

Axicon linear series barcode verifier

Installation and Operational Qualification results form v5



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)	
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 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:

(IQ) Test 4 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 5 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 6 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 7 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 8 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 9 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 10 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 11 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 12 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, advanced (page 17 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:

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:

(IQ) Test 15 21 CFR part 11 (page 18 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:

Final assessment

If all the tests have been passed, the verifier has passed its Installation 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

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Confirmed by: Date:

Company name: