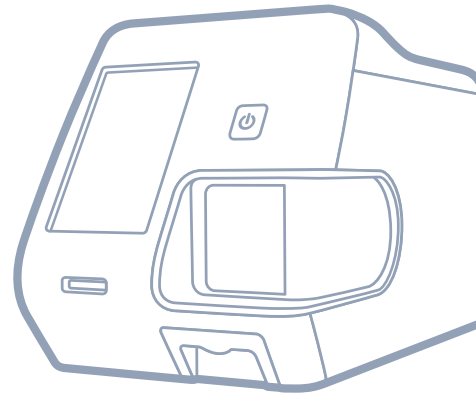
BIO TECHNOLOGY
boditech

IVD

AFIAS-1



AFIAS-1

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:

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CE

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

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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-1 products.

Symbol	Description
	Manufacturer
	Consult instructions for use
	For *in vitro* diagnostic use
	CE conformity marking
	Separate collection for electrical and electronic equipment
	Biohazard. To warn of a biological hazard. Taking care to avoid exposure to a biological hazard.
	Biological risks 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 into beam.
	Caution This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol "Caution" is still sometimes used to have the meaning of "Attention, see instruction for use".
 Danger	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-1 may cause electrocution, burns, fire and other hazards. To reduce the risk of electric shock:

- Use only the adaptor provided with AFIAS-1.
- Never try to disassemble AFIAS-1 as it does not have any operator-serviceable component.
- Do not allow AFIAS-1 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-1 from external power source before cleaning.
- Disconnect the adaptor during extended period of non-use and/or storage.

Laser Radiation

AFIAS-1 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-1. Unauthorized alternation and disassembly can cause exposure to laser radiation. When operating the AFIAS-1, 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-1 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 being potentially infectious material. 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-1 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.

Always dispose of biological waste in accordance with relevant regulations.

Caution

AFIAS-1 is meant for countertop operation under laboratory conditions.

To reduce the risk of damage to AFIAS-1:

- Handle AFIAS-1 gently with care to prevent damages to its internal components.
- Keep AFIAS-1 in a dust-free place.
- Do not expose AFIAS-1 to an environment having high humidity, direct sunlight and/or extreme temperature.
- Do not place anything on top of AFIAS-1.
- Use only the accessories provided with AFIAS-1 and 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-1.
- During transportation or storage, keep AFIAS-1 in dry conditions having -20~50 ℃ (-4~122 ℉) temperature 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-1 is in proper working condition before performing the test.
- AFIAS test setup should be arranged in an operational environment having temperature 15~35 ℃ (59~95 ℉) and humidity 10 ~ 70 %.
- Use AFIAS cartridges that have been stored in recommended storage conditions only.
- Expired cartridges must not be used.
- Before performing any AFIAS test, ensure that name of the test as well as lot number printed on the 'AFIAS ID chip' exactly match with those of 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 test, read the entire package insert of the test thoroughly

and follow the instructions carefully.

Failure to follow these precautions may yield misleading or erroneous results with the AFIAS-1 test.

2. Principle of Operation

Intended use

AFIAS-1 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-1 should be operated by healthcare professionals or trained medical technologists (professional use only).

Principle

AFIAS-1 is a fluorescence and europium nanoparticle scanning instrument to be used in conjunction with various AFIAS tests which are based on antigen-antibody reaction and fluorescence technology (Fluorescence and Europium Nanoparticle Immuno-Assay).

AFIAS-1 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 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 concentration of the analyte in test sample based on a pre-programmed calibration derived from the 'AFIAS ID chip' inserted in the ID chip port.

Computed and converted test result is displayed on the display screen of the AFIAS-1 in a quantitative manner.

AFIAS-1 tests are *in vitro* diagnostic tests intended for screening, monitoring and/or routine physical examination.

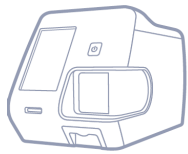
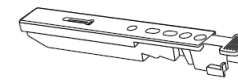
3. Commercial Package Contents

AFIAS-1 and its accessories are provided in a single box. For proper operation of the system, user must be familiar with the technical term and use of each component.

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

■ **Standard items**

1. 1 AFIAS-1
2. 1 Operation manual
3. 1 Set of AFIAS-1 system check cartridge and system check ID chip
4. 1 Set of AC adaptor and power cable
5. 1 Thermal printer paper roll
6. 1 AFIAS OS SD card (Inserted in the instrument)

1	2	3a
		
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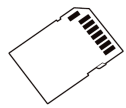
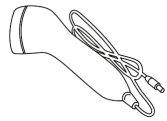
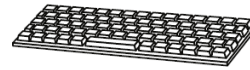
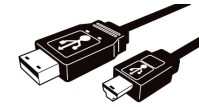
6		
		

■ **Optional items**

1. Barcode scanner
2. USB keyboard (86 keys)
3. USB OTG cable

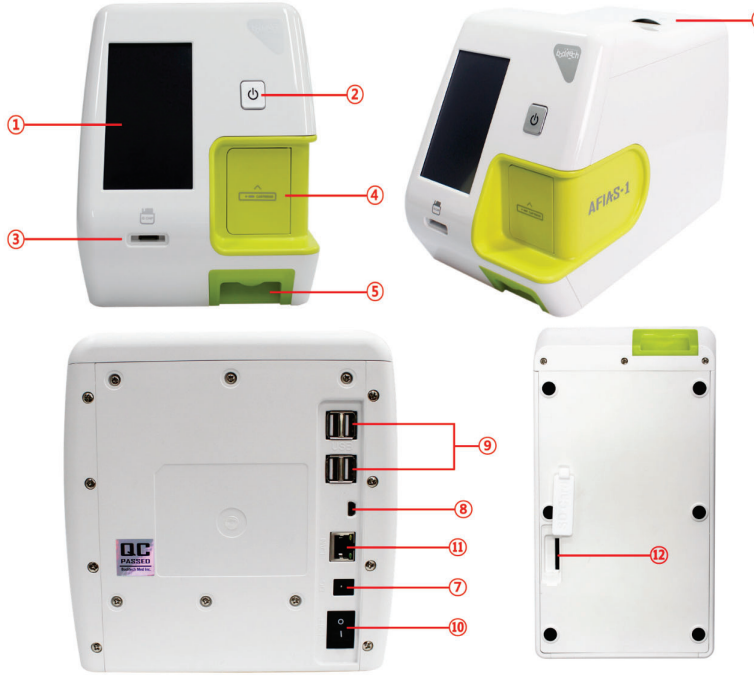
1	2	3
		

4. Specifications

● **Physical Features**		
❑ Dimensions	320.6 mm (L) x 180.6 mm (W) x 206.4 mm (H)	
❑ Weight	4.0 kg	
❑ Power supply	DC 12V / 5A AC/DC Adaptor Input : 100-240 V AC, 50~60 Hz, 1.5 A Output : DC 12V / 5A	
❑ Data output	LCD / Internal printer / USB OTG port	
● **Environmental Requirements**		
❑ Operation Temperature	15 ~ 35 ℃ (59 ~ 95 ℉)	
❑ Storage Temperature	-20 ~ 50 ℃ (-4 ~ 122 ℉)	
❑ Humidity	10 ~ 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	USB OTG	1 Port (only for manufacturer)
	USB	4 Ports
	LAN	1 Port (only for manufacturer)
	SD Card Slot	1 Port (only for manufacturer)
❑ Display	LCD (800x480 Graphic LCD, Touch-screen module)	

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

5. Operational and Functional Elements



No.	Description
① LCD display	Acts as the platform for inputting all information regarding the test. Displays test result and message alerts.
② Power button	For switching AFIAS-1 'On' or entering it in 'Sleep Mode'
③ ID chip port	For inserting ID chip
④ Holder	Accommodates cartridge holders meant for inserting AFIAS test cartridges
⑤ Tip box	Collects used pipette tips
⑥ Internal printer	Offers print-out of test result

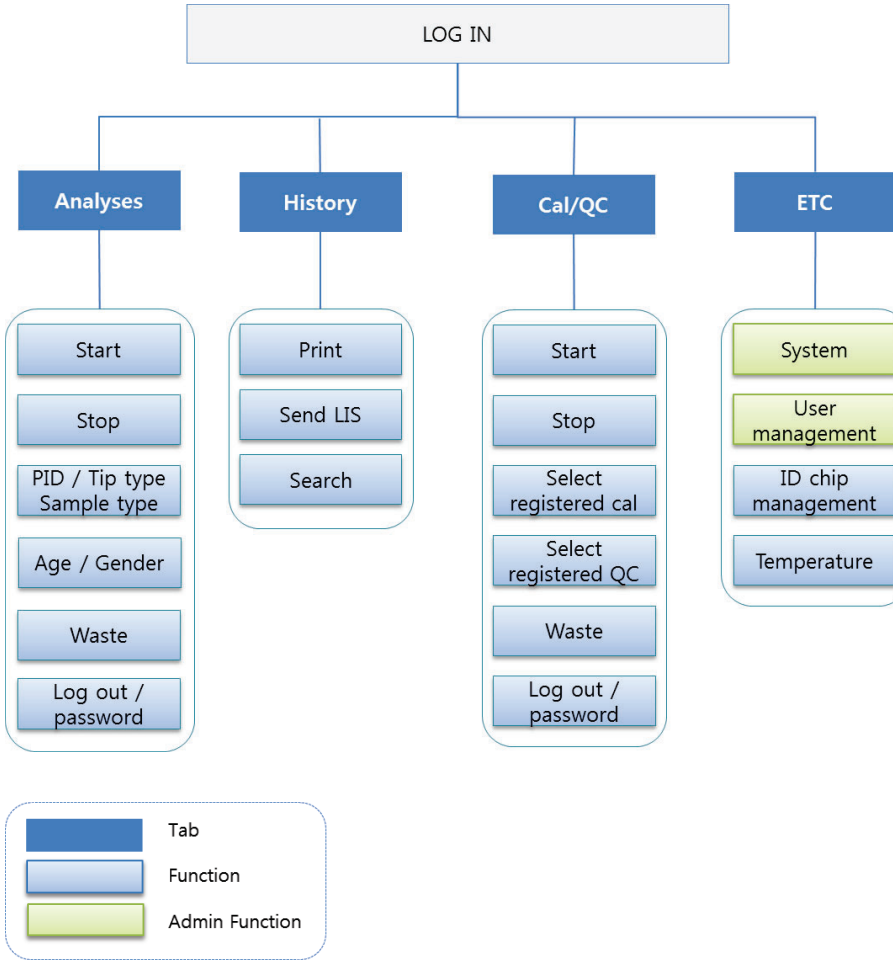
⑦ Power port	For connecting the AC adaptor
⑧ USB OTG port	For connecting PC (only for manufacturer)
⑨ USB port	For connecting Barcode scanner / Keyboard
⑩ Main power switch	For switching AFIAS-1 on/off
⑪ LAN port	For connecting to the internet (only for manufacturer)
⑫ SD card port	For software upgrade

Function key

Power Button	If you press this button momentarily, AFIAS-1 will enter/exit 'Sleep mode' and the LCD screen will be turned off/on. If you press this button for more than 4 seconds, AFIAS-1 will shut down.

5.1 Software menu tree

Menu tree of AFIAS-1 is as follow.



6. Installation

⚠ **Important**	Before using AFIAS-1, read the warnings and precautions described previously in 'Clause 1: General Warnings and Important Instructions' of this manual.

Power supply

AFIAS-1 will work on household 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-1 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). Room temperature of the operational chamber must be maintained in the range of 15~35 ℃ (59~95 ℉).

Installation procedure

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

AFIAS-1 is provided with a foam for protecting the inside of AFIAS-1. When one turns on the AFIAS-1, the holder will come out with a foam.

⚠	Please remove this foam before using the AFIAS-1 as shown above.

1. Connect the AC adaptor by inserting its connector into the power port.

2. Connect the power cord to external power outlet and turn on the main power switch.

3. Press the power button provided on the front of AFIAS-1.

4. Upon pressing the power button, AFIAS-1 will display Boditech Med's logo and it executes a series of system initialization and self-checking routines.

During system initialization, AFIAS-1 will display each test items, and the test results will be displayed. If there is any problem, an error message is displayed. If a user taps the "Confirm" button, he/she can use AFIAS-1 except for test functions. If you want to perform tests, please turn off AFIAS-1 using the main power switch (provided on the rear side of AFIAS-1) and restart AFIAS-1. If the same problems are present, please contact the local distributor or Technical Service of Boditech Med Inc.

5. After finishing the initialization, AFIAS-1 prints out "System OK!" and displays the popup window for selecting registered users.

6. When you select a user, AFIAS-1 displays "Log in" window. If you want to change the current user to another user, please tap the drop-down button and change the user.

