ENVIROLOGIX™
Putting Science to the Test

User Manual

DNAble® Reader & Desktop Application

DNABLE®
Rapid On-Site DNA Detection

Version 1.0
March 2013

1 PREFACE

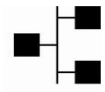
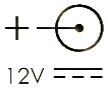
This manual, as well as the hardware and software described in it, is provided under license and may be used and/or copied only in accordance with the terms of such license. The content of this manual is furnished for informational use only, is subject to change without notice and should not be construed as a commitment by Axxin Pty. Ltd. or EnviroLogix Inc.

This document is provided as an operational summary to describe the use of the instrument accessed remotely using the supplied desktop software application. This document does not describe operation of the specific diagnostic test or provide any input to the requirements, safety or processing of the diagnostic test which is outside of the scope of Axxin Pty Ltd.

EnviroLogix Inc.

500 Riverside Industrial Parkway
Portland, ME 04103
Ph: 1-866-408-4597 (1-207-797-0300 outside U.S.)

1.1 CONVENTIONS

SYMBOL	*NAME*	*DESCRIPTION*
	**Warning**	Indicative of a situation which, if not avoided, could result in injury to the user and/or damage to the instrument.
	**Hot Surface**	This symbol is used to indicate potentially hot instrument surfaces.
	**USB Connector**	USB 2.0 High Speed interface connector
	**Ethernet Connector**	Wired Ethernet ,10/100 Mb/s connector
	**Power Connector**	DC Power connector, for connection with supplied external AC/DC power pack. 12V DC, 3.0 Amp maximum
NOTE	**Information**	Critical information relating to procedures or use of the instrument.

1.2 ABBREVIATIONS

ID	Identification	**PC**	Personal Computer
LCD	Liquid Crystal Display	**PCB**	Printed Circuit Board
LED	Light-Emitting Diode	**USB**	Universal Serial Bus

2 WARNINGS AND SAFE USE

	Always operate the instrument on a surface that is level and dry and not in direct sunlight.
	Never move the instrument while there is a test in progress.
	To avoid damaging the instrument, never place objects on top of it.
	**Warning:** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
	**Warning**: Any changes or modifications not explicitly approved by Axxin Pty Ltd could void the user's authority to operate this equipment
	**Warning:** If a USB extension cable is used with the instrument the total length should not exceed 3.0 meters.
	**Warning:** Hot Surfaces. The heater block in this instrument operates up to 65˚C and may cause contact burns or damage to materials in contact with these areas.
	**Warning:** This instrument is designed to operate only with the provided power supply plug pack. This module forms part of the system. Do not operate the system with a different power supply module. The correct power supply is required to maintain the safety and electromagnetic compatibility of the system.
	**Warning:** Risk of electrical shock. Do not operate the instrument or the power supply plug pack if it has been opened, damaged or exposed to moisture, condensation or rain. The external power supply plug pack is sealed with no user serviceable parts. Do not operate this module with any damaged or exposed parts.
	**Warning:** Do not open or attempt to repair the instrument or other accessories as there is a risk of damage to the instrument. This instrument does not contain serviceable parts and should be returned to the supplier for repair. Opening the instrument will also void the warranty. Real time clock coin battery included in the equipment will run for the operational life and is not a user replaceable item.
	**Warning:** Only operate the instrument for its intended purpose and in accordance with this user manual and warnings. Protection provided by the equipment may be impaired if the equipment is operated in a manner contradictory to the above. This instrument (including power supply) is designed to operate within the manufacturers specifications. Do not exceed the manufacturer's specifications when in use.
	**Warning:** Position the unit with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the unit off its work bench. The mains socket outlet intended to use with the DNAble Readers external power pack should be located near the equipment and should be readily accessible. It's recommended that the user unplug the DNAble Reader Instrument when not in use.
	**Warning:** USB and Ethernet Interfaces. If intended for connection to external equipment, please ensure that interfaces of such equipment are separated from mains by double the reinforced insulation and present no risk of electrical shock.

3 INTRODUCTION

This document describes setup, configuration and operation of the DNAble Reader Instrument that works in conjunction with the Desktop software application.

The DNAble Reader Instrument complies with the emission and immunity requirements described in *IEC61326-2-6*.

The instrument manufacturer advises the user to assess the electromagnetic environment of the intended operational environment of the device prior to use.

The instrument test set up is conducted on the DNAble Reader Desktop application and displays detailed test results of a test that can be exported or printed.

When running a test, the desktop application displays live graphs of the tube measurements. The application will save and allow measured data, including a .csv file and graph images, to be exported.

This document is provided as an operational guide to describe the use of the instrument. This document does not describe operation of the specific diagnostic test or provide any input to the requirements, safety or processing of any diagnostic test. See the specific product insert for assay procedure.

NOTE 1 It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

NOTE 2 It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

NOTE 3 This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

3.1 SAFE USE GUIDELINES

The DNAble Reader Instrument is designed to operate safely under these conditions:

- ✓ Indoor use (protected from water)
- ✓ Altitude up to 2000m
- ✓ Temperature 10°C to 30°C
- ✓ Relative humidity 10% to 70% non-condensing
- ✓ Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage
- ✓ Installation Categories (Overvoltage categories) II
- ✓ Pollution Category 2
- ✓ Use with specified and supplied external AC/DC power adaptor only
- ✓ Mains socket for AC/DC power pack should be readily accessible
- ✓ Set up unit on a stable, level bench, in an office or laboratory environment

