



# Instructions for Use





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> Document: V501007 Revision: 6-22/02

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Please ensure that you have read and fully understood the **Safety** Precautions and Limitations of Use in Section 2 of this manual before attempting to install or operate this product.

Failure to do so could result in severe injury or may damage the unit and invalidate the product warranty.







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# Symbols Used in this Instruction Manual

The following advisory symbols are used in this manual.

## **Table 1: Advisory Symbol Meanings**



DANGER

Indicates a Risk of Electric Shock which could, if not avoided, result in severe injury or death.



**DANGER** 

Indicates a Risk of Explosion which could, if not avoided, result in severe injury or death.



Indicates a hazardous situation which could, if not avoided. result in severe injury or death; or severely damage the unit.



Indicates a hazardous situation which could, if not avoided, result in minor or moderate injury; or degrade or impair the functionality of the unit.



CAUTION

Indicates an Electrostatic-Sensitive Device for which care should be taken not to touch the exposed electrical contacts as this could degrade or impair the functionality of the unit.



**CAUTION** 

Indicates a possible crush hazard due to moving parts which could, if not avoided, result in minor or moderate injury.



Advisory or other useful information.



Refer to Lu-mini App advanced features.

⇒ NN

Refer to "Section NN" for more details.



## 2 Safety Precautions and Limitations of Use

It is essential that all users of this equipment have fully read and understood the following safety precautions and limitations of use before installing or operating the Lu-mini unit.

# **@** IMPORTANT **@**



The protection provided by this equipment may be impaired if it is not used in a manner described in this manual.



It is essential that the user of this equipment is aware of the potential hazards associated with the unit and its accessories.

All operators should be familiar with the safety precautions and warnings given in these instructions before attempting to operate the unit.

Improper use of this unit or its accessories may impair their functionality and invalidate the manufacturer's warranty.

# **Unit Handling Precautions**



Care should be taken not to drop the unit or subject it to rough physical handling, both during normal use and during installation, transportation and storage.

**CAUTION** 

Do not use the unit if it shows any signs of damage or wear.



The unit should be held and supported in both hands when lifting or moving. Do not lift the unit by the lid.

Care should be taken to avoid trapping fingers under the unit when placing it down on a solid surface.



Care should be taken not to knock the LCD display.

Do not use excessive force when pressing the touchscreen buttons or when cleaning it.





## **Unit Installation and Operating Environment**



**DANGER** 

The Lu-mini unit is designed for indoor laboratory use only.

The acceptable operating temperature range is 18°C to 38°C, with a relative humidity of 20% to 85% non-condensing, at a maximum altitude of 2000m above sea level.



WARNING

If the unit is stored in conditions outside of these ranges, it must be left to stand unpowered until it has acclimatised to within these environmental limits before being powered.



**DANGER** 

Use the USB power adaptor provided with the unit.

Care should be taken when powering the unit from a computer USB port or alternative USB power source.



WARNING

Always ensure that the USB power cord is securely inserted into the rear of the unit.

Ensure that any excess power cord does not pose a potential trip or pull hazard.



**DANGER** 

Do not operate the unit in any area which is, or has been, or is thought to have been exposed to explosive or flammable gases, vapours or liquids.



**WARNING** 

The unit must be installed and operated on a solid, stable, vibration-free and level working surface.



For best results, the unit should be installed and operated in a stable thermal environment, out of direct sunlight and away from sources of heat or draught.







## **General Operating Precautions**



Ensure that the power is switched off at the mains outlet before inserting or removing the USB power cord.

**DANGER** 

If a spillage occurs in or over the unit, switch the power off and unplug the USB cord at the power adaptor before attempting to deal with the spill.



The unit is intended for use with aqueous solutions only.

Never use the unit with any explosive, volatile or highly reactive substances or chemicals.



To avoid liquid spills and possible cross-contamination of samples, use sealed or capped tubes of the type specified in Section 4.1.

Always follow prescribed laboratory procedures and use appropriate personal protective equipment (PPE - such as gloves, clothing, goggles, etc.) when handling samples.



**CAUTION** 

The unit lid poses a possible finger crush hazard.

Take care when opening and closing the lid to ensure hands, fingers and protective gloves do not get trapped.

Do not insert your finger into the sample read chamber.



**CAUTION** 

The unit lid catch contains a small magnet. Avoid direct contact with any magnetic-sensitive devices or assays.



Avoid touching the contacts of the USB port on the rear of the unit as an Electrostatic Discharge (ESD) could degrade or impair the functionality of the unit.







## **Unit Maintenance and Serviceability**



There are no user or operator serviceable parts inside the unit.

Do not remove the unit casework. Removal of the unit's casework will void the manufacturer's warranty.



Always disconnect the USB power cord from the unit before performing any cleaning or decontamination procedure.

**DANGER** 

If liquid is spilt into or over the unit, switch off and disconnect the USB from the source before attempting to deal with the spillage.



The use of harsh chemicals and cleaning agents may damage the unit and degrade its performance.

Always follow the cleaning and decontamination procedures specified in Sections 9.1 and 9.2 of this instruction manual.



## 3 Regulatory Limitations of Use

## **Declaration of Conformity**

Integrated Technologies Limited (ITL) affirm that this product fulfils the essential requirements of the Low Voltage Directive 2014/35/EU and the EMC Directive 2014/30/EU, when installed and operated in accordance with the instructions in this manual.



ELECTRICAL SAFETY
E113628

## **Safety Standards**

- BS EN 61010-1:2010+A1:2019
- UL/IEC 61010-1:2012 Edition 3.1 (CAN/CSA C22.2 61010-1 [2017])
- MET Labs NRTL Electrical Safety Listing No E113628



- BS EN 61326-1:2013, Class A
- FCC CFR 47 Parts 15.107 and 15.109, Class A

## **RoHS and WEEE Directive Compliance**



This product complies with the requirements of the RoHS2 Directive 2011/65/EU, its delegated Directive (EU) 2015/863, in accordance with EN 63000:2018.



Where applicable, the Lu-mini unit should be disposed of in accordance with the European Union WEEE Directive 2012/19/EU on Waste Electrical and Electronic Equipment.

Do not dispose of this product into unsorted municipal waste or public landfill. Please refer to Section 9.4 for details of how to correctly dispose of this product.

The Lu-mini unit is designed and manufactured under ISO 9001 by:

## **Integrated Technologies Limited**

Viking House, Ellingham Way, Ashford, Kent, TN23 6NF United Kingdom



# 4 **Lu-mini Unit Description**

The Lu-mini unit is a benchtop Luminometer and has the following external and internal features:

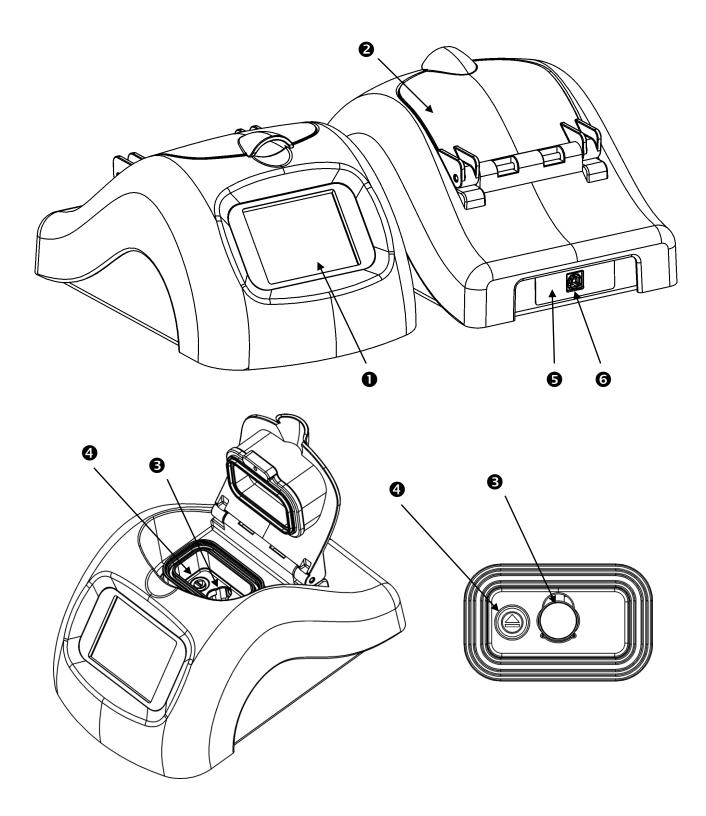
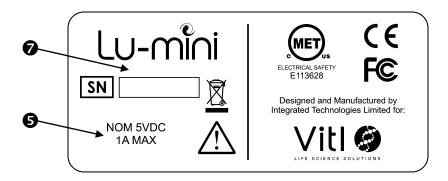


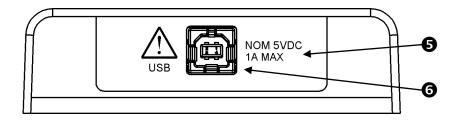


Table 2: Unit Features					
0	LCD Touchscreen User Interface	<i>⇒</i> 6.1			
2	Unit Lid	<i>⇒</i> 6.4			
8	Sample Read Chamber	<i>⇒</i> 4.1			
4	Sample Tube Eject Button	<i>⇒</i> 6.4.3			
6	Voltage and Power Ratings	<i>⇒</i> 11			
6	USB Power Inlet	<i>⇒</i> 5			
7	Unit Label and Serial Number	<i>⇒</i> Below			

The unit label is located on the underside of the unit and provides the unit serial number, and voltage and power ratings.



There is also a label surrounding the USB Power Inlet at the rear of the unit which provides the voltage and power ratings.



Refer to Section 11 for Lu-mini Technical Specification.



The unit is supplied with the following accessories:

Table 3: Unit Accessories				
	AC/DC USB Power Adaptor	<i>⇔</i> 6.2		
	USB Power Cable	<i>⇒</i> 6.2 <i>⇒</i> 11		
	Lu-mini App Install Flash Drive	<i>⇒</i> 7		
Lu-mini	Lu-mini Instructions for Use	<i>⇒</i> 1		



### 4.1 **Output** Acceptable Sample Tube Types and Fill Volumes

The Lu-mini unit is designed to accept the following sample tube types:

Table 4: Acceptable Sample Tube Types					
Tube	Туре	Tube Sizes	Sample Volumes		
Tube		Round round-bottomed 10mm to 12mm diameter 47mm# to 75mm* tall * Including cap	10mm   12mm Recommended: 500uL   800uL Minimum: 200uL   300uL		
Vial		Round flat-bottomed 15mm diameter 48mm <sup>#</sup> tall	15mm Recommended: 1500uL Minimum: 600uL		
Cuvette		Square flat-bottomed 12.5mm square 48mm# tall 10mm path length	12.5mm Recommended: 1000uL Minimum: 500uL		

The recommended tube type is the 12mm x 75mm (5mL) round-bottomed polypropylene test tube with a screw cap. Such as:

- Universal Medical Inc GS-6148R or GS-6148W
- Corning Life Sciences Falcon 352003, 352054 or 352058



To avoid liquid spills and possible cross-contamination of samples, use sealed or capped tubes whenever possible.



<sup>#</sup> Note: Refer to Section 6.4.3 for specific details on how to insert and remove the sample tubes from the Sample Read Chamber - especially for sample tubes with a height of less than 50mm.



#### 5 **Lu-mini Unit Installation**

Before installing the Lu-mini unit, please check that the delivery is complete (see Table 3) and that the unit and all accessory parts are intact and free from any signs of transportation damage. Also ensure that all external and internal packaging has been removed from the unit before installation.



Please retain all packaging for future transportation and storage of the unit and its accessories.

The Lu-mini unit should be installed in a location which meets the following requirements:

- Safe and suitable operating environment (see Section 2)
- Solid, stable, vibration-free and level working surface
- At least 10cm clearance around the unit to adjacent objects and walls
- · Out of direct sunlight and away from sources of heat or draught



Please also observe and abide by the Unit Installation and **Operating Environment** safety precautions and preconditions listed in Section 2 of this manual.



**Note**: When the unit is initially powered, or if it has been left in storage or unpowered for several months, the internal real-time clock battery will need recharging.

Please leave the unit powered for at least 2 hours (preferably 8 hours) to recharge the battery.



Please refer to Section 7.1 for details on installing the associated Lu-mini Windows Application.



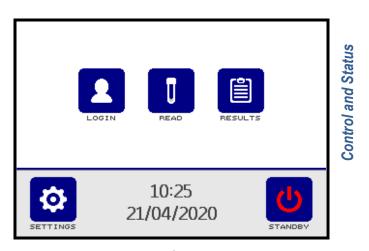
## **6 Basic Unit Operation**



Please ensure that you have read and fully understood all of the **Safety Precautions and Limitations of Use** listed in Section 2 before attempting to operate the Lu-mini unit.

### **6.1 User Display and Controls**

The unit's user interface consists of a colour LCD touch screen display. The menu structure is divided into two sections as shown below.



**Function and Option buttons** 

The above screen shows the **Main Menu** buttons, which provide the following functionality.

Table 5: Main Menu Button Functions					
	Select active User ID				
Ū	Select Protocol and perform Reading	<i>⇒</i> 6.4			
	View the Test Results <b>Database</b>	<i>⇒</i> 6.5			
<b>Ø</b>	Enter unit <b>Settings</b> menu	<i>⇒</i> 6.6			
<b>(</b>	Unit Standby and Wakeup modes	<i>⇒</i> 6.7			



Below is a list of other menu and data list navigation buttons and their functions.

Table 6: Navigation Button Functions					
<b>✓</b> ×	Accept or Cancel option	<i>⇒</i> 6.6			
	Return to Main Menu	<i>⇒</i> 6.1			
<b>←</b>	Exit to <b>Previous</b> menu	<i>⇒</i> 6.4			
<b>4</b>	Edit Sample ID	<i>⇒</i> 6.4			
	Start Test	<i>⇒</i> 6.4.4			
	Test result <b>Status</b> tag	<i>⇒</i> 6.4.6			
9	Change test result Comment	<i>⇒</i> 6.4.6			
<b>5</b>	Open test result <b>Details</b>	<i>⇒</i> 6.5			
<b>⊼</b> ⊻	Jump to <b>Top</b> or <b>Bottom</b> of data list	<i>⇒</i> 6.5			
^ ~	Move <b>Up</b> and <b>Down</b> data list or <b>Increase</b> and <b>Decrease</b> settings value	<i>⇒</i> 6.5			
<b>→</b>	Move to <b>Next</b> value	<i>⇒</i> 6.6			

Other function-specific button icons are explained in Sections 6.3 to 6.7.



There are also various status and prompt symbols that may appear in the main screen area, as detailed in Table 7 below.

	Table 7: Status and Prompt Symbols	
<u>[7</u>	Prompt: Open Lid	<i>⇒</i> 6.4.3
1	Prompt: Insert Sample tube	<i>⇒</i> 6.4.3
	Prompt: Use specified <b>Tube Number</b>	<i>⇒</i> 6.4.3
1	Status: Sample Inserted correctly	<i>⇒</i> 6.4.3
	Prompt: Close Lid	<i>⇒</i> 6.4.3
	Status: Ready to <b>Start</b>	<i>⇒</i> 6.4.3
<b>I</b>	Prompt: Remove Sample tube	<i>⇒</i> 6.4.3

When the lid is open, the unit also periodically beeps to prompt the user to close the lid as soon as possible.



Note: For optimum reader performance, the lid should always be kept closed when not inserting or removing a sample tube.



Please refer to Section 7 for additional buttons and symbols which relate to specific Lu-mini App features.



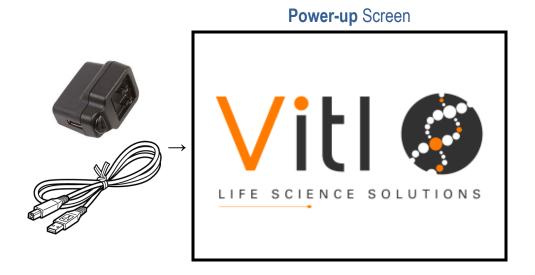
### 6.2 Powering-up the Lu-mini Unit

The Lu-mini unit is powered via a standard USB cable, from the supplied AC/DC USB Power Adaptor. However, it can also be powered from a USB port on a desktop or laptop computer, a USB battery pack or a 12V-to-5V USB Car Charger.



Plug the supplied USB Cable into the Lu-mini Unit and then into the power source, and (if necessary) switch on the power source.

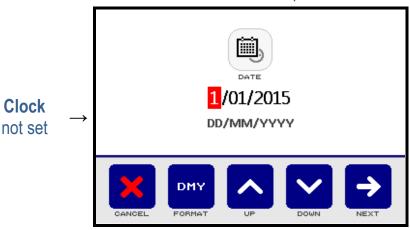
The Lu-mini unit LCD will light-up and display the power-up progress screen whilst the internal data memory is checked and the reader initialised.





Once complete, if the real-time Clock requires setting, the Date and Time setup screen will be displayed. Refer to Section 6.6.1 for more details.





Following this, the **Main Menu** screen is displayed.

Power-Up Screen

10:25
21/04/2020

Settings

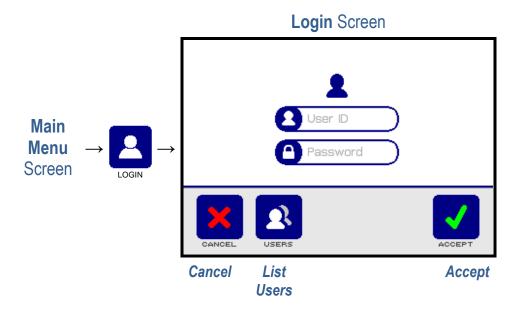
Standby

The current time and date are displayed on the **Main Menu** screen as a visual check that they are correctly set. This is important as the time and date are required for the **Read** and **Results** options to function correctly.



### 6.3 Selecting the Active User

The **User ID** function allows Test Results to be logged against a specific user. To change the User ID, press the **Login** button on the **Main Menu** screen.



To change User ID, press the **User ID** input box and the QWERTY keyboard will appear. Enter the User ID and press the **Accept** button.



If the User ID is password protected (see Section 7.6), press the **Password** input box, enter the password and press **Accept**.



The unit remembers the most recently logged-in User ID and selects this user when the unit is next powered up, automatically bringing up the **Login** screen if a password is required.

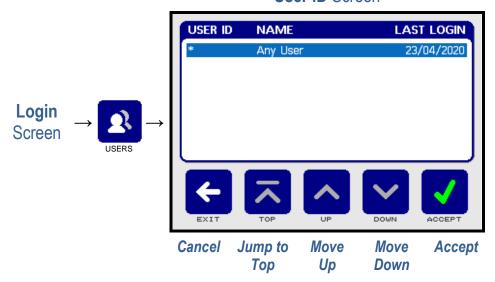


The user can be forced to always login after power-up by selecting the **User Login Required** option in the Lu-mini App. See Section 7.8.2 for details.



Alternatively, the User ID can be selected from the users list by pressing the **Users** button:

**User ID** Screen

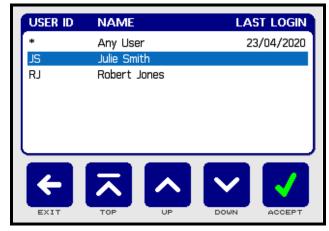


By default, the **User ID** is set to **Any User** and there are no other User IDs available to choose from, therefore the **Up** and **Down** buttons are disabled. To return to the main menu press the **Accept** button.



Additional User IDs can only be added and edited via the Lu-mini App. See Section 7.6 for details.

When additional User IDs have been downloaded to the unit, the **Up** and **Down** buttons will be enabled to allow the desired User ID to be selected from the list.



Select the user from the list, press the **Accept** button and (if required) enter the user password.



The active **User ID** and **Name** are displayed on the **Main Menu** screen.

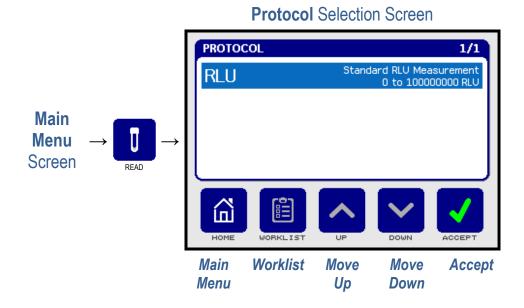


## 

Once the **User ID** has been checked and set, the sample measurement **Protocol** can be selected so that a sample test can be performed.

### 6.4.1 Selecting a Protocol

The Protocol function allows the user to select the appropriate measurement protocol for the test about to be performed. To select the measurement Protocol, press the **Read** button from the **Main Menu** screen.



By default, the **Protocol** list consists of just the **Standard RLU Measurement** with no other protocols to choose from, therefore the **Up** and **Down** buttons at the bottom of the screen are greyed-out.

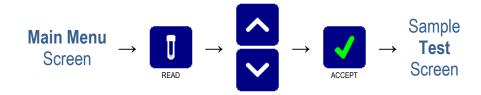


The **Worklist** button is also greyed-out at this point (see Section 7.9.3.3).



Additional Protocols and Worklists can only be added and edited via the Lu-mini App. See Section 7.9 for details.

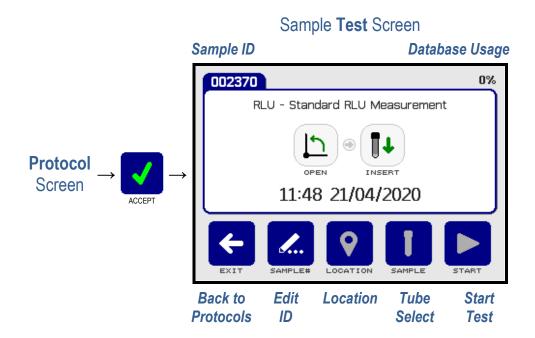
Once the required Protocol has been selected, press the **Accept** button to start the testing procedure.



### 6.4.2 **@** Editing the Sample ID

The top left corner of the **Test** screen shows the **Sample ID** which is a unique ID assigned to the test result. The figure in the top right corner of the screen shows how full the results Database is.

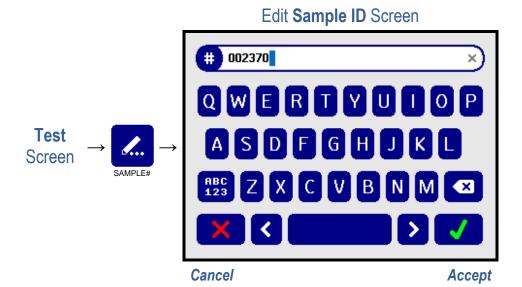
The selected protocol is displayed in the middle of the screen, along with the time and date and visual prompts instructing the user how to perform the test.



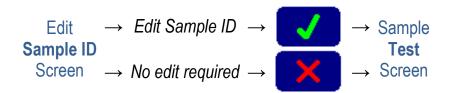
The default Sample ID allocation is a sequential numerical ID, however other Sample ID options can be selected from the unit **Settings** menu (see Section 6.6.3 for details).



If required, the Sample ID can be edited by pressing the **Sample#** edit button.



Using the keyboard, the Sample ID can be entered or edited. Once the desired ID has been entered, press the **Accept** button to continue or the **Cancel** button to undo and return to the **Test** screen.





If the unit has been set-up to have no automatic Sample ID (see Section 6.6.3) the QWERTY keyboard will automatically appear as soon as the test begins.



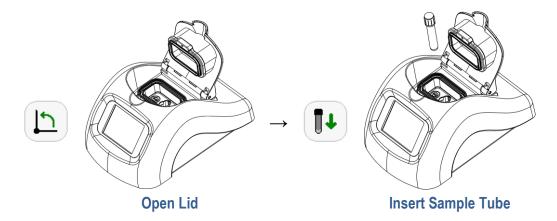
A barcode scanner can also be used to enter the Sample ID. Refer to Section 7.5 for details on the **Barcode Pass-through Function** of the Lu-mini App.

At the bottom of the sample **Test** screen, the **Location** and **Tube Select** buttons are greyed-out as these features are only available when using the Lu-mini App. See Section 7 for details.

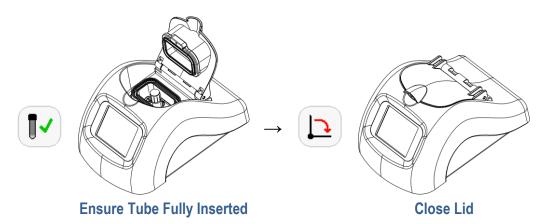


### 6.4.3 Sample Tube Insertion and Removal

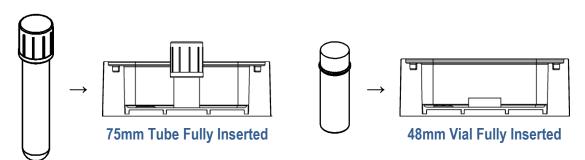
Once the Sample ID has been set (see Section 6.4.2), insert the test sample tube into the reader sample chamber, as detailed below.



Ensure that the sample tube is fully pushed down into sample chamber so that the bottom of the tube is touching the bottom of the read chamber.

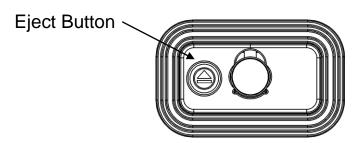


Once inserted, tubes that are less than 50mm tall are almost completely enveloped by the sample chamber and cannot be easily remove by hand.





The Lu-mini features a push button to allow for easy removal of short sample tubes. The tube Eject button is located next to the Sample Read Chamber inside the unit (see Section 4).

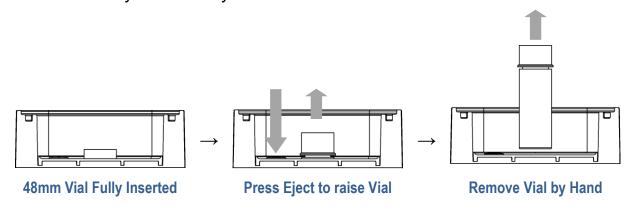


To remove a sample tube from the sample read chamber:

1) Open the unit lid when instructed to do so.



- 2) If the tube is easily accessible simply remove it by hand, otherwise use the tube **Eject** as detailed below.
- 3) Use a finger to push down on the **Eject** button. As the button is depressed the tube will be raised up out of the sample chamber slightly.
- 4) Release the **Eject** button.
- 5) There should now be enough of the tube protruding from the chamber to allow easy removal by hand.



6) Close the lid.



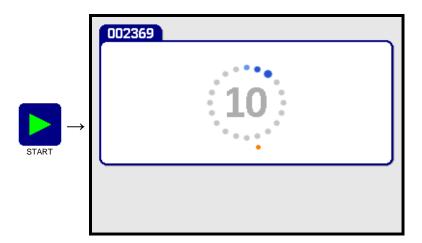


### 6.4.4 Performing a Sample Reading

Once the sample tube has been inserted into the unit and the lid closed (see Section 6.4.3 above), press the **Start** button to start the reading.



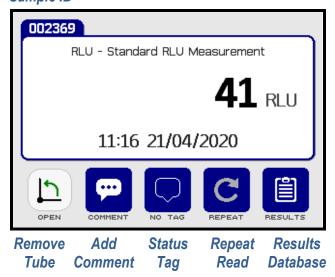
The measurement countdown begins.



At the end of the countdown period the test result is displayed on the **Test Result** screen.

Test Result Screen

Sample ID





At this point the user can choose to either:

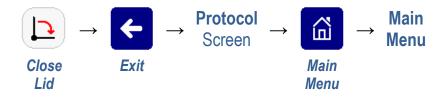
- 1) Remove the tube and perform another sample test
- 2) Add a comment to the test result (Section 6.4.5)
- 3) Change the result Status Tag (Section 6.4.6)
- 4) Re-read the same sample tube (if enabled see Section 7.9.4)
- 5) View the Test Results Database (Section 6.5)

To perform another sample test or return to the Main Menu, open the unit lid and remove the sample tube. See Section 6.4.3 for sample tube removal.



The sample **Test** screen will then appear. To perform another test, follow the visual prompts in the middle of the screen as detailed in Sections 6.4.2 thru 6.4.4 above.

Otherwise, to return to the **Main Menu**, remove the tube and press the **Exit** button to return to the **Protocol** screen where the **Main Menu** button can be pressed to return to the main menu screen.



## 6.4.5 Adding a Test Result Comment Note

The **Comment** button can be used to add a short note to the test result. This is particularly useful when the result status has been set to **Flagged** (see Section 6.4.6 below).



This comment text will appear in the **Notes** field of the Lu-mini App **Test Results Database** table when the result is uploaded (see Section 7.4).



### 6.4.6 Test Result Status Tagging

Each test result can be tagged with a **Status** icon to signify its overall result status, as listed in Table 8 below.

Table 8: Result Status Tag Symbols						
	None: Status unspecified					
æ	Good: Good protocol test result					
<b>#</b>	Uncertain: Unsure protocol test result					
<b>\$</b>	Bad: Bad protocol test result					
P	Flagged: Result flagged as interesting					
×	Invalid: Invalid/out-of-range test result					



**Note**: The test result **Status** tag can only be changed immediately after the test has been completed, and <u>before</u> the tube is removed.

Press the **Status** tag button to access the status options screen.

Result Status Screen

Result Screen

Result Screen

Result Screen

Result Screen

Result Status Screen

Result Screen

Result Screen

Result Status Screen

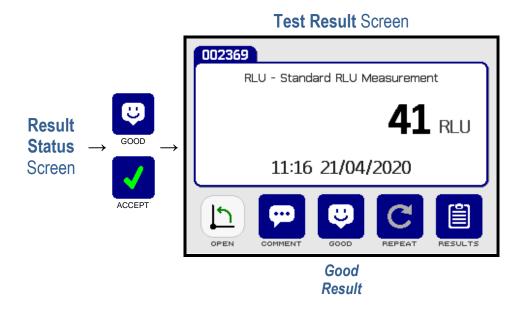
Accept





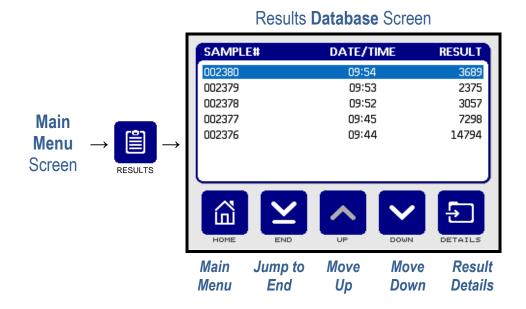
For user-defined Protocols (see Section 7.9), the user can be prevented from changing the pre-assigned status value, in which case the **Status** option buttons are greyed-out.

To change the result status icon, press the required **Tag** button in the middle of the screen, and then the Accept button. The display goes back to the Test **Result** screen with the new status icon shown at the bottom of the screen.



## 6.5 **Wiewing the Test Results Database**

The test results **Database** is where all the test results are stored and can be accessed either from the Main Menu or Test Result screen. To view the database, press the **Results** button.

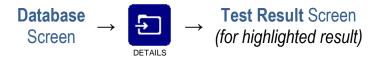




The **Database** screen displays a list of all the test results that have been completed. Results are listed in date/time order with the most recent result at the top of the list. For tests performed today, the test time is shown; otherwise the test date is displayed.

The **Up** and **Down** buttons can be used to scroll up and down the list one test at a time or alternatively use the **Top** or **End** button to quickly jump to the top or bottom of a long list of results.

When a result is highlighted, the **Details** button can be used to view the full-size Result screen for that specific result.



Press the **Results** button to return to the Database screen.



## 6.5.1 Oeleting Test Results from the Lu-mini Database

Test results cannot be directly deleted from the Lu-mini's Results **Database**. When the database is full, the oldest result is automatically overwritten.



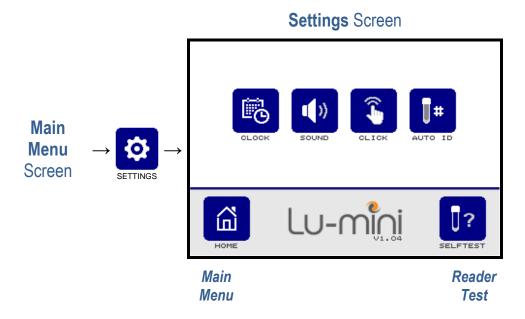
Results can only be deleted from the unit via the Lu-mini App. See Section 7.4.1 for details.



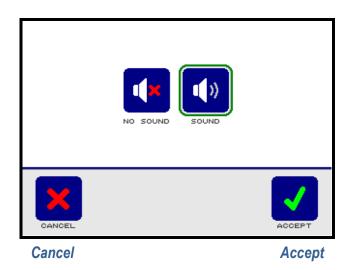
### 6.6 **Unit Set-up Options**

The unit **Settings** menu provides options for customising the unit's behaviour, and shows the current state of the settings.

Press the **Settings** button from the **Main Menu** screen to view the **Settings** menu.



To change a setting, press the associated option button in the middle of the screen, then select a new value (designated by the green ring) and press the **Accept** button to save the new setting.





The available options are summarised in Table 9 and described in the more detail in the following sub-sections.

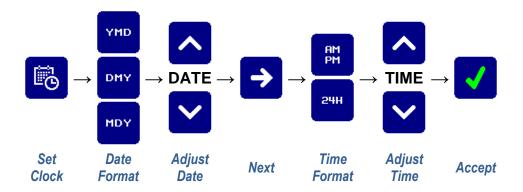
Table 9: Unit Set-up Options					
Set clo Date/T formats	ime	YMD Year/Month/Day  AM PM	DMY  Day/Month/Year  2чн	MDY  Month/Day/Year	<i>⇒</i> 6.6.1
		AM/PM	24 Hour		
Beeper volume		No Sound	(I))		<i>⇒</i> 6.6.2
Touchscreen button click volume		No Sound No Click	Sound  Click		⇒ 6.6.2
Sample auto-te		Edit Prefix  None	123 Auto Number	YMD Daily Number	<i>⇒</i> 6.6.3
Reade self-tes	r st mode	Start Test	Repeat Test		⇒ 6.6.4





### 6.6.1 **@** Setting the Clock and Date/Time Formats

The clock option allows the unit date and time to be changed, as well as the date and time formats (as listed in Table 9).





If using the Lu-mini App, the date and time can be automatically set and synchronised with the computer's clock. This will also set the date and time formats. See Section 7.8.3 for details.



**Note**: The Lu-mini Unit does not automatically handle Daylight Saving changes. This must be done manually by the users, or by the Lu-mini App (as per Section 7.8.3).

## 6.6.2 **@** Beeper and Button Click Volume

The unit beeper sounds at the end of each sample measurement. This can be muted if required.



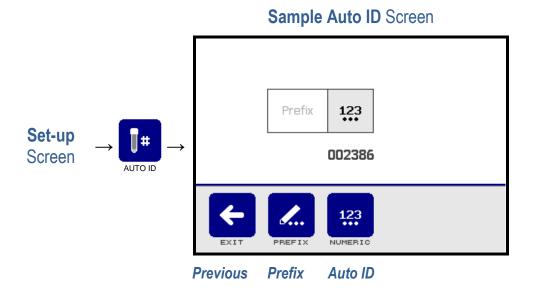
Likewise, the LCD touch screen button click can be independently set to silent if desired.





#### 6.6.3 **Opening the Automatic Sample ID Text Format**

The Sample ID text format can be edited as required using the sample ID editor function. From the **Set-up** menu select the sample **Auto ID** button.



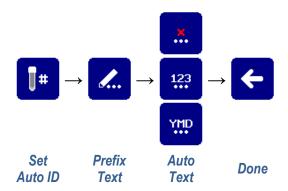
By default, the Sample ID is set to sequential numeric ID with no prefix. All the available options for ID editing are detailed in Table 10.

Table 10: Automatic Sample ID Buttons			
<i>d.</i> .	Edit <b>Prefix</b> Text (0 to 6 characters)	ABCDEF	
<b>×</b>	No Automatic ID		
123	Sequential <b>Numeric</b> ID (6 digits)	123456	
YMD	Daily Sequential ID (10 digits)	YYMMDD-123	

The Sample ID can be a maximum of 16 characters long i.e. if set to Daily Sequential ID with a 6-character prefix.



Press the appropriate buttons to set the sample ID as required.