7. Running Tests

⚠	Before performing any AFIAS test, please read the respective package insert carefully for other details of the test procedure.
	Before performing any AFIAS test, ensure that name of the test as well as the lot number printed on the 'AFIAS ID chip' exactly match with those on the 'AFIAS cartridge.' Otherwise AFIAS-1 will display an error message "Insert ID chip".
	AFIAS cartridges and Boditech Controls or Calibrators 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, a relevant error code or a message alert 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

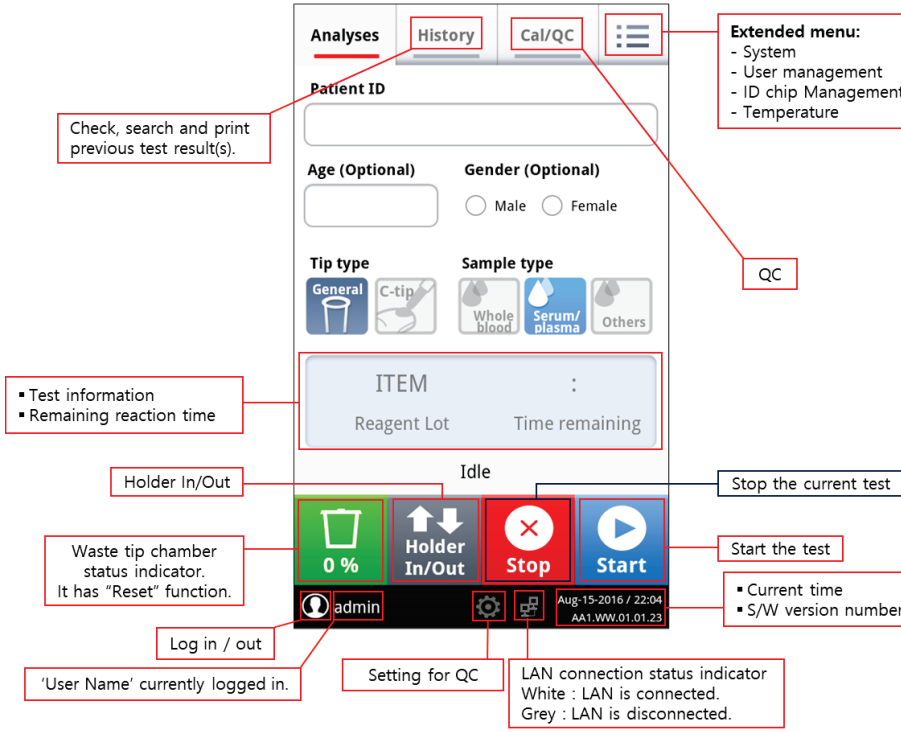
- For performing an AFIAS test, arrange the following items in addition to AFIAS-1 in a test-ready mode:
- AFIAS XXX ID chip(s)
- AFIAS XXX cartridge(s)
- Patient Sample(s) or Boditech XXX Control(s) or Calibrator(s)
  *(**Note**. XXX represents name of the AFIAS test being performed.)*
- Ensure that the name of the test as well as the lot number printed on the 'AFIAS ID chip' with those printed on the 'AFIAS cartridge' before removing the cartridge from its blister packing.
- Store patient sample(s) or control(s) and the cartridge(s) at room temperature for about 30 minutes before testing.

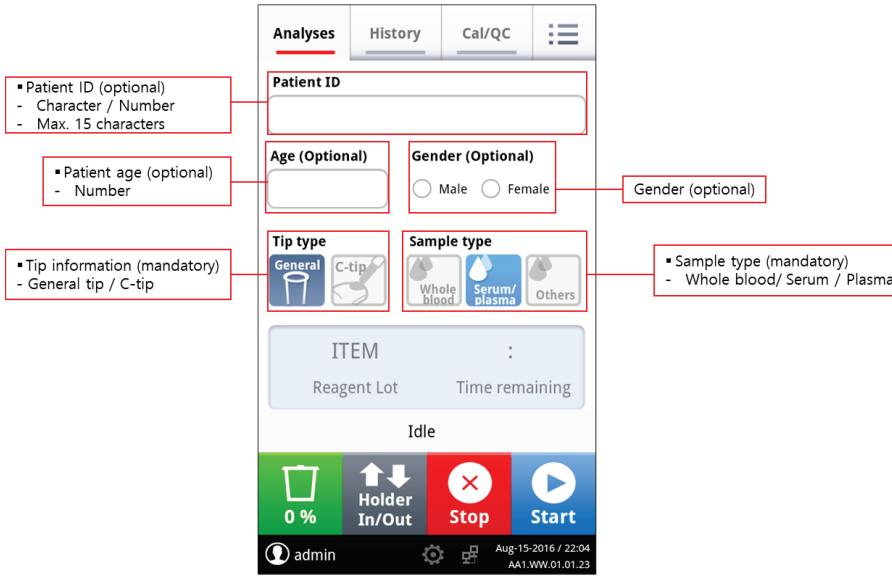
7.2 Logging in and Inputting required information

- As described in 'Clause 6: Installation', test-ready AFIAS-1 displays the "Log in" window.
- Input user name and password. The default 'user name' and 'password' are "admin" and "0000," respectively. You can change the password for 'admin' and add other users. Please refer to 'Clause 9.2: User management; for further details. If log in is successful, main menu will be displayed.

7.3 Main menu description

7.3.1 Details of the information/main menu displayed on the screen are as follow.





7.3.2 When you start the test after inserting ID chip, information of that ID chip will be stored/registered in AFIAS-1 automatically. If you want to test the same lot of AFIAS test, ID chip is not needed.

To register ID chip manually, refer to 'Clause 9.3 ID chip management'.

7.4 Inputting test information

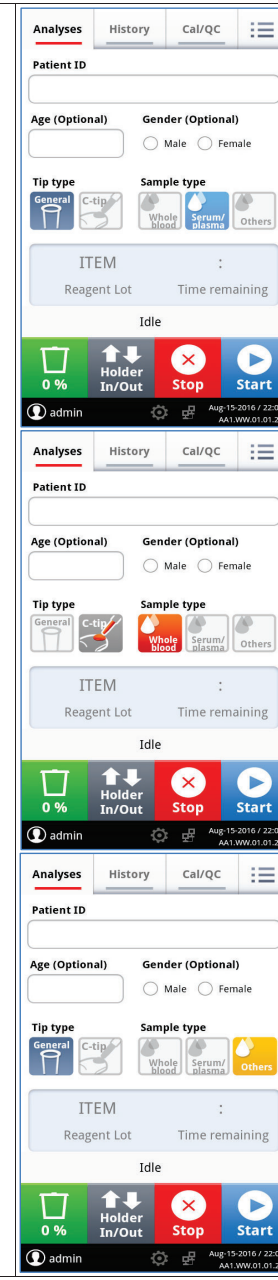
7.4.1

■ **Inputting required test information'**

– Select "Tip type" and "Sample type".

– If you select "General" as tip type, you should select "Sample type" among Whole blood, Serum/Plasma and Others.

– If you select "C-tip" as tip type, the sample type is selected as "Whole blood" automatically.



7.4.2

■ **Optional information**

– It is possible to perform a test without inputting the following 3 information.

■ Inputting Patient ID

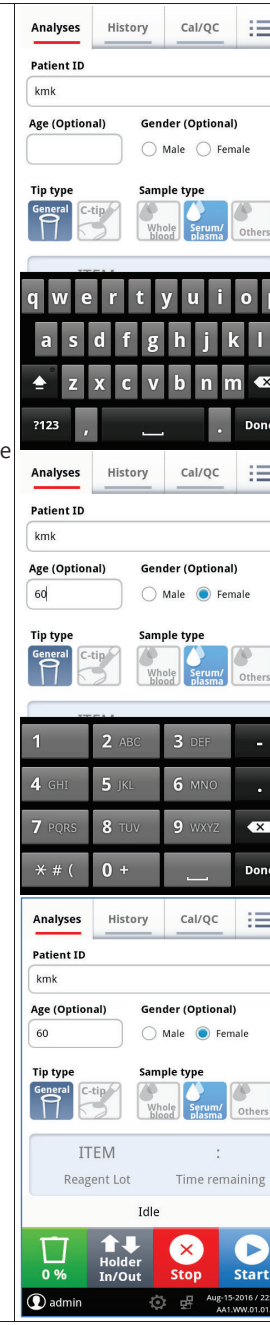
– Input a patient ID using a keyboard which is displayed on the LCD screen. When you tap the 'Done' button, the keyboard will disappear. If USB keyboard is connected, you can use it to input a patient ID.

■ Inputting Age

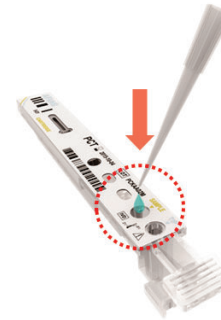
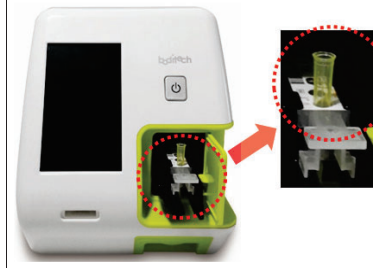
– Input patient's age using a numeric keypad which is displayed on the LCD screen. When you tap the 'Done' button, the keypad will disappear. If USB keyboard is connected, you can use it to input patient's age.

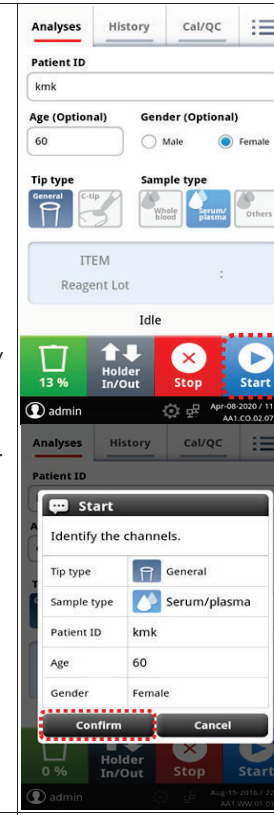
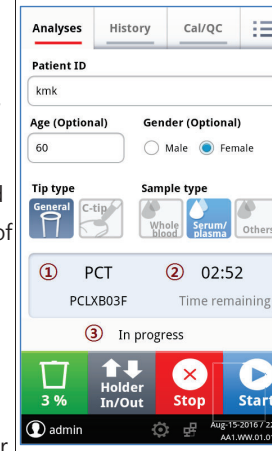
■ Gender

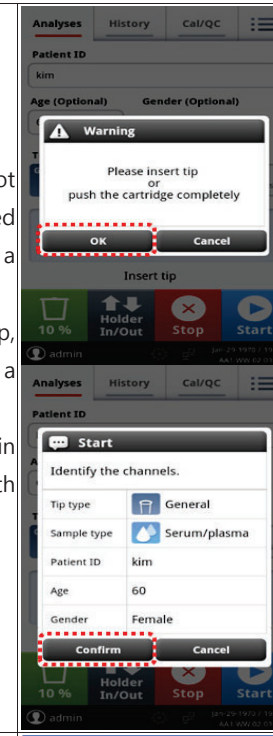
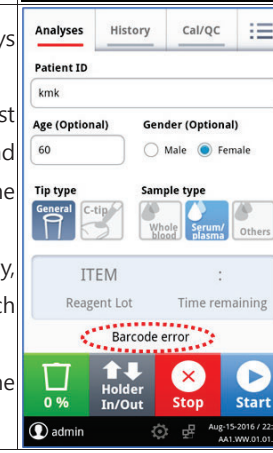
– Tap the blank box for 'Male' or 'Female'. If you want to cancel the selection, tap the selected box again.

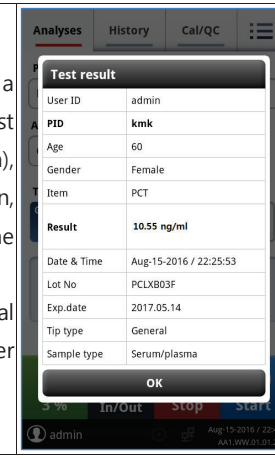


7.5 Inserting Sample-loaded Cartridge and Obtaining Test Result

7.5.1	■ Considering that 'AFIAS #### ID Chip' has been inserted in the ID chip port, proceed as follows for performing the AFIAS #### test on clinical sample: – Load recommended volume of the test sample into the 'Sample Well' of 'AFIAS #### cartridge'. (⚠ *Refer to the package insert of the AFIAS test being performed for details on sample processing, volume to be loaded, etc.)*	
7.5.2	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. While inserting the cartridge, sample well should be oriented outward from AFIAS-1. (⚠*For inserting the cartridge, 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.)*	 

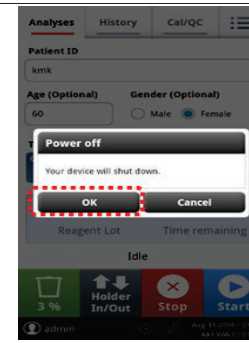
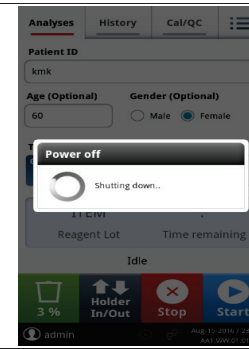
7.5.3	■ To proceed with the test, tap the "Start" button. ■ The new window pops up. Please check the inputted test information (Tip type / Sample type / Patient ID / Age / Gender). ■ To proceed with the test, tap the "Confirm" button. ■ If you want to cancel the test, please tap the "Cancel" button.	
7.5.4	■ AFIAS-1 reads the barcode of inserted AFIAS cartridge and check the test item and the lot number automatically. ■ AFIAS-1 checks whether a pipette tip is inserted or not automatically. ■ The name of test and lot number will be presented in the LCD display(refer to ①). ('PCT' is the name of the test and 'PCLXB03F' is the lot number.) ■ While the test is in process, "In progress" is displayed(refer to ③). ■ The remaining time is displayed in minutes and seconds (mm:ss) on the right of the test name(refer to ②).	

