

# Druglizer LE5 Drug Tester User Manual

---



## ***Disclaimer – External Documents note to reader***

The system is intended to be used by a trained professional to provide a first line screen. A positive response will require confirmation by a laboratory-based reference assay like Gas chromatography – Mass Spectrometry (GCMS) or Liquid Chromatography – Mass Spectrometry (LC-MSMS). Neither the manufacturer, the distributor, nor the owner accepts liability or responsibility due to any action or claim arising from the reading produced by this instrument, whether used correctly or incorrectly.

## Contents

<b>1</b>	<b>INTRODUCTION .....</b>	<b>3</b>
<b>2</b>	<b>TEST PRINCIPLE .....</b>	<b>3</b>
<b>3</b>	<b>MATERIALS PROVIDED .....</b>	<b>4</b>
<b>4</b>	<b>WARNINGS AND PRECAUTIONS .....</b>	<b>4</b>
<b>5</b>	<b>FUNCTIONAL FEATURES .....</b>	<b>6</b>
<b>6</b>	<b>MENU AND NAVIGATION .....</b>	<b>7</b>
<b>7</b>	<b>BATTERY CARE AND CHARGING.....</b>	<b>7</b>
<b>8</b>	<b>PRINTING AND BLUETOOTH.....</b>	<b>8</b>
<b>9</b>	<b>PERFORMING A TEST.....</b>	<b>9</b>
<b>10</b>	<b>INTERPRETATION OF RESULTS.....</b>	<b>12</b>
<b>11</b>	<b>TEST RECORDS .....</b>	<b>13</b>
<b>12</b>	<b>SERVICE LIFE .....</b>	<b>13</b>
	12.1 Calibration alerts.....	13
	12.2 Replacing sample module .....	14
<b>13</b>	<b>TECHNICAL SPECIFICATIONS .....</b>	<b>15</b>
<b>14</b>	<b>ALCOCONNECT.....</b>	<b>15</b>

## 1 INTRODUCTION

The Druglizer LE5 Drug Testing System is for the rapid oral fluid screening of drugs of abuse. The system incorporates a Druglizer LE5 Drug Tester Cartridge (Druglizer LE5 Cartridge), a Druglizer Oral Fluid Collector and a Druglizer LE5 Drug Tester instrument (Druglizer LE5, purchased separately). The system is intended to be used by a trained professional to provide a first line screen. A positive result displaying 'Unconfirmed' on-screen will require confirmation by a laboratory-based reference assay like Gas chromatography – Mass Spectrometry (GCMS) or Liquid Chromatography Mass Spectrometry (LCMS).

This document must be read carefully before using the Druglizer LE5 Drug Testing System and Certified Operator Training provided by Alcolizer Technology must be completed before using the Druglizer LE5 Drug Testing System. Keep the user manual available for the life of the instrument and ensure operators have access to the user manual at all times. You must always hand the user manual over to the subsequent instrument owner or user.

### WARNING

- Only human oral fluid should be used.
- Results on the Druglizer LE5 are preliminary qualitative analytical test results. A result displaying 'Unconfirmed' on-screen will require confirmation by a laboratory-based reference assay.
- The presumptive presence of drugs is not a measure of impairment.
- A negative result may not necessary indicate a drug free sample. Drugs may be present below the stated cut off.
- Foods/medicines or preclinical errors may result in false results.

The Druglizer LE5 must be stored at a temperature between  $-10^{\circ}\text{C}$  and  $+60^{\circ}\text{C}$ . Conduct drug screening tests at a temperature between  $+5^{\circ}\text{C}$  and  $+35^{\circ}\text{C}$ .

### **NOTE**

*This User Manual is applicable to the Druglizer LE5 with main module firmware version RN-1.5.0 and drug test module or later*

## 2 TEST PRINCIPLE

The Druglizer LE5 Drug Testing System is based on a competitive lateral flow immunoassay technique where drug molecules that may be present in the oral fluid sample compete with the same drug attached to the nitrocellulose wicking membrane, for limited binding sites on tagged drug specific antibodies.

The antibodies are tagged with gold colloids to produce a conjugate with a red colour. During testing, an oral fluid sample is absorbed onto the oral fluid collector pad. Chemicals react with the saliva to remove sample interferences and a portion of this sample wicks onto the

conjugate pad where drugs in the sample react with tagged antibody specific for that drug. The sample continues to wick by capillary forces along the nitrocellulose membrane, onto which is attached the same drug of interest. If no drug is present in the oral fluid sample the tagged antibody can bind to the drug bound to the nitrocellulose and a red line is produced.

If drugs are present in the oral fluid sample at concentrations greater than the cut-off concentration, the tagged antibody sites will be saturated with the drug and will not be able to bind to the nitrocellulose bound drug, hence no result is produced. As the drug concentration in the sample increases the colour intensity of the test line decreases. The test strip is not intended to be viewed visually rather it is intended to be interrogated by a meter. The instrument uses a sophisticated algorithm to determine the result.

### **3 MATERIALS PROVIDED**

The Druglizer LE5 is supplied with the following:

- Druglizer LE5 main module.
- Druglizer LE5 drug test module.
- USB cable.
- Battery Chargers (240VAC and 12VDC vehicle).
- Silicon protective cover, cartridge plug and wrist strap.
- Soft shoulder bag or hard plastic carry case (optional).
- Bluetooth printer (optional).

Updated user Manual and Alcoconnect can be downloaded from the <https://www.alcolizer.com/software-updates/>

Cartridges are not included with the purchase of an instrument. Cartridges are sold separately in cartons of 25 tests.

### **4 WARNINGS AND PRECAUTIONS**

The Druglizer LE5 has been manufactured and tested according to accepted technical principles. However, improper use may still lead to measuring errors and misinterpretations and the precautions should be observed:

- For professional use only.
- Always store instrument with Cartridge plug when not in use.
- Always transport the instrument in the carry case or bag.
- Always check the battery levels before use and recharge the instrument if necessary.
- Avoid storage Druglizer LE5 main module at low temperatures (< 0°C).

Precautions when working with Druglizer LE5 Cartridges:

- If storing pouches in a fridge, allow the pouch environment to reach room temperature (+15 to +30°C) before use.
- Do not open pouch until just prior to use.
- Do not utilise a pouch if it is damaged or has been tampered with.
- Do not use contents after expiration date.
- Pouch contents are for single use only.
- Take precautions with oral fluid.
- Dispose of as part of your non-recyclable waste and as per local waste requirements.
- DO NOT insert the Oral Fluid Collector into the Cartridge until the Collector indicator changes to an even blue colour that is consistent from edge to edge.

