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.

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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 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, 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 necessarily 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°C* and *+60°C*. Only conduct drug screening tests at a temperature between *+15°C* and *+35°C*.

NOTE

This User Manual is applicable to the *Druglizer LE5* with:

- main module firmware version *RN-1.21.1* or later
- drug test module *B-3.6.0* 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 Manuals and **AlcoCONNECT Toolbox** can be downloaded from https://www.alcolizer.com/software-updates/

AlcoCONNECT Toolbox *Version 1.6* or above is used to download test logs and configure the *Druglizer LE5*. (For **AlcoCONNECT Toolbox** instructions please refer to ***AlcoCONNECT*** *Toolbox User Manual*).

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 lead to measurement errors and misinterpretations and the following 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

Precautions when working with *Druglizer LE5 Cartridges*:

- If storing pouches in a fridge, allow the pouch environment to reach room temperature *(+15 to +35°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 a consistent from edge to edge

CAUTION

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

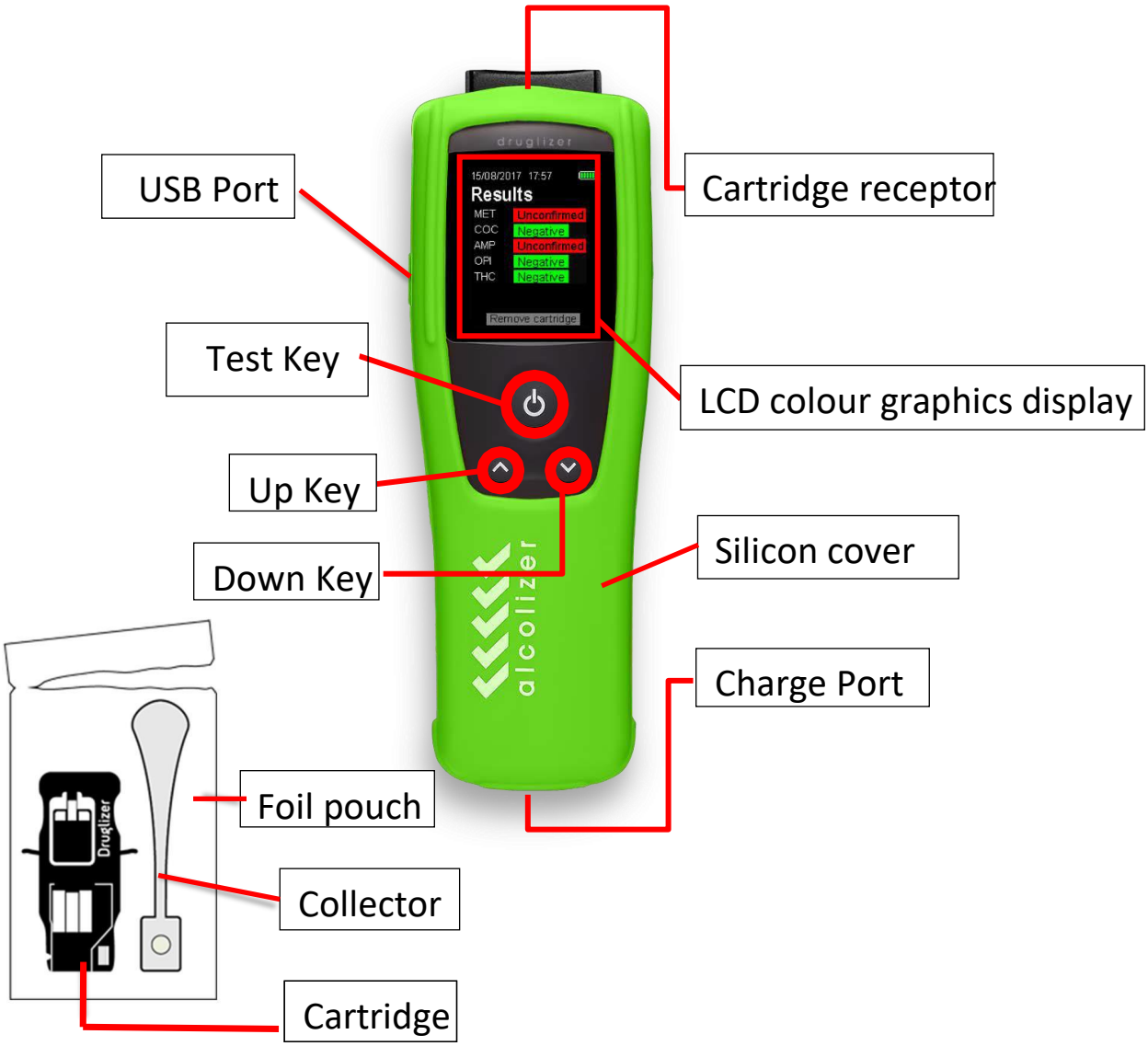
While the Druglizer LE5 is a robust instrument, it does contain sensitive instrumentation and should not be subject to rough handling or become submerged in water.

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

4.1 Cleaning Procedure

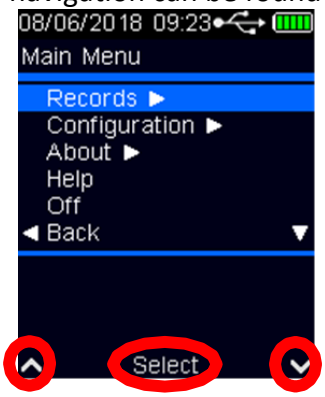
- Operators should use the appropriate personal protective equipment (PPE) when conducting a test – gloves, mask, protective eyewear, or full-face mask based on the situation.
- The instrument should be cleaned with a soft cloth and antibacterial spray or anti-bacterial wipes. It is recommended that the instrument is turned off before cleaning.
- The outside of the instrument can be cleaned by wiping it over with a soft moist cloth followed by a soft dry cloth.
- The screen of the instrument can be cleaned by wiping it over with a soft moist cloth followed by a soft dry cloth.
- **Do not** use alcohol-based cleaners.
- **Do not** use harsh cleaning agents, abrasive cleaning pads or chemicals.

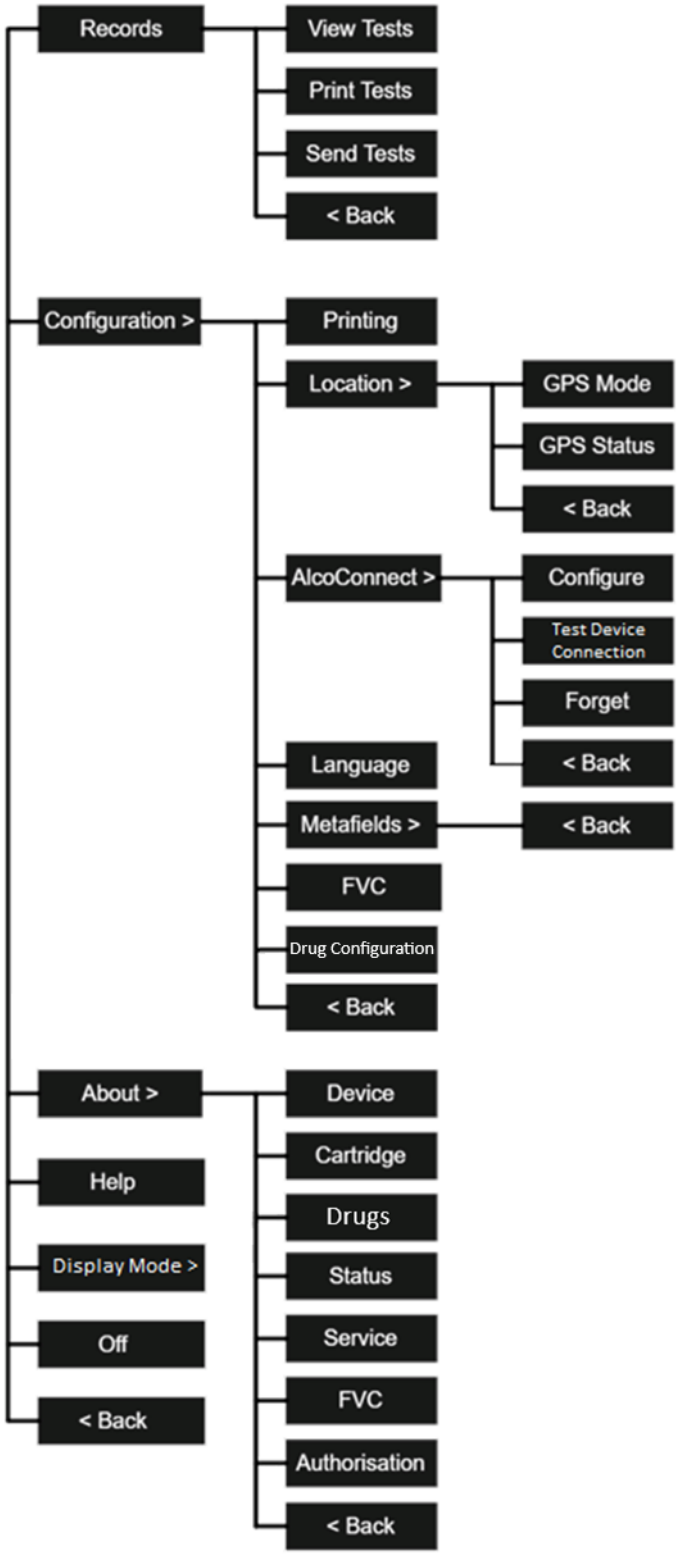
5 FUNCTIONAL FEATURES



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:





6.1 Records

6.1.1 View Tests

This function shows a list view of all the logged drug test and customer verification records. Each log entry users can see:

- Record ID
- Date and Time test was performed
- Overall result for the record

6.1.2 Print Test

This function enables users to print any drug test record from the list of all the logged records.

NB: Bluetooth connection between printer and device must be established prior to using this functionality.

6.1.3 Send Test

This function enables users to send any drug test record from the list of all the logged records.

NB: Bluetooth connection between the relevant Alcolizer app and Druglizer device must be established prior to using this functionality.

6.2 Configuration

6.2.1 Printing

The printing function enables the printing of records by connecting the *Druglizer LE5* to a portable printer via Bluetooth connection. The instrument supports the **Bixolon SPP- R200, POS-5802DD and WOOSIM WSP-i450** printers. For printing instructions please refer to section 7.

6.2.2 Location

This function enables users to configure whether the instrument will log GPS position fix with drug tests. It also shows location information for the acquired GPS fix.

6.2.3 AlcoCONNECT

The **AlcoCONNECT** function is used to allow you to connect to smart devices that have one of the Alcolizer apps installed on it.

6.2.4 Language

This function enables the user to change the language of the device

- English (Default)
- Bahasa
- Chinese (Simplified)
- Chinese (Traditional)
- French
- German
- Portuguese
- Spanish
- Vietnamese
- Dutch

If configured, the device can toggle between up to 5 different languages (4 non-English plus English) with the *Test Key + Up Key for 2 seconds* keybind.

6.2.5 Drug Configuration

The Druglizer device can be configured to ignore specific drugs. Before configuration, ensure you are testing in accordance with your company's policy. Navigate to the "*About > Drugs*" page to confirm which drugs are tested for (refer 6.3.3).

Configuration	Description	Drugs Ignored
00	Alcolizer Default 7 Drugs	None
01	6 Drugs Including BZO	OXY
02	6 Drugs Including OXY	BZO

6.3 About

6.3.1 Device

Main Module:

- Model Number
- Hardware Revision
- Software Version
- Serial Number
- Bluetooth BLE

Sample Module:

- Model number
- Software version
- Serial number
- Assembly number

6.3.2 Cartridge

When a cartridge is inserted into the device the expiry date is visible on the screen. If cartridge has expired the test will not be performed.

6.3.3 Drugs

This page shows which drugs are tested for. Refer to 6.2.5 for configuration options.

6.3.4 Status

This function shows the current status of the device or cartridge inserted into the device.

6.3.5 Service

The below information can be seen

- Last service date
- Next service due date
- Days remaining until service

6.3.6 FVC

The below information can be seen:

- Last Complete
- Next FVC Date
- Days Remaining
- Warning Date
- Days to Warning

6.4 Help

This menu provides instructions on the buttons required to perform functions on the device.

6.5 Display Mode

6.5.1 Guided Mode

Guided mode is intended for new users of the instrument, as it provides step-by-step prompts on how to conduct a drug test like an experienced operator would as per Alcolizer training and AS4760:2019.

This mode enables “extended logging” which will increase the test time by approximately 30 seconds.

6.5.2 Expert Mode

Expert mode assumes the operator is familiar with the device and provides no prompts on the drug testing process.

6.6 Off

This menu allows you to switch the device off.

