



# Quick Start Guide

# Axxin T8-ISO

## Instrument

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**D006093 Version 1.5**



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## Contents

1	Introduction .....	4
1.1	Operating Modes .....	4
1.2	System Components .....	4
1.3	Instrument Overview .....	5
2	Setup Guide .....	6
2.1	Initial Setup .....	6
2.2	Front Status Light .....	6
2.3	Power Button .....	6
2.4	User Interface .....	7
3	Power Up .....	9
3.1	Self Test .....	9
3.2	User Login .....	9
3.3	Home Menu .....	9
4	Run Test .....	10
4.1	Tube Results .....	11
4.2	Save Results .....	12
5	Test Results .....	13
6	Settings .....	14
6.1	Basic Settings .....	14
6.2	Administrator Settings .....	14
6.3	Factory Settings .....	14
7	Creating & Importing Test Type Packages .....	15
7.1	Importing Test Types from a USB .....	15
8	Data Export and Archive .....	16
8.1	Export Result Process .....	17
9	T8-ISO instrument Specifications .....	18



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## 1 Introduction

This document describes setup, configuration and operation of the T8-ISO Isothermal Test Instrument.

Axxin's advanced T8-ISO instrument provides next generation molecular testing in a compact, stand alone, high sensitivity instrument suitable for both laboratory and field-based applications.

The T8-ISO Instrument is a portable instrument that provides measurement of two fluorophores: FAM and ROX or other fluorophores with similar spectra.

This instrument is intended for research and development use only and is not intended for in vitro diagnostic (IVD) medical use without further assay and application specific, testing and certification.

The T8-ISO instrument forms part of a larger test system including the chemistry assay under test and risks for the overall system should be considered.

If the intended use carries risks of loss or injury, additional tests or indicators must be considered to mitigate these risks.

It is the user's responsibility to follow all diagnostic test kit instructions for use with T8-ISO Instrument. Any improper use leading to test failure such as contamination, lot expiry or incorrect sample handling is the responsibility of the user and falls outside the scope of Axxin.

This document is a quick guide to assist with instrument setup and use.

Refer the following full user manuals for detailed instructions and warnings:

D005566 User Manual, T8-ISO Instrument, Axxin T8-ISO.pdf

D005842 User Manual, T8 Desktop Application, Axxin T8-ISO.pdf

### 1.1 Operating Modes

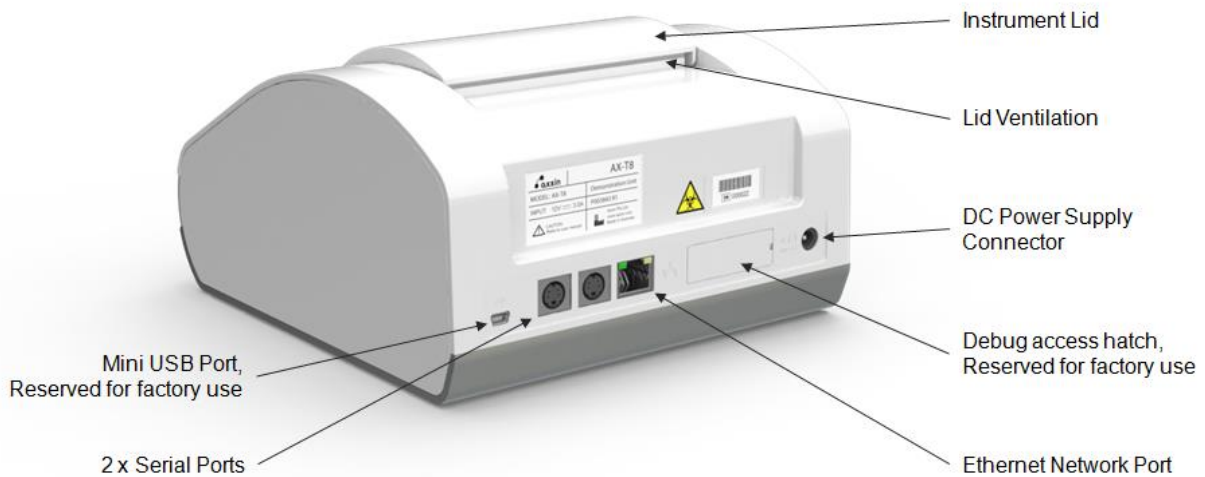
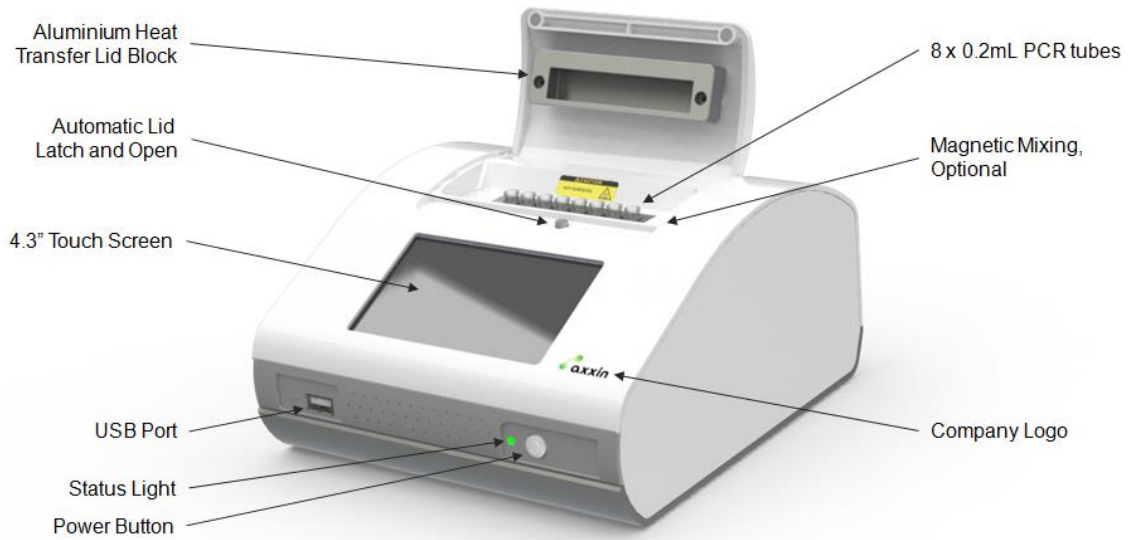
The T8-ISO instrument is designed to operate either in standalone mode or connected to the T8 Desktop Software application. The method of use depends on the end user's requirements and preferred setup. The Desktop Software provides the user the tools to configure test types for deployment to the T8 Instrument. This includes creating customised test result calling decision algorithms. Additionally, the user has the option to connect to Desktop Software to observe tests and assay development in real time on the pc screen. Note that all Tests are still initiated through the instrument and not from the Desktop Software. Test type algorithms can also be run with previously acquired test data for optimising results.

