iSeq™ 100 Sequencing System

Installation Qualification and Operational Qualification

|  |  |
| --- | --- |
| Type of Service | IQ/OQ  OQ |
| Customer/Institution Name | Type here. |
| iSeq 100 System Serial Number | Type here. |
| Date of Service | Click or tap to enter a date. |

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# Introduction

The iSeq 100 Installation Qualification and Operational Qualification (IQ/OQ) protocol describes the process to verify the correct installation of the iSeq 100 System. Successful completion of this protocol confirms that the iSeq 100 System is operating in accordance with Illumina specifications.

This protocol has an Installation Qualification (IQ) section and an Operational Qualification (OQ) section.

There are three situations in which you might perform an IQ or OQ:

* When the instrument is first received
* If the instrument is moved and regulations, standards, or internal procedures require the execution of an IQ and OQ
* After the instrument is returned from vendor repair

An OQ by itself may be required at a periodic interval based on internal procedures, regulations, or standards.

Illumina service personnel can perform the iSeq 100 IQ/OQ and provide a certified version of this document. For more information, refer to the Products section of the Illumina website.

When Illumina service personnel complete the IQ/OQ Service, they use this protocol for certification purposes. The Illumina Certification fields at the end of this document are for Illumina service personnel use only.

# Instructions

The IQ does not require any tests to be executed on the instrument, but the OQ does. There are two ways the OQ tests are run:

* **Automatically when the instrument is first received**: When the instrument is first received and turned on, the iSeq Control Software automatically launches and prompts you to run the First Time Setup module. First Time Setup automatically executes all the tests necessary for the OQ section of this IQ/OQ protocol. First Time Setup is only available when the instrument is first turned on.
* **Manually on demand**: If regulations, standards or internal procedures require, you may perform the IQ/OQ or OQ at a periodic interval or after repairs. First Time Setup is not available, but you can run the same tests on the instrument by launching the System Check module from the iSeq Control Software.

To perform only an IQ, fill out sections 4–9.

To perform an OQ, select the control software menu icon at the top left corner in the iSeq Control Software and select **System Check**. The tests take about 45 minutes to complete, and they write reports to the file system. All the reports are contained in a folder with a name constructed from the time and date the tests were run:

D:\Ilumina\ISeq System Checks\SystemCheckReport.YYYY-MM-DD-HH24-MI-SS

For example, the folder SystemCheckReport.2018-05-21-15-47-21 indicates that the test suite was run at 3:47:21 PM on May 21, 2018.

In the folder are subfolders corresponding to the subsystem tests in the test suite. Each folder contains a test report suitable for viewing in a spreadsheet, such as Excel. The subfolders and report files relevant to this qualification protocol are:

|  |  |
| --- | --- |
| Subfolder | Report File Name |
| CartridgeLoadAndLift | CartridgeLoadAndLiftReport1.csv |
| FoilPierce | FoilPierceReport1.csv |
| Heaters | HeatersReport1.csv |
| Illuminator | IlluminatorReport1.csv |
| LightbarAndUx | LightbarAndUxReport1.csv |
| PogoBlock | PogoBlockReport1.csv |
| PumpDrive | PumpDriveReport1.csv |
| PumpValve | PumpValveReport1.csv |
| ReagentValve | ReagentValveReport1.csv |
| ThermalAndFans | ThermalAndFansReport1.csv |

When the tests have finished, complete the protocol. For each section in the OQ:

1. Navigate to the folder for that section.
2. Open the folder’s .csv report file.
3. For each test in the relevant OQ section:
   1. Find the test entry in the report file.
   2. Note the parameter for that test.
   3. Compare the test’s value to the Specification listed in the OQ document.
   4. Check the appropriate box in the “Result” column of the OQ document.