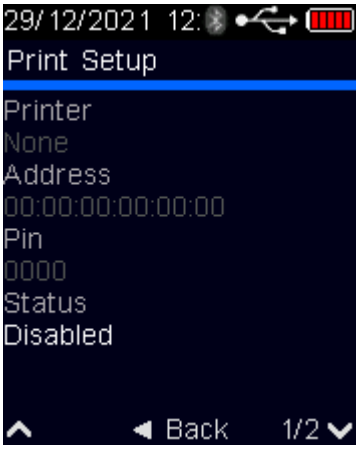
7 PRINTING AND BLUETOOTH

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:

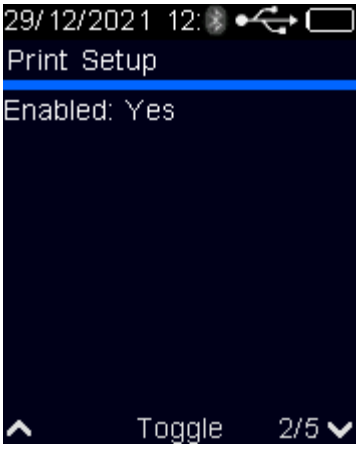
- Bixolon SPP-R200
- POS-5802DD
- WOOSIM WSP-i450

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 Printing. Then navigate down to the second screen and toggle to test button to enable Bluetooth.

- Screen 1 displays the Bluetooth 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 and pairing to your printer.

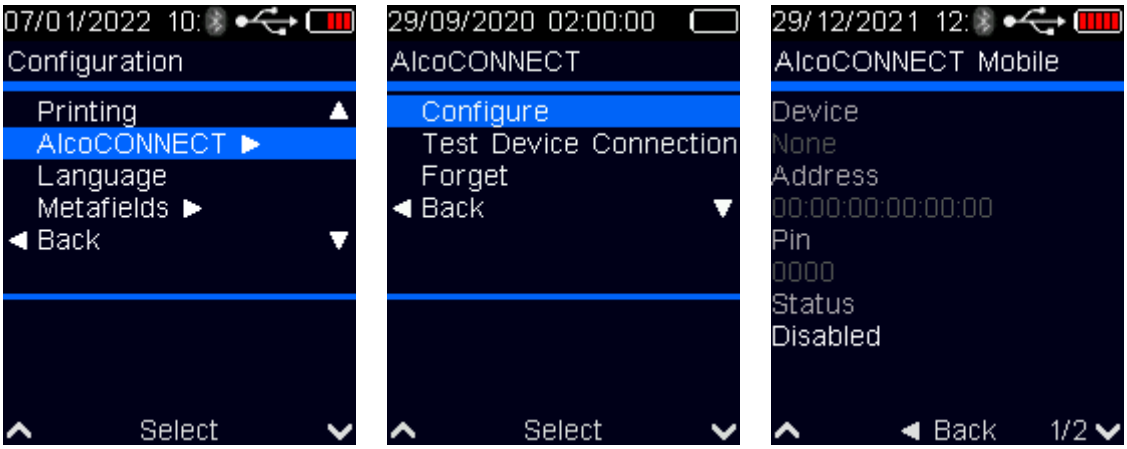
When the *Druglizer LE5* identifies the printer, it will automatically pair with the printer.

Standard Printers	PIN Digit Length	PINs	Communication Range
Bixolon SPP-R200	4	0000	Up to 10 meters
POS-5802DD		1234	
WOOSIM WSP-i450			

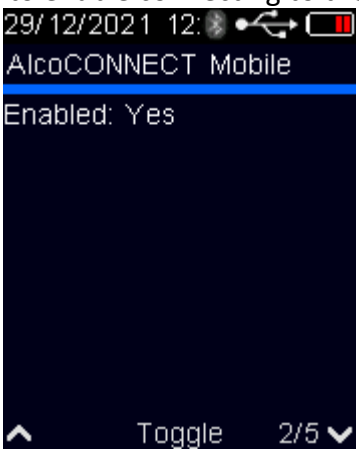
7.1 Pairing With OnSite Testing Mobile App

7.1.1 iOS

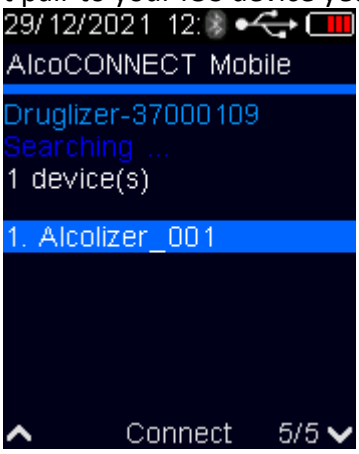
1. On the *Druglizer LE5*, open the menu and navigate to Configuration >> AlcoCONNECT >> Configure



2. On page 2, press the *test key* to enable connecting to the **OnSite Testing app**

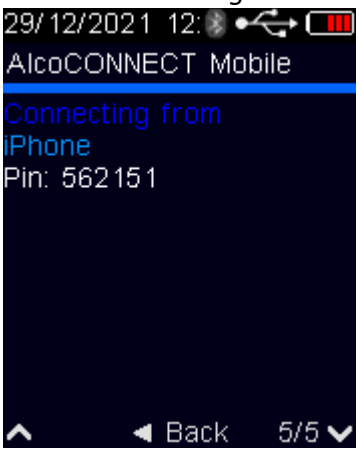


3. Navigate to page 5 but do not pair to your iOS device yet

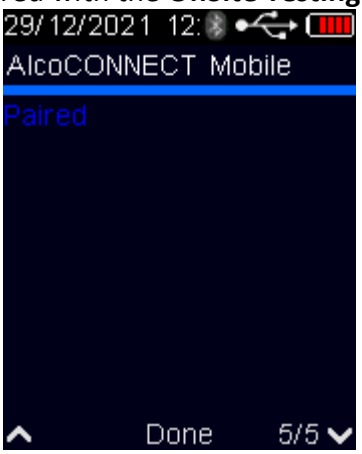


4. On the **OnSite Testing app**, open the settings page and press Pairing. You should see your *Druglizer LE5*

5. Press Pair and enter the PIN shown on the *Druglizer LE5* screen



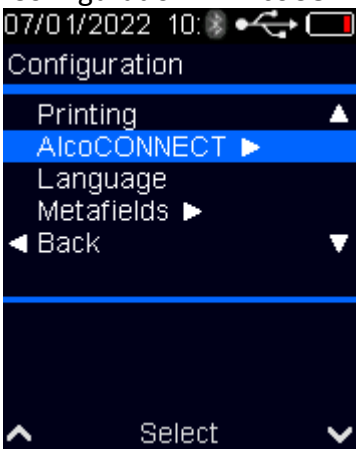
6. Your *Druglizer LE5* is now paired with the **OnSite Testing app** for iOS

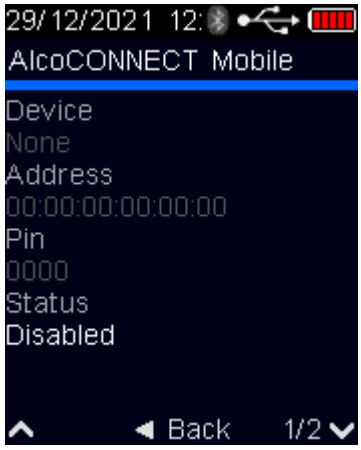


7. To disconnect a *Druglizer LE5* to an iPhone, you must forget the device from both the **OnSite Testing app**, as well as the iPhone's Bluetooth settings.

