

BioSieve™ ToxiSmart FIA Reader

Dear BioSieve™ ToxiSmart FIA Reader User,

Thank you for choosing the BioSieve™ ToxiSmart FIA Reader! The Reader has the advantages of easy operation, Robust, reliable results, and simple maintenance. It can be used widely in many areas, such as hospital, medical center, clinic, pharmacy, laboratory, etc.

This User Manual applies to BioSieve™ ToxiSmart FIA Reader, it provides detailed descriptions of the Reader's characteristics, graphical operation steps and other relevant information for your convenience. Please read this User Manual carefully before you use your Reader and keep your User Manual in a safe place, you may want to refer it in the future.

Thank you again for choosing the BioSieve™ ToxiSmart FIA Reader.

Principle

The BioSieve™ ToxiSmart FIA Reader works with BioSieve™ FIA Test Kit as a system for measuring the concentration of designated analytes in human clinical specimens. The Reader is an immunofluorescence detection device that is based on photoelectric detection principle. With the fluorescence immunochromatography technology and tiny sample, the Reader gives reliable result(s) in just a few minutes, which is ideally suitable for professionals to make quick and correct decision at the point of care. It is intended for professional use outside the body (*in vitro* diagnostic use).

Intended Use

BioSieve™ ToxiSmart FIA Reader is a portable fluorescence instrument for *in vitro* diagnostic use only. The Reader is designed to perform *in vitro* diagnostic tests on clinical specimens. This Reader can be used in a laboratory or in a point-of-care setting.

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CHAPTER 1: UNDERSTANDING YOUR READER

Introduction

1. Dimensions: 4.90 inches (124.5 mm) x 2.85 inches (72.5 mm) x 1.57 inches (40 mm)
2. Weight: 0.36 lbs

Please check whether any component is missing or damaged against the list below after opening the package.

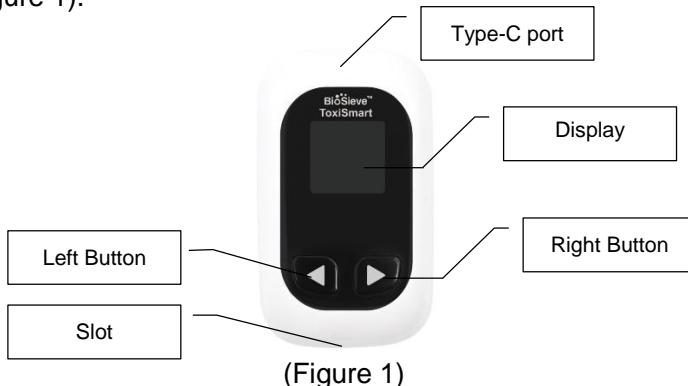
Note: If some parts are missing or damaged, please contact your Local Distributor or VivaChek Diagnostics Inc. USA immediately.

Components List

Number	Component	Quantity
1	BioSieve™ ToxiSmart FIA Reader	1
2	Type C & USB 2 in 1 cable	1
3	User's Manual	1
4	System quality control test device	1
5	Bluetooth printer (optional)	1

Structure

The actual appearance of Reader and accessories may vary with specific model (Figure 1).



Reader Display

Icon	What it means
S	Standard test mode
Q	Quick test mode
SQC	System Quality Control mode
Record	Memory
	Bluetooth
	Battery level
P	Printer

Reader Use and Precautions

- Keep your Reader in the temperature range of 14°F to 131°F (-10 to 50°C) and relative humidity range 10 to 90%.
- Reader will shut off by itself after 10 minutes of inactivity.
- Do not drop the Reader or get it wet. If you do drop the Reader or get it wet, check the Reader by running a quality control test.
- Do not use the Reader if it drops into water or other liquids or if water splashes on to it.
- Use only BioSieve™ FIA Test Kit with your Reader.
- Do not take the Reader apart. Taking the Reader apart will void the warranty.
- Refer to the **Caring and Maintenance** for details on cleaning the Reader.
- Keep the Reader and accessories parts out of reach of children.

