



# Hygiena™ EnSURE™ System

## Installation & Operational Qualification

**Site:**

**Instrument Serial Number:**

### Purpose

This Installation/Operational Qualification has been specifically designed for the qualification of the EnSURE™ Monitoring System.

The Installation Qualification (IQ) and Operational Qualification (OQ) sections verify and document that the EnSURE™ Monitoring System has been installed and operates in accordance with the design specifications and manufacturer's recommendations. 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

## Contents

### Installation Qualification

IQ-01	Document Verification
IQ-02	Initial Inspection and Equipment List Verification
IQ-03	Safety Verification
IQ-04	Operating Environment Requirements
IQ-05	Luminometer Set-up
IQ-06A	SureTrend Installation
IQ-06B	SureTrend Startup
IQ-07	Software Verification
Installation Qualification Checklist	

### Operation Qualification

OQ-01	Luminometer Startup Verification
OQ-02	Calibration Verification
OQ-03	Test Device Verification
OQ-04	Database Verification
Operational Qualification Checklist	

Appendix A: Discrepancy Report Form

## Installation Qualification

### IQ-01 Document Verification

#### 1. Objective

Verify that all the required documentation for the EnSURE Luminometer and SureTrend 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 Operator Manual, and Certificate of Conformity was received.

Record instrument serial number from Certificate of Conformity.

Attached Certificate of Conformity to this form.

#### 3. Instrumentation Documentation

Operator Manual

Present

Not Present

#### 4. Calibration Documentation

Instrument Serial Number on Certificate: \_\_\_\_\_

Certificate of Conformity

Present

Not Present

Certificate of Conformity attached to this form?

Yes

No

#### 5. Comments

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#### 6. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## IQ-02 Initial Inspection and Equipment List Verification

### 1. Objective

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

### 2. Test Procedure

Record the luminometer serial number received.

Verify that all the equipment ordered was received.

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

### 3. Equipment Record

Model No.:	Serial No.:
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All items on the packing list are present

 Yes

 No

Packing list (or copy) is attached

 Yes

 No

Equipment received was the equipment ordered?

 Yes

 No

Equipment received undamaged, visually?

 Yes

 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

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### 7. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## IQ-04 Operating Environment Requirements

### 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%

### 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

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### 7. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## IQ-05 Luminometer Set-Up

**1. Objective**

To set-up the luminometer

**2. Test Procedure**

1. Remove luminometer from packaging.
2. Insert batteries.
3. Set & verify date & time

**3. Acceptance Criteria**

The instrument is set-up correctly.

**4. Test Outcome**

Set-up is complete:

Yes  No

If "No," refer to Discrepancy Number \_\_\_\_\_

**5. Comments**

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**6. Test Certification**

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## IQ-06 SureTrend Installation

### 1. Objective

Verify that the SureTrend software is correctly installed.

### 2. Test Procedure

Ensure that the PC meets the following minimum requirements:

**Local Workstation Minimum Requirements**

Component	Specification
Computer	PC
Processor	Intel Dual Core or better
Operating System	Windows XP or newer
Memory	2 Gb RAM
Hard-Drive space	2 Gb free hard drive space
Monitor	Color
Mouse	Yes
Keyboard	Yes
Communications Port	USB
CD-ROM	Optional
Web Browser	Internet Explorer or Chrome
Windows Access	System Administrator Privileges

### Local Workstation Software Installation

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

Download latest version of SureTrend Software from: [www.hygiene.com/suretrend-download](http://www.hygiene.com/suretrend-download)

Software download complete:  Yes  No

Install latest version of SureTrend Software per Installation Guidelines found at the bottom of the page:  
[www.hygiene.com/suretrend-download](http://www.hygiene.com/suretrend-download)

Installation Complete:  Yes  No

### 3. Comments

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### 4. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## IQ-06b SureTrend Start-Up

**1. Objective**

Verify that the SureTrend software communicates properly with the luminometer.

**2. Test Procedure**

Connect the EnSURE™ luminometer to the PC using the USB cable provided.

Start SureTrend by double clicking on the SureTrend desktop icon.

**3. Acceptance Criteria**

The user must be able to log on to the SureTrend software.

**4. Test Outcome**

Meets acceptance criteria for SureTrend software:  Yes  No

If "No," refer to Discrepancy Number \_\_\_\_\_

**5. Comments**

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**6. Test Certification**

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_



## IQ-07 Software Verification

### 1. Objective

Verify that the version of the software is up to date

### 2. Test Procedure

Switch on the PC and log on to the SureTrend software. Select the **Help** pull down menu and select **About SureTrend**.

Compare the dialog box to the documentation received from the vendor. Record the details below.

SureTrend Version	
Operating System	

### 3. Acceptance criteria

The SureTrend version must be version 4.0 or higher.

