

Hygiena™ Innovate System



Installation & Operational Qualification



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Forward

The Innovate Installation/Operational Qualification has been specifically designed for the qualification of the Innovate instrument.

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Customer Support

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Email: diagnostics.support@hygiena.com

ROW: Visit www.hygiena.com/diagnostics/innovate for additional support information.

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Introduction

The Installation Qualification (IQ) and Operational Qualification (OQ) sections verify and document that the Innovate has been installed and operates in accordance with the design specifications, manufacturer's recommendations and Current Good Manufacturing Practices (cGMPs). These verifications will be documented in the attached test report forms. Any discrepancies will be documented and reconciled. A fully trained Hygiena representative will complete all forms, attachments and documentation at the time of installation.

Hygiena recommends that this document is fully reviewed and understood prior to initializing any of the testing contained therein.

Upon completion of each IQ or OQ test, the documentation should be signed, dated and witnessed. The following signatures are found throughout this document:

Signature	Print Name	Company / Function

Test Descriptions

- IQ-01 Document Verification: A review of the documentation and operating manuals associated with the instrument. Verifies that the appropriate manuals are readily available.
- IQ-02 Initial Inspection and Equipment List Verification: Verifies that the equipment received was the equipment ordered. Verifies that this equipment is visually undamaged upon receipt.
- IQ-03 Safety Checklist Review: A review of the manufacturer's safety precautions.
- IQ-04 Operating Environment Requirements: A review of the specifications for required and environment conditions.
- IQ-05 Innovate Luminometer Set-up: Verifies that the Innovate System is correctly assembled.
- IQ-06A Innovate Software™ Installation: Verifies that the Innovate Software™ is correctly installed.
- IQ-06B Innovate Software™ Start-Up: Verifies that the instrument correctly performs the microcomputer self-test. Verifies that the software login and password prompts occur correctly.
- IQ-07 Software and Firmware Verification: Verifies that the correct versions of firmware and software have been supplied with the instrument.
- OQ-01 Adding a User & Verifying Access Rights: Adds users to the Innovate Software™. Verifies log-on procedure and user rights.
- OQ-02 Reagent Injector Startup Verification: Verifies the injector startup procedure.
- OQ-03 Instrument Blank Verification: Verifies the Instrument Blank meets specifications.
- OQ-04 Reagent Blank Verification: Verifies the Reagent Blank meets specifications.
- OQ-05 ATP Positive Control Verification: Verifies the ATP Positive Control meets specifications.
- OQ-06 Database Verification: Verifies data is accurately transferred to the database.
- OQ-07 Reagent Injector Delivery Volume Verification: Verifies delivery volumes for each injector.
- OQ-08 Fault Insertion Tests: Deliberately challenges the Innovate luminometer error response in order to verify error messages.

1. Objective

Verify that all the required documentation for the Innovate and Innovate Software™ is available, complete and stored in the appropriate location.

Verify that the instrument calibration documentation is available and valid.

2. Test Procedure

Verify that the Innovate Operator Manual, Validation Guide, and Calibration Certificate was received.

Record instrument serial number from calibration certificate.

Attached calibration certificate to this form.

3. Instrumentation Documentation

Innovate Operator Manual Present Not Present

Validation Guide Present Not Present

4. Calibration Documentation

Instrument Serial Number on Certificate: _____

Calibration Certificate Present Not Present

Calibration Certificate attached to this form? Yes No

5. Comments

6. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

Verify and document that the correct equipment was received and is undamaged.

2. Test Procedure

Record the Innovate luminometer serial number received.

Verify that all the equipment ordered was received.

Visually inspect all equipment and verify that it was received undamaged.

Model No.: MCH4000 (220050) 100V-240V	Serial No.:
---------------------------------------	-------------

- | | | |
|---|------------------------------|-----------------------------|
| All items on the packing list are present | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Packing list (or copy) is attached | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Equipment received was the equipment ordered? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Equipment received undamaged, visually? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

4. Acceptance Criteria

All documents are present and all equipment specified on the packing list is present.

5. Test Outcome

Meets criteria for equipment received and initial inspection. Yes No

If "No," refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

To review the manufacturer's safety precautions for the equipment and reagents, and to ensure that these have been read and understood by a company representative. This safety checklist complements but does not replace Company specific employee safety training.

2. Safety Precautions

- Review the Operator Manual prior to use.
- Ensure that the Innovate luminometer is turned off and the power supply cord is disconnected prior to connecting the instrument to the PC.
- Operate the instrument in a dry environment only away from sunlight.
- Keep plate carrier door closed at all times except when loading/unloading microtiter plates. Utilize Innovate Software™ to load and unload microtiter plates. Do not attempt to manually open plate carrier door.
- Use only the power cord supplied with the instrument. Do not alter the power cord or instrument power supply in any way.
- When preparing the instrument for shipment or when moving the instrument, the transportation lock screw should be engaged.

3. Acceptance Criteria

The manufacturer's safety precautions for the instrument and reagents have been read and understood by the operators of the system.

4. Test Outcome

Meets acceptance criteria for safety checklist: Yes No If "No," refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

To review the system environment requirements.

2. Test Procedure

Review the environment requirements with the user.

3. Environment Requirements

Parameter	Specified
Temperature	15-30°C
Humidity	<85%
Clearance behind instrument	>15cm

4. Acceptance Criteria

The instrument is installed correctly and meets the required environment conditions.

5. Test Outcome

Reviewed Environment Requirements: Yes No If "No," refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

To set up the Innovate luminometer, waste container, reagent tray, and reagent cooling unit.

2. Test Procedure

Note: The instrument and accessories should be set-up so that the rear panel connection ports are easily accessible and not subject to physical stress. Allow sufficient space on the side of the instrument for the reagent tray and personal computer used for Innovate Software™.

1. Remove the white cap on the top of the instrument lid. Using the Ball Point Hex Screwdriver supplied, unscrew the instrument lid screw.
2. Lift the lid and remove all foam used for shipping.
3. Manually unscrew the transportation lock screw labeled with a red tag to release the plate carrier from its secure shipping position.
4. Rotate the red label inside the instrument to the right of the transport lock screw.
5. Close the instrument lid and replace lid screw and white cap.



6. Assemble the reagent tray using the Allen Wrench supplied. Orient the front PP vial holder with the slit facing forward so reagent levels can be easily monitored.
7. Place the reagent cooling unit in the reagent tray and connect the power supply to an electrical outlet.
8. Fill two PP vials with washing solution and place them into the appropriate location on the reagent tray.
9. Connect the supplied waste tubing and container to the waste outlet on the rear of the instrument as shown.



10. Add a few drops of antifoam to the waste container to prevent excess foam from washing solution.
11. Connect the instrument to the power outlet using the power cord supplied.
12. Instrument is shipped with external reagent tubing and injector needles attached to injectors 1, 2, and 3.

Place all three injector needles into washing solution.

NOTE: Wear gloves when handling the injector needles.

13. Open CellSolver and replace cap with single hole bottle cap. Place in reagent tray in the appropriate location.
14. Reconstitute ATX and Sensilux according to the kit insert and pour into PP vials. Place PP vials with reagent into the cooling unit.
15. Connect the supplied communication cable to the instrument. Do not connect the communication cable to the computer until after installing the software and driver.

3. Acceptance Criteria

Set-up is complete: Yes No If “No,” refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

Verify that the Innovate Software™ is correctly installed.

What type of installation is being performed?

Installation Type	Description	✓
Local Workstation	Non-networked computer and instrument	
Master Networked Workstation (See Appendix I-Networked Database Option)	Computer and instrument with database, preformatted reports, and/or preformatted queries shared on a network.	
Networked Workstation (See Appendix I-Networked Database Option)	Computer and instrument linked to networked database, preformatted reports, and/or preformatted queries of the master workstation.	
Remote Access Workstation (See Appendix I-Networked Database Option)	Computer (no instrument) linked to networked database, preformatted reports, and/or preformatted queries of the master workstation.	

2. Test Procedure

Ensure that the PC meets the following minimum requirements:

Local Workstation Minimum Requirements

Component	Specification
Computer	PC
Processor	1 GHz
Operating System	Windows 10
Memory	1 Gb RAM
Hard-Drive space	100 Mb free hard drive space
Graphics Card	1024 X 768 or higher
Monitor	Color
Mouse	Yes
Keyboard	Yes
Communications Port	USB
Web Browser	Internet Explorer 6.0 or higher (optional)
Windows Access	System Administrator Privileges

In addition to the above minimum system requirements, a Master Networked Workstation, Networked Workstation, or Remote Access Workstation must meet below minimum specifications.

IMPORTANT: Plate preparation files and database export drivers must be identical on all systems accessing the networked database tables. Report templates and pre-defined queries should be identical on all networked systems and can be controlled via the master workstation on the network. A license is required for remote access workstations to run Innovate Software™ as stand-alone.

Networked Workstation or Remote Access Workstation Minimum Requirements

Component	Specification
Software	Innovate Software™ v5.25 or higher
Network Access	Full Read/Write Permissions to the networked folder
Network Speed	1 Gbps for optimal performance
Operating System	Windows 10

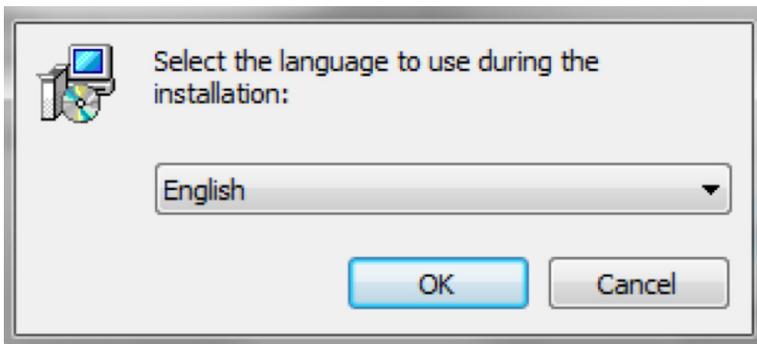
For the most reliable operation of Innovate Software™, Hygiena recommends that either a new computer is purchased, or if an existing computer is used, its hard drive is reformatted and the appropriate Operating System freshly reinstalled prior to installing Innovate Software™.

Local Workstation Software Installation

IMPORTANT: Ensure the Innovate luminometer is disconnected from the computer before beginning installation.

Open the Innovate Software™ download from the Hygiena website. Right click on the ‘Innovate.exe’ file and **Run as Administrator**.