Important Safety Information

- It is for *in vitro* diagnostic use by professionals only.
- Use the accessories provided by VivaChek with your BioSieve™ ToxiSmart FIA Reader. Do not use other accessories.
- Please read this User's Manual carefully before use and keep your User Manual in a safe place for referring it in the future.
- If the Reader emits peculiar smell, smoke or the liquid flows into the Reader, please turn off the power immediately and contact with your local distributor or VivaChek Diagnostics Inc. USA Technical Support.
- Please comply with all the national standards for health and safety. This includes (but not limited to) protective cover, and gloves when operating and maintaining the Reader.

- If the Reader is used in a manner not specified by the manufacturer, the protection provided by the Reader will be impaired.



Potential Biohazard

All products or objects, which come in contact with blood/urine/ respiratory secretions, even after cleaning, should be handled as if capable of transmitting viral disease.



Caution

It is for professional use only. Do not use the test kit out of the expiration date. Do not use if the Reader is reporting an error condition that cannot be corrected.

Electromagnetic Compatibility

Caution

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning

- Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. The device is to be used in professional healthcare facility environment.
- This equipment has been designed and tested to Group 1 Class B, in a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- It is forbidden to use the equipment near strong radiation source (such as unshielded RF source), otherwise it may interfere with the normal operation of the equipment.

Electromagnetic emission

Launch test	Compliance
IEC/EN 55011 Conducted emission	Group 1 Class B
IEC/EN 55011 Radiation emission	
IEC/EN 61000-3-2 Harmonic emission	Not applicable
IEC/EN 61000-3-3 Voltage fluctuation / flicker emission	Pass

Applicable EMC Standards

- IEC 61326-1: 2020/ EN61326-1:2021: Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements.
- IEC 61326-2-6: 2020/ EN 61326-2-6: 2021: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment.

Precautions for Instrument Cybersecurity

The reader uses Bluetooth for wireless communication. It can connect matching printer and mobile applications.

The following measures ensure information security:

- The reader uses the latest Bluetooth protocol version. The new version usually includes fixes for security vulnerabilities that existed in previous versions, improving connection security.
- Set a password to protect the Bluetooth connection. Ensure that communication between devices is encrypted to prevent unauthorized access and data leakage.
- Implement two-way authentication during data transmission only authenticated reader and BT APP can transmit data between each other.
- The Bluetooth function is disabled by default when the reader is turned on.

Although the reader has security features, communication security cannot always be guaranteed.

Users should be aware of the following precautions when using it:

- Control Bluetooth visibility: In order to protect personal privacy, it is recommended to set the Bluetooth device to the "invisible" state to avoid unauthorized devices connecting with your device.
- Don't connect unfamiliar devices at will: only connect devices that you know and trust. Connecting unfamiliar devices may lead to data leakage or spread of malware.
- Avoid connecting to unsafe public devices: Avoid connecting to unknown or untrusted public Bluetooth devices, especially in public places such as coffee shops, libraries or airports.
- Turn off Bluetooth after the connection is completed: When the Bluetooth function is not needed, it should be turned off to prevent unauthorized access or attacks.
- Clear the pairing list regularly: delete the pairing with the reader you no longer use or trust to reduce security risks.
- Pay attention to the possible security risks of Bluetooth: Bluetooth signals can be pierced through the wall, so nearby attackers may eavesdrop or interfere with your Bluetooth communication. In sensitive environments, it is better to avoid using Bluetooth devices or take other security measures

to protect communication.

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the extremity, with 0 mm separation. SAR compliance for body-worn operating configurations is limited to the specific configurations tested for this filing. Body-worn operations are restricted to belt-clips, holsters or similar accessories that have no metallic component in the assembly and must provide at least 15mm separation between the device and the body of the user. End-users must be informed of the body-worn operating requirements for satisfying RF exposure compliance. The highest reported SAR for body-worn accessory use conditions is 0.004W/kg.

FCC Regulations

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference.

