THE BARCODE EXPERTS

Axicon 15000 series barcode verifier

Installation and Operational Qualification results form V13



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	
Calibration card is valid	
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 camera verifier installed	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 4 Setup, appearances (page 7 of the instruction book).

Required	Results
Measurement units	
Colour for “Pass”	
Colour for “Warning”	
Colour for “Fail” Messages	
Option chosen for Pass Grade	
State minimum pass grade	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 5 Setup, plugins (page 8 of the instruction book).

Plugin list	Default	Changes made from default
80% Aperture	Off	
Brazil Healthcare	Off	
CIP	Off	
Code 39 Check Character	On	
DAVA Healthcare	Off	
GS1 Composite Linked Codes	On	
GS1 Data Content	Off	
GS1 Distribution	On	
GS1 Documents, Assets & Locations	On	
GS1 Global Service Relation Numbers	On	
GS1 Healthcare (bedside)	Off	
GS1 Healthcare Retail	On	
GS1 Logistic units	On	
GS1 Long distance scanning	Off	
GS1 Pharmacy & Distribution	On	
GS1 Retail	On	
GS1 Retail 2D	Off	
GS1 Retail & Distribution	Off	
GS1 UPC Human Readable	On	
HDA Shipping Case	Off	
HIBC	On	
ITF Check Digit	On	
Japanese convenience store	Off	
Latin-1 message	Off	
Luhn Check Digit (ITF)	Off	
MIL-STD-130N	Off	
Performance Qualification	Off	
Pharma Pack	Off	
Portuguese Medicines	Off	
PZN - Code 39	On	
Russian Dairy	Off	
Russian Pharmacy	Off	
Shift JIS Message	Off	
Turkish Healthcare	Off	
UTF-8 Message	On	

(IQ) Test 5 Setup, plugins (page 8 of the instruction book).

Required	Results
Allow multiple ‘Ask user’ plugins	
Allow to not apply any ‘Ask user’ plugin	
Default aperture setting	
When no plugins recommend an aperture (2D)	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 6 Setup, reports (page 9 of the instruction book).

Required	Results
Automatic file saving?	
Type of report	
Use Template Y/N?	
If enabled, which template tag used?	
Use Decode	
Use Time and Date	
Name of Output file used (Directory)	
Append option being used?	
Save as	
Allow Cancel?	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 7 Setup, saving (page 10 of the instruction book).

Required	Results
Autosave	
Autosave directory / Filename (if enabled)	
Use Template Y/N?	
If enabled, which template tag used?	
Use Decode	
Use Time and Date	
Save as	
Allow Cancel?	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 8 Lookup settings (page 12 of the instruction book).

Required	Results
If active, state ‘Lookup field’	
If active, state ‘results field’	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 9 Setup, user data (page 13 of the instruction book).

Required	Results
User Data activated?	
If Yes, List data fields	
If additional template files have been created, these should be listed	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 10 Setup, calibration (page 15 of the instruction book).

Required	Results
Rmin & Rmax set	
Calibration period set	
Prevent scanning if not calibrated	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 11 Settings for restricting users (page 15 of the instruction book).

Required	Results
State if the settings have been locked by the main user, and who this user is. Explain if any other restrictions have been made, and what they are	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 12 Settings for QR Code and DPM (page 18 of the instruction book).

Required	Results
State if the one module quiet zone for QR Code has been enabled	
State if the Direct Part Marking has been enabled	
State if the Enable Toolbar button has been enabled	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 13 Title 21 CFR Part 11 settings (page 18 of the instruction book).

Required	Results
State here how the verifier has been set up to meet these requirements, including names of users, time-out settings, and how saving of files has been established	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 14 Calibration authorisation (page 18 of the instruction book).

Required	Results
Users with details of permissions settings for the calibration function	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(IQ) Test 15 Audit log settings (page 20 of the instruction book).

Required	Results
Audit log enabled	
If Yes, enter file location	
Enter data range	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

Summary of tests for Installation Qualification

Test Number	Required	Completed
Test 1	Standard equipment	
Test 2	Software installation	
Test 3	Hardware installation	
Test 4	Setup – Appearances	
Test 5	Setup -Activate plugins + aperture settings	
Test 6	Setup – Saving reports	
Test 7	Setup – Saving scan files	
Test 8	Setup – Lookup	
Test 9	Setup - User data requirements	
Test 10	Setup - Calibration settings	
Test 11	Setup – Restricting users	
Test 12	Setup - QR Code and DPM settings	
Test 13	Setup - Title 21 CFR Part 11 settings	
Test 14	Set up – Calibration authorisation	
Test 15	Set up – Audit log settings	

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 have 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 Calibration (page 23 of the instruction book).

Required	Results
Serial numbers of calibration card and the certificate of conformance match	
Calibration card is not showing signs of wear or damage	
The certificate of conformance is valid	
“Calibration Successful” result	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

(OQ) Test 2 Operational Qualification protocol (page 29 of the instruction book).

Required	Results
All entries have been completed	
All appropriate boxes have been initialled and dated	
Name of person completing this document	
Position of person completing this document	
Company of person completing this document	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

Summary of tests for Operation Qualification

Test Number	Required	Completed
Test 1	Calibration card and calibration	
Test 2	Verifier and plugins function as expected	

Examiner Signature: ..... Date: .....

Confirmed by: ..... Date: .....

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 Operational 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: .....

This document was made using:
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