3.2 LAYOUT

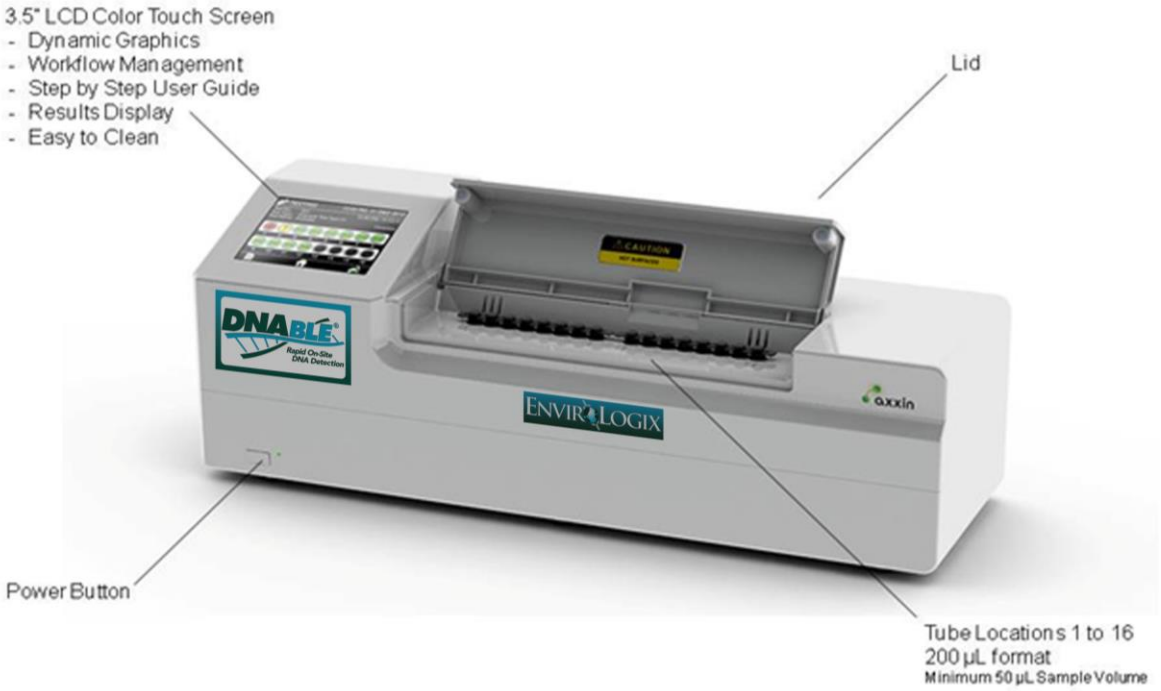


Figure 1 Front View

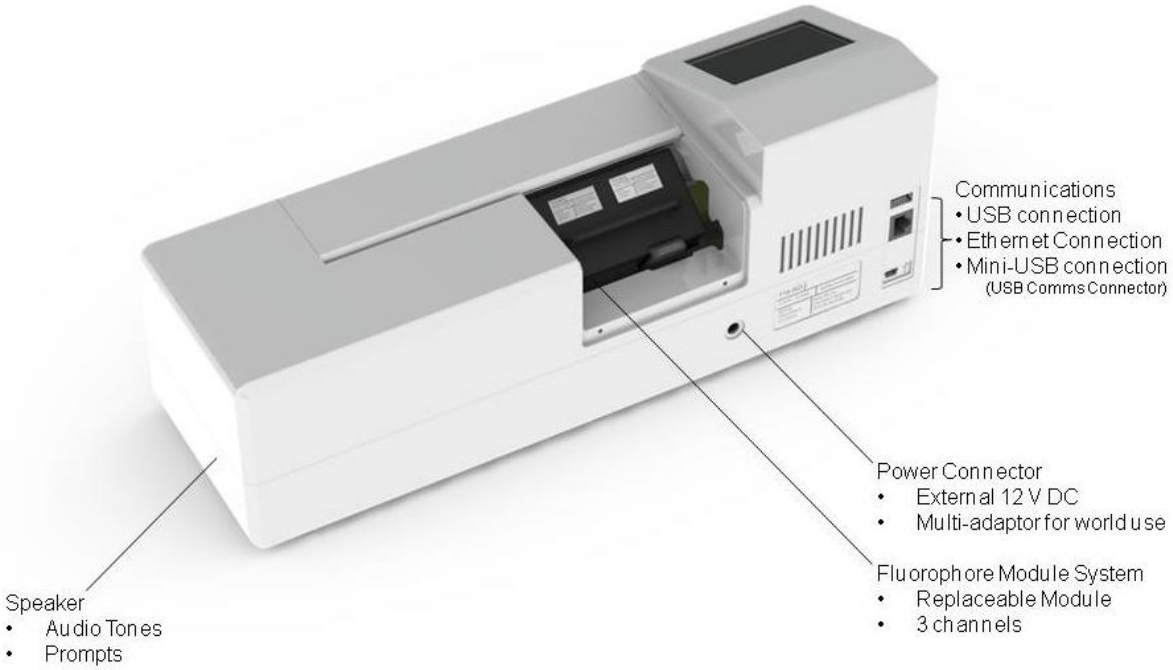


Figure 2 Back View

3.3 INSTRUMENT SPECIFICATIONS

Number of Tubes	Configured for up to 16 tubes
Measurement Technology	Fluorescent - 3 Channel
Color Touch Screen 3.5"	Simple workflow management Ease of use; Color icon driver menus and prompts.
Communications	Cable Ethernet for Data Transfer USB Port for data export, barcode reader and printer Mini USB Port for Laptop connection
Data storage	Up to 99 results (configurable)
Power	12V DC from external AC/DC supplied plug pack Battery power (optional) DC Voltage fluctuation ±10% DC Current consumption: 12V DC, 3.0 Amps
Dimensions	380 mm (L) x 122 mm (W) x 139 mm (H) 14.0" (L) x 4.8" (W) x 5.4" (H)
Weight	1.95 kg (4.1 lb)
Lifetime	3 year calibration life 5 year instrument life
Printers	Network Printer
Operating Environment	Indoor Use 10°C to 30°C 10% to 70% RH (non-condensing) 0 to 2000m altitude Pressure 0.763 bar (2000m) to 1.01 bar (sea level) Pollution category 2 Minimum light conditions of 100 LUX Maximum light intensity of 5,000 LUX
Storage Environment	0°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)
Cleaning	Isopropyl Alcohol (IPA), on a damp/lint-free wipe (no free liquid)

3.4 12V POWER SUPPLY ADAPTOR SPECIFICATIONS

The DNAble Reader Instrument is operated using only the specified and supplied AC/DC power adaptor to ensure both the EMC and safety compliance of the product. The Axxin supplied power adapter, 12V DC, 3.5 Amps

Part Number: P002090

Description: Power adapter input 100-240V AC~50/60Hz 1.2A. Output DC 12V, 3.5A Approval UL'CE; C-Tick; FCC and PSE 4 types plug to fit Australia type; UK type; US (Europe) type and China type.

Rated input voltage	100-240V AC
Rated input frequency	50/60Hz
Rated input current	1.2 Amps
Operating Environment	0°C to 40°C 10% to 80% RH (non-condensing)
Storage Environment	-20°C to 80°C 10% to 90% RH (non-condensing)
Output voltage	12V
Output current:	3.5 Amps

The supplied power adapter (P002090) is compliant with the following standards:

ARCANUM	*COUNTRY*	*CERTIFIED STATUS*	*STANDARD*
UL	USA	MEET	UL 60950-1
CSA	Canada	MEET	CSA C22.2 NO.950
TUV	Europe	MEET	TUV/VDE-EN60950-1
CE	Europe	MEET	Declared& CE Mark
PSE	Japan	/	J60950(H19)/J55001(H14)
BSMI	Taiwan	/	CNS13438
CCC	China	/	GB4943-2001
UK	Britain	MEET	EN60950-1:2000

3.5 POWER BUTTON

The DNAble 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. Once the instrument is running it can be turned off (shut down) by depressing the power button for 3 seconds or longer.

