AFIAS-1

AFIAS-1

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

For technical assistance, contact:

Boditech Med Inc.'s Technical Services

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

Boditech Med Incorporated

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

EC | REP 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

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Table of Contents

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
IVD	For *in vitro* diagnostic use
CE	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices
⚠	Attention! Read instructions before use
⌧	Separate collection for electrical and electronic equipment
☣	Bio Hazard. To warn of a biological hazard. Taking care to avoid exposure to a biological hazard.
⇠	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 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!**
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.

☣ **Biohazard!**

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.

> **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 °C (-4~122 °F) 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 %.

- AFIAS cartridge being used for the test must have been stored under recommended storage conditions and must not have passed the expiration date.

- 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 prior to performing the test actually and allow it to attain room temperature for at least 30 minutes.

- Before performing any AFIAS test, read the package insert of the test completely and follow the instructions carefully.

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

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2. Principle of Operation

Intended Use

AFIAS-1 is a fluorescence and Europium nanoparticle scanning instrument to be used in conjunction with various AFIAS immunoassay test(s) for measuring the concentration of designated analyte(s) in human blood, urine or other specimens; duly tested in accordance with the test procedure recommended by Boditech Med Incorporated.

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 in correlation to the intensity of fluorescence produced on the cartridge membrane.

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 in centralized laboratories of hospitals and physician clinics.

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 item.

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
3b	4	5
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 °C (59 ~ 95 °F)

- ❑ Storage Temperature   -20 ~ 50 °C (-4 ~ 122 °F)

- ❑ Humidity   10 ~ 70 %

- ❑ Location   Dry, clean, flat and horizontal surface in an in-door 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 meets the EMC guideline as per EN 61326-2-6.

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5. Operational and Functional Elements

5.1 Hardware

Front view

Top view
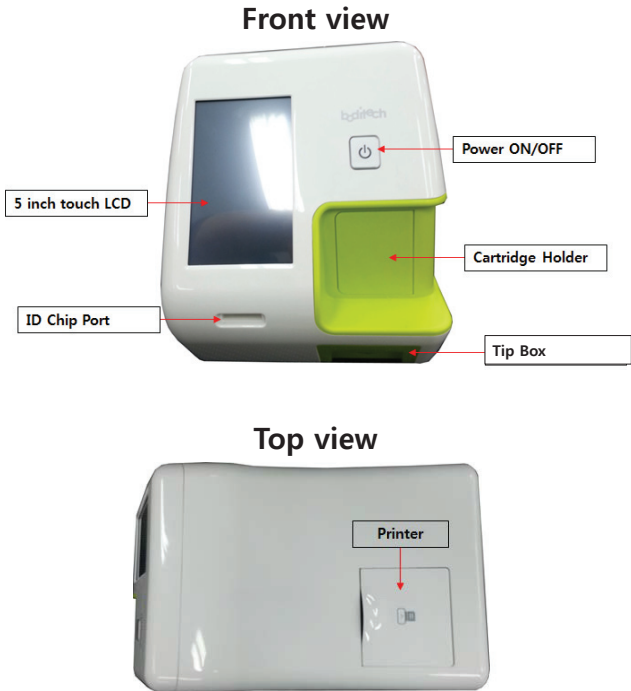
①	LCD display	Acts as the platform for inputting all information regarding the test. Displays test result and message alerts.
②	Power Button	For switching AFIAS-1 'On' or entering it in 'Sleep Mode'
③	ID Chip port	For inserting ID Chip
④	Holder	Accommodates cartridge holders meant for inserting AFIAS test cartridges
⑤	Tip box	Collects used pipette tips
⑥	Internal Printer	Offers print-out of test result

Rear view
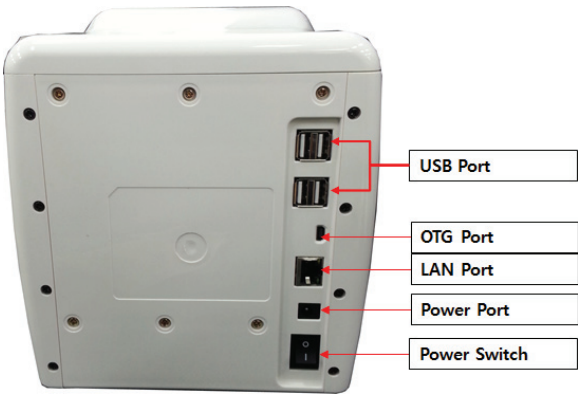
⑦	Power port	For connecting the AC adaptor
⑧	USB OTG port	For connecting PC (only for manufacturer)
⑨	USB port	For connecting Barcode scanner / Keyboard
⑩	Main Power switch	For switching AFIAS-1 on/off
⑪	LAN port	For connecting internet (only for manufacturer)

Bottom view
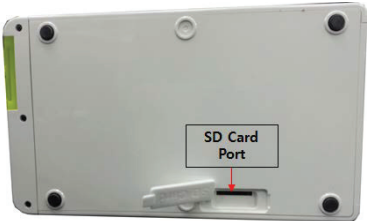
⑫	SD Card port	For upgrade software

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.

5.2 Software menu tree

Menu tree of AFIAS-1 is as follow.
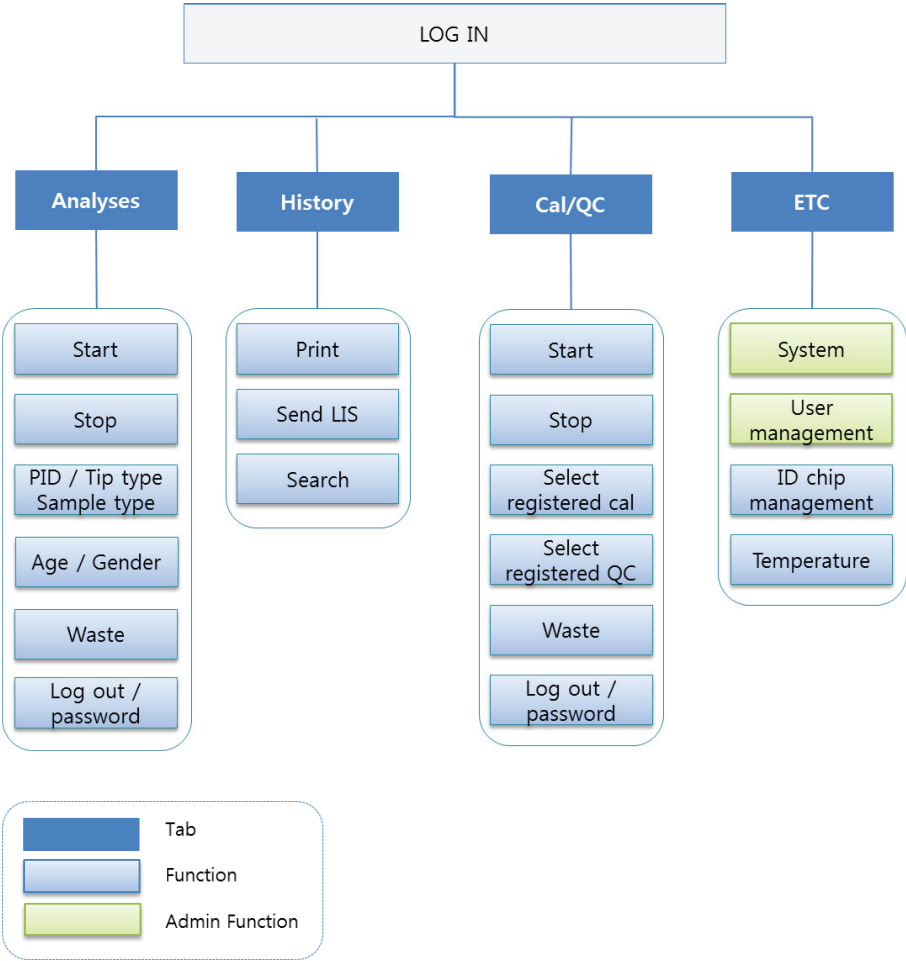
6. Installation