The following screen appears:



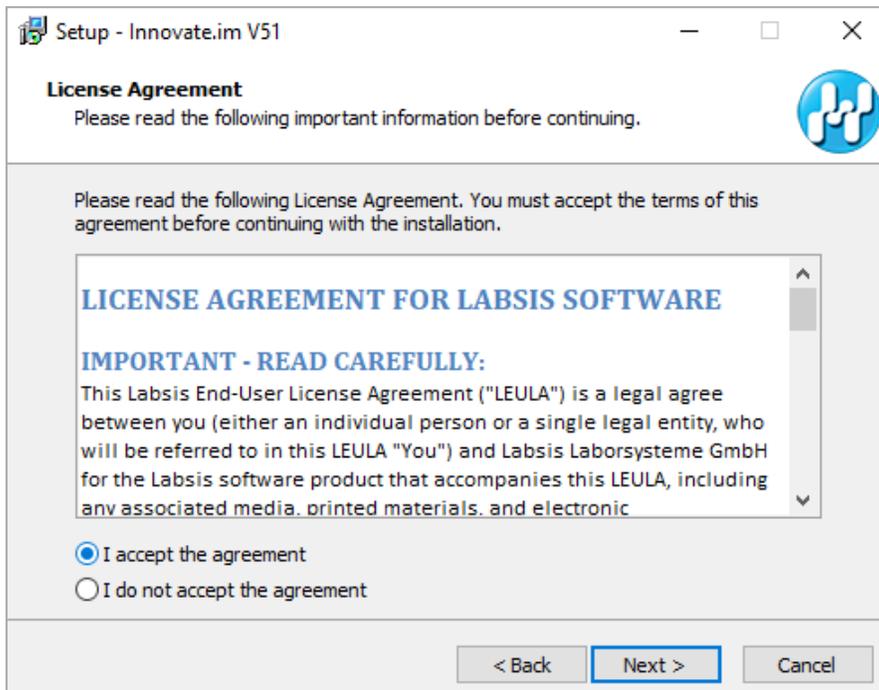
Screen appeared: Yes No

Select the appropriate language and select **OK**. The following screen appears:



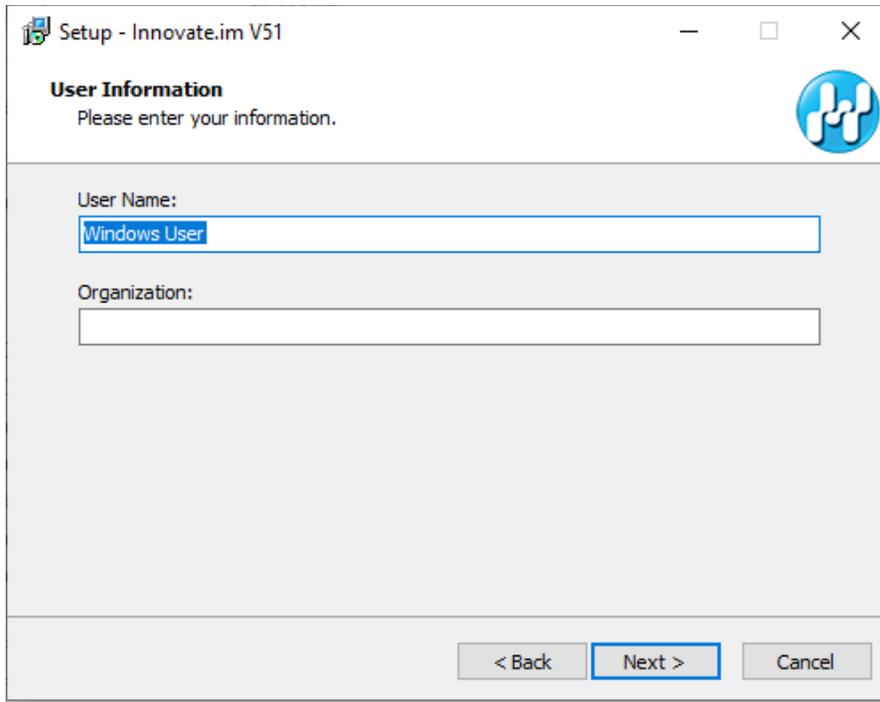
Screen appeared: Yes No

Select **Next**. The following screen appears:



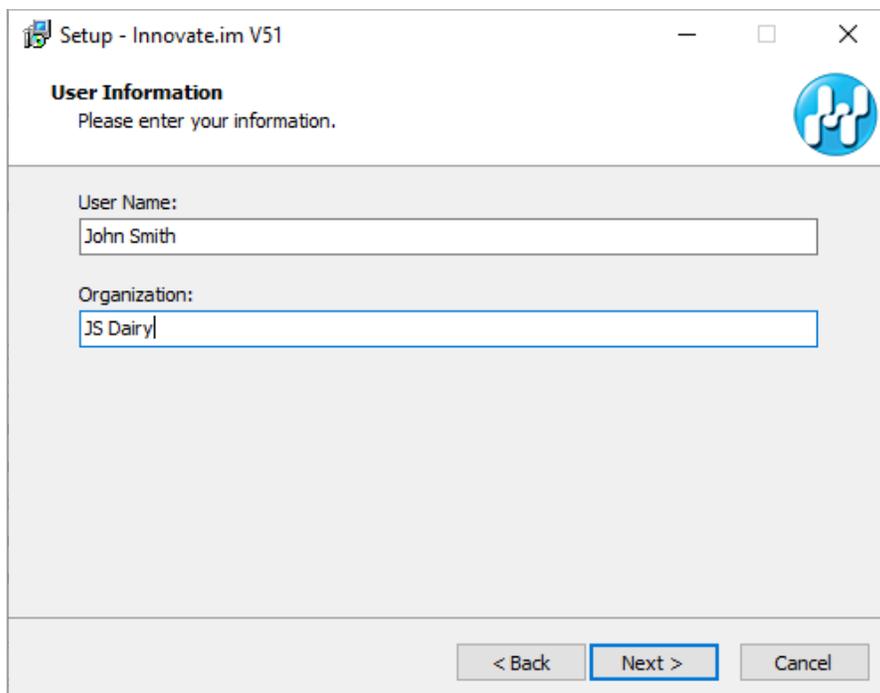
Screen appeared: Yes No

Confirm that the user accepts the End User License Agreement and select **Next**. The following screen appears:

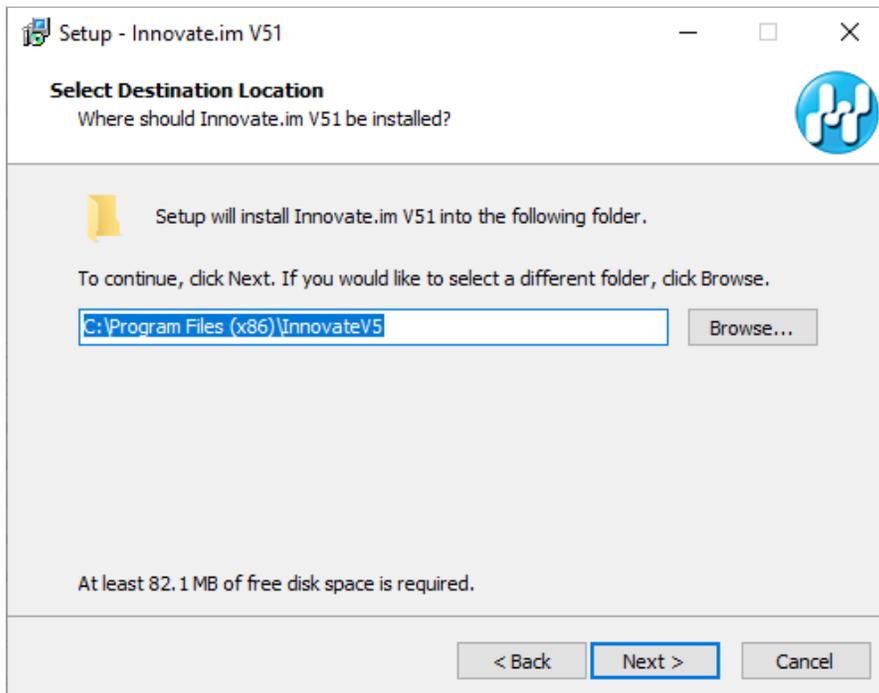


Screen appeared: Yes No

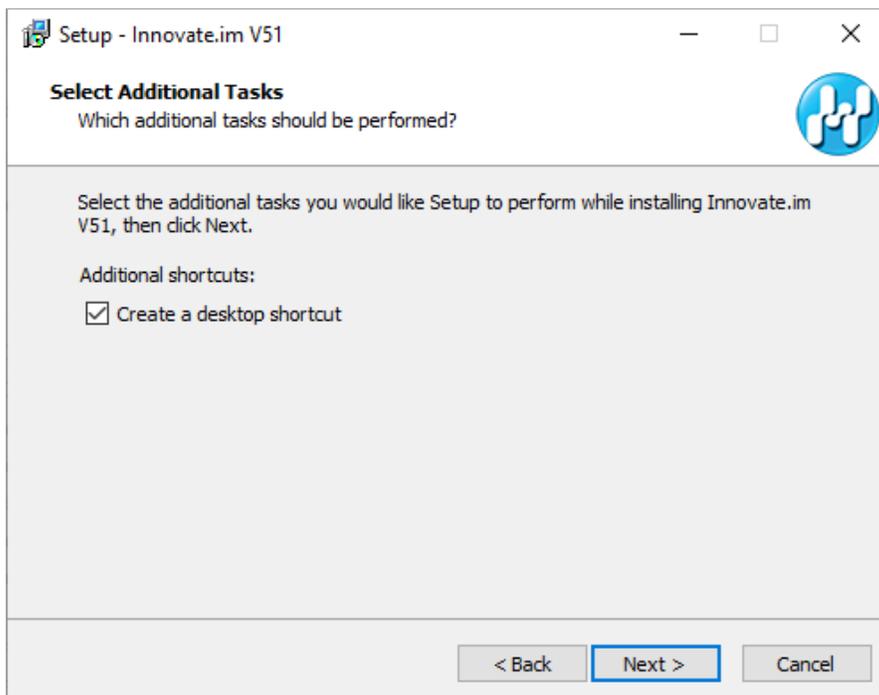
Enter the User Name and Company Name (John Smith and JS Dairy are examples):



The software completes installation and the following screen appears:

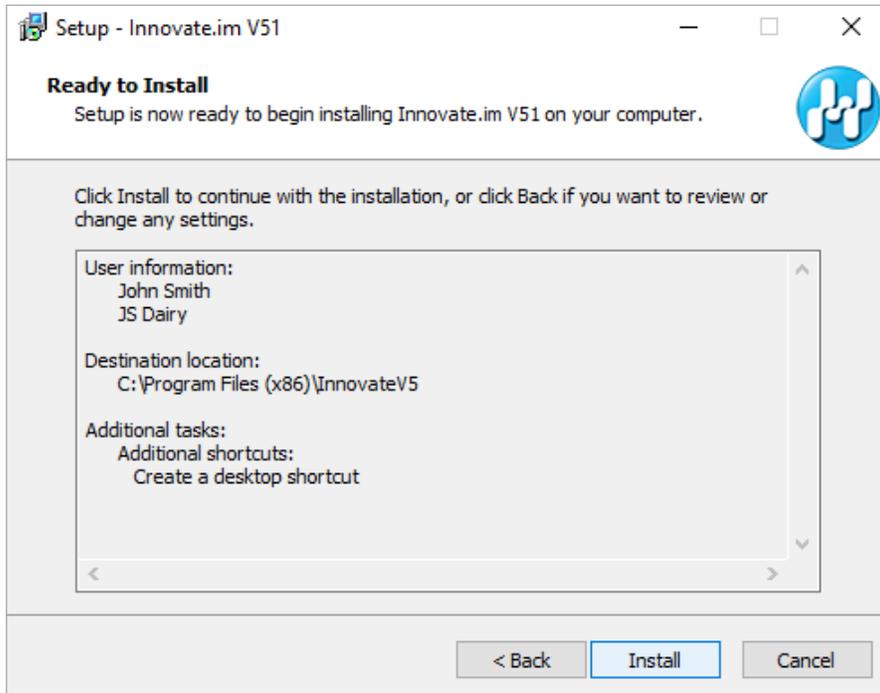


Screen appeared: Yes No



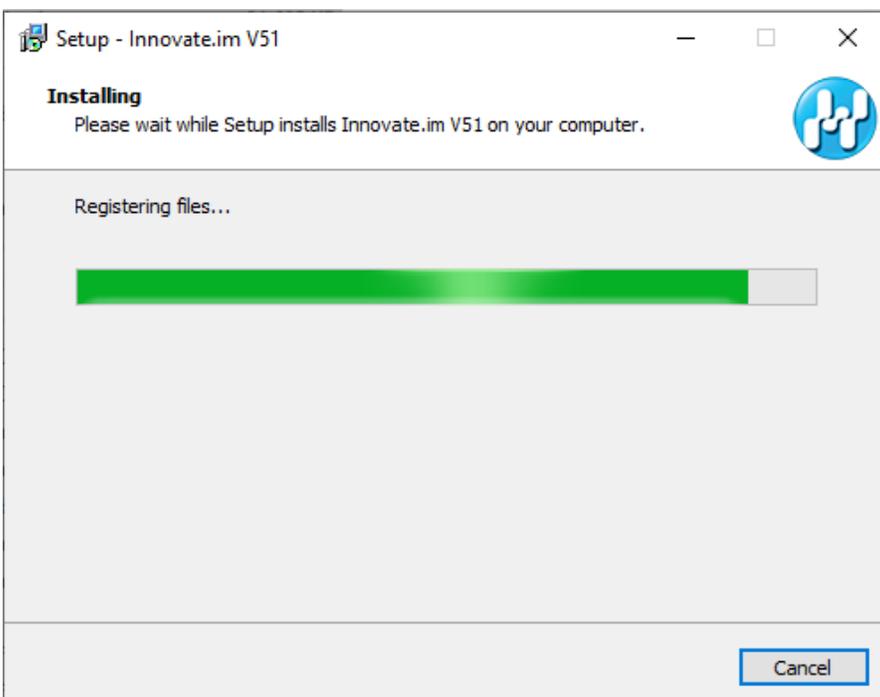
Screen appeared: Yes No

Select **Next**. The following screen appears:



Screen appeared: Yes No

Select **Install** and the following progress screen appears:



Screen appeared: Yes No

The software completes installation and the following screen appears:



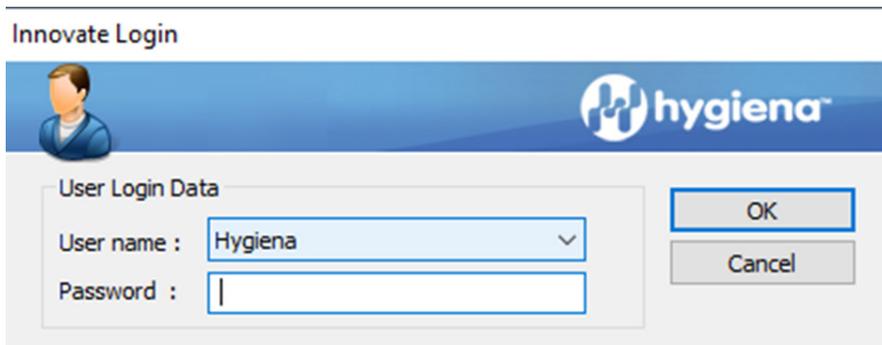
Screen appeared: Yes No

Select **Finish**.

Start the Innovate Software™ by double clicking the desktop icon:

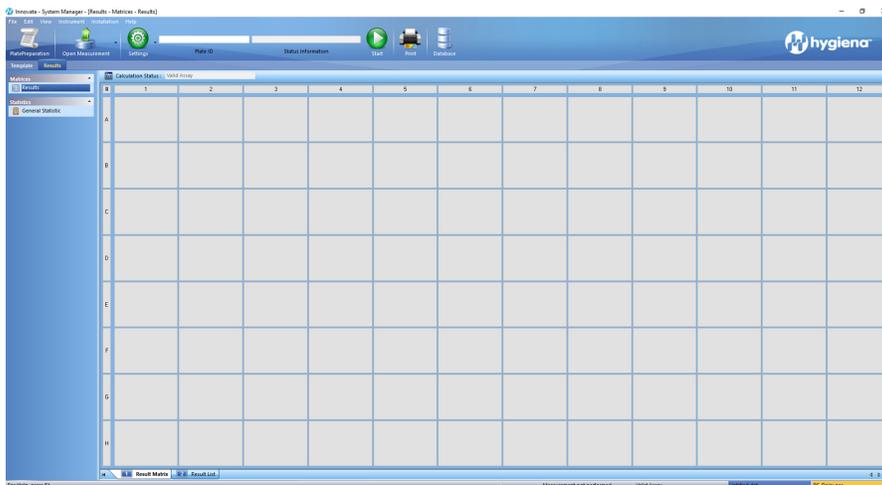


Login to the Innovate Software™ with username **System Manager**.
Refer to your Hygiena Technical Representative for the password.



The image shows a dialog box titled "Innovate Login". It features the Hygiena logo and a user icon. Below the header, there is a section labeled "User Login Data" containing a dropdown menu for "User name" with "Hygiena" selected, and a text input field for "Password". To the right of these fields are two buttons: "OK" and "Cancel".

Once logged in, the following screen should appear:



Screen appeared: Yes No

1. Objective

Verify that the Innovate Software™ communicates properly with the Innovate luminometer and exercises the correct password control for initial installation.

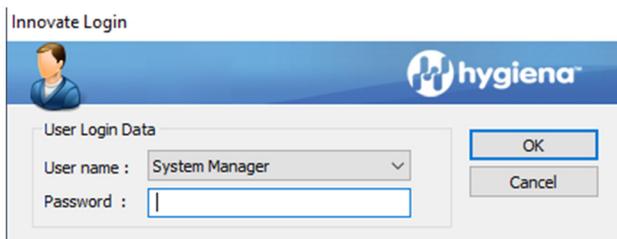
2. Test Procedure

Plug the USB cable from the Innovate luminometer into a USB port on the PC.

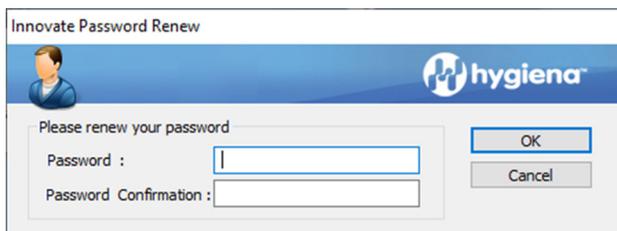
Switch on the Innovate system and the PC **in that order**.

Start Innovate Software™ by double clicking on the Innovate software desktop icon.

The following screen appears:



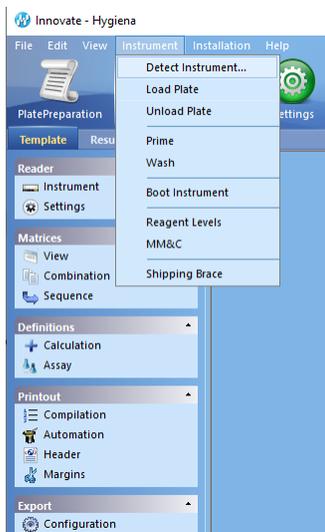
When logging onto Innovate Software™ for the first time, select **System Manager** in the **User** name drop down. Log in using the password "**Default**". Once logged in, create a new password in the pop-up screen (shown below)



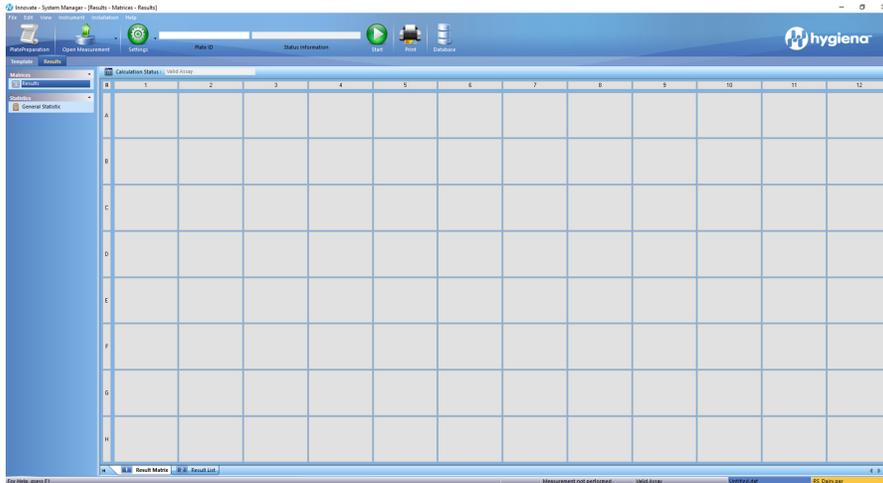
Screen appeared: Yes No

Enter **Default1** for the system manager and select **OK**.

If the Innovate Software™ is having difficulty locating an instrument, navigate to **Instrument** → **Detect Instrument**.



Upon successfully logging into Innovate Software™, the Result Matrix view screen should appear with System Manager logged on:



Screen appeared: Yes No

3. Acceptance Criteria

The user must be able to log on to the Innovate Software™ software.

4. Test Outcome

Meets acceptance criteria for Innovate Software™ Yes No If “No,” refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

Verify that the correct version of the software and driver has been supplied with the instrument and the correct version of instrument firmware is installed on the Innovate luminometer.

2. Test Procedure

Switch on the PC and log on to the Innovate Software™. Select the **Help** pull down menu and select **About Innovate**.



The following screen appears:



Dialog box appeared: Yes No

Compare the dialog box to the documentation received from the vendor. Record the details below, and attach printout to this Form.

