EnSURE® and SystemSURE *Plus*® Monitoring System Installation & Operational Qualification

Site:	Instrument Serial Number:

Purpose

This Installation/Operational Qualification has been specifically designed for the qualification of Hygiena's EnSURE® and SystemSURE *Plus*® Monitoring Systems.

The Installation Qualification (IQ) and Operational Qualification (OQ) sections verify and document that the EnSURE or SystemSURE *Plus* 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	Printed Name	Company/Function

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Installation Qualification

IQ-01 Document Verification

1. **Objective**
   Verify that all the required documentation for the luminometer 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 were received.
   Record instrument serial number from Certificate of Conformity.
   Attach Certificate of Conformity to this form.

3. **Instrumentation Documentation**
   Operator Manual (link): ☐ Yes ☐ No

4. **Calibration Documentation**

Instrument Serial Number on Certificate:

Certificate of Conformity: ☐ Yes ☐ No
Certificate of Conformity attached: ☐ Yes ☐ No

5. **Comments**

_____

_____

_____

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

3. Equipment Record

Serial Number on Instrument:

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 is visually undamaged:	☐ 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

_____

_____

_____

7. Test Certification

Documented by: _____ Date: _____

Verified by: _____ Date: _____

IQ-03 Operating Environment Requirements

1. **Objective**
   Review the system environment requirements.

2. **Test Procedure**
   Review the environmental requirements with the user.

3. **Environment Requirements**

Parameter	Specified
Operating Temperature	5 °C to 45 °C
Relative Humidity Range	20% to 85% non-condensing

4. **Acceptance Criteria**
   The instrument is installed correctly and meets the required environmental conditions.

5. **Test Outcome**
   Reviewed Environment Requirements: ☐ Yes ☐ No
   If “No”, refer to Discrepancy Number _____.

1. **Comments**

_____

_____

_____

2. **Test Certification**

Documented by: _____ Date: _____

Verified by: _____ Date: _____

IQ-04 Setup and Registration

1. **Objective**
   Set up the EnSURE or SystemSURE *Plus* instrument and SureTrend® software.

2. **Test Procedure**
   Follow the instructions in the *Operator Manual* to complete the setup and instrument registration.

3. **Acceptance Criteria**
   The instrument is set up correctly.

4. **Test Outcome**
   Setup is complete: ☐ Yes ☐ No
   If "No," refer to Discrepancy Number _____.

5. **Comments**

   _____

   _____

   _____

6. **Test Certification**

   Documented by: _____ Date: _____

   Verified by: _____ Date: _____

Installation Qualification Checklist

IQ-01 Document Verification:	☐ Passed	☐ Failed
IQ-02 Initial Inspection and Equipment List Verification:	☐ Passed	☐ Failed
IQ-03 Operating Environment Requirements:	☐ Passed	☐ Failed
IQ-04 Setup and Registration:	☐ Passed	☐ Failed
Installation Qualification passed? If "Yes," then proceed to *Operational Qualification*.	☐ Yes	☐ No

Comments:

_____

_____

Documented by: _____ Date: _____

Verified by: _____ Date: _____

Operational 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**
   Detailed instructions for the use and storage of Hygiena test devices are found in their respective kit inserts and on the website. Follow the instructions on the kit insert to activate the test and measure the results using the luminometer.

   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**
   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)
   EnSURE or SystemSURE *Plus* Luminometer

3. **Test Procedure**
   Detailed instructions for the use of Hygiena calibration verification devices are found in their respective kit inserts and on the website. Follow the instructions on the kit insert to perform the calibration verification.

4. **Records**
   Record the results for calibration verification (as applicable) in the spaces provided below.

   CalCheck (Cat No. CAL)
   Calibration Verification test 1: _____, test 2: _____, test 3: _____.

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

6. **Test Outcome**
   Meets acceptance criteria for Calibration Verification: ☐ Yes ☐ No

7. **Comments**

   _____

   _____

8. **Test Certification**

   Documented by: _____ Date: _____

   Verified by: _____ Date: _____

OQ-03 Test Device Verification

1. **Objective**
   Establish the competency of the user to test a surface using the luminometer and test device.

2. **Materials and Reagents**
   UltraSnap® or SuperSnap® device
   EnSURE or SystemSURE *Plus* luminometer

3. **Test Procedure**
   Follow the instructions on *Form 1031, In-Service/Competency Checklist* and attach when complete.

4. **Records**
   Attach *In-Service Competency Checklist*.

5. **Acceptance Criteria**
   The Checklist is attached and all boxes are marked "Yes."

6. **Test Outcome**
   Meets acceptance criteria for Test Device Verification: ☐ Yes ☐ No

7. **Comments**

   _____

   _____

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 software.
   Open the Sync application and press 'Sync Now' on the luminometer to upload data.
   Verify that the data generated for OQ-3, OQ-4 was accurately transferred to the database.
   Print the results from the database and attach them 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**

   _____

   _____

   _____

6. **Test Certification**

   Documented by: _____ Date: _____

   Verified by: _____ Date: _____

Operational Qualification Checklist

OQ-01 Luminometer Startup Verification:	☐ Passed	☐ Failed
OQ-02 Calibration Verification:	☐ Passed	☐ Failed
OQ-03 Test Device Verification:	☐ Passed	☐ Failed
OQ-04 Database Verification:	☐ Passed	☐ Failed
Operational Qualification passed?	☐ Yes	☐ No

Comments:

_____

_____

Documented by: _____ Date: _____

Verified by: _____ Date: _____

End of Document

Appendix A: Discrepancy Report Form

Test ID: _____ **Discrepancy Number:** _____

Discrepancy	
Discrepancy Workout	_____Permanently resolved. See Resolution below. _____Temporarily resolved. See Resolution and Action Plan below.
Resolution	
Action Plan	

Done By/Date:	
Verified By/Date:	