⚠	Before using AFIAS-1, read the warnings and precautions described previously in 'Chapter 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 in-door setting away from direct sunlight, mechanical vibration and any source of electromagnetic radiation (e.g. power transformers). Room temperature of the chamber must be maintained in the range of 15~35 ℃ (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 inside of AFIAS-1. When it 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 jack 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. Up on 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 for the relevant item is displayed. If a user tap the "Confirm" button, he/she can use AFIAS-1 except test functions. If you want to perform tests, please turn off AFIAS-1 using the main power switch (which is 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 Boditehc Med Inc.
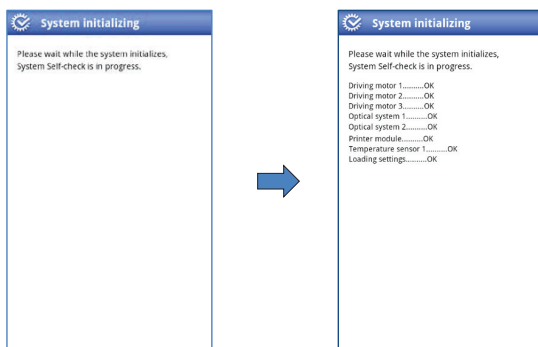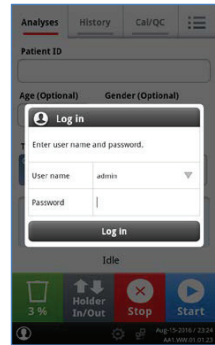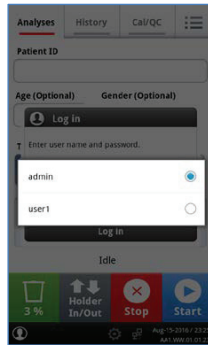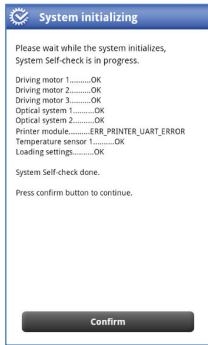
5. After finishing the initialization, AFIAS-1 prints out "System OK!" and displays the popup window for selecting registered users.

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

7. Running Tests on AFIAS-1

⚠	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 test as well as 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 AFIAS Controls must have been stored in recommended storage conditions and must not have passed respective expiration date otherwise the test may yield misleading/ erroneous results.
	If scanning of cartridge is terminated abruptly or any problem occurs, relevant error code or message alert will be displayed. Refer to 'Chapter 11: Troubleshooting' for probable cause(s) and remedial/corrective measure(s) for the error code or message alert being displayed.

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 AFIAS XXX Control(s)

(**Note**: *XXX represents name of the AFIAS Test being performed*.)

- Match the name of test as well as lot number printed on the 'AFIAS ID Chip' with those of the 'AFIAS Cartridge' before removing the cartridge from its blister packing.

- Allow patient sample(s) or control(s) and the cartridge(s) to attain room temperature for about 30 minutes before using for the test.

7.2 Logging in and Inputting required information
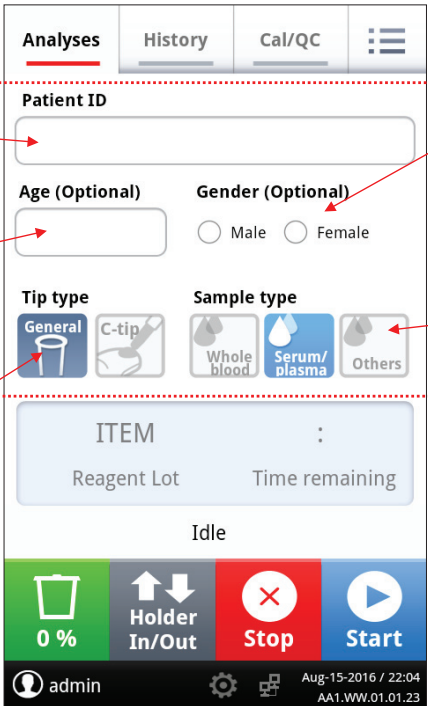
▪ As described in 'Chapter 6: Installation', test-ready AFIAS-1 displays the "Log in" window.

7.2.1 Input 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 users. Please refer to 'Clause 9.2:User management; for further details. If log in is successful, main menu will displayed.

7.3 Main menu description

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

Check, search and print previous test result(s).

Calibration / QC

Test information / Remaining reaction time

Holder In/Out

Waste tip chamber status indicator. It has "Reset" function.

Extended menu:
- System
- User management
- ID chip
  Management
- Temperature

Stop the current test

Start the test

Current time and S/W version number

Log in / out

'User Name' currently logged in.

Setting for Cal./QC

LAN connection status indicator
White : LAN is connected.
Grey : LAN is disconnected.

Patient ID (optional)
- Character / Number
- Max. 15 characters

Patient age (optional)
- Number

Tip information (mandatory)
- General tip
- C-tip

Gender (optional)

Sample type (mandatory)
- Whole blood
- Serum / Plasma
- Others
  (urine, feces and etc.)

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 for test.

To register ID Chip by manual, refer to 'Clause 9.3 ID Chip Management'.

7.4 Inputting test information

7.4.1	**Inputting required test information'** o Select "Tip type" and "Sample type". o If you select "General" as tip type, you should select "Sample type" among Whole blood, Serum/Plasma and Others. o If you select "C-tip" as tip type, the sample type is selected as "Whole blood" automatically.	

| 7.4.2 | • **Optional information**

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

• Inputting Patient ID
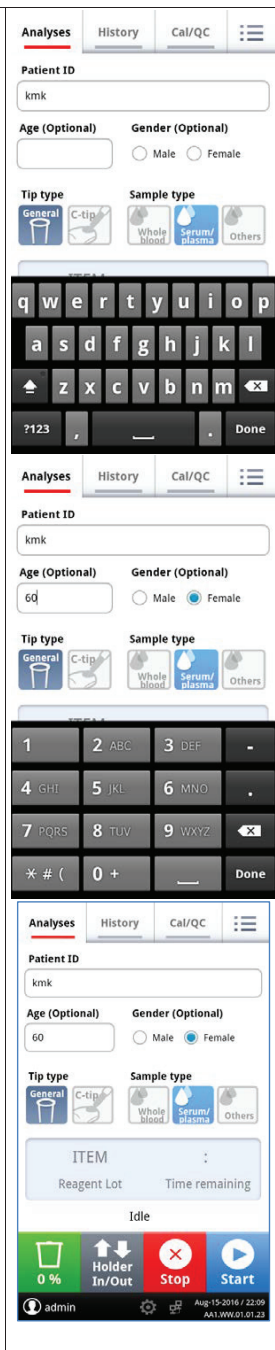
  o Input a patient ID using a key board which is displayed on the LCD screen. When you tap the 'Done' button, the key board will be disappeared. If USB key board is connected, you can use it to input a patient ID.