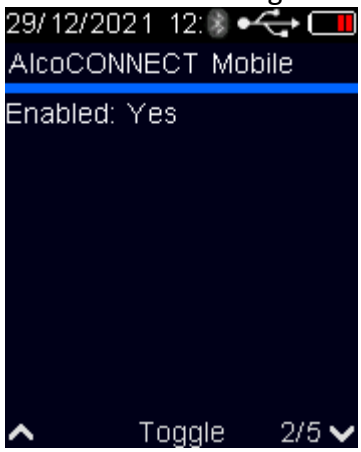
7.1.2 Android

1. On your Android device, go to the Bluetooth settings and search for nearby devices
2. On the Druglizer LE5, open the menu and navigate to
   Configuration >> AlcoCONNECT >> Configure

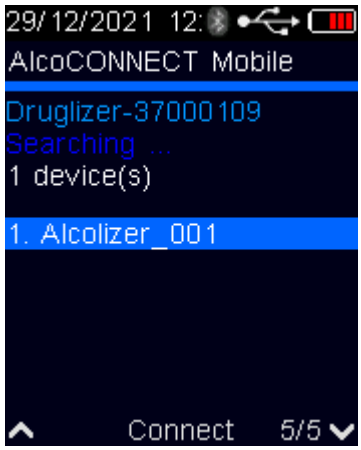




3. On page 2, press the *test key* to enable connecting to the ***OnSite Testing app***



4. Navigate to page 5
5. Highlight and select your Android device



7.2 Bluetooth Troubleshooting

See the Appendix and Annex B for assistance in troubleshooting Bluetooth

8 GPS

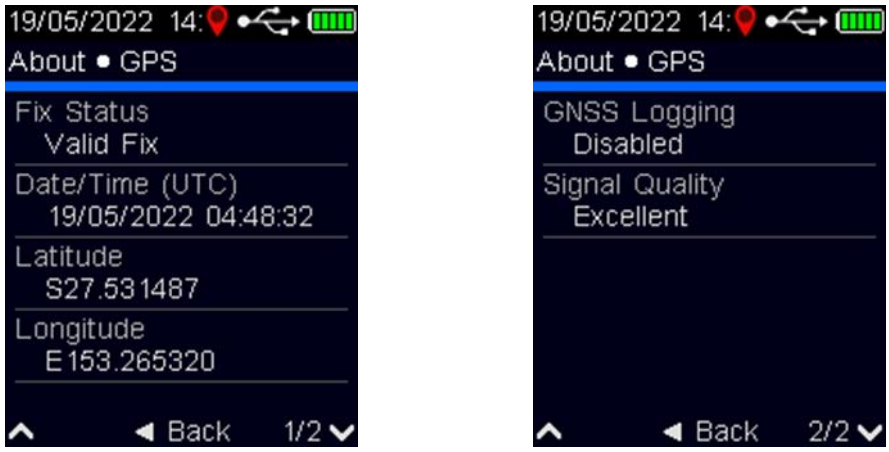
The Global Positioning System (GPS) function (if installed) enables the exact location of the instrument to be known and under certain circumstances, the location of testing to be recorded.

8.1 Acquiring GPS Satellites

To acquire GPS location information, perform the following:

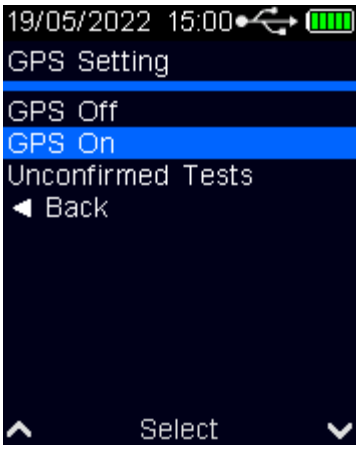
- With screen displaying insert cartridge, Press the Up and Down buttons simultaneously to enter main menu.
- Select Configuration | Location | GPS Status.
  Note: This is only available for User-Admin authorisation role.

- Select GPS Status to view GPS information.



8.2 GPS Mode Configuration

The GPS can be configured in three different logging modes: on, off and unconfirmed.



8.2.1 GPS On

In this mode GPS logging is enabled and the location of the instrument will be logged with every drug test. If location could not be retrieved, then “Location Unavailable” will be logged with the drug test result.
When enabled, the GPS logo should be visible in the status bar. If GPS location fix has been acquired, the logo will be displayed in red, otherwise it is displayed in grey.

8.2.2 GPS Off

In this mode the GPS logging mode is disabled, therefore location information will not be recorded with drug test results.

8.2.3 Unconfirmed Tests

In this GPS logging mode, the location of the instrument is logged only if at least one the drugs being tested has an unconfirmed result.

9 SET DATE AND TIME

To set the date and time of the instrument, refer to the *AlcoCONNECT Toolbox User Manual*

10 BATTERY CARE AND CHARGING

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

The *Druglizer LE5* is equipped with a rechargeable Li-ION battery. 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.

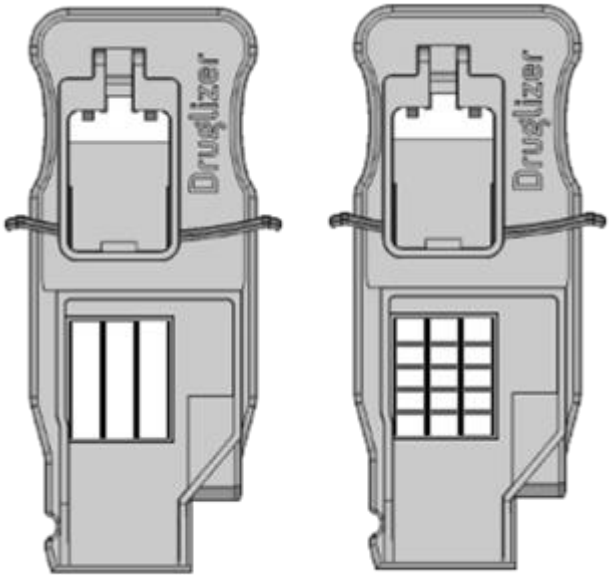
The battery status is indicated in the top right of the display. The icon changes to red when the instrument is connected to the power supply and charging. A small amount of power consumption is unavoidable even in standby mode, and this causes the batteries to slowly discharge. Please observe the following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

11 FVC (Field Validation Cartridges)

For instruments supplied with *Field Validation Cartridges* (this feature is normally disabled); The Drug modules are shipped with two sets of *Field Verification Cartridges* (FVC). The field verification is a process performed by users to verify their *Druglizer LE5* is operating within allowable tolerances for drug testing.