### 4. Test Outcome

Meets acceptance criteria for SureTrend software verification:  Yes  No

If "No," refer to Discrepancy Number \_\_\_\_\_

### 5. Comments

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### 6. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

### Installation Qualification Checklist

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 Verification	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
IQ-04 Operating Environment Requirements	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
IQ-05 Luminometer Set-up	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
IQ-06A SureTrend Installation	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
IQ-06B SureTrend Start-up	<input type="checkbox"/> Passed	<input type="checkbox"/> Failed
IQ-07 Software 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: \_\_\_\_\_

## Operation Qualification

### OQ-01 Luminometer Start-Up Verification

#### 1. Objective

Verify the operation of the luminometer.

#### 2. Materials and Reagents

Test Kit Name \_\_\_\_\_

Cat. No. \_\_\_\_\_ Lot No. \_\_\_\_\_ Exp. \_\_\_\_\_

#### 3. Test Procedure

**Note:** Detailed instructions for the use and storage of the Hygiena™ test devices are found in the respective kit inserts and on the website. Following the instructions on the kit insert, activate the test and measure it using the EnSURE™.

Results Screen appeared:  Yes  No

#### 4. Acceptance Criteria

The results must appear on the instrument screen. If results appear out of range, please refer to OQ-03 Calibration Verification.

#### 5. Test Outcome

Meets acceptance criteria for Luminometer Startup:  Yes  No

If "No," refer to Discrepancy Number \_\_\_\_\_

#### 6. Comments

\_\_\_\_\_  
\_\_\_\_\_

#### 7. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## OQ-02 Calibration Verification

### 1. Objective

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

### 2. Materials and Reagents

CalCheck LED Calibration Verification Device (Cat No. CAL) or Calibration Control Kit (Cat No. PCD4000)  
EnSURE™ Luminometer

### 3. Test Procedure

Detailed instructions for the use of Hygiena™ calibration verification devices are found in the respective kit inserts and on the website. Following the instructions on the kit insert perform the calibration verification.

### 4. Records

Record the results for each calibration verification in the spaces provided below.

CalCheck (Cat No. CAL)

Positive Check: test 1: \_\_\_ test 2: \_\_\_ test 3: \_\_\_

Negative Check: test 1: \_\_\_ test 2: \_\_\_ test 3: \_\_\_

Calibration Control Kit (Cat No. PCD 4000)

Positive Rod: test 1: \_\_\_ test 2: \_\_\_ test 3: \_\_\_

Negative Rod: test 1: \_\_\_ test 2: \_\_\_ test 3: \_\_\_

### 5. Acceptance Criteria

The Calibration Verification must fall within accepted range as outlined in the respective kit insert.

### 6. Test Outcome

Meets acceptance criteria for Calibration Verification:  Yes  No

### 7. Comments

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### 8. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## OQ-03 Test Device Verification

**1. Objective**

To establish the competency of the user to test a surface using the luminometer and test device.

**2. Materials and Reagents**

UltraSnap™ or SuperSnap™, EnSURE™ Luminometer

**3. Test Procedure**

Follow the instructions on the In-Service/Competency Checklist and attach when complete.

**4. Records**

Attach In-Service Competency Checklist.

**5. Acceptance Criteria**

The Checklist attached, all boxes marked "Yes"

**6. Test Outcome**

Meets acceptance criteria for Test Device Verification:  Yes  No

**7. Comments**

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**8. Test Certification**

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## OQ-04 Database Verification

### 1. Objective

Verify that data generated by the luminometer is transferred to the SureTrend database.

### 2. Test Procedure

Open SureTrend by selecting the icon on the desktop.

Connect the luminometer to SureTrend using the included USB cable and click **Synchronize** in SureTrend to upload results. Verify that the data generated for OQ-3, OQ-4 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 must appear in the database.

### 4. Test Outcome

Meets acceptance criteria for Database Verification:  Yes  No

If "No," refer to Discrepancy Number \_\_\_\_\_

### 5. Comments

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### 6. Test Certification

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

## Operational Qualification Checklist

- |  |                                 |                                 |
|--|---------------------------------|---------------------------------|
| QQ-01 Luminometer Startup Verification | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| QQ-02 Calibration Verification         | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| QQ-03 Test Device Verification         | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| QQ-04 Database Verification            | <input type="checkbox"/> Passed | <input type="checkbox"/> Failed |
| Operational Qualification passed?      | <input type="checkbox"/> Yes    | <input type="checkbox"/> No     |

Comments: \_\_\_\_\_  
\_\_\_\_\_

Documented by: \_\_\_\_\_ Date: \_\_\_\_\_

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

End of Document

## Appendix A: Discrepancy Report Form

Test ID: \_\_\_\_\_

Discrepancy Number \_\_\_\_\_

Discrepancy:	
Discrepancy Workout	<input type="checkbox"/> Permanently resolved. See Resolution below. <input type="checkbox"/> Temporarily resolved. See Resolution and Action Plan below.
Resolution	
Action Plan	

Done By / Date:	
Verified By / Date:	