### 1.2 System Components

The following system components are supplied with the T8-ISO instrument:

- T8-ISO Instrument
- Power Supply and region specific power adapters
- Printer Cable
- Barcode Scanner Cable

### 1.3 Instrument Overview



## 2 Setup Guide

### 2.1 Initial Setup



#### Unpack T8-ISO instrument

Unpack the T8-ISO instrument and set up on a stable, level bench, in a clean office or lab type environment.



#### Power Supply

Configure the power supply for your region.  
 Connect the 12V power supply to the T8-ISO instrument.



#### Test Types on USB Key

Use a USB key to import test types onto the T8-ISO instrument.



#### Power Off/Standby

It is recommended that the T8-ISO instrument is powered down when not in use.

### 2.2 Front Status Light

The instrument has a fixed intensity white, front panel LED to indicate power status:

<b>Rapid Flash</b>	5 Hz: Instrument is in bootloader mode (shown during Instrument software updates)
<b>Medium Flash</b>	Instrument is heating up to set temperature (approx. 1 flash per second)
<b>Slow Flash</b>	Instrument is in sleep mode (approx. 1 flash per 4 seconds)
<b>On Solid</b>	Instrument is running and at set temperature

### 2.3 Power Button

The T8-ISO instrument incorporates a front mounted power button. Once power is connected to the rear of the instrument, press the button for one second to power up and start the instrument. When the instrument is running it can be turned off (shut down) by pressing and holding the power button for 3 seconds or longer.

## 2.4 User Interface



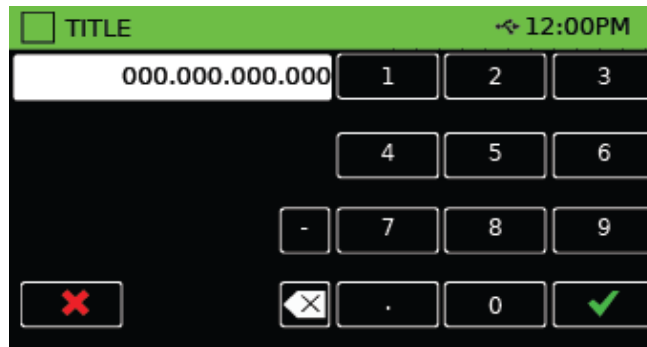
**Button:** Touch the button to perform action.



**Editable text:** Touch the yellow text box to edit text.

If the text is a single digit, the digit will increase by 1 with each touch.

If the text is a number, the numerical keypad will be displayed:



If the text is a text string, the QWERTY keypad will be displayed:



**Text:** Text such as reading results or settings is displayed in a white text box. This text is not editable.



**Test:** Touch the Test button / icon to run a new test.



**Test Results:** Touch the Test Result button to navigate to the Test Results menu and access test result history.



**Settings:** Touch the Settings button to navigate to the settings menu.



**In Standard User:** Allows password input for user to change to either Admin or Factory User

**In Admin/Factory User:** Allows access to Admin settings menu



**Factory Settings:** Available to Factory users only, touch the Factory Settings icon to navigate to the factory settings menu.



**OK:** Touch the OK icon to confirm an action, input or settings change, acknowledge information or perform another action as specified by instructions on screen. The OK icon must be touched to proceed.



**Cancel:** Touch the Cancel icon to cancel an action, input, settings change, or perform another action as specified by instructions on screen. The cancellation of an action may need to be confirmed e.g. when cancelling a running test.



**Up / Down:** Touch Up or Down icons to navigate through screens, e.g. through a list or menu which flows over multiple screens.



**Return / Next:** Touch the Return or Next icon to navigate through screens.



**Print:** Touch the Print icon to print information on screen. Printer must be connected to instrument.



**Export:** Touch the Export icon to export test result or other content as specified by instructions on screen. An FAT32-formatted USB key must be connected to instrument.



**Import:** Touch the Import icon to import test packages or other content as specified by instructions on screen. An FAT32-formatted USB key must be connected to instrument.



**Error:** An error screen is displayed when an action could not be completed, e.g. a test could not be completed, USB key was not found, or the self test was failed. Touch the ✓ icon to acknowledge the error.



**Warning:** A warning screen is displayed when confirmation of an action is required e.g. user cancels a test in progress. Touch the ✓ icon to confirm the action. Touch the ✗ icon to cancel the action.



**Information:** An information screen is displayed to notify the user of information, e.g. export was successful. Touch the ✓ icon to acknowledge the information.



**Waiting:** A waiting screen is displayed when an action is in progress. Touch the ✗ icon to cancel process.



## 3 Power Up

### 3.1 Self Test

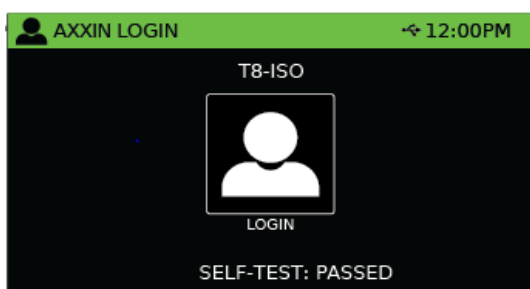


Connect the 12V power supply adaptor to the T8-ISO instrument.

Press and hold the power button until the instrument shows the loading screen.

The instrument will perform a self test.

### 3.2 User Login



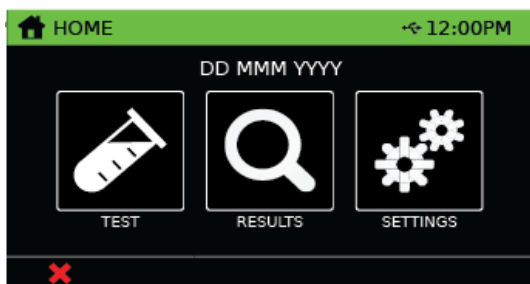
Enter User Name and password if requested. (Login requirements are set by the Admin User in Section **Error! Reference source not found..**)

**Standard User:** A standard user has access to the home menu, testing, result review and basic settings.

**Admin User:** The admin user has access to the all the same functionality as the standard user as well as to the "Admin Settings" screens.

**Factory User:** The factory user has access to the all the same functionality as the standard user as well as to the "Admin Settings" screens and "Factory Settings" screens. Factory Mode is indicated by a yellow header bar.

### 3.3 Home Menu

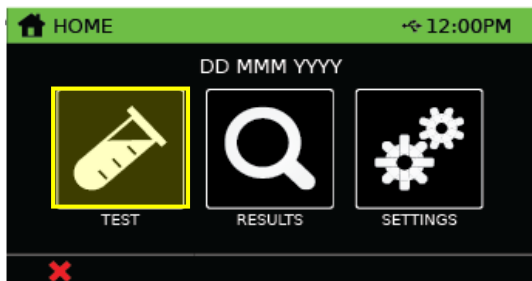


The "Home Menu" is displayed after start up, self test and user login.