Innovate Software™, Version	
License No.	
Assembly Code	
Assembly Code	

Record the firmware version by clicking on **View** in the main menu bar and selecting **Statistics>General statistic**. The following screen appears:

---- General Data ----	
Measurement	Type: EndPoint, Time: 0/0/0000 / 0:00:00 xx, State: Measurement not performed
Template	Template loaded during measurement time : Untitled template file;
Files	Data file : untitled.dat - 00:00:00 / 00:00:00 - Created with Version 5.25.10 Template file : RS_Dairy.par - 4/28/2020 / 17:30:18 - Created by Hygiena - Created with Version 5.25.08
Sample IDs	Sample ID Data not found!
Reader	Hygiena CellScan Innovate, Driver Version: 3.17 , Injector 1 Volume 60 Speed middle Measurement Mode by Plate Repeated operation Yes Name Shake Duration [s] 600.0 Speed Fast Diameter 0.2 Type Square Measurement Mode by Plate Repeated operation Yes Injector 2 Volume 60 Speed middle Measurement Mode by Well Repeated operation Yes Name Delay Duration [s] 0.5 Measurement Mode by Well Repeated operation Yes Name Background Counting Time [s] 2.00 Measurement Mode by Well Name Delay Duration [s] 2.0 Measurement Mode by Well Repeated operation Yes Injector 3 Volume 60 Speed middle Measurement Mode by Well Repeated operation Yes Name Delay Duration [s] 0.5 Measurement Mode by Well Repeated operation Yes Name Measurement Counting Time [s] 4.00 Measurement Mode by Well
Calculation	Calculation Status : Valid Assay, Calculation Time : 4/15/2021 / 12:15:41
User	User Name : System Manager, User Account : Administrator
Program	Innovate, Version 5.25.10 (Beta Version); License No. : 116990 Assembly Code A : 0007 0000 0000 0000 0000 FFFF Assembly Code B : 00E8 8300 0003 FE40 2040 FFFB
System	Operating System Name : Windows 10, System User : wganon
Printer	Printer Name : HP OfficeJet 5200 series [D7103F]

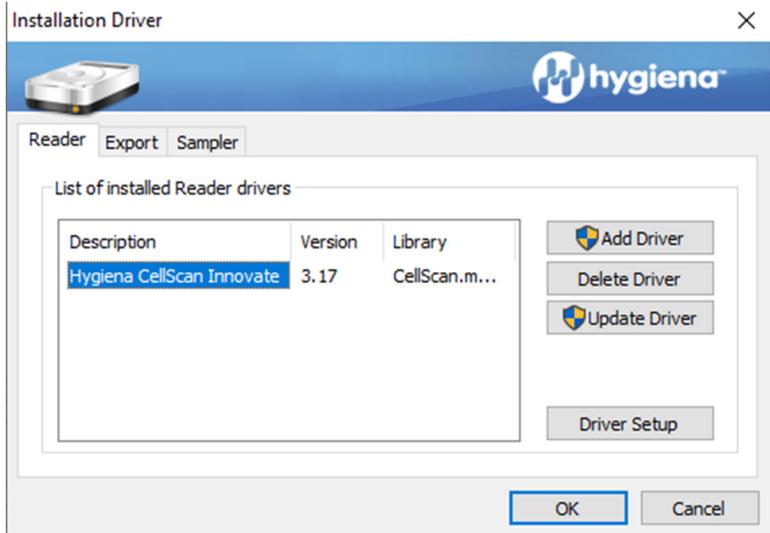
Screen appeared: Yes No

The firmware version can be found in the Reader line as **Embedded Version** number. Record the firmware version below.

Innovate Firmware (Embedded Version)	(v3.17 or higher)
---	-------------------

IQ-07: Software, Driver and Firmware Verification **Page 3 of 3**

To verify the driver version, select **Installation** from the top menu bar and click **Driver**. The following dialog box appears:



Screen appeared: Yes No

Record the driver version below.

Innovate Driver	
-----------------	--

3. Acceptance criteria

The Innovate Software™ version and driver version must be that specified by the vendor on the packing list. The firmware version must be version 3.17 or higher.

4. Test Outcome

Meets acceptance criteria for Innovate Software™ Yes No If “No,” refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

Installation Qualification Checklist

Page 1 of 1

- | | | |
|--|---------------------------------|---------------------------------|
| IQ-01 Document Verification | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-02 Initial Inspection and Equipment List Verification | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-03 Safety Checklist Review | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-04 Operating Environment Requirements | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-05 Innovate Luminometer Set-up | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-06A Innovate Software™ Installation | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-06B Innovate Software™ Start-up | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| IQ-07 Software, Driver and Firmware Verification | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| Installation Qualification passed? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If “Yes,” then proceed to Operational Qualification.

Comments

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

Add a user to Innovate Software™ and verify that users and supervisors have appropriate rights for creating, editing and deleting assays and measurements.

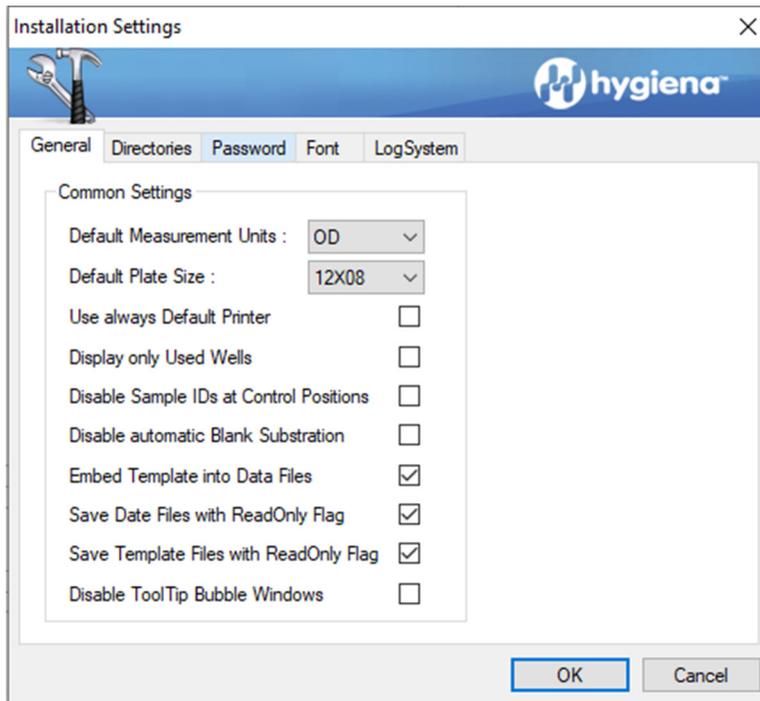
2. Test Procedure

Note: Only a user with Administrator or Supervisor level access rights may add new users. Please refer to the Innovate Software™ Manual for details.

Select the **Installation** pull down menu and choose **Settings**.

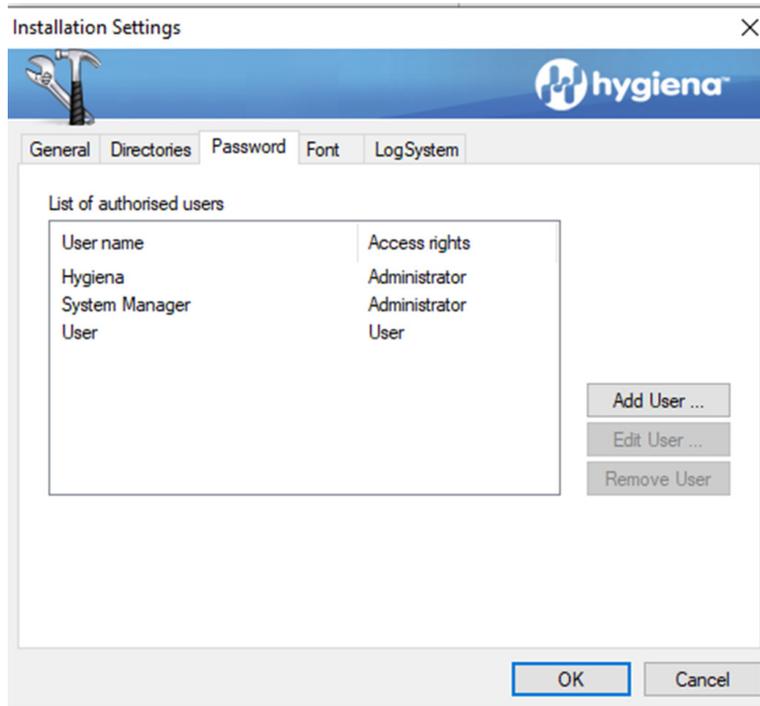


The following screen appears:



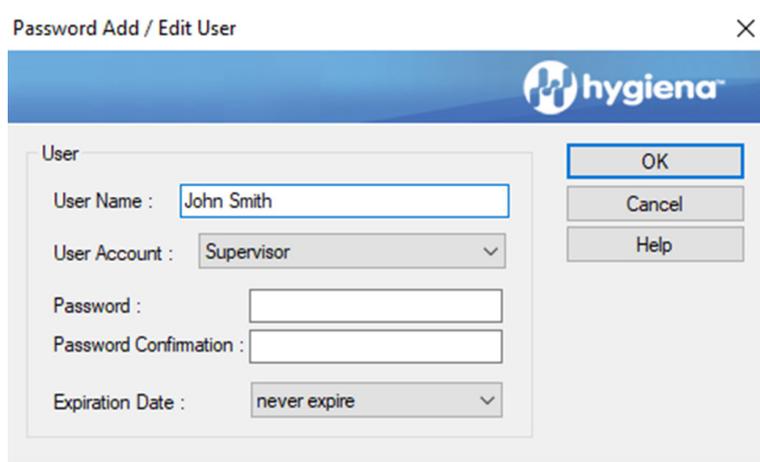
Screen appeared: Yes No

Select the **Password** tab:



Screen appeared: Yes No

Select **Add User**.



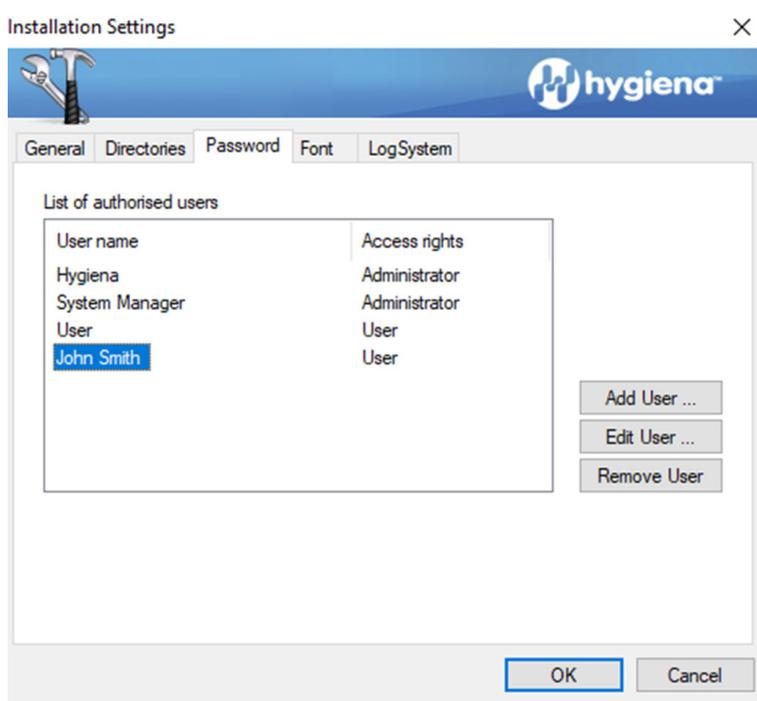
Screen appeared: Yes No

Type in the name of a new user. This field is case sensitive, so be sure to remember the way the user name was originally typed. The name John Doe is an example.

Select **User Name**, **User Account level**, **Password and Confirmation**, and **Expiration Date** of the password. The user name and password should be a minimum of 8 characters (including one lower case letter, one upper case letter and one number and must be between 8-32 characters total).

Select desired **Access Rights** for the user. Pre-defined access rights can be selected. Refer to the system manual for a detailed explanation of access rights.

Select **OK** when the user permissions have been defined and the following screen appears with the new user ID in the list of authorized users:



List of authorized users:

Screen appeared with new user ID: Yes No

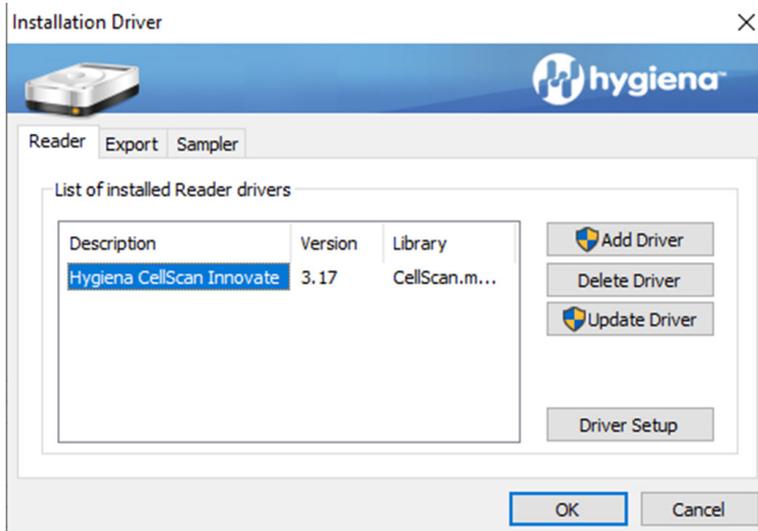
Close Installation Settings by selecting **OK** and log off of Innovate Software™.

Challenging Access Rights Administrator Rights:

Verify that a user with Administrator level access rights can access the appropriate menu options.

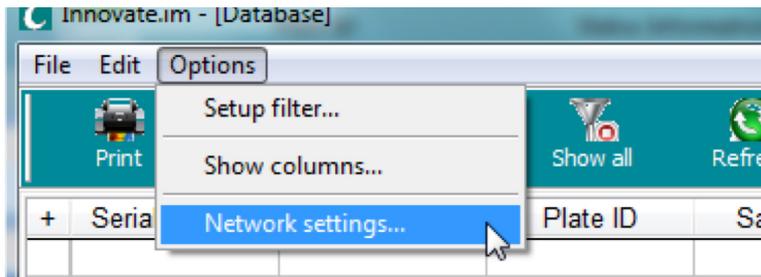
Note: Prior to the next step in this test, confirm that users with access rights of Administrator and User have been created per the Innovate Software™ Operator’s Manual.

Logon as a user with **Administrator** level permissions. Select **Installation** from the top menu bar and select **Driver**. The following screen should appear:



Screen appeared: Yes No

Open the database and select **Options** from the top menu bar. The following screen should appear with Administrator level menu options.



Screen appeared with the following menu options present:

Options>Network Settings: Yes No

User Rights:

This test will verify that a user cannot access Administrator level menu options.

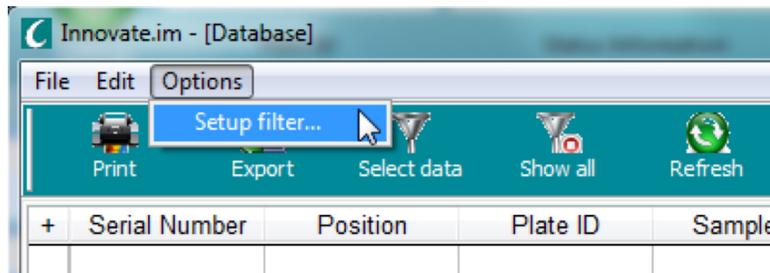
Logon to Innovate Software™ with **User** level permissions. Select **Installation** from the top menu bar and select **Driver**. The following screen should appear with installation menu options grayed out:



Screen appeared with installation menu grayed out: Yes No

Allowed to select Driver from the Installation menu: Yes No

Open the database and select **Options** from the top menu bar. The following screen should appear with User level menu options.



Screen appeared with the following menu options absent:

Options>Setup filter: Yes No

3. Acceptance Criteria

The User Administration must accept a new user ID and password. Appropriate rights for each new user (Administrator, User) should be granted.

4. Test Outcome

Meets acceptance criteria for adding a new user: Yes No

Meets acceptance criteria for normal or master rights: Yes No

If "No," refer to Discrepancy Number _____

5. Comments

6. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

Verify the operation of the injector wash and prime sequence.

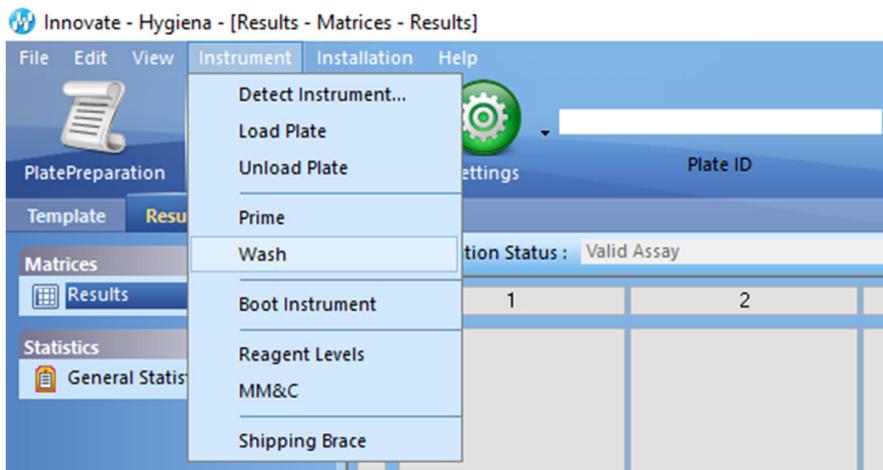
2. Materials and Reagents

Reagent Kit Name _____
 Cat. No. _____ Lot No. _____ Exp _____

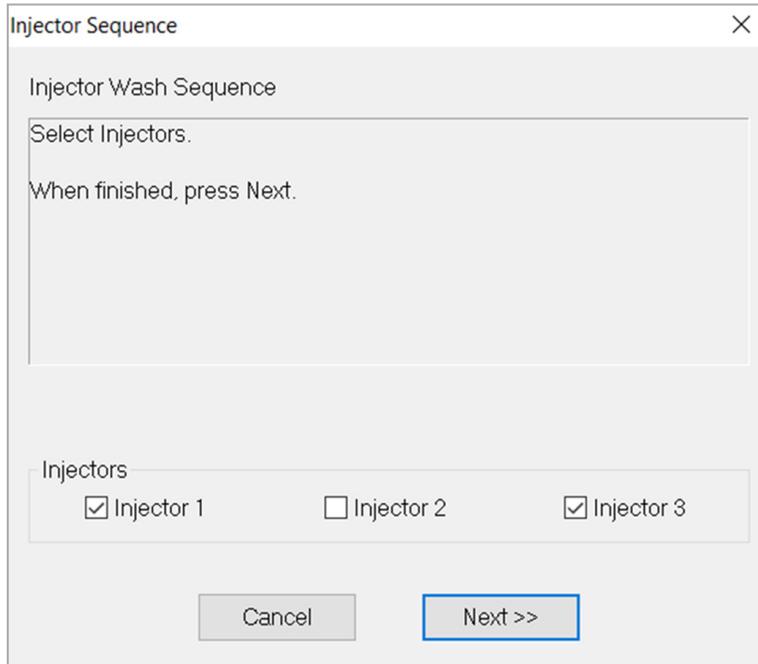
3. Test Procedure

Note: Detailed instructions for the reconstitution, use and storage of the reagents are found in the respective kit inserts.

Select the **Instrument** pull down menu and select **Wash**.



The following screen appears:



Injector Sequence

Injector Wash Sequence

Select Injectors.

When finished, press Next.

Injectors

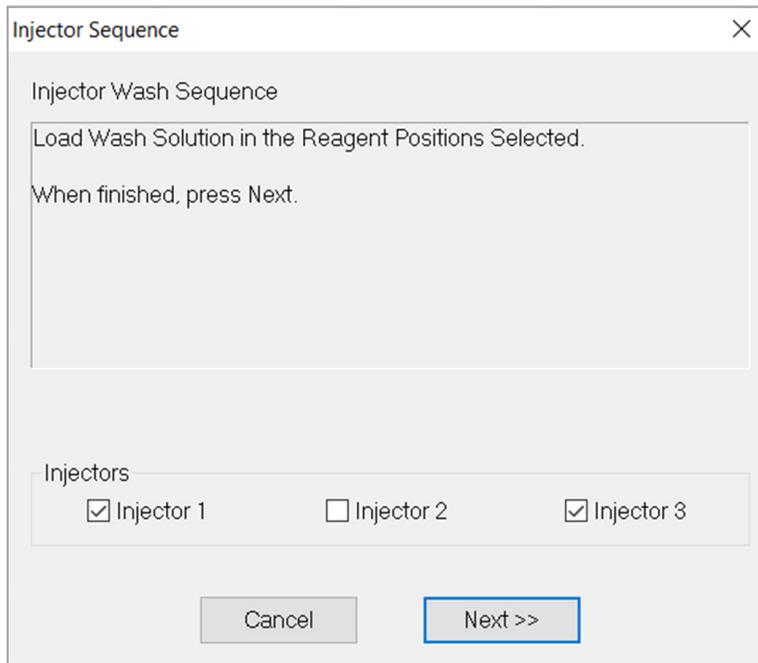
Injector 1 Injector 2 Injector 3

Cancel Next >>

Screen appeared: Yes No

Select injectors **1, 2, and 3** and Click **Next**.

The following screen appears:



Injector Sequence

Injector Wash Sequence

Load Wash Solution in the Reagent Positions Selected.

When finished, press Next.

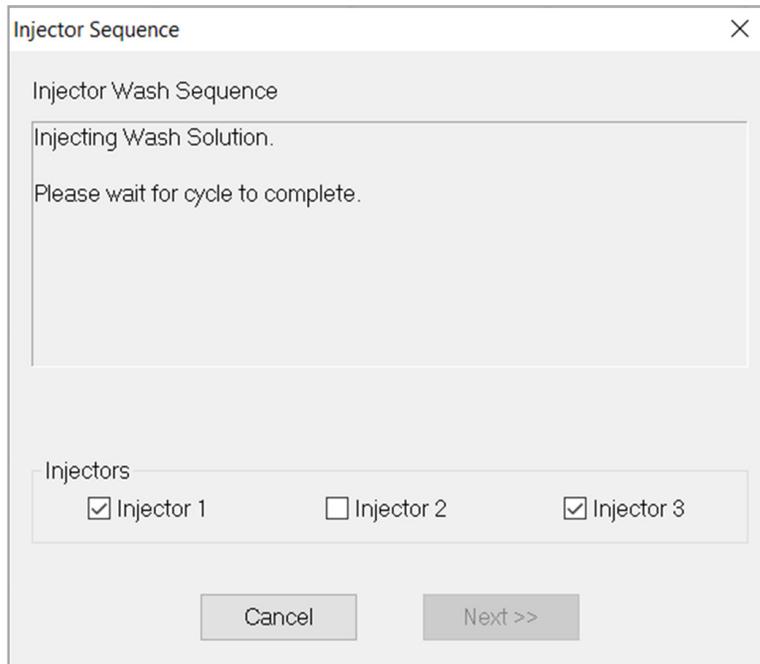
Injectors

Injector 1 Injector 2 Injector 3

Cancel Next >>

Screen appeared: Yes No

Transfer the injector needles to washing solution and press **Next**.



Injector Sequence

Injector Wash Sequence

Injecting Wash Solution.

Please wait for cycle to complete.

Injectors

Injector 1 Injector 2 Injector 3

Cancel Next >>

Screen appeared: Yes No

Reconstitute reagents and place in appropriate location on the reagent tray. Select the **Instrument** pull down menu and select **Reagent Levels**. The following screen appears.