CHAPTER 2: INSTALLATION AND USE CONDITIONS

Installation

Please use the Reader under the proper conditions.

Step 1: Place the Reader on a stable and level surface. The unit is portable and can be moved to a suitable location for testing. Avoid direct sunlight.

Step 2: Press the right button “▶” for 3 seconds to turn on the Reader.

Use Conditions

Positioning and Placement Requirements

(1) The Reader should be placed on a stable and level surface, and in an indoor environment free of dust, direct sunlight or corrosive gases. The surface must be able to sustain a weight of at least 0.36 lbs (165 g)

(2) The Reader should be placed in a well-ventilated place (without strong vibration source and electromagnetic fields around). There should be at least 3.93 Inches (10 cm) space around the Reader to ensure the necessary space for operation and maintenance.

Storage and Transport Conditions

(1) Storage Conditions

Storage temperature: 14°F ~ 131°F (-10 ~ 50°C)

Relative humidity: 10 to 90%

Atmospheric pressure: 86 to 106 kPa

(2) Transport Conditions

Avoid moisture, impact and severe vibration.

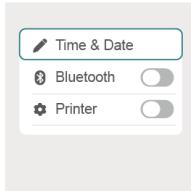
CHAPTER 3: SETTING UP YOUR READER

Before using the Reader for the first time, you should check and update your Reader settings.

Setting

Press the right button “▶” for 3 seconds to turn on the Reader. Press the left button “◀” for 3 seconds to enter the "Menu".

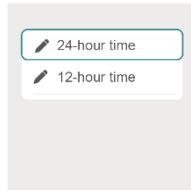
Press the right button “▶” to select "Setting", and press the left button “◀” to enter the interface of "Setting" (Figure 2).



(Figure 2)

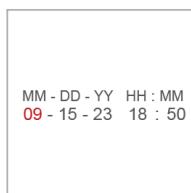
Set the Time and Date

Press the left button “◀” to enter the interface (Figure 3). Press the right button “▶” to select 24-hour time or 12-hour time format.



(Figure 3)

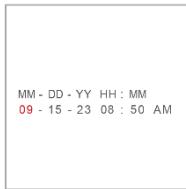
Press the left button “◀” to enter the 24-hour time format (Figure 4).



(Figure 4)

Press the left button “◀” to adjust the digit. Press the right button “▶” to move to the next digit. Repeat the above action until the date and time setting is completed. Press the left button “◀” for 3 seconds to keep the settings.

Press the left button “◀” to enter the 12-hour time format (Figure 5).

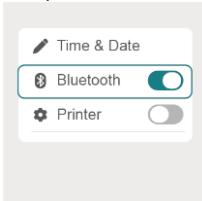


(Figure 5)

Press the left button “◀” to adjust the digit. Press the right button “▶” to move to the next digit. Repeat the above action until the date and time setting is completed. Press the left button “◀” for 3 seconds to keep the settings.

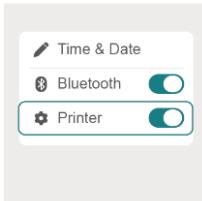
Bluetooth Pinter Connection

Press the right button “▶” to select "Bluetooth", and press the left button “◀” to turn on the Bluetooth (Figure 6).



(Figure 6)

Press the right button “▶” to select "Printer", and press the left button “◀” to connect the printer (Figure 7).



(Figure 7)

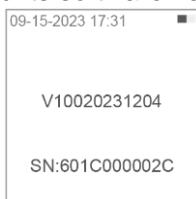
If the function of Bluetooth and printer is turned on, the interface will show the icons “” and “” (Figure 8). When the test is finished, press the right button “▶” and the left button “◀” at the same time to print the test result.



(Figure 8)

About

Press the left button “◀” to enter the interface (Figure 9). You can check the serial number of the reader and its software version.



(Figure 9)

CHAPTER 4: OPERATION INSTRUCTIONS

Set up your Reader correctly and have all the materials you will need ready before you begin testing. It includes your BioSieve™ ToxiSmart FIA Reader and BioSieve™ FIA Test Kit.