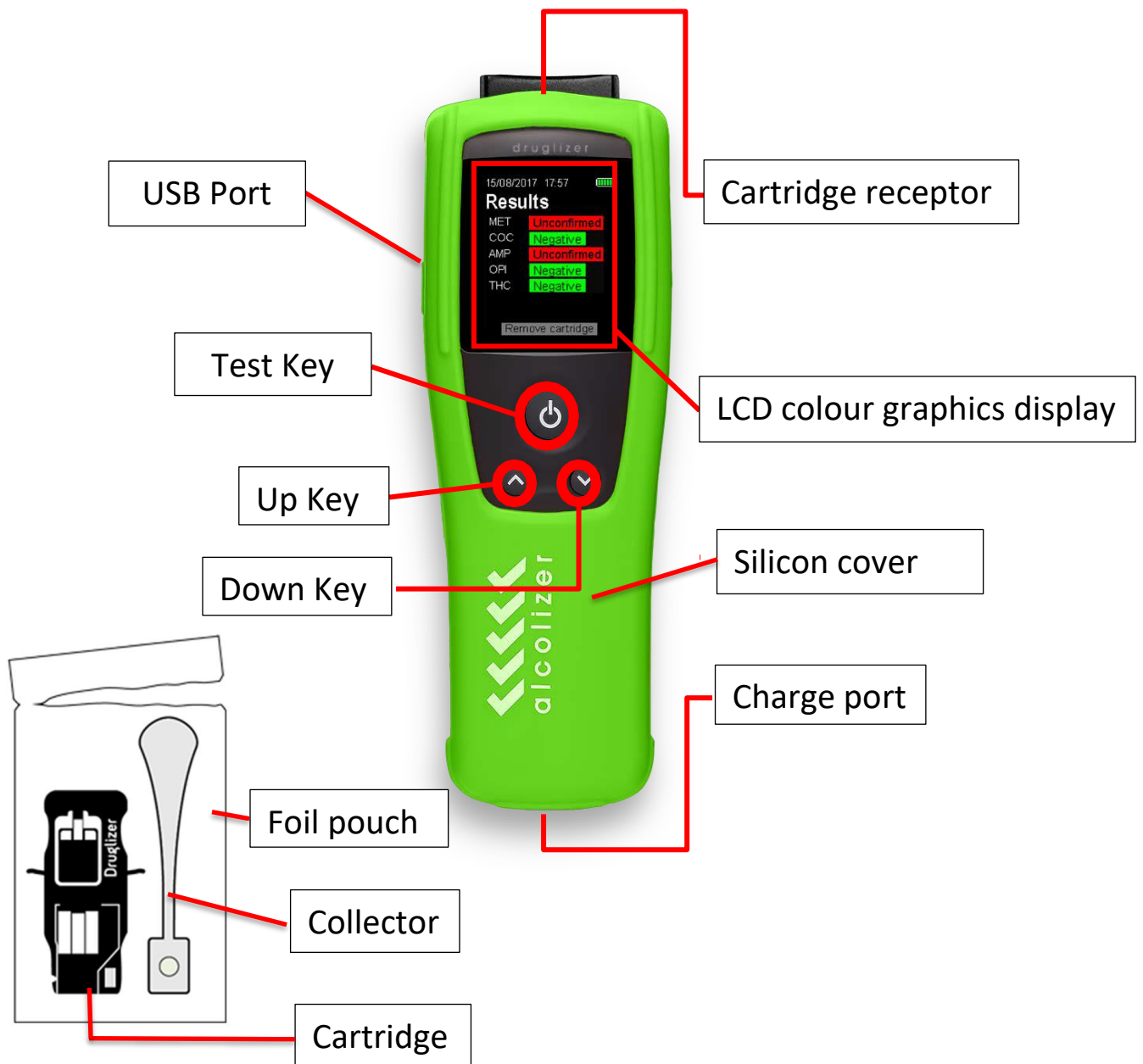
**CAUTION**

*Failure to follow this warning may result in an "Invalid" test.*

*While the Druglizer LE5 is a robust instrument, it does contain sensitive instrumentation and should not be subject to rough handling or become submerged in water.*

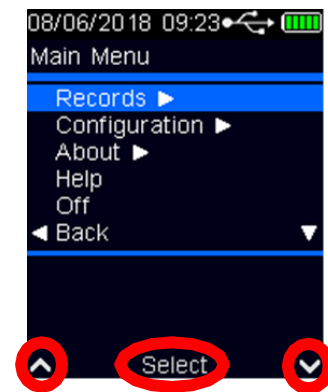
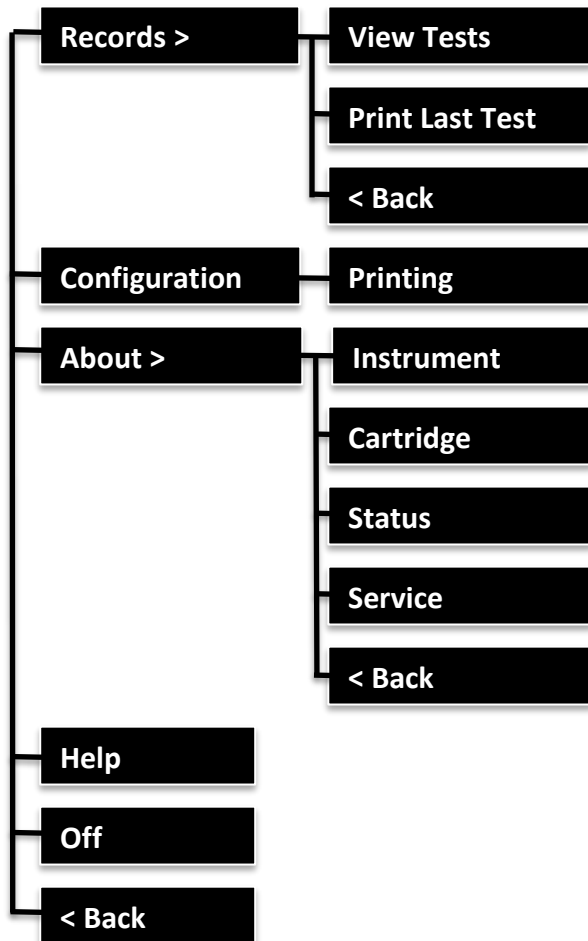
*Do not store instrument in direct sunlight or places where extreme temperature conditions can occur.*

## 5 FUNCTIONAL FEATURES



## 6 MENU AND NAVIGATION

The Up and Down buttons allow access to various sub menus. Operation of both buttons also facilitates access to the *Off* function. The menu structure looks as follows and the navigation can be found on the bottom of the screen as shown below:



## 7 BATTERY CARE AND CHARGING

The Battery Charging Port is located beneath the wrist strap bracket and facilitates connection to the battery chargers included with the instrument.

The Druglizer LE5 is equipped with rechargeable Li-ION batteries. As such it should not be tampered with in anyway. Should any problems occur that are related to the battery, contact your local Alcolizer Technology representative for advice. Only use the battery charger supplied with this instrument by Alcolizer Technology. Use of non Alcolizer Technology supplied battery chargers could damage the instrument and render it inoperative.

The battery status is indicated in the top right of the display. The icon changes to red when the instrument is connected to the power supply and charging. A small amount of power consumption is unavoidable even in standby mode, and this causes the batteries to slowly

discharge. Please observe the following instructions for charging of the batteries and storage of the Druglizer LE5 and printer:

- Always check the battery levels before use and recharge the instrument if necessary.
- Avoid a deep discharge of the batteries to keep them working as efficiently as possible.
- Avoid storage at low temperatures (< 0°C).
- Disconnect the Druglizer LE5 and the printer from the power supply before use.

When the battery is fully charged, the battery level indicator on the LCD Colour Graphics Display will display five bars green.

## 8 PRINTING AND BLUETOOTH

The printing function enables the printing of records by connecting the Druglizer LE5 to a portable printer via Bluetooth connection. The instrument supports the following printer:

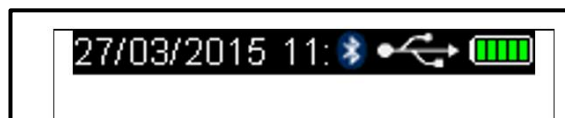
- Bixolon SPP-R200.

Place the Druglizer LE5 instrument next to the Bluetooth printer and then switch the printer on. In order to establish the connection with the printer via Bluetooth, access to the instrument set up menu is required. Navigate through Configuration to the Printing. Then navigate down to the second screen and toggle to test button to enable Bluetooth.

- Screen 1 displays the status of the blue tooth status.
- Screen 2 allows you to enable/disable Bluetooth.
- Screen 3 allows you to set pin length.
- Screen 4 is used to set up and enter the printer pin.
- Screen 5 will automatically begin searching for your printer.

When the Druglizer LE5 identifies the printer, it will automatically pair with the printer.

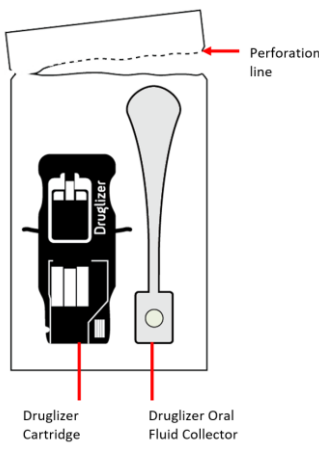

Whenever the Druglizer LE5 instrument has a successful connection with the printer, the Bluetooth icon will be blue. If there is no connection to the printer the Bluetooth icon will be grey.