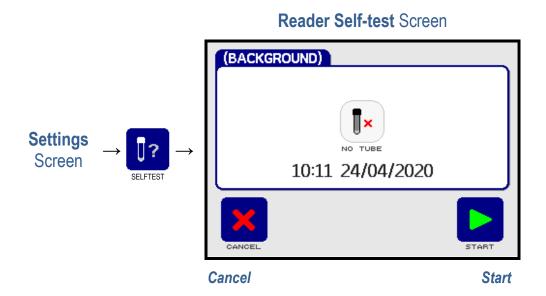


**Note**: It is possible to have no automatic ID and no prefix set. In this case, when a sample Test is performed, the unit automatically prompts to user to manually enter the Sample ID by displaying the QWERTY keyboard. A sample ID must be given to the sample before a test can be performed.

#### 6.6.4 Reader Self-test Mode

The reader self-test mode allows background reading to be performed either with or without a sample tube present in the unit.

Press the reader **Selftest** button on the set-up menu to display the reader self-test screen.



Press the **Start** button to perform a reading using the Standard RLU Measurement protocol. When the test result is displayed, either press **Repeat** to perform another reading or press **Cancel** to return to the **Settings** menu.

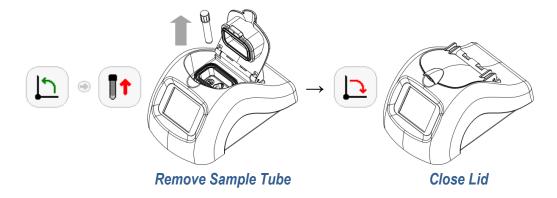


**Note**: As these are only background self-test readings, they are not stored in the unit's results database.

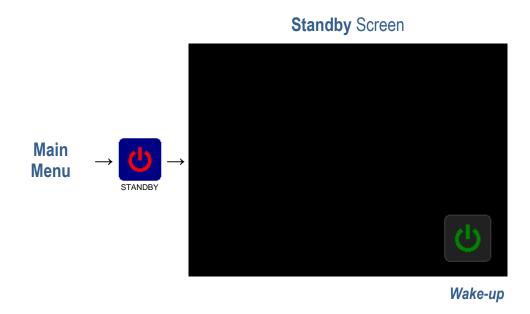
### 

After use, and before switching off the power to the unit, it is recommended to put it in standby mode.

Firstly, remove any sample tube that may be present in the unit, and close the unit lid.



Then, on the Main Menu screen, press the **Standby** button to activate the standby mode.



Once the unit is in standby mode, the power can be safely removed.

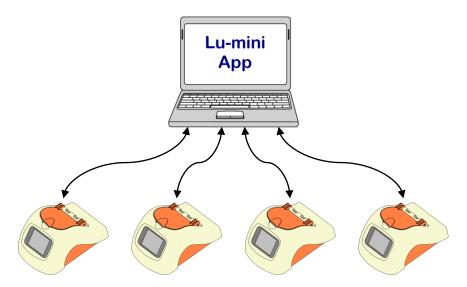
To wake-up the unit from standby mode, press the **Wake-up** button on the standby screen.



# 

The Lu-mini Windows App provides the following additional settings and features on the Lu-mini Unit:

- Uploading of Test Results to a common results Database
- Export of Test Results to an Excel compatible CSV file
- Creation of User IDs with optional passwords
- Creation of custom Protocols and Assays
- Management of multiple Lu-mini units to ensure common settings



Multiple Lu-mini units can be connected to a single computer using several USB ports or a powered USB hub.

# 7.1 Installing the Lu-mini Windows App and USB Driver

# **2** DISCLAIMER **2**

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BY INSTALLING OR USING THIS SOFTWARE YOU ARE AGREEING TO BE BOUND BY THE CONDITIONS OF THIS AGREEMENT.



To install the Lu-mini App, run the **Install**.msi file from the Installation Drive to initiate the install procedure. Then follow the on-screen prompts.



The Lu-mini App is designed to run on 32-bit and 64-bit versions of Windows 7, 8 and 10. To install the software you may require additional administrator access rights from your **IT Administrator**.



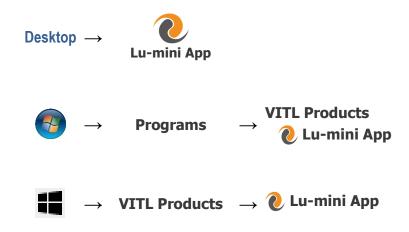
Always ensure that you install the latest version of the Lu-mini App, as previous versions are incompatible with the latest software features.

Next the USB Driver must be installed. This is done by running the appropriate driver install program from the **CP210x\_Driver** sub-folder on the Installation Drive and following the onscreen prompts:

- For 64-bit Windows: Run CP210xVCPInstaller\_x64.exe
- For 32-bit Windows: Run CP210xVCPInstaller\_x86.exe

Alternatively, this can also be done by selecting the **Install USB Driver** option from the **Help** menu in the Lu-mini App (see Section 7.2.3 from details).

To run the Lu-mini App, click on the **Lu-mini App** icon on the desktop, or in the **VITL Products** section of the programs **Start** menu.

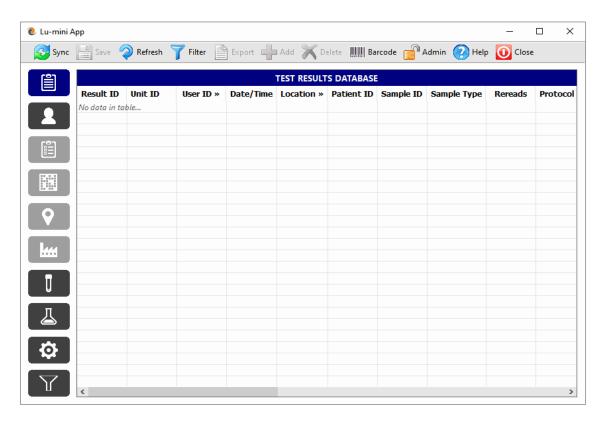




### 7.2 **Lu-mini App Basic Functionality**

The Lu-mini App enables data to be transferred to and from the Lu-mini unit and a Windows computer, making it easy to add User IDs and customise the unit with specific sample measurement Protocols.

The application display format consists of a spreadsheet-style layout, with Table selection buttons down the left-hand side of the screen and a Toolbar across the top.





## 7.2.1 Table Selection Buttons

The Lu-mini App features numerous spreadsheet-style **Tables**, which are selected by clicking the associated **Table** select button down the left-hand side of the application Window.

Table 11: Lu-mini App Table Select Buttons				
	Test Results Database	<i>⇒</i> 7.4		
2	User IDs	<i>⇒</i> 7.6		
	Future Feature: Scheduled Test Sample Work List			
	Future Feature: Test Plans			
♥	Future Feature: Sample Testing Locations			
<b>L</b>	Future Feature: Sites			
U	Sample Measurement Protocols	<i>⇒</i> 7.9		
	Reagent Assays	<i>⇒</i> 7.10		
<b>\$</b>	Unit Settings	<i>⇒</i> 7.7		
Y	Test Results Filters	<i>⇒</i> 7.4.4		

Please refer to the subsequent Sections for more details.



# 7.2.2 **@** Toolbar Options

The toolbar provides the basic data functions as follows:

Table 12: Lu-mini App Toolbar Options				
	Sync	Synchronise Lu-mini Unit to the Lu-mini App	<i>⇒</i> 7.3	
	Save	Save table data changes to disk	<i>⇒</i> 7.2.4	
2	Refresh	Reload table data from disk	<i>⇒</i> 7.2.4	
7	Filter	Sort and Filter table data	<i>⇒</i> 7.4.4	
	Export	Export data to Excel compatible CSV file	<i>⇒</i> 7.4.2	
	Add	Create new User, Protocol, etc	<i>⇒</i> 7.2.4	
×	Delete	Delete existing data within App	<i>⇒</i> 7.2.4	
BOOK SEE	Barcode	Barcode Pass-through Function	<i>⇒</i> 7.5	
	Admin	Application and Unit Administrator Settings	<i>⇒</i> 7.8	
	Help	Help menu	<i>⇒</i> 7.2.3	
0	Close	Close Lu-mini App		

Please refer to the specific Sections for more details.

# 7.2.3 • Help Menu Options

The **Help Menu** is accessed by clicking on the **Help** button in the toolbar, and provides the following options:

Table 13: Lu-mini App Help Menu Options			
Instructions for Use	Open Lu-mini User's Manual		
Capture Unit Screenshot	Capture Lu-mini screen image		
Install USB Driver	Install appropriate USB Driver		
<b>Check online for App Updates</b>	Future Feature		
<b>Recover Unit Software Update</b>	Future Feature		
Support	Open Support web page		
About Lu-mini App	Lu-mini App software details		



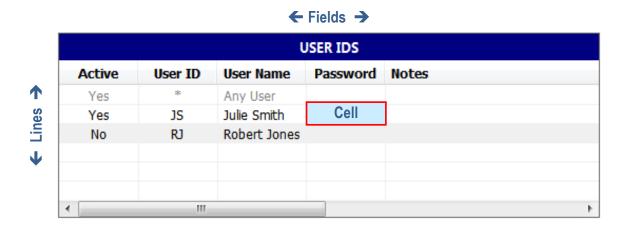
The **Install USB Driver** option can be used the install the Windows USB Driver for the Lu-mini Unit. Using this method, the application automatically detects the Windows version and loads the appropriate driver.



The **Capture Unit Screenshot** option can be useful for taking snapshots of the current display on the Lu-mini Unit, so they can be pasted into your own Standard Operating Procedures.

## 7.2.4 **O** Data Table Editing and Context Menu

Each **Table** displays a specific spreadsheet, consisting of a matrix of data **Cells**, organised in **Lines** (running down the sheet in rows) of related data **Fields** (arranged across the sheet in columns).



**Lines** or **Cells** which are greyed-out cannot be changed. All other cells in the table can be edited in following ways:

(a) Double-clicking on the **Cell** text:

(b) Right-clicking on the Cell and selecting the Edit option from the Context Menu:





After changing the Cell text, press the **Enter** key to accept the new value; or press the Escape key to cancel editing; or press the Tab key to accept the new value and move to the next cell to be editd.



WARNING: There is no Undo button; hence any changes made to the table data cannot be easily reversed. The only way to restore the table values is to Exit the application without saving, or to use the Refresh button to reload the data (see below for details).

When a data cell value has been changed, the line text colour changes to Blue to signify that it has been modified but has not yet been saved to disk.

To save any changes to disk, simply click the Save button in the Toolbar. The modified lines will then turn black again.

If changes have been made to the data, but you have changed your mind, there is no **Undo** option. However, the entire data table can be reloaded from disk to the state it was when last saved by clicking the Refresh button.

New data **Lines** can be added to the end of the table in the following ways:

(a) Clicking the **Add** button in the Toolbar:

$$ightharpoonup 
ightharpoonup 
igh$$

(b) Right-clicking on a Line and then selecting the Add Duplicate Line option from the Context Menu:





One or more data **Lines** can also be deleted in the following ways:

(a) Selecting the **Lines** to be deleted and then clicking the **Delete** button in the Toolbar:

(b) Selecting the **Lines** to be deleted and then right-clicking on a **Lines** and then selecting the **Delete Line** option from the Context Menu:



The full list of right-click Context Menu options are listed in Table 14 below.

Table 14: Data Cell Context Menu Options			
Edit	Edit cell value		
Go to Definition	Jump to cell data definition   ⇒ Belo		
Copy Cell(s)	Copy cell value to paste clipboard	<i>⇒</i> 7.4.2	
Copy Line(s)	Copy selected line(s) to clipboard	<i>⇒</i> 7.4.2	
Copy Line(s) with Header	Copy Header and Selected line(s)	<i>⇒</i> 7.4.2	
Select All	Select all lines		
Select None	Select no lines		
Create New Line	Insert a new data line	<i>⇒</i> Above	
Add Duplicate Line	Duplicate entire line contents	<i>⇒</i> Above	
Delete Line	Delete selected line(s)	<i>⇒</i> Above	

Some cells may refer to definitions on other tables, such as the **Assay** in the **Protocols** table. These are denoted by a "»" symbol in the field heading (e.g. **Assay** »). Right-clicking on the cell and selecting the **Go to Definition** option will jump to the definition for that cell in the associated table.

