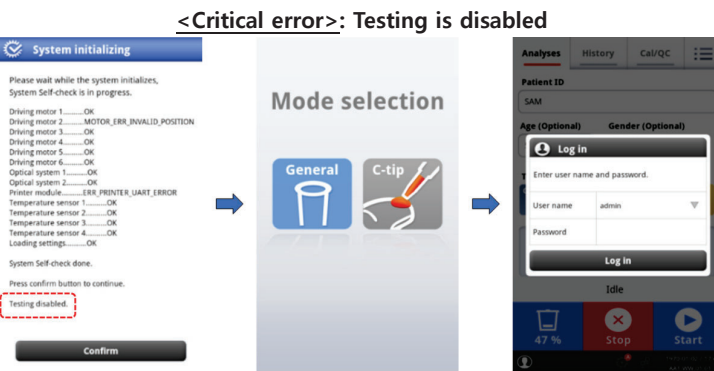
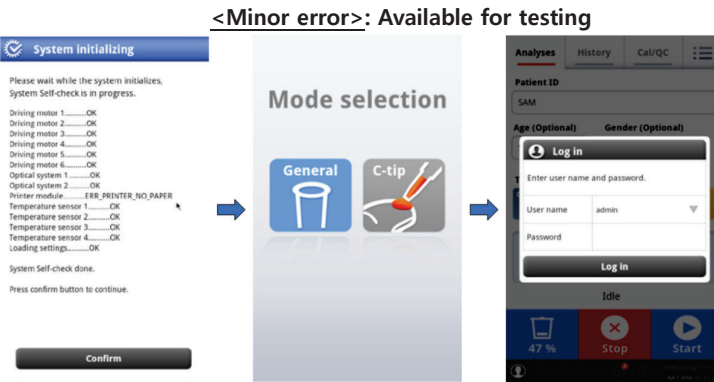
4. Connect the power cord to an external power outlet and press the power button on the front of AFIAS-6.



5. Upon pressing the power button, AFIAS-6 will display the Boditech Med's logo while simultaneously executing a series of system initialization and self-checking routines; upon successful completion, the printer will print out 'System OK!'. The 'log in' window will follow.

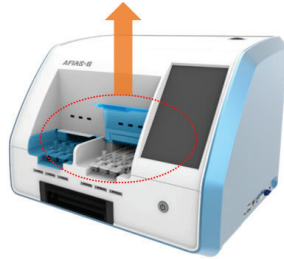


During system initialization, AFIAS-6 will display each test items and the test results will be displayed. After finishing this step, AFIAS-6 will display the mode selection window. If a user does not select a test mode within 10 seconds, the test mode is set to 'General mode' by default. Then AFIAS-6 will display the log-in window. If there is any problem, an error message is displayed. If a user taps the 'Confirm' button, AFIAS-6 will be ready for testing.





6. 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-6



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-6 will display an error message 'Insert ID chip'.



AFIAS cartridges, Boditech controls and Boditech calibrators should be stored in recommended storage conditions and must be within the expiry date. If not, the test may yield misleading/ erroneous results.



If scanning of cartridge is terminated abruptly or any problem occurs, a 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 displayed error code or message alert.

---

### 7.1 Test setup:

- For performing an AFIAS test, following items in addition to AFIAS-6 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 the name of the AFIAS test being performed. AFIAS-6 can simultaneously perform up to 6 tests of the same or different types of test items.)*

- Ensure that the name of the test as well as the lot number printed on the 'AFIAS ID chip' match with those printed on the 'AFIAS cartridge' before removing the cartridge from its blister packing.
- Store patient sample(s) or control(s) or calibrator(s) and the cartridge(s) at room temperature for about 30 minutes before testing.



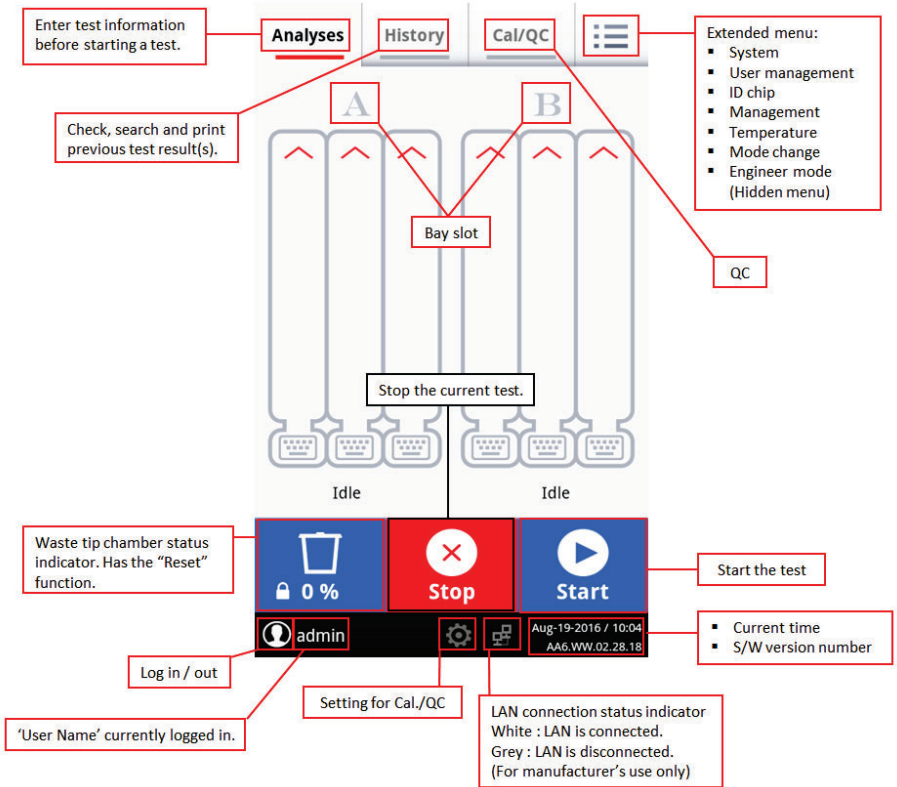
## 7.2 Logging in and entering required information:

- As described in 'Clause 6: Installation', the test-ready AFIAS-6 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:



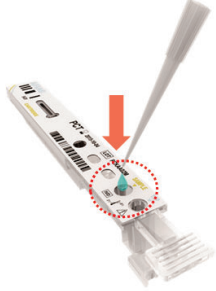
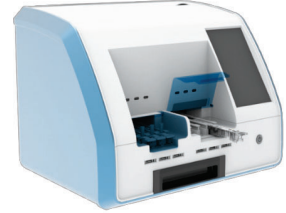

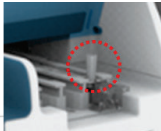

<p>7.2.3</p> <p>✓ <b>General mode</b></p> <p>■ <b>'Entering test information'</b></p> <p>Tap the section shown with a red-dotted circle on the right to enter the patient ID and to select a sample type.</p>	
---	--

<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 a 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 cartridge holder, 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><i>(Note. 'Start' button on the right bottom of the screen is disabled when 'C-tip' mode is selected.)</i></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 a 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 at the top of the slot and the patient ID at 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><i>(Note. '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'.)</i></p>	
<p>7.2.9</p>	<ul style="list-style-type: none"><li>■ When the test is completed, AFIAS-6 displays the test result under the item name.</li></ul>	

- **Note. To perform additional test while the intended bay is in use, press 'Start' button when it gets activated. This function is available only in the C-tip mode.**

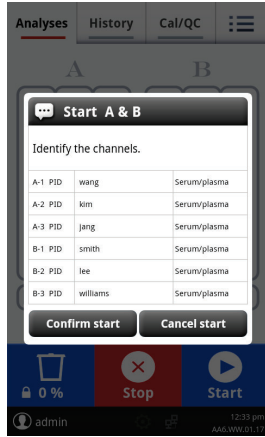
### 7.3 Inserting sample-loaded cartridge and obtaining test result

<p>7.3.1</p>	<ul style="list-style-type: none"><li>■ With a 'AFIAS XXXX ID Chip' in the ID chip port, proceed as follows to run a AFIAS XXXX test on a clinical sample:</li><li>■ Load recommended volume of the test sample into the 'sample well' of a 'AFIAS XXXX cartridge'.</li></ul> <p><i>(Note. Refer to the package insert of the AFIAS test for details)</i></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-6.</li></ul> <p><i>(Note. 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.)</i></p>	   



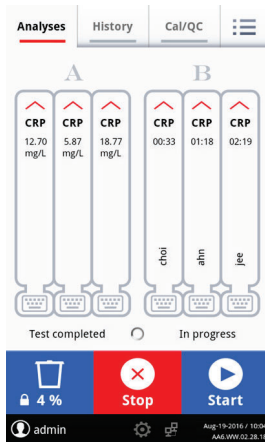
7.3.3

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



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 bays (A or B); each bay accommodates three test cartridge holders.
- Time (Minutes: Seconds) remaining to complete 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



	<p>screen display columns corresponding to the bay.</p>	
<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 'Insert tip' upon starting the test.</li><li>■ The user should insert a 'pipette tip' into the 'tip slot' to start the test by following steps according to 7.2.3.</li></ul>	
<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><li>■ The user should select an appropriate sample type as described in step 7.2.4.</li></ul>	

<p><b>7.3.7</b></p>	<ul style="list-style-type: none"><li>■ If the test starts without a test cartridge in any of the cartridge holders, the system will display 'Insert reagent cartridge'.</li><li>■ Users should restart the run as described in steps as per 7.2.3.</li></ul>	
<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>■ AFAS-6 can save up to 5,000 test results in its internal memory. (Refer to Clause 8.2 for details of retrieval/printing of stored test results.)</li></ul>	
<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> <ol style="list-style-type: none"><li>① <b>Collect finger blood using a C-tip that comes with the AFAS test cartridge box.</b></li><li>② <b>Follow step 7.2.6 ~ 7.2.9 to proceed the test.</b></li></ol>	



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

---



When an AFIAS cartridge with a mismatch lot number is inserted, an 'Insert ID chip' error alert will be displayed.