Start

Press the right button “▶” for 3 seconds to turn on the Reader (Figure 10).



(Figure 10)

Choose Test Mode

Standard Test Mode

Press the left button “◀” twice to change the test mode to standard test. When the test mode is changed successfully, the Reader will display “S” in the right corner (Figure 11).



(Figure 11)

In the standard test mode, you need to insert the test device immediately after adding the sample, and the Reader will display the test result when the countdown is finished.

Quick Test Mode

Press the left button “◀” twice to change the test mode to quick test. When the test mode is changed successfully, the Reader will display “Q” in the right corner (Figure 12).



(Figure 12)

In the quick test mode, you need to insert the test device after the reaction

time is completed, and the Reader will display the test result in a few seconds.

System Quality Control Mode

Press the left button “◀” twice to change the test mode to system quality control test. When the test mode is changed successfully, the Reader will display “SQC” in the right corner (Figure 13).

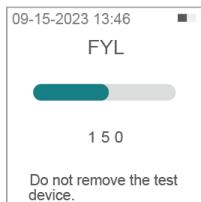


(Figure 13)

Standard Test

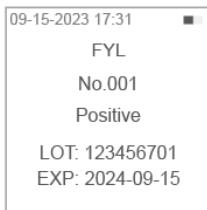
Step 1: Take the test device out of the foil pouch and place it on a clean, dust-free and flat surface. Refer to the package insert to add the sample.

Step 2: Insert the test device into the slot immediately. The Reader will start a countdown (Figure 14)



(Figure 14)

Step 3: The Reader will display the test result after the countdown is finished (Figure 15). Do not remove the test device when testing is being performed. The count down time is the pre-determined incubation time of the item you test. Please wait for the pre-determined incubation time for each test.



(Figure 15)

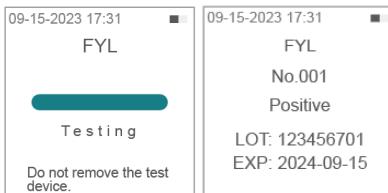
Quick Test

Step 1: Take the test device out of the foil pouch and place it on a clean,

dust-free and flat surface.

Step 2: Refer to the package insert to add the sample wait for the pre-determined incubation time.

Step 3: Insert the test device into the slot after the pre-determined incubation time. The Reader will display the test result in a few seconds (Figure 16, 17). Do not remove the test device when testing is being performed.



(Figure 16, 17)

QC Test

Quality Control Test

Each lab should use its own standard and procedures for performance. You should perform a control test: Control test for the following conditions.

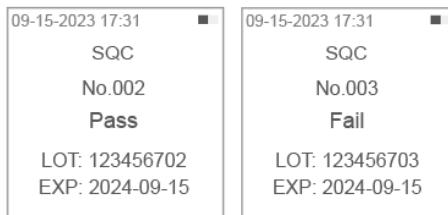
- (1) Each new lot of test received.
- (2) Each new shipment.
- (3) Each new operator.
- (4) Monthly to determine that tests are working properly.
- (5) Test results seem inaccurate.

System Quality Control Test

System quality control by testing the system quality control test device ensures the normal operation of the circuit and optical path.

Step 1: Insert the SQC test device into the slot.

Step 2: The Reader will display the SQC test result in a few seconds (Figure 18, 19). Do not remove the SQC test device when testing. If the Reader works normally, the interface will display "Pass". Otherwise, it will display "Fail".



(Figure 18, 19)

Viewing Your Test Results

Press the left button "◀" for 3 seconds to enter the "Menu".

Test Record

Press the left button “◀” to enter the interface of "Test Record" (Figure 20).



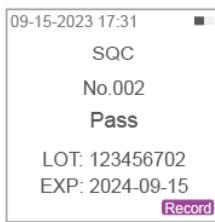
(Figure 20)

Press the “◀” or “▶” button to view the previous or next test results.

SQC Record

Press the right button “▶” to select “SQC Record” in the “Menu” interface.

