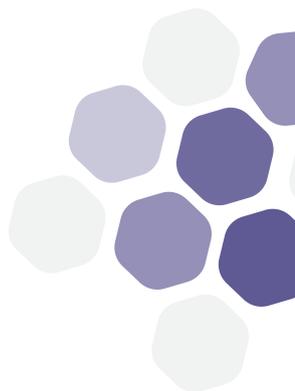


# BioSieve™ ToxiSmart FIA Reader

## Fluorescence Immunoassay

# User's Manual



Rx Only

# 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 in a laboratory or in a point of care setting.

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 urine 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.

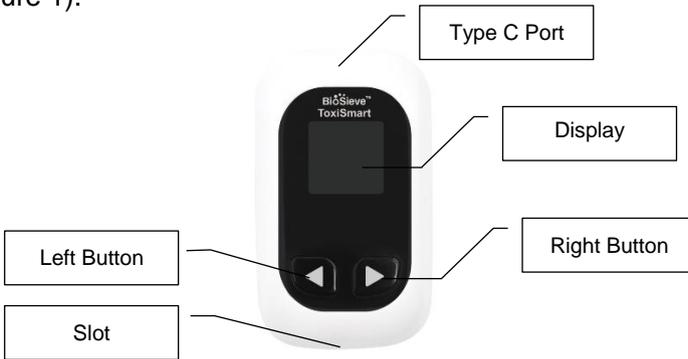
**Note:** If some parts are missing or damaged, please contact your Local Distributor or VivaChek Diagnostics Inc. USA immediately. The contact information for VivaChek Diagnostics Inc. USA is shown on the last page in this User Manual.

## 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).



(Figure 1)

# Reader Display

Icon	What it means
	Standard test mode
	Quick test mode
	System Quality Control mode
	Memory
	Bluetooth
	Battery level
	Printer
	Illegal devices attempting to connect

## A List for Interface That Is Expected to Receive and/or Send Testing Results:

Interface Name	Functionality	Incoming, Outgoing, or Both	Destination End-point
BLE Module	Testing result transmission	If user chooses to connect the printer with reader: Outgoing; If user does not buy printer or not to choose to connect printer with reader: Neither incoming nor outgoing.	If user chooses to connect the printer with reader: Manufacturer supplied (assigned) printer; If user does not buy printer or not to choose to connect printer with reader: No destination end-point.

## SBOM Information

The BioSieve™ ToxiSmart FIA Reader is controlled by embedded firmware, which is proprietary and was developed internally. The firmware does not comprise or incorporate any commercial software, open-source software, third party components, or off-the-shelf software components.

The Software Bill of Materials (SBOM) for BioSieve™ ToxiSmart FIA Reader's Firmware includes Hardware Abstraction Layer, Service Domain, Application Layer and Cybersecurity Control components. The firmware is required to be actively supported and maintained once the readers are manufactured and distributed in accordance with our quality system procedures and forms.

If user requests more information regarding the SBOM please contact us using the contact information shown on the user manual or outer box.

## Reader Use and Precautions

- Keep your Reader in the temperature range of 50°F ~ 86°F (10 ~ 30°C) and relative humidity range 10 to 90%.
- Without inserting a test device into the reader, the 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 may be impaired.



### Potential Biohazard

All products or components, which come in contact with blood, urine, or respiratory samples, 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 Reader is to be used in professional healthcare facility environment.
- This equipment has been designed and tested to Group 1 Class A, 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 signals for those RF emitters, like MRI, diathermy, electrocautery and Wireless power transfer (WPT), otherwise it may interfere with the normal operation of the equipment.
- The reader should be used no closer than 5 m (200 inches) to the printers specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- The reader is MR Unsafe device and should remain outside the MRI scanner room.

- It is recommended that Operator should not use the device and check below items if the functions or performance of the device may be lost or degraded due to electromagnetic disturbances:

Please check whether above cautions and warnings regarding electromagnetic compatibility in this user manual are followed.

Please try to increase distance between the device and source of the interference if it is suspected that function or performance is affected by strong electromagnetic interference.

Portable RF communications equipment (such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to this device.

You can contact the distributor for technical support using the contact information listed in the user manual or outer box.

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### Electromagnetic emission

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#### Launch test

#### Compliance

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CISPR 11  
Conducted emission

Group 1 Class A

---

CISPR 11  
Radiation emission

---

IEC/EN 61000-3-2  
Harmonic emission

Not applicable

---

## **Applicable EMC Standards**

- IEC 60601-1-2:2014+A1:2020
- EN 60601-1-2:2015+A1:2021
- IEC TS 60601-4-2:2024

## **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 A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference Professional medical institution environment. 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.