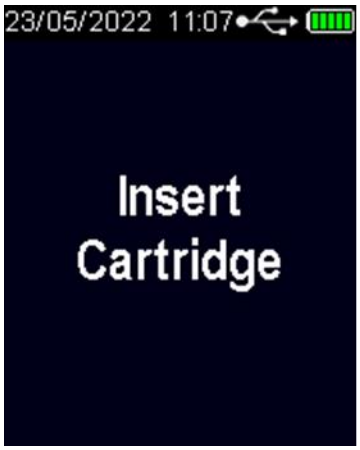


FVC - 1.1 FVC - 1.2

To conduct an FVC check, cartridges are inserted in sequence with operator following on screen instructions. A successful FVC process takes ~30 seconds and, after which the drug testing can proceed normally.

11.1 Operation

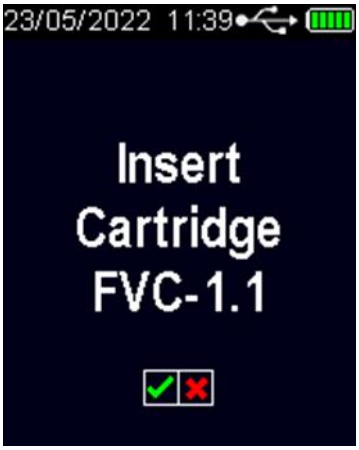
The FVC process is started by inserting the first cartridge in the FVC-1 set (FVC-1.1). The "Verifying" screen is displayed for several seconds, while the instrument is busy, before showing the result screen.



When the first cartridge is removed, progress of the FVC process is illustrated by a box for each cartridge in the set.

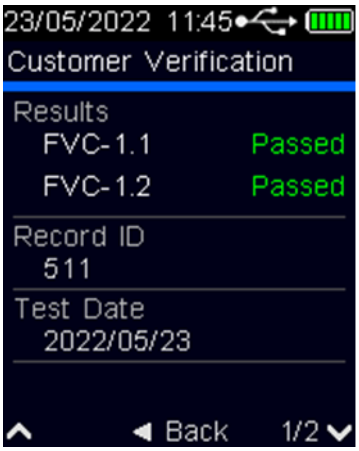
☑	Pass
▣	Cartridge yet to be tested
☒	Fail

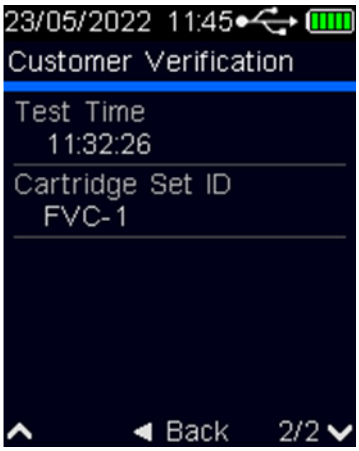
If all the cartridges in the FVC set have passed, the device will return to idle screen and drug testing can continue as normal. However, if a cartridge has failed then the instrument will display status of the process. There is no limit to the number of times the FVC check can be performed, but device will be locked on failure.



11.2 Logging

Results of the FVC process (passed/failed) are logged as FVC records. These records show the result of each cartridge in the sequence and can be viewed from Records • View Tests.



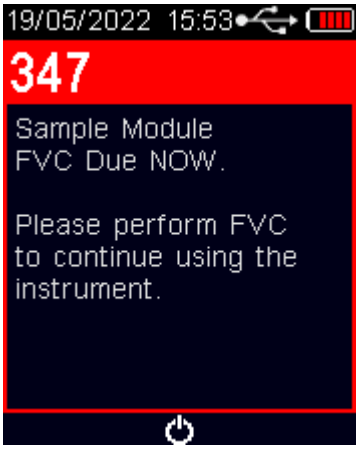


11.3 Alert

The *Druglizer LE5* requires FVC check to be performed regularly to maintain optimum performance. The instrument by default will require FVC check every 28 days and display 'FVC Due Soon' warning message seven days before the check is required.

The 'FVC Due Soon' will be displayed each time the instrument is turned on until FVC check is performed.
Press the Test Key to cancel the message and continue testing.

When the 'FVC Due Soon' message period has expired, 'FVC Due Now' message is displayed, and the instrument will lock preventing further testing until the FVC check is completed successfully.



11.4 FVC Cartridge Care and Storing

The cartridges must be stored in a cool, dry place, away from moisture and direct sunlight. It is also very important that the cartridges are kept in a dust free environment as the FVC can fail due to debris and contamination of the cartridges.

Ideally the cartridges are stored in a sealed, plastic bag, or airtight container.

The electrical contact of the memory chip PCB can be affected by oxidisation or contamination, leading to poor electrical connectivity, and subsequent data transfer problems. The contacts can simply be wiped with a cloth damped with isopropyl or an eraser. **Do not** spray isopropyl or any other fluid near the cartridge, the strips must not be damaged.

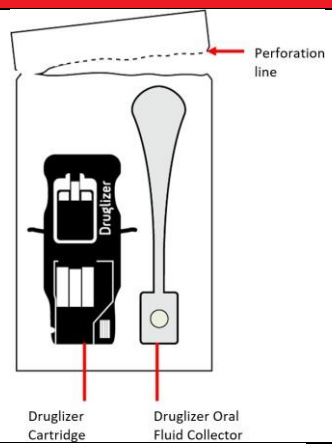
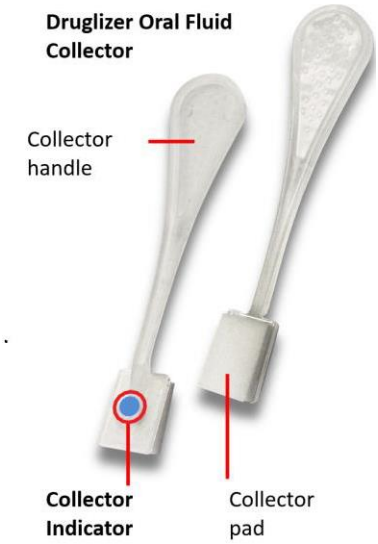
The FVC cartridges are checker cartridges only and cannot be used to conduct a drug test. Therefore, it is extremely important **not to** insert a collector in FVC cartridges to avoid damaging the cartridge set.

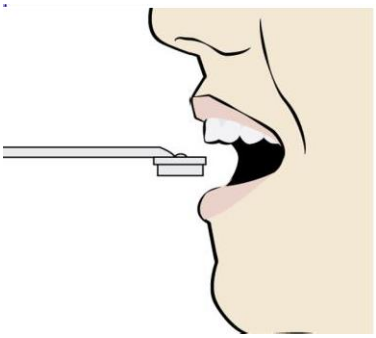
12 QR Assist

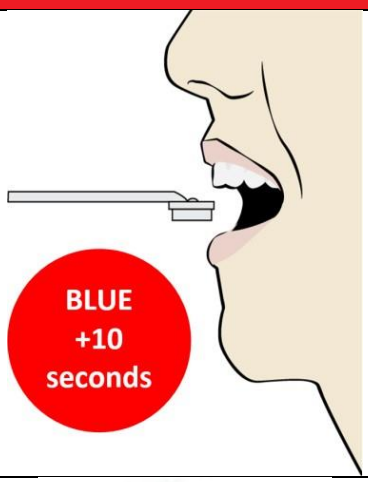
Some status items have a QR codes which, when scanned, will go to a help page for the asserted status item on the Alcolizer website.

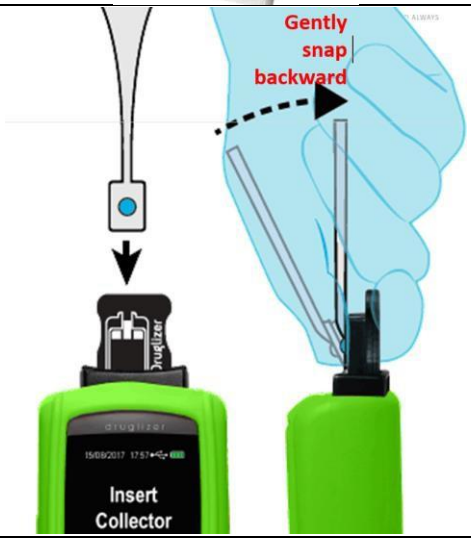
13 PERFORMING A TEST

For a written, more detailed guide, refer to Annex A - Druglizer Testing Procedure

Step	Diagram	Steps
1		• It is recommended the subject not consume food, beverages or smoke including vaping at least 15 minutes prior to oral fluid (saliva) collection. • To encourage saliva production, instruct the subject to press the inside of their cheeks with the tip of their tongue four times. • Tear open the pouch containing a Druglizer Cartridge and Druglizer Oral Fluid Collector.
2		• Approximately 500uL (half a millilitre) of saliva is required per drug test. • If insufficient saliva is taken, an 'Invalid' test result may occur. • A Collector Indicator is located opposite the Collector pad and will change to a blue colour **when sufficient saliva is taken.**

3		• Firstly, instruct the subject to insert the collector pad into their mouth then:
		  ○ Rub on inside of both cheeks, 5 times each.
		  ○ Collect saliva around mouth and under the tongue.
		• Ensure the sponge is not chewed.

Step	Diagram	Steps
4		• 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. • Place collector on top of tongue, close mouth, and tilt head in a chin to chest motion • IMPORTANT: *Druglizer LE5* training MUST be undertaken in order to ascertain correct saliva collection. Repeat collection steps until the Collector indicator changes to a BLUE that is consistent from edge to edge
5		• Turn the *Druglizer LE5* on and "Insert Cartridge" message will display. • Take the Druglizer Cartridge and insert it into the top of the LE5 Drug Reader Module. • 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".
6		• When the cartridge is inserted, the instrument will start a 60 second countdown. • Instruct the subject to continue collecting saliva until the countdown timer expires.
7		• When enough saliva is taken, the Collector Indicator will change to a BLUE that is consistent from edge to edge

Step	Diagram	Steps
8		• After the 60 second countdown, the instrument will prompt the operator to confirm whether the collector indicator is solid blue.
9		• For optimal hygiene – both in a test and for a *Druglizer LE5* – ensure the sampled Collector surface is not pooled with excessive saliva.
10		• Position the Collector in an upright position with the Collector pad facing downward. • Insert Collector into the Druglizer Cartridge recess and with your thumb on the indicator, gently snap backward into place. • Press the Test Key to confirm that the collector has been inserted. • 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.

Step	Diagram	Steps
11		• The *Druglizer LE5* will automatically detect the wetted Collector and begin analysing. • Typically, drug test analysis will appear from between 15 and 30 seconds. • Orientation alerts will help you from moving or tilting the instrument whilst it is analysing.
12		• Results are updated as they are analysed. • A "Time Elapsed" counter is displayed.
13		• The "**Results**" screen is displayed once analysis of all drugs are complete. • Results displayed are either of the following: Negative Unconfirmed Invalid • The Time Elapsed counter is replaced by a "**Remove cartridge**" message.
14		• Once the Druglizer Cartridge is removed the screen will then reset and return to the "Insert Cartridge" message. • Dispose of the Cartridge and Collector along with other non-recyclable waste.

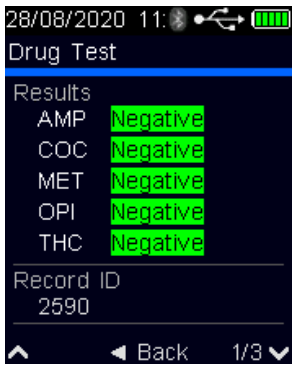
14 INTERPRETATION OF RESULTS

- **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.
- **INVALID** (grey) – likely due to insufficient or premature saliva sampling.

15 TEST RECORDS

Records are retained in the instrument and can be downloaded via **AlcoCONNECT** Toolbox. 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.
- Navigate to Records menu and select View Tests.
  Record browser will be displayed with the list of all the logged drug test and customer verification records.
- Use the up/down to select the desired record and press the test key. Browser menu will be displayed with an option to view record.
- Select View. Record will be shown as 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** Toolbox is recommended.

16 SERVICE LIFE

16.1 Calibration Alerts

The *Druglizer LE5* requires calibration every twelve months to maintain optimum performance. The instrument will display 'Service Life Pending' warning message 28 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.

16.2 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.

> ***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.*

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.