1

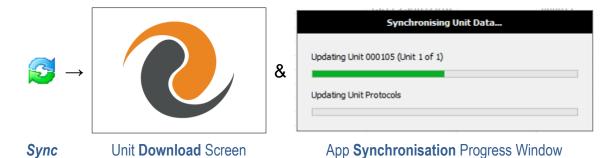


#### 7.3 **Output** Data Synchronisation

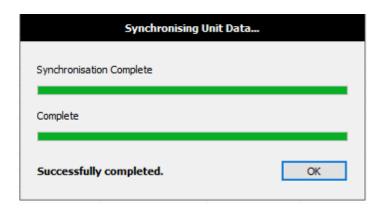
The toolbar **Sync** button is used to transfer data between the Lu-mini App and all attached Lu-mini Units, by performing the following tasks:

•	Discover and add New Unit details	<i>⇒</i> 7.7.
•	Upload test results from Unit	<i>⇒</i> 7.4
•	Delete test results from Unit's database	<i>⇒</i> 7.4
•	Check for Unit Software updates	
•	Update Unit's time and date settings [Optional]	<i>⇒</i> 7.7
•	Update Unit's User IDs list	<i>⇒</i> 7.6
•	Update Unit's Protocols list	<i>⇒</i> 7.9

Click the **Sync** button on toolbar to initiate the data transfer. The Lu-mini Unit will display the Download screen until the process is complete.



When synchronisation is completed, the Lu-mini Unit will restart. Click the **OK** button to close the progress window.



Once restarted, the attached Units will have any new User and Protocol data loaded on to them from the Lu-mini App, and the App will contain all the test results data from the Units.





**Note**: Uploading the test results removes them from the Lu-mini Unit and permanently stores them in the Lu-mini App **Test Results Database** table (see Section 7.4).

#### 7.4 Test Results Database Table

The Test Results Database table stores all the test results that have ever been uploaded from the Lu-mini Units.

The Test Results Database table data fields are listed in Table 15 below.

Table	15: Test Results Database Data Fields	
Results ID	Unit test result unique ID within the database	
Unit ID	Unit serial number and name	<i>⇒</i> 7.7.1
User ID	User ID	<i>⇒</i> 7.6
Date/Time	Date and Time when sample test performed	<i>⇒</i> 7.8
Location	Future Use: Sample location name	
Patient ID	Future Use: Patient ID from Worklist	
Sample ID	Test Sample ID	<i>⇒</i> 6.4.2
Tube Type	Sample tube type (S, C, 1, 2, 3, 4, 5 or 6)	<i>⇒</i> 7.9.3
Rereads	Number of times the tube was re-read	<i>⇒</i> 7.9.4
Protocol	Protocol name	<i>⇒</i> 7.9.2
<b>Measurement Type</b>	Measurement type	<i>⇒</i> 7.9.5
Tube Reading	Sample tube reading	<i>⇒</i> 7.9.6
Reading Units	Tube reading Units-of-measurement	<i>⇒</i> 7.9.6
Percentage	Tube percentage reading relative to Control tube	<i>⇒</i> 7.9.6
Test Result	Test Result	<i>⇒</i> 7.9.6
Results Units	Result Units-of-measurement	<i>⇒</i> 7.9.6
Status	Overall test result Status tag	<i>⇒</i> 6.4.6
Band	Banded result Name	<i>⇒</i> 7.9.6
Lower Limit	Banded result lower limit	<i>⇒</i> 7.9.6
<b>Upper Limit</b>	Banded result upper limit	<i>⇒</i> 7.9.6
Kinetic Rate	Number of seconds per a kinetic data point	<i>⇒</i> 7.9.5
Kinetic Data	Kinetic data points	<i>⇒</i> 7.9.5
Notes	Optional: Additional notes	<i>⇒</i> 7.2.4

None of these data field values can be edited except for the **Notes** field.



### 7.4.1 **Outploading Test Results Data**

Each time the Lu-mini App synchronises with a Lu-mini Unit any new test results are uploaded and stored in the Test Results Database table.



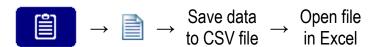
Once the results have been uploaded and saved in the Lu-mini App they are automatically deleted from the Lu-mini Unit.

### 7.4.2 **@** Exporting Test Results Data

Test results data can be exported to an Excel compatible CSV file by clicking the **Export** button on the toolbar.



This can either be all of the data in the table, or just the selected lines.



Alternatively, the data can be Copied and Pasted into an existing Excel sheet. This is achieved by selecting the **Lines** to be copied and then right-clicking on a **Line** and clicking the **Copy Line(s)** option in the Context Menu.



To export Kinetic Data (see Section 7.9.5 for protocol setting), select the required results data lines then click the **Export** button and select the **Export Selected Kinetic Data** option.





In addition, the **Filter** feature can be used to first narrow-down the data and reduce the number of lines and fields before exporting them. See Section 7.4.4 for details.

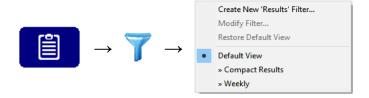
# 7.4.3 **Operation 7.4.3 Deleting Test Results Data**

Results are automatically deleted from the unit when they are uploaded to the Lu-mini App during the synchronisation process. All results data from the unit is stored in the application database until it is deleted by the user.

To delete results data from the application's Test Results Database, refer to Section 7.2.4 for details.

# 7.4.4 Sorting and Filtering Test Results Data

The Test Results data can be sorted and filtered using the toolbar **Filter** function of the Lu-mini App.



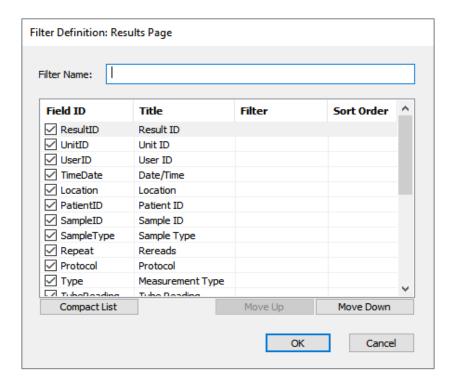
The toolbar Filter menu has the following options:

Table 16: Lu-mini App Filter Menu Options			
Create New Filter Create a new filter			
Modify Filter Modify the currently active filter			
Restore Default View Close filter and restore normal view			
<b>Default View</b> Filter: Default View			
» Custom Filters Filters: more user-defined filters			

User-defined filters can be selected from the list at the bottom of the menu. The dot indicates the currently active filter.

To create a new filter select the **Create New Filter** option, which brings up the Filter Definition box. Enter a new **Filter Name** and specify the filter as described below.



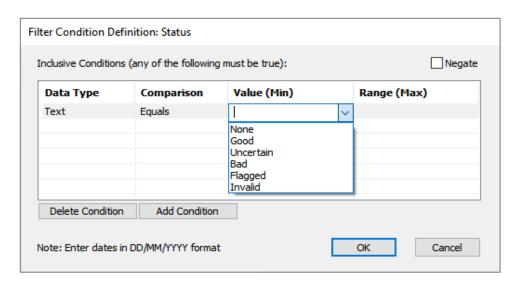


The number of visual fields can be reduced by unticking the check boxes next to the Field ID. Fields can also be reordered by selecting the field line and then using the **Move Up** and **Move Down** buttons.

The displayed field **Title** can be changed by double-clicking on the name.

The **Sort Order** can be set to **None**, **A-Z** (ascending) or **Z-A** (descending). If more than one field has sorting enabled, priority is given to the top-most field in the list. This can be altered by moving the fields **Up** or **Down**.

Double-clicking on the **Filter** cell brings up the condition definition box:





One or more lines can be added to the field filter condition. The available condition options are:

Table 17: Lu-mini App Filter Definition Options			
Nogato	Unticked	Inclusive conditions (any conditions must be true)	
Negate	Ticked	Exclusive conditions (all conditions must be false)	
	Text	Compare text (case insensitive)	
Data Type Number		Compare numerically	
	Date	Compare dates	
	Equals	Exactly equals Value	
Comparison Range		Is within the range Value (Min) to Range (Max)	
	Contains	Contains the text Value	
Value (Min)	Value	Value or range minimum	
Range (Max)	Value	Range maximum	

For **Range** comparisons, the **Min** or **Max** value can be left empty to indicate an open range, for example:

Value (Min)	Range (Max)	Condition	
1200	30000	Values between 1200 and 30000	
1200		Values of 1200 and over	
	30000	Values of 30000 and under	

**Note**: Dates must be entered in the format shown at the bottom of the definition window – which is as specified by the global **Time and Date Format** settings in the **Admin** menu (see Section 7.8.3).

For date ranges, the **Max** value can be specified relative to the **Min** value, for example:

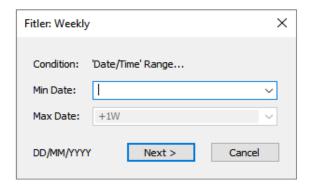
Range (Max)	Maximum Date Calculation	<b>Total Days</b>
+1D	Minimum date plus 1 day	1
+3D	Minimum date plus 3 days	3
+1W	Minimum date plus 1 week	7
+4W	Minimum date plus 4 weeks	28
+1M	Minimum date plus 1 calendar month	28 to 31
+12M	Minimum date plus 1 calendar year	365 or 366
+1Q	Minimum date plus 1 quarter year	90 to 92
+1Y	Minimum date plus 1 calendar year	365 or 366



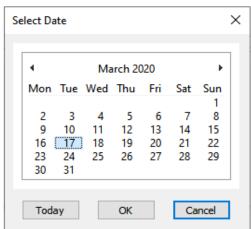
User-specified values can also be selected by entering a Question Mark in the **Value** or **Range** cells instead of a fixed value. For example:

Data Type	Comparison	Value (Min)	Range (Max)
Date	Range	?	+1W

This will prompt the user to enter the missing value when the filter is selected from the **Filter** menu.

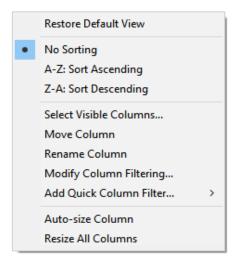


Values can be typed-in or selected from the dropdown list. For dates, they can be entered in the format shown or selected from the calendar by clicking to dropdown arrow:



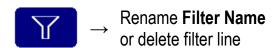


The currently active filter definition can changed be selecting the **Modify** Filter option from the Filter menu, or by clicking on the field heading in the data table and selecting from the available options:



To return to the normal data view, select the **Restore Default View** option.

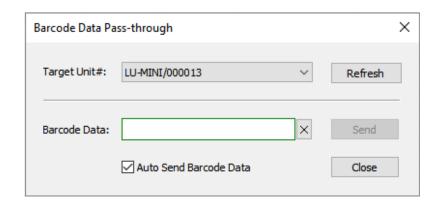
To rename or delete a filter definition, select the **Filters** table and then perform the required action:



# 7.5 **®** Barcode Pass-through Function

The Lu-mini App can be used to pass barcode data to a Lu-mini Unit, for use when entering a Sample ID.

First connect a USB or Bluetooth **HID Keyboard** compatible barcode scanner to your computer, then click on the Barcode option in the Lu-mini App toolbar to open the following window.





Next select the **Target Unit#** from the dropdown list. Then, whilst in this window and the **Barcode Data** edit box is green (as shown above), whenever barcode data is received by the Lu-mini App it will be sent to the Lu-mini Unit.

For the unit to accept the barcode data it must be in one of the following operating states:

- Waiting for Keyboard input such as Sample ID entry
- Results Database to find associated sample test result
- Protocol Work List to find the associated sample entry

#### 7.6 **User IDs Table**

By default, the Lu-mini unit has only a single generic **Any User** profile. The User IDs table allows more User profiles to be created, for both the unit and the application as required.

New users are created by adding a new line to the User IDs table (see Section 7.2.4).



The available User IDs table data field options are listed in Table 18 below.

	Table 18: User IDs Data Fields	
Active	Selects whether the User ID is downloaded to the unit	<i>⇒</i> Below
User ID	Unique User ID (1 to 5 characters)	<i>⇒</i> 6.3
<b>User Name</b>	Name associated with the User ID	<i>⇒</i> 6.3
Password	Optional password	<i>⇒</i> 6.3
App User	Allow User to Login to Lu-mini App	<i>⇒</i> Below
Notes	Optional: Additional notes	<i>⇒</i> 7.2.4

New User IDs will appear on the Lu-mini unit when the **Sync** button is next clicked.



User IDs are created with the **Active** field set to **Yes**, meaning the User ID will be loaded onto the Lu-mini unit when it is next synchronised with the application.



