

Axicon linear series barcode verifier

Installation and Operational Qualification results form



Equipment being validated

Axicon model:

Serial number:

Test performed: Full / Partial (if partial then specify)

Installation qualification (IQ):

Operational qualification (OQ):

Name:

Position within company:

Date:

Installation Qualification

Test protocol results

(IQ) Test 1 Standard equipment (page 5 of the instruction book).

| Required | Results |
|---|---------|
| Axicon model number | |
| Serial number of verifier | |
| User guide | |
| Calibration card | |
| Serial number of calibration card | |
| Expiry date of calibration card (one year from test date) | |
| CD containing installation software | |
| Software version number | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 2 Software installation (page 6 of the instruction book)

| Required | Results |
|---|---------|
| Administrator rights to install software? | |
| Administrator rights to update software? | |
| Name of administrator | |
| Contact details of administrator | |
| The location of the software installation | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 3 Hardware installation (page 7 of the instruction book)

| Required | Results |
|------------------------------------|---------|
| USB drivers for verifier installed | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 4 Optional plugins features (page 7 of the instruction book)

| Required | Results |
|---|---------|
| Note the installation directory for the plugins | |
| List all activated plugins | |

Examiner signature: Date:

Confirmed by: Date:

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(IQ) Test 5 Calibration card (page 8 of the instruction book)

| Required | Results |
|---|---------|
| Calibration card certificate of conformance - serial number | |
| Does serial number on the calibration card match that on the certificate? | |
| The calibration card is still valid? | |
| Confirm that the calibration card has not been damaged or discoloured. | |
| The Rmin figure shown on the calibration card | |
| The Rmax figure shown on the calibration card | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 6 Calibration of verifier (page 8 of the instruction book)

| Required | Results |
|---|---------|
| Rmin figure in the dialogue box. | |
| Rmax figure in the dialogue box. | |
| Confirm that both Rmin and Rmax figures are the same as those shown on the calibration card | |
| Confirm that the initial calibration has been performed successfully. | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 7 Setup, general (page 9 of the instruction book)

| Required | Results |
|--|---------|
| “Standards” selected | |
| “Unit of Measurement” selected | |
| Confirm that “GS1 Genspec” box is ticked on | |
| Confirm ‘GS1 Scanning Environment’ required. | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 8 Setup, Check character (page 10 of the instruction book)

| Required | Results |
|--|---------|
| Interleaved 2 of 5 settings - Check digit validation on/off. | |
| Code 39 settings - Check digit validation on/off. | |
| Codabar settings - Check digit validation on/off. | |
| MSI Plessey settings - Check digit validation on/off. | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 9 Setup, appearances (page 11 of the instruction book)

| Required | Results |
|-------------------------|---------|
| Pass/Fail colours | |
| Pass/Fail sounds | |
| Pass/Fail screen format | |
| Warnings colours | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 10 Setup, printing (page 12 of the instruction book)

| Required | Results |
|--------------------------|--------------------------|
| Print Command settings | Standard report |
| | Reflectance report |
| | Dimensional analysis |
| | Traditional analysis |
| | Custom report via RepGen |
| Report Generator options | |
| Autoprint settings | |
| Font Size settings | |
| Graph settings | |
| Print Header settings | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 11 Setup, logging (page 13 of the instruction book)

| Required | Results |
|--|---------|
| Autosave setting | |
| Location of scan files | |
| Saved File Log settings - location | |
| Saved File Log settings - command parameters | |
| Saved File Log settings - saving options | |
| Simple CSV file settings | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 12 Setup, calibration (page 15 of the instruction book)

| Required | Results |
|--|---------|
| Location of calibration log file | |
| Frequency of calibration | |
| Action after calibration period has expired | |
| Requirement for calibration password | |
| Any changes to list of allowable codes (write "default" if default list is used) | |
| Calibration scan action - plugins | |
| Calibration scan action - Autosave | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 13 setup, plugins (page 16 of the instruction book)

| Required | Results |
|--|---------|
| The installed plugins and their configuration settings | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 14 Setup, email (page 17 of the instruction book)

| Required | Results |
|-----------------------|---------|
| E-mail details | |
| Configuration details | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 15 Setup, advanced (page 18 of the instruction book)

| Required | Results |
|---|---------|
| Password details (or a note of where the information is stored) | |
| All non-default settings | |