7.5.5	■ It is impossible to start a test if a pipette tip is not inserted or a test cartridge is not inserted completely. In this case, AFIAS-1 displays a "Warning" window and the test does not proceed. ■ You need to solve the problems(insert a pipette tip, or a test cartridge) and tap 'OK' button to start a test. ■ For proper operation, tap the 'START' button, then in a new popup display, tap 'CONFIRM' to proceed with further steps.	
7.5.6	■ If a test cartridge is not inserted, AFIAS-1 displays 'Barcode error'. ■ If AFIAS-1 displays 'Barcode error' although a test cartridge is already inserted, please remove and insert the test cartridge again. Then proceed with the test. ■ If AFIAS-1 displays 'Barcode error' continuously, please contact Technical Service center of Boditech Med Inc. or regional distributor. ■ You need to insert a test cartridge and resume the test procedure according to Clause 7.5.	

7.5.7	■ When the test is completed, AFIAS-1 will display a new pop-up window. You can find the test information(mandatory and optional information), cartridge information and the test result. In addition, AFIAS-1 will print out the test result using the internal thermal printer. ■ AFIAS-1 can save 5,000 test results in the internal memory. (To check the saved test results, please refer to Clause 8.2.)	

⚠	Before performing any AFIAS test, ensure that the name of the test as well as the 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 an error alert, 'Insert ID chip'.
☣	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.

7.6 Finishing Working With AFIAS-1

7.6.1	■ Before shutting down AFIAS-1, ensure that ID chip(s) and cartridge(s) have been removed from ID chip port(s) and cartridge holder(s), respectively.	
7.6.2	■ Press the 'Power button' for more than 4 seconds.	
7.6.3	■ Power off' menu will be displayed. ■ Tap 'OK' to shut down AFIAS-1.	
7.6.4	■ 'Power off' will be executed. ■ The cartridge holder will retract automatically. ■ AFIAS-1 will shut down.	

7.6.5	■ Turn off the main power switch provided on the rear side of AFIAS-1.	
7.6.6	■ If you do not intend to use the system for a long period (e.g. more than 2 days), unlpug AFIAS-1 power cord from the external power outlet.	
7.6.7	■ Remove the power cable from the 'Power Port'.	

8. Supportive Procedures

For ensuring efficient and reliable performance as well as proper recording and reporting of test results, the overall operation of AFIAS-1 essentially involves following supportive procedures in addition to running AFIAS-1 tests.

8.1 System check, Calibration and QC

■ System check
- To perform a system check, a user needs to use a specific system check cartridge and a system check ID chip.
- AFIAS-1 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-1 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-1 is installed initially.
- When AFIAS-1 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.

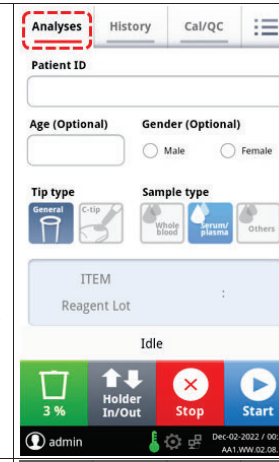
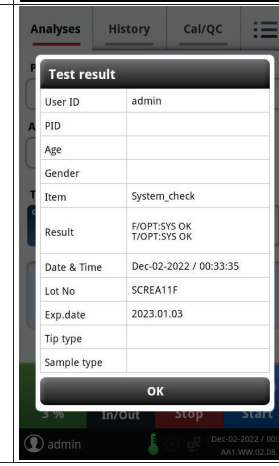
■ Calibration
- The master calibration curve for cartridges is stored in the ID chip included in the cartridge box and no separate calibration process is required for the new reagent.
- Calibration curves stored in the ID chip may not be valid for all test environments. In this case, it is required to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

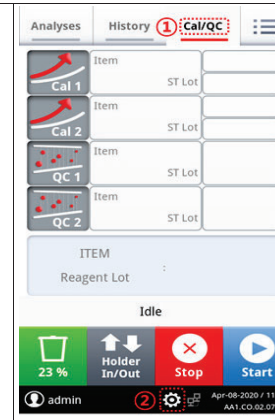
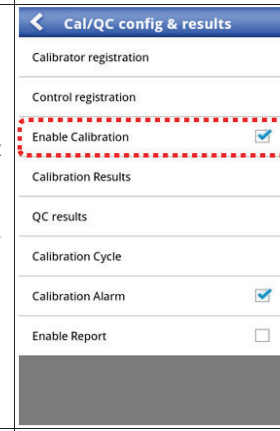
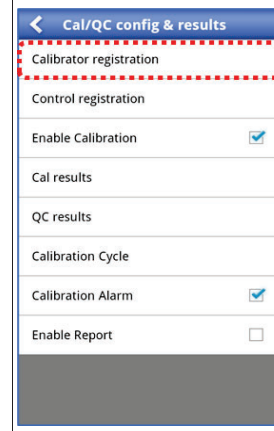
■ The calibration is needed as below.
- When the QC test results are out of range.
- When the test results are suspected to be abnormal.

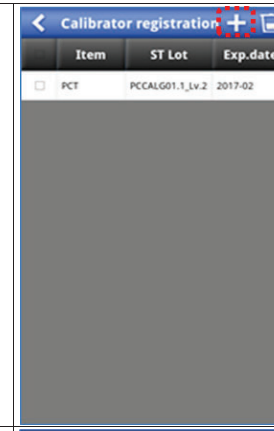
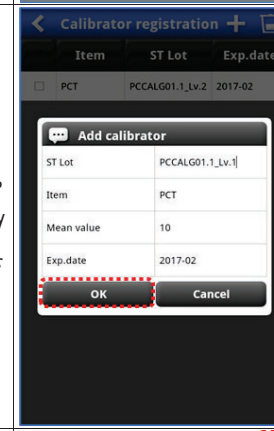
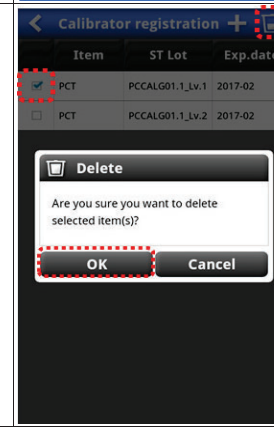
※ AFIAS test system is designed for point of care, emergency, and small-volume testing. Therefore, a regular calibration is not required/recommended.

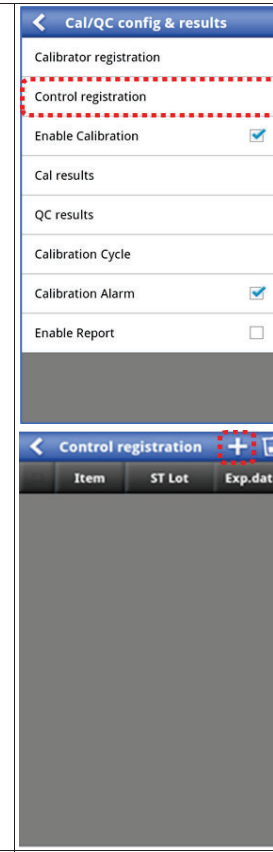
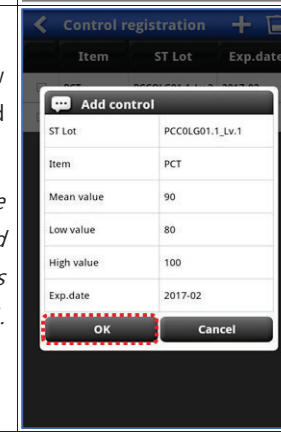
■ QC (Quality control)
- To perform QC, a user needs to use specific quality control reagent which is supplied by the manufacturer on demand.

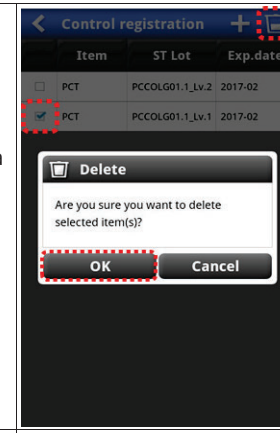
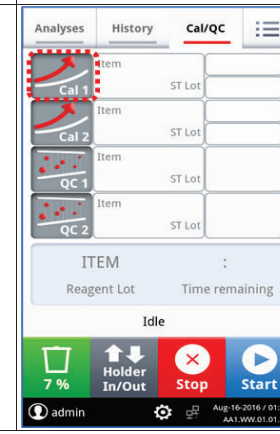
■ The QC is needed as below.
- When a test lot is changed.
- When a test result is considered abnormal or differs from the reference value.
- When a test result is not consistent with symptoms.
- For teaching or learning the system.

8.1.1	■ To run a system check, select the 'Analyses' ■ Insert a system check cartridge and a system ID chip into AFIAS-1. ■ Tab the 'Start' icon. ■ To confirm information and start a system check tap the 'confirm start' button.	
8.1.2	■ During system check, 'In progress' will displayed. ■ When the system check is completed, "SYS OK' and 'Test completed' will be displayed.	

8.1.3	■ To do calibration and QC, you need to activate this function. ■ Select the ① 'Cal/QC' tap. ■ To acitvate 'Cal/QC' function, please tap the setting icon ②.	
8.1.4	■ Tap the 'Enalble Calibration' menu. The check box will be toggled whenever you tap this menu. To activate the calibration and QC function, the check box should be checked with ☑.	
8.1.5	■ To do calibration and QC, you need to register a calibrator and a control. Select the 'Calibration registration' menu to register a calibrator.	

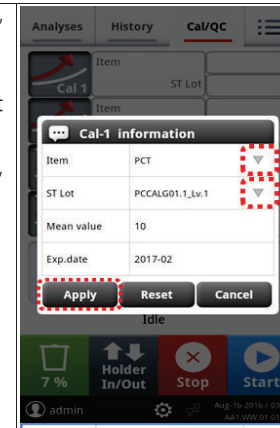
	■ Tap the icon to register a calibrator	
8.1.6	■ 'Add calibrator' window will pop-up. ■ Input a lot number, item name, mean value and expiration date using key pad or a barcode reader. ***Note.*** *The expiration date is set as YY-MM. The actual date will be set as the last day of the selected month. For example, if you set expiration date as 2015. 11, the detailed expiration date is 2015. 11. 30.* ■ To apply this information, tap the 'OK' button.	
8.1.7	■ If you want to delete a registered calibrator, select a calibrator what you want to delete. ■ Tap the icon to delete a registered calibrator. ■ Tap the 'OK' button for confirmation.	

8.1.8	■ Select the 'Control registration' menu to register a control. ■ Tap the icon to register a control.	
8.1.9	■ 'Add control' window will pop-up. ■ Input a lot number, item name, mean value, low value, high value and expiration date using key pad or a barcode reader. ***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 2015. 11, the detailed expiration date is 2015. 11. 30.* ■ To apply this information, tap the 'OK' button.	

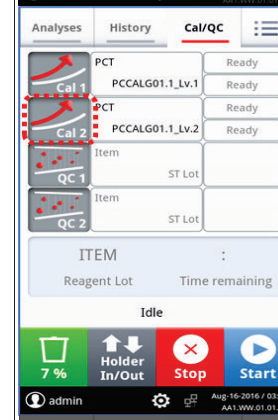
8.1.10	■ If you want to delete a registered control, select a control that you want to delete. ■ Tap the icon to delete a registered control. ■ Tap the 'OK' button for confirmation.	
8.1.11	■ To do calibration and QC, please prepare a test cartridge that you want to test. ■ Dispense a calibrator and control into the sample well of the cartridge. ■ Insert the cartridge into the cartridge holder and insert tips.	
8.1.12	■ Tap the 'Cal 1' button to perform Cal/QC.	

8.1.13

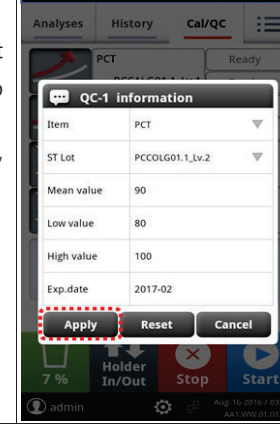
- When you tap 'Cal 1' button, 'Cal-1 information' window pop-up.
- You can select item and lot number that you want to select by tapping a drop down button.
- To apply the relevant information, tap the 'Apply' button.

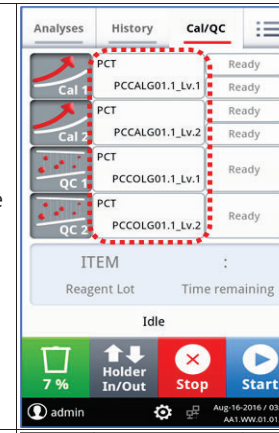
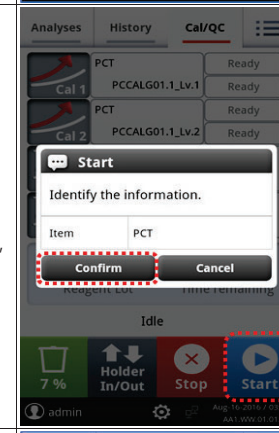
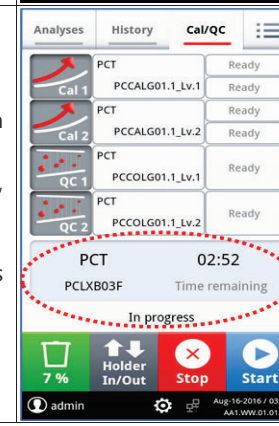


- Proceed with 'Cal 2' following the same steps.



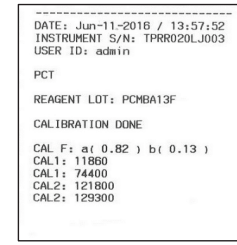
- Tap 'QC 1' button, you can select item and lot number that you want to select by tapping a drop down button.
- To apply the relevant information, tap the 'Apply' button.
- Proceed with 'QC 2' following the same steps.



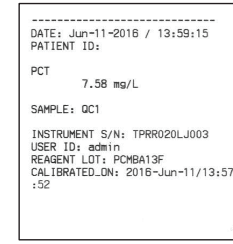
8.1.14	▪ When selection of all calibrators and controls are completed, the relevant information is displayed.	
8.1.15	▪ Tap 'Start' button to start calibration and QC. ▪ 'Start' window will pop-up. ▪ Check the lot number and the test item. ▪ To confirm and proceed with test, tap 'Confrim' button.	
8.1.16	▪ When the test starts, AFIAS-1 checks the test item and lot number automatically. ▪ The name of the test is displayed and 'In progress' message will be presented below. ▪ While the test is in progress, the remaining time is displayed.	

8.1.17

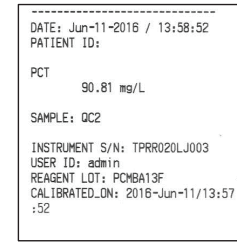
- When the test is completed, AFIAS-1 will generate a buzzer signal, and the slot comes out.
- The test results are saved in the internal memory automatically, and the thermal printer will print out the test results automatically.



<Printed Calibration test result>



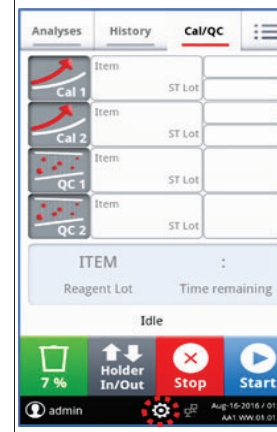
<Printed QC1 test result>

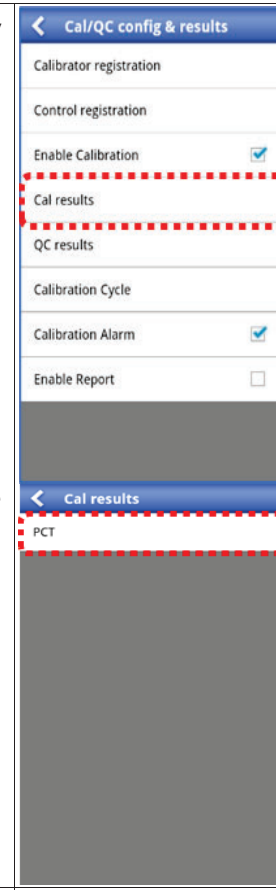
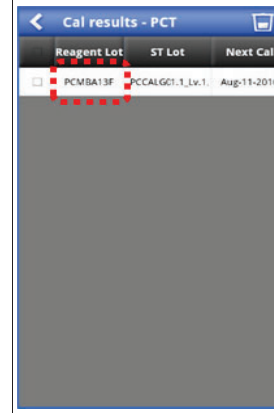


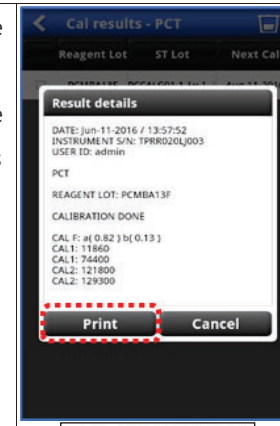
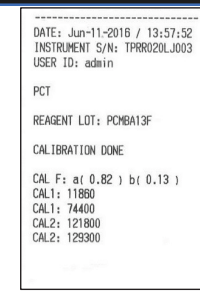
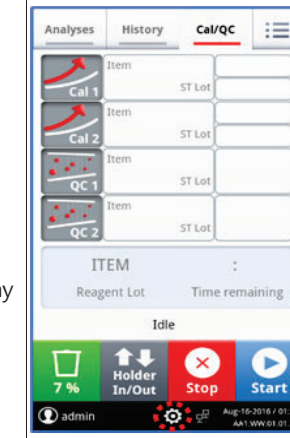
<Printed QC2 test result>

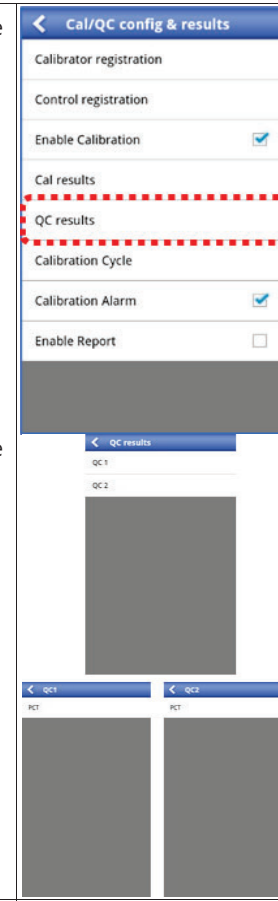
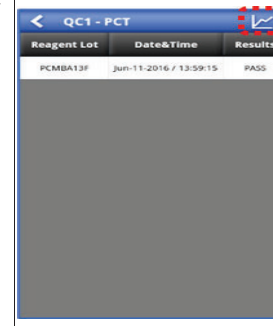
8.1.18

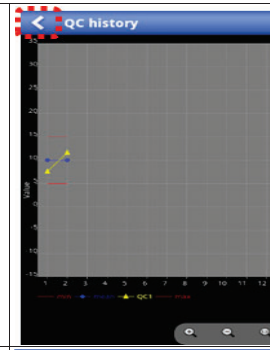
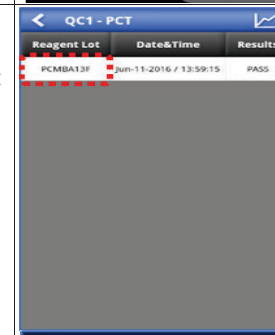
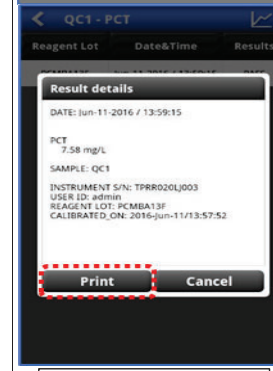
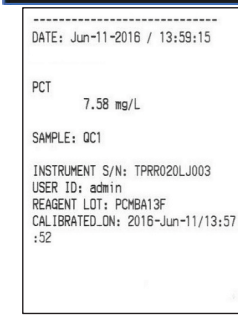
- To check the calibration results, tap the setting icon at the bottom of the Cal/QC screen.



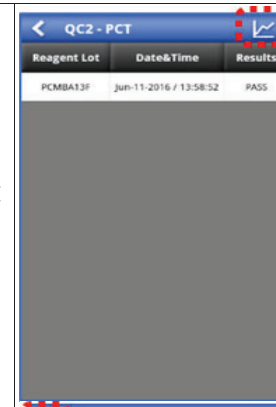
	■ Tap the 'Cal results' menu. Then AFIAS-1 will display the available test items. ■ Tap a test item for which you want to check the results.	
8.1.19	■ AFIAS-1 displays the lot number of cartridges and calibrators and the next calibration date. ■ To check the detailed calibration result, tap the item that you want to check.	

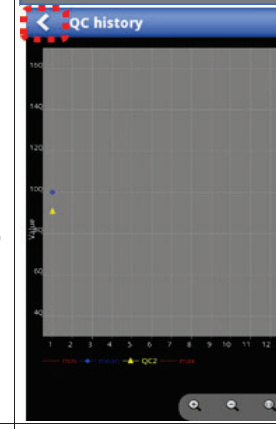
	■ 'Result details' window will pop up and shows the detailed test information as follows. - Date / Instrument serial no. / User ID / Name of test item / Reagent Lot / Calibration results ■ If you want to print out this inforamtion, tap the 'Print' button. Then AFIAS-1 will print out the detailed test infromation.	 
8.1.20	■ To check the QC results, tap the setting icon at the bottom of the Cal/QC screen. ■ Tap the 'QC results' menu. Then AFIAS-1 will display QC1 and QC2.	

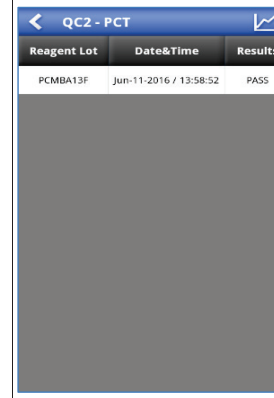
	■ Tap QC1 or QC2. Then AFIAS-1 will display the available test items for QC1 and QC2. ■ Tap a test item for which you want to check the results.	
8.1.21	■ Checking QC1 ■ AFIAS-1 displays the lot number of cartridges, QC date & time and QC result. ■ If you want to check the QC history, tap icon.	

	■ AFIAS-1 displays the QC1 history as presented on the right. ■ If you want to go back to the previous screen, tap the icon.	
8.1.22	■ To check the detailed QC1 result, tap the item that you want to check(refer to step 8.1.18). ■ 'Result details' window will pop up and show the detailed test information as follows. ■ If you want to print out this information, tap the 'Print' button. ■ Then AFIAS-1 will print out the detailed test information. - QC Date / Name of test item / Test value / Instrument serial no. / User ID / Reagent Lot / Calibration date	  

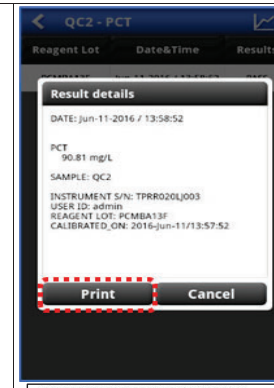
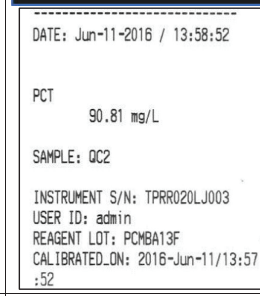
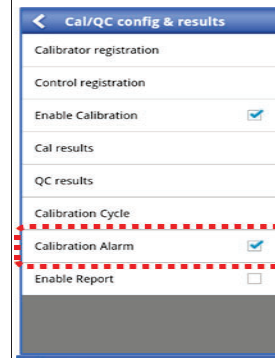
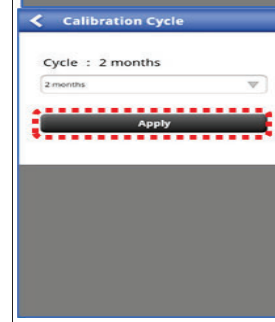
<table>
<tr>
<td>8.1.23</td>
<td>
■ Checking QC2
■ AFIAS-1 displays the lot number of cartridges, QC date & time and QC result.
■ If you want to check the QC history, tap icon.

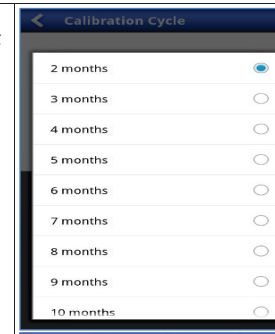
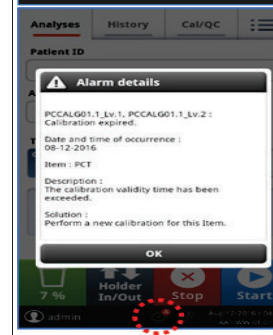
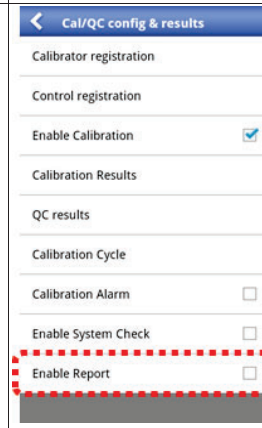
■ AFIAS-1 displays the QC2 history as presented on the right.
■ If you want to go back to the previous screen, tap the icon.
</td>
<td>




</td>
</tr>
<tr>
<td>8.1.24</td>
<td>■ To check the detailed QC2 result, tap the item that you want to check(refer to step 8.1.18).</td>
<td>


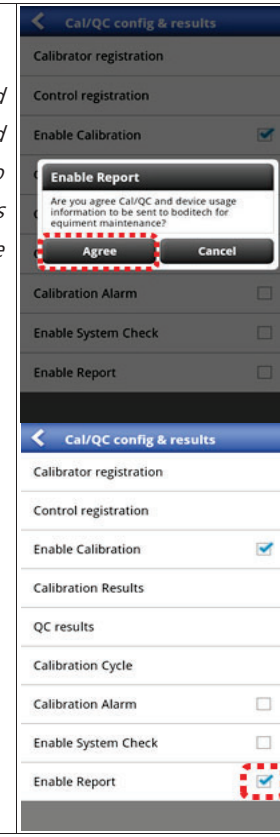
</td>
</tr>
</table>

	■ 'Result details' window will pop up and show the detailed test information as follows. ■ If you want to print out this inforamtion, tap the 'Print' button. Then AFIAS-1 will print out the detailed test infromation: - QC Date / Name of test item / Test value / Instrument serial no. / User ID / Reagent Lot / Calibration date	 
8.1.25	■ Tap the 'Calibration Alarm' menu. The check box will be toggled whenever you tap this menu. If you want to get an alarm for a past due calibration cycle, the check box should be checked with ☑. ■ To change a calibration cycle, tap the 'Calibration cycle' menu. ■ AFIAS-1 displays the 'Calibration cycle' window. ■ You can change a calibration cycle by tapping the dropdown button in the 'Calibration cycle' window. To confirm the change of a calibration cycle, tap the 'Apply' button.	 

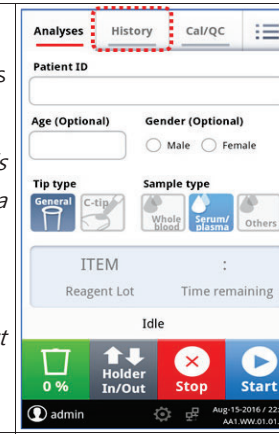
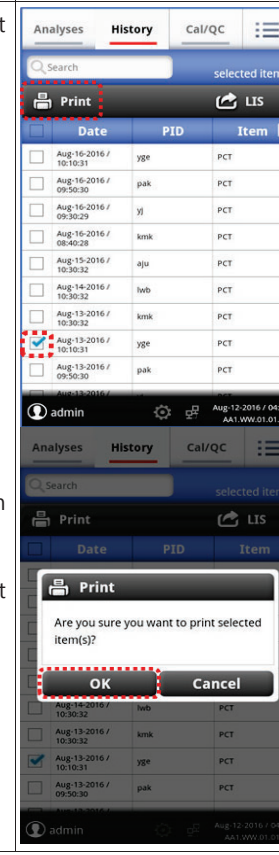
	Note. *You can change a calibration cycle by day, week and month.* ■ If a calibration cycle is past due, AFIAS-1 displays 'Alarm details' window. Also a red colored 'A' marking is displyed on the setting icon under the main screen. In this case, you need to perform a new calibration.	 
8.1.26	'Enable Report' is for sending Cal/QC data to the server. ■ Tap the 'Enable Report' menu to activate this function. ■ AFIAS-1 displays 'Enable Report' window for confirmation of sending Cal/QC data to Boditech's server only for maintenance purposes. ■ If you agree with the use of this function, tap the 'Agree' button. ■ If you do not agree, tap the 'Cancel' button.	

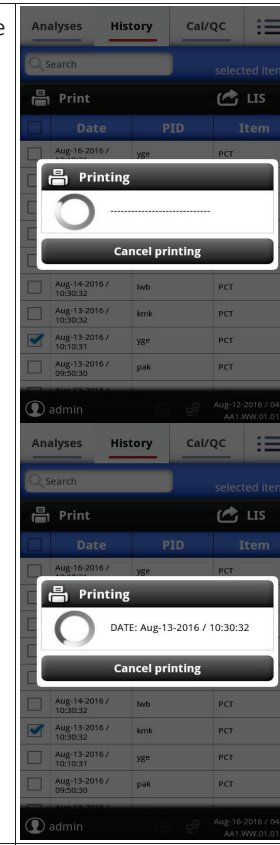
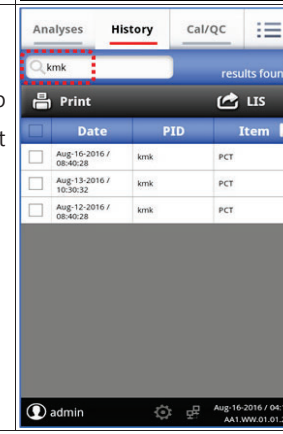
■ The check box will be checked as ☑.

Note. *When the 'Enable Report' menu is activated and AFIAS-1 is connected to LAN, AFIAS-1 will send Cal/QC data and the device usage history to Boditech's server automatically. This information is used only for maintenance purposes by the manufacturer.*



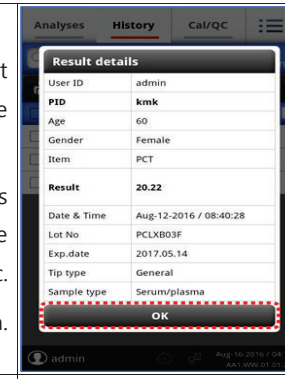
8.2 Retrieval/Printing of stored test results

8.2.1	▪ AFIAS-1 can save up to 5,000 test results in its internal memory. ***Note.*** *If the number of stored test results excceeds 5,000 results, the oldest result will be deleted when a new test result is saved.)* ▪ 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", datewise log of stored test results is displayed in a reverse chronological order. ▪ Select the test result(s) you want to print out. ▪ It is possible to 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 intend to print out the selected test results, tap 'Cancel'.	

	■ After tapping 'OK' button, AFIAS-1 will display the printing status and print out selected result(s).	
8.2.3	■ If you want to search specific test result(s), tap "Search" and input the search term (e.g. date, patient ID, user name, test name etc.) ■ Tap the search icon . ■ Searched results will be displayed.	

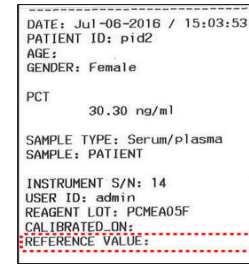
8.2.4

- If you just want to note the details of stored test result(s) without printing, tap the field displaying the test result of your interest.
- A new window will pop up displaying details such as patient ID, test name, test result, date & time of the test, lot number and expiry date of test reagents, etc.
- If you want to close this window, tap the 'OK' button.



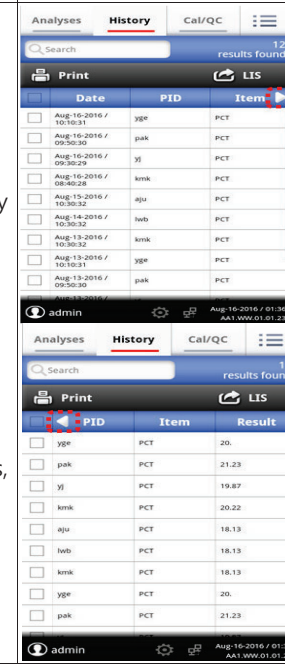
8.2.5

- Printout generated by the built-in thermal printer contains the test result alongwith relevant information as shown herewith.
- The printout will also contain test-specific reference values/interval for the specific patient population if such information has been previously inputtted by the laboratory.

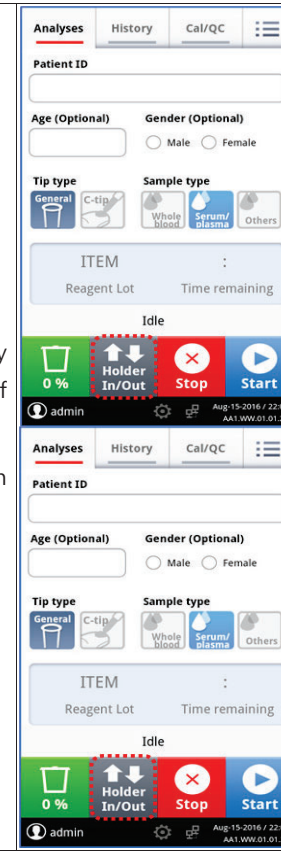


8.2.6

- You can find Date, PID, Item and Result in this History screen.
- If you want to align and check the results by items, please tap the arrow button next to Item.



8.3 Holder In/Out

8.3.1	■ The cartridge holder will go inside or come out by tapping the Holder In/Out button at the bottom of the screen. ■ The In/Out button cannot be used while a test is in progress.	

9. Configuring

Following settings and/or parameters of AFIAS-1 can be adjusted.

	Clause 9.1 and 9.2 are only accessible to the 'Administrator' only.

9.1 Configuring System Operation

9.1.1 Date, Time, Date & Time format

9.1.2 Language

9.1.3 Printer Option

9.1.4 Test menu

9.1.5 Device Information

9.1.6 Test counter

9.1.7 Setting Tip / Sample type

9.1.8 LIS Configuration

9.1.9 Updating the S/W

9.2 User management

9.3 ID chip management

9.4 Temperature

9.1 Configuring System Operation

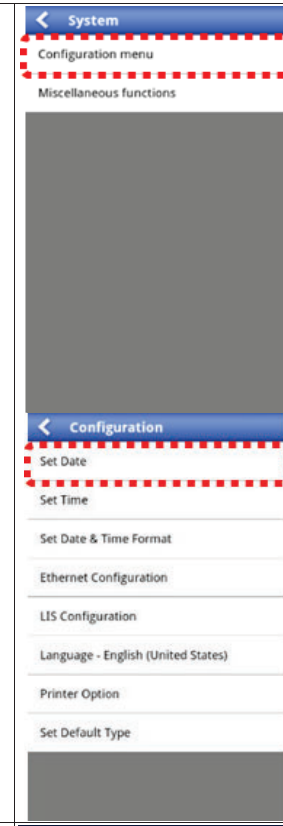
9.1.1.1

9.1.1 Date, Time Date & Time format

■ **Setting the 'Date':**

① Tap the 'Configuration menu'.

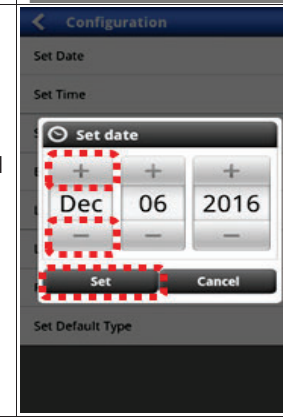
② Tap the 'Set date' menu.

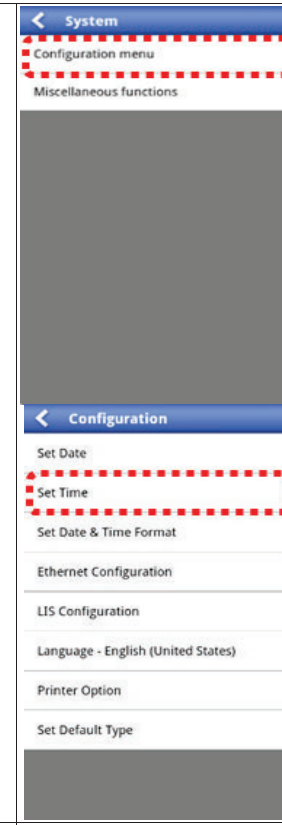
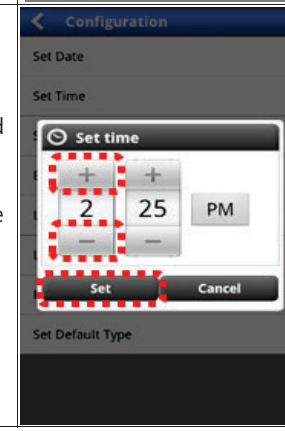


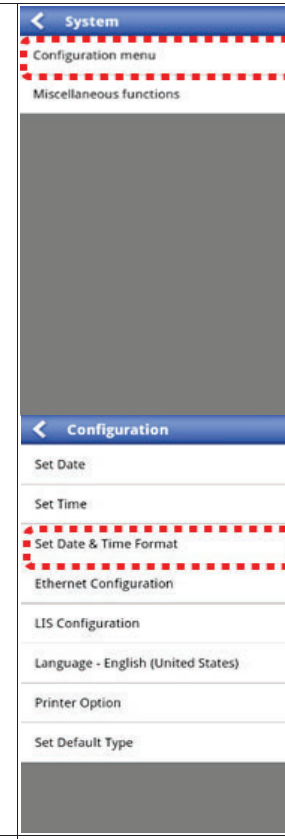
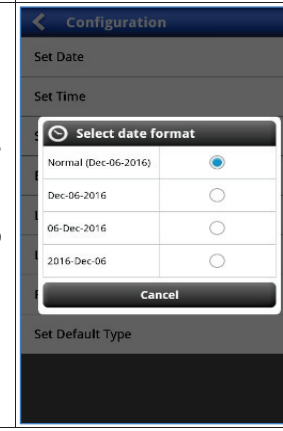
9.1.1.2

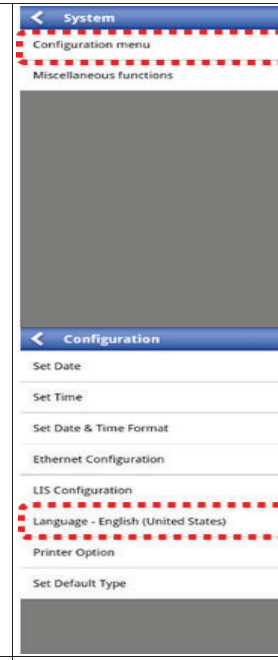
■ Tap the + or − button(s) to set the desired month, date and year.

■ To set the changed date, tap 'Set'.



9.1.1.3	■ **Setting the** '**Time**': ① Tap the 'Configuration menu'. ② Tap the 'Set time' menu.	
9.1.1.4	■ Tap the + or − button(s) to set the desired values for hour and minute. ■ You can set the time as 'AM' or 'PM' by tapping the adjcent tab. ■ To set the changed time, tap 'Set'.	

9.1.1.5	■ **Setting the Date Format** ① Tap the 'Configuration menu'. ② Tap the 'Set Date & Time format' menu.	
9.1.1.6	■ Check/tap the blank box corressponding to the date format you want to select. ■ If you want to cancel changing the date format, tap 'Cancel'.	

9.1.2.1	**9.1.2 Language** ■ **Setting the Language:** ① Tap the 'Configuration menu'. ② Tap the 'Language' menu.	
9.1.2.2	■ Select the language you want to use. ■ The system reboot process is required for the selected language to be applied.	

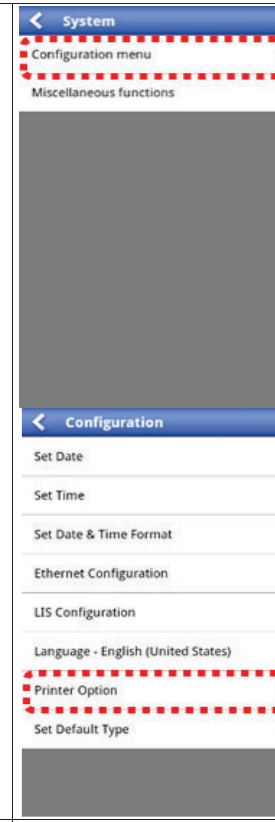
<table>
<tr>
<td>9.1.3.1</td>
<td>

9.1.3 Printer Option

■ **Turning the Printer On / Off**:

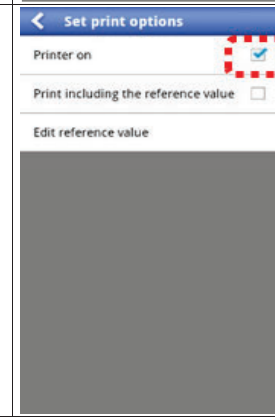
① Tap the 'Configuration menu'.

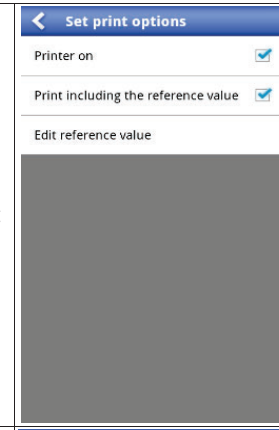
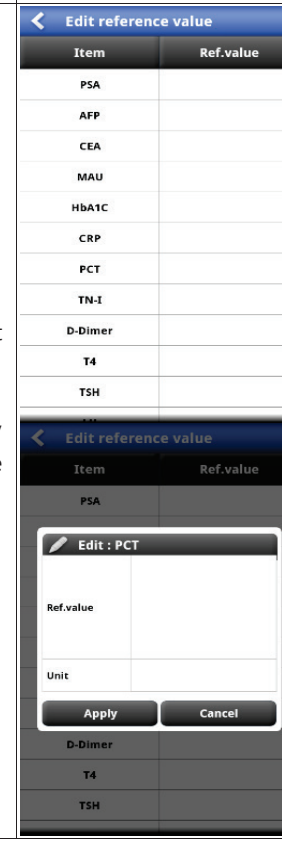
② Tap the 'Printer Option' menu.

</td>
<td> 
</td>
</tr>
<tr>
<td>9.1.3.2</td>
<td>

■ Check/tap the blank box of the 'Printer on' menu to turn the printer 'on'.

■ Uncheck/tap the checked box of the 'Printer on' menu to turn the printer 'off'.

</td>
<td> 
</td>
</tr>
</table>

9.1.3.3	■ If you want to print out a test result with a 'Reference Value', check/tap the blank box of 'Print including the reference value'.	
9.1.3.4	■ If you want to edit 'Reference value', tap the 'Edit reference value' menu. ■ When you tap a blank area next to the item name, AFIAS-1 displays an edit window for a reference value and unit.	

9.1.4 Test Menu

Setting 'Test Menu':

■ You can test functions for LCD display, LCD touch, LAN connection(only for manufacturer), SD card connection(only for manufacturer) and printer connection.

9.1.4.1

① Tap the 'Miscellaneous functions' menu.

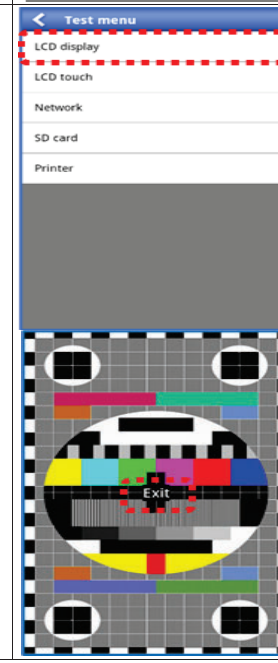
② Tap the 'Test menu'.

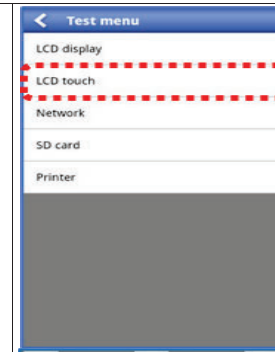
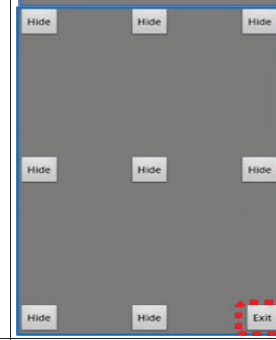
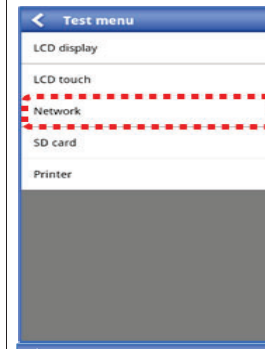
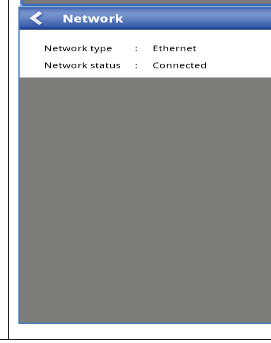
9.1.4.2

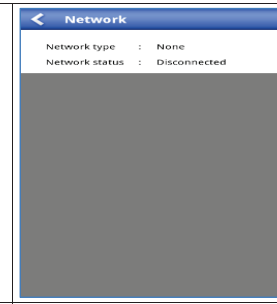
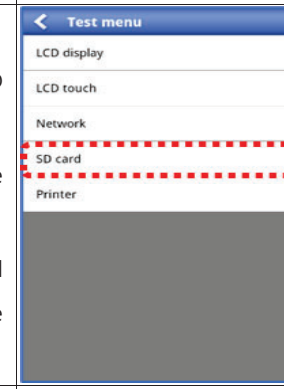
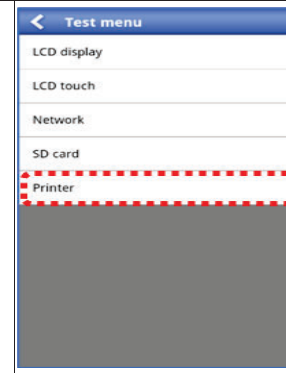
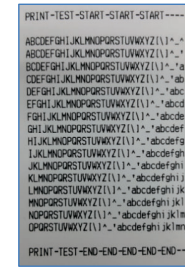
■ To test LCD display, tap the 'LCD display' menu.

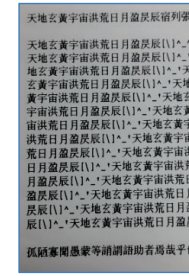
■ AFIAS-1 displays various colors on the screen during LCD display testing.

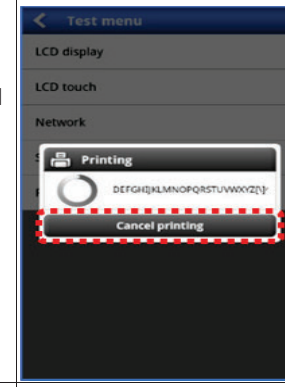
■ If there is no problem with the LCD display, tap the 'Exit' button in the center of the screen. If you find some problems with the LCD display, please contact Boditech Med's Technical Service or a regional distributor.

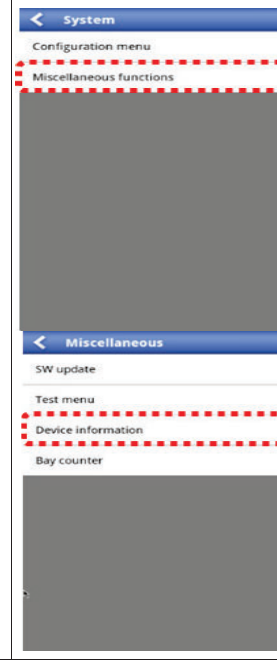


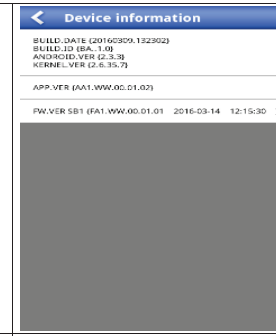
9.1.4.3	■ To test 'LCD touch', tap the 'LCD touch' menu. ■ AFIAS-1 will display 9 blocks(8 'Hide' blocks and 1 'Exit' block). ■ To test 'LCD touch', tap the 8 'Hide' blocks. ■ To complete this test, tap the 'Exit' block.	 
9.1.4.4	■ To test the network connectivity, tap the 'Network' menu. ■ If the LAN is connected, the Network type is displayed as 'Ethernet' and Network status is displayed as 'Connected'.	 

	■ If the LAN is not connected, Network type is displayed as 'None' and Network status is dispalyed as 'Disconnected'.	
9.1.4.5	■ To check a SD card, tap the 'SD card' menu. ■ AFIAS-1 will check the SD card inserted in the 'SD card slot'. ■ If SD card has been inserted, screen will display the alert, 'SD card mounted'. ■ 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'.	
9.1.4.6	■ To test printer connection, tap the 'Printer' menu. ■ AFIAS-1 prints out standard texts according to language setting as shown in the pictures herewith.	  English format

<table>
<tr>
<td></td>
<td>■ To stop the printer connection test, tap ‘Cancel printing’.</td>
<td> 

Chinese format

</td>
</tr>
<tr>
<td>9.1.5</td>
<td>■ Checking ‘Device information’:
① Tap the ‘Miscellaneous functions’ menu.

② Tap the ‘Device information’ menu.</td>
<td> 
</td>
</tr>
</table>

	③ Following information related to the system will be displayed: ▪ Build Date ▪ Build ID ▪ Android Version ▪ Kernel Version ▪ Application Version ▪ Firmware Version	
9.1.6	▪ **Setting the Test counter:** You can use this function to find out the cumulative number of tests performed in AFIAS-1. You can identify the following: C1 : Total number of tests performed since the initial use C2 : Total number of tests performed after the latest repair or servicing of the system ① Tap the 'Test counter' menu. ② To check C1 and C2, tap the 'Reset' menu. ▪ If you want to reset C2, tap the 'Reset' button.	

9.1.7

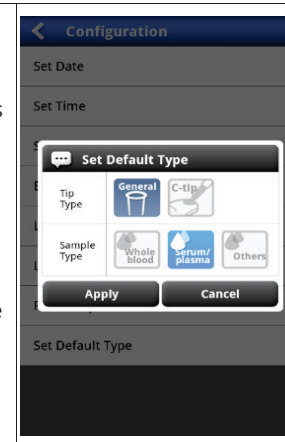
▪ Setting Default Type

This is for setting default Tip/Sample type.
In following cases, AFIAS-1 sets Tip/Sample type as the default setting automatically.

① When AFIAS-1 turns on.

② After finishing a test.

③ When user stops a current test by tapping the 'Stop' button.



9.1.8

▪ LIS Configuration

For sending test results from AFIAS-1 to the LIS server via Local Area Network or RS232C.

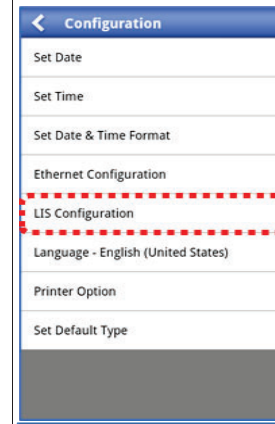
① Tap the 'LIS configuration' menu.

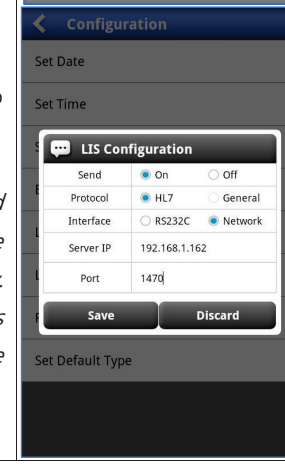
② To send test results by LIS after finishing tests, select 'On' in the 'Send' item. In the opposite case, select "Off".

③ Please select the data format.

④ Please select the type of interface you wish to use.