---



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 normally without affecting the test result.

---

### 7.4 Shutting AFIAS-6 down:

<p>7.4.1</p>	<ul style="list-style-type: none"><li>■ Before turning off AFIAS-6, make sure that ID chip(s) and cartridge(s) have been removed from ID chip port(s) and cartridge holder(s), respectively.</li></ul>	
<p>7.4.2</p>	<ul style="list-style-type: none"><li>■ Close the protective cover of each 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-6.</li></ul>	

<p>7.4.5</p>	<ul style="list-style-type: none"> <li>■ 'Power off' will be executed.</li> <li>■ AFIAS-6 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-6.</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, it is highly recommended to unplug AFIAS-6 power cord from the external power outlet.</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-6 provides following auxiliary features.

### 8.1 Calibration, QC and system check

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

#### 8.1 Calibration, QC and system check:

##### ■ 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.


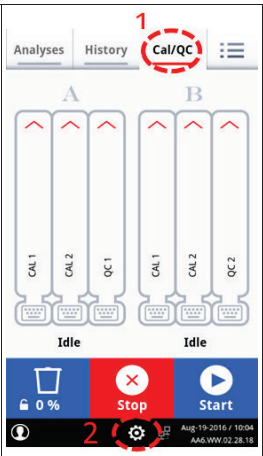
- When a test lot is changed.
- When a test result is considered abnormal or differs from the reference value.
- When a test result is not consistent with symptoms.
- For teaching or learning the system.

### ■ System check

- To perform a system check, a user needs to use a specific system check cartridge and a system check ID chip.
- AFIAS-6 measures the intensity of fluorescence and compares that result with pre-set value to inspect if the measured signal agrees with pre-set values.
- AFIAS-6 repeats the measurement several times to ensure stable performance of a fluorescence system when checking the system.

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


- When AFIAS-6 is installed initially.
- When AFIAS-6 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.


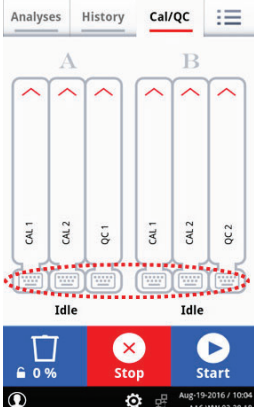
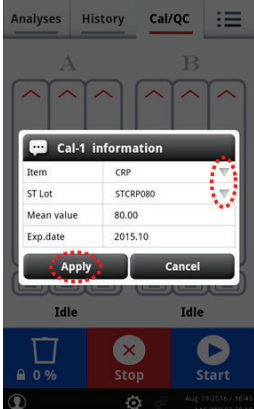
<p><b>8.1.1</b></p>	<ul style="list-style-type: none"><li>■ To run a calibration and QC, you need to activate this function.</li><li>■ Select the 'Cal/QC' tap.</li><li>■ To activate 'Cal/QC' function, please tap the setting icon .</li></ul>	
---------------------	---	---



<p><b>8.1.2</b></p>	<ul style="list-style-type: none"> <li>■ Tap the 'Enable Calibration' menu. The check box will be toggled whenever you tap this menu.</li> <li>■ To activate the calibration and QC function, the check box should be checked.</li> </ul>													
<p><b>8.1.3</b></p>	<ul style="list-style-type: none"> <li>■ To do calibration and QC, you need to register a calibrator and a control.</li> <li>■ Select the 'Calibration registration' menu to register a calibrator.</li> <li>■ Tap the  icon to register a calibrator.</li> </ul>	<table border="1" data-bbox="740 981 1001 1141"> <thead> <tr> <th>Item</th> <th>ST Lot</th> <th>Exp.date</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> CRP</td> <td>STCRP120</td> <td>2015.11</td> </tr> <tr> <td><input type="checkbox"/> CRP</td> <td>STCRP100</td> <td>2015.10</td> </tr> <tr> <td><input type="checkbox"/> CRP</td> <td>STCRP080</td> <td>2015.10</td> </tr> </tbody> </table>	Item	ST Lot	Exp.date	<input type="checkbox"/> CRP	STCRP120	2015.11	<input type="checkbox"/> CRP	STCRP100	2015.10	<input type="checkbox"/> CRP	STCRP080	2015.10
Item	ST Lot	Exp.date												
<input type="checkbox"/> CRP	STCRP120	2015.11												
<input type="checkbox"/> CRP	STCRP100	2015.10												
<input type="checkbox"/> CRP	STCRP080	2015.10												



8.1.7	<ul style="list-style-type: none"><li>■ An 'Add control' window will pop-up.</li><li>■ Enter the lot number of the control, item name, mean value, low value, high value and expiration date. <i>Note. 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.</i></li><li>■ To apply this information, tap the 'OK' button.</li></ul>	
8.1.8	<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>8.1.9</b></p>	<ul style="list-style-type: none"><li>■ To run a calibration and QC, please prepare a test cartridge that you want to test.</li><li>■ Dispense a calibrator and control into the sample well of the cartridge.</li><li>■ Insert the cartridges into the cartridge holders and insert pipette tips.</li></ul>	
<p><b>8.1.10</b></p>	<ul style="list-style-type: none"><li>■ Tap each keyboard icon to select a calibrator and control information for each slot.</li></ul>	
<p><b>8.1.11</b></p>	<ul style="list-style-type: none"><li>■ When you tap the keyboard icon for 'Cal 1' slot, the 'Cal-1 information' window will pop-up.</li><li>■ You can select the item and lot number you want to calibrate by tapping the triangular icon.</li><li>■ To apply the change, tap the 'Apply' button.</li><li>■ Proceed with 'Cal 2' and 'QC 1' following the same steps.</li></ul>	

<p><b>8.1.12</b></p>	<ul style="list-style-type: none"> <li>When all calibrators and controls are selected, each lot numbers will be displayed in each slot.</li> </ul>	
<p><b>8.1.13</b></p>	<ul style="list-style-type: none"> <li>To start calibration and QC, tap the 'Start' button.</li> <li>A 'Start A &amp; B' 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 start' button.</li> </ul>	

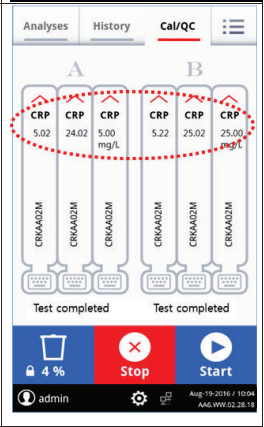
**8.1.14**

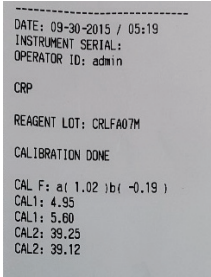
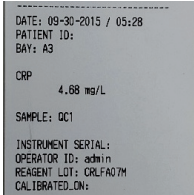
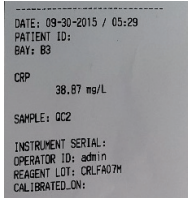
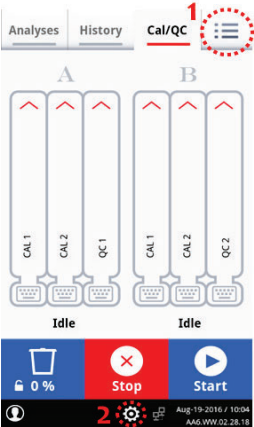
- When the test starts, AFIAS-6 will check item names and lot numbers.
- The name of items will be displayed, and the test status will be displayed as 'In progress'.
- During the test, the remaining times are displayed under item names.


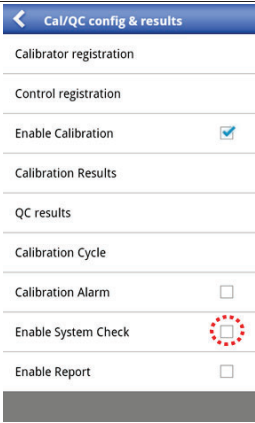

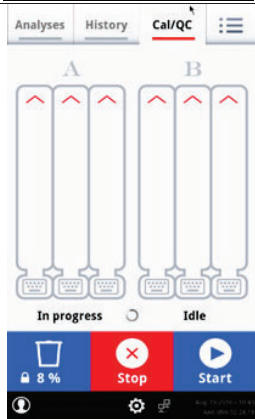


**8.1.15**

- When the test is completed, the test result is displayed under the item name.
- AFIAS-6 generates a buzzer signal, and each slot opens.
- The test results are saved in the internal memory and printed automatically.


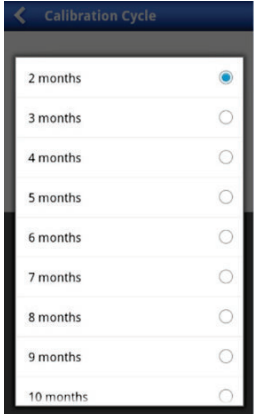
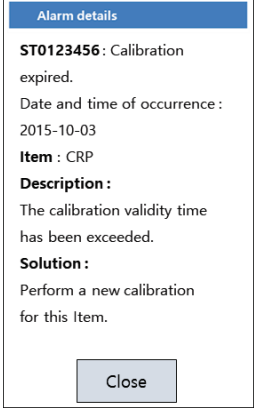


		 <p>&lt;Calibration test result&gt;</p>  <p>&lt;QC1 test result&gt;</p>  <p>&lt;QC2 test result&gt;</p>
<p><b>8.1.16</b></p>	<ul style="list-style-type: none"> <li>■ To run a system check, select the 'Cal/QC' tab.</li> <li>■ Tap the setting icon to enable the system check.</li> </ul>	

<p><b>8.1.17</b></p>	<ul style="list-style-type: none"><li>■ Tap the 'Enable System check' menu. The check box will be toggled when you tap this menu.</li><li>■ To activate the system check, the check box should be checked as .</li></ul> <p><i>Note. This check box returns unchecked upon rebooting.</i></p>	
<p><b>8.1.18</b></p>	<ul style="list-style-type: none"><li>■ Insert a system check cartridge and a system ID chip into AFIAS-6.</li><li>■ Tap the 'Start' icon.</li><li>■ To confirm information and start a system check, tap the 'Confirm start' button.</li></ul>	
<p><b>8.1.19</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><b>8.1.20</b></p>	<p>■ The result of the system check will be printed.</p>	
<p><b>8.1.21</b></p>	<p>■ To change/adjust a cycle of Cal/QC, tap the 'Calibration cycle'.</p>	

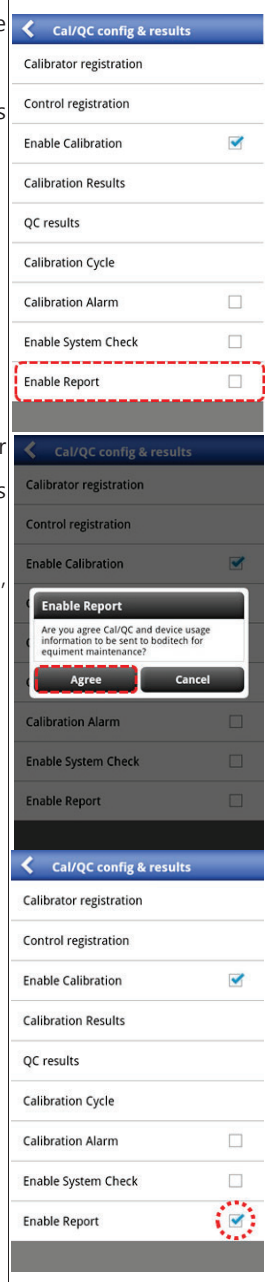
<ul style="list-style-type: none"><li>■ The 'Calibration cycle' window will pop-up.</li></ul>	
<ul style="list-style-type: none"><li>■ You can change/adjust the period of calibration by selecting the time period. <i>Note. You can change/adjust the period of Calibration in days, weeks or months.</i></li></ul>	 

	<ul style="list-style-type: none"> <li>■ If the calibration period is past due, an 'Alarm details' window will pop-up. And the red sign is marked on the setting icon. In this case you need to perform a new calibration.</li> </ul>	
<p><b>8.1.22</b></p>	<ul style="list-style-type: none"> <li>■ Tap the 'Calibration Alarm' menu. The check box will be toggled when you tap this menu.</li> <li>■ To activate Calibration alarm, the check box should be checked as <input checked="" type="checkbox"/>.</li> <li>■ When the Calibration period is past due, an 'Alarm' window will appear if the 'Calibration Alarm' menu was previously selected. If the 'Calibration Alarm' menu was not selected, the 'Alarm' window would not appear.</li> </ul> <p><i><b>Note.</b> This check box will remain checked when AFIAS-6 is rebooted.</i></p>	

8.1.23

- 'Enable Report' is for sending Cal/QC data to the server.
- Tap the 'Enable Report' menu to activate this function.
- AFIAS-6 displays an 'Enable Report' window for confirmation of sending Cal/QC data to Boditech's server only for maintenance purposes.
- If you should agree with the use of this function, tap the 'Agree' button.
- If you should not agree, tap the 'Cancel' button.
- The check box will be checked as  .

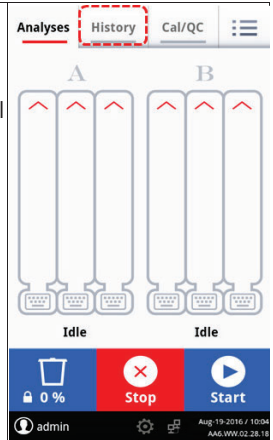
**Note.** When the 'Enable Report' menu is activated and AFIAS-6 is connected to LAN, AFIAS-6 will send Cal/QC data and the device usage data to Boditech's server automatically. This information is used only for maintenance purposes by the manufacturer.



**8.2 Retrieval/printing/LIS of stored test results:**

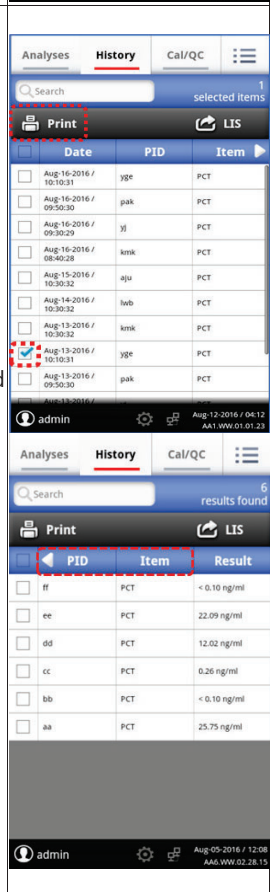
8.2.1

- AFIAS-6 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.*

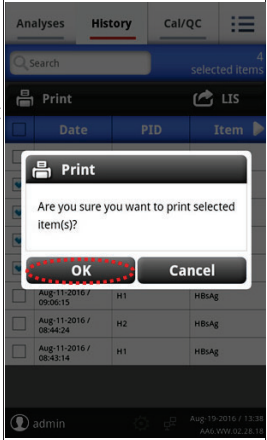


8.2.2

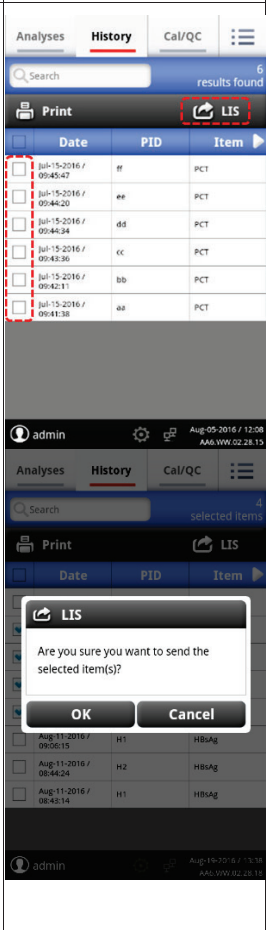
- Upon tapping 'History', a chronological log of stored test results is displayed in a reverse order.
- Select the test result(s) you want to print.
- One can select up to 5,000 test results.
- Tap 'Print' to print out the selected test result(s).



- 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'.

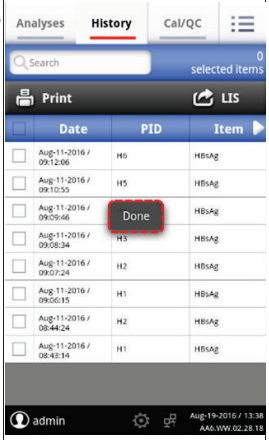
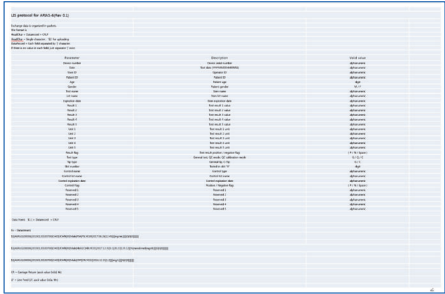


- 8.2.3
- Select the test result(s) you want to send via LIS.
  - It is possible to select up to 5,000 test results.
  - Tap 'LIS' to send the selected test result(s) by LIS.
  - A new window will pop up. Tap 'OK' to confirm sending action.
  - If you do not intend to send the selected test results, tap 'Cancel'.



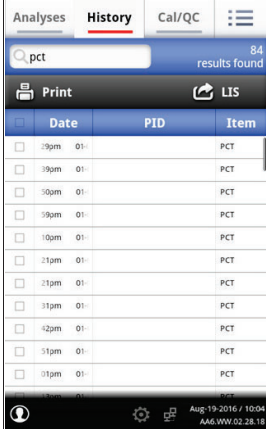
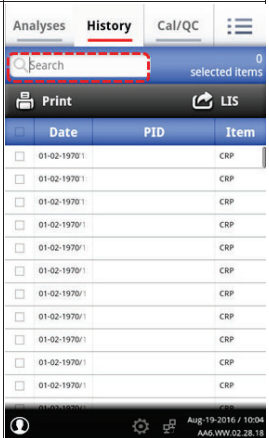
- LIS procedure is completed, AFIAS-6 will display 'Done'.

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



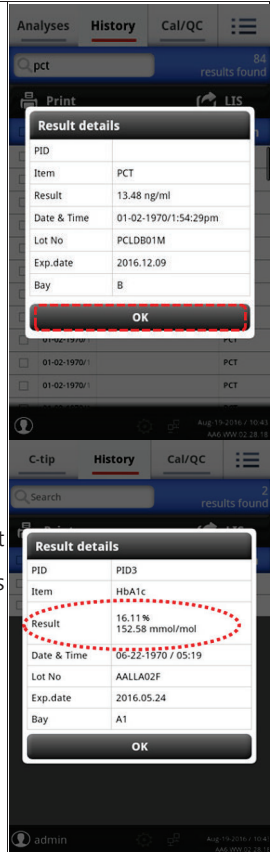
8.2.4

- If you want to search specific test result(s), tap 'Search' and enter the search key word (e.g. patient ID, test name)
- Tap the search icon 🔍
- Search results will be displayed.



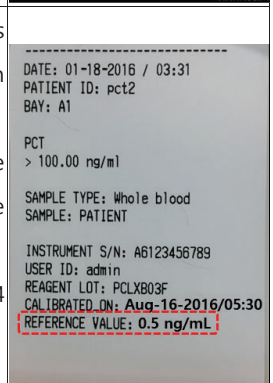
8.2.5

- If you just want to browse stored test result(s) without printing, tap the field displaying the test result of your interest.
- A new window will pop-up, displaying details including the patient ID, test name, test result, date & time of the test, lot number and expiry date of test reagents etc.
- In case of HbA1c test result, AFIAS-6 will display test result in NGSP (%) and IFCC (mmol/mol) units simultaneously.



8.2.6

- Print-out generated by the built-in printer contains the test result along with other information as shown in the picture on the right.
- The print-out will also contain reference values/intervals for a specific patient population if the laboratory has previously provided them.
- In order to edit the reference value, refer to 9.1.14 and 9.1.15.





## 9. Configuring AFIAS-6

Following settings and/or parameters of AFIAS-6 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
- Bay counter

### 9.2 User management



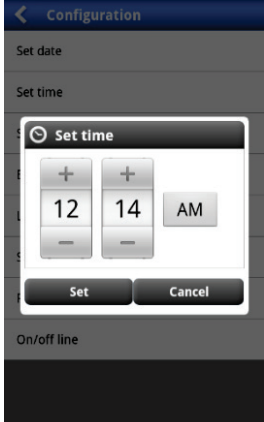
### 9.3 ID chip management

### 9.4 Temperature

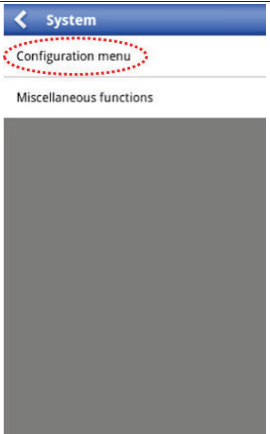
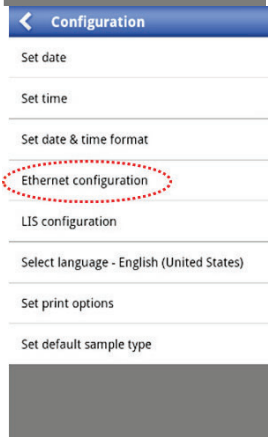

### 9.5 Mode change

## 9.1 System configuration

<p><b>9.1.1</b></p>	<p>■ <b>Setting the 'Date':</b></p> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Set date' menu.</p>	<p>The screenshot shows the 'System' menu with 'Configuration menu' circled in red. Below it, the 'Configuration' menu is shown with 'Set date' circled in red. Other options in the configuration menu include 'Set time', 'Set date &amp; time format', 'Ethernet configuration', 'LIS configuration', 'Select language - English (United States)', 'Set print options', and 'Set default sample type'.</p>
<p><b>9.1.2</b></p>	<p>■ Tap the <b>+</b> or <b>-</b> button(s) to set the desired month, date and year.</p> <p>■ To set the changed date, tap 'Set'.</p>	<p>The screenshot shows the 'Set date' dialog box with a date of 'Jan 02 1970'. The 'Set' button is circled in red. The dialog box has '+' and '-' buttons for each field and a 'Cancel' button.</p>

<p><b>9.1.3</b></p>	<p>■ <b>Setting the 'Time':</b></p> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Set time' menu.</p>	 
<p><b>9.1.4</b></p>	<ul style="list-style-type: none"><li>■ Tap the <b>+</b> or <b>-</b> 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 set the changed time, tap 'Set'.</li></ul>	

<p><b>9.1.5</b></p> <p>■ <b>Setting the date format</b></p> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Set date &amp; time format' menu.</p>	<p>The screenshot shows the 'System' menu with 'Configuration menu' circled in red. Below it, the 'Configuration' screen is shown with 'Set date &amp; time format' circled in red.</p>										
<p><b>9.1.6</b></p> <p>■ Check/tap the blank box corresponding to the date format you want to select.</p> <p>■ If you want to cancel changing the date format, tap 'Cancel'.</p>	<p>The screenshot shows the 'Select date format' dialog box with the following options:</p> <table border="1"> <thead> <tr> <th>Select date format</th> <th>Selection</th> </tr> </thead> <tbody> <tr> <td>Normal (jul-05-2016)</td> <td><input type="radio"/></td> </tr> <tr> <td>jul-05-2016</td> <td><input checked="" type="radio"/></td> </tr> <tr> <td>05-jul-2016</td> <td><input type="radio"/></td> </tr> <tr> <td>2016-jul-05</td> <td><input type="radio"/></td> </tr> </tbody> </table> <p>A 'Cancel' button is located at the bottom of the dialog box.</p>	Select date format	Selection	Normal (jul-05-2016)	<input type="radio"/>	jul-05-2016	<input checked="" type="radio"/>	05-jul-2016	<input type="radio"/>	2016-jul-05	<input type="radio"/>
Select date format	Selection										
Normal (jul-05-2016)	<input type="radio"/>										
jul-05-2016	<input checked="" type="radio"/>										
05-jul-2016	<input type="radio"/>										
2016-jul-05	<input type="radio"/>										

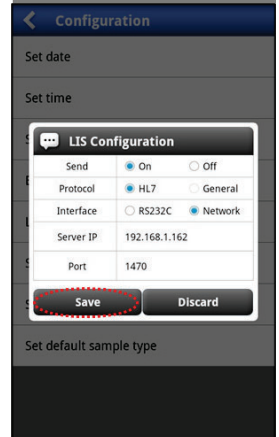
<p><b>9.1.7</b></p>	<p>■ <b>Ethernet configuration:</b> For connecting AFIAS-6 to the Local Area Network.</p> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Ethernet configuration' menu.</p>	 
<p><b>9.1.8</b></p>	<ul style="list-style-type: none"> <li>■ 'Configure ethernet devices' window will pop-up.</li> <li>■ 'Ethernet Devices' is 'sit0' and 'Connection Type' is 'DHCP' by default.</li> <li>■ Select 'Ethernet Devices' as 'sit0' from the options available in the drop down box</li> <li>■ Select 'DHCP' as the 'Connection Type'.</li> <li>■ Tap 'Save' to save the configuration.</li> </ul>	

9.1.9

■ LIS configuration:

For sending test results from AFIAS-6 to the LIS server via Local Area Network or RS232C.

- ① Tap the 'Configuration menu'.
- ② Tap the 'LIS configuration' menu.
- ③ If you do not wish to send test results by LIS, select 'Off.'
- ④ Please select a desired data format.
- 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.

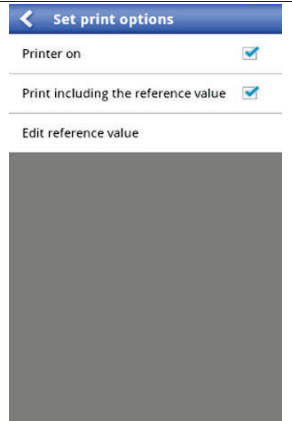




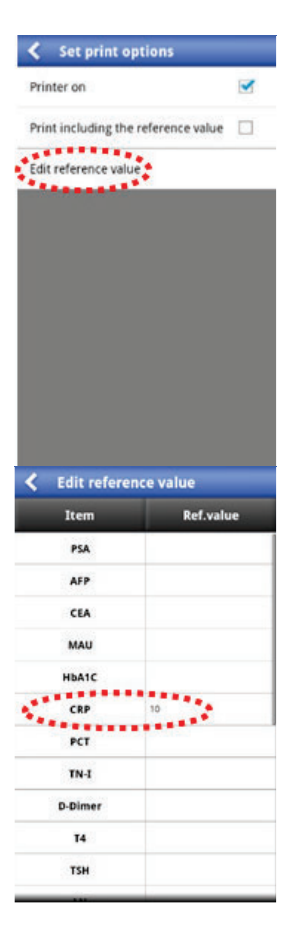
<p><b>9.1.11</b></p>	<p>■ <b>Turning the printer On / Off:</b></p> <p>① Tap the 'Configuration menu'.</p> <p>② Tap the 'Set Printer options' menu.</p>	<p>The screenshot shows the 'System' menu with a back arrow on the left. The 'Configuration menu' option is circled in red. Below it is a section for 'Miscellaneous functions' which is currently greyed out.</p>
<p><b>9.1.12</b></p>	<p>■ To turn the printer on, check/tap the blank box of the 'Printer on' menu.</p> <p>■ To turn the printer off, uncheck/tap the blank box of the 'Printer on' menu.</p>	<p>The screenshot shows the 'Set print options' menu with a back arrow on the left. The 'Printer on' option has a checked checkbox, which is circled in red. Below it are 'Print including the reference value' (unchecked) and 'Edit reference value' (greyed out).</p>



9.1.13 ■ When the blank box of the 'Print including the reference value' menu is checked, test results are printed including the reference value.



9.1.14 ■ **Edit reference values:**  
① If you choose the 'Edit reference value', you can find the reference value information.



	<p>② If you choose an item that you want to edit, a new window will pop-up for editing the reference value.</p>	
<p>9.1.15</p>	<p>■ <b>Set default sample type</b></p> <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>9.1.16</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 for the general mode test.</li> </ul>	
<p>9.1.17</p>	<p><b>Updating software:</b></p> <p><i>Note. 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.</i></p> <ul style="list-style-type: none"> <li>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.</li> <li>If you want to update S/W via a network, you can tap 'Network' menu. Please refer to 9.1.22.</li> </ul>	

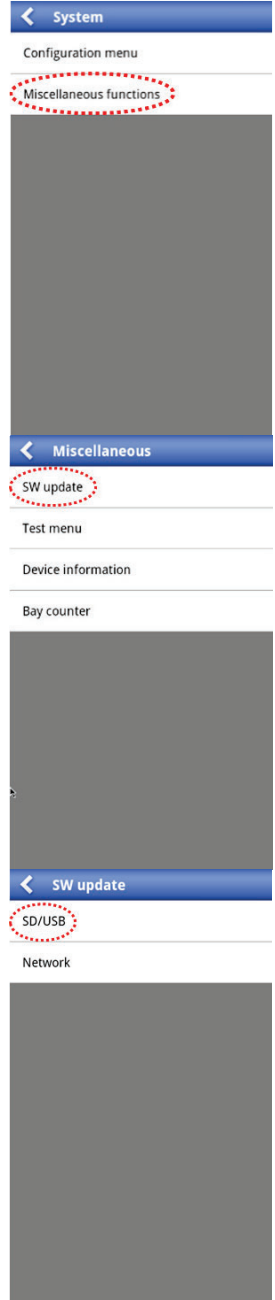
■ **Updating firmware via a SD card:**

① Tap the 'Miscellaneous functions' menu.

② Tap the 'SW update' menu.

③ Tap the 'SD/USB' menu.

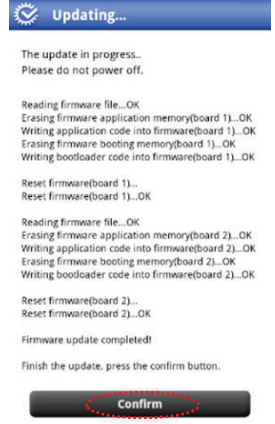
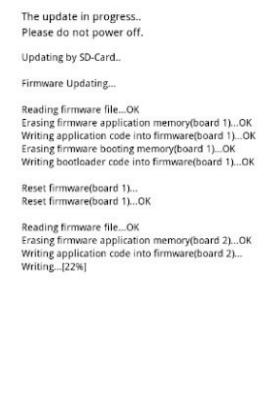
**9.1.18**


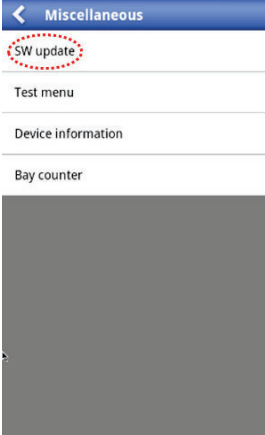


④ 'Update via SD-Card' window will pop up.

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

⑥ If you insert a SD card with updated version of firmware, it will start to update automatically.



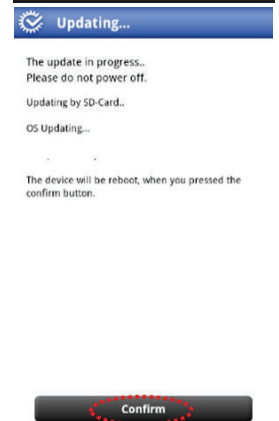
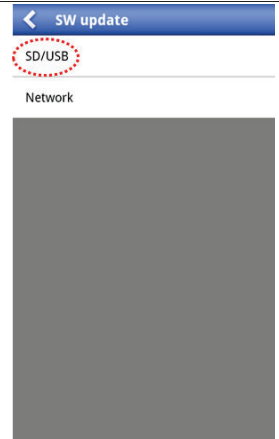
	<p>⑦ If you tap the 'Confirm' menu, it will automatically reboot.</p> <p>⑧ Update will be completed after rebooting.</p> <p><b>Note.</b> You can check whether the firmware update is successful by accessing the 'Device information menu as described in Step 9.1.28.</p>	
<p>9.1.19</p>	<p>■ <b>Updating the 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>	 

③ Tap the 'SD/USB' menu.

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.

⑦ When Android OS update is completed, AFIAS-6 will reboot automatically.

*Note.* You can check if the Android OS update is successful by accessing the 'Device information' menu as described in Step 9.1.28.





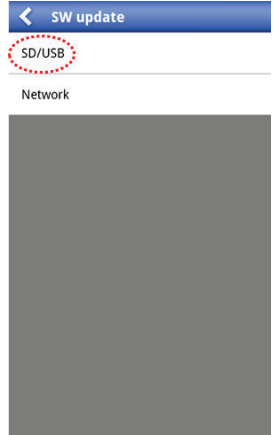
**■ Updating the application via a SD card:**  
: To update the 'Application', insert the 'Upgrade SD card' (provided by the manufacturer or its authorized service representative) into the 'SD card port'.

① Tap the 'Miscellaneous functions' menu.

② Tap the 'SW update' menu.

③ Tap the 'SD/USB' menu.

9.1.20



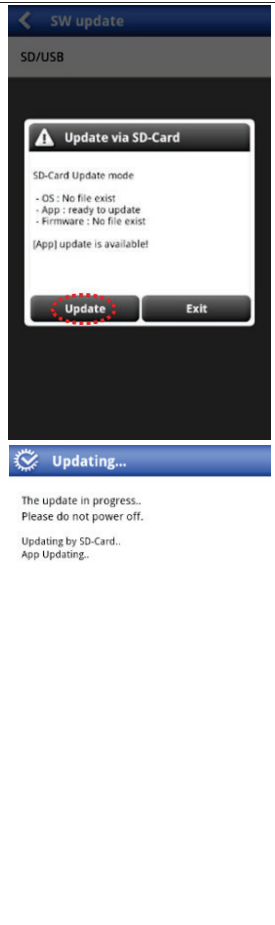
④ 'Update via SD-Card' window will pop-up.

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 'Confirm' 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 9.1.29.

**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.



9.1.21

■ **Updating software through a network**

: To update software via a network, AFIAS-6 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-6 is not registered, 'Device Registration' window will be displayed.



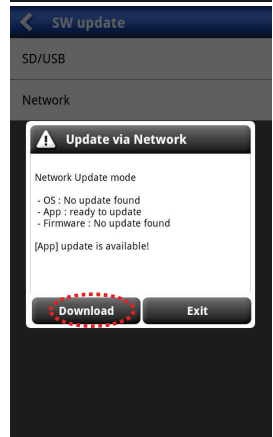
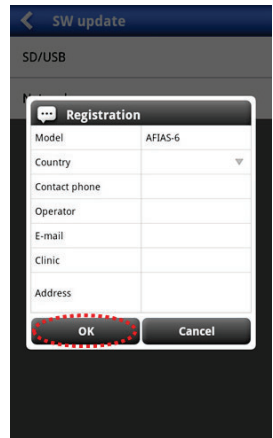
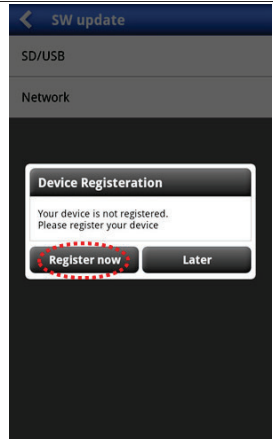
③ Tap the 'Register now' button to register the device.

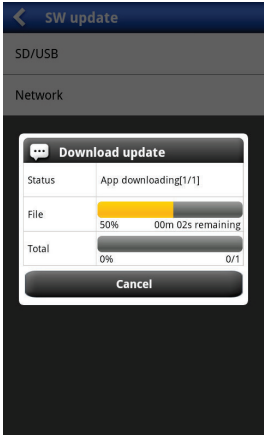
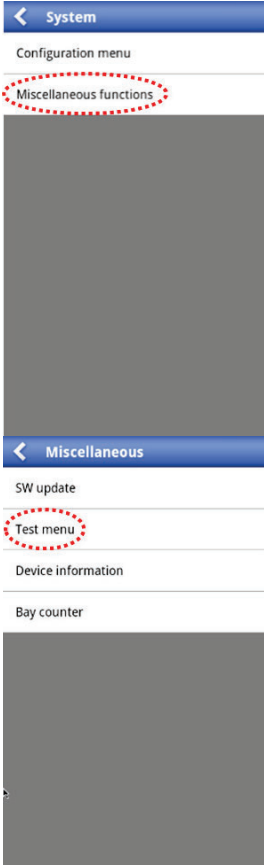
**Note.** If you tap the 'Later' button, the update function will be disabled.

④ Enter registration information and tap the 'OK' button. Then tap the 'Network' menu again(refer to Step 1 of clause 9.1.22.).

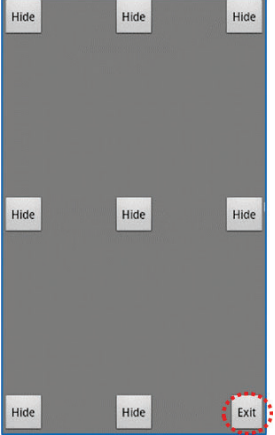
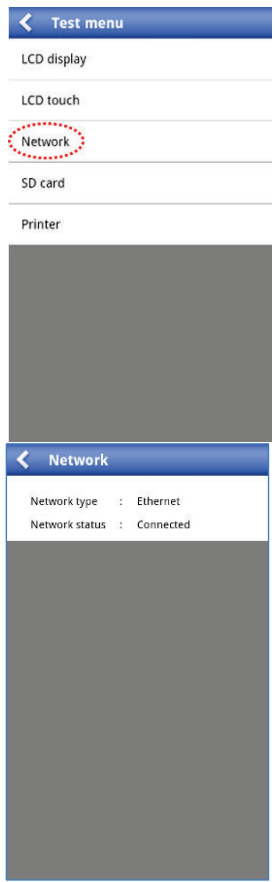
⑤ AFIAS-6 displays 'Update via Network' window and you can check the available updates.



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



	<p>⑦ AFIAS-6 displays 'Download update' window and the downloading progress is displayed.</p> <p>⑧ When the download is completed, AFIAS-6 performs the update automatically.</p>	
<p>9.1.22</p>	<p>■ <b>Configuring the 'Test Menu':</b></p> <p>: In 'Test menu', you can test LCD display, LCD touch, LAN connectivity, SD card and printer connectivity.</p> <p>① Tap the 'Miscellaneous functions' menu.</p> <p>② Tap the 'Test menu'.</p>	

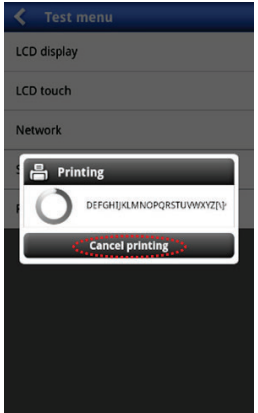
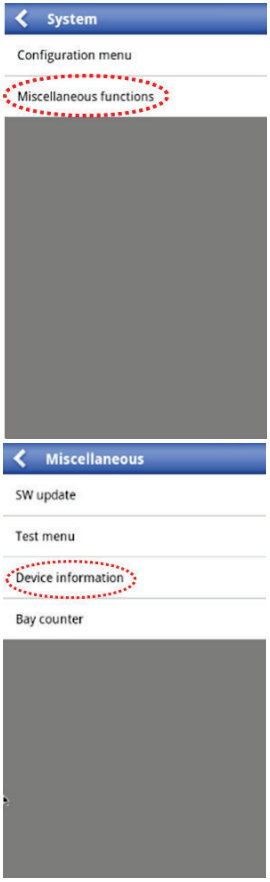
<p>9.1.23</p>	<ul style="list-style-type: none"><li>■ To test 'LCD display', tap the 'LCD display' menu.</li><li>■ AFIAS-6 will display various colors to test LCD display.</li><li>■ When the test is finished, tap 'Exit'.</li></ul>	<p>The screenshot shows a mobile application interface titled 'Test menu'. The menu items are: 'LCD display' (circled in red), 'LCD touch', 'Network', 'SD card', and 'Printer'. Below the menu is a large grey rectangular area. At the bottom, there is a test pattern consisting of a grid with a central circle containing various colors and patterns, and an 'Exit' button circled in red.</p>
<p>9.1.24</p>	<ul style="list-style-type: none"><li>■ To test 'LCD touch', tap the 'LCD touch' menu.</li></ul>	<p>The screenshot shows the same 'Test menu' interface as above, but with 'LCD touch' selected instead of 'LCD display'. The rest of the interface, including the grey area and the test pattern at the bottom, is identical to the previous screenshot.</p>

	<ul style="list-style-type: none"><li>■ AFIAS-6 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>9.1.25</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>	
9.1.26	<ul style="list-style-type: none"><li>■ To check a SD card, tap the 'SD card' menu.</li><li>■ AFIAS-6 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>	

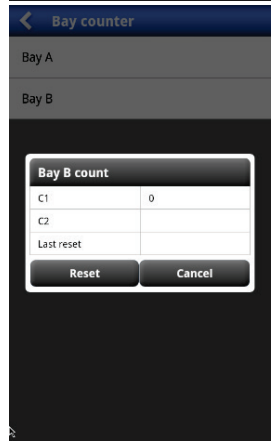
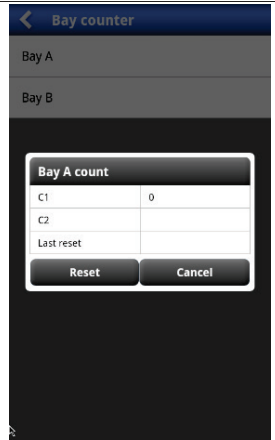




	<ul style="list-style-type: none"><li>■ To stop the printer test, tap 'Cancel printing'.</li></ul>	
<p>9.1.28</p>	<ul style="list-style-type: none"><li>■ <b>Checking 'Device information'</b></li><li>① Tap the 'Miscellaneous functions' menu.</li><li>② Tap the 'Device information' menu.</li></ul>	

	<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> </ul>	
<p><b>9.1.29</b></p>	<p>■ <b>Setting the bay counter:</b></p> <p>You can use this function to check/verify the cumulative number of tests performed in each bay. You can find the following types of counts:</p> <ul style="list-style-type: none"> <li>- <b>C1</b> Total number of tests performed since the initial use</li> <li>- <b>C2</b> Total number of tests performed after latest repair or servicing of the system</li> </ul> <p>① Tap the 'Bay counter' menu.</p> <p>② Tap 'Bay A' or 'Bay B' to check the corresponding number of tests performed in each bay.</p>	

③ To reset the count C2 (i.e. number of tests performed since latest repair or servicing of the system) for each bay, tap 'Reset'.



## 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-6 will display the warning message 'Access denied for xxxx'.

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.

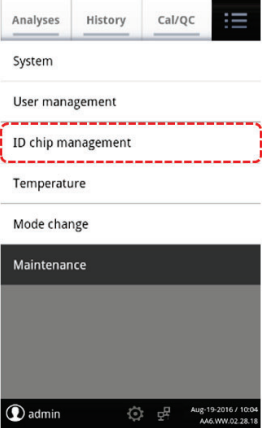
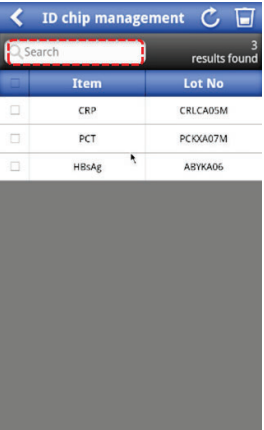
⑥ Tap 'Cancel' if you do not intend to proceed.