• Inputting Age

  o Input patient's age using a numeric key pad which is displayed on the LCD screen. When you tap the 'Done' button, the key pad will be disappeared. If USB key board is connected, you can use it to input patient's age.

• Gender

  o 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
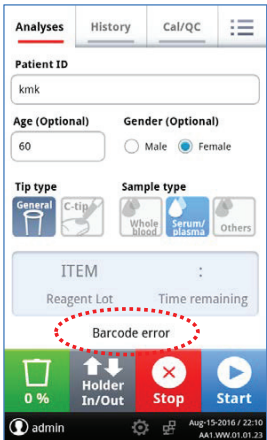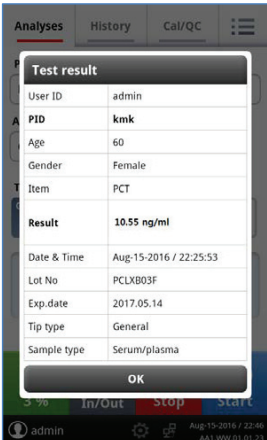
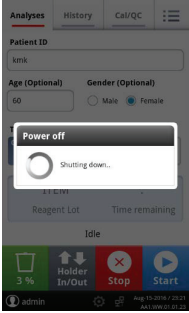|		
7.5.1	• Considering that 'AFIAS PCT ID Chip' has been inserted in the ID chip port, proceed as follows for performing the AFIAS PCT test on clinical sample: ○ Load recommended volume of the test sample into the 'Sample Well' of 'AFIAS PCT Cartridge'. (⚠ *Refer to the package insert of the AFIAS test being performed for details of 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.)*	
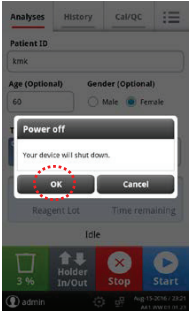
| 7.5.3 | ▪ To proceed the test, tap the "Start" button.

 ▪ The new window pops up. Please check the inputted test information(Tip type / Sample type / Patient ID / Age / Gender).

 ▪ To proceed the test, tap the "Confirm" button.

 ▪ If you want to cancel the test, please tap the "Cancel" button. |

  |

7.5.4	• AFIAS-1 reads a barcode of inserted AFAIS cartridge and check the test item and 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 test and 'PCLXB03F' is lot number.) • During the test is going on, "In progress" is displayed(refer to ③). • The remaining time is displayed with 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 to the end of the holder. In this case, AFIAS-1 displays "Warning" window and does not start a test. • You need to solve problems and tap 'OK' button to start a test.	

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 a test cartridge again. Then continue 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 continue 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 name of the test as well as lot number mentioned on the 'ID Chip' must match with that of the 'AFIAS Cartridge'.
⚠	'AFIAS Cartridge' having a lot number mismatching with that of the 'ID Chip' will lead to display of the error alert 'Insert ID chip'.
☣	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 quitting working with 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 go inside automatically. ▪ AFIAS-1 will shut down.	

7.6.5	▪ Turn off the main power switch provided in 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'.	

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8. Supportive Procedures

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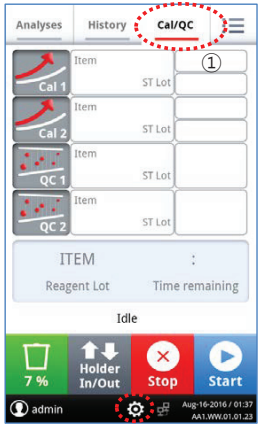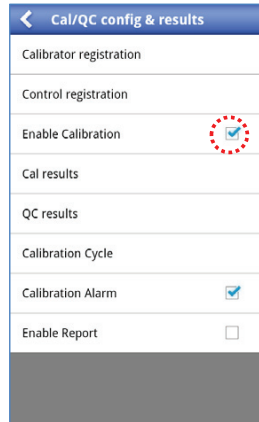
8.1 System check, Calibration and QC

8.2 Retrieval/Printing of stored test results

8.1   System check, Calibration and QC

- System check
  - To perform system check, a user needs to use specific system check cartridge and system check ID chip.
  - The AFIAS-1 measures intensity of fluorescence and compares that result with pre-set value to inspect measured intensity has same with pre-set values.
  - The AFIAS-1 repeats measurement several times to secure stable performance of a fluorescence system when checking system.

- The system check is needed as below.
  - When the AFIAS-1 is installed initially.
  - When you move the AFIAS-1 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
  - To perform calibration, a user needs to use specific calibrators.
  - Calibration should be performed with the AFIAS test cartridge.
  - Calibrators are supplied with 2 levels. These 2 levels are determined according to the kind of AFIAS tests.
  - Calibrators are supplied on demand.

- The calibration is needed as below.
  - When a test lot is changed.
  - When a test result is considered abnormal or differs from the reference value.

- 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 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.	
8.1.2	• Tap the 'Enalble Calibration' menu. The check box will be toggled whenever you tap this menu. To activate the calibration, the check box should be checked with ✓.	