The "Home Menu" screen provides access to the following functions:

- Test
- Results History
- Settings

## 4 Run Test



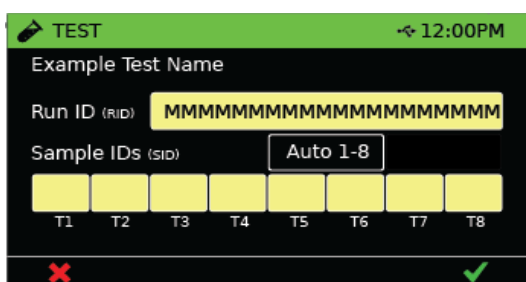
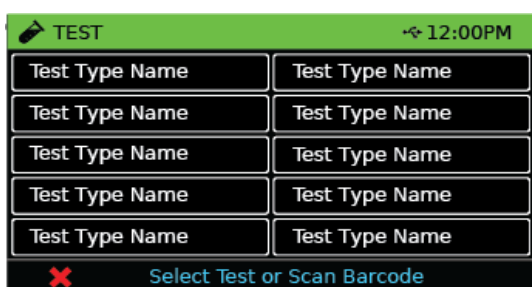
### Run Test

Select the "Test" icon on the Home Screen.

Touch a Test Type in the list of test types installed on the instrument.

Alternatively, scan a Test Type barcode.

Touch the  icon to cancel.



### Edit Test Details, Run ID & Test ID

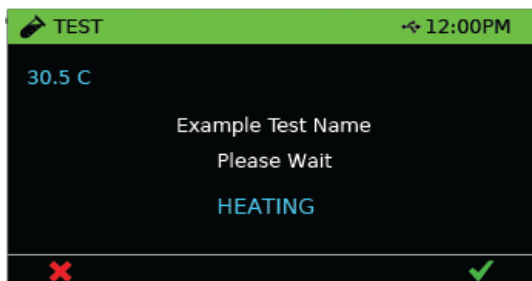
Enter a test name: touch the yellow "Run ID" field.

Enter sample IDs: touch the yellow "Sample ID" fields for Tube 1 to Tube 8.

Auto fill Sample IDs: enter text in the T1 field, then touch the "Auto 1-8" button.

Touch the  icon to continue.


Touch the  icon to cancel.

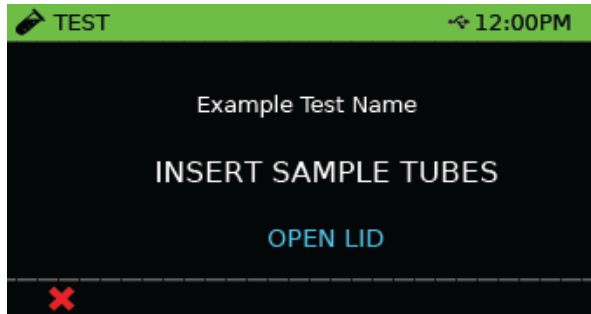


### Heating to Test Temperature

Wait for the heater block to reach the pre-set test type temperature.

Touch the  icon to cancel.

Factory users will be presented with a  icon, allowing them to perform diagnostics without the instrument heating to test temperature.



### Insert Samples and Close Lid

Insert sample tubes.

Close the lid.

The instrument will detect that the lid is closed and automatically proceed to the next screen.

Touch the **X** icon to cancel.

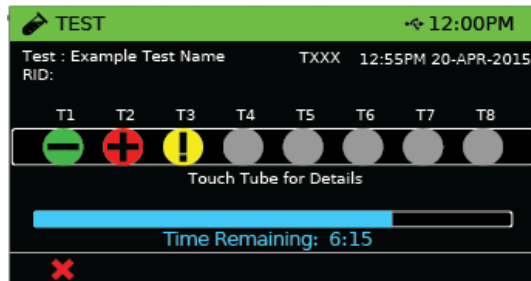
## 4.1 Tube Results

The following results are possible for each tube:

 **Negative Result**

 **Positive Result**

 **Invalid Result**

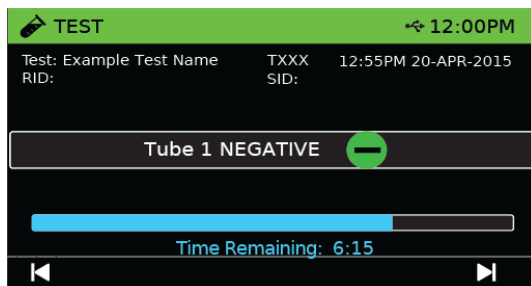



### Test Running


The Run ID (“RID”) and Sample ID (“SID”) entered in Section **Error! Reference source not found.** are displayed on this screen.