## **Precautions for Instrument Cybersecurity**

The Reader has a type C USB port and Bluetooth. The Reader uses

Bluetooth for wireless communication. The Bluetooth module on the Reader is only used for connecting to a printer. The Bluetooth connected printer is only used for printing the test results. The primary display of test results is with the Reader. Use of a printer is optional by the user. The Reader does not rely on networking or network connections to perform its intended use. The type C USB port is disabled except for recharging the battery.

The following measures ensure information security:

- The Reader is designed such that it does not connect to the cloud, internet or cellular network.
- The Reader is designed such that it can only be selected to connect with the manufacturer provided printer for printing test result only (this is the point-to-point communication) or selected to be not connected.
- BLE protocol is implemented, authentication is used for test result transmission. And implement communication authentication by using BLE between reader and printer for authentication and integrity of test results transmission.
- If external device attempts to connect to the Reader by BLE and does not have the correct password for identity authentication, then the Reader will regard this as an attempt from external device and reject the connection attempt.
- The type C USB port is disabled except for recharging the battery.
- Please follow the cybersecurity instructions for details in Cybersecurity Instruction Document.

Although the reader has security features, users should be aware of the following precautions when using it:

- Control Bluetooth visibility: To protect personal privacy, it is recommended to set the Bluetooth to the "Off" state to avoid unauthorized devices connecting with your Reader.
- Connect with the Bluetooth printer with the manufacturer supplied printer only. Any attempt to connect to the Reader other than the assigned printer provided by manufacturer will be rejected along with a warning.
- When the Bluetooth function is not needed, it can be turned off to prevent unauthorized connection.
- Physical distance between reader and manufactured supplied (assigned) printer for connection recommended to be within five meters if you select to use and connect the printer with reader.
- 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.
- Please contact the distributor for any questions regarding cybersecurity

control or cybersecurity vulnerability by calling toll-free telephone or sending us email listed in the user manual or outer box.

## **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: Room temperature

Relative humidity: 10 to 90%

Atmospheric pressure

##### **(2) Transport Conditions**

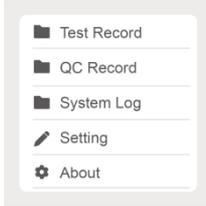
Avoid moisture, impact and severe vibration.

# CHAPTER 3: SETTING UP YOUR READER

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

## System Log

Press the right button “▶” for 5 seconds to turn on the Reader. Press the left button “◀” for 3 seconds to enter into the "Menu" (Figure 2).



(Figure 2)

Press the right button “▶” to select "System Log", and press the left button “◀” to enter into the interface of " System Log " (Figure 3).



(Figure 3)

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

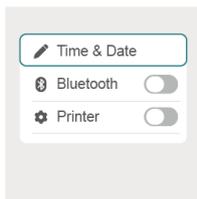
If there are illegal devices attempting to connect the Reader, the interface will show the icon “!” as a notification to the user (Figure 4). The Reader will create, store and archive log file information in Read-Only Memory in MCU when an external device attempts to connect and when the reader finds the identity authentication fails.



(Figure 4)

## Setting

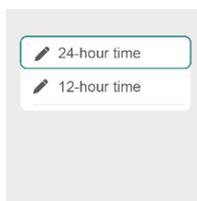
Press the right button “▶” to select "Setting", and press the left button “◀” to enter into the interface of "Setting" (Figure 5).



(Figure 5)

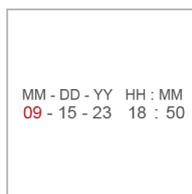
## Set the Time and Date

Press the left button “◀” to enter into the interface (Figure 6). Press the right button “▶” to select 24-hour time or 12-hour time format.



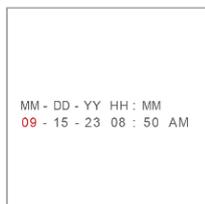
(Figure 6)

Press the left button “◀” to enter into the 24-hour time format (Figure 7).



(Figure 7)

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 into the 12-hour time format (Figure 8).



(Figure 8)

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.

**Note:** Press the left button “◀” for 3 seconds to return to the previous interface.

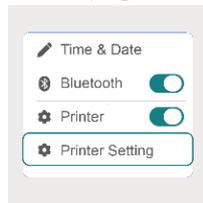
### Bluetooth Pinter Connection

Press the right button “▶” to select "Bluetooth", and press the left button “◀” to turn on the Bluetooth (Figure 9).



(Figure 9)

Press the right button “▶” to select "Printer", and press the left button “◀” to connect the printer. The function of "Printer" is turned on, the "Printer Setting" will appear on the interface (Figure 10).