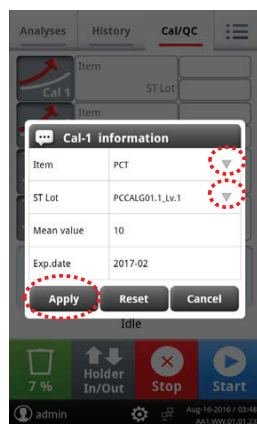| 8.1.3	▪ To do calibration and QC, you need to register a calibrator and control. Select the 'Calibration registration' menu to register a calibrator. ▪ Tap the ⊕ icon to register a calibrator	
8.1.4	▪ 'Add calibrator' window will pop-up. ▪ Input a lot number, item name, mean value and expiration date using key pad or a barcode reader. Note : The format of expiration date is only year and month. The 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.	
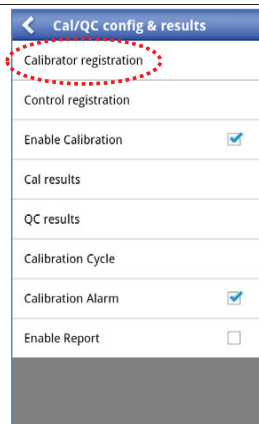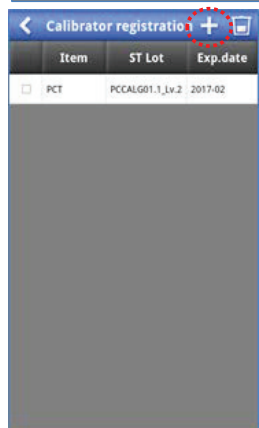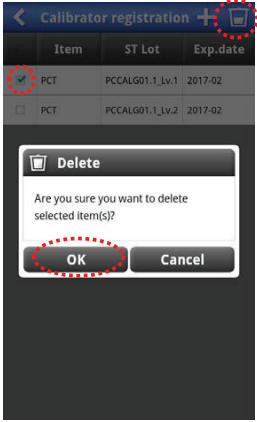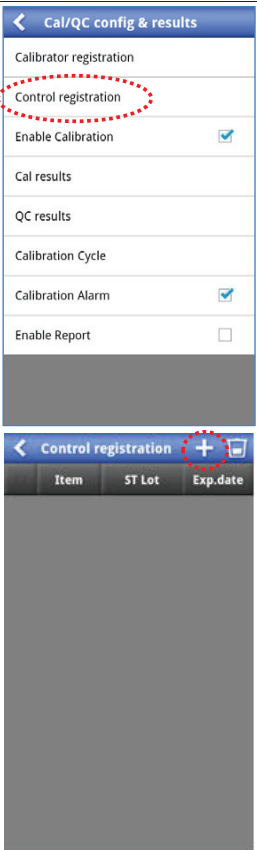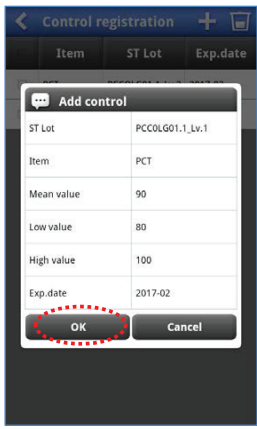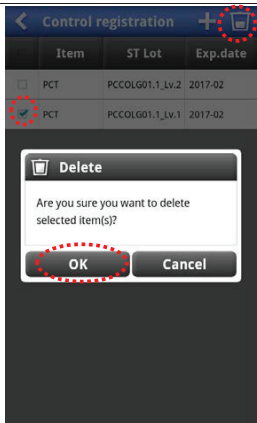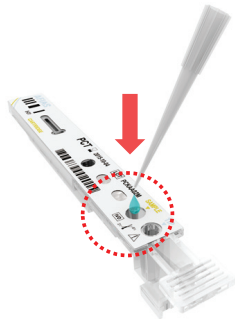
8.1.5	▪ If you want to delete a registered calibrator, select a calibrator what you want to delete. ▪ Tap the 🗑 icon to delete a registered calibrator. ▪ Tap the 'OK' button for confirmation.
8.1.6	▪ Select the 'Control registration' menu to register a control. ▪ Tap the ➕ icon to register a control.

8.1.7	'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 format of expiration date is only year and month. The 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.	
8.1.8	- If you want to delete a registered control, select a control what you want to delete. - Tap the icon to delete a registered control. - Tap the 'OK' button for confirmation.	
8.1.9	- To do calibration and QC, please prepare a test cartridge what you want to test. - Dispense a calibrator and control into the sample well of the cartridge. - Insert each cartridge into the each slot and insert a tip.	

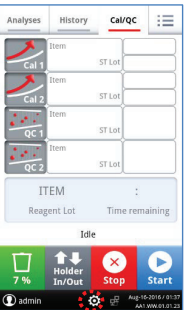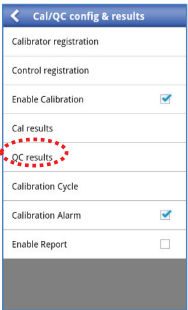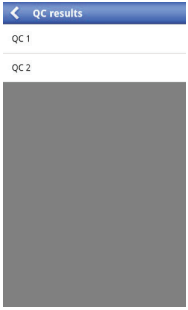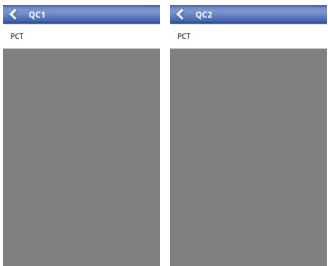| 8.1.10	▪ Tap the 'Cal 1' button to perform Cal/QC.	
8.1.11	▪ When you tap 'Cal 1' button, 'Cal-1 information' window pop-up. ▪ You can select item and lot number that you want to select by tapping a drop down button. ▪ To apply the relevant information, tap the 'Apply' button. ▪ Regarding 'CAL 2', you can follow the same way. ▪ Tap 'QC 1' button, you can select item and lot number that you want to select by tapping a drop down button.	
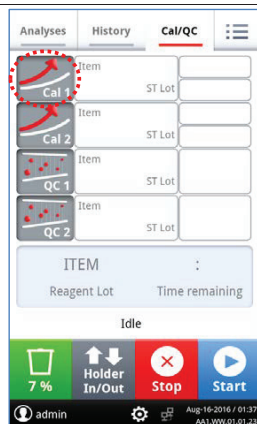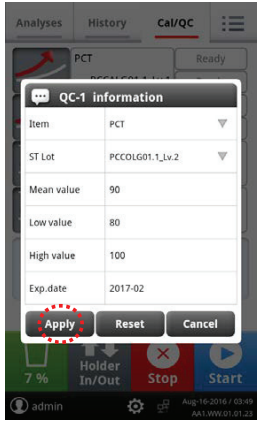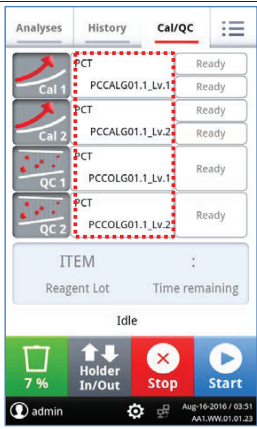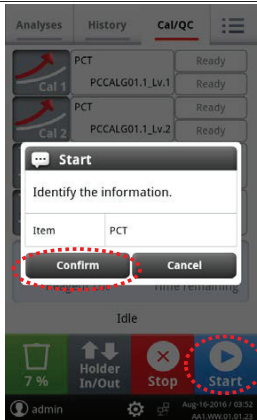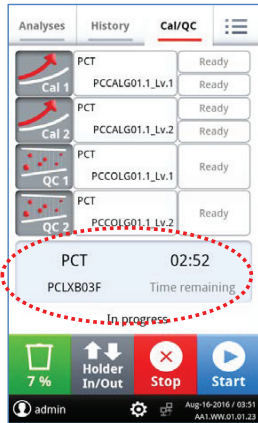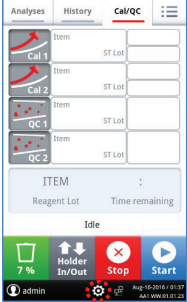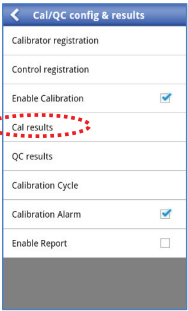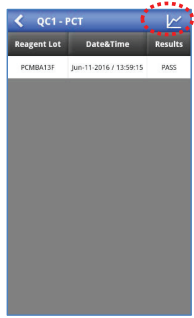
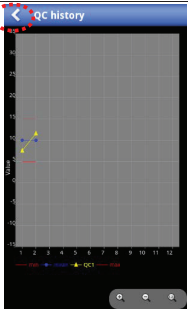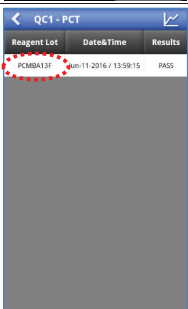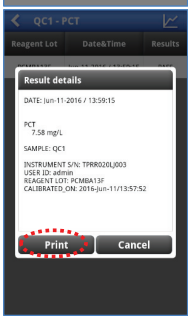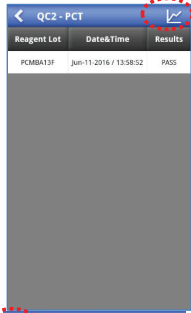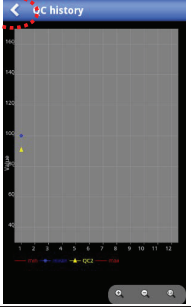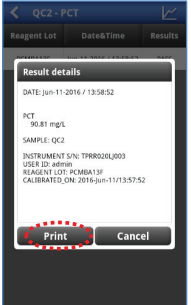|		
	• To apply the relevant information, tap the 'Apply' button. • Regarding 'QC 2', you can follow the same way.	
8.1.12	• When selection of all calibrators and controls are completed, the relevant information is displayed.	
8.1.13	• Tap 'Start' button to start calibration and QC. • 'Start' window will pop-up. • Check LOT number and test item. • To confirm the start of test, tap 'Confrim' button.	