There is no limit to the number of User IDs that can be created in the Lu-mini App, however only 50 active Users IDs can be stored in the Lu-mini Unit. Hence, to limit the size of this list to 50 users, the **Active** field may need to be changed from **Yes** to **No** for some Users IDs.

The optional **Password** is used on both the Lu-mini Unit and the Lu-mini App when logging in.

The **App User** field specifies whether the user is permitted to login to the Lumini App (if this feature is enabled - see to Section 7.8.1 for details), irrespective of the state of the **Active** field.

# 7.7 **Unit Settings Table**

The Unit Settings table stores a list of all the Lu-mini units which have been synchronised with the Lu-mini App.



The available Unit Settings table data fields are listed in Table 19 below.

	Table 19: Unit Settings Data Fields	
<b>Unit Number</b>	Fixed: Unique Lu-mini Unit serial number	
Unit Name	Optional: Name that appears at the top of unit's Main Menu screen	<i>⇒</i> 7.7.1
Last Synced	Fixed: The date and time when unit was last synchronised	
Notes	Optional: Additional notes	<i>⇒</i> 7.2.4

For other global Unit Configuration Settings refer to Section 7.8.3.



### 7.7.1 **Adding a New Lu-mini Unit**

New Lu-mini units are automatically added to the Unit Settings table whenever a **Sync** is performed.

The **Unit Name** field can then be set to a short description which will appear across the top of the unit's Main Menu screen when it is next synchronised.



# 

The Admin option on the Lu-mini App toolbar gives access to global Application and Unit settings:

Table 20: Lu-mini App Admin Menu Options		
Administrator Login	Login as Administrator	<i>⇒</i> Below
<b>Application Administrator Settings</b>	Global Application settings	<i>⇒</i> 7.8.1
Unit Configuration Settings	Global Unit settings	<i>⇒</i> 7.8.2
Time and Date Formats	Global Time and Date settings	<i>⇒</i> 7.8.3

These Admin menu options are protected and require Administrator Login to be accessed.



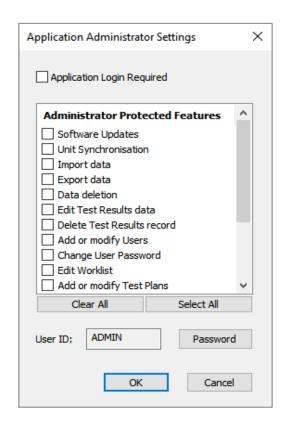
**Note**: Administrator Login is only possible if an **ADMIN** User is defined in the User IDs table (see Section 7.6).

If predefined, the default ADMIN Password is "admin".



### 7.8.1 **@** Application Administrator Settings

The Application Administrator Settings option from the Admin menu provides global Application settings for protecting the application data and features from unauthorised users.



Tick the Application Login Required check box to force authorised users to login to the Lu-mini App. See Section 7.6 for details of how to add application users.





Various features of the Lu-mini App can be protected against accidental or unauthorised access:

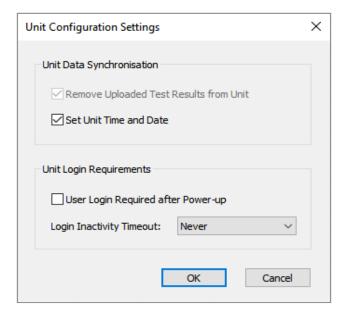
Table 21: Lu-mini App Protected Features		
Software Updates	Lu-mini Unit software updates	
Unit Synchronisation	Data synchronisation via the Sync button	
Import data	Future feature	
Export data	Exporting of data to a CSV file	
Data deletion	General deletion of any data from any table	
Edit Test Results data	Editing data in the Test Results table	
<b>Delete Test Results record</b>	Deletion of a record from the Test Results table	
Add or modify Users	Add or change data in the User IDs table	
<b>Change User Password</b>	Changing a password in the User IDs table	
Edit Worklist	Future feature	
Add or modify Test Plans	Future feature	
Add or modify Locations	Future feature	
Add or modify Sites	Future feature	
Add or modify Protocols	Add or change data in the Protocols table	
Add or modify Assays	Add or change data in the Assays table	
Modify Unit Settings	Change data in the Unit Settings table	
Create or Modify Data Filters	Add or change data in the Filters table	

To access any of the selected protected features, the ADMIN user must login to unlock the feature (see Section 7.8 above).



# 7.8.2 Unit Configuration Settings

This option of the **Admin** menu changes the global Unit Settings.





When the Lu-mini Unit synchronises with the Lu-mini App (see Section 7.3), the Test Results data is uploaded and stored in the Lu-mini App, and then deleted from the Lu-mini Unit. Currently the Remove Uploaded Test Results feature cannot be disabled.

Ticking the **Set Time and Date** option will set the Lu-mini Unit clock to the computer's local time and date when the unit is synchronised. Refer to Section 7.8.3 for more details.

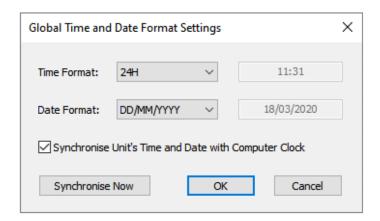
Ticking the User Login Required after Power option will force Lu-mini Unit users to login before they can perform any reading or use other unit functions.

The **Login Inactivity Timeout** specifies how long a user may leave the unit unused before they are automatically logged out. This can be set to Never if not required.



#### 7.8.3 Time and Date Formats

The **Time** and **Date** formats used by the **Test Results Database** table are defined via the Time and Date Formats option of the Admin menu:



Time and Date Format options are listed in Table 22 below.

Table 22: Time and Date Format Options			
Time Former	AM/PM	12-hour clock	
Time Format	24H	24-hour clock	
	YYYY/MM/DD	Year/Month/Day	
Date Format	DD/MM/YYYY	Day/Month/Year	
	MM/DD/YYYY	Month/Day/Year	

Ticking the Synchronise with Computer Clock option with set all connected Lu-mini Unit's clocks and formats to the computer's local time and date whenever the **Sync** button is pressed.

The **Synchronise Now** button can be clicked to set the clocks of all the connected Lu-mini Units to the current time and date. This can be useful after daylight saving changes as the unit does not handle this automatically.



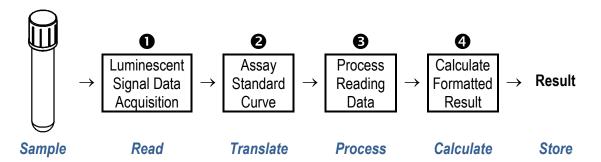
#### 7.9 **Output** Sample Measurement Protocols Table

By default, the Lu-mini Unit only has the Standard RLU Measurement protocol loaded. The Protocols table allows custom sample measurement protocols to be created and developed as required.

When the Lu-mini unit measures a test sample, it performs the following automated steps, as defined by the selected **Protocol**:

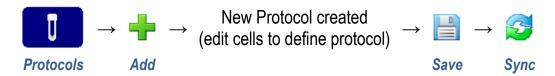
Acquire measurement data	
→ Optional: Pre-zero phase	<i>⇒</i> 7.9.5
→ Open internal shutter	
→ Initial 10-second reading	
→ Optional: Additional 1 to 600-second data collection	<i>⇒</i> 7.9.5
→ Close internal shutter	
2 Translate reading data according to Assay curve	<i>⇒</i> 7.10
Process reading data (as per Protocol definition)	<i>⇒</i> 7.9.5
Calculate final test result value	<i>⇒</i> 7.9.6

Hence the measurement sequence is:



# 7.9.1 Creating a New Measurement Protocol

To create a new Protocol, click the toolbar Add button and then enter all the appropriate data field values.





Alternatively, an existing Protocol can be copied and modified by right-clicking on the existing protocol Line and then selecting the Add Duplicate Line option from the Context Menu and editing the required data field values.



The available Sample Measurement Protocols table data fields are listed in Table 23 below.

	Table 23: Protocols Table Data Fields	
Active	Selects whether protocol is downloaded to unit	<i>⇒</i> Below
<b>Protocol Name</b>	Unique name for this protocol	<i>⇒</i> 7.9.2
Description	Description of the protocol	<i>⇒</i> 7.9.2
Assay	Assay name from Reagent Assay Table	<i>⇒</i> 7.9.2
Scaling Factor	Assay reading scaling factor	<i>⇒</i> 7.9.2
Sample Method	Sample method (S, C, C+1 to C+6)	<i>⇒</i> 7.9.3
Rereads	Sample re-read method	<i>⇒</i> 7.9.4
Measurement Type	Sample measurement type	<i>⇒</i> 7.9.5
T1	Result analysis start time t1 in seconds	<i>⇒</i> 7.9.5
T2	Result analysis end time t2 in seconds	<i>⇒</i> 7.9.5
Window	Result analysis window size in seconds	<i>⇒</i> 7.9.5
Threshold	Percentage change threshold limit	<i>⇒</i> 7.9.5
Show Graph	Show data progress graph for long measurements	<i>⇒</i> 7.9.5
Result DPs	Result display number of decimal-places	<i>⇒</i> 7.9.6
Result Units	Result Units-of-measurement	<i>⇒</i> 7.9.6
Limit Result	Limit result value to maximum/minimum bands	<i>⇒</i> 7.9.6
Result Banding	Result status and colour banding data	<i>⇒</i> 7.9.6
Lock Status	Prevent user from changing the result status	<i>⇒</i> 7.9.6
Comparison Bands	Comparative result acceptance range data	<i>⇒</i> 7.9.6
<b>Show Relative</b>	Show comparative result as relative percent	<i>⇒</i> 7.9.6
Notes	Optional: Additional notes	<i>⇒</i> 7.2.4



The **Active** field can be used to specify which Protocols are downloaded to the Lu-mini units. This is handy when developing new or experimental Protocols to select which definitions appear on the Lu-mini unit.

	Table 24: Protocol Activation States
No	Protocol is not downloaded to the unit
Yes	Protocol downloaded and appears on the unit
Disabled	Protocol downloaded to the unit but appears as greyed-out
Hidden	Protocol downloaded to the unit but is not visible

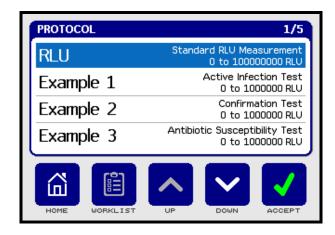
Please refer to the relevant Sections for specific details on other field usage.

# 7.9.2 Protocol Name and Reagent Assay

The first group of Protocol definition fields define the protocol name and associated Assay (see Section 7.10).

<b>Protocol Name</b>	Unique name for this protocol	
Description	Description of the protocol	
Assay	Assay name from Reagent Assay Table	
Scaling Factor	Scale assay reading to allow for different units of measurement (0.000001 to 1000000.0 but normally 1.0)	

The **Protocol Name** and **Description** appear on the Lu-mini Unit in the Protocol selection screen (along with the **Result Units** of measurement).



The **Assay** is the name of the **Reagent Assay** (see Section 7.10) being used for this protocol. Usually multiple protocols will use the same Assay.

The assay **Scaling Factor** can be used to convert the **Assay** output reading into different units of measurement (for instance) or to correct for calibration rescaling. See Section 7.9.6 for additional details.



### 7.9.3 **Output** Sample Test Methods

The Sample Method field defines how many related tests will be performed on an individual donor sample.

Table 25: Sample Method Options		
Single Tube	One standard test per sample volume (1 tube required)	
<b>Control Only</b>	One control test per sample (such as a QC check)	
Control + 1 Tube	One baseline control test plus one comparative test per sample (2 tubes required)	
Control + 2 Tubes	One baseline control test plus up to two comparative tests per sample (3 tubes required)	
etc	Etc	
Control + 6 Tubes	One baseline control test plus up to six comparative tests per sample (7 tubes required)	

This setting determines how the Lu-mini Unit processes the sample tube readings and displays the result to the user, as detailed below.

# 7.9.3.1 Single Tube Measurements

For the Single Tube and Control Only options, the Lu-mini Unit measures a single test tube and presents the result in the specified numerical format with optional result Banding (see Section 7.9.6).