The time remaining until test completion is shown at the bottom of the screen.

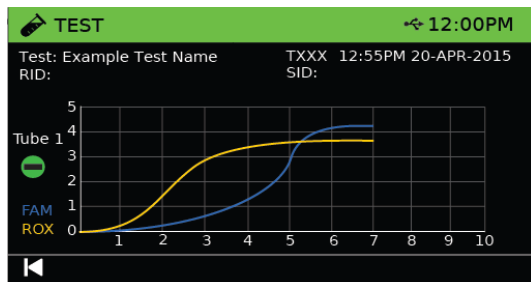
Touch the **X** icon to cancel.

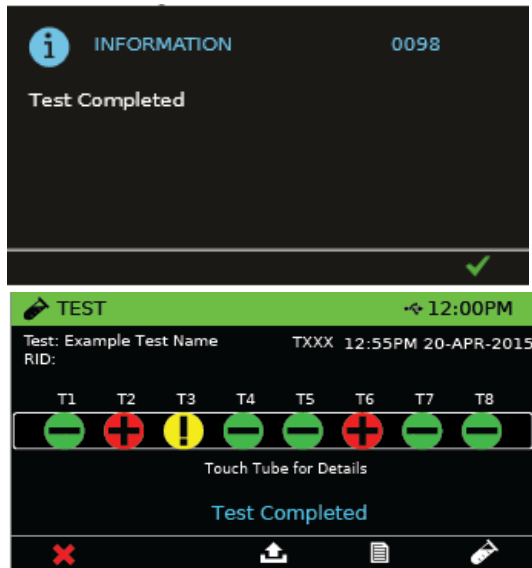


Detailed results for each tube can be accessed by touching its results icon ().

Touch the  icon, or click the result to navigate to the graph for the selected tube.

Touch the  icons to navigate between screens.








### Test Results screen


The “Results” screen is displayed when test is completed.

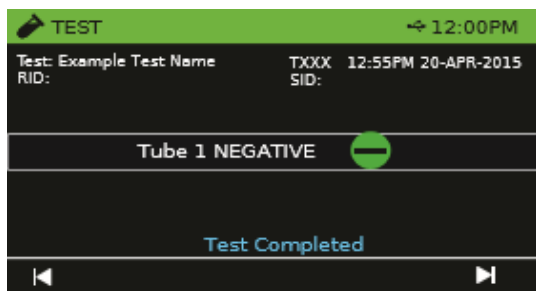
Touch a Tube icon to view detailed results.

Touch the  icon to print test result.

Touch the  icon to export test result.

Touch the  icon to run a new test.



Touch the  icon to cancel and navigate to the Home Screen.

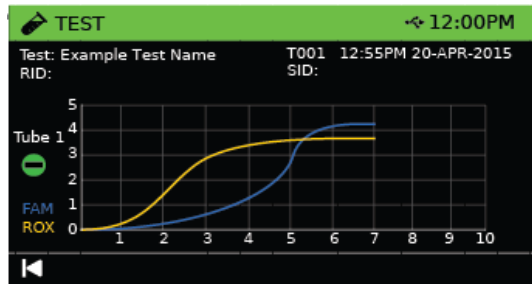


### Test Result Details

Detailed “Results” screens.

Touch the tube result (“Tube 1 NEGATIVE” in the screenshot) to view the result graph (if enabled in the test type).

Touch the   icons to navigate between screens displayed on the left.



## 4.2 Save Results

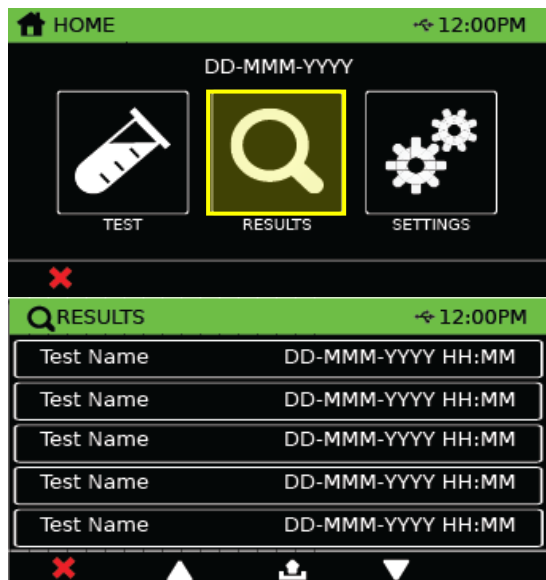
The application automatically saves test results to a location in the T8-ISO Instrument memory.

Refer to section 8 for details of exporting test results to a USB key.