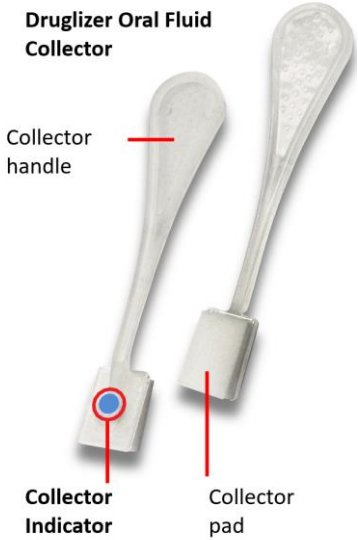
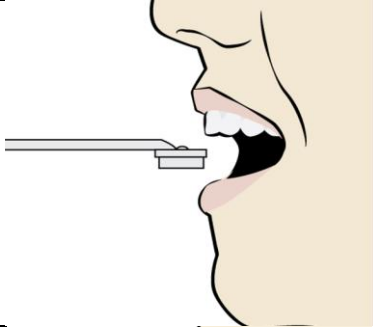
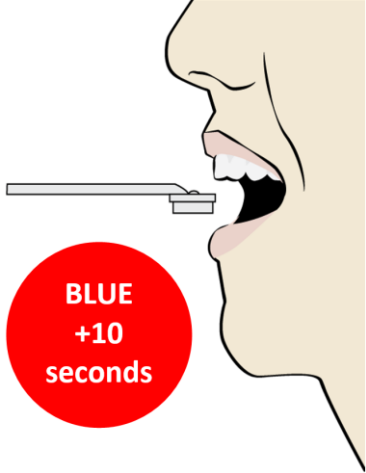
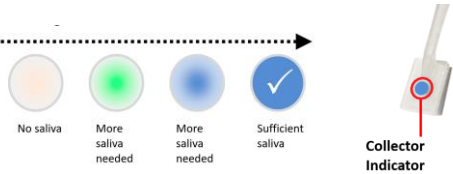










Standard Printers	PIN Digit Length	PINs	Communication Range
<i>Bixolon SPP-R200</i>	4	0000	<i>Up to 10 metres</i>

## 9 PERFORMING A TEST

Step		
1		<ul style="list-style-type: none"> <li>• It is recommended the subject not consume food, beverages or smoke at least 10 minutes prior to oral fluid (saliva) collection.</li> <li>• To encourage saliva production, instruct the subject to press the inside of their cheeks with the tip of their tongue four times.</li> <li>• Tear open the pouch containing a Druglizer Cartridge and Druglizer Oral Fluid Collector.</li> </ul>
2		<ul style="list-style-type: none"> <li>• Turn the Druglizer LE5 on and “Insert Cartridge” message will display.</li> <li>• Take the Druglizer Cartridge and insert it into the top of the LE5 Drug Reader Module.</li> <li>• The flat area should face back while the area with the collector recess should face towards the front. When inserted the screen will display “Insert Collector”.</li> </ul>

<p>3</p>	<p><b>Druglizer Oral Fluid Collector</b></p>  <p>Collector handle</p> <p>Collector Indicator</p> <p>Collector pad</p>	<ul style="list-style-type: none"> <li>• Approximately 500uL (half a millilitre) of saliva is required per drug test.</li> <li>• If insufficient saliva is taken, an 'Invalid' test result may occur.</li> <li>• A Collector Indicator is located opposite the Collector pad and will change to a blue colour when sufficient saliva is taken.</li> </ul>
<p>4</p>		<p>Firstly, instruct the subject to insert the collector pad into their mouth then:</p> <ul style="list-style-type: none"> <li>• rub on inside of both cheeks;</li> <li>• collect saliva around mouth and under the tongue.</li> </ul> <p>Ensure the sponge is not chewed.</p>
<p>5</p>		<ul style="list-style-type: none"> <li>• Instruct the subject to insert the Collector into their mouth and rub the pad onto the inside of both cheeks as well as under the tongue and around the mouth.</li> <li>• <b>IMPORTANT:</b> Druglizer LE5 training <b>MUST</b> be undertaken in order to ascertain correct saliva collection. Collect saliva until the Collector indicator changes to a BLUE that is consistent from edge to edge.</li> </ul>
<p>6</p>	 <p>No saliva</p> <p>More saliva needed</p> <p>More saliva needed</p> <p>Sufficient saliva</p> <p>Collector Indicator</p>	<ul style="list-style-type: none"> <li>• When enough saliva is taken, the Collector Indicator will change to a BLUE that is consistent from edge to edge</li> </ul>