(Figure 10)

**Note:** The printer cannot be connected unless the "Bluetooth" is turned on beforehand.

Press the right button “▶” to select "Printer Setting", and press the left button “◀” to enter into the interface (Figure 11).



(Figure 11)

Based on the last four digits of the printer, press the left button “◀” to adjust the digit. Press the right button “▶” to move to the next digit. Repeat the above action until the setting is completed. Press the left button “◀” for 3 seconds to keep the settings.

**Note:** If the Reader is matched with one printer. After the Reader is

successfully connected to the printer, last four digits of the connected printer model are displayed on the interface.

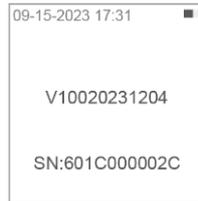
If the Reader's Bluetooth and printer are turned on, the interface will show the icons "Bluetooth" and "P" (Figure 12). When the test is finished, press the right button "▶" and the left button "◀" at the same time to print the test result.



(Figure 12)

## About

Press the left button "◀" to enter into the interface (Figure 13). You can check the serial number of the reader and its software version.



(Figure 13)

## 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 14).



(Figure 14)

### 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 bottom right corner (Figure 15).



(Figure 15)

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 bottom right corner (Figure 16).



(Figure 16)

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 bottom right corner (Figure 17).

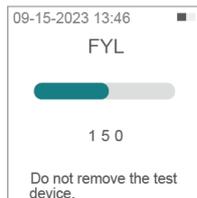


(Figure 17)

### Standard Test

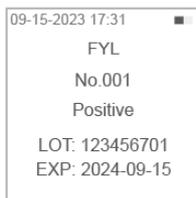
Step 1: Take the test device out of the foil pouch and place it on a clean, dust-free and flat surface. Refer to the package insert to add the sample.

Step 2: Insert the test device into the slot immediately. The Reader will start a countdown (Figure 18).



(Figure 18)

Step 3: The Reader will display the test result after the countdown is finished (Figure 19). Do not remove the test device when testing is being performed. The countdown time is the pre-determined incubation time of the item you test. Please wait for the pre-determined incubation time for each test.



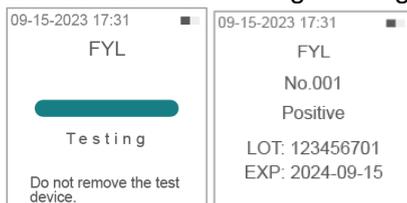
(Figure 19)

## 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 and 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 (Figures 20, 21). Do not remove the test device when testing is being performed.



(Figures 20, 21)

## QC Test

### Quality Control Test

*User should follow federal, state and local guidelines for testing quality control materials.*

Each lab should use its own standard and procedure for performance.

You should perform a control test: Control test for the following conditions.

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

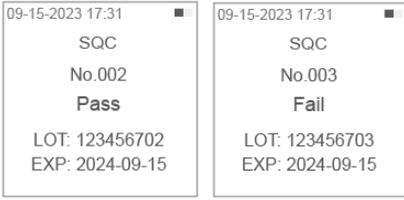
### System Quality Control Test

System quality control by testing the 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 (Figures 22, 23). Do not remove the SQC test device when testing. If the

Reader works normally, the interface will display “Pass”. Otherwise, it will display “Fail”.



(Figures 22, 23)

## Viewing Your Test Results

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

### Test Record

Press the left button “◀” to enter into the interface of "Test Record" (Figure 24).



(Figure 24)

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 into the interface of "SQC Record" (Figure 25) to read the detailed information.



(Figure 25)

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 turn off 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 battery is not recharged.

## 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 $\overline{=}$ , 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 86°F (30°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): Check that the Reader displays the battery icon and repeats the recharging status from through , , ;

Step 5): Check whether the Reader displays battery icon , this means that the battery is fully charged. If not, please continue to recharge.

Step 6): Recommend recharging the Reader for three hours.

Step 7): Remove the Type C & USB 2 in 1 cable from the Reader after recharging.

Step 8): 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 for 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 Reader should be cleaned and disinfected a minimum of once per week.

## **Precautions for Reader Use**

1. Please use the Reader in accordance with the User's Manual provided by the manufacturer.
2. Reader data preservation and recovery procedures: The Reader can save the user test records. The test results will be automatically saved in the Reader's in the memory. 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 Immunochromatography
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	Room temperature
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 carefully 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
	Unique device identifier
	Magnetic Resonance unsafe
Rx only	For prescription use only

# 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 \_\_\_\_\_

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Toll Free No.: (888) 860-3894

Our service time is Monday-Friday, 8:00AM-5:00PM, Eastern Standard Time.



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