Following the replacement of the sample module, send the out-of-calibration 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: service@alcolizer.com; or Web: www.alcolizer.com

17 Drug Configuration

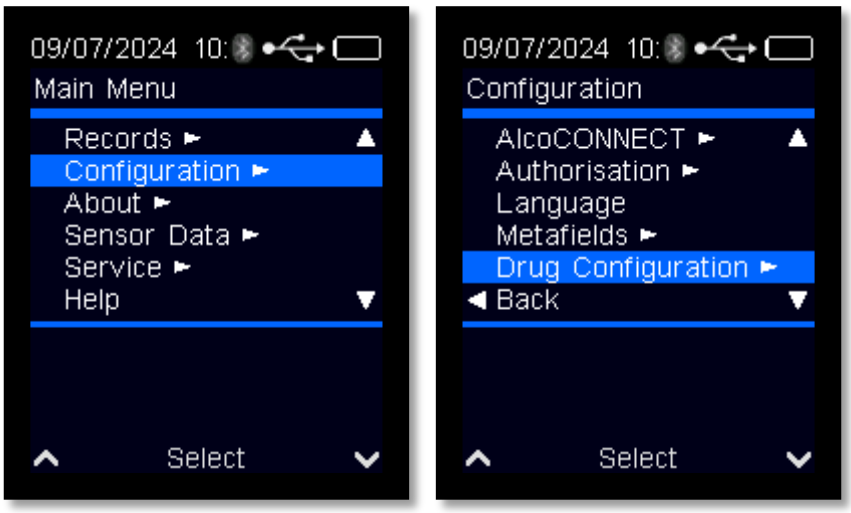
ATTENTION

Before proceeding, ensure you are familiar with and testing in accordance with your company's Drug and Alcohol policy.

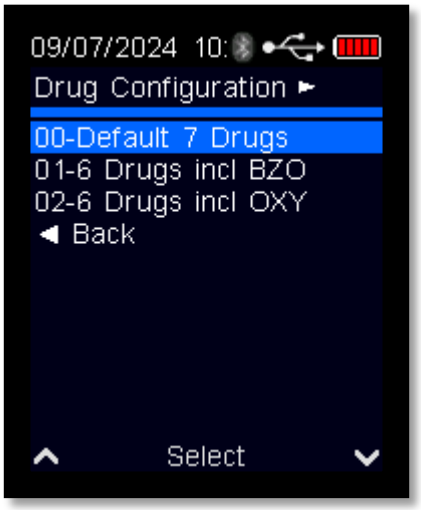
Remove any cartridge from the device before configuration.

17.1 Configuration

To disable testing of a drug, open the *Main Menu* by pressing the *Up* and *Down* keys at the same time. Then, use the arrow keys to navigate to *Configuration* > | *Drug Configuration* >.

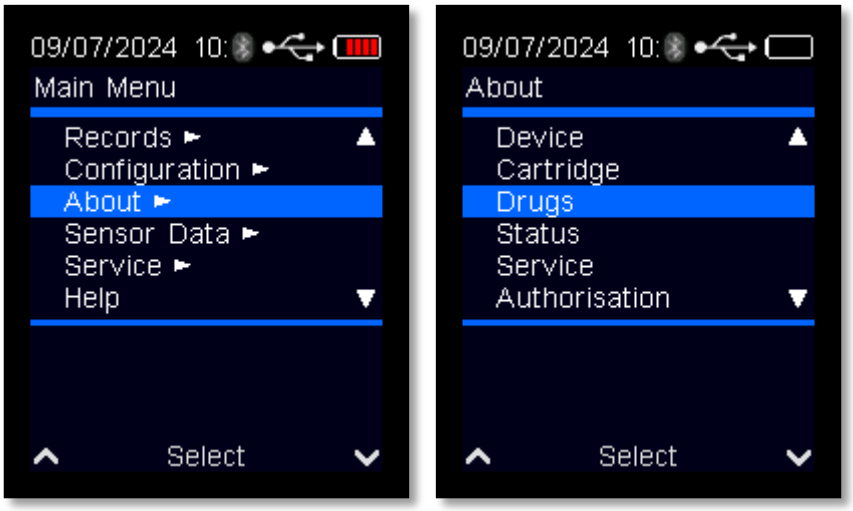


From here, you can select a configuration which will ignore at least one drug. Refer to 6.2.5 for which drugs will be ignored for a config.

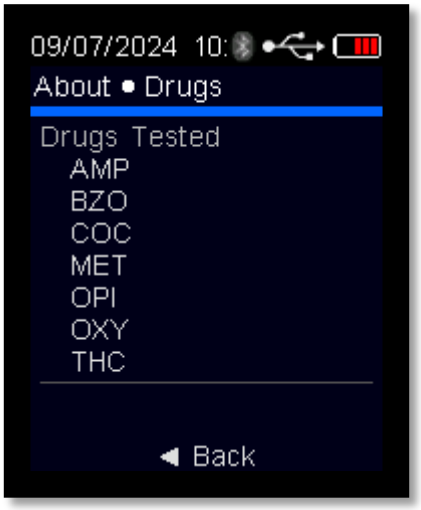


17.2 Config Verification

It is possible to verify the configuration has taken affect or to view which drugs are tested for. Start by opening the *Main Menu* by pressing the *Up* and *Down* keys at the same time. Then, use the arrow keys to navigate to *About* > | *Drugs*.



This page will list which drugs the instrument will test for.



18 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

19 Appendix

19.1 Annex A - Druglizer Testing Procedure

STEP 1. Preparing for the test. Ensure you have a suitable area to perform the test and a flat area to lay the Druglizer while it is analysing. Check that the Druglizer has sufficient charge and that you have a box of Druglizer Cartridges, inspecting the 'Temperature Card' on the inside of the box to check for the possibility of heat damage (the card stays with the box until all Cartridges are used).

For an individual test, check you have three new Cartridges. The foil packaging of each Cartridge should be free from damage and remains hermetically sealed. Check the expiry date of each cartridge by reading the date printed on the back of the foil packaging. Store Cartridges in a safe place in between tests.

STEP 2. Ask the donor when they last had something to eat or drink – strict compliance with AS 4760:2019 specifies nil by mouth 15 minutes prior to test, this includes not smoking/vaping in that time.

TIP – Coffee, Tea & other milk products have been found to cause severe 'dry mouth' in donors

STEP 3. Ask the donor to select one of the three Druglizer cartridges, use the one they select in their test. Open the foil packaging and carefully remove the cartridge from the packaging. Immediately insert the cartridge into the Druglizer placing the small plastic bag containing the Collector next to the instrument.

STEP 4. Now open the plastic bag containing the Collector, carefully remove the Collector from the packaging, handing it immediately and directly to the donor. Ensure nothing touches the sponge.

Instruct the donors to press the inside of their cheeks with the tip of the tongue 5 times to encourage the production of saliva.