The test results are .CSV files that can be opened and viewed on a PC and printed.

## 5 Test Results

The T8-ISO instruments test results screen enable the user to search through the test data stored. Such information can be searched via a number of different test fields.



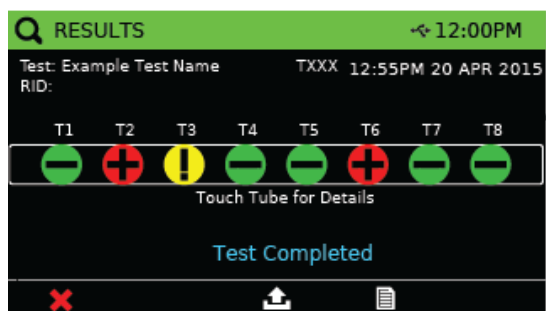
### Results List Menu

Touch the "Results" icon on the Home Screen.

A list of test results is displayed.


Touch a test result in the list to view result.


Touch Export Results  icon to export results to a USB key.




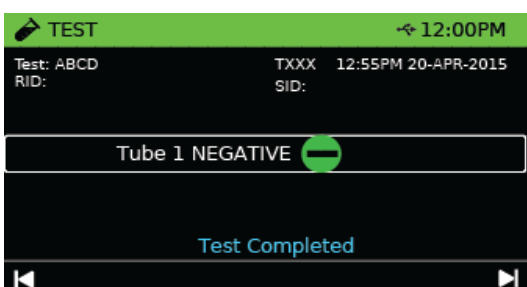
### Results screen

Touch a Tube icon to view detailed results.

Touch the  icon to cancel and navigate to the "Home Screen".



Touch the  icon to print test result (refer to section **Error! Reference source not found.**).

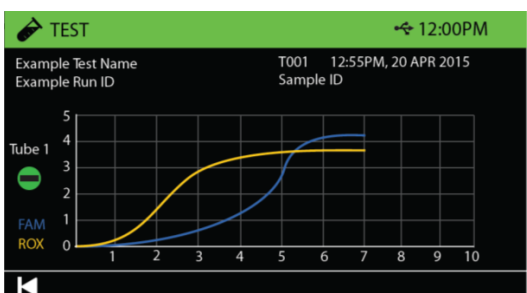
Touch the  icon to export test result



### Result Details

Detailed results screens.

Touch the Forward icon  to navigate to the next screen and the  to go back to the previous screen.



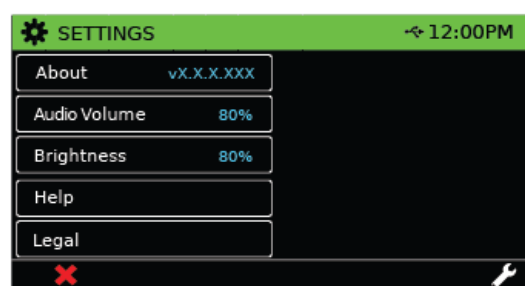
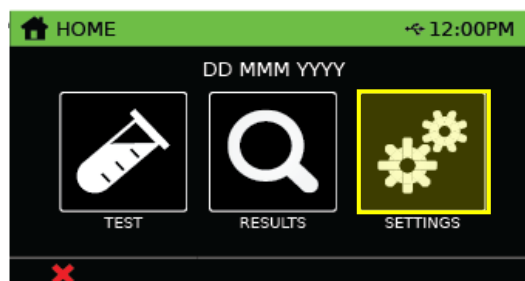
## 6 Settings

### 6.1 Basic Settings

The “Settings” menu is available to all Users.  
Touch the Settings icon on the “Home Screen”.  
Touch a menu button to navigate to that item.


The following selections are available under settings:

- About
- Audio Volume
- Brightness
- Help
- Legal



### 6.2 Administrator Settings

Admin settings are available to Admin and Factory Users.

Navigate to the Admin Settings by selecting the  icon on the “Settings” screen.

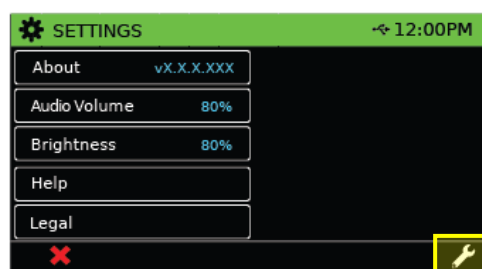
The following selections are available under settings for the Admin user:

- |                         |                    |
|-------------------------|--------------------|
| - User List             | - Language         |
| - User Login            | - Temperature      |
| - Auto Logout           | - Update Software  |
| - Set Admin Password    | - Restore Defaults |
| - Set Clock             | - Import Resources |
| - Test List             | - Open Lid         |
| - Default Test Settings | - Run Self Test    |
| - Print Options         | - Export Logfile   |

A password is required to access the Admin settings. The default setting is “admin”

### 6.3 Factory Settings

Refer to the full user manual, D005566 User Manual, T8-ISO Instrument, Axxin T8-ISO for calibration and factory functions in the instrument.