# Roles and Responsibilities

If you request Illumina certification of the IQ/OQ service, the following roles and responsibilities apply:

1. The sole purpose of this IQ/OQ Service and this IQ/OQ Document is to verify and certify that the system referenced by a serial number listed on the cover page (“**System**”) is operating in accordance with Illumina specifications. This IQ/OQ Service and IQ/OQ Document are not to be used, or relied upon, by you or a third party for any other purpose.
2. The IQ/OQ Document and Illumina’s certification that the IQ/OQ Service has been completed does not guarantee the performance of the System or constitute any warranty with respect to the System.
3. Illumina’s terms and conditions of sale provided to you when you acquired the System solely govern any applicable performance guarantees and warranties for the System (“**Illumina Warranties**”).
4. You irrevocably accept the System; provided that, Illumina’s obligations to you under the Illumina Warranties shall survive acceptance.
5. Only an Illumina certified copy of this IQ/OQ Document is valid. Certified copies of this IQ/OQ Document can be obtained exclusively from Illumina and you may incur additional charges for this. Copies from other sources and electronic copies are invalid.
6. You have read the IQ/OQ Document in its entirety, have been given the opportunity to ask questions, and understand this IQ/OQ Document including these terms and conditions and the Legal Notices.
7. Once the IQ/OQ Service is initiated, you are responsible for the entire cost of the IQ/OQ Service even if you cancel the IQ/OQ Service or stop Illumina from performing it.
8. You certify, represent, and warrant that you have read and understand the Illumina Site Preparation Guide for the System (“**ISPG**”).
9. The System may not perform properly if the requirements set forth in the ISPG are not strictly followed.
10. The physical location where the System is/has been installed meets the physical space requirements set forth in the ISPG.
11. The site meets the environmental considerations set forth in the ISPG including those concerning temperature, humidity, altitude, and ventilation.
12. The electrical requirements for the System set forth in the ISPG have been met and will be maintained.
13. Illumina recommends running the System off an Uninterruptible Power Supply (UPS).
14. The site meets the network requirements for the System set forth in the ISPG.
15. You consent to the performance of the IQ/OQ Service.
16. If this protocol execution is for OQ only, and the OQ box is checked on the cover page of this document, then the IQ sections are to be left blank.

# Contact and Instrument Location Information

Customer/Institution Information

|  |  |
| --- | --- |
| Customer/Institution Name | Type here. |
| Contact Name | Type here. |
| Address | Type here. |
| Telephone | Type here. |
| Email | Type here. |

Instrument Location

|  |  |
| --- | --- |
| City | Type here. |
| Building | Type here. |
| Floor and Room | Type here. |

Illumina Personnel Information (for Illumina personnel only)

|  |  |
| --- | --- |
| Name | N/A |
| Title | N/A |
| Telephone | N/A |
| Email | N/A |

# Installation Qualification Protocol

|  |  |
| --- | --- |
| IQ Segments | Description |
| Documentation Verification | Verifies that the customer has received the iSeq 100 System documentation. |
| Instrument Identification | Verifies that the correct instrument was shipped and is being qualified. |
| Setup Verification | Verifies that physical elements of the instrument are properly installed. |
| Summary Installation Qualification Result | Verifies that the instrument meets all acceptance criteria. |

# Documentation Verification

|  |  |
| --- | --- |
| Action | Result |
| Make sure that these documents are present in hard copy or electronic format:   * *iSeq 100 Sequencing System Safety and Compliance Guide*, Document #1000000035336 * *iSeq 100 Sequencing System Guide*, Document #1000000036024 * *iSeq 100 Sequencing System Setup Poster*, Document #1000000035963 * *RFID Reader Compliance Guide*, Document #1000000002699 * *Illumina Proactive Technical Note*, Document #1000000052503 | Complete N/A |
| Inform the customer that Illumina Proactive is set to ON by default for this instrument. | Complete N/A |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Instrument Identification

| Instrument Identification | Instrument Description | Result |
| --- | --- | --- |
| The instrument undergoing the IQ is the instrument for which the customer intends this service to be performed. | The instrument being qualified is an iSeq 100, which is identified by the catalog number on the back label, 20021532 | Pass Fail N/A |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Setup Verification