Instruct the donor to rub the collector up and down 5 times on the inside of each cheek, then back and forth on the tongue 5 times (sponge side on the cheek). Finally, place the Collector on top of the tongue with the sponge facing down (the sponge should be towards the middle/back of the donors' tongue).

Instruct the donor to tilt their head forwards and rest in a "chin to chest" position.
Ensure the collector sponge is not chewed or sucked at any time in this process.
The collector should remain in the mouth for a minimum of 1 minute, with the donor in a "chin to chest" position, to allow for sufficient saliva to be collected.

TIP – advise the donor not to be concerned about excess saliva on the collector and not to suck or bite the sponge during the sample collection process or when removing it from their mouth.

STEP 5. Once the full minute has elapsed, advise the donor to raise their head, open their mouth fully and, without sucking on the collector, remove the collector from their mouth avoiding contact with their teeth.

TIP – This action will ensure that all the accumulated saliva is retained on the Collector sponge.

STEP 6. Once removed from the mouth, ask the donor to show you the moisture sensitive dot on the back of the collector and ensure that it is solid blue, consistent from edge to edge, as per the display examples on the screen of the Druglizer.

With the moisture dot being solid blue, proceed with the test by taking the Collector from the Donor. Ensure the sponge does not encounter anything. (If the moisture dot is not a solid blue, advise the donor to repeat the saliva collection process for a further 10-15 seconds and repeat Step 6. Do this twice if necessary).

TIP – If the Dot does not turn a solid blue, discard the Collector, and allow the donor to rehydrate with standard drinking water. Wait 15 minutes and retest with a new Cartridge and Collector.

STEP 7. Insert the Collector at a 45° angle into the Cartridge inside the Druglizer and slowly lower the Collector down in a smooth motion until the collector clicks firmly into place (it cannot be removed easily once correctly attached). Press the Test Key to confirm that the collector has been inserted.

TIP – if you see a slight pooling of saliva in the box around the collector sponge, this is a good sign that sufficient saliva has been collected.

STEP 8. The analysis will start shortly after the Collector has been inserted. The Druglizer unit must remain flat (horizontal) while analysing. An orientation sensor will sound an alert if the Druglizer is picked up and not lying horizontally during testing.

TIP – You have 20 seconds to return the Druglizer to horizontal before the test will be aborted.

STEP 9. The Druglizer will display “Analysing” within 15-30 seconds of the Collector being inserted into the cartridge. As the analysis commences an increasing time counter will be visible at the bottom of the Druglizer screen.

STEP 10. At approx. 90 seconds on the counter, the first test result should appear on the screen. The instrument is still analysing other drug classes, do not move the Druglizer until all expected drug classes have displayed a result on the screen, which typically takes 120-160 seconds.

A completed test will provide either a NEGATIVE result in green, or an UNCONFIRMED result in red.

TIP – The amount of time to complete a test varies from donor to donor based on their individual saliva. The Druglizer will display “INSUFFICIENT SALIVA” or an “INVALID’ test

result if there was not enough saliva collected. In which case, repeat the test process from step 2 with a new test cartridge.

STEP 11. Once all results are displayed, remove the Cartridge and (the attached) Collector from the top of the Druglizer as a complete unit, dispose of them appropriately.

The Druglizer screen will now return to the “Insert Cartridge” screen and is ready to perform another test.

19.2 Annex B – Bluetooth Troubleshooting

Quick Fix Guide: Resolving Stale Bonding Issues between Tablet, App, and Alcolizer Bluetooth Device

Introduction:

Stale bonding issues can occur when there is a disruption in the Bluetooth communication between your tablet (or other device), the app hosted on it, and a third-party device you are trying to connect to. This guide provides steps to troubleshoot and resolve these problems, ensuring a seamless Bluetooth connection.

What is Stale Bonding?

Stale bonding is not an uncommon Bluetooth condition and refers to a situation where a previously established Bluetooth connection between devices becomes inactive or "stale." This can result in difficulties re-establishing a stable and secure connection between devices, leading to communication problems and disruptions in functionality.

Step-by-Step Quick Fix Guide:

Step 1: Check Device Compatibility:

Ensure that nothing has changed and that the tablet, the app, and the Alcolizer device are all compatible with each other's Bluetooth protocols and specifications. Outdated or incompatible devices may lead to bonding issues.

Step 2: Turn Bluetooth Off and On:

- On your tablet, access the Settings menu.
- Locate and tap on "Bluetooth" to toggle it off.
- Wait for a few seconds and then toggle Bluetooth back on.

Step 3: Forget and Re-pair the Device (from the Tablet and Device):

- From the Tablet:
  - Access the tablet's Bluetooth settings.
  - Locate the entry for the third-party device that you're experiencing bonding issues with.

    - Tap on the device's name and select "Forget" or "Unpair."
    - Restart both your tablet and the third-party device.
    - Re-pair the devices by following the initial pairing steps provided by Alcolizer.
- From the Device:
    - Access the device (Druglizer) configuration menu to forget the BT connection: > Configuration > AlcoConnect > Forget
    - For LE5 Breathalyser you will need to access the 5000 menu (see user manual)
    - Restart both your tablet and the third-party device.
    - Re-pair the devices by following the initial pairing steps provided by Alcolizer.

(note: Users may wish to perform both steps in parallel)

The following steps are more aggressive in nature and will clear cached memory so should only be undertaken by skilled IT professionals and/or under support/supervision of a competent IT person.

Step 4: Clear App Cache and Data:

- On your tablet, navigate to the "Settings" menu.
- Locate and select "Apps" or "App Manager."
- Find the app associated with the Alcolizer device.
- Tap on the app and select "Storage."
- Choose "Clear Cache" and "Clear Data."
- Restart your tablet and launch the app again.

Step 6: Reset Network Settings:

- On your tablet, navigate to the "Settings" menu.
- Select "System" or "General Management."
- Choose "Reset" or "Reset Options."
- Select "Reset Network Settings."
- Confirm the reset and allow your tablet to restart.

Step 7: Update App and OS:

- Open the app store on your tablet (e.g., Google Play Store or Apple App Store).
- Check if there are any updates available for the app you're using.
- Update the app to the latest version.
- Similarly, ensure that your tablet's operating system is up-to-date by checking for system updates in the device's settings.

Step 8: Contact Support:

- If the issue persists after following the above steps, it's advisable to contact your I.T. Department for assistance who may escalate to Alcolizer support who can provide further assistance and troubleshooting tailored to your specific situation.

Conclusion:

By following these steps, you can troubleshoot and resolve stale bonding issues between your tablet, the app hosted on it, and a third-party device. These actions help ensure a stable and reliable Bluetooth connection, enabling you to fully utilize the capabilities of your devices and maintain smooth communication.