



## Enigma<sup>®</sup> MiniLab Operator Manual

For *In Vitro* Diagnostic Use Only.  
Not for sale or use in the USA.

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## 1. General Information

### 1.1 Intended Use

The Enigma MiniLab is a self-contained molecular diagnostic Platform. In combination with its unique and test specific test cartridge, the Enigma MiniLab allows Polymerase Chain Reaction (PCR) technology to be performed on samples taken directly from the patient and provides a result in under an hour. The Enigma MiniLab is therefore ideally suited to a range of clinical settings from the point-of-care clinic where fast results are imperative, to central laboratory use. The Enigma MiniLab is a fully automated and rapid Platform capable of carrying out *all* of the processes required for PCR testing; including - automating the laborious sample preparation steps through to determining complex result interpretations all with minimal input from the operator who is not required to be familiar with PCR technology.

### 1.2 Introduction

The Enigma MiniLab is a completely self-contained molecular diagnostic Platform. The Platform operates with reagents stored at ambient temperatures in a single use disposable cartridge, removing the costly and time-consuming logistical challenges and sample preparation procedures normally associated with PCR.

The Enigma MiniLab has a modular, easily scalable architecture providing flexibility and choice in different healthcare settings. At entry level, as a single control module with a single processing module, it is a compact Platform ideally suited to settings where usage is low and space is limited. At the other end of the scale, up to six processing modules can be controlled by a single control module allowing parallel running of different samples and test types and at independent times.

The Platform incorporates a novel disposable consumable cartridge, which can accommodate a range of clinical samples, including swabs, without any requirements for manual processing. All reagents and sample preparation tools are held on the self-contained single use cartridge and all steps are fully automated, minimising the risk of human error and sample to sample contamination. The Platform includes a simple touch-screen Graphical User Interface (GUI) for data entry and result reporting, plus an integrated results printer.

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The Platform features:

- Fully automated sample preparation
- Unique direct heating thermal cycling
- PCR chemistries
- Freeze-dried PCR reagents with ambient storage
- Single use, disposable Enigma MiniLab cartridges with all reagents pre-loaded
- Uses an industry standard tube for patient samples & swabs
- Minimum operating burden for the user
- Built-in barcode reader for logging patient, operator and test cartridge details
- Built-in UVC decontamination hardware
- Communication with the Platform through an easy to operate Graphical User Interface (GUI)
- Full sample traceability
- Automated data interpretation for a 'sample in / result out' process

### 1.3 Sample Preparation

The Enigma MiniLab uses magnetic bead technology for fast and reproducible sample preparation. The benefits of magnetic bead sample extraction are its abilities to be automated and to provide highly purified nucleic acids. Using magnetic beads provides the flexibility to process a range of different sample types and significantly increases sample preparation efficiency.

The Enigma MiniLab Platform is equipped with a magnetic rod, a sample heater and mechanical actuators, which operate with the sample preparation tools on the Enigma MiniLab Cartridge. The tools include a sheath (wand) for the magnetic rod and heater, two pipettes, a stopper and a foil piercing tool. Multiple wells clipped into the cartridge contain the sample extraction reagents for separation, washing





and concentration of the target nucleic acid and the freeze-dried PCR reagents that are needed for the amplification, detection and identification of the target of the test. Also included in the Enigma MiniLab cartridge is a process and internal PCR test control.

**1.4 Polymerase Chain Reaction (PCR)**

The Polymerase Chain Reaction (PCR) is already widely used for diagnosis purposes and is currently the gold standard technology for many diagnostic applications. PCR may be used qualitatively for determining the presence or absence of specific nucleic acid sequences. It is suitable for detecting infectious agents such as bacteria and viruses at extremely low levels. Viruses containing an RNA genome may require an additional reverse transcriptase step to convert the target sequence into DNA for PCR. The PCR reagents are also accommodated in the freeze-dried PCR mixes that are provided in the Enigma MiniLab test specific cartridge.

The enabling technology for PCR is thermal cycling, to heat and cool the sample to enable the enzymatic amplification of the target DNA sequence. In the Enigma MiniLab, the thermal cycler is an electrically conducting polymer (ECP) PCR reaction vessel contained within each single use test cartridge and allows rapid and localised thermal transitions. The Enigma MiniLab, with its high specification optics Platform and ECP technology, uses fluorescently labeled probes to perform rapid PCR. The two excitation sources and six detection channels in the Enigma MiniLab optics allow highly specialised multiplexed analysis to be performed in parallel which includes internal PCR and process controls for the provision of highly accurate results. Multiplex analysis by melt is also possible on the Enigma MiniLab furthering the Platform’s multiplex capabilities.

**1.5 Platform Symbols**

The following symbols are used in labels on the Enigma MiniLab Platform and Enigma MiniLab cartridge to point out important information:

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Symbol	Description
	Biological Hazards: Refer to accompanying documents
	Caution: Refer to accompanying documents Caution: Platform configurations are heavy
	Class II laser hazards
	Moving mechanical parts
	Ultra Violet (UV) Light hazards
	Conformité Européenne (European Conformity) for electrical devices
	<i>In Vitro</i> Diagnostic
	Serial Number
	Device Reference Number





Refer to Instructions for Use



Direct Current



The equipment must not be disposed of in the municipal waste platform



Manufacturer of the device



Date of manufacture

## 1.6 Warnings & Cautions

- To ensure accuracy of the results, the Enigma MiniLab Platform is **only** designed to be used with the sample kits containing Viral Transport Medium (VTM) and swabs provided by Enigma Diagnostics Ltd.
- To ensure accuracy of the results, **only** use Enigma MiniLab Platform parts supplied by Enigma Diagnostics Ltd.
- To avoid damage to the Platform, the Enigma MiniLab **must only** be connected to an earthed main power supply using the protective earth power cable supplied with the MiniLab Platform.
- To avoid biological hazards, the Enigma MiniLab Platform **must only** be operated with operators wearing laboratory gloves.
- To ensure accuracy of the results, the Enigma MiniLab cartridge should be **used only** as directed in the Instructions For Use (IFU) accompanying each specific test cartridge set.
- To ensure only valid results are produced, the Enigma MiniLab Platform will notify the operator if the Platform software has been manipulated from what was intended to be used for clinical testing. If an unpermitted change has been made to the software the GUI and result files will display “**Uncontrolled Software**” and therefore the results **should not** be used as an aid to diagnostics.
- To avoid wasted samples, **always** check the expiry date and stock levels of test cartridges prior to obtaining clinical samples.
- To avoid biological hazards, **always** regard the cartridge as potentially bio-hazardous and handle according to the local safety requirements at the site of use.
- To ensure the Enigma MiniLab performs correctly, **never move** test tools or open the reagent wells or pots on the test cartridge.
- To avoid any spillages of biological material, **ensure** the used cartridges are kept level disposing of spent cartridges.
- To avoid damage to the cartridge, **do not** touch the PCR reaction vessel in the consumable cartridge (see section 2.6).
- Apart from the thermal printer paper there are **no** operator serviceable parts contained in the Enigma MiniLab Platform.
- Operational use outside of the normal procedures described in this document and the Enigma MiniLab Quick Reference Guide may impair product safety. **Always** follow the instructions provided.
- The electromagnetic environment **should** be evaluated prior to operating this equipment, as these may interfere with proper operation.
- **Do not** use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional radio frequency sources), as these may interfere with proper operation.
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it **may** cause radio interference, in which case, you may need to take measures to mitigate the interference.