8.1.14	▪ When the test starts, AFIAS-1 check the test item and LOT number automatically. ▪ The name of test is displyed and 'In progress' message will be presented under the name of test item. ▪ During the test is in progress, the remaining time is presented.	
8.1.15	▪ When the test is completed, AFIAS-1 sounds buzzer and 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\>

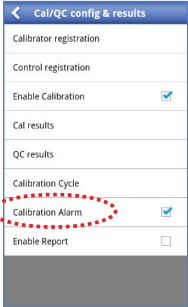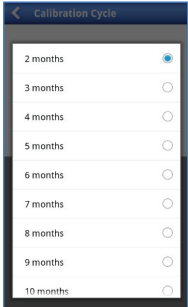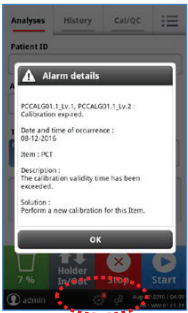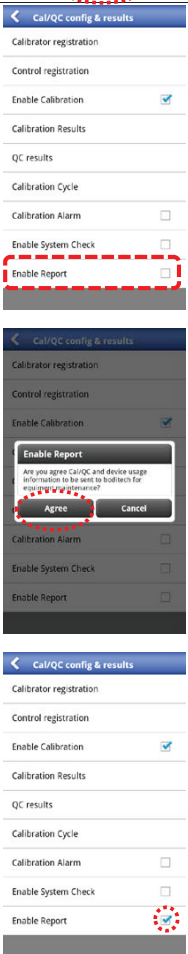|			
			------------------------------ DATE: Jun-11-2016 / 13:58:52 PATIENT ID: PCT 　　　　90.81 mg/L SAMPLE: QC2 INSTRUMENT S/N: TPRR020LJ003 USER ID: admin REAGENT LOT: PCMBA13F CALIBRATED_ON: 2016-Jun-11/13:57 :52 <Printed QC2 test result>
8.1.16	▪ To check the calibration results, tap the setting icon in 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 that you want to check the results.		

8.1.17	▪ AFIAS-1 displays the Lot number of cartridges and calibrators and the next calibration date. ▪ To check the detailed calibration result, tap the item what you want to check. ▪ 'Result details' window pops-up and shows the detailed test information as follow. - 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.	
8.1.18	▪ To check the QC results, tap the setting icon in the bottom of the Cal/QC screen.	

	▪ Tap the 'QC results' menu. Then AFIAS-1 will display QC1 and QC2. ▪ Tap the QC1 or QC2. Then AFIAS-1 will dispay the available test items for QC1 and QC2 respectively. ▪ Tap a test item that you want to check the results.	
8.1.19	▪ QC1 checking ▪ 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 in the right screen. • If you want to go back to the previous screen, tap the ◄ icon.	
8.1.20	• To check the detailed QC1 result, tap the item what you want to check(refert to the step 8.1.18). • 'Result details' window pops-up and shows the detailed test information as follow. • 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	

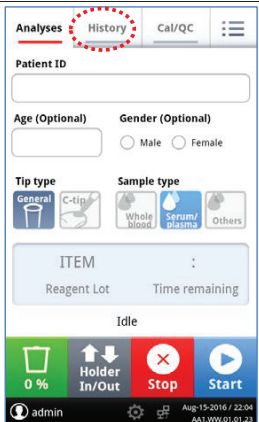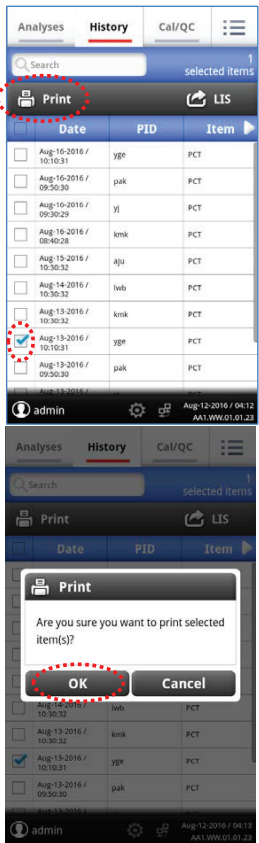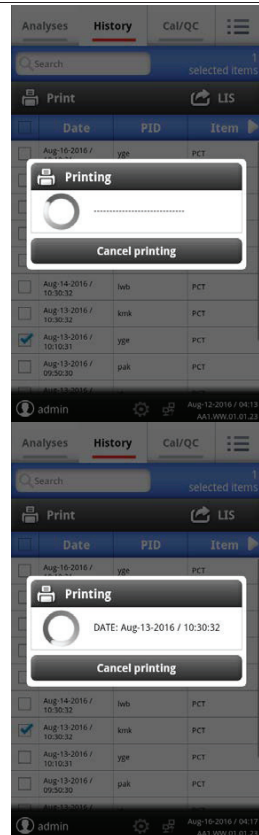|		
8.1.21	- QC2 checking - AFIAS-1 displays the Lot number of cartridges, QC date & time and QC result. - If you want to check the QC history, tap ⬚ icon. - AFIAS-1 displays the QC2 history as presented in the right screen. - If you want to go back to the previous screen, tap the ◁ icon.	
8.1.22	- To check the detailed QC2 result, tap the item what you want to check(refert to the step 8.1.18). - 'Result details' window pops-up and shows the detailed test information as follow. - 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	