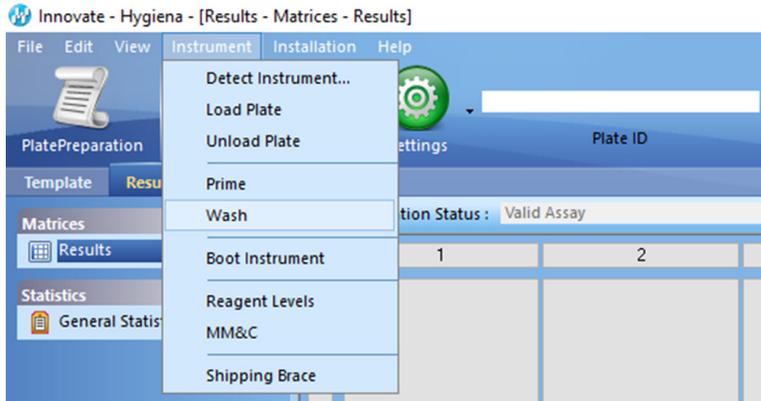
Reagent	Present Volume	Press to Add (or Subtract)	Amount
Inj 1	0.00 ml	Add/Subtract	0.00
Inj 2	0.00 ml	Add/Subtract	0.00
Inj 3	0.00 ml	Add/Subtract	0.00

Last Settings Close

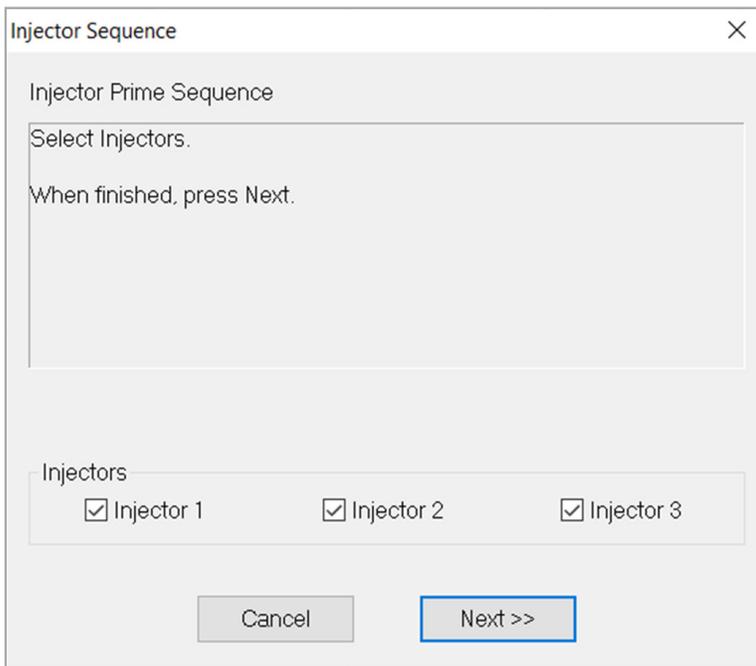
Screen appeared: Yes No

Enter the volumes of each reagent for each injector and click **Add/Subtract** to add the amount to the present volume. Click **Close**.

Select the **Instrument** drop down and Click **Prime**.

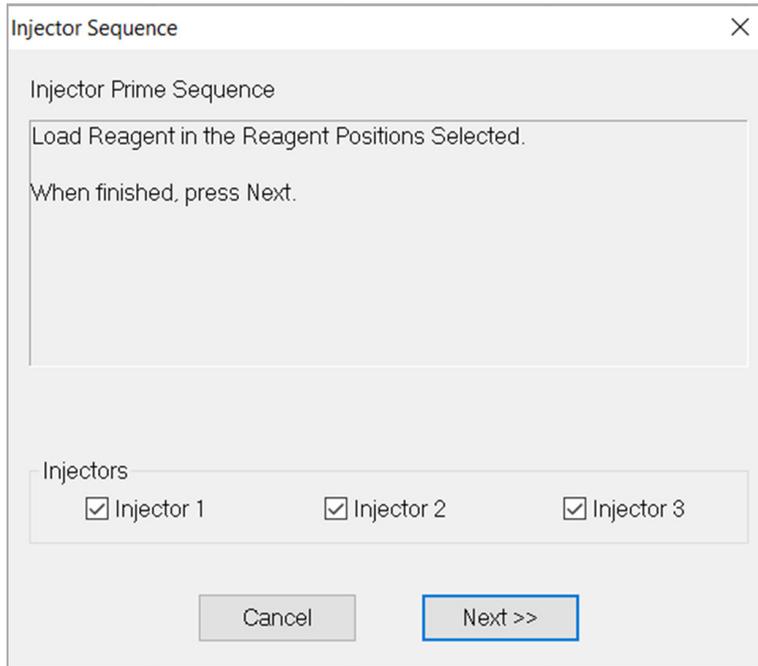


The following screen appears.



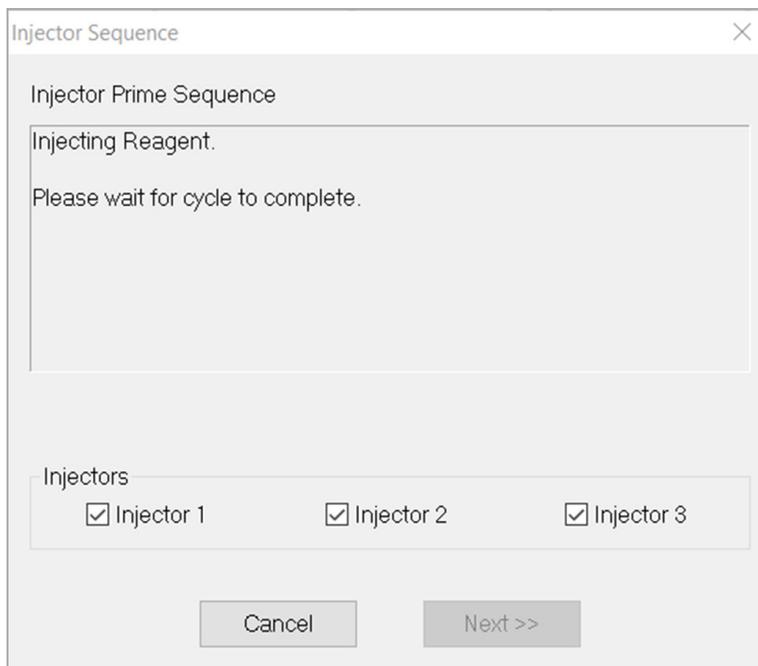
Screen appeared: Yes No

Select all three injectors and click **Next**.



Screen appeared: Yes No

Transfer the injector needles to the reagent positions. Click **Next**.
The following dialog box appears:



Screen appears: Yes No

4. Acceptance Criteria

The dialog boxes must appear as specified.

5. Test Outcome

Meets acceptance criteria for Reagent Injector Startup Yes No If "No," refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

To establish the Instrument Blank RLU value and verify that this value is within the acceptable range.

2. Materials and Reagents

Microtiter Plate

3. Test Procedure

- a) Select the **Plate Prep** icon in the menu bar.
- b) Type “OQInsBlank” in the Plate ID field and press **Enter**.
- c) From the **Protocol** drop down menu, select a **Control** protocol.
- d) In the **Assay** drop down menu, select **InsBlank**.
- e) Select 10 wells in the plate grid corresponding to 10 empty wells on the microtiter plate.
- f) Type “OQ InsBlank” in the Sample ID column for each well selected.
- g) Click **Run Plate** and click **Start**.

4. Records

Record the results for each test assay in the spaces provided below.

RLU 1: _____	Result: _____
RLU 2: _____	Result: _____
RLU 3: _____	Result: _____
RLU 4: _____	Result: _____
RLU 5: _____	Result: _____
RLU 6: _____	Result: _____
RLU 7: _____	Result: _____
RLU 8: _____	Result: _____
RLU 9: _____	Result: _____
RLU 10: _____	Result: _____

5. Acceptance Criteria

The Instrument Blanks must meet specification with a result of **OK**.

6. Test Outcome

Meets acceptance criteria for Instrument Blank: Yes No If the response is “No,” is a retest required?

Yes; Proceed to Section 7 “Retest Provision.”

No; Justify this decision in the comments section.

7. Retest Provision

If the results are out of specification, the Innovate luminometer may need more time to stabilize. This may happen occasionally after shipping.

8. Retest Procedure

Leave the Innovate luminometer switched on, allow to equilibrate for two hours and repeat the Test. Record the Equilibration Start and Finish Times. Record the RLU results obtained.

Equilibration Start Time: _____ Finish Time: _____

RLU 1: _____	Result: _____
RLU 2: _____	Result: _____
RLU 3: _____	Result: _____
RLU 4: _____	Result: _____
RLU 5: _____	Result: _____
RLU 6: _____	Result: _____
RLU 7: _____	Result: _____
RLU 8: _____	Result: _____
RLU 9: _____	Result: _____
RLU 10: _____	Result: _____

9. Retest Outcome

Meets acceptance criteria for Instrument Blank: Yes No If "No," refer to Discrepancy Number _____

10. Comments

11. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

5. Acceptance Criteria

The Reagent Blank must meet specification with a result of **OK**.
If “No,” refer to Discrepancy Number _____

6. Test Outcome

Meets acceptance criteria for Reagent Blank: Yes No

7. Comments

8. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

To establish the ATP Positive Control RLU value and verify that this value is within the acceptable range.

2. Materials and Reagents

Detailed instructions for the reconstitution, use and storage of the ATP Positive Control are found in the kit insert.

Microtiter Plates

ATP Positive Control Cat. No. _____ Lot No. _____ Exp. _____

Reagent Kit Name _____
Cat. No. _____ Lot No. _____ Exp. _____

Reagent 1 Name _____
Cat. No. _____ Lot No. _____

Reagent 1 Name _____
Reconstitution Buffer Cat. No. _____ Lot No. _____

Reagent 2 Name _____
Cat. No. _____ Lot No. _____

Reagent 3 Name _____
Cat. No. _____ Lot No. _____

Reagent 3 Name _____
Reconstitution Buffer Cat. No. _____ Lot No. _____

3. Test Procedure

- a) Ensure that reagents are loaded on the instrument.
- b) Pipette 50µl of ATP positive control into each of 10 wells of a microtiter plate.
- c) Select the **Plate Prep** icon in the menu bar.
- d) Type "OQATPPosCntrl" in the Plate ID field and press **Enter**.
- e) From the **Protocol** drop down menu, select a **Control** protocol.
- f) In the **Assay** drop down menu, select **ATP**.
- g) Select the 10 wells in the plate grid corresponding to wells on the microtiter plate with ATP positive control.
- h) Type "OQATPPosCntrl" in the Sample ID column for each well selected.
- i) Click **Run Plate** and click **Start**.

4. Records

Record the results for the test assays in the spaces provided below.

RLU 1: _____	Result: _____
RLU 2: _____	Result: _____
RLU 3: _____	Result: _____
RLU 4: _____	Result: _____
RLU 5: _____	Result: _____
RLU 6: _____	Result: _____
RLU 7: _____	Result: _____
RLU 8: _____	Result: _____
RLU 9: _____	Result: _____
RLU 10: _____	Result: _____

5. Acceptance Criteria

The Positive Control must meet test specification with a result of **OK**.

6. Test Outcome

Meets acceptance criteria for Positive Control RLU: Yes No

7. Comments

8. Test Certification

Documented by: _____ Date: _____

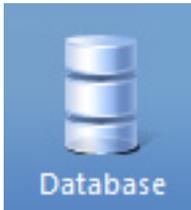
Verified by: _____ Date: _____

1. Objective

Verify that data generated by Innovate Software™ is transferred to the database.

2. Test Procedure

Open the database by selecting the icon on the menu bar.