3.6 EXTERNAL CONNECTORS

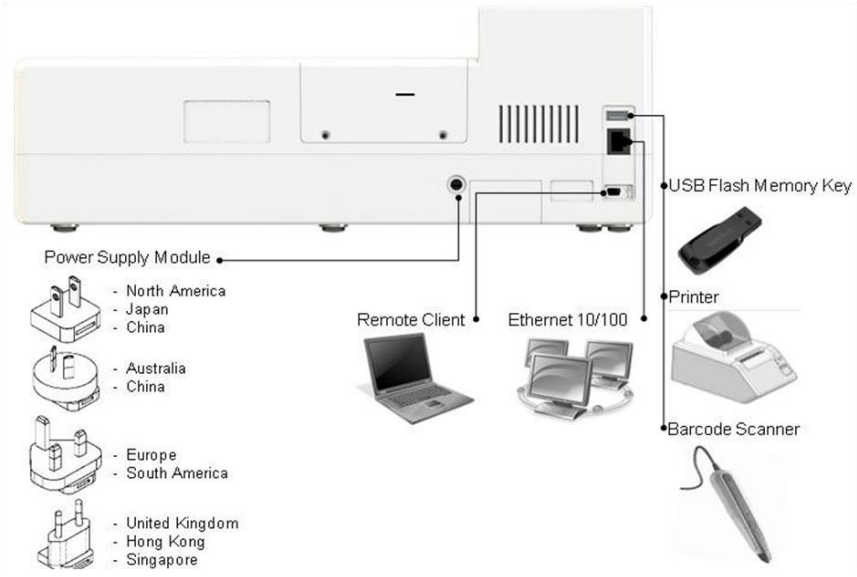


Figure 3 DNAble Reader Instrument, Back View, External Connectors

3.7 PC REQUIREMENTS

PC system requirements for DNAble Reader Desktop Application:

Operating System	Windows 7 - Use Windows Update to make sure you have the latest Service Pack installed for your computer
Memory	Minimum 1GB RAM
Processor	Minimum Intel® Core™ i3 Processor
Peripherals	Ethernet Connection USB Port
Printer Requirements	Network printers over Wi-Fi or Ethernet USB printer

4 SETUP AND INSTALLATION

4.1 SETUP GUIDE

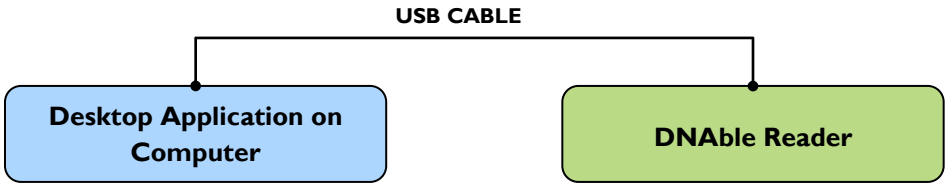
	**DNAble Reader Instrument:** Unpack the DNAble Reader Unit and set up unit on a stable, level bench, in a clean office or lab type environment.
	**Power Supply:** Configure the power supply for your region Connect the 12V power supply to the unit
	**Windows Laptop:** Refer to PC Requirements section
	**Mini USB PC Cable**
	**USB key:** SanDisk, Cruzer Blade brand flash memory key formatted for FAT32 with only 1 partition

4.1.1 INSTRUMENT MODES

Stand-alone mode: allows the instrument to run independently with the use of its touch screen. There is no need for a network or computer in this mode

Remote Connection mode: allows a computer with DNAble Reader Desktop installed to control the instrument and obtain data from it. To allow remote connection, navigate Instrument GUI Remote Mode Screen (Home > Settings > Remote Mode). Select the "Default Remote Mode Startup."

4.1.2 CONNECT READER TO COMPUTER



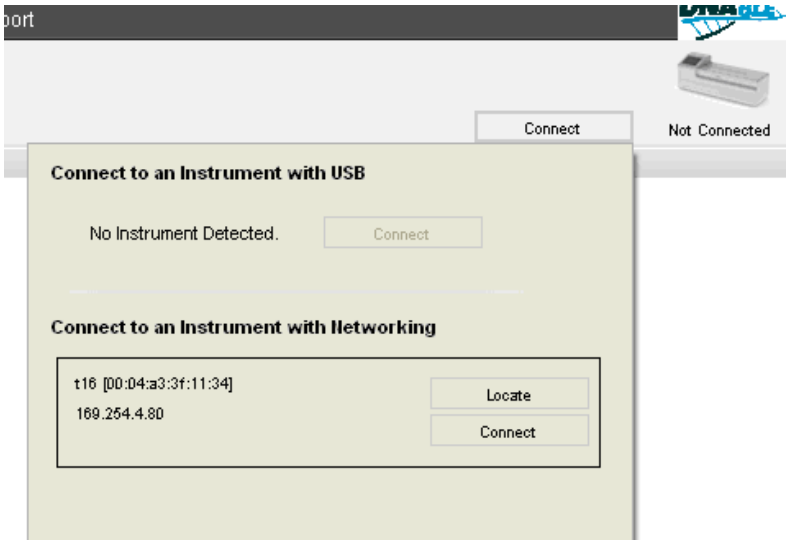
A. Follow remote connection setup guide (Section 4.1 above), connecting instrument to computer via USB Cable.

B. Press the instrument power button for one second to power up and start the instrument. Confirm that splash screen is displayed at power up.

C. Ensure Instrument is in Remote Mode.

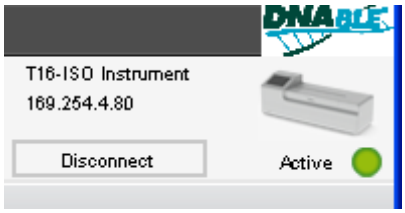
D. On desktop software, click Connect to view available units.

E. Click to connect to instrument.



F. Click disconnect when session is complete.

G. Connection successful.



5 DESKTOP SOFTWARE

The application aims to provide a means of navigating between available functions. It also provides a means of navigating between pages. Tabs will remain fixed. Navigating between pages shall not reset or change the content (e.g. data received for a currently running test shall update the corresponding results page, regardless of whether the user is viewing the page).