7		<ul style="list-style-type: none"> <li>• For optimal hygiene – both in a test and for a Druglizer LE5 – ensure the sampled Collector surface is not pooled with excessive saliva.</li> </ul>
7		<ul style="list-style-type: none"> <li>• Position the Collector in an upright position with the Collector pad facing downward.</li> <li>• Insert Collector into the Druglizer Cartridge recess and with your thumb on the indicator, gently snap backward into place.</li> <li>• Position the LE5 Drug Tester horizontally – preferably on a flat surface. Orientation alerts will help you from moving or tilting the instrument whilst it is analysing a test sample.</li> </ul>
8		<ul style="list-style-type: none"> <li>• The Druglizer LE5 will automatically detect the wetted Collector and begin analysing.</li> <li>• Typically, drug test analysis will appear from between 15 and 30 seconds.</li> <li>• Orientation alerts will help you from moving or tilting the instrument whilst it is analysing.</li> </ul>

9		<ul style="list-style-type: none"> <li>• Results are updated as they are analysed.</li> <li>• A “Time Remaining” counter is displayed.</li> </ul>
10		<ul style="list-style-type: none"> <li>• The “Results” screen is displayed once analysis of all drugs are complete.</li> <li>• Results displayed are either of the following:  <div style="display: flex; flex-direction: column; gap: 5px;"> <div style="background-color: #90EE90; padding: 2px;">Negative</div> <div style="background-color: #FF0000; padding: 2px;">Unconfirmed</div> <div style="background-color: #D3D3D3; padding: 2px;">Invalid</div> </div> </li> <li>• The Time Remaining counter is replaced by a “Remove cartridge” message.</li> </ul>
11		<ul style="list-style-type: none"> <li>• Once the Druglizer Cartridge is removed the screen will then reset and return to the “Insert Cartridge” message.</li> <li>• Dispose of the Cartridge and Collector along with other non-recyclable waste.</li> </ul>

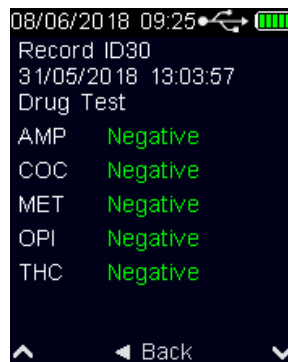
## 10 INTERPRETATION OF RESULTS

- **INVALID** (grey) – likely due to insufficient or premature saliva sampling.
- **NEGATIVE** (green) – drug concentration is zero or below the detectable level of the test.
- **UNCONFIRMED** (red) – concentration of drug is above detectable level of the test.

## 11 TEST RECORDS

Records are retained in the instrument and can be downloaded via the AlcoCONNECT software support. It is recommended that records are periodically downloaded and erased from the instrument. Access the records as follows:

- Switch the instrument on.
- Press the Up and Down buttons simultaneously.  
The User Menu will be displayed.
- Using the down button, scroll down to record as displayed below:



As the instrument automatically stores records, the memory will eventually reach capacity and the oldest record will be automatically overwritten.

Regular downloading of records using AlcoCONNECT is recommended.

## 12 SERVICE LIFE

### 12.1 Calibration alerts

The Druglizer LE5 requires calibration every six months to maintain optimum performance. The instrument will display 'Service Life Pending' warning message 30 days before calibration is required.