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DATE: Jun-11-2016 / 13:58:52


PCT
        90.81 mg/L

SAMPLE: QC2

INSTRUMENT S/N: TPRR020LJ003
USER ID: admin
REAGENT LOT: PCMBA13F
CALIBRATED_ON: 2016-Jun-11/13:57
:52
```

	▪ Tap the 'Calibration Alarm' menu. The check box will be toggled whenever you tap this menu. If you want to get an alarm for expired calibration cycle, the check box should be checked with ![checkbox].
8.1.23	▪ 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 expired, 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.	
8.1.24	'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 purpose. ▪ If you agree with the use of this function, tap the 'Agree' button. ▪ If you do net 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 information to Boditech's server automatically. This information is used only for maintenance purpose by the manufacturer.*	

8.2 Retrieval/Printing of stored test results
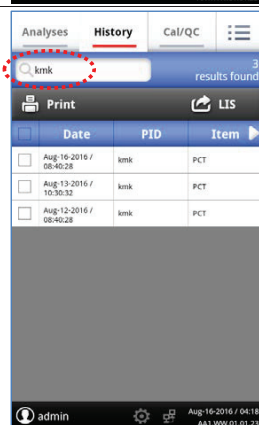
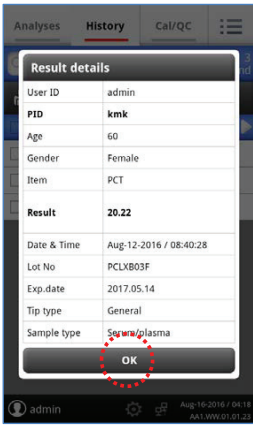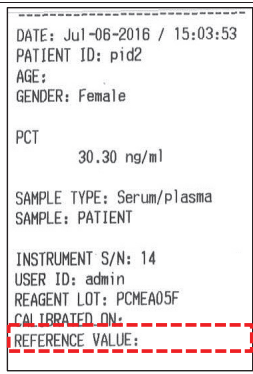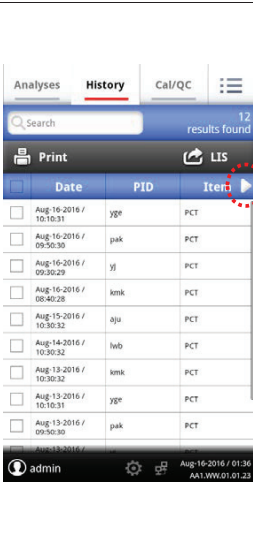|		
8.2.1	▪ AFIAS-1 can save up to 5,000 test results in its internal memory. (Note: If the number of stored test results excceeds 5,000 results, the oldest result will be deleted when a new test result is saved.) ▪ To print out stored test result(s), tap 'History'. Note : Stored test results cannot 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'.	

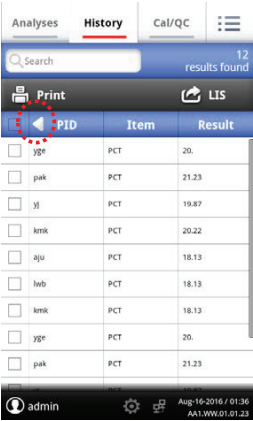|		
	▪ After tapping 'OK' button, AFIAS-1 will display the status of printing and print out selected result(s).	
8.2.3	▪ If you want to search specific test result(s), tap "Search" and input the search term (e.g. date, patient ID, user name, test name etc.) ▪ Tap the search icon 🔍. ▪ Searched results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

8.2.4	• If you just want to note the details of stored test result(s) without printing the same, 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	• Print-out generated by the built-in thermal printer contains the test result alongwith relevant information as shown herewith. • The print out will also contain test-wise reference values/interval for the specific patient population if information regarding the same 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.

![Boditech BIO TECHNOLOGY logo]

8.3 Holder In/Out

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

9. Configuring AFIAS-1

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

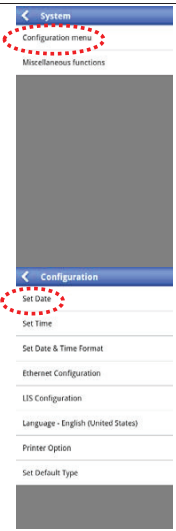| ⚠	Clause 9.1 and 9.2 are only accessible to the 'Administrator' only.

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

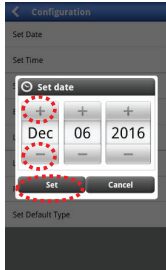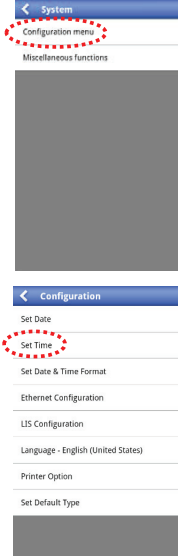9.1.8 LIS Configuration

9.1.9 Updating the S/W via Network
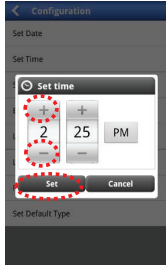
9.2 User management
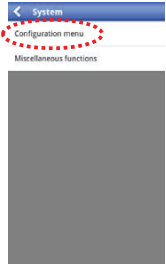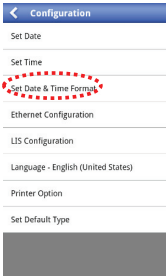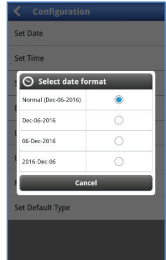
9.3 ID chip management
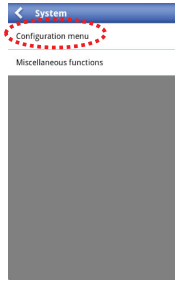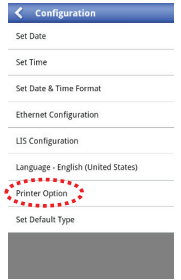
9.4 Temperature
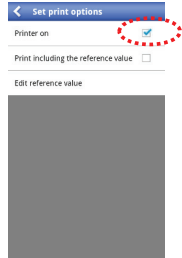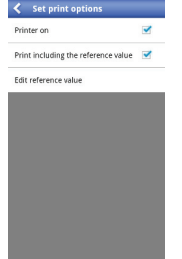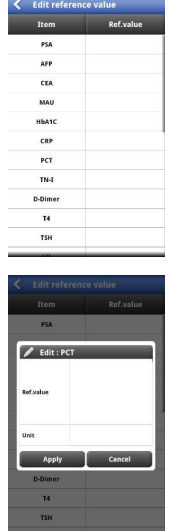
9.1 Configuring System Operation
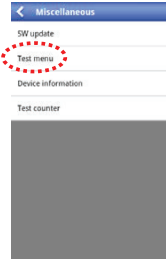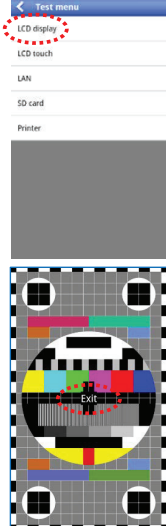
9.1.1.1	**9.1.1 Date, Time Date & Time format**
	
	▪ **Setting the 'Date':**
	
	  1. Tap the 'Configuration menu'.
	
	  2. Tap the 'Set date' menu.	
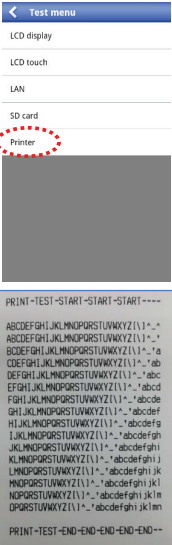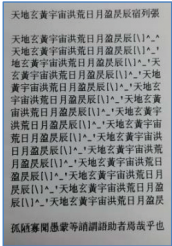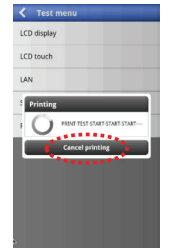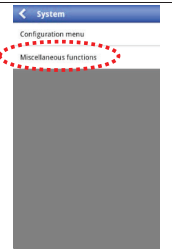
9.1.1.2	▪ Tap the ➕ or ➖ button(s) to set the desired month, date and year. ▪ To effect the changed date, tap 'Set'.
9.1.1.3	▪ **Setting the** '**Time**': 1. Tap the 'Configuration menu'. 2. Tap the 'Set time' menu.