## 7 Creating & Importing Test Type Packages

When the T8-ISO instrument is first shipped or after it is returned to the User Default state by an admin user, a single default test will be available for selection by the user for the purposes of evaluation and demonstration.

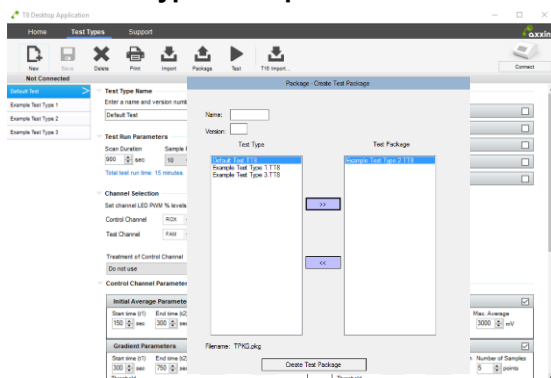
A user can create tests specific to their application using the associated Desktop application for the T8 instrument. These customer specific tests can then be run on the T8-ISO instrument. Two methods are provided to run user created tests on the instrument. These are:

- Up to 10 tests types can be imported from a USB key and saved within the instrument memory to be run at any time.
- A test type can read from a 2 dimensional QR code using an attached barcode reader and run immediately.

### 7.1 Importing Test Types from a USB

The user can create Test Types on the Desktop Application and import these onto the instrument using a USB key.

#### Create Test Types & Export onto USB



After creating a Test Type on the Desktop Application, export it as a package onto a USB key.

*Refer to D005842 User Manual, T8 Desktop Application, Axxin T8-ISO on how to create and export a Test Type Package.*

#### NOTE:

Ensure that **only 1 Test Type Package file** (\*.pkg) is present on the USB key.

Ensure that the Test Type Package is saved at the USB root level (**not nested in any folders**).

#### Insert USB into T8-ISO Instrument




Insert USB key with the Test Type Package file (\*.pkg) into the T8-ISO instrument's USB port, located on the front of the instrument.

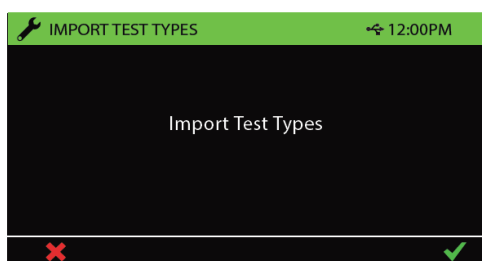
## Import Test Types into T8-ISO Instrument




Log in as an admin/factory user (*section **Error! Reference source not found.***).

Navigate to the Test List screen under admin settings (*section **Error! Reference source not found.***).

Select the  icon to import Test Type Package from the USB key.



Touch  to import Test Type Package.

Touch  to cancel and return to Test List screen.

When the Test Type Package has been successfully imported, the Test Types will be available in the Test List screen.

## 8 Data Export and Archive

The instrument has an internal test result memory capacity of 50 tests.

**Test Results and Data Archive Recommendation:** It is highly recommended that test results are exported to an external USB Key and that this data is stored separately from the T8-ISO instrument as a backup.

The results from each test on the T8-ISO instrument get saved as

- a test results .csv file, which contains all the test parameters, measured data and final results
- a summary .pdf file, which contains only the final results and corresponds to the printed results page

The file names are structured in this fashion:

Instrument model - serial number – year – month – day - file number - test name.csv

e.g. T8-S000000-2014-09-07-12-Case 2.csv

A user can export individual test results or all test results on the instrument.

An admin or factory user can delete all tests on the instrument at the completion of a successful export.




## 8.1 Export Result Process



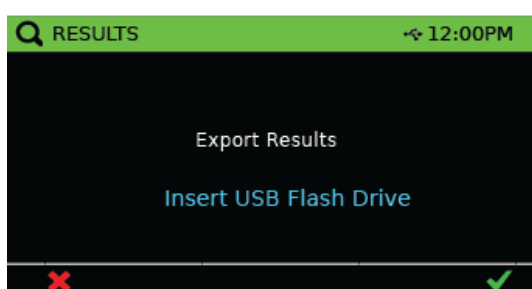
### Choose Test Result for Export

Touch ▼▲ to navigate through the “Results” screens.