Press the left button “◀” to enter the interface of "SQC Record" (Figure 21) to read the detail information.



(Figure 21)

Press the “◀” or “▶” button to view the previous or next SQC test results.

Print Record

Press the right button “▶” and the left button “◀” at the same time to print the current record.

Note: Please ensure the functions of Bluetooth and printer are turned on at first.

Turning Off the Reader

Press the right button “▶” for 3 seconds to shut down the Reader.

CHAPTER 5: MAINTENANCE AND PRECAUTIONS

Maintenance

The Reader includes a rechargeable 3.7 Volt Lithium Ion battery. The battery will automatically charge while plugged into AC power. The Reader will automatically switch to battery power when AC power is not available.

Charging Instructions

Indications on the Reader displayed for when the Reader is properly connected, actively charging, and adequately recharged:

When the Reader is properly connected and actively charging, the Reader displays the battery icon and repeats the charging status from through , , . When the Reader is fully charged, the Reader displays the battery icon .

Recommendations for Recharging Battery:

The Reader battery may be charged using one of the following options:

- Type C & USB 2 in 1 cable (computer charging)
- Type C & USB 2 in 1 cable with the AC adapter (wall charging)

To optimize battery life, it is recommended to recharge the battery when the critical battery level (running out of battery) () appears. When using the USB port on your computer to recharge the battery, be sure the computer is turned on and not in standby mode. If the Reader is not recharged, try using another USB port on your computer. Contact seller to confirm whether the AC adapter meets following specifications before purchasing it:

Input: 100-240V~, 50/60Hz, 0.2A Max; Output: 5.0V=, 1.0A;

Standard ANSI/AAMI ES

Warnings for Recharging Battery:

- Do not disassemble the Reader and take battery out for recharging.
- Do not use the Type C & USB 2 in 1 cable, AC adapter or Reader if it is damaged, discolored or deformed.
- Do not put the Reader on the thermally insulating materials such as clothing, carpet, blanket, or plastic surface while recharging.
- Do not recharge the Reader in outdoors, sunlight, a wet area or a very hot area.
- Do not place the Reader in environmental temperature above 131°F (50°C), such as outdoors for recharging to avoid overheating, smoking, and catching fire; the Reader can be safely recharged at normal indoor temperatures.

Recommended Procedures for Recharging Battery:

Step 1): Select a recharging method from the options below:

Option A: Using a Type C & USB 2 in 1 cable by connecting computer, the

computer should be turned on during recharging;

Option B: Using a Type C & USB 2 in 1 cable by connecting AC adapter, the AC adapter should meet the specifications in the section “Recommendations for Recharging Battery” in the User Manual.

Step 2): Check and ensure the contents in the section “Recommendations for Recharging Battery” are followed.

Step 3): Check and ensure that the applicable contents in the section “Warnings for Recharging Battery” are followed.

Step 4): After connecting the Reader, check that the main button flashes with green color during recharging.

Step 5): Check that the Reader displays the battery icon and repeats the recharging status from through , , ;

Step 6): Check whether the Reader displays battery icon , this means that the battery is fully charged. If not, please continue to recharge.

Step 7): Recommend recharging the Reader for three hours.

Step 8): Remove the Type C & USB 2 in 1 cable from the Reader after recharging.

Step 9): Your Reader is now ready to use.

Cleaning

(1) Please keep BioSieve™ ToxiSmart FIA Reader clean. There is no other special maintenance required.

(2) Do not disassemble the Reader. The internal hardware and software of BioSieve™ ToxiSmart FIA Reader can only be repaired, replaced or upgraded by the manufacturer. Please contact your local distributor or Vivachek Diagnostics inc, USA technical support.

(3) To avoid the possible electrical shock, please turn off and unplug the cable prior to cleaning. Do not clean the ports on the Reader.

(4) Do not immerse or spray the Reader in liquid.

Maintenance Method

Your BioSieve™ ToxiSmart FIA Reader does not require special maintenance or cleaning. The purpose of cleaning step is to remove the potential dirt and dust particles and make sure that the surface is clean for the next disinfection step. The purpose of disinfection step is to disinfect the microorganisms on the whole surface of the Reader.

External cleaning and maintenance method: A cloth dampened with 70% alcohol can be used to wipe the outside of the Reader. Do not use strong bleach ($\geq 0.5\%$ bleach solution), because oxidizing substances and solvents may damage the Reader's parts and touch screen. Take care to avoid getting liquids, dirt, blood or buffer into the Reader through the slot or type C port. Wipe the external surfaces only. Use only Clorox™ Healthcare Bleach

Germicidal Wipes (EPA Registration No. 67619-12), which has been approved for use with the BioSieve™ ToxiSmart FIA Reader.

Maintenance Plan

The meter should be cleaned and disinfected a minimum of once per week.

Precautions for Reader Use

1. Please use the Reader in strict accordance with the User's Manual provided by the manufacturer, otherwise, the warranty provided by the Reader will be void.
2. Reader data preservation and recovery procedures: the Reader can save the user test records. The test results during the normal use of the user will be automatically saved to the Reader in the form of records. The Reader can save up to 999 records. The saved data can be recovered automatically after power failure and will not be lost.

CHAPTER 6: TECHNICAL INFORMATION

System Specifications

Feature	Specification
Principle	Fluorescence Immunoassay
Dimensions	4.90 inches (124.5 mm) x 2.85 inches (72.5 mm) x 1.57 inches (40 mm)
Weight	0.36 lbs (165 g)
Display size	1.54 Inches LCD
Power source	Rechargeable 3.7 Volt Lithium Ion battery
Charging current	300mA, = Direct current
Operating temperature	50°F ~ 86°F (10 ~ 30°C)
Storage temperature	14°F ~ 131°F (-10 ~ 50°C)
Operating humidity	10 ~ 90% (non-condensing)
Storage humidity	10 ~ 90% (non-condensing)
Atmospheric pressure	86 ~ 106 kPa
Bluetooth	BLE 5.0
Memory	Up to 999 test results

Limitations

- Please use the Reader strictly according to the User's Manual provided by manufacturer.
- Do not insert anything else into the slot except the test device.
- The tested urine samples are potentially contagious. Please take protective measures such as wear protective gloves to avoid skin contact with the urine sample.
- The Reader must be disposed of in a safe and compliant manner. Applicable Federal, State and Local regulatory requirements should be followed to ensure the Reader is not disposed of as municipal waste. If you are unsure on the proper methods for disposal, contact a certified waste management company for guidance.
- Dispose the tested samples and materials carefully. Treat them as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing them.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the BioSieve™ POCT system.

Symbols	Explanation
	Consult instructions for use or consult electronic instructions for use
	Manufacturer
	Temperature limit
	Humidity limitation
	Batch code
	Catalogue number
	Model number
	Serial Number
	Caution, consult accompanying documents
	<i>In vitro</i> diagnostic medical device
	Dispose items according to local relevant laws regarding disposal and recycle
	Keep away from sunlight and heat
	Biological Hazard

Warranty

Please complete the warranty card that came with the product and mail it to your distributor to register your purchase.

If the Reader fails to work for any reason other than obvious abuse within the first three (3) years from purchase, we will repair or replace it with a new one free of charge. For your records, also write the purchase date of your product here.

Date of purchase: _____

Note:

This warranty applies only to the Reader in the original purchase, and does not apply to the battery supplied with the Reader.

Warranty Card

Please complete this warranty card to validate your warranty. Mail it within 30 days of purchase to your local distributor.

If the Reader does not work for any reason other than obvious abuse in the first 3 years after purchase, we will repair or replace it with a new or equivalent Reader free of charge.

Date of purchase _____ / _____ / _____

Reader serial number (e.g. 601A0000001) _____

Purchased from _____

Telephone number _____

Email address _____

Suggestion/Comments _____



VivaChek Biotech (Hangzhou) Co., Ltd.

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