## 2. Technical Specifications

### 2.1 Physical Specification

The Enigma MiniLab Platform is modular and expandable via a 'daisy-chain' configuration. A single Control Module (CM) can be attached to a single Process Module (PM) or up to a maximum of six PM units.

Platform Configuration	Width (mm)	Height (mm)	Depth (mm)	Weight (kg)
1 CM & 1 PM	315	355	430	19.4
1 CM & 2 PM's	440	355	430	30.8
1 CM & 3 PM's	565	355	430	42.1
1 CM & 4 PM's	690	355	430	53.4
1 CM & 5 PM's	815	355	430	64.7
1 CM & 6 PM's	940	355	430	76.1

Some Platform configurations can be heavy. A CM and a single PM should be handled with care and according to the manual handling regulations referred to in the local Health & Safety Policy regarding lifting. For Platform configurations larger than a CM and a PM, the units should be separated prior to moving the MiniLab Platform. Please contact your Enigma Diagnostics product support engineer for assistance. The side covers of the PM and CM have no handles.



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**WARNING:** To avoid personal injury, never try to lift more than a 1CM + 1PM configuration

### 2.2 Platform Specification

<b>Power supply</b>	
AC/DC mains PSU	100-240V ~50/60Hz, 500W
Output voltage	48V DC, 10.42A
Idle power requirement	<15W per Processing Module
Max power requirement	40W for Control Module, 50W for Processing Modules
Fuses	2x T8A, 250V HBC
Power connector	IEC Inlet, filtered, 6.35 x 0.8mm terminals
<b>Electrical</b>	
Data ports	Ethernet RJ-45 Connector, USB, CAN Bus, Serial
Graphical User Interface	5.7" VGA TFT Display, 4:3 aspect ratio with touch-screen
Decontamination lamp	UV lamp can be turned on from the service interface on the control module
<b>Environmental</b>	
Operating conditions	15°C - 35°C Do not subject to external shock or vibration during operation To be sited and operated on a flat, firm surface
Test site	Point Of Care (POC) facility, Laboratory
Ingress protection rating	IP2X (tested according to IEC 60529/1999)
Transportation for shipping	Temperature: -20°C - +60°C
Electromagnetic compatibility	EN 61326-1 and EN 61326-2-6
Disposal of equipment	The disposal of any electrical equipment should be in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU

### 2.3 Acknowledgments

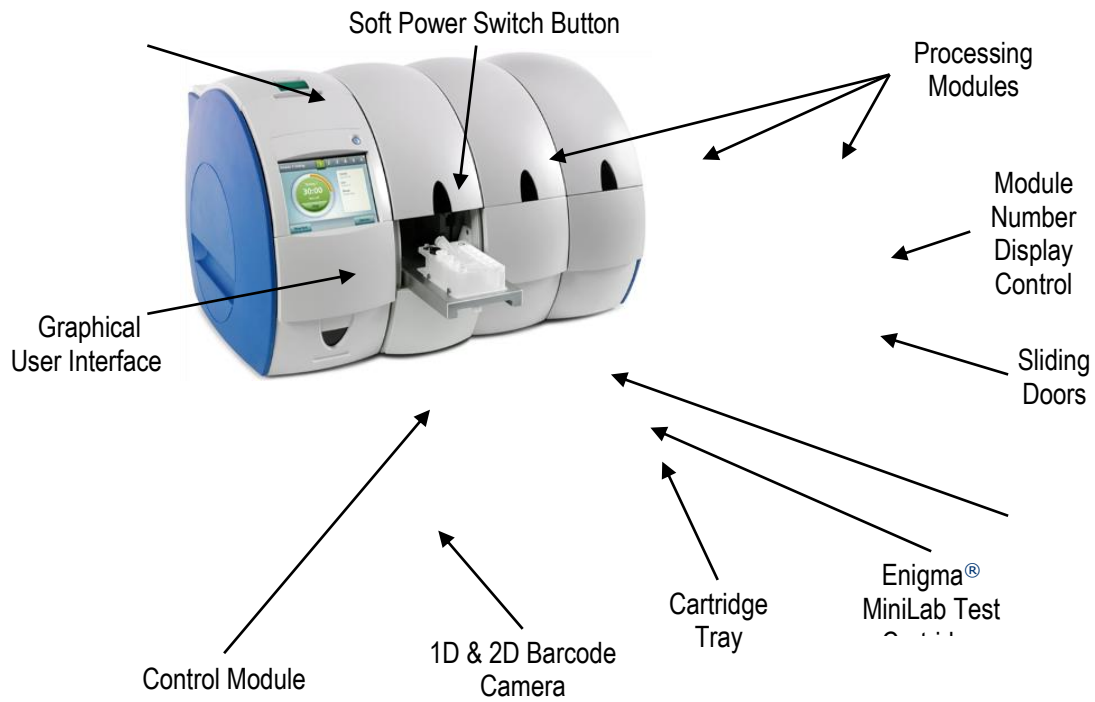
- The Enigma MiniLab Software makes use of the GNU (free open source operating Platform) libconfig library covered by the GNU Lesser General Public License. Details and a copy of the source code can be found at <http://www.hyperrealm.com/libconfig/>