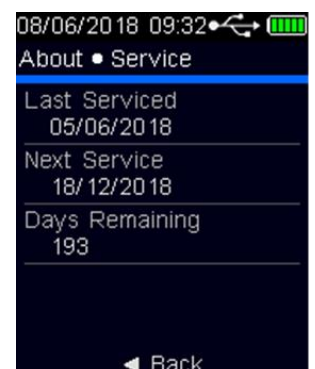
The 'Service Life Pending' will be displayed each time the instrument is turned on until calibration is performed.

Press the Test Key to cancel the message and continue testing.

When the 'Service Life Pending' message period has expired, 'Service Life Expired' message is displayed, and the instrument will lock preventing further testing until the instrument is calibrated.

At any time, you can review the service dates.

The user is not authorized to maintain or calibrate the instrument in any way with the exception cleaning of the instrument's housing. Any other form of maintenance must not be carried out by the user. Opening the instrument will render any warranty claims null and void.



The instrument is factory-calibrated. The instrument must only be repaired or calibrated by authorized, qualified personnel.

The instrument may be damaged by liquid ingress. Please ensure that water and other liquids are prevented from penetrating the instrument. If any fluid enters the internal parts of the instrument, switch off the instrument immediately and return to authorised service centre.

## 12.2 Replacing sample module

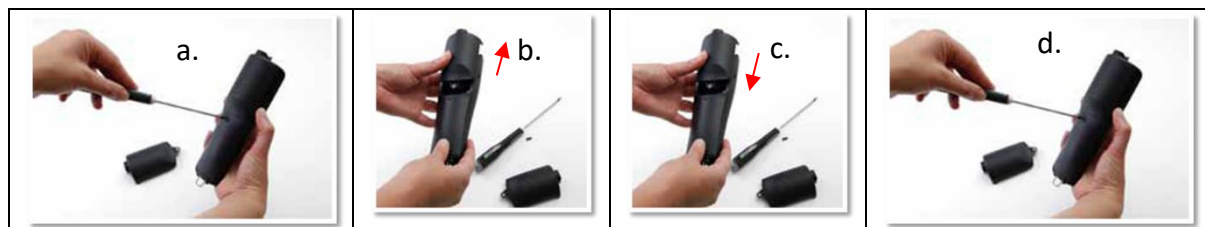
Rather than returning the instrument to Alcolizer for service, the module can be removed and sent in. This saves money and if the owner details are known and maintained with Alcolizer Technology, arrangements can be made to forward a replacement sample module prior to the calibration being overdue.

Remove and replace the sample module as follows:

- a. Undo the single screw on the back of the main module.
- b. Slide off the out-of-calibration sample module.
- c. Slide on the new sample module.
- d. Do up the single screw on the back of the main module.

### **CAUTION**

*Do not over tighten the sample module securing screw as this will damage the threaded portion. Tighten only enough to prevent the sample module from sliding away from the main module.*



Following the replacement of the sample module, send the out-of-cal module back to Alcolizer.

The instrument can be returned to Alcolizer Technology for calibration should the owner prefer prior to the number of days warning message period expiring. To arrange calibration, contact Alcolizer Technology.

Phone: 1300 789 908;

Email: [sales@alcolizer.com](mailto:sales@alcolizer.com); or

Web: [www.alcolizer.com](http://www.alcolizer.com)

## 13 TECHNICAL SPECIFICATIONS



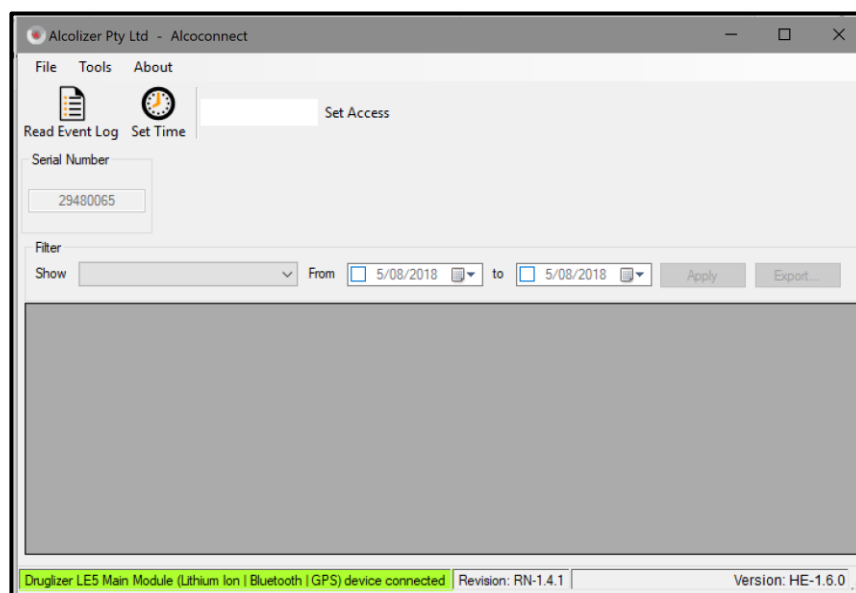
INSTRUMENT APPLICATION	▶ Law enforcement and Industry
SENSOR TYPE	▶ Lateral flow strips with patented Optoelectronic sensor
ACCURACY	▶ Designed to Australian Standards AS 4760-2006 (Procedures for specimen collection and the detection and quantitation of drugs in oral fluid)
TEST TIME	▶ Test results from 90 seconds
DISPLAY	▶ Transreflective colour graphics LCD screen
MOUTHPIECE	▶ Druglizer Oral Fluid Collector
CALIBRATION	▶ Module exchange system for on-site calibration
POWER SUPPLY	▶ Rechargeable Li-Ion battery system
WEIGHT	▶ 310g (including battery and cover)
DIMENSIONS	▶ 196mm H x 66mm W x 43mm D

## 14 ALCOCONNECT

AlcoCONNECT Toolbox Version 1.6 or above is used to download test logs and configure the Druglizer LE5. AlcoCONNECT Toolbox can be downloaded from

<https://www.alcolizer.com/software-updates/>

Connect your Druglizer LE5 to the computer via the USB cable, Double click the AlcoCONNECT icon and turn the instrument on. A successful connection between the Druglizer LE5 and the computer will be shown by a green segment on the bottom right of the window.



Once installed onto the computer, access AlcoCONNECT Toolbox allow you functionality as follows (more details in the AlcoCONNECT user guide):

- View Test records.
- Download Test records.
- Set date and time.
- Upgrade Firmware.

The screenshot shows the 'Alcolizer Pty Ltd - Alcolconnect' application window. It features a menu bar (File, Tools, About), a toolbar with 'Read Event Log' and 'Set Time' buttons, and a 'Set Access' field. Below this is a 'Serial Number' input field containing '29480065'. A filter section shows 'Show -- All records --' and a date range from '11/05/2018' to '12/07/2018'. The main area is a table with the following data:

Record ID	Event	Main Module Serial Number	Main Module Version	Drug Tester Module Serial Number	Drug Tester Module Version	Test Batch	Test Supply	Test Date	Result	Description	AMP	COC	MET	OPI	THC
10	Drug Test	29480065		28480040		180316-01	11/30/2019	5/11/2018 2:43 PM	Negative		Negative	Negative	Negative	Negative	Negative
12	Drug Test	29480065		28480040		180316-01	11/30/2019	5/11/2018 2:59 PM	Negative		Negative	Negative	Negative	Negative	Negative
13	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 7:23 AM	Negative		Negative	Negative	Negative	Negative	Negative
14	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 8:15 AM	Negative		Negative	Negative	Negative	Negative	Negative
15	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 8:28 AM	Negative		Negative	Negative	Negative	Negative	Negative
16	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 9:17 AM	Invalid	Invalid control site	Unconfirmed	Negative	Negative	Negative	Invalid
17	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 9:41 AM	Negative		Negative	Negative	Negative	Negative	Negative
18	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 10:17 AM	Negative		Negative	Negative	Negative	Negative	Negative
19	Drug Test	29480065		28480040		180321-01	11/30/2019	5/30/2018 10:43 AM	Unconfirmed		Negative	Negative	Negative	Negative	Unconfirmed