axicon

THE BARCODE EXPERTS

Axicon 15000 series barcode verifier

Installation and Operational Qualification

results form V7

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	
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	

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

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

Plugin list	Default	Changes made
80% Aperture	Off	
Brazil Healthcare	Off	
CIP	Off	
Code 39 Check Character	On	
DAVA Healthcare	Off	
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 (point of sale)	On	
GS1 Retail (point of sale) & Distribution	Off	
GS1 UPC Human Readable	On	
HIBC	On	
ITF Check Digit	On	
Luhn Check Digit (ITF)	Off	
MIL-STD-130N	Off	
Performance Qualification	Off	
Pharma Pack	Off	
Portuguese Medicines	Off	
Russian Dairy	Off	
Russian Pharmacy	Off	
Turkish Healthcare	Off	
UTF-8 Message	On	

Required	Results
List all activated plugins with their status (On, Always Show, or Ask User)	
Allow multiple 'Ask user' plugins	
Allow 'Ask user' plugins to be switched off	
Default aperture setting	

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

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

Required	Results
Automatic file saving?	
Report format set	
Name of Output file used	
Append option being used?	

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

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

Required	Results
Autosave	
Autosave directory / Filename (if appending is enabled)	
Decode	
Use Time and Date	
Save as	
Allow Cancel?	

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

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

Required	Results
State if a database has been established to use as the basis for Lookup, and provide relevant details about this, and the data that is to be displayed and recorded.	

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 settings have been enabled.	
State if the Direct Part Marking setting have 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, export to CSV location	

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 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 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: ....

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