Available Tabs:

Home	Instrument	Support

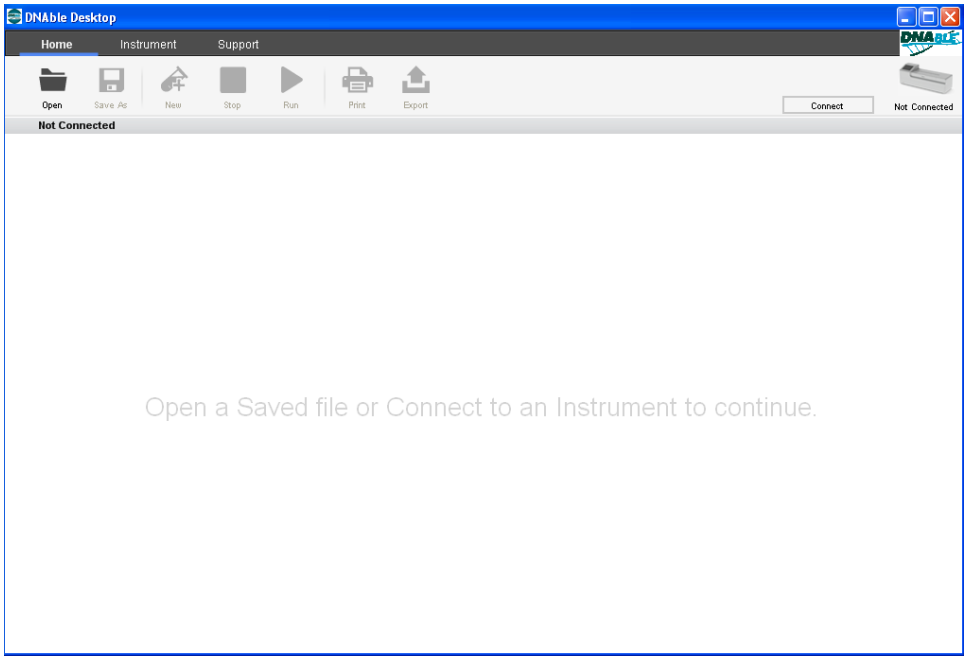
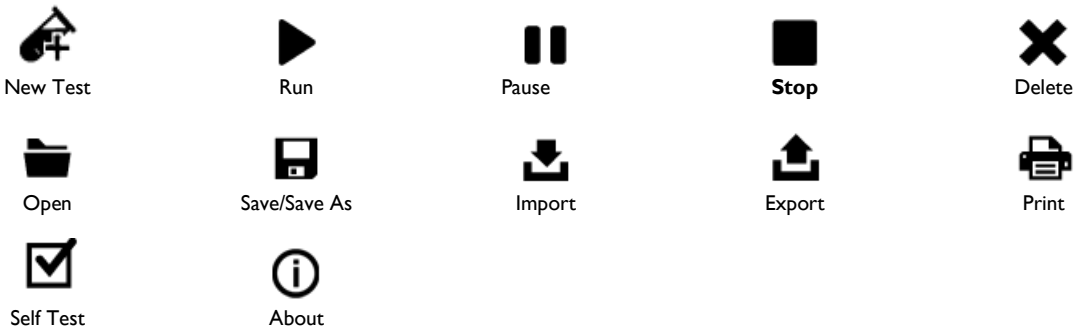


Figure 4 Desktop Application opening screen

5.1 ICONS



5.2 HOME PAGE

The Home tab enables viewing of incoming results from the DNAble Reader. It displays these results in both a graphic and numeric format during and once testing is complete. It presents various view points for a test result.

The Run button is disabled if no device is connected. Use the "Select Test Type" selection box to make a test type selection prior to running test.

Navigation between tabs or Tube menu does not hinder incoming results on a running test. User can navigate and return.

5.3 TEST SETUP

To run a test, select a Test Type from the drop down list and click "OK"

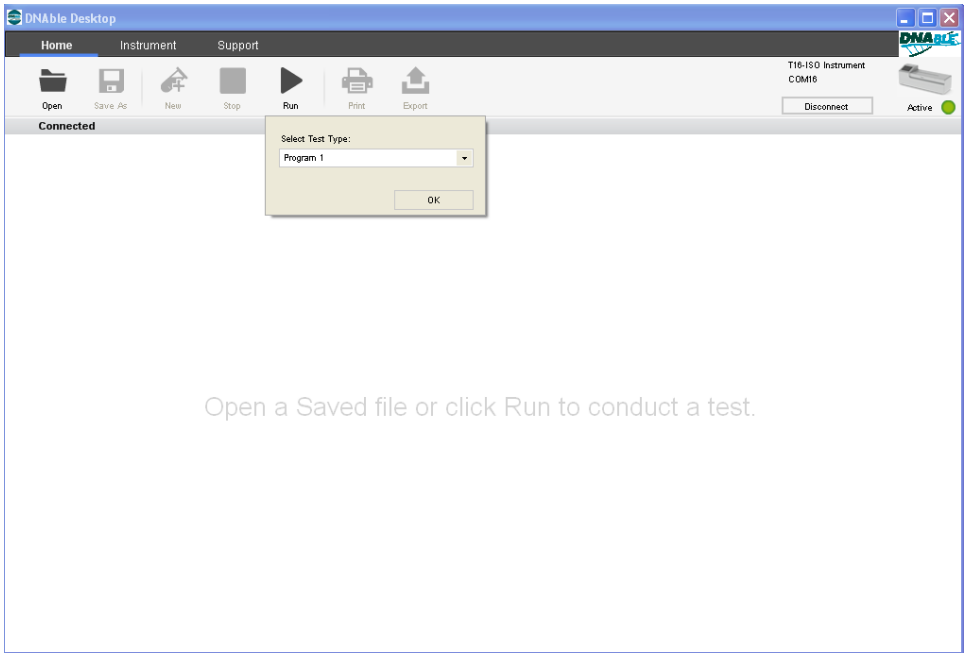


Figure 5 Home > Run > Select Test Type

Enter the:

- User Name of the Tester
- Lot ID of the kit reagents
- Sample ID for the tubes undergoing test.

The DNAble Reader will continue to heat up until the device has reached the correct temperature for testing. The Start Workflow button located at the bottom of the screen will be disabled until the device is ready.

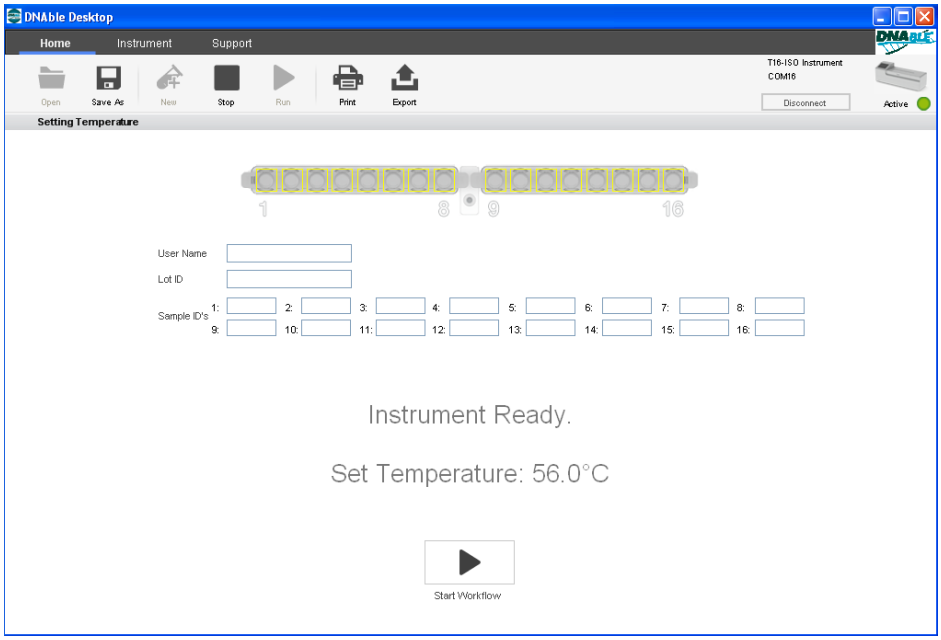


Figure 6 Setup/Start Workflow screen

Sample IDs: Entering Sample IDs into DNAble Reader Application is recommended.