**2.4 Platform Overview** (example: 1 CM & 3 PM configuration)



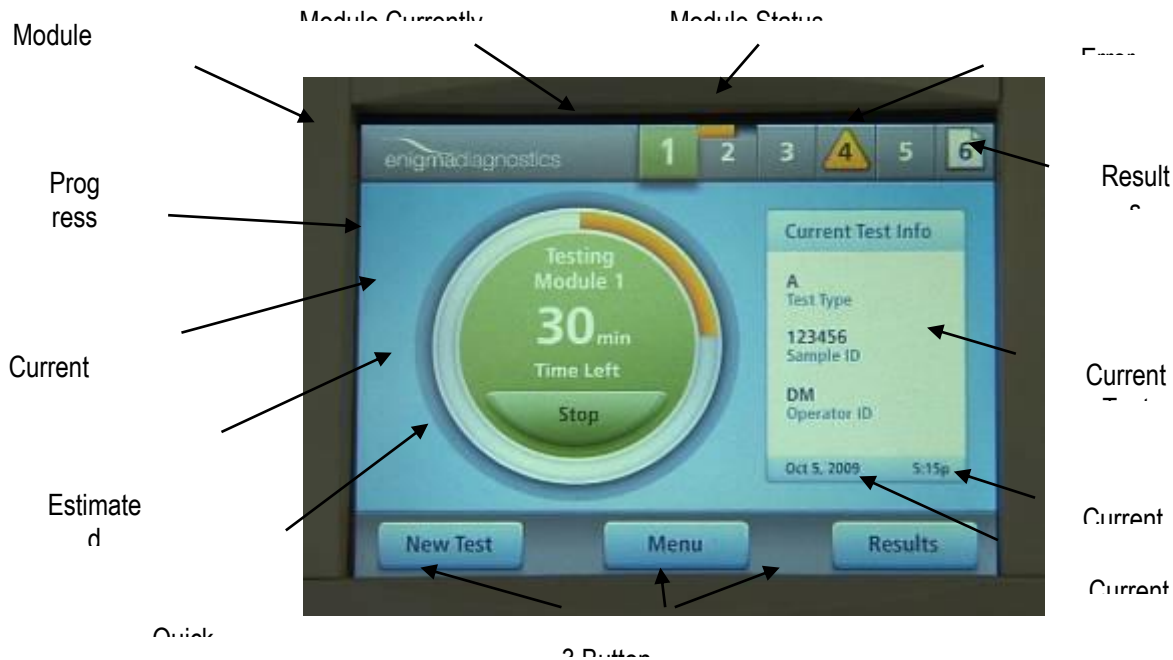
**Figure 1:** Example of a 1CM + 3PM configuration





### 2.5 Graphical User Interface (GUI)

The MiniLab Platform is driven via the touch screen Graphical User Interface (GUI) on the Control Module. Shown below (Figure 2) is a typical screen showing the major parts of the GUI.

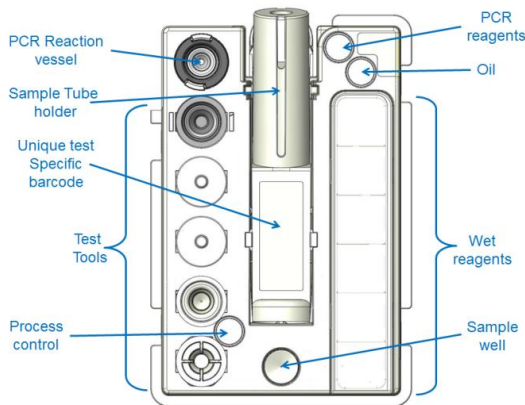


**Figure 2:** Graphical User Interface (GUI)

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### 2.6 Test Cartridge

The Enigma MiniLab Platform uses a self-contained, single use and test specific plastic consumable cartridge. Sample processing tools and sample processing reagents are contained on either side of the cartridge. A unique and test specific barcode is located on the top of the sample collection tube holder housed in the centre of the cartridge. The PCR reaction vessel is located on the top left of the diagram below; this should **not** be touched either before or after testing.



**Figure 3:** Enigma MiniLab test specific plastic consumable cartridge



**WARNING:** To ensure the Enigma MiniLab performs correctly, **never** move test tools or open the reagent wells or pots on the test cartridge.



**WARNING:** To avoid damage to the cartridge, do **not** touch the PCR reaction vessel in the consumable cartridge (see section 2.6).





### 3. Platform Installation & Set-Up

#### 3.1 Platform Components

Enigma MiniLab Control Module (CM)  
[EML-IA-0002]  
(Contains both UK & Euro Plug)



Processing Module (PM) side panel  
Right Panel [EML-IA-0203]



Side panel fixing kit [EML-IA-0204]



Thermal printer paper roll [EML-PP-0302]  
(Contained in printer housing)



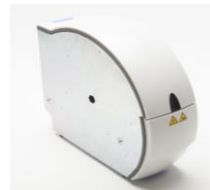
Appropriate mains power cable  
Euro spec [EML-IA-0206]  
UK spec [EML-IA-0205]



Wall standoff (4cm) [EML-IA-0207]



Enigma MiniLab Processing Module (PM)  
[EML-IA-0003]



Hex bolt 18mm [EML-IA-0208]  
(for PM module attachment)



PM daisy chain cable [EML-IA-0209]





## 3.2 Enigma MiniLab Installation

The Enigma MiniLab Platform should only be installed by a technical representative of Enigma Diagnostics Ltd. or a representative of an Enigma Diagnostics Ltd. appointed aftersales service provider.

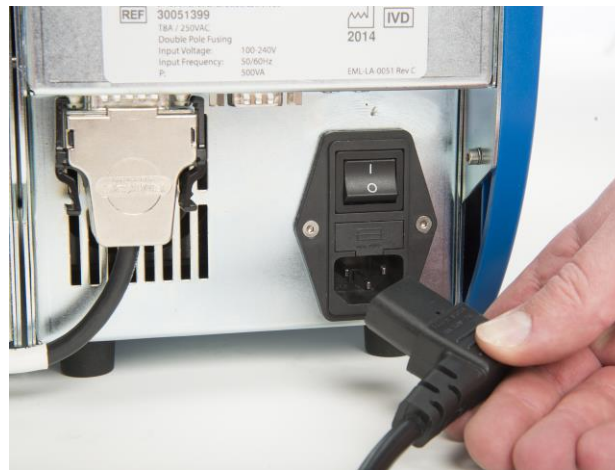
### 3.2.1 Initial Enigma MiniLab Set-Up

During the installation and commissioning procedure, a series of calibrations and Platform functional checks will take place. A positive and negative control PCR test will also be carried out on each PM to pass the Enigma MiniLab Platform as ready for clinical use.

### 3.2.2 Attaching Enigma MiniLab Power Cables

Plug in the appropriate power cable supplied with the Enigma MiniLab Platform (100-240 volts corresponding to the country of use), into the main input socket on the rear of the CM unit.

Insert the power cord plug into a mains outlet at the clinical site and turn the power ON at the wall socket (see Figure 4).



**Figure 4:** Inserting the appropriate power supply cable into the CM





### 3.2.3 Powering up the Enigma MiniLab Platform

Ensure the PM isolator switch, positioned at the bottom centre of the Platform label, is in the “I” position on the back of each PM (see Figure 5).



**Figure 5:** PM platform label & PM isolator switch in the “I” position representing power as ‘ON’

Power to the Enigma MiniLab Platform is switched on using the rocker switch at the rear of the CM above the main power lead socket. Switch the rocker switch to the “I” position (see Figure 6).



**Figure 6:** CM rocker switch in the “I” position representing power as ‘ON’

### 3.2.4 Soft Power Up

Once the  button is pressed (see Figure 7), the Platform will initiate which will take approximately 1 minute.



**Figure 7:** The power button on the front of the control module





### 3.2.5 Power-On-Self-Test (POST)

The Platform will automatically go through a Power-On-Self-Test (POST) for each PM attached in the MiniLab Platform.

When the POST has successfully completed simultaneously on all modules, a sequential set of numbers will be displayed on the front of each one of the PMs in ascending order from left to right. This informs the operator that all the modules have been detected and have passed their individual POST.


