Vertu[™] TOUCH

User Manual





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1.0 Introduction

Thank you for choosing the Vertu™ TOUCH. We are confident that this product will become an integral part of your daily work.

Portable testing without an accessible lab is a challenge. Using the wealth of experience obtained from providing reflectometric detection technology to thousands of customers worldwide, the specialists at VICAM have developed a new generation reader for mobile applications. The Vertu TOUCH is a highly sensitive, robust, and cost-effective measurement system for lateral flow tests. This flexible and reliable system, based on a ready-to-use concept, enables the users to easily run lateral flow tests.

This manual describes how to operate the Vertu TOUCH. Before using the device, it is essential that you read this user manual carefully.

1.1 General Information

1.1.1 Technical Assistance

The VICAM technical services and applications team has earned a global reputation for excellence in high quality, accessible and personalized support. Our team is staffed by experts with theoretical and practical knowledge and expertise in the use of VICAM products. If you have any questions or experience any difficulties regarding the Vertu TOUCH products in general, do not hesitate to contact us.

VICAM customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to the researchers at VICAM. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact the VICAM Technical Services Department (see chapter Technical service support on Page 24).

For up-to-date information about the Vertu TOUCH products, visit www.vicam.com

1.1.2 Policy Statement

It is the policy of VICAM to improve products as new techniques and components become available. VICAM reserves the right to change the specifications of products at any time.

1.2 Intended Use of the Vertu TOUCH

The Vertu TOUCH instrument is designed to perform reflective optical measurements that can be used to detect and/or quantify target analytes on lateral flow test strips.

The Vertu TOUCH is intended to be used only in combination with lateral flow tests indicated for use with the Vertu TOUCH, and only for applications that are described in the respective handbooks from test manufacturers.

2.0 Safety Information

The instructions and safety information in this user manual must be followed to ensure safe operation of the Vertu TOUCH. Please note that if the equipment is used in a manner not specified by VICAM, the safe use of the equipment, and its warranty, may be compromised.

The following types of safety information appear throughout the Manual.

WARNING	The term WARNING is used to inform you about situations that could result				
	in personal injury to other persons.				
	Details about these circumstances are provided in the box like this.				
CAUTION	The term CAUTION is used to inform you about situations that could result				
	in damage to the instrument or other equipment.				
	Details about these circumstances are provided in the box like this.				

Note: The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in user's country.

2.1 Proper Use

The Vertu TOUCH must be operated by personnel familiar with the use of the associated VICAM instrumentation. Personnel must have been trained in its use or have read and demonstrated an understanding of this Manual.

As potentially mycotoxin contaminated samples specimens will be measured with the Vertu TOUCH, VICAM recommends using appropriate personal safety equipment such as gloves.



2.2 Electrical Safety

	Do not expose the reader to strong electromagnetic radiation. It is the responsibility of
	the user to ensure that a compatible electromagnetic environment is maintained for the
CAUTION	instrument in order to guarantee conform performance. This device conforms with the
	emitted interference and emitted immunity requirements of the standard DIN EN 61326-2-6.
<u> </u>	The electromagnetic environment of the device should be assessed prior to its application.
	Do not use this device in proximity to sources of intense electromagnetic radiation because
	proper use may be disturbed.

2.3 Environment

If the Vertu TOUCH is to be used in a working environment prone to dirt build-up, clean the device regularly. For cleaning, please follow the instructions provided in chapter Cleaning.

2.4 Environmental Hazards

Do not expose the Vertu TOUCH to direct sunlight during operation.
Protect the reader from high humidity and contact with liquids.

2.5 Heat Hazard



2.6 Maintenance Safety

To assure optimal performance and safety, perform routine maintenance as recommended in this reference guide chapter "Maintenance.

2.7 Waste Disposal

Wastes may contain certain hazardous chemicals or contagious/bio-hazardous materials and must be collected and disposed properly in accordance with all national, state, and local health and safety regulations and laws.

2.8 Symbols on the Vertu TOUCH Instrument

The following symbols may appear on the Vertu TOUCH instrument.

Symbol	Location	Description
CE	Type plate on the back of the instrument.	CE mark for Europe.
SN	Type plate on the back of the instrument.	Serial number.
	Type plate on the back of the instrument.	Legal manufacturer.
	Type plate on the back of the instrument.	Date of manufacture.
	Type plate on the back of the instrument.	Waste Electrical and Electronic Equipment (WEEE)

Symbol	Location	Description
REF	Type plate on the back of the instrument.	Catalog number.
	Type plate on the back of the instrument.	Consult instructions before use.
IP 10	Type plate on the back of the instrument.	IP Classification.

2.9 Symbols on the Package of the Reader

Symbol	Location	Description	
Transpot Conditions Storage -20°C +50°C +15°C +40°C	On the package.	Transport and Storage conditions ¹ .	
Ť	On the package.	Keep package dry!	
	On the package.	Handle package with care!	

¹ Allowed Temperature range for storage and transportation as specified in the chapter "Technical Data" on page 25.

3.1 Hardware

- 1. Touch display
- 2. Power button with LED
- 3. Sample drawer for calibration cards and test strips



- 4. Handle
- 5. Ethernet port (RJ-45)
- 6. USB port (type A)
- 7. Connector for power supply
- 8. Type Plate



3.2 Contents of the Kit

- Vertu TOUCH instrument
- Quick Start guide
- Power supply including international connection adapter
- Network Cable and USB to Ethernet Adaptor
- Temperature Sensor

4.0 Unpacking and Set-up Procedures

4.1 Unpacking of the Vertu TOUCH

Take out the Vertu TOUCH from its transport case, place it on a stable and leveled surface and check whether it contains all items as listed in chapter Contents of the kit.

Carefully examine the instrument to make sure that it has not been damaged during the shipment. In case of damage or any parts missing (refer to chapter Contents of the kit), contact immediately your supplier.

4.2 Setup and Connection of the Vertu TOUCH

Place the Vertu TOUCH on a stable and leveled surface.

Plug the power supply cable (low voltage end) into the connector at the back side of the device (pos.7 in chapter Hardware). Plug the power supply cable (mains end) into a power outlet. Make sure that the cable is plugged in properly on both sides. Plug in Temperature Sensor to one of the USB outlets.

4.3 Requirements

The Vertu TOUCH is a highly sensitive and precise optical device. <u>The result can be influenced by vibrations</u> e.g. if the device is used close to vibrating machines.

The device has internal correction for normal levels of ambient light. <u>Highly intense light</u> falling into the test strip insertion port can cause serious interference with the measurement and must be avoided where possible.

The device measures the ambient temperature during operation. Test results may be influenced when reader is placed in close proximity to heating or cooling sources.

4.4 AC Power Connection

The Vertu TOUCH must only be used with the power supply provided with the device.

4.5 Hardware Installation / Accessories

Installation of power supply options and accessories:

- External power supply: connect external power supply to power port. A blue LED light in the power switch will indicate the connection to a power supply. If you would like to power your device with an external power bank, ask your VICAM Sales Representative for appropriate models.
- Thermal printer: The Vertu TOUCH can be connected to a Dymo TM 450 label writer with large address labels (2 X 4 inches or 101 x 54 mm) via USB.



Be aware **NOT** to plug in the power supply cable of the **<u>DYMO printer</u>** into the Vertu TOUCH. This can cause **permanent damage** to the Vertu TOUCH.

4.6 Relocating the Vertu TOUCH

The Vertu TOUCH is a mobile device that can be relocated easily. Make sure that general operating conditions are always met (see Technical Data).

5.0 General Operation

5.1 Powering the Vertu TOUCH on and off

<u>Switch on</u> the device by pressing the power button (Pos. 2 in chapter <u>Hardware</u>). The device will show a standard black screen and switches after 15 seconds to a boot screen. After successful initialization of all components, the home screen is visible.

<u>Switch off</u> by pressing the power button for at least 1 second. The Reader will ask for confirmation on the DISPLAY before shutting down.

Note that the blue LED will stay on even if the device is turned off.

5.2 Instrument Startup

Push the power button, the operating system and application will boot up.

The internal self-check routine will be performed to check if the values from internal reference standards are within the defined tolerance range. If the measured values of the internal reference standards are outside the tolerance range a warning message will be displayed.

NOTE: Please make sure, that the original drawer is inserted (see chapter Unpacking and Set-Up Procedures).

First Login

The reader will have the user management be turned on by default. To log in, use the default user which is pre-installed named <u>"ADMIN". The initial password is "0000"</u>

User management can be configured in the menu under System/Settings/Admin Areas/User Management (see chapter User Management). New users can be added, passwords can be changed, and user management can be turned off.

5.3 Menu Structure

The graphic below shows the menu structure of the Vertu TOUCH



5.4 Home Screen

When the System has started successfully, the home screen is visible. It is divided into several parts (see numbers)



- 1. Button to start a new measurement
- 2. Button to review results
- 3. Button to view status and change settings
- 4. Button to log off from device
- 5. Status Bar displaying Date/Time and status symbols if applicable

6.1 Starting a Test

To start a new run, press the [Start new Test] button on the home screen. The display shows



6.1.1 New Method

If the desired test is NOT on the list or no test is installed

Step 1 press on [New Method] to import a new test method from the barcode card, which is in the package of your test kits. The screen will guide you through the required steps to import a new method.

SELECT METHOD New Meth			

Step 2 The workflow starts with a screen, prompting the user to insert the test barcode card. Insert the barcode card and press [Read Barcode] to start the reading process.



Step 3 The DISPLAY prompts you to remove the barcode card and press [X] to close the window



► For further instructions and troubleshooting for method import refer to chapter "Update Tests"

6.1.2 Select Method

If the screen shows the installed tests

Step 1 Select the desired test by a click on the test name.



Step 2 the DISPLAY proceeds to the LOT selection screen where you choose the desired LOT Number for your chosen test.

SELECT LOT#	New Lot#
035-035A.0	035-036A.0

Step 3 Again: If the LOT number is missing, you can import the actual test with the right LOT number by select [New Lot#]. Then follow 6.1.1 step 2 to scan a new barcode.

6.1.3 Enter Sample ID

Here you enter the sample ID either via the keyboard on the DISPLAY,

<	ENT	FER S.	AMPL	EID	Cor	n001		•	×
1	2	3	4	5	6	7	8	9	0
0		#	%	&	*	•	+	()
1/2	1		<	>	1	1	4	1	?
ABC .									
Method: Afla-V (A) Lot#: 035-036A.0 Continue									

The [Continue] button appears if at least one number or one character is entered. Pressing [Continue] leads to the final screen before the measurement starts and prompts the user to insert the test strip/cassette into the drawer.



Insert the test cassette now into the drawer. Ensure to have the test cassette placed in the correct orientation, round circle in first, close the drawer and press [Start Measurement] immediately.



After measurement, the result is displayed on a result summary screen:



- ▶ Press [Print] to print the result.
- ▶ Press [Same Barcode] to run the next test using the same lot of strips and same method.
- ▶ Press [Change Barcode] to change the method or lot of strips being used.
- ▶ Press [Home] to go back to Home Screen.

6.2 Review Results

The result screen shows all test results in a tile view. Different actions for filtering are feasible.



	Action Order
1	Short press on a tile opens the single result view with all result details.
2	Enter test name, date or username to apply a filter results for this attribute. The results will be displayed immediately.
3	Swipe over the result list to scroll down the list.

Long press on a result tile opens a menu with additional actions

	Action Order
4	Mark those results which shall be exported or printed
5	Select or unselect all results
6	Save selected results to an USB stick in csv format
7	Print selected results

7.0 System and Settings

The System Menu offers 4 main sections for

- Reviewing status information of your reader like actual SW version, IP address or serial number.
- Update the test menu
- Change device settings
- Maintenance of the device
- 7.1 Status

Press System / Status to enter a menu where you can choose to show device information. There are 2 options available:

- 1. [Info Menu]: to display IP address, device name, device ID, serial number, Software ID, software version and operating system version
- 1. [Show event log] shows a chronological list with device actions like log in attempts, device actions and error messages. This list can be exported on an USB stick

Both menus can be left via the "back" button

7.2 Update Tests

Enter this menu, to update the device with new test methods.

> This menu is accessible for each user level, since methods can be added or deleted.



The menu shows an overview of all scanned test barcodes. Via the search field, filtering for a set of dedicated test methods can be applied. To import a new test method, press [New Method]. A window prompts you to insert now a barcode card, which contains the test method to be imported.



Make sure, the barcode card is positioned on the left upper side of the drawer. Your drawer will contain a small bar to give you an edge for the card which shall be placed above (see red arrow).

- ► The import of a new method takes some time (up to 1min)
- > In case you get an error message that your barcode card cannot be read, try following actions and retry import:
 - Rotate barcode card by 180° to change the order of the 2 barcodes from top to down
 - Ensure that the barcode card is not bent or has blots on the barcode
 - Change slightly its position in the drawer

► In case that despite of the above-mentioned actions, your barcode does not get read, contact Techservice or sale support for further help.

7.3 Settings

The settings menu is split into a protected area for the administrator (called Admin Area) and a non-protected area for all users, called **Preferences**

7.3.1 Preferences

Within the menu preferences, the user can select to adjust the screen brightness (80% is the default level) and to select the device language.

The desired language will be immediately applied by pressing a tile of the available languages.



7.3.2 Admin Area

This menu can only be accessed with administrator user level. If the user management is turned off, this menu is freely accessible.

In this menu, the user can change the following reader settings:

- Date & Time of the reader
- Manage Data to delete installed test methods or results
- User Management to add, administrate and delete user
- **Update Software** to install an instrument software update
- **Cassette Settings** Select No Cassette Barcode Check
- Manufacturer Reset to delete all data and methods from the reader
- **Communication Settings** to configure network connections for data transfer
- Shutdown Settings to configure the time when the reader shuts down by itself



7.4 Menu Structure in the Admin Area

7.4.1 Date & Time

Enter this menu to change date, date format and time of the Vertu TOUCH.



You can select between 2 date formats (2) which are yyyy-MM-dd and yyyyMMdd Change values using the up and down arrows beside the date and time numbers (3). Save your selection by pressing "save" (1)

7.4.2 Manage Data

In this menu you can delete data or export the result data base. The user has following functions available:

- Delete methods
- Delete results
- Delete event log
- Delete unsent results (in case the device is connected to a connect server)
- Export raw data

The menus work quite similar

Choosing the desired item (Test method or results) shows you an overview of all existing test methods or results. The text search function allows to search and filter for individual results or test methods.

A Long Press on a tile will open the selection mode in which you can select individual or all tiles. If at least one tile is marked, the "Delete" button gets active and selected tiles can be deleted



7.4.2.1 Show and Delete Unsent Results

If the device is established to report its results to a connect server, this menu shows unsent results. This can happen due to network interruption or a server issue. In case the connection to the server is working again, the device will automatically try to push out all remaining results. However, if the user decides not to send unsent results to the server, he can delete them in this menu from the queue. This will only prevent selected results from being sent. Results still remain on the device.

7.4.2.2 Export Raw Data

This menu allows to export the whole result data base to an USB stick. Sometimes these data are needed for troubleshooting purpose or further analysis. The file is encrypted and can only be accessed by the test provider.

7.4.3 User Management

The Vertu TOUCH can be used with user management which is turned on by default. The user management offers a protection of the device against non-authorized access and use of it and protects the device against change of settings and non-authorized deletion of data.

It can be chosen between 2 user level:

- → Administrator: can change settings and delete data in the Settings menu
- → Lab User: use all functions except the settings in the administrator area
- > See chapter Menu Structure for an overview of the DISPLAY structure and visualization of administrator menus .

7.4.4 Update Software

An administrator level user can update the software by inserting a USB stick containing either instrument software update or language update files.

7.4.5 Cassette Settings

VICAM's tests currently only support "No Casssette Barcode Check" ensure that this feature is selected.

7.4.6 Manufacturer Reset

Pressing the button [Manufacturer reset] will open an orange warning screen asking for confirmation to proceed:



If the user proceeds, the following data get deleted from the reader:

- Deletion of all measurement results, test methods and entries in event log
- Deletion of <u>all users</u>, except default user which is the default administrator user
- Reset password of <u>default administrator user to "0000"</u> and <u>turn user management "on"</u>
- Set language to "English" and screen brightness to 80%
- Set all <u>Communication Settings to OFF</u> and set default entries.
- Set Cassette mode to No Cassette Barcode Check

7.4.7 Communication Settings

In this menu, the user can manage network connections and is able to set up the connection to the "connect" software, an external server/client solution to manage and view results from external devices.

The menu offers 3 sub menus called

< соммиліс	ATION SETTINGS	
	Network	
	Connect	
	Security	

7.4.7.1 Submenu Network within Communication Settings

In this menu, the network properties of the reader can be configured such as its IP address, its subnet mask, the default gateway. Alternatively, DHCP (Dynamic host configuration protocol) can be turned on and the reader will receive its network configuration from a DHCP server.



Settings and changes get saved by pressing the "save" button.

7.4.7.2 Submenu Connect within Communication Settings

If the reader shall report its results to the "connect" software, the connect functionality needs to be turned "on". Now the connect server IP address and port number need to be entered and changes need to be saved.

ADDRESS:	127.0.0.1
PORT NO.:	8000
Test	Save

A "Test" button will ping the server and show a success message in case, the connection could successfully establish.

7.4.7.3 Submenu Security within Communication Settings

This menu allows enabling or disabling dedicated network ports and services to increase network security. The SSH service (secure shell protocol) can be turned on to be able to connect to the reader using user ID and PW and the ports to the developer software can be enabled.

Note: These connections are disabled by default to guarantee highest network security.



7.4.8 Shutdown Settings

Enabling an automated device shutdown and an automated auto log off will increase device security, protect components like display and save energy.

The user can select between 3 different time periods after reader inactivity until the system will shut down.

If automated user log off is turned "on" the user will automatically be logged of <u>after 10 min</u> of **DISPLAY** inactivity and the device DISPLAY is protected against unauthorized use.



8.0 Maintenance

This section is intended for qualified users with maintenance tasks. The instructions provide the user with necessary information on proper maintenance and care of the Vertu TOUCH.

Note: the safety information must be read thoroughly and understood before starting maintenance and servicing work.

8.1 Menu "Maintenance" within System Menu

In case the device will prompt a warning during self-test, stating that the optical system did only partially or did not meet the required values, the user can clean the internal reference material using swabs, provided by your test supplier. Entering this menu will show a live view of the inside device and will turn on the light inside the system. The user can now clean the internal reference material and restart the device for another attempt for the self-check.

Steps to clean:

- Turn on the reader
- Obtain a lint free swab (recommended: Techspray, Super-Tip Foam Swab, Product 2306)
- Completely eject the drawer of the reader
- Go to System / Maintenance → the life stream starts
- Inspect the inside compartment of the reader: carefully clean dust and dirt particles which may be present on the inner surface of the screen.



► Note: This mode can only be left by performing a hard shutdown, meaning that the power button needs to be pressed for at least 6 seconds until the device powers down completely. After restarting the device, the reader will perform a self-check and the main menu will appear.

8.2 Cleaning

In order to clean the device, use a damp cloth. If the dirt is persistent, rub the surface of the device with a cloth that has been moistened with 70-80% alcohol dissolvent. Aggressive cleaning agents such as acetone may damage reader components and should be avoided. If the inside of the device becomes contaminated, contact service.

For more persistent stains and for disinfecting the instrument, it is possible to clean the surface with a cloth dipped in 1% bleach (1% active chlorine) followed by wiping with water. The procedure can be repeated 2-3 times. It is also possible to use the 80% alcohol dissolvent to wipe off the remaining traces of bleach.

The test cassette holder should be cleaned using dust free swabs or appropriate cloth.

When cleaning the drawer, note that the moving surfaces are treated with silicone oil. Cleaning with solvent at these surfaces leads to a loss of lubrication. This can lead to increased wear and even to a stiff drawer.

8.3 Device Self-check

The Vertu TOUCH is a highly sensitive optical device for quantitative measurements. In order to check the status of the main mechanical, electronic and optical components of the instrument, a self-check is performed after the device has been switched on. In case of calibration failure, a warning message will be displayed.

If calibration fails, the Vertu TOUCH prevents further measurements but is still usable to review results or change settings. Contact VICAM's technical service team with any questions or difficulties during reader calibration or testing. The following conditions may contribute to reader signal changes:

- Contamination of the optical parts
- Electromagnetic interferences
- Temperature/Humidity changes
- Mechanical movements
- Wrong drawer

NOTE: Please make sure, that the original drawer is inserted (see chapter Unpacking and Set-Up Procedures).

8.4 Troubleshooting and Messages

Following table lists information or error messages which might pop up including potential mitigation measures:

Message on DISPLAY	Potential Root Cause	Possible User Action
"Barcode not found	No barcode is in the drawer.	
Check barcode on test card and retry" Err: 2001	Only one of the two method barcodes found. Barcode not readable	Check barcode card in the drawer and retry
"Invalid barcode / method." Err. 2002	Protocol incorrect (e.g. cassette barcode instead of method barcode inserted)	Check barcode card in the drawer and retry
"Test expired. Check expiry date of test" Err: 2003	Expiry date of test is exceeded.	Check Expiry Date of Test or Date on Device
"Test <-> cassette mismatch" Err. 2004 and Err. 2016	The chosen method does not correspond to the barcode on cassette (Product ID and/or Lot ID).	Insert cassette that corresponds to chosen method.
"No Cassette found" Err: 2006 and Err. 2010	Cassette size incorrect or no cassette inserted	Verify to have the correct cassette inserted
"Wrong cassette orientation" Err. 2007 and Err. 2017	Cassette facing the wrong direction	Flip Cassette by 180° and retry
"Device error" Err 2009 and Err. 1003	Failure at self-check mechanism	Reboot device or call if error message persists
"System error. Text: xx Number: yy Mode: zz" Err. 2000	Potential Hardware or Software Error	Reboot device or call service if error message persists
"Maintenance recommended" Err. 2011	Self-check values are in warning limit	Perform maintenance inside device

8.5 Technical Service Support

In case the instrument requires service by the manufacturer, the customer must contact VICAM. The customer will get all necessary information and instructions to send the device back for repair.

VICAM shall authorize the return by providing the customer with a Return Material Authorization (RMA) number which from this point on should be used as reference number on all correspondence pertaining to the repair of the device.

The customer is obliged to sign the "Declaration of Contamination Status" document which he obtains from the Service Team. A copy of the signed declaration must be sent prior to shipping to VICAM and the original document must be placed in the package with the returned device.

The device must be returned in the original packaging. If not available anymore, please inform VICAM.

Note: The corresponding device will be excluded from further processing if the customer does not supply VICAM with a filled and signed "Declaration of Contamination Status".

For additional information, support and technical service, please contact VICAM or your local distributor

Phone: 1-800-338-4381 or +1-508-482-4935

e-mail: techservice@vicam.com

VICAM reserves the right to change specifications at any time.

9.0 Technical Data

Dimensions and Weight of the Instrument

Dimensions	H / W / D: 150 x 150 x 150 mm (6 x 6 x 6 in)
Weight	Approx. 1.2 kg (2.6 lb)

Mechanical Data and Hardware Features

Test format dimensions	Determined by the drawer for the respective test
User interface	Interactive 10.9 cm (4.3 in.) touchscreen
Noise	< 10 db(A)
Connections	3 x USB, Ethernet
Memory capacity	Up to 99 test methods and up to 300 test results
Operating conditions	15–35 °C (59–95 °F), humidity < 70 %, not condensing
Transport conditions	-20 - to 50°C
Storage conditions	+15 to +40°C
IP-classification	IP10

Optics

Optical system	5 Mpix camera (8Bit)
Signal detection	Colorimetric
Colorimetric detection	Colloidal gold, colored latex beads, carbon particles, etc.
Measurement time	< 20 seconds
Surveillance	Internal reference check among solid standards

Power Requirements of the Instrument	
External power supply	Input: 100–240 V AC, 0.5 A, 50-60 Hz;
Output:	+12 V DC / 1.67 A

Optional Accessories

External printer	Dymo 450 Label Printer
Barcode reader	Model Zebra DS 2208
Printer labels	Dymo large address labels (2" x 4" or 101 mm x 54 mm)
Cleaning swabs	Techspray, Super-Tip Foam Swab, Product 2306

Waters" | VICAM.

Key Locations

Headquarters:

34 Maple Street Milford, MA 01757 USA Tel.: +1 800 338 4381 +1 508 482 4935 Fax: +1 508 482 4972

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