Note. *Once 'Network' is selected as a preferred interface, only HL7 protocol is available and the protocol item will be changed to 'HL7' automatically. Server field is only available when 'Network' is selected. You can input a server IP or PORT in the server field.*
To apply setting, please tap the 'Save' button.





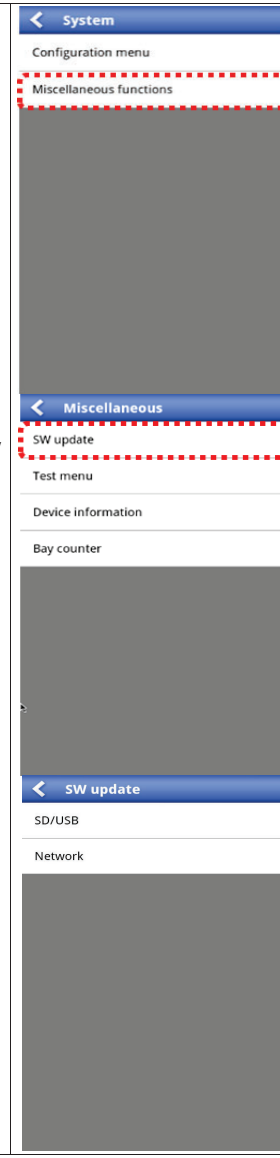
9.1.9.1

■ **Updating Software:**

Note. *This function should be handled only by the 'administrator', a trained engineer or manufacturer's authorized representative. Incorrect or unwarrented use of this function can cause serious problems in system operations.*

■ 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.

If you want to update S/W via network, you can tap 'Network' menu. Pleae refer to 9.1.9.4



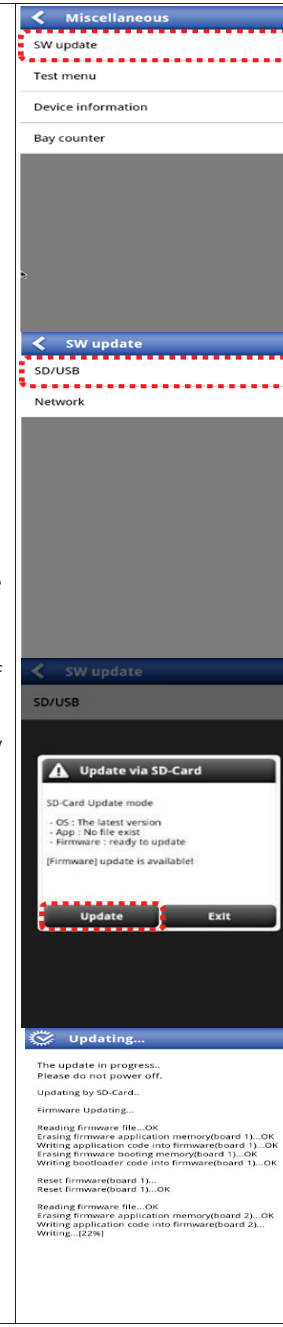
9.1.9.2

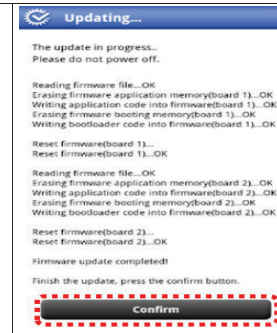
■ **Updating Firmware via a SD card**:

1. Tap the 'Miscellaneous functions' menu.
2. Tap the 'SW update' menu.
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.

① If you insert a SD card with an updated version of firmware, it will start to update automaticallly.
② If you tap the 'Confirm' menu, it will automatically reboot.
③ Update will be completed after rebooting.

Note. *You can check whether the firmware update is successful by accessing the 'Device information' menu as described in Step 9.1.5.*





9.1.9.3

■ **Updating the Android Operating System via SD card:**

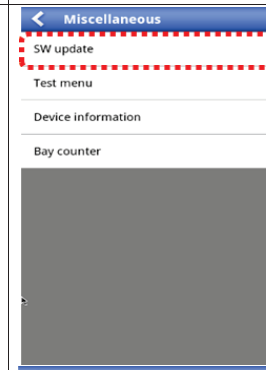
: To update the 'Android OS', insert the 'Upgrade SD Card' (provided by the manufacturer or its authorized service representative) into the 'SD card port'.

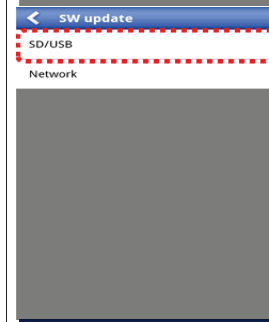
1. Tap the 'Miscellaneous functions' menu.
2. Tap the 'SW update' menu.
3. Tap the 'SD/USB' menu.
4. 'Update via SD-Card' winddjow will pop up.
5. Tap the 'Update' menu after confirming the information in the pop-up box.

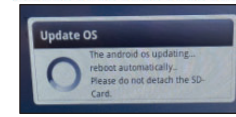
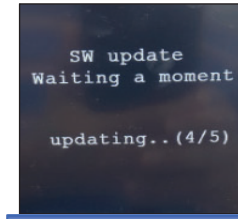
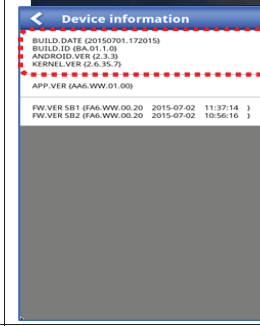
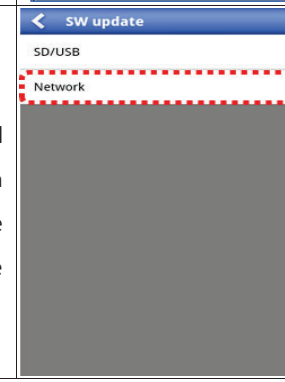
① If you insert a SD card with an updated version of Android OS, it will start to update automaticallly.

② If you tap the 'Confirm' menu, it will automatically reboot.

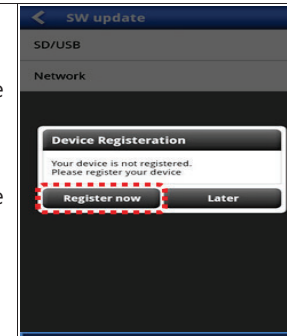
③ Update will be completed after rebooting.





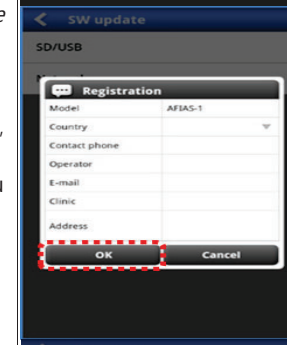
	6. Then "SW update" screen will be presented. To finish Android OS update, it takes about 4 minutes. 7. When Android OS update is completed, AFIAS-1 will reboot automatically. ***Note.*** *You can check if the Android OS update is successful by accessing the 'Device information' menu as described in Step 9.1.29.*	   
9.1.9.4	▪ **Updating the S/W via Network:** : To update the S/W via network, AFIAS-1 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-1 is not registered, 'Device Registration' window will be displyed.
3. Tap the 'Register now' button to register the device.

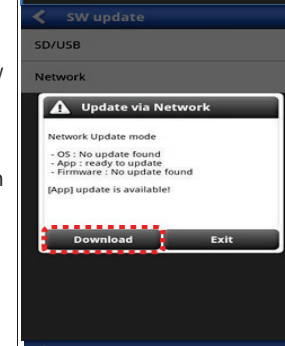


Note. *If you tap the 'Later' button, It will not update S/W via network.*

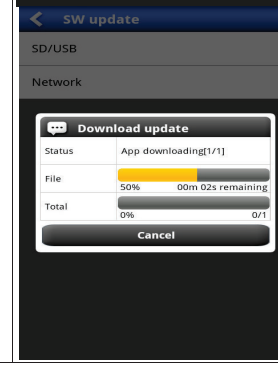
4. Input registration information and tap the 'OK' button. Then tap the 'Network' menu again(refer to Step 1).



5. AFIAS-1 displays 'Update via Network' window and you can check the available updates.
6. Tap the 'Download' button to proceed with the update.



7. AFIAS-1 displays 'Download update' window and the downloading progress is displayed.
8. When the download is completed, AFIAS-1 performs the update automatically.



9.2 User management

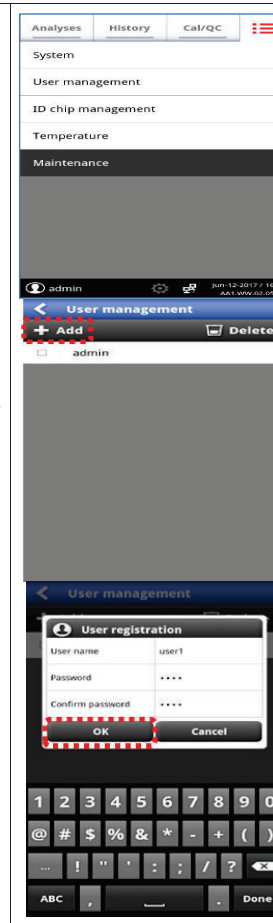
9.2.1

- 'User Management' is accessible 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 at a given time.

1. Tap the 'User management' menu.
   (If any registered user (xxxx) other than the 'administrator" tries to access the 'User management' menu, AFIAS-1 will display the warning message 'Access denied for xxxx'.)
2. Tap the '+' icon to add a user.
3. Input suitable 'user name' and 'password'.
4. Confirm/re-enter the password.

⚠ User name and password should comprise of at least 4 characters each.

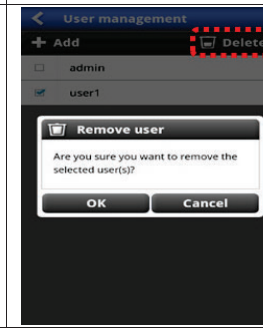
5. Tap 'OK' to add the user with above user name and password.
6. Tap 'Cancel' if you do not intend to proceed.



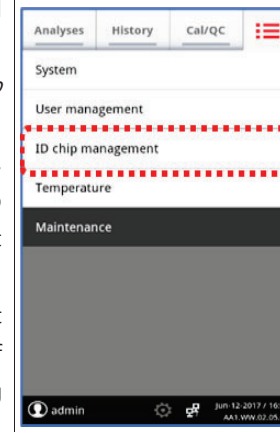
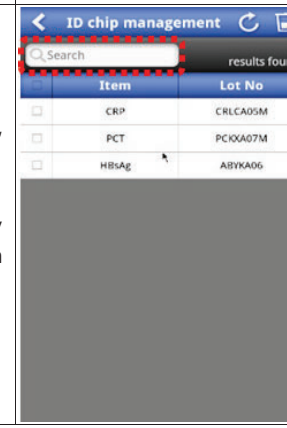
9.2.2

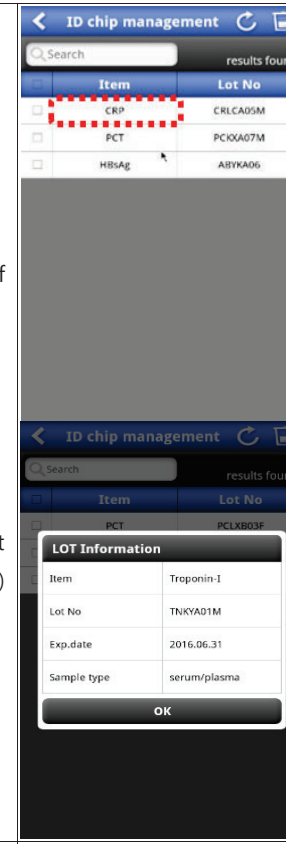
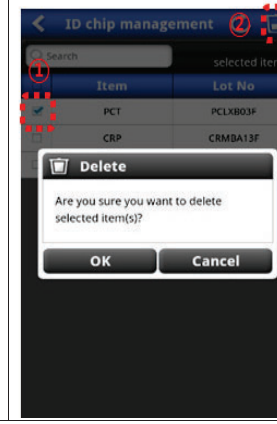
- To delete an existing/registered user, check/select the blank box corresponding to the 'user name' you want to delete.
- Tap 'Delete'.
- Tap 'OK' to confirm deleting the selected user.

(⚠ 'Admin' being the default user name, cannot be deleted or modified.)



9.3 ID chip Management

<table>
<tr>
<td>9.3.1</td>
<td>When any ‘AFIAS Test ID chip’ is inserted into the ID chip slot, relevant information in the ID chip will be saved in the internal memory of AFIAS-1.
Note. AFIAS-1 can save ID chip information from up to 500 ID chips.
■ By accessing the ‘ID chip management’ menu, you can search and check relevant ID chip information such as name of AFIAS test, Lot number, Expiry date and sample type(s)
■ You can also delete an ID chip information that is now irrelevant or outdated on account of inventory with the particular lot number being exhausted.
■ Tap the ‘ID chip management’ menu.</td>
<td> 
</td>
</tr>
<tr>
<td>9.3.2</td>
<td>■ To search ID chip information, tap the ‘Search’ icon.
■ Input appropriate term/keyword (e.g. test name, lot number, sample type etc.) for the information you want to search and tap ‘search’.</td>
<td> 
</td>
</tr>
</table>

9.3.3	■ List of the search results will be displayed. ■ To get the ID chip information, tap the name of the test listed under the column 'Item'. ■ Relevant information (test name/item, lot number, expiry date and sample type) corressponding to the ID chip will be displayed.	
9.3.4	■ To delete the ID chip information, select/check the blank box corressponding to the ID chip. ■ Tap the ' ' icon. ■ Tap 'OK' to confirm deleting the ID chip information.	