If, after POST, an “E” is displayed on any of the PM please refer to section 5.9.

**N.B:** Between 1 and 6 PMs can be connected to the right hand side of a CM. PM number 1 is always closest to the Control Module.



**Figure 8:** The processing module #1 displaying it is ready for use

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The “**Begin**” screen will then appear on the CM screen (see Figure 9). Press the  button in the bottom right hand corner of the display.



**Figure 9:** The “Begin” screen

**NB.** To ensure only valid results are produced, the MiniLab Platform will notify the operator if the Platform software has been manipulated from what was intended to be used for clinical testing. If an unpermitted change has been made to the software the GUI and result files will display “**Uncontrolled Software**” and therefore the results should not be used as a diagnostic aid.





## 4. Testing & Results

*Note. For test specific instructions please refer to the Instructions For Use (IFU) for the appropriate test being used.*

### 4.1 Getting Started

The following **Ready** screen should be displayed (see Figure 10), indicating the Enigma MiniLab is ready for use.

Three functions are available to the operator when using the buttons located at the bottom of the 'Ready' screen: Start a **"New Test"**, go to the **"Menu"** and view recent **"Results"**. The **"Menu"** and **"Results"** functions will be discussed later in this manual.

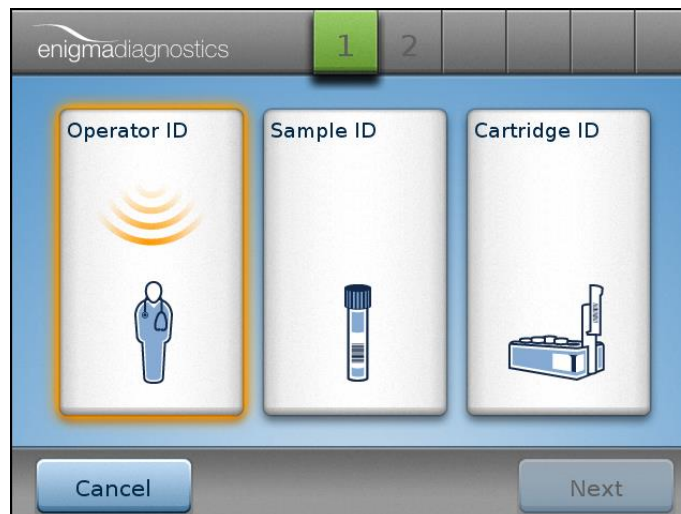


**Figure 10:** The MiniLab "Ready" screen & the "New Test", "Menu" & "Results" buttons

**N.B:** the most recent QC information is displayed on the right with the last control result.

### 4.2 Beginning a Test

Start a new test by pressing the **New Test** button in the bottom left hand side of the screen. The GUI display will prompt the operator to enter the Operator ID (see Figure 11).



**Figure 11:** The Operator ID icon is highlighted, prompting the operator to enter identification via either the barcode scanner or manual entry







#### 4.3 Entering Operator ID - With Barcode

If the operator is to be identified by an operator specific barcode, relevant to the facility where the testing is being performed, then simply place the barcode in front of the barcode reader at the front of the Control Module (see Figure 12). An audible “beep” will be heard once the relevant information has been captured.




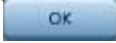
**Figure 12:** The barcode scanner location & laser scanner beam



**WARNING:** To avoid damage to eyes, do not look into laser beam

#### 4.4 Entering Operator ID - Without Barcode

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If the operator does not have a barcode ID then press the Operator ID icon  on the screen. A QWERTY keyboard is displayed (see Figures 13a-c). Simply manually enter the Operator's ID into the test box and then select the  button.



**Figure 13a:** The QWERTY keyboard for the manual data input  
(*N.B:* delete key bottom left, space key bottom right)





To enter lower case letters or numerical digits, press the **ABC/abc/123** button either once for lower case or twice for numeric keys. The keyboard will reappear as a lower case QWERTY keyboard pad or a numerical keypad (see Figures 13b-c).




**Figure 13b:** Showing the lower case QWERTY keyboard for manual data input



**Figure 13c:** Showing the numerical keypad for manual data input





Key in the relevant details and select the  button. The display will indicate the successful completion of the Operator ID by displaying a green tick and the Operator's ID at the top of the Operator ID box (see Figure 14). The display will then prompt for the Sample ID to be entered.

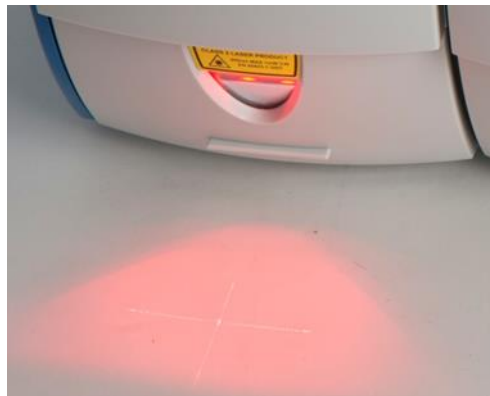


**Figure 14:** Screen showing a successful Operator ID has been captured & prompt for the Sample ID

#### 4.5 Entering Sample ID

The interface will now prompt for a Sample ID. Each sample tube can be issued with a facility specific barcode ID by adhering it to the tube. Scan the barcode using the barcode reader (see Figure 15). An audible “beep” will be heard once the information has been captured.

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**Figure 15:** Capturing the Sample ID by scanning its assigned barcode



**WARNING:** To avoid damage to eyes, do not look into laser beam



The Sample ID can be added manually by pressing the Sample ID icon  on the GUI and adding the relevant ID using the same method as entering the Operator ID (above).

**N.B:** More detailed information will be required just prior to or during the test (covered later in this section).





#### 4.6 Loading a sample

The cartridge is now ready to receive the sample tube. Please consult the test specific Instructions For Use (IFU) document accompanying the test being used.

##### Sample & Cartridge Loading Overview:

Pull up the tube holder in the centre of a new cartridge until it is vertical. Insert the sample tube to the bottom of the sample tube holder and push down the sample tube holder, containing the sample tube, firmly back into the cartridge body until it clips into place. (See Figure 16).



**Figure 16:** Illustrations demonstrating an overview of sample & cartridge loading

#### 4.7 Entering the ID of the test cartridge

A successful entry of the Sample ID will be indicated with a green tick in the central sample ID box (see Figure 17). The display will then prompt for the Cartridge ID to be inputted.



**Figure 17:** Screen showing successful Operator ID & Sample ID entry & prompt for the Cartridge ID

Each cartridge type has a unique barcode associated with it, which will be read by the barcode reader. The barcode incorporates details of the specific test and other test related information.

Place the appropriate cartridge in front of the barcode reader as shown in Figure 18. An audible “beep” will then be heard once the information has been captured. The test cartridge information will also be shown on the GUI.





**Figure 18:** Capturing cartridge ID by scanning barcode from the centre of the test cartridge



**WARNING:** To avoid damage to eyes, do not look into laser beam

**CAUTION:** Ensure test cartridges are within date, only cartridges within the expiry date will be accepted

**CAUTION:** Test cartridges are single use, only test cartridges that are un-used will be accepted

The interface will then display three green ticks for each of the three component IDs captured (see Figure 19)




**Figure 19:** Screen indicating all three IDs have been successfully entered





## 4.8 Loading a Cartridge

Select  on the GUI. The Enigma MiniLab interface will randomly select an available PM. Wait 20 seconds for the door to open and the tray to be fully extended. An **Insert Cartridge** instruction window will be displayed (see Figure 20).



**Figure 20:** Prompt for the Enigma MiniLab cartridge to be inserted




**WARNING:** To avoid personal injury, keep fingers clear of the extending cartridge tray and opening door

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Clip the cartridge into its recessed position on the tray with the cartridge label on the right hand side of the cartridge (see Figure 21).



**Figure 21:** Correct loading of the cartridge into the extended tray

Press  on the touch screen. The tray will retract into the Processing Module and the door will close.



**WARNING:** To avoid personal injury, keep fingers clear of the retracting cartridge tray and closing door





### 4.9 Entering Patient Information

*Note: The properties of this function are enabled/disabled/amended through the Menu button on the Ready Screen as described in 5.3 Settings Menu.*

Select the **Patient Information** button to add the relevant patient information (see Figure 22). Add the appropriate patient's **Family Name**, **Given Name**, **Gender**, **Date of Birth**, **Location** and **Specimen Type** in the relevant boxes by pressing the associated area of the screen.





**Figure 22:** Patient Information Input Displays

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**N.B:** The default option is for Patient Information **not** to be entered. If this function is turned on the button will read **"Patient Information"** instead of **"Start"**.

When adding the patient's **Date of Birth**, a default date is provided in the centre of the display (see Figure 23).

Use the  or  arrows buttons above or below each digit and adjust to the correct date of birth.




**Figure 23:** Date of birth adjustment display

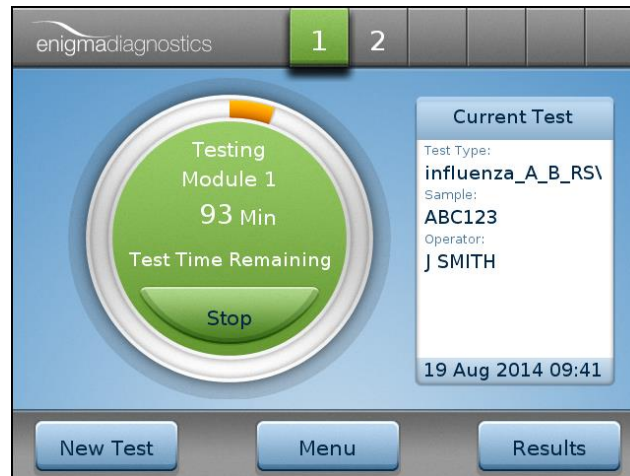






## 4.10 Starting a Test

Select  and the Enigma MiniLab will begin processing the sample automatically. The display will indicate the progression of the test in the progress indicator, shown as a circular series of orange segments (see Figure 24). The time shown in the middle of the circle is a countdown timer, displaying an estimated time to result.



**Figure 24:** Display showing: Progress of the test, Test ID, Sample ID & Operator ID

## 4.11 Aborting a Test

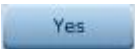

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The test can be stopped at any time by pressing the  button in the lower centre of the green circle (see Figure 24).

Once the button is pressed a confirmation box is displayed (see Figure 25).



**Figure 25:** Confirmation screen to confirm test stop

Selecting  will abort the test. Selecting  will return to the current test screen. It may take some time in stopping the test as the Enigma MiniLab will attempt to make the cartridge safe for you to remove. This may require some manipulation of the cartridge within the Enigma MiniLab depending upon the point at which the test is stopped.


**NB:** Once a test is aborted it will no longer be possible to run that test cartridge again.





### 4.12 Test Results

When the test has finished the result will be displayed automatically accompanied with an audible “beep”.

The results can also be viewed by pressing the module number  icon at the top of the GUI.


A typical set of results from one test is shown below in Figure 26.

To alter the information that is included with each result, refer to section 5.6. Included as standard within each result is the following:

<b>Test Date</b>	<b>Operator ID</b>	<b>Cartridge Lot Number</b>
<b>Patient Name</b>	<b>Specimen Type</b>	<b>Platform Serial Number</b>
<b>Patient Gender</b>	<b>Cartridge ID</b>	<b>Platform Software Version Number</b>
<b>Patient Location</b>	<b>Cartridge Expiry Date</b>	




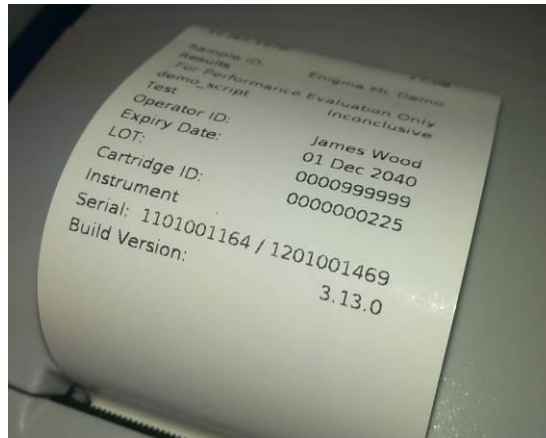
**Figure 26:** 2 GUI screens showing an example of a test result viewed from the interface

Press  to open the tray for removal of the spent cartridge. Refer to section 4.13



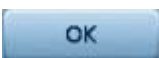


Press  to print a hard copy of the test result via the on-board thermal printer (see Figure 27).



**Figure 27:** An example of a test result viewed on a print out

**NB.** To ensure only valid results are produced, the Enigma MiniLab Platform will notify the operator if the Platform software has been manipulated from what was intended to be used for clinical testing. If an unpermitted change has been made to the software the GUI and result files will display “**Uncontrolled Software**” and therefore the results should not be used as an aid to diagnostics.

Press  to return to the **Ready** screen to start the next test. Refer to section 4.2

#### 4.13 Disposal of Test Cartridges

Test cartridges should be disposed of and treated as clinical waste and in accordance with local regulations at the site of use.




**WARNING:** To avoid any biological hazards, always handle spent test, or QC cartridges as if they are bio-hazardous. They should be handled appropriately and in accordance with local regulations at the site of use



**WARNING:** To avoid contamination, extra care should be taken not to dislodge or remove the ECP Stopper from the top of the ECP when either removing or disposing of spent cartridges



**WARNING:** To ensure your safety, do not try to move or disassemble any tool or component contained within the test cartridge

Once the cartridge has been removed press the  button. The Platform will then return to the **Ready** screen, to start a new test. Refer to Section 4.

#### 4.14 Switching Between PMs


At any time during Platform operation, it is possible to switch the screen view between other PMs (if attached) whilst the PMs are in operation. This may be to start other patient tests, start QC tests, perform UV cleans or to view past test results held on other PMs.

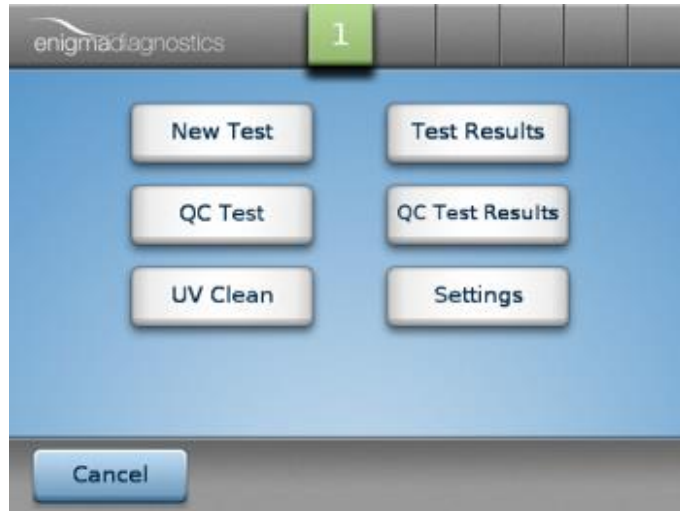
To switch between PMs and from any screen location, press the desired PM number on the module status summary bar at the top of the GUI (see 2.4).





## 5. Menu Screen

Selecting the  button at any time will access the main menu (see Figure 28) where it is possible to: start a **“New Test”**, view previous **“Test Results”**, start a **“QC Test”**, view previous **“QC Test Results”**, start a **“UV Clean”** and adjust the Enigma MiniLab Platform **“Settings”**. Each of these processes will be discussed in turn in this section.






**Figure 28:** Menu display showing main menu options

Also shown are the **“Test Results”** or **“QC Test Results”** access buttons & platform **“Settings”** button.

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### 5.1 Retrieving Test Results



To review past QC test results press the  button.

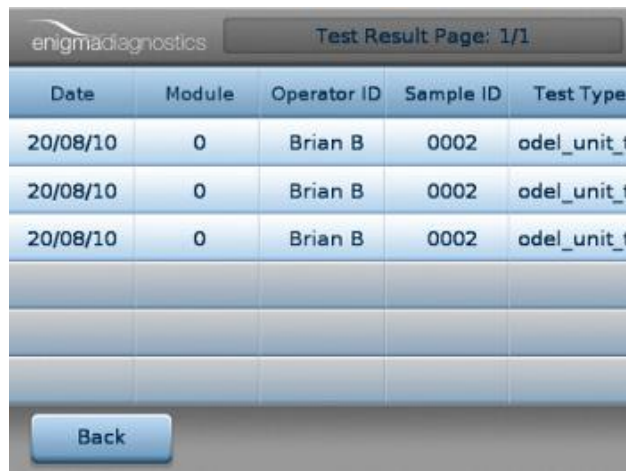
To review past test results select  or, the **Ready** screen, press the  button. The following display (see Figure 29) will be presented showing all the Processing Modules that are connected to the Control Module and the results that are available for each Module. Select the relevant Module to be accessed by pressing the desired PM number at the top of the GUI.

Module	Available	Date	Time	Runs
1	Yes	N/A	N/A	0

**Figure 29:** Platform summary result display




All the test results available for that PM will be displayed (see Figure 30). To view a particular result, press the area of the screen displaying the required result. Use the  or  buttons to move through the result pages. Refer to section 4.12 for details of test results.



Date	Module	Operator ID	Sample ID	Test Type
20/08/10	0	Brian B	0002	odel_unit_b
20/08/10	0	Brian B	0002	odel_unit_b
20/08/10	0	Brian B	0002	odel_unit_b


**Figure 30:** Module Specific Summary Result Display

## 5.2 UV Cleaning

To avoid any potential contamination due to spillages etc, the onboard UV cleaning lamp can be activated. The UV cleaning protocol can be run by entering the “Menu” display (see section 5) and pressing the  button. Select the module to be cleaned by pressing the appropriate module.

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An Operator ID will need to be identified to indicate the UV Clean mode (see Figure 31). Either scan or manually enter the Operator ID (section 4.3 or 4.4 respectively).

Once the Operator ID has been entered, press the  button. The PM tray will be extended so that the operator can clean the tray. See section 6 of this manual for details of the cleaning procedures. The UV cleaning process will take 30 minutes to complete.



**Figure 31:** Scan operator ID display to start UV cleaning protocol



**WARNING:** UV light is harmful to the eyes; do not attempt to look inside the Platform when the UV lamp is functioning.

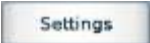

**WARNING:** The UV Decontamination protocol should only be used as part of the larger cleaning process following any spillage. Please consult section 6 for full details of cleaning and decontaminating the Enigma MiniLab Platform.






**Figure 32:** UV cleaning protocol display

**NB:** Eject the tray for cleaning before the UV clean commences. To do this press the  button after the Operator ID has been identified.

### 5.3 Settings Menu

Selecting the  button from the **Menu** display (Section 5) will launch the settings option display. From this location the Platform settings can be adjusted by pressing the  button. See section 5.4.

The test information settings can be adjusted from this settings menu by pressing the  button. See section 5.6.

The  and  settings are also accessed from this location however, these are not functional at this moment in time. These settings will be covered in a separate manual describing Enigma MiniLab connectivity to an existing Laboratory Information Platform (LIS) via a network in a future software release.



**Figure 33:** The Enigma MiniLab settings menu





### 5.4 Platform Settings



Selecting the **Instrument** button from the Setting menu display will launch the Platform settings display (see Figure 34). From this location the following can be adjusted or toggled by pressing the relevant area on the display:

**- Date**

To set the Platform to the current date. This will be reported along with each test and QC test result. See section 5.5.

**- Time**

To set the Platform to the current time. This will be reported along with each test and QC test result. See section 5.5.

**- Backlight level**

Adjustments to the backlight level can be carried in order to see the GUI more clearly in different lighting conditions.

**- Language**

The current Enigma MiniLab Platform GUI is only currently available in English. Future Software upgrades will support a greater range of international languages. These languages will be available by accessing this function.

**- Auto Printing**

Completed results can be printed automatically once the test or QC results become available. This function can be toggled **on/off** in this setting.

**- Volume**

The volume level of the audible “*beep*” can be adjusted. Audible beeps are heard when screen keys are pressed, barcodes scanned or when warnings are prompted. Four volume levels are available to be set: “Off”, “Low”, “Med” and “High”.



**Figure 34:** Platform setting options (Screens 1 & 2)

### 5.5 Adjusting the Date & Time

Setting the date and time on the Enigma MiniLab is achieved by pressing the [ **Date** ] or [ **Time** ] boxes on the Platform settings display (Section 5.3). Selecting the date option displays the current set date in the centre of the display in UK format.





Use the  or  arrows above or below each digit and adjust to the correct date (see Figure 35a). The same process is required for adjusting the time (see Figure 35b).







Figure 35a: Date adjustment display



Figure 35b: Time adjustment display

### 5.6 Adjusting Required Test Information


Selecting the  button on the Settings menu display will launch the Test Information settings display (see Figure 36). From this location, the “Operator ID”, “Patient Name”, “Date of Birth”, “Gender”, “Specimen Type” and “Patient Location” can all be toggled “Yes/No” depending on their requirement by pressing the relevant area on the display.




Figure 36: Test information to be included in results

The purpose of having the option of including the above patient test information being captured, is to ensure no misread or misassigned sample IDs are captured. The information captured here is therefore considered confidential. As such, efforts should be made to house and operate the Enigma MiniLab in a secure environment in order to not expose the confidential information to individuals who are not at liberty to access such information.

### 5.7 Closing down the MiniLab Platform

When the last sample of the day has been tested, ensure that the test cartridge has been removed and disposed of appropriately in accordance with local procedures for handling potentially bio-hazardous material. See section 4.13.

Once all the Processing Modules are in their idle state (i.e. not running any processes), switch off the Platform by pressing the soft power button  on the front of the Control Module.



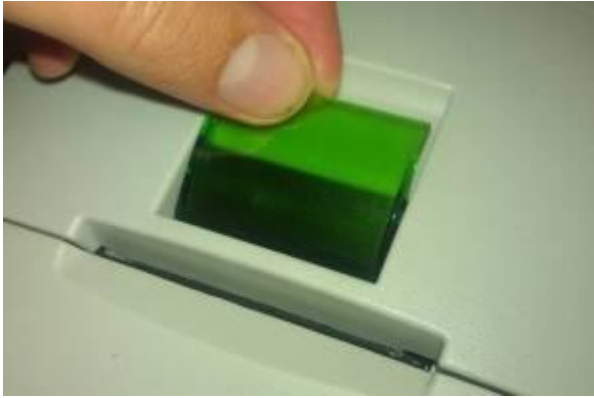


**NB:** As a failsafe feature, it is not possible to switch off the MiniLab Platform using this button when PMs are active.

Switch the rocker switch at the back of the control unit to “OFF”.

### 5.8 Replacing the Printer Paper

When the thermal printer paper has been used, an alert will be displayed on the GUI and an audible “beep” will sound. To replace the paper: (i) simply lift the green catch of the printer compartment on top of the CM; (ii) remove the plastic centre of the spent printer roll and discard;



Pull up the clear CM printer housing catch



Centre of spent roll to be removed

(iii) with the paper rolling forwards from the bottom of the new roll, drop the roll into its holding cup; (iv) close the printer housing allowing the printer paper to travel through the recess in the printer compartment, below the catch.

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Drop in new printer roll as shown




Paper travels through the gap  
(below the clear printer housing)

**NB:** Ensure the new thermal paper roll is inserted in the correct orientation as shown above. Failure to do so will not allow results to be visible when printed.





## 5.9 Error Screen

If the Error icon  is shown on the module status bar at the top of the display, it warns that an error has occurred in the PM. Press the error icon to display the error description.

In the example below (Figure 37), an attempt to start a new test has been tried with an existing cartridge still in the tray. The error has occurred in PM 1 and the Platform is prompting the operator to eject the tray to investigate the problem.



**Figure 37:** Reporting that an error in PM 1 has occurred, prompting the operator to eject the tray

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## 5.10 Platform Alerts and Error Codes

The CM will give audible and visual alert messages to the operator if an incorrect process has been attempted or Platform checks have detected a fault or error.

For example, displayed below is an error that has occurred due to the operator trying to advance away from the Results display having not removed the used test cartridge.



**Figure 38:** Alert screen prompting the operator to remove the spent test cartridge before returning to the main screen





To remove alerts, simply accept the alert on the GUI by pressing the OK button being displayed in the alert window. The Platform will then prompt you to carry out the relevant action to clear the alert.

The most common alerts are described below with a text description, as the above example. Similar alert messages will be displayed when the following have occurred:

1. If the test cartridge has expired
2. If the test cartridge has already been used
3. If the printer paper has run out
4. If the PM door(s) have been open for more than 2 minutes

Any other, uncommon alerts, will be displayed as **“Call Service: Code XXXX”** or **“Error Code XXXX”**, where code **XXXX** is the four digit code given in the alert window.

Error Code Series	High Level Error	1st Action	2nd Action
14XX - 17XX	PM Thermal Error	Contact Enigma Technical Support	~
18XX	PM Tool Sensor Error	Contact Enigma Technical Support	~
19XX	Power Supply Error	Contact Enigma Technical Support	~
20XX & 21XX	PM Thermal Error	Contact Enigma Technical Support	~
22XX	PM Door Error	Contact Enigma Technical Support	~
23XX	General PM Error	Contact Enigma Technical Support	~
2313	General PM Error	Ensure Module Connector Cable is connected correctly	Contact Enigma Technical Support
2318	General PM Error	Ensure Module Connector Cable is connected correctly	Contact Enigma Technical Support
		Ensure Processing Module Isolation Switch (back of PM) is in the down position	
2319	General PM Error	Ensure Module Connector Cable is connected correctly	Contact Enigma Technical Support
		Ensure Processing Module Isolation Switch (back of PM) is in the down position	
2320	Module Software Mismatch Error	Contact Enigma Technical Support	~
24XX	Barcode Error	Contact Enigma Technical Support	~
25XX	CAN Connection Error	Contact Enigma Technical Support	~
27XX	Algorithm Error	Contact Enigma Technical Support	~
28XX	PM Barcode Error	Contact Enigma Technical Support	~
29XX	PM Configuration Error	Contact Enigma Technical Support	~
30XX	PM Door Error	Contact Enigma Technical Support	~
31XX	Eventing Error	Contact Enigma Technical Support	~
32XX	Environment Error	Contact Enigma Technical Support	~
34XX	LED Error	Contact Enigma Technical Support	~
35XX	Logging Error	Contact Enigma Technical Support	~
36XX	PM Optics Error	Contact Enigma Technical Support	~
38XX	CM Printer Error	Contact Enigma Technical Support	~
39XX	Results Error	Contact Enigma Technical Support	~
40XX	PM Sensors Error	Contact Enigma Technical Support	~
41XX	PM Motors Error	Contact Enigma Technical Support	~
42XX	PM Thermal Error	Contact Enigma Technical Support	~
43XX	PM UV lamp Error	Contact Enigma Technical Support	~

If any of these errors occur, please call Enigma Diagnostics Ltd. using the number given in Appendix 1 and inform them of the error code produced.





### 5.11 MiniLab Troubleshooting

Should an issue be evident with the Enigma MiniLab Platform, follow the primary troubleshooting suggestions detailed below regarding the specific fault. If these primary suggestions do not solve the issue or if another issue has occurred that is not listed below, then please contact Enigma Diagnostics Ltd. or their appointed aftersales service provider.

Issue	Possible Cause	Primary Solution	Secondary Solution
CM will not turn on	<ul style="list-style-type: none"> <li>- Power cord not plugged in</li> <li>- CM not turned on at rocker switch</li> <li>- Mains not switched on</li> </ul>	<ul style="list-style-type: none"> <li>- Re-position CM mains power cord</li> <li>- Ensure rocker switch is set to On</li> <li>- Ensure mains outlet is On</li> </ul>	Call Service Engineer
PM(s) will not boot up	<ul style="list-style-type: none"> <li>- PM Isolator switch(es) are off (see 3.2.3)</li> <li>- PM connection cable not attached correctly</li> </ul>	<ul style="list-style-type: none"> <li>- Check the isolator switch(es) are in the "I" position</li> <li>- Check PM data / power cables are attached correctly in the back of the CM and all PM's</li> </ul>	Call Service Engineer
PM display "E" instead of unit number	<ul style="list-style-type: none"> <li>- An internal Error has occurred within PM(s)</li> </ul>	<ul style="list-style-type: none"> <li>- Call Service Engineer</li> </ul>	N/A
Touchscreen (GUI) not working	<ul style="list-style-type: none"> <li>- Broken touchscreen (GUI)</li> </ul>	<ul style="list-style-type: none"> <li>- Call Service Engineer</li> </ul>	N/A
PM door won't open	<ul style="list-style-type: none"> <li>- Possible obstructions</li> </ul>	<ul style="list-style-type: none"> <li>- Check for obstructions &amp; remove if apparent</li> </ul>	Call Service Engineer
PM door won't close	<ul style="list-style-type: none"> <li>- Possible obstructions</li> </ul>	<ul style="list-style-type: none"> <li>- Check for obstructions &amp; remove if apparent</li> </ul>	Call Service Engineer
Cartridge ID not accepted	<ul style="list-style-type: none"> <li>- Cartridge expired</li> <li>- MiniLab not set-up for that test type</li> </ul>	<ul style="list-style-type: none"> <li>- Ensure cartridge being use are within date</li> <li>- Call Service Engineer</li> </ul>	Call Service Engineer
PM tray won't extend	<ul style="list-style-type: none"> <li>- Possible obstructions</li> </ul>	<ul style="list-style-type: none"> <li>- Check for obstructions &amp; remove if apparent</li> </ul>	Call Service Engineer
Barcode not read	<ul style="list-style-type: none"> <li>- Misaligned cartridge in beam</li> <li>- Barcode obstructed or missing</li> </ul>	<ul style="list-style-type: none"> <li>- Ensure barcode is under beam and in the centre of the beam</li> <li>- Check that barcode on cartridge is complete and unobstructed visually and to the scanner</li> </ul>	Call Service Engineer
CM Printer not working	<ul style="list-style-type: none"> <li>- Check printer paper is installed</li> <li>- Check the printer paper is the correct way round</li> </ul>	<ul style="list-style-type: none"> <li>- Replace Paper</li> <li>- (See section 5.8 of this manual)</li> </ul>	Call Service Engineer

### 5.12 MiniLab Servicing

To ensure the Enigma MiniLab Platform is functioning normally and to fully maintain its performance, it is highly recommended that the Enigma MiniLab is serviced once annually post its installation date. This service is provided by Enigma Diagnostics Ltd. and/or an approved aftersales service provider, during which full functionality of the entire Enigma MiniLab Platform will be checked. The calibration of the Enigma® MiniLab will also be checked. Should a calibration be required, this will also be included within the service regime.

Enigma Diagnostics Ltd., or an approved aftersales service provider, will inform you when the six-month anniversary is approaching in order to schedule a suitable visit time. Appropriate certification will be provided detailing the service work conducted and any maintenance or calibration work that was required.





## 6. Cleaning the Enigma MiniLab Platform

Cleaning of the Enigma MiniLab Platform maybe required for a number of reasons: as part of routine laboratory cleaning procedures; after a spill, prior to an annual or ad-hoc on-site service or repair; or prior to shipping back to Enigma Diagnostics Ltd.

In order to thoroughly clean an Enigma MiniLab Platform that has been exposed to a Biosafety Level (BSL) II environment, the following procedure should be followed:

- Close down the Enigma MiniLab Platform according to section 5.7 of the Enigma MiniLab Operator Manual.
- Ensure the mains power cable is **removed** from the back of the CM.
- Ensure that all the PM cartridge trays, within the Enigma MiniLab Platform to be cleaned, are accessible and clear of any test cartridges. Wearing disposable gloves open each PM unit manually by slowly sliding down the doors until they are fully open. Reach inside each PM and pull to extend the trays out to their fully open most position to allow cartridges to be removed and an efficient clean to be performed.
- Wipe all external surfaces and cables of the CM and PM(s) including each cartridge tray (but **NOT** the GUI) with a **damp** cloth containing 10% solution of household bleach (Sodium Hypochlorite (NaOCl), 1 in 10 dilution with water). A **damp** cloth containing isopropyl alcohol (IPA) can also be used on all external Platform surfaces, the cartridge tray and the GUI.
- Leave all external surfaces and the upper and lower surfaces of the tray wetted with the above solutions (**NOT** dripping wet) for 10 mins.
- With a damp cloth (**NOT** dripping wet) containing only water, wipe over to rinse and remove the remaining cleaning solution residue. Leave for 10 mins to air dry.
- Dispose of any used test cartridges and cleaning materials according to local biohazard procedures at the clinical site of use.
- Switch on the Enigma MiniLab using the rocker switch on the back of the CM and then the soft power button on the front of the CM.
- The PM(s) will indicate a power on self-test (POST) and will retract the PM trays and close the doors.
- Initiate the UV cleaning protocol on each PM by referring to section 5.2 of the Enigma MiniLab Operator Manual.

**N.B:** For BCL III and above please refer to and comply with the local decontamination/sterilisation procedures at the site of use.







## Appendix 1.

### Enigma Diagnostics Ltd. Technical & Product Support



Enigma Diagnostics Ltd. strives to support its customers and collaborators to the very best of its ability. Should you have any enquires please contact the Technical Support Department.

**+44 207 030 3353**

[technical.support@enigmadiagnostics.com](mailto:technical.support@enigmadiagnostics.com)







## Appendix 2.

### Return to Enigma Diagnostics Ltd. - Decontamination Form

In order to safely ship a Platform back to Enigma Diagnostics Ltd, follow the cleaning and decontamination instructions detailed in section 6.

#### Decontamination Certificate

Enigma MiniLab Serial Number	
Reason for Return	
Return Material Authorisation Number (RMA #) – <i>Issued by Enigma Diagnostics Ltd.</i>	
Decontamination solution used	
Decontamination performed by	
Company / Institute Address	
Department	
Contact Phone Number	
Date	
Signature	
Position held at Company / Institute	