## Confirm Accessories

| Accessories List | | | |
| --- | --- | --- | --- |
| Reusable Test flow cell |  | Reusable Test Cartridge |  |
| Power Cord |  | Ethernet Cable |  |

## Confirm Setup Actions

| Action | Result |
| --- | --- |
| Accessories inspected and in good condition per Accessories List. | Complete N/A |
| Inspected the instrument externally for visible damage. | Complete N/A |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Summary Installation Qualification Result

|  |  |  |
| --- | --- | --- |
| Qualification Type | Specification | Result |
| Installation Qualification | All tasks completed. | Pass Fail N/A |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Operational Qualification Protocol

## OQ Segments

|  |  |
| --- | --- |
| OQ Segments | Description |
| Instrument Identification | Verifies that the correct instrument was shipped and is being qualified. |
| Motion Qualification | Verifies that all important transport components are functioning properly, and that the components meet Illumina specifications. |
| Optics Qualification | Verifies that all imaging module components are functioning properly, and that the optical system meets Illumina specifications. |
| Fluidics Qualification | Verifies that the fluidics system in this instrument meets Illumina specifications. |
| Heaters Qualification | Verifies that the heating components in this instrument meet Illumina specifications. |
| RFID Qualification | Verifies that the RFID component in this instrument operates within Illumina specifications. |
| Thermal and Fans Qualification | Verifies that the thermal system in this instrument meets Illumina specifications. |
| Software Identification | Verifies the software installed on the iSeq 100Instrument. |
| Software Configuration | Verifies the configuration of certain operating system parameters. |
| Summary Operational Qualification Result | Verifies that this instrument meets all Illumina specifications. |

# Instrument Identification

| Instrument Identification | Instrument Description | Result |
| --- | --- | --- |
| The instrument undergoing the OQ is the instrument for which the customer intends this service to be performed. | The instrument being qualified is an iSeq 100, which is identified by the catalog number on the back label, 20021532 | Pass Fail N/A |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Motion Qualification

## Cartridge Load and Lift

Open the file CartridgeLoadAndLiftReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (ms) | Result |
| --- | --- | --- |
| Unload Time | X <= 60000 | Pass Fail |
| Load Time | X <= 60000 | Pass Fail |
| Engage Time | X <= 60000 | Pass Fail |

## Foil Pierce

Open the file FoilPierceReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (ms) | Result |
| --- | --- | --- |
| Pierce Time | X <= 15,000 | Pass Fail |
| Unpierce Time | X <= 15,000 | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Optics Qualification

## Illuminator - LED Median Intensity

Open the file IlluminatorReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (counts) | Result |
| --- | --- | --- |
| GreenLedIlluminatorMedianIntensity | X > 100 | Pass Fail |
| BlueLedIlluminatorMedianIntensity | X > 100 | Pass Fail |

## Illuminator - LED Uniformity

Open the file IlluminatorReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (%) | Result |
| --- | --- | --- |
| GreenLedIlluminatorUniformity | 75 < X <= 100 | Pass Fail |
| BlueLedIlluminatorUniformity | 75 < X <= 100 | Pass Fail |

## Light Bar and UX

Open the file LightbarAndUxReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (mA) | Result |
| --- | --- | --- |
| LightbarRedCurrent | 0 <= X <= 100000 | Pass Fail |
| LightbarGreenCurrent | 0 <= X <= 100000 | Pass Fail |
| LightbarBlueCurrent | 0 <= X <= 100000 | Pass Fail |
| LightbarWhiteCurrent | 0 <= X <= 100000 | Pass Fail |
| UxLampWhiteCurrent | 0 <= X <= 100000 | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Fluidics Qualification

## Pump Drive

Open the file PumpDriveReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (s) | Result |
| --- | --- | --- |
| PumpAspirateResponseTime1500 | X <= 9999 | Pass Fail |
| PumpDispenseResponseTime1500 | X <= 9999 | Pass Fail |