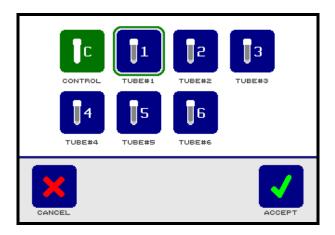
# 7.9.3.2 Multiple Tube Measurements

For multiple tube tests (Control + 1 Tube thru Control + 6 Tubes) however, the additional Tube results are compared against the baseline Control test result and displayed as a bar chart (see Section 7.9.6 for details).

The first test is always performed on the Control sample, and is represented as normal numeric value (as shown in Section 6.4.4).



When the **Control** tube is removed, the **Tube Selection** screen is displayed.



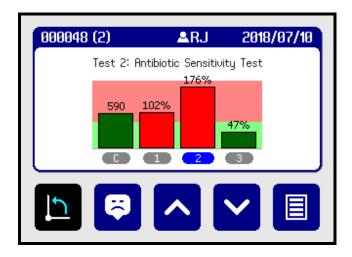
This show that the **Control** tube has been measured and that **Tube 1** to **6** are still to be tested. Press the appropriate tube button (i.e. 1, 2, 3, 4, 5 or 6) to select the next tube to be measured, then press the Accept button, or the **Cancel** button, to return to the **Protocol** selection screen.

The **Test** screen then prompts for the specific tube number for be inserted, or press the **Tube Select** button again to select a different tube.

**Test** Screen 002398 (1) 0% Example 3 - Antibiotic Susceptibility Test **Tube** Selection 11:43 10/05/2020 Screen Cancel Sample Location **Tube** Start ID Select



Once two or more tubes have been measured, the result is displayed as a comparative bar chart.

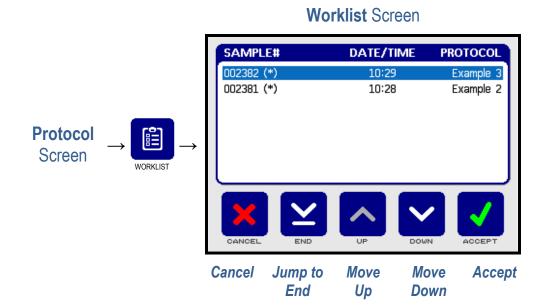


Refer to Section 7.9.6 for details of how the define the Comparison Band limits.

### 7.9.3.3 Continuing a Multi-Tube Test from the Worklist

For a multi-tube test, it may be necessary to perform the **Control** reading and then return sometime later to perform the related sample Tube measurement (for instance if the sample tube must be incubated first).

This is achieved by pressing the Worklist button on the Protocol screen to display and select any unfinished tests.





Highlight the required sample test from the list and press the Accept button to continue with that test (as described in Section 7.9.3.2), or the Cancel button to return to the Protocol selection screen.

# 7.9.4 **O** Sample Tube Re-read Methods

Depending on the value of the Rereads field, an individual sample tube can be re-read several times, at the user's discretion (up to a maximum of 15 times); and the resultant reading stored in the Results Database.

The **Rereads** option determines how each re-reading is processed:

	Table 26: Tube Re-read Method Options		
No	Tube re-reads not allowed – store first reading only		
Yes	Tube re-reads allowed – store final reading		
Minimum	Tube re-reads allowed – store minimum reading		
Average	Tube re-reads allowed – store averaged reading		
Maximum	Tube re-reads allowed – store maximum reading		
Multiple	Tube re-reads allowed – store all readings individually		

Selecting a reread method with enable the **Repeat** button on the Lu-mini's Test Result screen.

Below is an example of an **Average** reread:

Test Result Screen





## 7.9.5 Measurement Types

The next group of Protocol definition fields relate to how the sample tube is measured by the Lu-mini Unit to produce a test result value.

The associated measurement parameters fields are:

Measurement Type	Sample measurement type	
T1	Result analysis start time t1 in seconds (usually 0)	
T2	Result analysis end time t2 in seconds	
Window	Result analysis window size in seconds	
Threshold	Percentage change threshold limit (for peak detection)	
Show Graph Show data collection progress graph for long measurement		

The Measurement Type defines how the measurement data is acquired and processed by the Lu-mini unit:

Table 27: Sample Measurement Types				
Standard	Simple reading with additional averaging window (T2)			
<b>Dual Point (T2-T1)</b>	Difference Reading between readings at T1 and T2			
<b>Reaction Rate</b>	As Dual Point but result expressed as per second			
Peak Detect	Peak detection between <b>T1</b> and <b>T2</b> , with movingwindow average and detection threshold			
Kinetic Data	Captures real time readings data for offline analysis.  Refer to Section 7.4.2 for data export options			
Discrete Maximum	Peak detection using a series of discrete measurements and detection threshold			



Hence, the **Measurement Type** determines the function of the other four measurement parameters:

Table 28: Sample Measurement Parameters						
Measurement Type	T1 (seconds)	T2 (seconds)	Window (seconds)	Threshold (%)	Total Time (seconds)	Numeric Result
Standard	Averaging Window Start	Averaging Window End	0	0	10 + T2	Average
Dual Point (T2-T1)	Start Time	Maximum Time	Averaging Window Size	0	10 + T2	T2Average – T1Average
Reaction Rate	Start Time	Maximum Time	Averaging Window Size	0	10 + T2	(T2Avg – T1Avg) / (1 + T2 - T1)
Peak Detect	Start Time	Maximum Time	Averaging Window Size	Percentage Drop	≤ 10 + T2	Peak Reading
Kinetic Data	0	Total Data Points	Data Sub-rate	0	10 + (T2 * Window)	Last Reading
Discrete Maximum	Start Reading	Total Readings	Reading Window Size	Percentage Drop	≤ 10 + (T2 * Window)	Maximum Reading

For **Kinetic Data** capture, the **Window** value defines the number of 1-second reading to be averaged per outputted data point and **T2** defines to total number of data points; thus, the total capture time is **T2** \* **Window** seconds plus the initial 10-second reading time. The numeric result is the last reading.

The **Show Graph** option is mainly intended for use when developing a new Protocol so that the reaction data can be observed in real time. Then, once the protocol parameters have been finalised, this option can be set to **No** to hide the graph from the normal end-user.



### 7.9.6 Test Result Formatting and Banding Options

Once the final test result value has been calculated by the Lu-mini Unit, there are two further steps that determine how the result is displayed on the unit.

The first set of options control how the numeric result is formatted:

Result DPs	Number of decimal-places displayed (0 to 3)	
<b>Result Units</b>	Units of measurement (e.g. RLU)	

The Result DPs is intended for use in conjunction with the Scaling Factor (Section 7.9.2) to convert a reading to specific **Result Units** of measurement.

The second set of options control how the result is qualified:

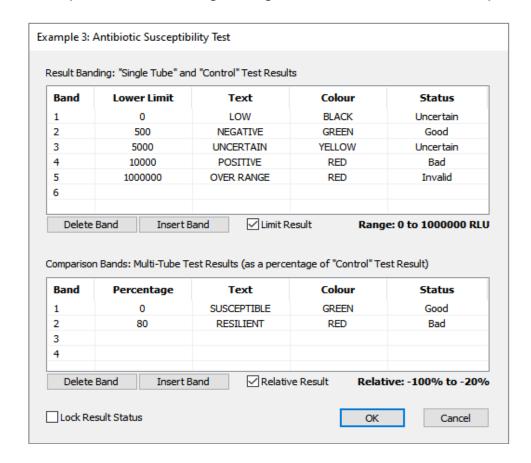
Limit Result	Limit result value to within overall Banding limits	
Result Banding	Qualify result using individual Banding limits	
Lock Status	Prevent user from changing pre-assigned Status value	
<b>Comparison Bands</b>	Qualify multi-tube result using comparison Banding	
<b>Show Relative</b>	Show comparison result as relative percentage	

If enabled, Result Banding is applied to all Sample Method types (Section 7.9.3): individual Single Tube or Control Only samples; or multi-tube Control + Tube.

However, Comparison Bands only relate to the Control + Tube method.



Double-clicking on (or **Edit**ing) either the **Result Banding** or **Comparison Bands** fields opens the following configuration window. For example:



The **Lower Limit** and **Percentage** specify the starting value of the band. See Sections 7.9.6.1 and 7.9.6.2 for an explanation of the above example.

The **Colour** defines the colour of the displayed band, as follows:



If the colour is set to **NONE**, the result band is not displayed on the Lu-mini Unit, however it will still appear in the test results database when the result is uploaded to the Lu-mini App.

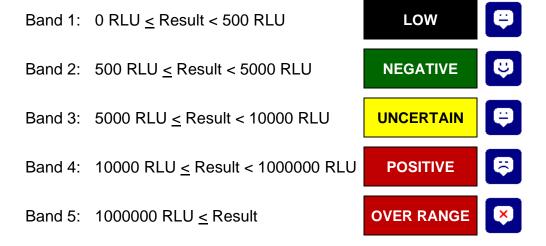
The **Status** indicates the overall result status, as described in Table 8. Ticking the **Lock Result Status** check box prevents the unit user from changing the result **Status** tag (see Section 6.4.6).



# 7.9.6.1 Single Tube Result Banding

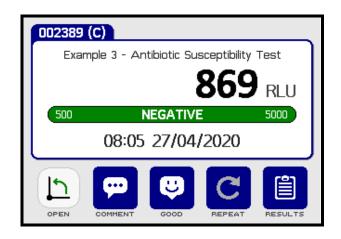
For Single Tube and Control Only readings, the quantitative result value can be qualified by checking it against up to six Result Bands.

For instance, the above example translates as:



Ticking the **Limit Result** check box will restrict the test result value to within the minimum and maximum bands limits; in this example, 0 to 1000000 RLU.

On the Lu-mini unit Result screen this is displayed as:





### 7.9.6.2 Multiple Tube Comparison Bands

For multi-tube tests (**Control + 1 Tube** thru **Control + 6 Tube**) the **Tube** readings can be compared against the baseline **Control** reading and qualified by checking it against up to four **Comparison Bands**. For instance, the previous example above translates as:

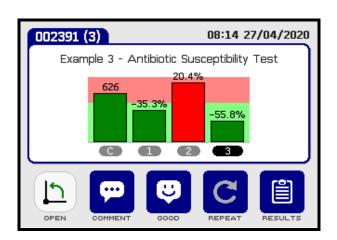
(Relative Result = Percent Result – 100%)

Ticking the **Relative Result** check box displays the result as a relative percentage with respect to the Control tube reading.

Band 1: 0% ≤ Percent Result < 80% (-100% ≤ Relative Result < -20%) SUSCEPTIBLE

Band 2: 80% ≤ Percent Result (-20% ≤ Relative Result)

On the Lu-mini unit Result screen this is displayed as:

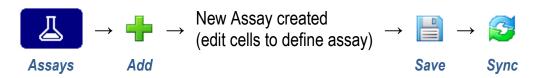




# 7.10 Reagent Assays Table

The **Reagent Assay** table allows standardised assays to be defined. In general, one assay will be used by several Protocols with different measurement and result parameters.

To create a new Assay, click the toolbar **Add** button and then enter all the appropriate data field values.



Alternative, an existing Assay can be copied and modified by right-clicking on the existing assay **Line** and then selecting the **Add Duplicate Line** option from the Context Menu and editing the required data field values.



The available Reagent Assay data fields are listed in Table 29 below.

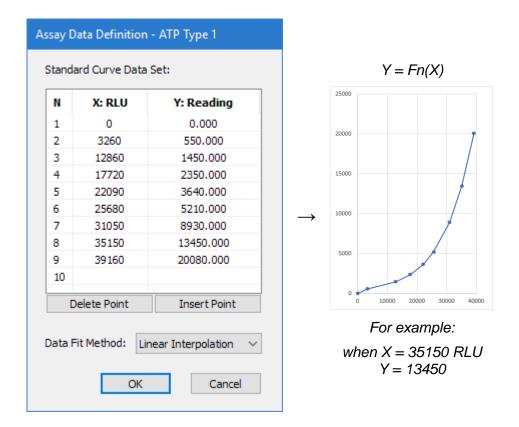
Table 29: Reagent Assay Data Fields					
Assay Name	Unique name of Assay	<i>⇒</i> 7.9.2			
<b>Detection Type</b>	Method of assay output quantitative detection	<i>⇒</i> 7.10			
Curve X-Data	Standard calibration curve x-axis data	<i>⇒</i> 7.10			
Curve Y-Data	Standard calibration curve y-axis data	<i>⇒</i> 7.10			
<b>Curve Fit</b>	Curve fit method	<i>⇒</i> 7.10			
Notes	Optional: Additional notes	<i>⇒</i> 7.2.4			

The **Assay Name** is the unique name used to identify and select the Assay in the associated Protocols table (see Section 7.9.2).