Examiner signature: Date:

Confirmed by: Date:

(IQ) Test 16 21 CFR part 11 (page 19 of the instruction book)

| Required | Results |
|--|---------|
| Decision about whether to configure system to meet FDA requirements. | |
| Details of configuration, if FDA requirements are necessary | |

Examiner signature: Date:

Confirmed by: Date:

Summary of tests for Installation Qualification

| Required | Completed |
|--|-----------|
| Confirm that all entries have been completed. | |
| Confirm that all appropriate boxes have been initialled and dated. | |
| Enter name of person completing this document | |
| Enter position of person completing this document | |
| Enter company of person completing this document | |

Examiner signature: Date:

Confirmed by: Date:

Final assessment

If all the tests have been passed, the verifier has passed its Performance Qualification, and the following certificate of conformance may be completed. If any of the tests has failed, contact Axicon or your reseller to arrange for the verifier to be serviced.

Certificate of Installation Qualification

This is to certify that I have checked the following verifier today:

Axicon verifier model:

Serial number:

in accordance with the Axicon Installation Qualification test protocol.

The verifier will now operate in accordance with Axicon's specifications and has been configured to meet the user's requirements.

Examiner signature: Date:

Confirmed by: Date:

Company name:

Operational Qualification

Test protocol results

(OQ) Test 1 hardware connections (page 21 of the instruction book)

| Required | Results |
|----------------------|---------|
| Hardware connections | |

Examiner signature: Date:

Confirmed by: Date:

(OQ) Test 2 Calibration card details (page 21 of the instruction book)

| Required | Results |
|---|---------|
| Calibration card's serial number | |
| Serial numbers on calibration card and its certificate match. | |
| The calibration card has not expired. | |
| Calibration card is clean and undamaged. | |
| Rmin figure shown on card | |
| Rmax figure shown on card | |

Examiner signature: Date:

Confirmed by: Date:

(OQ) Test 3 Calibration record (page 22 of the instruction book)

| Required | Results |
|--|---------|
| Rmin figure in dialogue box. | |
| Rmax figure in dialogue box. | |
| Rmin and Rmax figures match those on card. | |
| Calibration has been performed successfully. | |

Examiner signature: Date:

Confirmed by: Date:

(OQ) Test 4 Calibration record 2 (page 22 of the instruction book)

| Required | Results |
|--|---------|
| Check ambient lighting consistency since last calibration | |
| Check ambient temperature consistency since last calibration | |
| Re-calibration performed | |

Examiner signature: Date:

Confirmed by: Date:

Summary of tests for Operational Qualification

| Required | Completed |
|--|-----------|
| Confirm that all entries have been completed. | |
| Confirm that all appropriate boxes have been initialled and dated. | |
| Enter name of person completing this document | |
| Enter position of person completing this document | |
| Enter company of person completing this document | |

Examiner signature: Date:

Confirmed by: Date:

Final assessment

If all the tests have been passed, the verifier has passed its Performance Qualification, and the following certificate of conformance may be completed. If any of the tests has failed, contact Axicon or your reseller to arrange for the verifier to be serviced.

Certificate of Operational Qualification

This is to certify that I have checked the following verifier today:

Axicon verifier model:

Serial number:

in accordance with the Axicon Installation Qualification test protocol.

The verifier will now operate in accordance with Axicon's specifications and has been configured to meet the user's requirements.

Examiner signature: Date:

Confirmed by: Date:

Company name: