



CUP READER

User Manual



ACR-100

HANGZHOU ALLTEST BIOTECH CO., LTD

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Chapter 1 Introduction

1.1 Intended Use

The Cup Reader is an instrument intended to read the results of the DOA urine cup digitally and provide the results in electronic and printable forms. It displays and prints the qualitative results only. The Reader is designed to gather the product information through QR Code and can be used exclusively with DOA test cups manufactured by **AllTest**. The Cup Reader offers the advantages of high accuracy and fast results. The Cup Reader should be only used with consumables manufactured by **Hangzhou AllTest Biotech Co., Ltd.** as per package insert provided.

Please read this User Manual carefully before operation.

1.2 Scope of Application

The Cup Reader is intended to be used for reading the test results obtained with urine DOA rapid test cup for detection of drugs of abuse in the urine. It's for professional *in vitro* diagnostic and Point of Care Use. It may be used in central laboratories of medical institutions, outpatient or emergency departments, clinical departments or medical services (such as community health centers), or medical center, etc. It can also be used in research laboratories.

1.3 Product Name and Model Type

- Product name: **Cup Reader**
- Model/Specifications: **ACR-100**

Chapter 2 Warnings and Safe Use

Warnings:

- 1) Failure to comply with the User Manual could lead to damage and inaccurate results.
- 2) Patient ID and Test Type cannot be edited once the test begins.
- 3) Do not open the Cup Reader Chamber Cap during reading.
- 4) Do not test the used test cup again once the result has been reported.
- 5) Do not remove the USB drive during the software update.

Cautions:

- 1) Use only the power supply that is recommended by Cup Reader. Use the power adapter provided with the Cup Reader. The correct power supply can maintain the safety and electromagnetic compatibility of the Cup Reader.
- 2) Always operate the Cup Reader on a clean, flat, level and stable surface not in direct sunlight.
- 3) Do not move the Cup Reader while a test is in progress.
- 4) Follow proper infection control guidelines for handling all specimens and related items. Properly dispose of all contaminated waste according to local regulations. Clean the Cup Reader and external surfaces according to instructions provided in **Chapter 7 Daily Maintenance and Cleaning**.
- 5) Risk of electrical shock. Do not operate the Cup Reader, if it has been opened, damaged or exposed to moisture, condensation or rain.
- 6) Do not disassemble or attempt to repair the Cup Reader or other accessories as there is a risk of damage to the Cup Reader. The Cup Reader does not contain serviceable parts and should be returned for repair. Disassembling the Cup Reader will also void the warranty.
- 7) Only operate the Cup Reader for its intended purpose and in accordance with this user manual and warnings. If the Cup Reader is used in a manner not specified in the user manual, protection provided by the warranty stands will be cancelled. The Cup Reader (including power supply) is designed to operate within the manufacturer's specifications.
- 8) Position the Cup Reader with clear access to connectors. Keep connected cables clear of work areas so that tripping or entangling will not pull the Cup

Reader off its work bench. The mains socket outlet intended for use with Cup Reader power supply should be located near the Cup Reader and be readily accessible. Manufacturer recommends that cables are disconnected when not in use for an extended period.

- 9) Do not immerse the cup reader in water or cleaning solutions.
- 10) Clean only with indicated solutions.

Chapter 3 Components and Structure

3.1 Standard Equipment List

Packing List

No.	Description	Model	Quantity
1	Reader	ACR-100	1
2	Power Adapter	GSM40A12-P1J	1
3	Power Cord	/	1
4	Print Paper Roll	57*30 mm	1
5	User Manual	/	1
6	Calibration Cup	/	1
7	Touch Pen	/	1
8	Scanner	/	Optional

On receiving the box, please check the contents with this list and ensure that nothing is missing. Scanner is an optional accessory, which is available only against specific requirement and not as a standard accessory.

Note: If some parts are missing or damaged, please contact with local distributor.

3.2 Cup Reader

3.2.1 External View (Ref Fig 1, Fig 2)

The power switch is on the rear side of the reader. Adapter connection port, LAN Port and USB ports are on the left side of the reader for the purposes of connecting the reader with the mains socket, computer and/or Laboratory Information System, mouse and so on.



Fig 1



Fig 2

3.2.2 Power adapter (Ref Fig 3)



Fig 3

3.3 Technical Specification

• Principle	Photoelectric Conversion
• Test formats	Cup
• Touch Screen	7 inches
• Measurement	Qualitative
• Read Time	1-2.5 minutes (Depends on the placement of QR code)
• Power Source	DC 12 V, 2 A
• Dimensions	221 mm (Length) x215 mm (Width) x165 mm (Height)
• Weight	< 1.5 kg
• Mains supply voltage fluctuations	±10%
• Overvoltage category	II
• Pollution Degree	2
• Excitation light source	LED
• Connecting Ports	LAN Port, 4 USB Ports
• Storage Conditions	Temperature: -10-60 °C; relative humidity: 20% to 90%; atmospheric pressure: 86 to 106 kPa and in a ventilated environment free of corrosive gases. Measures should be taken to avoid moisture and prevent impact and severe vibration during transportation.
• Operating Conditions	15-30 °C
• Printer	Built-in thermal printer
• Place	Indoor use, stable table, avoid of direct strong light and strong electromagnetic interference source.
• Altitude	Up to 2 ,000 m

Chapter 4 Installation

4.1 Checklist upon Opening the Box

4.1.1 Check before opening the box:

Before opening the box, check the packaging is in good condition and box was not damaged during transportation.

4.1.2 Check after opening the box:

- ① Open the box carefully, check the contents according to **3.1 Standard Equipment List** to ensure it is complete.
- ② Examine the reader power adapter to see whether it is in good condition. If any defects are found, please contact the manufacturer or your local agent.

Note-1: Please keep the original box of reader and packing materials for any future shipping/reference purpose.

Note-2: *AllTest* strives to provide the right kind of power plug suitable for each country. However, in some cases, it may not be possible. Use of right kind of adapter to connect to power supply is recommended in such cases.

4.2 Environmental Requirement

- Surrounding temperature: 15-30 °C;
- Relative Humidity: 20% to 90% RH;

Avoid strong magnetic field, vibration, shock, corrosive gas, direct sunlight, high humidity, and high temperature in work area, where the reader is placed for operation.

4.3 Placement

- ① The reader should be placed on a stable and level countertop, and in an indoor environment free of dust, direct sunlight or corrosive gases. The countertop must be able to sustain a weight of 1.5 kg.
- ② No strong vibration source and strong electromagnetic fields around.
- ③ The reader should be placed in a well-ventilated place. There should be at least 10 cm space around the reader to ensure the necessary space for operation and maintenance.

4.4 Power Supply Voltage Requirements



The power supply of the reader varies between 100- 240 V /50/60 Hz AC depending on countries where the reader is used. The input voltage is 12 V DC. Avoid short circuit and electric shock during the use. The reader is grounded through power adapter.

4.5 Reader Installation

Please use the reader under the proper conditions mentioned in **4.2 Environmental Requirement.**

1. Place the reader on a stable platform.
2. Loading paper

Open the printer cover, place the printing paper into the printer, pull out approximate 3 cm of paper from the roll, then close the cover of the printer.

3. Connect the power adapter and the power connector of reader.
4. Turn on the power switch and start the reader.

Chapter 5 Directions for Use

The Cup Reader can be operated by commands on touchscreen.

5.1 Start the Reader


Connect power with cup reader through the DC adapter and press the power switch to turn on the reader. The initializing screen will display as Fig 4.



Fig 4

After initializing, fill in the username and password (Ref Fig 5), the reader will have a self-testing. If the self-testing is passed, it will enter the main operation interface.

5.1.1 Login

Tap  to initiate the virtual keyboard, fill in the username and password, the initial username: **admin**, and the initial password: **admin**, tap “**Login**” to enter. Users can be added or deleted refer to **5.2.1.3 User Management**.

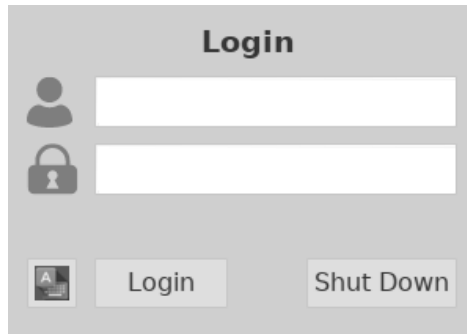


Fig 5

5.1.2 Shut Down

Tap **"Shut Down"**, a prompt will display as Fig 6, tap **"Yes"** to turn off the reader, tap **"Cancel"** to give up.

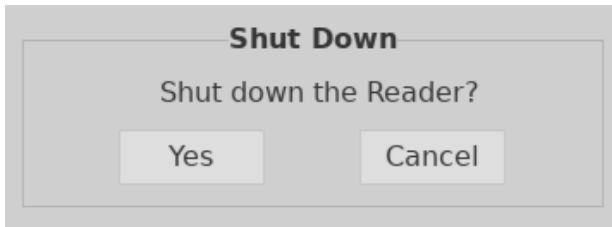


Fig 6

5.1.3 Self-Testing

After login, reader will enter the self-testing procedure. (Ref Fig 7)

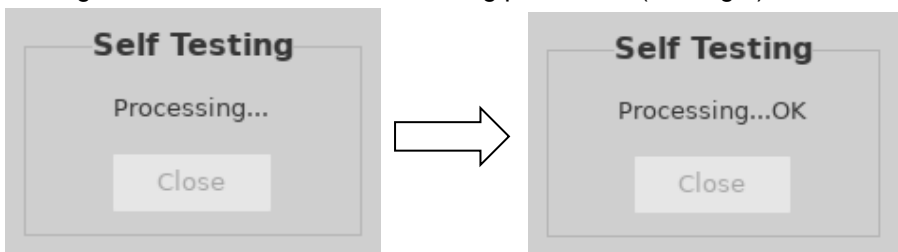


Fig 7

5.2 Main Functions

There are five main functions: Setting, Records, Read, Upload and Print, and several Auxiliary Functions. (Ref Fig 8)



Fig 8

5.2.1 Setting




Press “Setting” to switch to the interface. (Ref Fig 9)



Fig 9


5.2.1.1 Preferences Functions Setting

- 1) **Language:** The language can be selected, English is the default selection.


- 2) **Date & Time:** Press  at the right side of date displaying box to select target date, fill in the target time with the virtual keyboard, press  to save the change. (If the reader is connected to the Ethernet via LAN Port, the date and time will be synchronized on the network, and cannot be changed.)
- 3) **Timezone:** The country and city can be selected to set the time zone and press  to save the change.
- 4) **Print Mode:** Select “**Automatic**” to print test result automatically after each test, if “**Manual**” is selected, the test result will not be printed automatically after each test and the user should give a print command, if a printout is desired.

5.2.1.2 LIS Connection Setting

- 1) **LIS Connection:** The reader can be connected to LIS via Ethernet.

Step 1: Select communication protocol in protocol drop down box, press  to save.

Step 2: Connect Ethernet

Step 3: Fill in the server IP address and port information in the server IP and Port respectively, press  to save.

- 2) **Upload Mode:** Select “**Automatic**” to upload test result automatically after each test, if “**Manual**” is selected, the test result will not be uploaded automatically after each test.

5.2.1.3 User Management

Press  to set user management, then it shows as Fig 10.



Fig 10

- **Add User:** Press **Add**, fill in username, password and confirm password, tap **Save** to save and tap **Exit** to give up.(Ref Fig 11)



(a)



(b)

Fig 11


- **Delete User:** Select user which needs to be deleted, press **Delete**. (Ref Fig 12)



Fig 12

5.2.1.4 About

Press  to display the software version and the serial number as is shown in

Fig 13. Press  to return to the main operation interface.

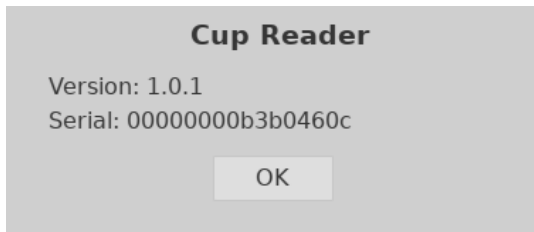


Fig 13

5.2.2 Records

Press “**Records**” to switch to the records interface (Ref Fig 14). The results will be displayed in the records, and the detailed information will be displayed in result area. Press the target row, the detailed information will be shown accordingly. The functions of buttons are explained in table 1.

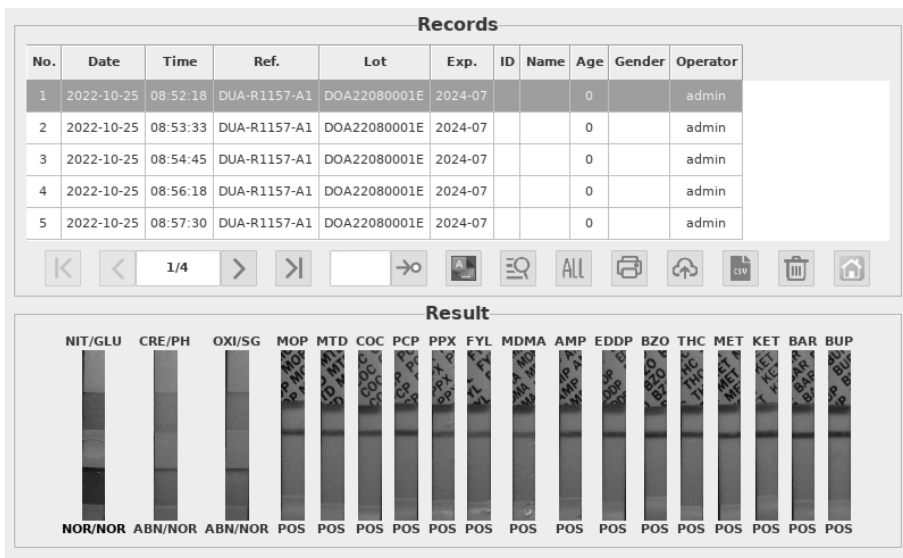


Fig 14

Table 1 Function Buttons

Button	Function
	Previous or Next Page
	The First or Last Page
	Jump into the target page filled in the dialog box
	Press to initiate or collapse Virtual Keyboard
	Search records with the information filled in the dialog box.
	Display all records
	Print the selected record(s)
	Transfer the selected record(s) to LIS
	Export record(s) as an excel
	Delete selected record(s)
	Return to the main operation interface

5.2.3 Read

Allow the cup, urine specimen, and /or controls to reach room temperature (15-30 °C) prior to testing.

1) System Calibration

Step 1: Take out the calibration cup; put the cup into reader detection chamber.

Step 2: Tap “Read” to read the results. (Ref Fig 15)

Note:

- 1) The reading time may take 1 minute to 2 and half minutes, which depends on the placement of QR code.
- 2) When placing the cup into the reader chamber, align QR code on the cup label to the direction as shown in Fig 17 for faster results.

Interpretation of result:

PASS result means system running is normal, user can perform a test. While the calibration result is **FAIL**, please do not use the device, and contact **AllTest** for Technical Support.

The screenshot displays the AllTest mobile application interface. At the top, there are navigation icons, the 'DitelL' logo, and the date and time '2022-10-25 09:38:29'. Below this, there are two main sections: 'Cup' and 'Patient'. The 'Cup' section contains fields for 'Ref.' (filled with 'Calibration_Cup'), 'Lot' (filled with 'N/A'), and 'Exp.' (filled with 'N/A'). The 'Patient' section contains fields for 'ID', 'Name', 'Age', and 'Gender'. Below these sections is a 'Result' section showing 15 vertical bars, each labeled T1 through T15. Each bar has a green segment at the bottom, and the word 'PASS' is written below each bar. At the bottom of the screen, there are five buttons: 'Setting', 'Records', 'Read', 'Upload', and 'Print'.

Fig 15

2) Run a test

Step 1: Bring the cup pouch to room temperature before opening. Remove the cup from the sealed pouch and use it within one hour.

Step 2: Collect specimen.

Step 3: Secure the cap and put the cup on a flat surface.

Step 4: Check the temperature label up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The

proper range for an unadulterated specimen is 32-38 °C (90-100 °F).

Step 5: Date and initial on the security seal and attach the security seal over the cup cap.


Step 6: Peel off the label on the cup.


3) Read the results by Reader

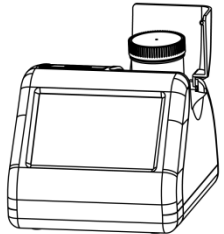
Step 1: Fill in patient information, such as ID, Name, Age and Gender on the screen.

Step 2: Put the cup into reader detection chamber at 5 minutes and close the chamber cap, as shown in Fig 16.

TEST PROCEDURE Cup

- 

• Open the Cap and add specimen
- 

• Peel off the label
- 

• Put the cup into reader detection chamber at 5 min, close the chamber cap and click "Read" to read the results.

Fig 16 Operation of the urine cup

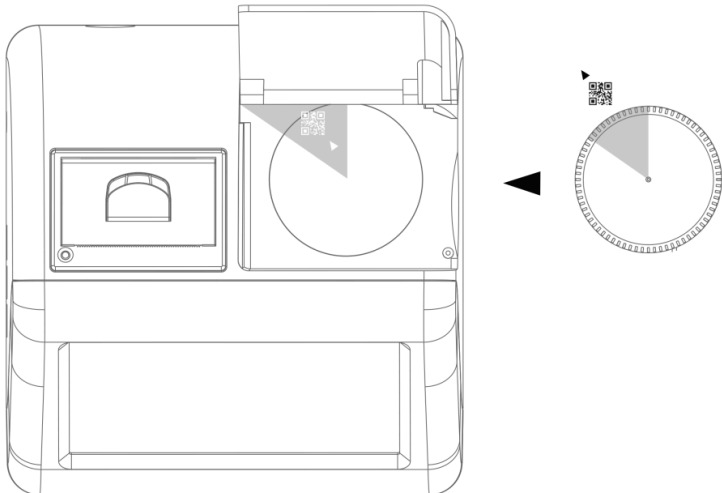


Fig 17 Orientation of the urine cup

Step 3: Tap “Read” to read the results. (Ref Fig 18)

The screenshot shows the EZDitell application interface. At the top, there is a navigation bar with the EZDitell logo and the date/time '2022-10-25 09:40:19'. Below the navigation bar, there are two main sections: 'Cup' and 'Patient'. The 'Cup' section has three input fields: 'Ref.' (empty), 'Lot' (empty), and 'Exp.' (empty). The 'Patient' section has four input fields: 'ID' (123), 'Name' (Abc), 'Age' (20), and 'Gender' (Male). Below these sections is a large 'Result' area which is currently empty. At the bottom of the screen are five buttons: 'Setting', 'Records', 'Read', 'Upload', and 'Print'.

Fig 18

The cup information will be filled in the boxes automatically after a few seconds of starting test, and the process will change continuously from 0% to 100%. (Ref Fig 19)

The screenshot shows the EZDitell application interface. At the top, there is a navigation bar with the EZDitell logo and the date/time '2022-10-25 09:40:35'. Below the navigation bar, there are two main sections: 'Cup' and 'Patient'. The 'Cup' section has three input fields: 'Ref.' (DUA-R1157-A1), 'Lot' (DOA22080001E), and 'Exp.' (2024-07). The 'Patient' section has four input fields: 'ID' (123), 'Name' (Abc), 'Age' (20), and 'Gender' (Male). Below these sections is a large 'Result' area which now displays 'Processing... 10%'. At the bottom of the screen are five buttons: 'Setting', 'Records', 'Read', 'Upload', and 'Print'.

Fig 19

Step 4: When the process reaches 100%, the test result will display on the screen as Fig 20.

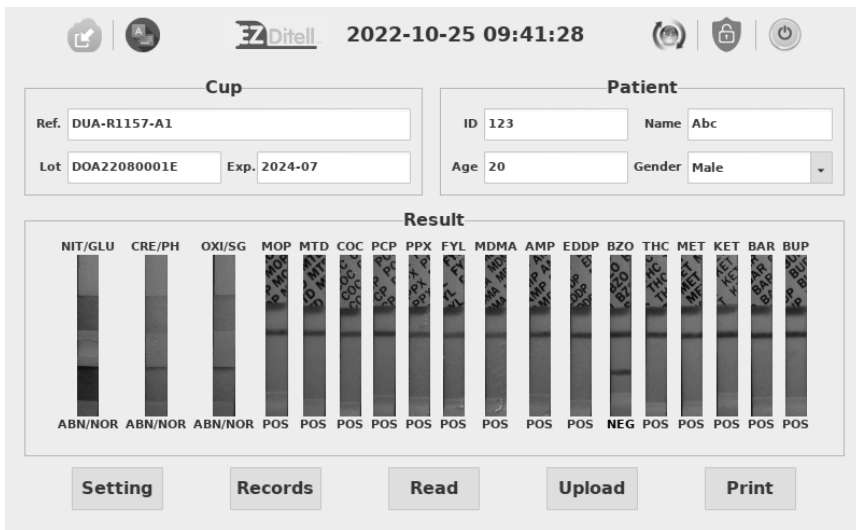


Fig 20

5.2.4 Upload

After each test, press “**Upload**” to transfer the result to LIS. (The result will be transferred automatically on the condition that the LIS setting has been set correctly.) (Ref Fig 21)

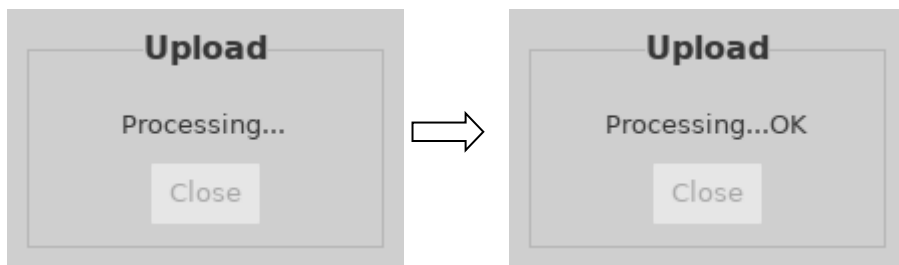


Fig 21

5.2.5 Print

Press “**Print**” to print the current result with the built-in thermal printer. (Ref Fig 22) (The result will be printed automatically on condition that the automatic function of print is switched on.)

TEST REPORT	
1) CUP	
Ref.: DOA-A1157-007-A1	
Lot: DOA1908021U	
Expiry Date: 202108	
2) PATIENT	
ID:	
Name:	
Age: 0	
Gender:	
3) RESULT	
ITEM	RESULT
BUP	NEG
THC	NEG
TCA	NEG
MET	NEG
AMP	NEG
BZO	NEG
BAR	NEG
HTD	NEG
COC	NEG
POP	NEG
EDDP	NEG
OXY	NEG
MEMA	NEG
OP1	NEG
MDP	NEG
Tested: 2020-05-05 19:59:24	
Printed: 2020-05-05 20:25:50	


Fig 22

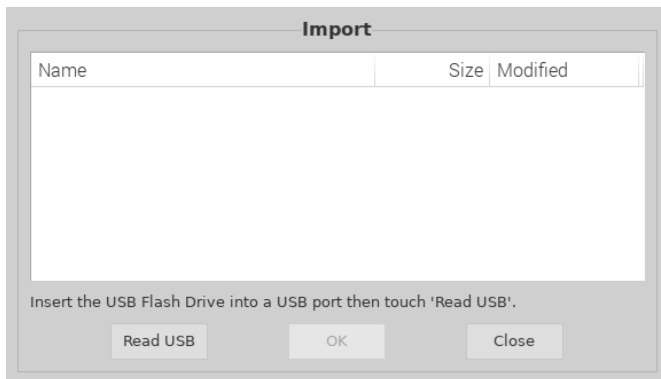
5.3 Auxiliary Functions

Auxiliary functions including: Import, Update, Locked and Shutdown.

5.3.1 Import

A specific configuration file will be provided with one batch of test cups. If a new batch arrives, the configuration file should be stored in a USB disk and imported

into the reader by pressing the button . (Ref Fig 23)