Figure 7 Auto-filled Sample ID

To enable the rapid entry of Sample IDs, if an alpha followed by a numeric Sample ID is entered (for example ABC01) then the information can be auto filled. The auto fill icon will appear in the Tube 01 Sample ID field only once a numeric has been entered.

5.4 RUNNING A TEST

Once the sample tubes have been inserted, the User, Lot, and Sample IDs have been entered, the DNAble Reader is at temperature, and the device lid is closed, then the user is ready to start a test.

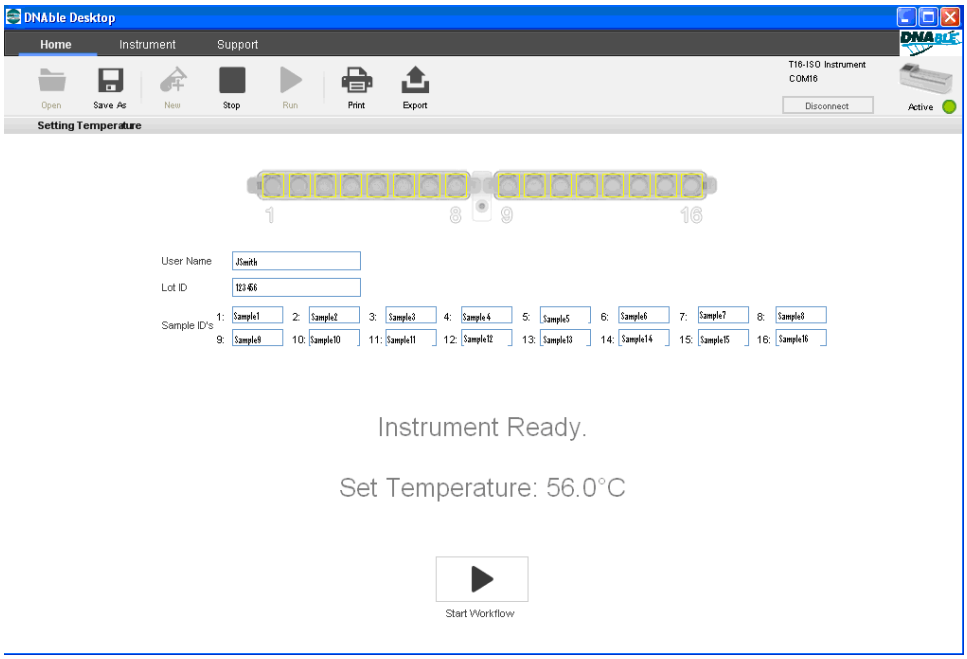


Figure 8 Test is ready to start

Close Lid: The device lid is required to be closed to initiate the start of a test. Once the test workflow has started, lid open and close events will be recorded in the .csv file for review.

6 RESULTS DISPLAY

All Tubes: Test results will be displayed in either an eight or sixteen-tube format, depending on the number of tubes to be run. Below is an example of a sixteen-tube summary shown in the results screen.

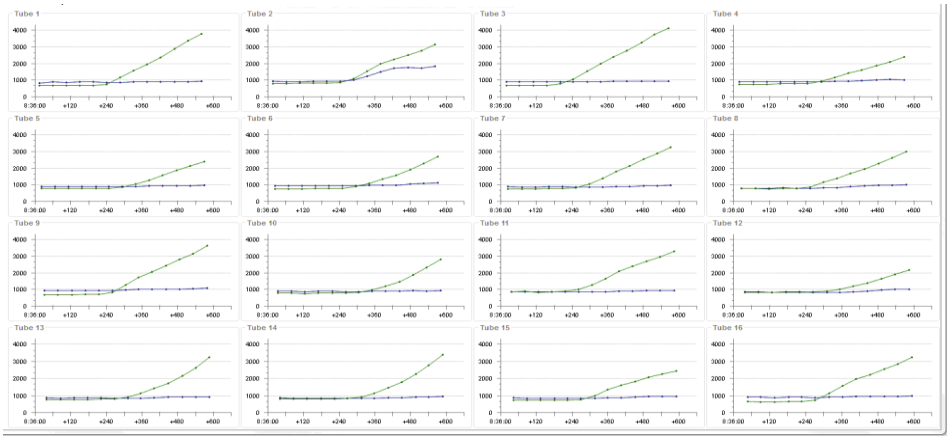


Figure 9 All Tubes graph summary

To change the views of the All Tubes graph summary, the user can switch between the test and control channels to display.

Tube Overlay: The tube overlay graph displays the data readings for all Tubes tested in one graph. The graph can only display results for one channel (Control or Tests) at a time. Tubes hidden and displayed are configurable by the check boxes on the right-hand side of the application window.

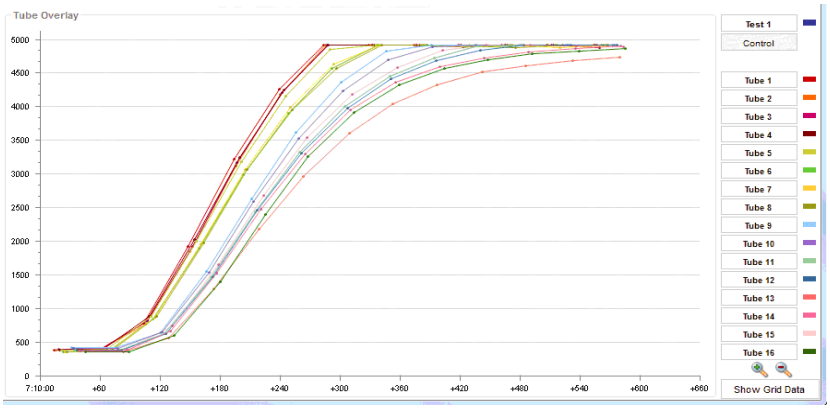


Figure 10 Tube Overlay graph

Results: The results view visually displays the tube results with one of the following possible results:

Positive Result		Negative Result		Invalid Result	

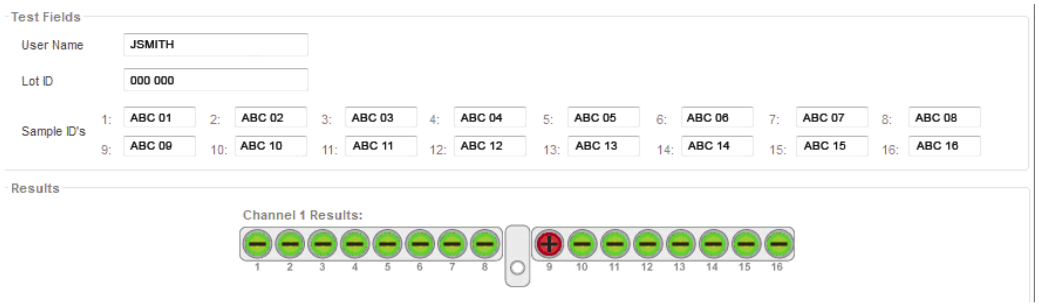


Figure 11 Test Results showing Positive and Negative results

Tube 1 to Tube 16: Displays an individual graph for each tube and offers the same graph configurations available in the All Tubes view. 'Mouse-Over' style hovering on data points displays information about that data point (e.g. time, raw figures).

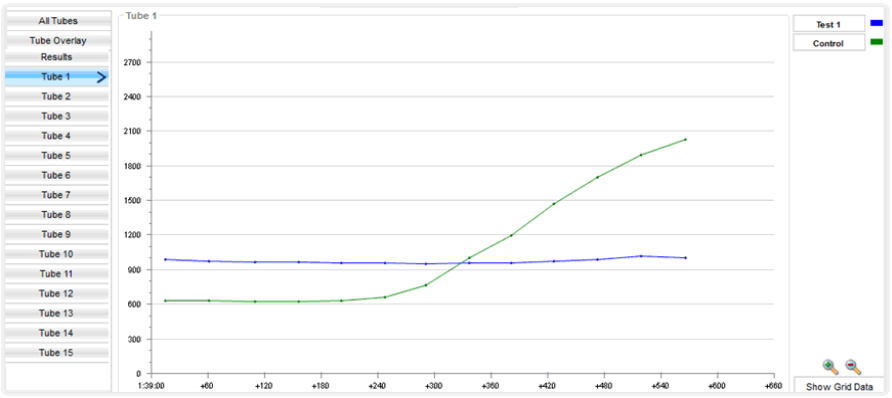


Figure 12 Single Tube graph

Comments: Fields can be entered and edited on running test, completed test, and previously saved test. Additional Test information can be added to the comments section to help a user distinguish tests.

6.1 SAVE AS

The application automatically saves test results to a windows file location. The default file location allocated during the application installation process is:

Local Disk (C:\ > Program Files > Axxin > Axxin T16 ISO Desktop > Test Results

C:\Program Files\Axxin\Axxin T16 ISO Desktop\TestResults

.JSON data: The test results are .JSON files that can be opened, viewed, exported and printed within the DNAble Reader Desktop Application. The test results are automatically assigned a default file name.

FILENAME FORMAT	**Instrument ID**	**_**	**YYYY**	**MM**	**DD**	**hh**	**mm**	**ss**	**File extension**
EXAMPLE	CCEEC413	_	2012	04	27	10	51	01	.json
	e.g. CCEEC413_20120427105101.json								

The Save As function allows the user to resave a results file under a default name or with a user configured name in a user specified file location.

CSV (Spreadsheet) data: The test data is automatically saved in .csv file format upon completion of a test. The .csv files are automatically assigned a default file name.

FILENAME FORMAT	**Instrument ID**	**_**	**YYYY**	**MM**	**DD**	**hh**	**mm**	**ss**	**File extension**
EXAMPLE	CCEEC413	_	2012	04	27	10	51	01	.csv
	e.g. CCEEC413_20120427105101.csv								

6.2 PRINT

Print and/or Save a .pdf report of test results either upon completion of a test run or from the review memory screens.

The DNAble Reader Application offers two print options:

- **Summary Report:** A one page summary based on the application results view.
- **Tube Graphs:** Includes Tube 1 to 16 Results, Tube Overlay (as configured on screen).

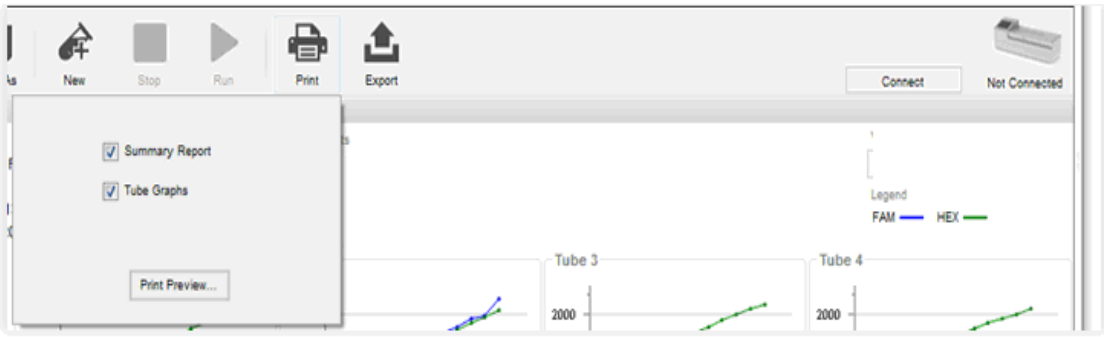
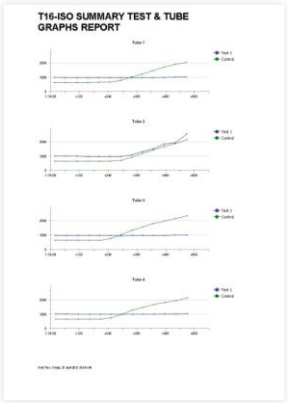
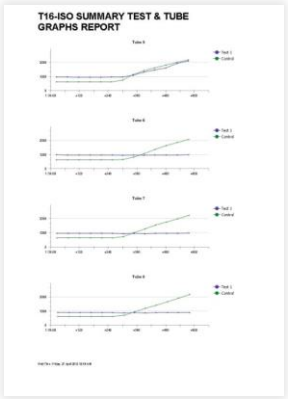