Verify that the data generated for OQ-3, OQ-4, and OQ-5 was accurately transferred to the database. Print the results from the database and attach to this form.

Data Transferred: Yes No

Results Attached: Yes No

3. Acceptance Criteria

The data generated in OQ-3, OQ-4, and OQ-5 must appear in the database.

4. Test Outcome

Meets acceptance criteria for Database Verification: Yes No If "No," refer to Discrepancy Number _____

5. Comments

6. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

1. Objective

Verify that the reagent volume dispensed by each injector is within the specified range.

2. Materials and Reagents

Microtiter Plates

ATP Free Red Dilutor Cat. No. _____ Lot No. _____ Exp _____

Balance (4 decimal)

Note: If ATP Free Red Dilutor is not available, washing solution should be used.

3. Test Procedure

- a) Perform a wash by selecting **Instrument** from the top menu bar and then selecting **Wash**. Follow the onscreen prompts.
- b) Prime the instrument with ATP Free Red Dilutor (or washing solution).
- c) Using a 4 decimal balance weigh an empty microtiter plate. Record the pre-injection weight in table 4.1 below.
- d) Create a new plate by selecting **Plate Prep** in the menu bar. Name the plate OQInjCheck1, select **Injector Test** from the Protocol drop down menu, and select **Injector 1** from the Assay drop down menu.
- e) Select 8 consecutive wells in the plate grid.
- f) Select **Run Plate** and **Start**.
- g) Once the assay is complete, unload the plate.
- h) Weigh the plate and record the post injection weight in table 4.1 below.
- i) Repeat steps a-h for each injector recording the results in the appropriate tables below.
- j) Subtract the pre-weight injection from the post weight injection to obtain the dispensed weight.
- k) Divide the total dispensed reagent weight by 8 to calculate the weight per well.
- l) Using the conversion factor of 1000µl/g, calculate the volume of dispensed reagent.
- m) Using the correct target volume, calculate the % accuracy of each injector. Contact Hygiena technical support for correct target volumes based on the kit being used.

4. Records

4.1 Data and Calculations for Injector 1

Pre-Injection Weight (g)	Post Injection Weight (g)	Dispensed Reagent (g) (Pre-Injection weight – Post Injection weight)
Dispensed Reagent Weight per well		
Conversion Factor		x 1000µl/g
Injected Volume (µl):		
Injector 1 Target Volume (µl):		
% Accuracy = $\frac{\text{Injected Volume}}{\text{Target volume}} \times 100\%$		

4.2 Data and Calculations for Injector 2

Pre-Injection Weight (g)	Post Injection Weight (g)	Dispensed Reagent (g) (Pre-Injection weight – Post Injection weight)
Dispensed Reagent Weight per well		
Conversion Factor		x 1000µl/g
Injected Volume (µl):		
Injector 2 Target Volume (µl):		
% Accuracy = $\frac{\text{Injected Volume}}{\text{Target volume}} \times 100\%$		

4.3 Data and Calculations for Injector 3

Pre-Injection Weight (g)	Post Injection Weight (g)	Dispensed Reagent (g) (Pre-Injection weight – Post Injection weight)
Dispensed Reagent Weight per well		
Conversion Factor		x 1000µl/g
Injected Volume (µl):		
Injector 3 Target Volume (µl):		
% Accuracy = $\frac{\text{Injected Volume}}{\text{Target volume}} \times 100\%$		

5. Acceptance Criteria

For each injector, the Percent Accuracy must be 90–110%.

6. Test Outcome

Meets acceptance criteria for Injector 1: Yes No

Meets acceptance criteria for Injector 2: Yes No

Meets acceptance criteria for Injector 3: Yes No

If “No,” refer to Discrepancy Number _____

7. Comments

8. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

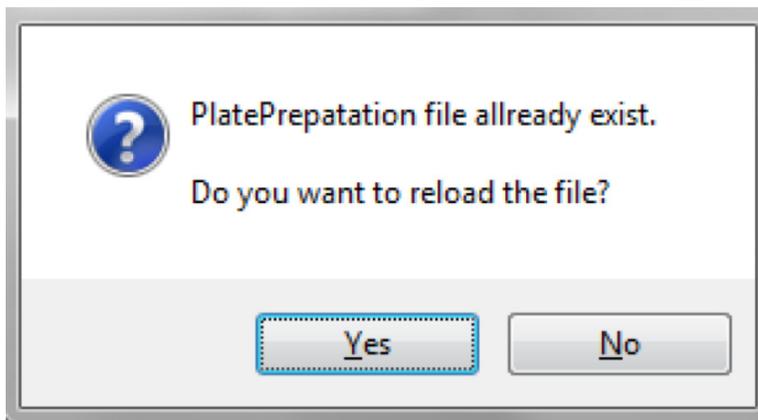
1. Objective

To challenge the Innovateluminometer error response in order to verify error messages.

2. Test Procedure

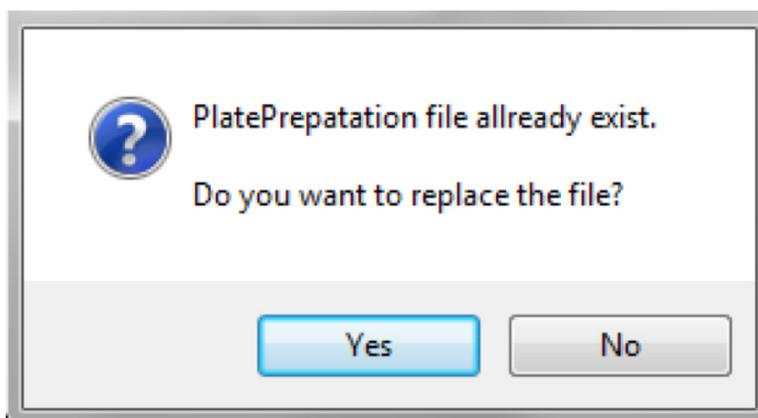
2.1 Save a plate with the same name as a previously saved plate

Select Plate Prep from the top menu bar and type FaultTest1 in the Plate ID field. Prepare the plate to run an instrument blank assay. Once the plate prep is complete, select Run Plate and Start the assay. When the assay is complete, prepare a new plate by clicking the Plate Prep icon. Type FaultTest1 in the Plate ID field and press Enter on the keyboard. The following dialog box appears:



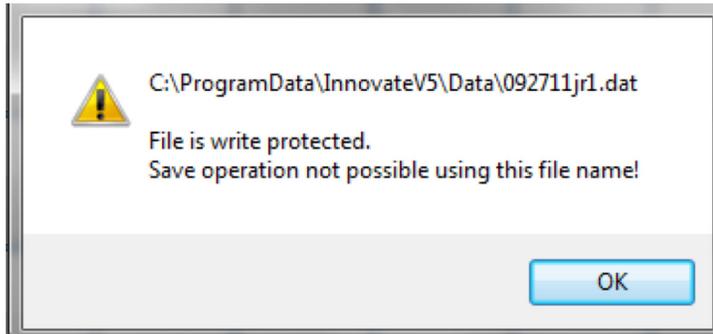
Screen appeared: Yes No

Click **Yes** to reload the plate. Setup the plate to run an instrument blank assay by selecting non-grayed out wells in the plate grid. Click **Run Plate**. The following dialog box appears.:



Screen appeared: Yes No

Click **Yes** and **Start**. The following dialog box appears.



Screen appeared: Yes No

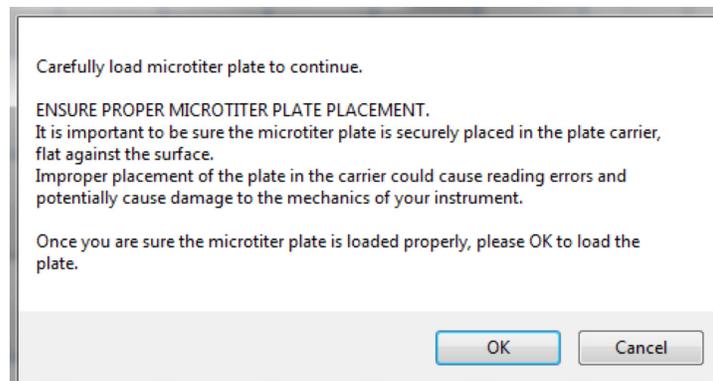
Click **OK** and document observations below.

2.2 Starting an assay without a plate loaded

Select Plate Prep from the top menu bar and prepare a new plate to run instrument control assays. Once the plate prep is complete, select **Run Plate** and start the assay. When prompted to load the microtiter plate, the following dialog box appears:



Do NOT place the plate onto the plate carrier and select OK. The following screen appears again:



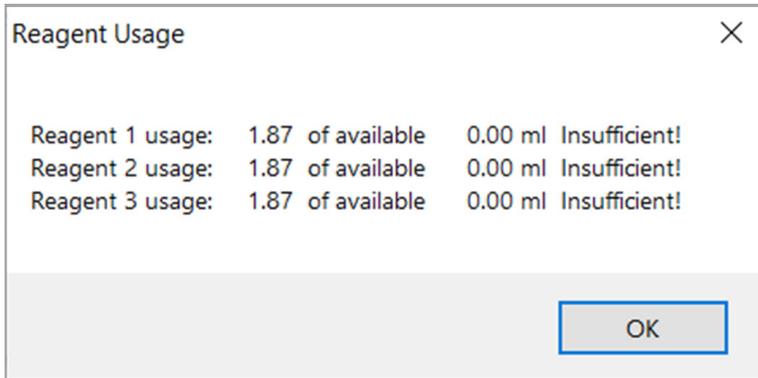
Screen appeared: Yes No

Select **Cancel** and document observations below.

2.3 Priming the instrument with insufficient reagent loaded.

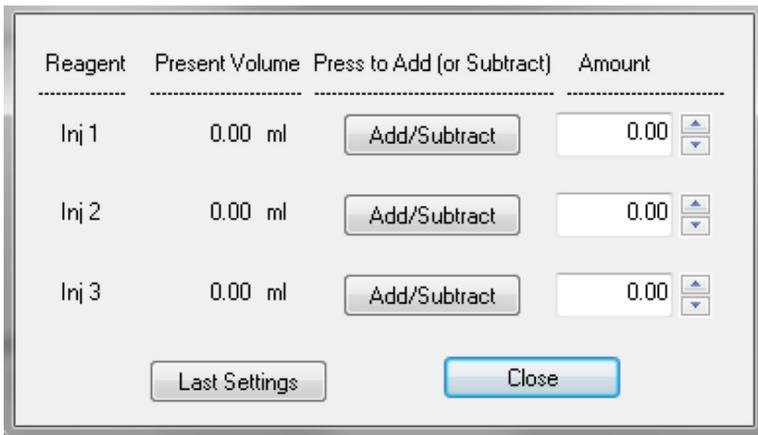
Ensure the Innovate luminometer communication cable is plugged into the PC. Log into Innovate Software™ and change all reagent levels to zero by selecting **Instrument** from the top menu bar and then clicking **Reagent Levels**. Select **Instrument** from the top menu bar and select **Prime**.