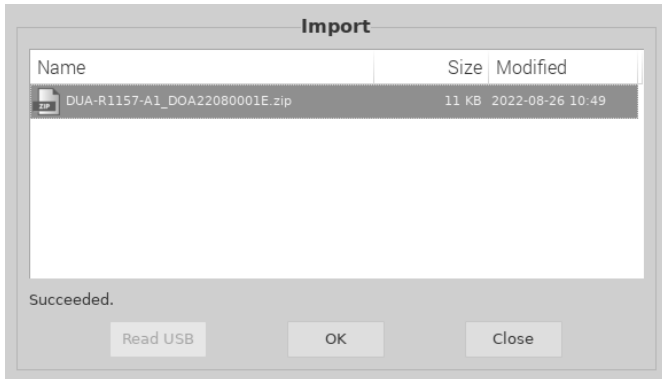
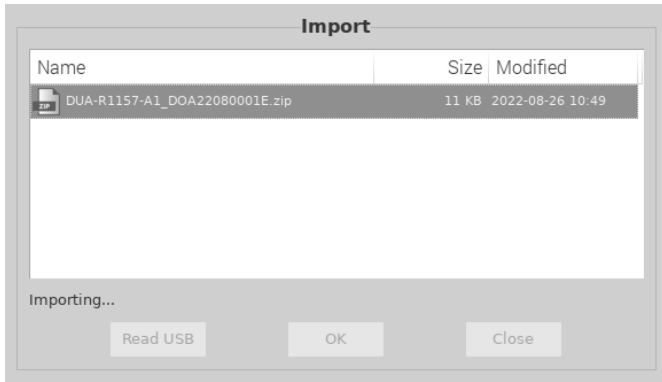
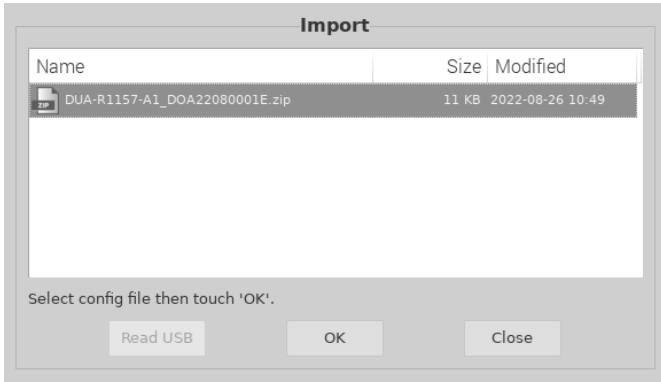



Fig 23

5.3.2 Update

The software is updated via USB port. A new software version will be provided by email when the Reader does not work properly due to software damage.

Pressing  in the main operation interface. (Ref Fig 24) Tap “Yes” to enter update procedure, tap “Cancel” to give up.

Warning: Do not remove the USB drive during the software update.

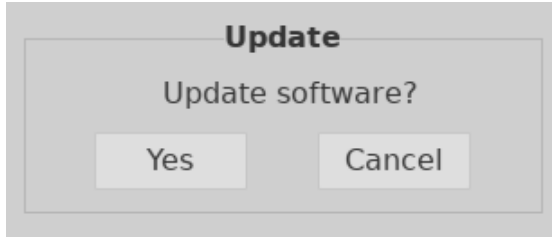




Fig 24

5.3.3 Locked

During one day, when the Reader is not in use, it can be temporarily locked by tap the icon . When it is used again, enter the username and password to enter the operation interface. We recommend that the instrument be turned off after using in one day.

5.3.4 Shutdown

Press  to turn off the reader. A prompt “Shut down the reader?” will be displayed on the screen, press “Yes” to turn off, press “Cancel” to give up.

Note: Do not turn off the power switch immediately after the screen is turned off, about 1 minute later, the power switch can be turned off.

Chapter 6 Troubleshooting

Operating and maintaining the cup reader following the instructions in this User Manual usually enables the reader to function correctly. Some common faults may be encountered during the use of the reader. The following table will introduce the common faults and solutions:

Table 2 Troubleshooting

Error Description	Solutions
Invalid username or password prompts when login.	<ol style="list-style-type: none">1. Make sure the username or the password are existed and right, login again.2. If the prompt still exists, fill in the original username and password to check the added user information.
The virtual keyboard blocks the login interface.	<ol style="list-style-type: none">1. Tap the password input box, press the Tab key and then tap Enter key, it will be ok.2. Tap the virtual keyboard icon to initialize the keyboard.3. If the error still exists, please contact the local distributor or the manufacturer.
The batch information was not found.	<ol style="list-style-type: none">1. Import the corresponding batch configuration file and try again.2. If the error still exists, please contact the local distributor or the manufacturer.
Prompt “Invalid cups?”	<ol style="list-style-type: none">1. Take the cup out; make sure there is a QR code on the cup label.2. Make sure the QR code direction is correct; put the cup in the chamber as shown in Fig 17.3. If the error still exists, please contact the local distributor or the manufacturer.
The touchscreen is stuck.	<ol style="list-style-type: none">1. Switch off and restart the Cup Reader.2. If the error still exists, please contact the local distributor or the manufacturer.