Figure 13 Print Results window

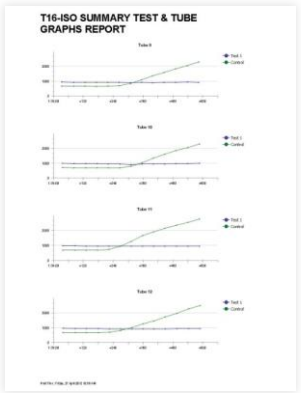
SUMMARY REPORT



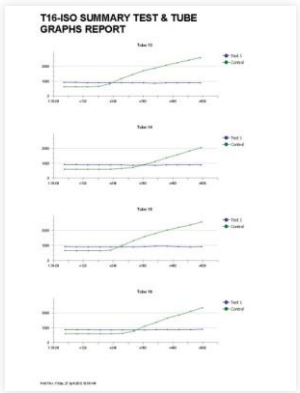
TUBE GRAPHS, PAGE 1/5



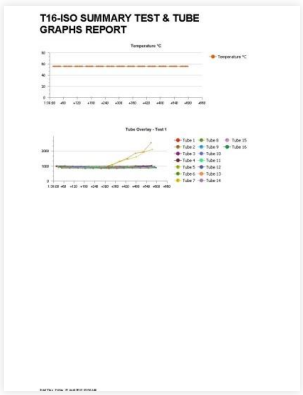
TUBE GRAPHS, PAGE 2/5



TUBE GRAPHS, PAGE 3/5



TUBE GRAPHS, PAGE 4/5



TUBE GRAPHS, PAGE 5/5

Figure 14 Print Results preview, Summary Report and Tube Graphs

Graphs: The following graphs generated as part of the DNAble Reader Test result are included in the printed report:

• All individual Tubes • Tube Overlay Defaults	• Tube overlay as configured on screen • Temperature

6.3 OPEN

Previously saved test data can be opened from a file directory and viewed, **only** if there is not a test in process.

6.4 NEW TEST

The tab cannot display a previous test when a test is running. If a user is currently viewing a test result and wishes to clear the screen and begin a new test, simply press the "New Test" button.

7 INSTRUMENT TAB

The Instrument tab displays information about a currently connected DNAble Reader device with the aim of aiding in the identification of an attached DNAble Reader Instrument. Instrument logs and an export/print function are also available.

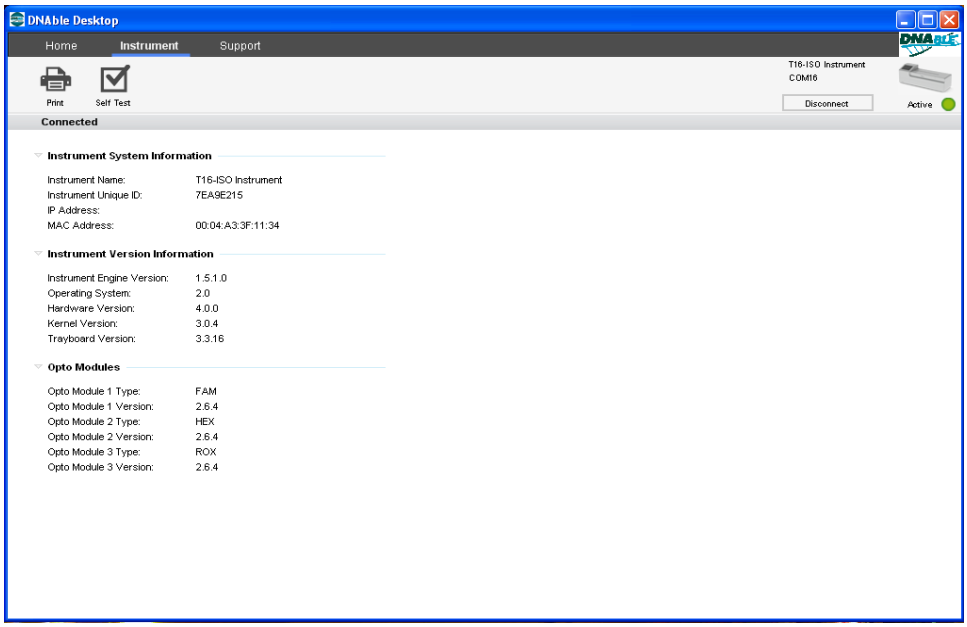


Figure 15 Connected DNAble Reader Information page

7.1 PRINT

Using the print function the user can generate a one page A4 report on the DNAble Reader Instrument used for testing.

8 SUPPORT TAB

The DNAble Desktop application "support" tab provides a copy of the DNAble Reader User Manual as well as information about the DNAble Reader Application and an import function to enable users to import Test Profiles.

8.1 USER MANUAL

The DNAble Reader Instrument system user manual is embedded into the application as a .pdf file and can be saved or printed from this screen. The .pdf viewer also provides a "find" function to enable quick search of key terms. (Note: Adobe Reader must be installed to view help files.)

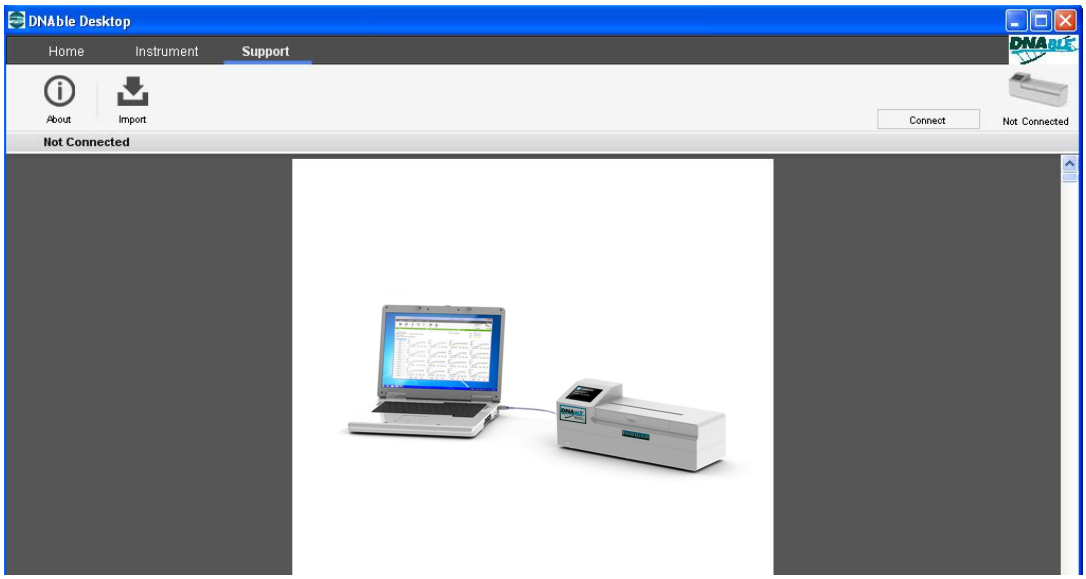


Figure 16 Support tab window

8.2 ⓘ ABOUT

The About function provides Version information:

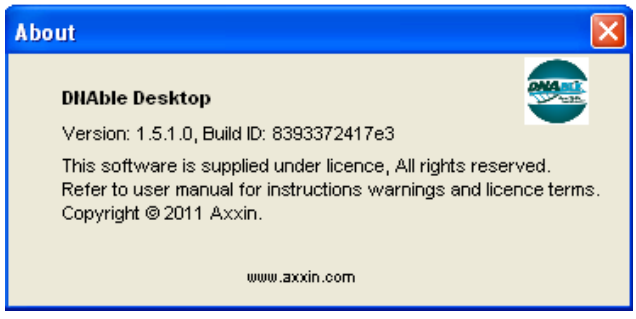


Figure 17 About window

8.3 IMPORT

The import function allows the user to update the DNAble Reader desktop software when new Test Types become available (e.g. new assay developed by EnviroLogix). The update file (.tar file) will be provided by EnviroLogix when needed.