The **Detection Type** defines the quantitative method of detection used by the assay. Currently the Lu-mini only supports **Luminescence**, but future versions will support alternative methods.



The remainder of the parameter fields allows a standard calibration curve to be implemented. Double-clicking on either of the **Curve X-Data**, **Curve Y-Data** or **Curve Fit** fields opens the following definition window.



This provides a transfer function between **Standard Lu-mini RLU**s (X-input) and the required **Assay Reading** (Y-output) to implement a Standard Curve, as illustrated above.

However, this can be as simple as offsetting the reading by a fixed amount. For instance, to subtract 200 RLU from all readings, the Curve Data Set would be defined as:

N	X: RLU	Y: Reading		
1	200	0	$\rightarrow$	Y = X - 200
2				

Currently the only **Data Fit Method** available is **Linear Interpolation** between the data points (with Linear Extrapolation at the extremes).



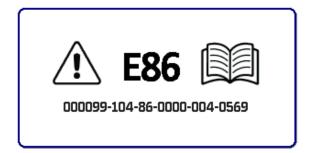
# **8 Troubleshooting**

For technical enquiries, please contact your distributor or Vitl at the address given on Page 2 of this manual.

Table 30: Troubleshooting Suggestions	
Unit will not turn on	
<ul> <li>No power → Check power is switched on at wall outlet socket</li> </ul>	<i>⇒</i> 6.2
<ul> <li>Bad USB connection → Ensure power connector fully inserted into rear of unit</li> </ul>	<i>⇒</i> 6.2
Unit spuriously resets or restarts automatically	
<ul> <li>Power connecter loose → Ensure USB connecter fully inserted at rear of unit</li> </ul>	<i>⇒</i> 6.2
<ul> <li>Bad USB cable → Use good quality USB 2.0 cable, as supplied with the unit</li> </ul>	<i>⇒</i> 6.2
<ul> <li>Supply brown-outs or black-outs → Power unit from a stable AC mains supply</li> </ul>	<i>⇒</i> 11
Unit does not recognise sample tube insertion	
<ul> <li>Tube too small → Ensure minimum tube requirements met</li> </ul>	<i>⇒</i> 4.1
Measurement result lower than expected	
<ul> <li>Tube poorly inserted → Ensure tube is pushed fully down in tube holder</li> </ul>	<i>⇒</i> 4.1
• Low sample volume → Ensure sample greater than minimum operating volume	<i>⇒</i> 4.1
<ul> <li>Wrong protocol selected → Ensure using correct measurement protocol</li> </ul>	<i>⇒</i> 6.4
<ul> <li>Dirty chamber → Check that dirt not built up in sample read chamber</li> </ul>	<i>⇒</i> 9.1
Measurement result higher than expected	
<ul> <li>Wrong protocol selected → Ensure using correct measurement protocol</li> </ul>	<i>⇒</i> 6.4
<ul> <li>Light ingress → Do not use unit in direct sunshine or under infrared lighting</li> </ul>	<i>⇒</i> 5
Lu-mini App reports No Units Attached	
<ul> <li>USB Driver → Ensure that the USB Driver is installed</li> </ul>	<i>⇒</i> 7.1



If the software detects a problem with the unit, it displays the following error popup showing one of the error codes listed in Table 31.



If the problem persists, please contact your distributor or Vitl for assistance, quoting the error code and the 22-digit report code.

A copy of the unit screen image can be captured using the **Capture Unit Screenshot** option in the Lu-mini App **Help** menu (see Section 7.2.3).

Table 31: Lu-mini Unit Error Codes						
Code	Meaning	Suggested Remedy				
E10	User Settings not set	Review option settings and adjust as required	<i>⇒</i> 6.6			
E86	Real-Time Clock battery flat	Leave the unit plugged in for at least two hours to recharge clock battery	<i>⇒</i> 6.6.1			
All others	Internal unit fault	Contact distributor for further assistance	<i>⇒</i> 10			



# 9 Maintenance and Servicing

Although the Lu-mini unit does not require any scheduled servicing, the operator should regularly clean and inspect the unit for defects, as described in Section 9.1 below.



Please observe and comply with all of the **Unit Maintenance** and Serviceability safety precautions listed in Section 2.

**DANGER** 

Always unplug the unit before performing any cleaning or disinfecting tasks.



Never remove the unit casework. There are no user or operator serviceable parts inside the unit.

WARNING

Never use alcohol-based cleaners on the black surfaces inside the lid as it will remove the coating and significantly degrade the unit's performance.



Practise anti-static precautions by avoiding directly touching the exposed electrical contacts or using statically charged cleaning cloths.

For technical and service-related enquiries, please contact your distributor or Vitl at the address given on Page 2 of this manual.

# 9.1 Routine Cleaning and Inspection

The unit casework should be cleaned and inspected at regular intervals, and whenever contamination or spillage occurs, as follows:

- 1. Disconnect the USB power cord from the unit before performing any inspection checks or cleaning.
- Wearing suitable PPE, clean the casework using a damp cloth or 2. cotton bud soaked with a suitable disinfectant solution (such as Virkon). Do not over wet.
- Clean around the LCD fascia and touchscreen, taking care to avoid 3. over wetting or pushing debris into the bezel gap.
- Clean inside the lid, taking particular care not to rub away the black 4. coating.
- If necessary, carefully clean the sample chamber using a damp longstick cotton bud only. Do not push anything else into the cavity as it may get caught on the tube alignment string and damage the unit.







After cleaning, ensure that the unit is thoroughly dry before reconnecting the power cord to the unit.



### 9.2 **Decontamination Procedure**

The unit and accessories should be decontaminated using the following procedure before being stored or transported, as per Section 9.1.

## **Certificate of Decontamination**

We respect the health and safety of our clients and employees, and request that any products or accessories being returned are decontaminated in accordance with the procedure below.

#### 1. Decontamination Procedure

Thoroughly clean all outside surfaces of the product (including any accessories, power cords, manuals, packaging, etc) with a damp cloth soaked with suitable disinfectant solution (such as Virkon).

Allow to dry fully before packing.

2 Decontamination Declaration

2. Doodinamination Doolaration	
Company Name:	

Address:						
Product Code:	Lu-mini					
Serial Number:	Serial Number:					
Reason For Return:	Reason For Return:					
Where Product Used	Where Product Used:					
Please tick the appropriate option(s) below:  □ I certify that I have decontaminated the product as per the above procedure.  Decontaminant Used:						
☐ I certify that the product has <u>not</u> been exposed to any chemical or biological materials.						
Title:		Name:				
Signature:		Date:				
Telephone:		Email:				



### 9.3 Transportation and Storage

The Lu-mini unit and its accessories should be thoroughly decontaminated using the procedure detailed in Section 9.2 before being placed in its original packaging for transportation or storage.



Refer to Section 11 for the acceptable range of Storage and Transportation environmental conditions.

Always ensure that the unit and accessories are completely dry and free of any condensation before being packed.

# 9.4 Product Disposal

At end-of-life, this product must be disposed of in accordance with your local authority regulations for the disposal of potentially hazardous waste and electronic equipment.

The unit and its accessories should be decontaminated using the procedure detailed in Section 9.2 before disposal or shipping.



Do not dispose of this product into unsorted municipal waste or public landfill.

Please contact your distributor (or Vitl at the address on Page 2 of this manual) for details of how to correctly dispose of this product.

China RoHS	This table has been prepared in accordance with SJ/T 11364 此表格表明符合SJ/T 11364标准						
Part Name	Toxic and Hazardous Substances and Elements 有毒有害物质或元素						
部件名称	Pb 铅	Hg 汞	Cd 镉	Cr6 六价铬	<b>PBB</b> 多溴联苯	PBDE 多溴二苯醚	EFUP 环保使用期限
CASEWORK	0	0	0	0	0	0	е
CONTROL PCB	Х	0	0	0	0	0	50
READER MODULE	Χ	0	0	0	0	0	25
TUBE DETECTOR CABLE	0	0	0	0	0	0	25
	EFUP No (Overall) 环保使用期限						

O: Indicates that the part contains hazardous a substance below the level listed in GB/T 26572 表示料件所包含有害物质低于在GB/T 26572中列出的标准。

X: Indicates that the part contains hazardous a substance above the level listed in GB/T 26572 表示料件所包含有害物质超过在GB/T 26572中列出的标准。



# 10 Warranty and Returns

Integrated Technologies Limited (ITL) warrants the Lu-mini product, when purchased new and installed and operated in accordance with the instructions of this manual, to be free from defects in materials and workmanship, and will repair or replace, at their discretion, any unit or accessory which exhibits such defects.

In no event will ITL be liable for any indirect, incidental or consequential damages resulting from any defect or warranty claim.



NOTE

Unspecified use or unauthorised modification of any part of the Lumini unit or its accessories or the use or attachment of any adaptor or peripheral not supplied, specified or sanctioned by ITL will invalidate this warranty.

This warranty is provided to the original purchaser of the product for one year from the date of purchase.

Under the terms of this warranty, the product must be returned in its original packaging, transportation prepaid by the sender, with a copy of the Proof of Purchase and a detailed description of the problem.



The product must be decontaminated using the procedure detailed in Section 9.2 and a Certificate of Decontamination supplied with any return. If the product is considered too hazardous to be shipped, please contact Vitl on the number given on Page 2 of this manual for further instructions.

Please contact your distributor (or Vitl on the number given on Page 2 of this manual) to receive authorisation to return the product.



# 11 @ Technical Specification

# **Physical Unit Properties**

Dimensions (W x D x H) 160 mm x 235 mm x 140 mm

Weight 1.9 kg

**Power Supply** 

Power Adaptor Input Voltage 100 to 240V AC ±10%, 50/60 Hz ±5%

Power Adaptor Consumption 25W max

Power Adaptor Output 5.0V DC ±5%, 1.0A max

Unit Input Voltage and Current USB-B: 5.0V DC ±5%, 1.0A max Overvoltage Category II (Building wiring up to 300V)

**Operating Environment** 

Temperature Range +15 to +35 °C

Relative Humidity Range 20% to 85% non-condensing

Maximum Operating Altitude 2000 m above sea-level

Pollution Degree 2 (Non-conductive pollution)

**Storage and Transportation** 

Temperature Range -10 to +50 °C

Relative Humidity Range 20% to 95% non-condensing

**Sample Tube Types** 

Round Bottomed Tubes 10-15mm diameter, 47-75mm tall

Flat Bottomed Vials 15mm diameter, 48mm tall Square Cuvettes 12.5mm square, 45mm tall

Minimum Sample Volume Refer to Table 4

**Measurement Range** 

Standard RLU Protocol 0 to 8x10<sup>6</sup> RLU Standard Linear Range 0 to 5x10<sup>6</sup> RLU

**Unit Data Storage Capacity** 

Users 50 Test Protocols 100

Test Results 1000 (up to 30000 kinetic data points)



## **Lu-mini App Storage Capacity**

Unlimited (50 Active) Users

User ID Length 1 to 5 characters 1 to 20 characters User Name Length

**User Password Length** 20 characters maximum

**Test Protocols** Unlimited (100 Active)

**Protocol Name Length** 1 to 12 characters **Protocol Description Length** 1 to 40 characters

**Test Results** Unlimited

1 to 16 characters Sample ID

**Result Decimal Places** 0 to 3 digits

Units of Measurement 1 to 7 characters

Test Result Bands

**Band Name** 1 to 12 characters **Result Bands** 6 bands maximum 4 bands maximum Comparison Bands

Comparison Range 0 to 10000%

Reagent Assays Unlimited

1 to 20 characters **Assay Name Assay Curve Points** 10 points maximum

**Unit Settings** 

**Unit Name** 30 characters maximum



# 12 @ Glossary of Terms and Abbreviations

CSV (file) Comma Separated Values

**EMC Electro-Magnetic Compatibility** 

Keeping an organism, cell or cell culture at the **Incubate** 

optimum temperature for growth and development

Personal Protective Equipment **PPE** 

**RLU** Relative Light Units. An arbitrary unit of light

measurement