Chapter 7 Daily Maintenance and Cleaning

7.1 Maintenance

Basic maintenance is to keep the outside of the Cup Reader clean.

External cleaning and maintenance method: Clean the outer surface of the reader with a damp cloth with no more than 70% alcohol. Do not use strong bleach ($\geq 0.5\%$ bleach solution), because oxidizing substances and solvents may damage the reader's parts and touchscreen. **Do not clean any internal parts and inner surface.**



Turn off the power switch before cleaning! Ensure the power cord is disconnected to avoid the risk of short circuit and electric shock!

7.2 Maintenance Plan

Maintenance item	Every week	When needed
Dust cleaning	X	
Replace print paper		When the paper runs out

7.3 Precautions

- i. Do not place the reader in a position that is difficult to operate or inconvenient to disconnect.
- ii. Treat tested samples as potentially contagious and use protective gloves and other protective measures.
- iii. Use test kits manufactured by Hangzhou AllTest Biotech Co., Ltd. and supplied by authorized distributors of Hangzhou AllTest Biotech Co., Ltd. only.
- iv. Do not replace the removable MAINS power cord with an improperly rated power cord.
- v. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.

Chapter 8 Service, Repair and Disposal

Cup Reader does not require special maintenance except for keeping it clean and replacing printing paper when necessary. If service is required, please contact with the local distributor.

Cup Reader's internal parts, including the circuit boards, optical detection modules, display, and built-in thermal printer, can only be provided by manufacturer. Such items should not be sourced from any third-party, even if they claim to provide the same function. When issues related to the reader occur, contact the local distributor. We provide technical support for users to perform troubleshooting. If the reader needs to be sent back to manufacturer, please contact local distributor and/ or Hangzhou AllTest Biotech Co., Ltd. It normally takes about one week to fix problems. If it turns out that the reader cannot be repaired within warranty period, we will replace it with a new one. If for any reason the reader needs to be disposed of, please follow the procedures and rules of local regulations.

We provide technical support and software maintenance, including functional maintenance, corrective maintenance, software fixes or upgrade. We are only responsible and provide services when the reader is properly used in compliance with the manufacturer's instructions, otherwise any damages incurred will not be covered.

This product is required to comply with the European Unions' Waste Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.



Chapter 9 Manufacturer Information

Name: Hangzhou AllTest Biotech Co., Ltd.

Address: # 550, Yinhai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018 P.R. China

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Web: www.alltests.com.cn

Email: info@alltests.com.cn

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		<i>In vitro</i> diagnostic medical device
	Temperature limit		ACR-100		Authorized representative in the European Community/ European Union
	Manufacturer		CE Mark		Keep dry
	Fragile, handle with care		Keep away from sunlight		Protect from heat and radioactive sources
	Caution		Biological risks		Unique device identifier
	Serial Number		Date of manufacture		Humidity limitation



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Borkstrasse 10,
48163 Muenster,
Germany

Number: 14601670900

Revision date: 2023-07-06

Appendix

A. Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.

For your records, write the purchase date of your starter kit here:

Note: This warranty applies only to the reader in the original purchase. It does not apply to the other materials included with the reader.

Hangzhou AllTest Biotech Co., Ltd. warrants to the original purchaser that this reader will be free from defects in materials and workmanship for a period of one year (12 months).

The one year starts from the later of the date of original purchase or installation (except as noted below). During the stated one year period, **AllTest** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. **AllTest** shall not be responsible for shipping charges incurred in the repair of such a reader.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. **AllTest** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the reader in accordance with the operations manual, or maintenance by anyone other than **AllTest**.

Furthermore, **AllTest** assumes no liability from malfunction or damage to readers caused by the use of products other than products manufactured by **AllTest**. **AllTest** reserves the right to make changes in the design of this reader without obligation to incorporate such changes into previously manufactured readers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties expressed or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by **AllTest**.

Limitations of Liability

In no event shall **AIITest** be liable for indirect, special or consequential damages, even if **AIITest** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

B. Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within one year of purchase.

Purchaser	
Model	
Serial Number	
Date of Purchase	
Address	
Telephone Number	
E-Mail Address	



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