## Pump Valve

Open the file PumpValveReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification (s) | Result |
| --- | --- | --- |
| WasteToFlowcellResponseSeconds | 0<= X <= 0.7 | Pass Fail |
| FlowcellToWasteResponseSeconds | 0 <= X <= 0.7 | Pass Fail |

## Reagent Valve

Open the file ReagentValveReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

The actual values can be a negative number. Enter the absolute value if the actual value is a negative number.

| Test | Specification (s) | Result |
| --- | --- | --- |
| MovePort6to20\_ResponseTime | 0 <= X <= 10 | Pass Fail |
| MovePort20to10\_ResponseTime | 0 <= X <= 10 | Pass Fail |
| MovePort10to20\_ResponseTime | 0 <= X <= 10 | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Heaters Qualification

## CMOS Heater Verification

Open the file HeatersReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification | Result |
| --- | --- | --- |
| CmosHeaterRampDurationTo60 | X <= 300 (ms) | Pass Fail |
| CmosTemperatureStabilityAt60 | X <= 0.5 (degrees C) | Pass Fail |
| CmosHeaterCoolingRampDurationTo40 | X <= 600 (ms) | Pass Fail |

## Sample Heater Verification

Open the file HeatersReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification | Result |
| --- | --- | --- |
| SampleHeaterEngageTime | 0 <= X <= 10000 (ms) | Pass Fail |
| SampleHeaterDisengageTime | 0 <= X <= 10000 (ms) | Pass Fail |
| SampleHeaterRampDuration | X <= 480 (s) | Pass Fail |

## Pogo Block

Open the file PogoBlockReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification | Result |
| --- | --- | --- |
| CmosRtdTemperatureMilliDegreesCelcius | 0 <= X <= 100000 (mC) | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# RFID Qualification

Open the file RfidReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification | Result |
| --- | --- | --- |
| RfidTagReadSuccessful | X >= 1 | Pass Fail |
| RfidRssi | 2<= X <= 7 | Pass Fail |
| RfidReadWriteCompare | X >= 1 | Pass Fail |
| RfidReadWriteCompareInverted | X >= 1 | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Thermal and Fans

Open the file ThermalAndFansReport1.csv and find the following Test parameters in the file. Then compare the Specification with the value in the report file and check the appropriate Result.

| Test | Specification | Result |
| --- | --- | --- |
| Pdb1Temperature | 0 <= X <= 100 (C) | Pass Fail |
| Pdb2Temperature | 0 <= X <= 100 (C) | Pass Fail |
| IdbTemperature | 0<= X <= 100 (C) | Pass Fail |
| Pdb1Humidity | 0 <= X <= 100000 (m%) | Pass Fail |
| Pdb2Humidity | 0 <= X <= 100000 (m%) | Pass Fail |
| LEDFanPPM | X >= 8000 (ppm) | Pass Fail |
| SystemCoolingFanPpm | X >= 8000 (ppm) | Pass Fail |
| CmosHeaterFanPpm | X >= 13000 (ppm) | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Software Identification

Record the software version number in the field below.

|  |  |
| --- | --- |
| Software | Version |
| iSeq 100 Control Software (in the menu at the top left, select About) | Type here. |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

# Summary Operational Qualification Result

|  |  |  |
| --- | --- | --- |
| Qualification Type | Specification | Result |
| Operational Qualification | Meets all specifications. | Pass Fail |

|  |
| --- |
| Comments (Enter N/A if no comments) |
| Type here. |

Illumina Certification

I certify that all information I have provided in this document is true and accurate. I certify that all tests I have performed were conducted in accordance with published Illumina procedures that apply to the instrument listed on this form.

|  |  |
| --- | --- |
| Illumina Personnel Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Printed Name | Type here. |
| Printed Title | Type here. |
| Date | Click or tap to enter a date. |