9.1.1.4	▪ Tap the ➕ or ➖ button(s) to set the desired values for hour and minute. ▪ You can set the time as 'AM' or 'PM' by tapping the adjcent tab. ▪ To effect changed time, tap 'Set'.
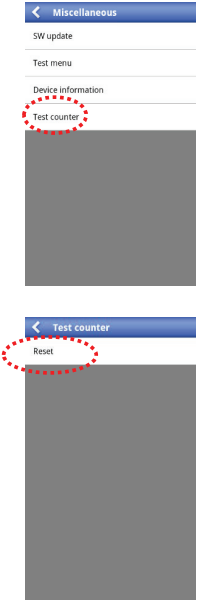
9.1.1.5	▪ **Setting the Date Format** 1. Tap the 'Configuration menu'. 2. Tap the 'Set Date & Time format' menu.	
9.1.1.6	▪ Check/tap the blank box corressponding to the date format you want to select. ▪ If you want to cancel changing the date format, tap the 'Cancel'.	
9.1.2.1	**9.1.2 Language** ▪ **Setting the Language:** 1. Tap the 'Configuration menu'. 2. Tap the 'Language' menu.	
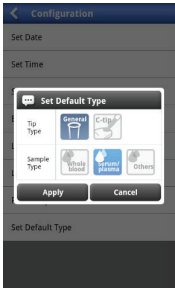
9.1.2.2	▪ You can select either Engligh or 中文(Chinese) as the user interface language. ▪ Defualt user interface language is English. If you select "中文", user interface will be programed in Chinese language.	
9.1.3.1	**9.1.3 Printer Option** ▪ **Turning the Printer On / Off**: 1. Tap the 'Configuration menu'. 2. Tap the 'Printer Option' menu.	
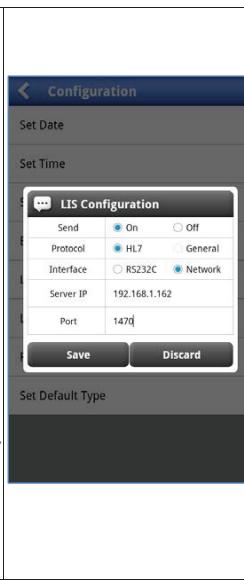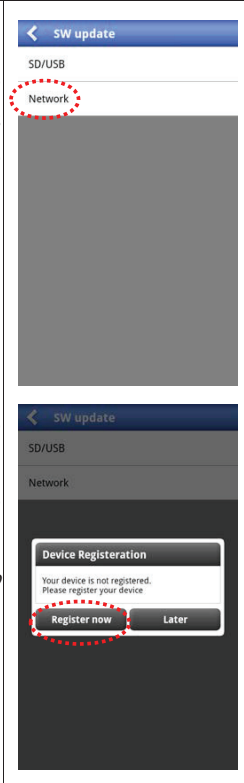
9.1.3.2	▪ Check/tap the blank box of the 'Printer on' menu to turn the printer 'on'. ▪ Uncheck/tap the checked box of the 'Printer on' menu to turn the printer 'off'.	
9.1.3.3	▪ If you want to print out a test result with a 'Reference Value', check/tap the blank box of the 'Print including the reference value'.	
9.1.3.4	▪ If you want to edit 'Reference value', tap the 'Edit reference value' menu. ▪ When you tap a blank area beside of the item, AFIAS-1 displays an edit window for a reference value and unit.	
9.1.4.1	**9.1.4 Test Menu** **Settomg '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.	

	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 in the screen during LCD display testing. ▪ If there is no problem in LCD display, tap the 'Exit' button in the center of the screen. If you find some problems in 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 printer connection, tap the 'Printer' menu. ▪ AFIAS-1 prints out standard texts according to language setting as shown in the pictures herewith. ▪ To stop the printer connection test, tap 'Cancel printing'.	English format Chinese format
9.1.5	▪ **Checking 'Device information':** 1. Tap the 'Miscellaneous functions' menu. 2. Tap the 'Device information' menu. 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 check/know the cumulative number of tests performed in AFIAS-1. You can know the following types of counts: C1 : Total number of tests performed since the initial use C2 : Total number of tests performed after 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 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 what you want to use data format.

4. Please select what you want to use interface.

Note: In case of 'Network' is selected, only HL7 protocol is available. 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 sevier field.
To apply setting, please tap the 'Save' button.

| 9.1.9 | ▪ **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 is impossible to 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 updating.
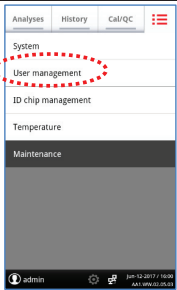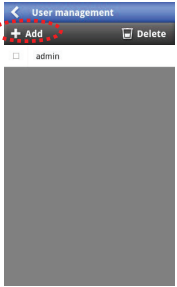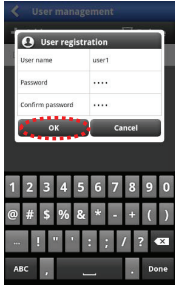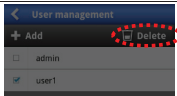
7. AFIAS-1 displays 'Download update' window and the downloading progress is displayed.
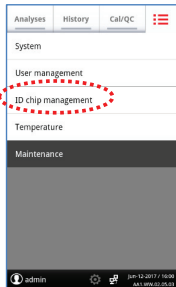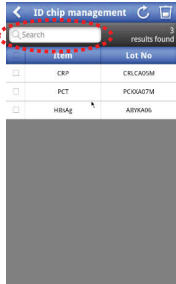
8. When the downloading is completed, AFIAS-1 performs the updating automatically.

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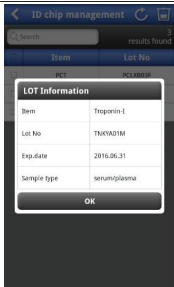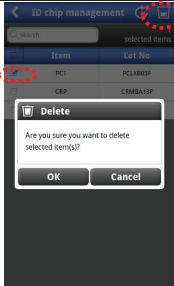
9.2 User management

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 suiable 'user name' and 'password'. 　　4. Confirm/re-enter the password. ⚠ User name and password should comprise atleast 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