Select all injectors and begin the priming sequence by clicking **Next**. When prompted to load reagent, leave injector needles in washing solution and press **Next**. The following screen appears:



Screen appeared: Yes No

Click **OK** and the following screen appears:

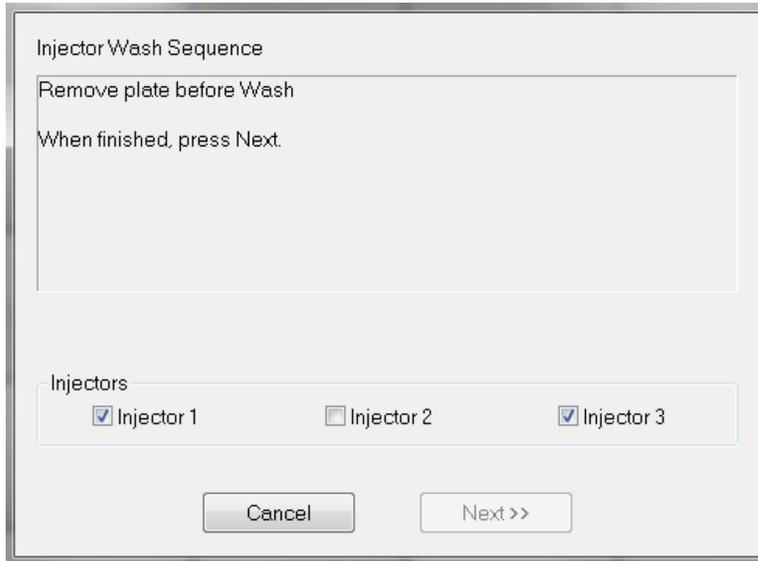


Screen appeared: Yes No

Click close and document observations below.

2.4 Perform wash cycle with plate loaded in the instrument

Load a microtiter plate into the Innovate system. Select **Instrument** from the top menu bar and select **Wash**. Click **Next** in the injector sequence dialog box. The following dialog box appears:



Screen appeared: Yes No
 Select Cancel and document observations below.

3. Records

3.1 Save a plate with the same name as a previously saved plate

Error boxes appeared? Yes No

3.2 Starting an assay without a plate loaded

Allowed to continue? Yes No

Load plate dialog boxes appeared? Yes No

3.3 Starting Innovate Software™ with communication cable unplugged

Installation driver window appeared? Yes No

Program activation window appeared? Yes No

3.4 Priming the instrument with insufficient reagent loaded

Reagent usage dialog box appeared? Yes No

Reagent level adjustments dialog box appeared? Yes No

3.5 Perform wash cycle with plate loaded in the instrument

“Remove plate before wash” screen appeared? Yes No

4. Acceptance Criteria

The Innovate luminometer must display the appropriate error messages or dialog boxes.

5. Test Outcome

Meets acceptance criteria for Fault Insertion Tests:

Save a plate with the same name as a previously saved plate Yes No

Starting an assay without a plate loaded Yes No

Starting Innovate Software™ with communication cable unplugged Yes No

Priming the instrument with insufficient reagent loaded Yes No

Perform wash cycle with plate loaded in the instrument Yes No

If “No,” refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

Operational Qualification Checklist

Page 1 of 1

OQ-01 Adding a User & Verifying Access Rights	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-02 Reagent Injector Startup Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-03 Instrument Blank Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-04 Reagent Blank Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-05 ATP Positive Control Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-06 Database Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-07 Reagent Injector Delivery Volume Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
OQ-08 Fault Insertion Tests	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
Operational Qualification passed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

End of Document

1. Objective

Verify that the networked database option is correctly installed.

2. Test Procedure

Ensure that the PC meets the following minimum requirements:

Local Workstation

Component	Specification
Processor	1 GHz
Operating System	Windows 10
Memory	1 Gb RAM
Hard-Drive space	100 Mb free hard drive space
Graphics Card	1024 X 768 or higher
Monitor	Color
Mouse	Yes
Keyboard	Yes
Communications Port	USB
Web Browser	Internet Explorer 6.0 or higher (optional)

In addition to the above minimum system requirements, a Master Networked Workstation, Networked Workstation, or Remote Access Workstation must meet below minimum specifications.

IMPORTANT: Plate preparation files and database export drivers must be identical on all systems accessing the networked database tables. Report templates and pre-defined queries should be identical on all networked systems and can be controlled via the master workstation on the network. A license is required for remote access workstations to run Innovate Software™ as stand-alone.

Networked Workstation or Remote Access Workstation

Component	Specification
Software	Innovate Software™ v5.25 or higher
Network Access	Full Read/Write Permissions to the networked folder
Network Speed	1 Gbps for optimal performance
Operating System	Windows 10

For the most reliable operation of Innovate Software™, Hygiena recommends that either a new computer is purchased, or if an existing computer is used, its hard drive is reformatted and the appropriate Operating System freshly reinstalled prior to installing Innovate Software™.

A desk jet or laser printer should be available at the time of installation.

3. Networked Workstation Setup

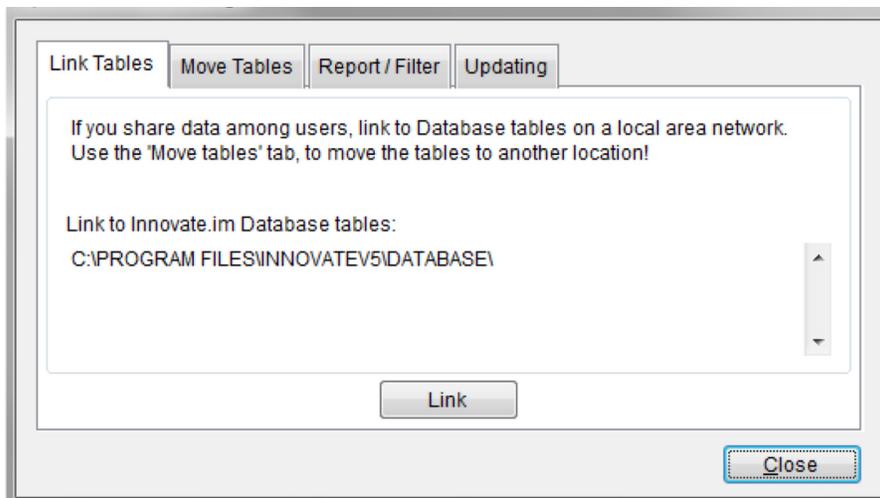
A multiple user network can be utilized to access a single database table located on a network using multiple workstations. This enables users to centrally manage and access sample data. A master workstation should be setup first to establish the database tables on the network and manage report templates and pre-defined queries. Following setup of the master workstation, other workstations can be added to the network and linked to the report templates and queries.

Master Workstation

Perform the following steps to setup a master workstation on a networked database.

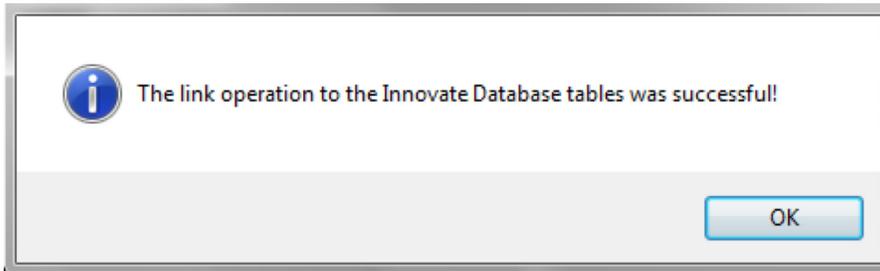
With assistance from network administration personnel, create an Innovate Software™ database folder on a network drive that can be accessed by all workstations. Grant all Innovate Software™ users full permissions to this folder.

Transfer database tables to the database folder on the network by first logging into Innovate Software™ with system administration privileges. Click on the **Database** icon to open the database. From the **Options** menu, select **Network Settings**. The following screen appears:



Screen appeared: Yes No

Select the **Move** tab and select **Move**. In the browser window that appears, navigate to the database table folder on the network drive and click **Open**. The following screen appears:



Screen appeared: Yes No

The workstation is now set up as the master workstation and linked to the network database table.

Navigate to the network folder and ensure below files are present.

- | | | |
|--------------------------|------------------------------|-----------------------------|
| DatabaseSyncAll.DBF | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| databasetable.cdx | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| databasetable.dbf | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| databasetablearchive.cdx | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| databasetablearchive.dbf | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

The database files on the local workstation will be renamed using the following convention:

beforemoving_YYYYMMDD_hhmmssFileName

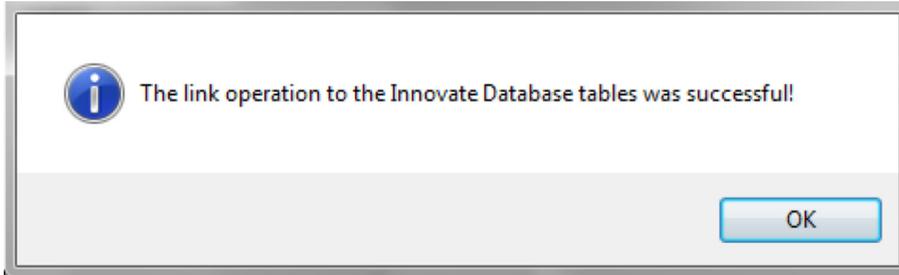
Navigate to the Innovate Software™ folder on the local drive of the workstation and ensure the following files have been renamed.

- | | | |
|--|------------------------------|-----------------------------|
| beforemoving_YYYYMMDD_hhmmssdatabasesyncall.DBF | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| beforemoving_YYYYMMDD_hhmmssdatabasetable.cdx | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| beforemoving_YYYYMMDD_hhmmssdatabasetable.dbf | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| beforemoving_YYYYMMDD_hhmmssdatabasetablearchive.cdx | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| beforemoving_YYYYMMDD_hhmmssdatabasetablearchive.dbf | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Networked Workstation

After setting up the master workstation above, follow these steps to link subsequent workstations to the networked database tables.

Login to Innovate Software™ with system administration privileges and open the Database. From the **Options** menu, select **Network Settings**. Select **Link** and navigate to the database folder on the network. Open the folder and select “**databasetable.dbf**” and then select **Link**. The following screen appears:



Screen appeared: Yes No

Files in the Innovate Software™ Database application directory of the local workstation will be renamed using the following convention:

linkrename_yyyymmdd_hhmmssFileName

Navigate to the InnovateIM folder on the local drive of the workstation and ensure the following files have been renamed in the database directory.

- | | | |
|--|------------------------------|-----------------------------|
| linkrename_yyyymmdd_hhmmssdatabasesyncall.DBF | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| linkrename_yyyymmdd_hhmmssdatabasetable.cdx | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| linkrename_yyyymmdd_hhmmssdatabasetable.dbf | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| linkrename_yyyymmdd_hhmmssdatabasetablearchive.cdx | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| linkrename_yyyymmdd_hhmmssdatabasetablearchive.dbf | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Remote Access Workstation

Computers with Innovate Software™ installed can access network database tables from a remote location without having an instrument attached. A program activation code must first be issued along with a license for using a stand alone version of the software. Contact a Hygiena representative in order to obtain a stand alone license and setup a remote access workstation.

4. Acceptance Criteria

The screens and files must appear as shown above.

5. Test Outcome

Meets acceptance criteria for Innovate Software™ software installation and set-up: Yes No

If “No,” refer to Discrepancy Number _____

6. Comments

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

Test ID: _____ **Discrepancy Number** _____

Discrepancy:

Discrepancy _____ Permanently resolved. See Resolution below

Workout _____ Temporarily resolved. See Resolution and Action Plan below.

Resolution:

Action Plan:

Done By / Date: _____

Verified By / Date: _____