### 9.2.1



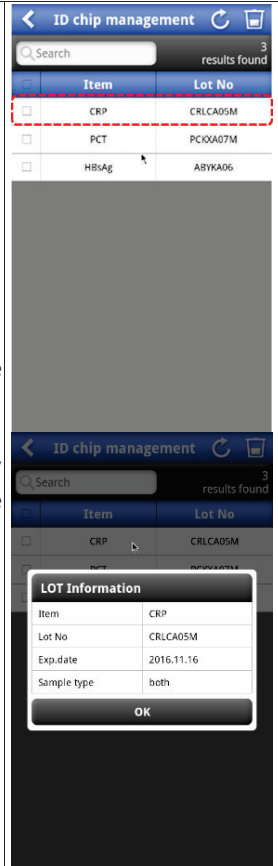
<p>9.2.2</p>	<ul style="list-style-type: none"><li>■ To delete an existing/registered user, check/select the blank box corresponding to the 'user name' you want to delete.</li><li>■ Tap 'Delete'.</li><li>■ Tap 'OK' to confirm deleting the selected user.</li></ul> <p><b>Note.</b> 'Administrator' being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

### 9.3 ID Chip Management

<p><b>9.3.1</b></p>	<ul style="list-style-type: none"> <li>■ 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-6.</li> </ul> <p><i>Note. AFIAS-6 can save ID chip information from up to 500 ID chips.</i></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 with options: Analyses, History, Cal/QC, System, User management, ID chip management (highlighted with a red dashed box), Temperature, Mode change, and Maintenance. At the bottom, it shows 'admin', a gear icon, 'ID', and the date/time 'Aug-19-2016 / 10:04 AM, WW-02, 28.18'.</p>												
<p><b>9.3.2</b></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 with a search bar (highlighted with a red dashed box) and 3 results found. Below is a table:</p> <table border="1"> <thead> <tr> <th></th> <th>Item</th> <th>Lot No</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td>CRP</td> <td>CRLCA05M</td> </tr> <tr> <td><input type="checkbox"/></td> <td>PCT</td> <td>PCIXA07M</td> </tr> <tr> <td><input type="checkbox"/></td> <td>HBsAg</td> <td>ABYKA06</td> </tr> </tbody> </table>		Item	Lot No	<input type="checkbox"/>	CRP	CRLCA05M	<input type="checkbox"/>	PCT	PCIXA07M	<input type="checkbox"/>	HBsAg	ABYKA06
	Item	Lot No												
<input type="checkbox"/>	CRP	CRLCA05M												
<input type="checkbox"/>	PCT	PCIXA07M												
<input type="checkbox"/>	HBsAg	ABYKA06												

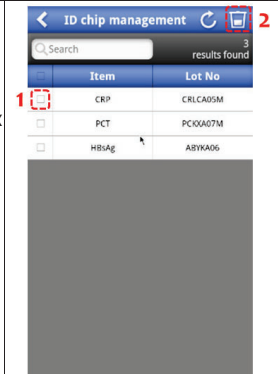
9.3.3

- List of the search results will be displayed.
- To get the ID chip information, tap the test name listed under the column 'Item'.
- Relevant information (test name/item, lot number, expiry date and sample type) corresponding to the ID chip will be displayed.



9.3.4

- To delete an ID chip info, select/check the blank box corresponding to the ID chip.
- Tap the '🗑️' icon.
- Tap 'OK' to confirm deleting the ID chip info.



## 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.

① Tap the 'Temperature' menu.

② Operating temperature of both bays will be displayed.

### 9.4.1

**Note.** If 'Incorrect temperature' or 'Error status' appears, AFIAS tests will not run until the temperature is brought within the acceptable operational range.

Analyses History Cal/QC

System

User management

ID chip management

Temperature

Mode change

Maintenance

admin Aug 19 2016 / 10:04 AAG-000-C2-28.15

< Temperature

Bay	Temperature(°C)	Status
A	35.0	●
B	35.1	●

- - Ok, no errors
- ! - Incorrect temperature
- - Error status

<Normal status>

< Temperature

Bay	Temperature(°C)	Status
A	30.1	!
B	29.7	!

- - Ok, no errors
- ! - Incorrect temperature
- - Error status

<Incorrect status>



## 9.5 Mode change

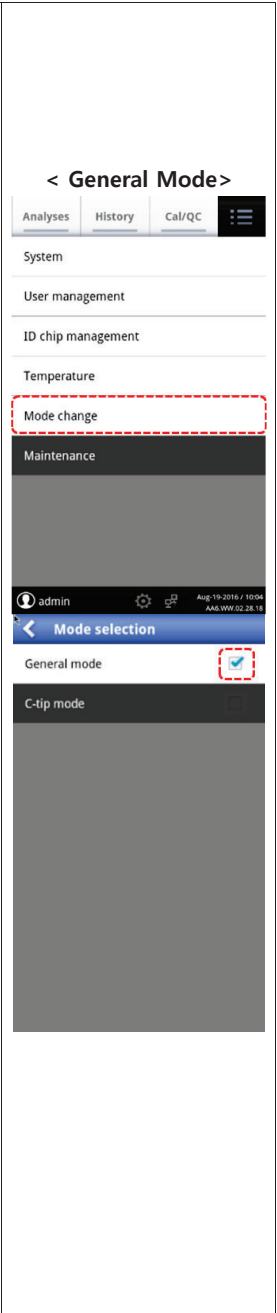
- You can access this function to change the test mode from 'General mode' to 'C-tip mode' or 'C-tip mode' to 'General mode'.

### <General Mode>

① Tap the 'Mode change' menu.

② Check the test mode you want to change.

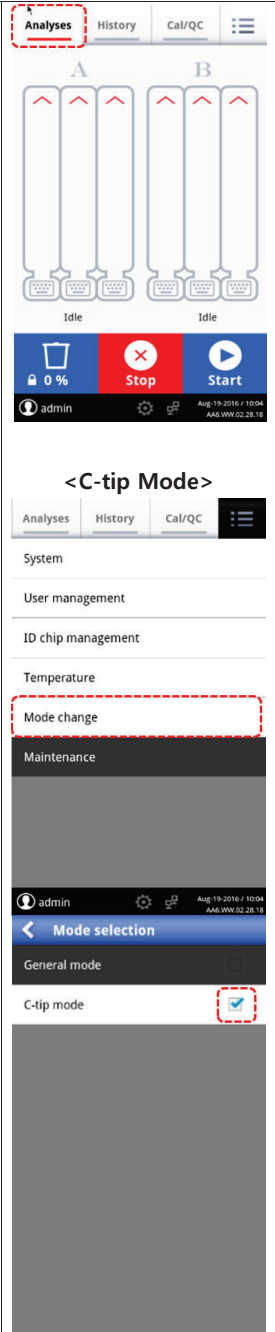
### 9.5.1

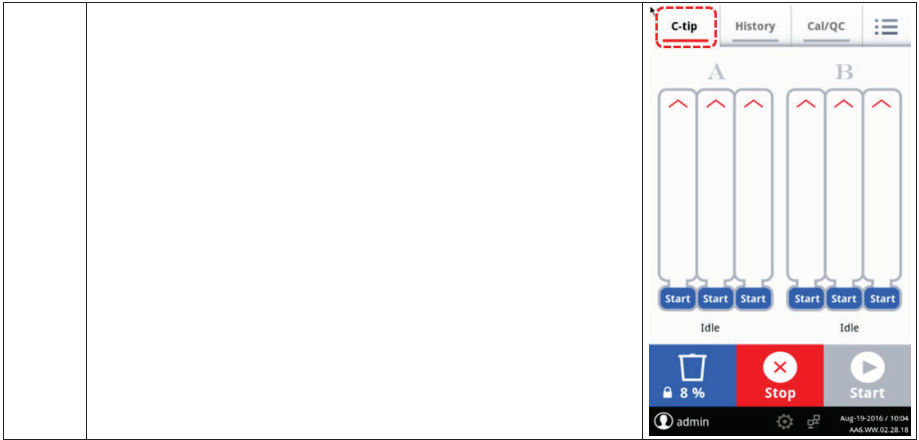


**<C-tip Mode>**

① Tap the 'Mode change' menu.

② Check the test mode you want to change.





## 10. Maintenance, servicing and disposal

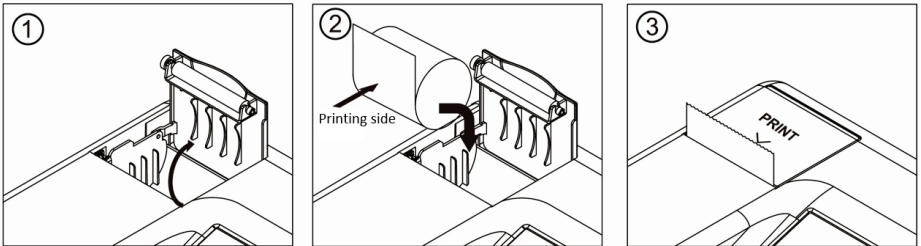
### 10.1 Maintenance:

No maintenance other than the following is required for AFIAS-6:

- 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 in the proper 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.

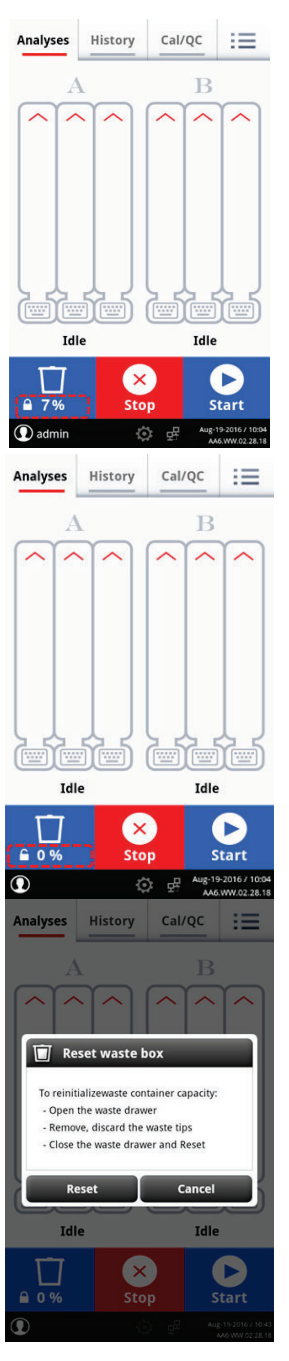


Be careful exerting excessive force when opening or closing the printer cover to prevent malfunctioning of the built-in printer.

**■ Emptying the 'Waste tip box' and resetting the waste tip counter:**

- ① To reset the counter indicating the collection status of used pipette tips, open the waste tip box.
- ② The screen icon will automatically change from  to .
- ③ Tap the  icon to reset the waste tip counter.
- ④ The 'Reset waste box' window will pop-up.
- ⑤ Tap  to reset the waste tip counter.
- ⑥ Tap  to terminate the procedure.

10.1.1



	<p>■ <b>Management of waste box:</b></p> <ul style="list-style-type: none"> <li>- When the waste box is 100 to 120 % full, a 'Warning' window will pop up.</li> <li>- When the waste box reaches over 120 %, a 'Testing locked' window will pop up.</li> </ul> <p>(The waste box displays only up to 100 %, and &gt;100 % is calculated internally.)</p>	
<p>10.1.2</p>	<p>■ <b>Raw data backup:</b></p> <ul style="list-style-type: none"> <li>- Raw data for the tests are needed to identify causes of troubles and errors when and if they should occur.</li> </ul> <p>① Tap the 'Extension menu' in the main menu.</p>	

② Tap the 'Maintenance' menu.

③ Tap the 'Raw data' menu.

④ Insert a SD card into the SD card port.

⑤ Select raw data you want to backup by tapping the check box.

⑥ Tap the 'Backup' button.



	<p>⑦ Tap the 'OK' button to proceed to backup.</p> <p><b>Note.</b> <i>The backup data is saved in boditech/raw data folder. This data is encoded and it is only accessible by the manufacturer.</i></p>	
<p>10.1.3</p>	<p>■ <b>Washing tip adapter:</b></p> <p>.This function is to wash the tip adaptor</p> <ul style="list-style-type: none"> <li>- The tip adaptor is the segment where pipette tips are connected to the pumping module.</li> <li>- When the tip adaptor is contaminated by clinical samples or buffer, this may cause the degradation or malfunction of AFIAS-6. The recommended washing cycle is once every other week. To perform this function, a specific washing cartridge is required.</li> </ul> <p>① Tap the 'Extension menu' in the main menu.</p> <p>② Tap the 'Maintenance' menu.</p>	

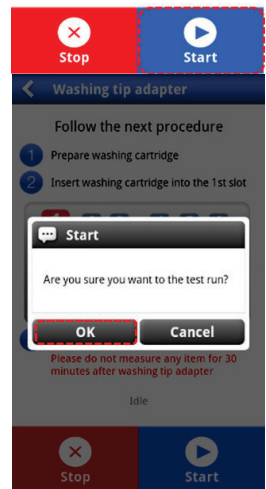
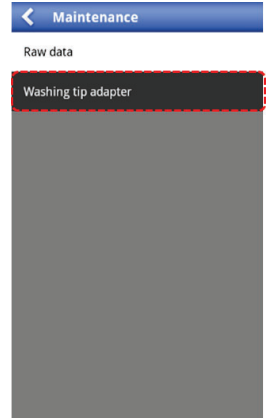


③ Tap the 'Washing tip adapter' menu.

④ Insert the 'Washing cartridge' into the slot 1 of the Bay A.

⑤ Tap the 'Start' button

⑥ To confirm the start, tap the 'OK' button.



<p>⑦ It will take about 2-3 minutes to finish the washing process.</p> <p>⑧ When the washing is finished, AFIAS-6 displays 'Washing completed' message.</p> <p>⑨ Leave AFIAS-6 for about 30 minutes for drying of the tip adaptor. During this period, do not run tests on AFIAS-6.</p>	<p>Washing tip adaptor</p> <p>Follow the next procedure</p> <ol style="list-style-type: none"><li>1 Prepare washing cartridge</li><li>2 Insert washing cartridge into the 1st slot</li><li>3 Tap start button</li></ol> <p>Please do not measure any item for 30 minutes after washing tip adaptor</p> <p>In progress</p> <p>Stop Start</p> <p>Washing tip adaptor</p> <p>Follow the next procedure</p> <ol style="list-style-type: none"><li>1 Prepare washing cartridge</li><li>2 Insert washing cartridge into the 1st slot</li><li>3 Tap start button</li></ol> <p>Please do not measure any item for 30 minutes after washing tip adaptor</p> <p>Washing completed</p> <p>Stop Start</p>
---	---

## 10.2 Cleaning:

- It is advised to occasionally clean the cartridge holders and exterior of AFIAS-6 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-6 from external power source before cleaning.

## 10.3 Servicing

- AFIAS-6 does not have any operator-serviceable components.
- If any technical servicing or maintenance is required, AFIAS-6 should be sent back to Boditech Med Inc. or its authorized service agents.

## 10.4 Disposal

- If AFIAS-6 is to be disposed of for any reason, the user is advised to follow the applicable local regulations for disposing of electrical equipment.



### Important!

At the end of its useful life, AFIAS-6 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-6. The same container/box is also recommended for extended storage.



When transporting or storing AFIAS-6, keep it dry in an upright position and protect it from mechanical shocks.

---

## 11. Troubleshooting

AFIAS-6 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-6 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 (connecting the SMPS to AFIAS-6) 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-6 is in the 'sleep' mode	Gently press the power button located on the front of AFIAS-6. 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.

<p>'LCD Display' does not function properly.</p>	<p>Electrostatic shock</p> <hr/> <p>Electrical circuit failure</p>	<p>Connect to a grounded external power outlet. Remove any source of electrostatic charge. Reset the system.</p> <hr/> <p>Call Boditech Med Inc.'s technical services.</p>
<p>Barcode error</p>	<p>AFIAS-6 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.</p> <hr/> <p>Malfunction of the barcode-reading/scanning module.</p>	<p>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'.</p> <hr/> <p>Call Boditech Med Inc.'s technical services.</p>
<p>Insert printer paper</p>	<p>No paper in the built-in printer.</p>	<p>Load a new paper roll.</p>
<p>Error 25-29</p>	<p>Technical problem with the 'AFIAS test Cartridge' or malfunction.</p> <hr/> <p>Malfunction of AFIAS-6.</p>	<p>Repeat the test using a new 'AFIAS test cartridge'.</p> <hr/> <p>Call Boditech Med Inc.'s technical services.</p>
<p>Insert reagent cartridge</p>	<p>Test run has been initiated without inserting AFIAS test cartridge into the cartridge holder.</p> <hr/> <p>AFIAS-6 can't identify the 'AFIAS test cartridge' inserted in the cartridge holder.</p>	<p>Insert sample-loaded 'AFIAS test cartridge' into the cartridge holder before initiating the test run (i.e. before tapping 'Start' on the screen display)</p> <hr/> <p>Call Boditech Med Inc.'s technical services.</p>

Insert tip	<p>Test run has been initiated without placing a 'pipette tip' into the 'tip slot' of the AFIAS test cartridge inserted in the cartridge holder.</p>	<p>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 (i.e. before tapping 'Start' on the screen display)</p>
	<p>AFIAS-6 can't detect the 'pipette tip' placed into the 'tip slot' of the inserted test cartridge.</p>	<p>Call Boditech Med Inc.'s technical services.</p>
Please wait until the reader reaches recommended temperature	<p>The system temperature is outside the permissible or operational temperature range, Or Malfunction of the built-in temperature sensor.</p>	<p>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.</p>
Select sample type	<p>The user has attempted to initiate the test run without selecting the sample type.</p>	<p>Select/enter appropriate sample type on the screen before initiating the test run.</p>
Insert ID chip	<p>A system check cartridge is not inserted. The test is performed without an ID chip.</p>	<p>Insert a system check cartridge and do system check. Insert an ID chip and do the test again.</p>

	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.	Set the printer 'on' by accessing the 'Pinter on/off' menu. (Refer to Clause 9.1.11 ~ 9.1.12).
	Printer error	Call Boditech Med Inc.'s technical services.

## 12. Warranty

AFIAS-6 has passed 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 the warranty service, the consumer must return the defective AFIAS-6 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-6 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-6 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, 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-6.

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

Product Name	AFIAS-6
Catalog No.	FPRR020
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