9.3.1	When any 'AFIAS Test ID Chip' is inserted into the ID chip slot, relevant information derived from the ID chip will be saved in the internal memory of AFIAS-1. **Note:** AFIAS-1 can save ID chip information of 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 the ID chip information which is now irrelevant or outdated on account of the particular lot number invetory being exhausted. ▪ Tap the 'ID chip management' menu.	
9.3.2	▪ 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'.	
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) corresponding 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; the information of which you want to delete. ▪ 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 for each bay. **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 till the ambient temperature is managed to a value in the operational range.	<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 purpose

Loading Paper in the Printer:

▪ Open the printer cover as shown in the figure below, insert the paper with correct direction, and take out the paper at least 1 cm.

▪ Remove the remaining paper, if any.
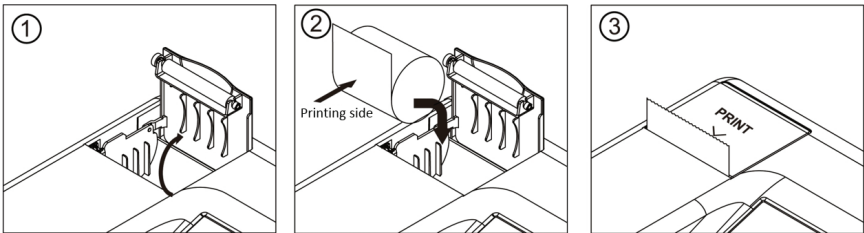
⚠	When the printer cover is closed, built-in printer ejects the printer paper a little for initialization.
⚠	Be careful excessive force when opening or closing the printer cover for preventing malfunction of built-in printer.

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** button.
- If you want to terminate this procedure without reset, tap **Cancel** button.
- If reset is completed, the percentile under the trash can icon will be presented as "0 %".
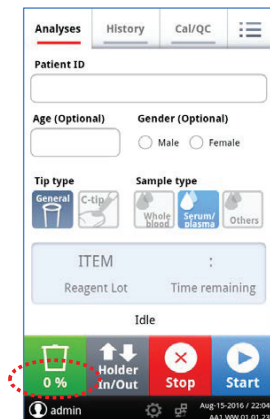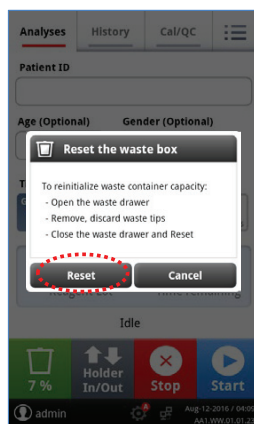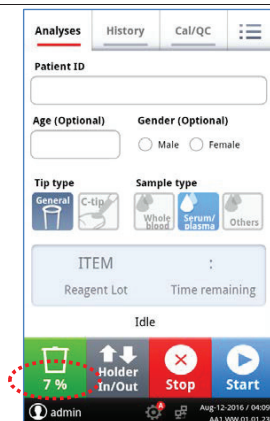
Warning message when user does not empty the 'Waste Tip Box':

▪ AFIAS-1 dispalys an 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 a test without empting 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%.
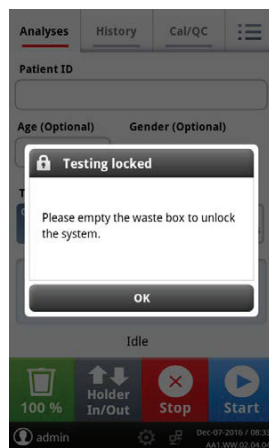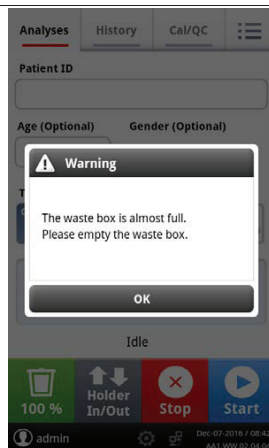
▪ **Raw data backup:**

▪ Raw data for the tests are needed to identify reasons of problemas and solve them when some problems are occurred.
▪ Tap the 'Extention menu' in the main menu.
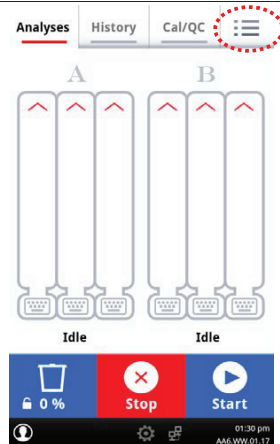
- Tap the 'Maintenance' menu.

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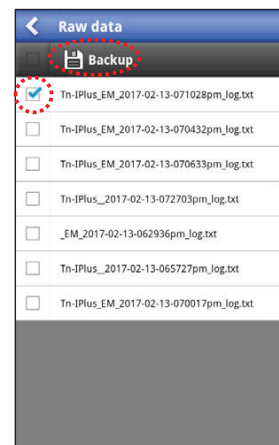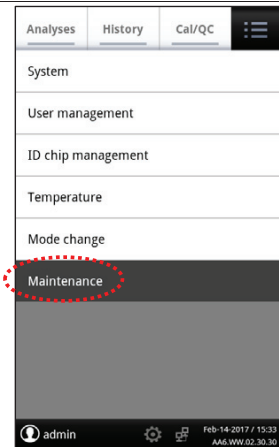
• Tap the 'OK' button to proceed backup. *Note. The backup data is saved in boditech/raw data folder. This data is encoded and it is only accessible by the manufacturer.*	
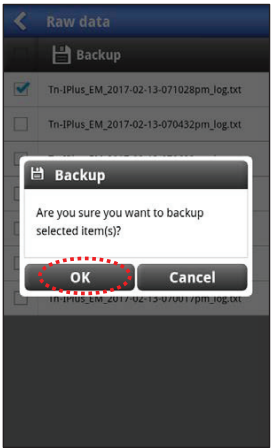
10.2 Cleaning

- 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 observe 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 storing AFIAS-1 over an extended period of non-use.

⚠	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. User's action is 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 blemishes 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 system check.
	The test is performed without inserting ID chip.	Insert an ID chip and do test again.
	Lot number of ID chip and test cartridge is not match.	Match lot number of ID chip and test cartridge and test again.
Error_S1	System check is not successful. Problems in the optical parts.	Try again 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 Sections 9.1.9~9.1.10).
	Malfunction of the printer.	Call Boditech Med Inc.'s Technical Services.

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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 it's 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 Incorporated

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: support@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
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.

Obelis s.a