Touch the Test Name.

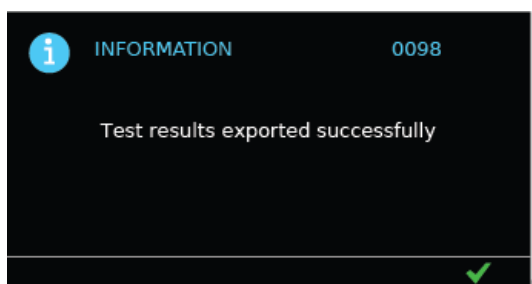
Touch the  icon to export the selected test to a USB device.

Touch the  icon to cancel.




Insert a FAT32 formatted USB flash memory key.

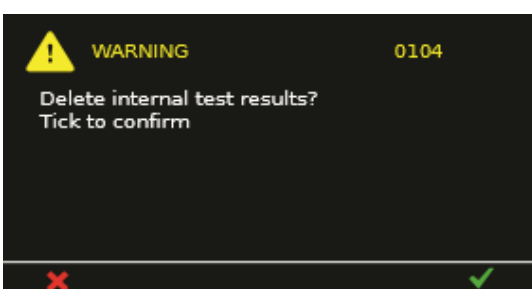
Touch the  icon to export results.



### Export Success

Test results were successfully exported to the connected USB key.


Touch the  icon to acknowledge.

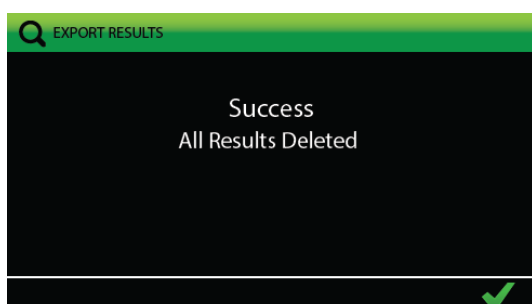


### Delete Results


If the user is logged in as Admin User or Factory User, an additional screen asks if you wish to delete all test results in the instrument's test result history.

Touch the  icon to confirm removal.

If you want to retain the test results on the instrument, touch the  icon.



### Results Deleted

If the  icon was selected on the previous screen, this message will indicate that the instrument's test result history was successfully deleted.



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## 9 T8-ISO instrument Specifications

<b>Number of Tubes</b>	Configured for 8 tubes Accepts 8 x 200µL PCR tubes (standard 8 tube strip)
<b>Scan Time</b>	10, 15 or 20 seconds
<b>Data Storage</b>	50 test results can be stored on the instrument. History Records allow search and retrieval. Archive or export via USB/ Ethernet.
<b>Multiple Assays, Test Types</b>	Supports multiple assay types and test protocols defined on the T8-ISO Desktop Utility. 10 test types can be stored on the instrument, imported from a USB data file or scanned from a QR code.
<b>Measurement technology</b>	2 Fluorescent Channels. FAM and ROX as standard. Optional FAM, HEX, ROX, Custom, or bioluminescence.
<b>Colour Touch Screen</b>	4.3 inch TFT LCD. Simple workflow management Ease of use; Colour icon driver menus and prompts.
<b>Communications</b>	Ethernet Network Connection Mini USB Port for PC connection USB Port for Data Export, Software Update and Test Types import
<b>Power</b>	12 V DC from external AC/DC supplied plug pack. DC Voltage fluctuation ±10% DC Current consumption: 12V DC, 3.0 Amps Power supply adaptor is configured for different regions.
<b>Dimensions</b>	Width 185mm (7.28") Depth 203mm (8.00") Height 110mm (4.33")
<b>Weight</b>	2.3 kg (5.1 lb)
<b>Lifetime</b>	5 year design life or 10,000 test whichever occurs first
<b>Printer Support</b>	Label printer connected via Serial cable
<b>Barcode Reader</b>	Barcode reader connected via Serial cable
<b>Operating Environment</b>	Indoor Use. 10°C to 30°C, 10% to 80% RH (non-condensing). 0 to 2000m altitude. Pollution degree: 2 Pressure 0.763 bar (2000m) to 1.01 bar (sea level) Minimum light conditions of 100 LUX. Maximum light intensity of 5,000 LUX
<b>Storage Environment</b>	2°C to 45°C, 20% to 70% RH (non-condensing) for at least 7 days. Pressure 0.763 to 1.01 bar. 0 to 2000m altitude. Maximum duration 1 month (cumulative)
<b>Cleaning</b>	Isopropyl Alcohol (IPA) or 10% bleach solution, on a damp, lint-free wipe. (No free liquid)