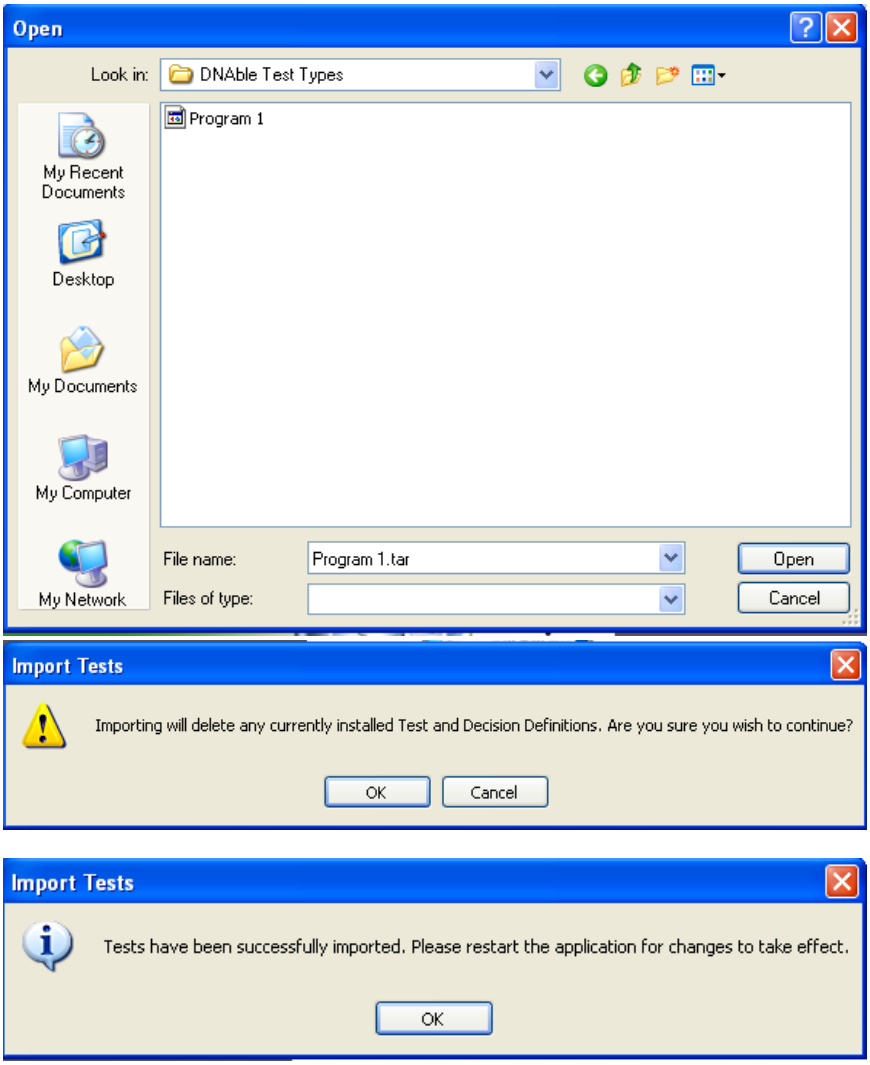


Figure 18 Import test types process

9 MAINTENANCE

9.1 CLEANING

The DNAble Reader Instrument can be cleaned using a lint-free wipe, damp with Isopropyl Alcohol (IPA). Avoid using free liquids to clean the device.

To clean the wells of the DNAble Reader, we advise the use of a foam tip swab such as Chemtronics Foamtips (Product Number CF4050). Dip the foam tip swab into the isopropyl alcohol and allow any excess fluid to flow off the swab. Insert the swab into the instrument well and circle the tube wall. Dispose of swab if any lint or dust is visible and repeat for remaining wells. Use spray bottle with compressed air to clean wells of debris.

9.2 FAQ & TROUBLESHOOTING

Contact EnviroLogix at DNAble@envirologix.com.

10 WARRANTY & END-USER LICENSE AGREEMENT

The software is warranted against defects in materials and workmanship for a period of one (1) year. For specific warranty information, contact EnviroLogix. If any defects should occur during the warranty period, EnviroLogix will replace the defective parts without charge. However, the following defects are specifically excluded:

- Defects caused by improper operation or by improper packaging of returned goods.
- Repair or modifications done by anyone other than EnviroLogix.
- Use with tubes or materials not specified by EnviroLogix.
- Deliberate or accidental misuse.
- Damage caused by disaster.
- Damage due to use of improper solvent or sample.

The warranty does not apply to fuses.

For inquiry or request for repair service, contact EnviroLogix after confirming the serial number of your instrument.

10.1 LIMITATIONS

In no event shall licensor or its suppliers be liable to you or any third party for any special, incidental, indirect or consequential damages of any kind, or any damages whatsoever, including, without limitation, those resulting from loss of use, data or profits, whether or not licensor had been advised of the possibility of such damages, and on any theory of liability, arising out of or in connection with the use of the licensed works. Some jurisdictions prohibit the exclusion or limitation of liability for consequential or incidental damages, so the above limitations may not apply to you. These limitations shall apply notwithstanding any failure of essential purpose of any limited remedy.

10.2 DESIGN LIFE AND UPDATES

This instrument has a design life of five years. After this period, the equipment must be decommissioned and not used, or specifically evaluated for any further application or extension of life and support. EnviroLogix Inc. reserves the right to issue a "change notice" relating to the construction, software or use of the instrument at any time. The instrument must be quarantined from use immediately after a change notice is issued and until the update is completed.

10.3 INSTRUMENT FAILURE AND ERRORS

The instrument and its associated software are constructed using standard components and methods. The instrument and the software can fail or provide incorrect readings or result in error. These risks should be considered by the intended user and where applicable mitigated by other methods independent of the EnviroLogix-supplied equipment, such as:

- Warnings
- Use of other indicators or readings.
- Secondary, independent, testing or measurement.

10.4 LICENSING AND THIRD PARTY INTELLECTUAL PROPERTY

The DNAble Reader Instrument is a general purpose instrument and can run many different types of chemistry, assays and test types. It is the responsibility of the user to ensure they have acquired the applicable licenses or rights to use the intellectual property of others for a specific test protocol, reading protocol, chemistry, assay or test type. The requirements may vary by the intended test type applicator, region chemistry or applied test result method used.

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