9.4 Temperature

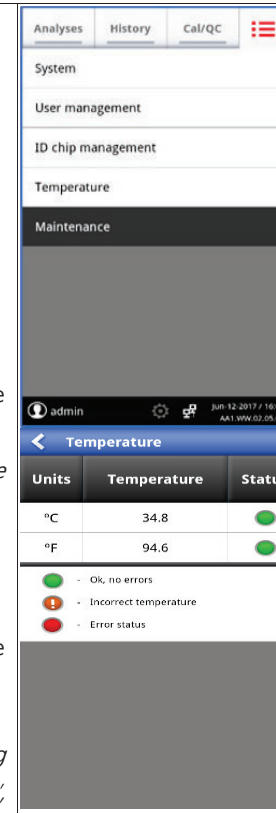
9.4.1

■ You can access this function to check the operating temperature.

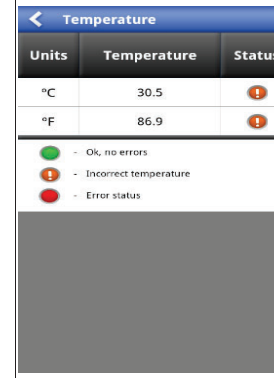
Note. *The normal/operational temperature range is 33~37 ℃.*

1. Tap the 'Temperature' menu.
2. Operating temperature status of AFIAS-1 will be displayed.

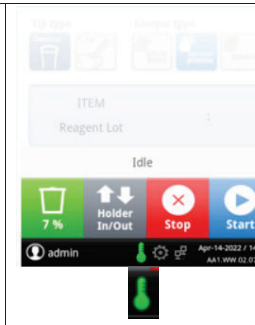
Note. *If operating temperature status is being shown as 'Incorrect temperature' or 'Error status', you cannot perform AFIAS tests on the system untill the ambient temperature is managed to a value in the operational range.*



<Normal status>



<Incorrect status>

9.4.2	■ If operating temperature is out of range, warning message 'Please wait until the reader reaches recommended temperature.' keeps displaying. ■ Perform the tests after checking the temperature icon and when it changed to green color tests can be performed.	 <Normal status> <Incorrect status>

10. Maintenance, Servicing and Disposal

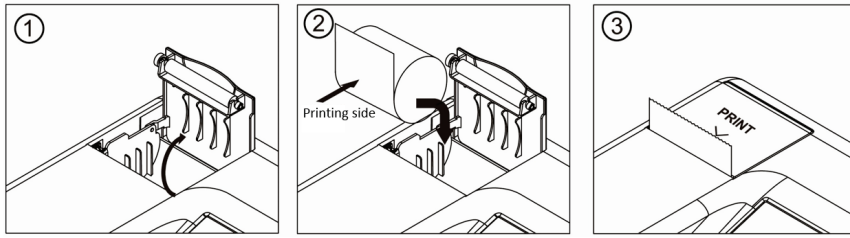
10.1 Maintenance

No maintenance other than the following is required for AFIAS-1:

- 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

Loading Paper in the Printer:

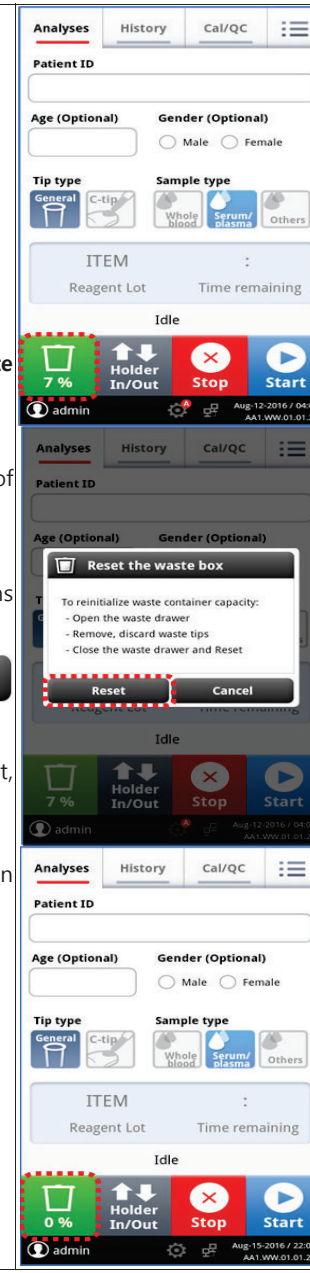
- Open the printer cover as shown in the figure below, insert the paper in the proper direction, and take out the paper at least 1 cm.
- Remove the remaining paper, if any.



⚠	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 for preventing malfunction of built-in printer.

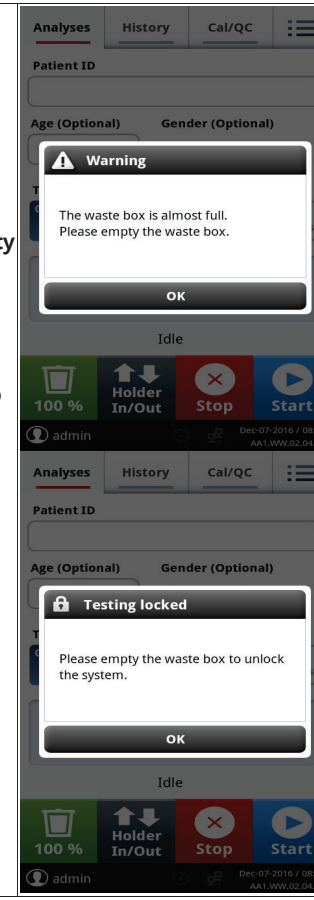
Emptying the 'Waste Tip Box' and Resetting the waste tip counter:

- To reset the counter indicating the collection status of wasted pipette tips, pull out the waste tip box.
- The 'Reset waste box' will pop-up.
- Empty the 'Wast Tip Box' according to the instructions in the pop-up window.
- To reset the waste tip counter, tap **Reset** buttion.
- If you want to terminate this procedure without a reset, tap **Cancel** button.
- If reset is completed, the percentage under the trash can icon will be presented as "0 %".



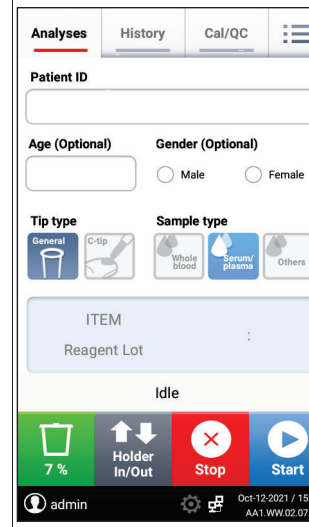
Warning message when user does not empty the 'Waste Tip Box':

- AFIAS-1 displays a warning pop-up window for recommending that user needs to empty the waste tip box before starting a test. In this case, you need to empty the waste tip box and reset the waste tip counter by tapping the icon.
- If you proceed with a test without emptying the waste tip box and resetting the waste tip counter, AFIAS-1 will lock all functions for test when the waste tip counter reaches to the 120%.

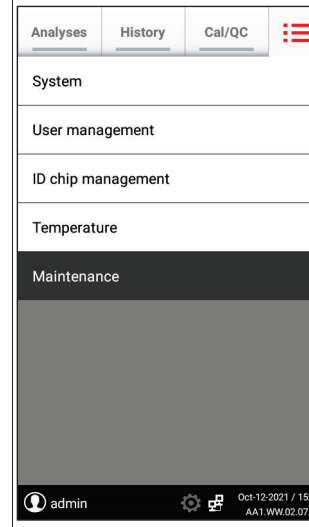


Raw data backup:

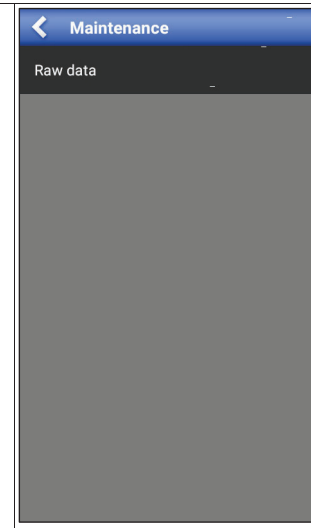
- Raw data for the tests are needed to identify the cause of problems and solve them when these problems occur.
- Tap the **'Extension menu'** in the main menu.



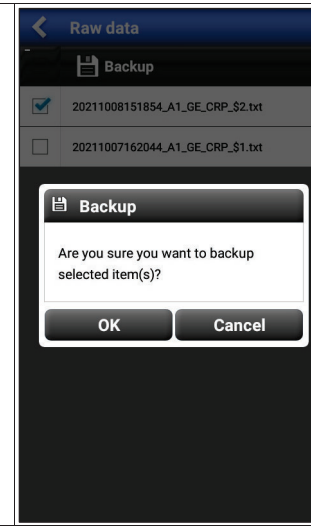
- Tap the 'Maintenance' menu.



■ Tap the 'Raw data' menu.



■ Insert a SD card into the SD card port.
■ Select raw data that you want to backup by tapping the check box.
■ Tap the 'Backup' button.

■ Tap the 'OK' button to proceed with backup. ***Note.*** *The backup data is saved in boditech/raw data folder. This data is encoded and it is only accessible by the manufacturer.*	

10.2 Cleaning

- Occasionally clean the cartridge holders and exterior of AFIAS-1 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.

Danger	Unplug AFIAS-1 from external power source before cleaning.

10.3 Servicing

- AFIAS-1 does not have any operator-serviceable component.
- If any technical servicing or maintenance is required, AFIAS-1 should be sent back to Boditech Med Inc. or its authorized service agent.

10.4 Disposal

- If AFIAS-1 is to be disposed of for any reason, the user is advised to follow local regulations as applicable to the disposal of electrical equipment.

	At the end of its useful life, AFIAS-1 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-1. The same container/box is also recommended for an extended storage period.

	When transporting or storing AFIAS-1, keep it dry in an upright position and protect it from mechanical shocks.
	Before transporting AFIAS-1, remove tips from the tip box.

11. Trouble shooting

AFIAS-1 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-1 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 and reconnect firmly.
	Faulty power adapter	Call Boditech Med Inc.'s Technical Services.
	Faulty power cable	Call Boditech Med Inc.'s Technical Services.
	Main Power Switch is 'Off'.	Turn the main power switch 'On'.
	AFIAS-1 is in 'sleep' mode	Gently press the power button located on the front of AFIAS-1. In the problem still persists, call Boditech Med Inc.'s Technical Services.
'Cartridge Holder' does not protrude out as and when required.	Mechanical failure	Call Boditech Med Inc.'s Technical Services.
	Software malfunction	Turn the power 'Off' and turn it 'On' again.

'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.
Clicking noise generated while the cartridge holder(s) protrudes out	Normal mechanical setting. No corrective measures are not required.	
Barcode error	AFIAS-1 can't read the barcode of the AFIAS test cartridge on account of the barcode being misprinted or obscured due to presence of deformation or foreign matter.	Remove any foreign matter obscuring the barcode and continue the test by reinserting the same cartridge. If the error code persists, 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'.

Insert tip	Test run has been initiated without placing a 'pipette tip' into the 'tip slot' of the AFIAS test cartridge inserted in the cartridge holder.	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).
	AFIAS-1 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.	System temperature is outside the permissible or operational temperature range.	After pressing the 'stop' button, check the temperature status of the system (Please refer to '**Clause 9.4: Temperature'**.) If system temperature is outside the operational range, wait for about 15 minutes. Proceed with the test(s) after temperature status of the system changes to 'normal'.
ERR_60	Malfunction of the built-in temperature sensor.	Call Boditech Med Inc.'s Technical Services.
Insert ID chip	System check cartridge is not inserted.	Insert a system check cartridge and do a system check.
	The test is performed without inserting ID chip.	Insert an ID chip and do the test again.
	Lot number of ID chip and test cartridge do not match.	Perform the test again with matching ID chip and test cartridge.

Error_S1	System check is not successful. Problems in the optical parts.	Try to perform another round of system check. If this error is repeated, call Boditech Med Inc.'s Technical Services.
The password does not match.	Inputted password does not match with the administrator's password.	Input correct password (for administrator). If administrator has forgotten his/her password, call Boditech Med Inc.'s Technical Services for resetting administrator's password.
	Inputted password does not match with the registered user's password.	Input 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	The printer has not been set 'on'	Set the printer 'on' by accessing the 'Pinter on/off' menu. (Refer to Clause 9.1.9~9.1.10).
	Malfunction of the printer.	Call Boditech Med Inc.'s Technical Services.

12. Warranty

AFIAS-1 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-1 unit or any component thereof; along with proof of purchase to Boditech Med Inc. or its nearest Authorized Service Agent.

Warranty Information

During the warranty period (24 months from the date of purchase), defective or spontaneously malfunctioning AFIAS-1 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-1 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-1.

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-1
Catalog No.	FPRR019
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	

www.boditech.co.kr

Respect for life

Boditech Med Inc.

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