Installation Qualification and Operational Qualification for

SG Systems Traceability Suite V5.8

Customer Address

This document contains the process for performing a combined Installation Qualification (IQ) and Operational Qualification (OQ) for SG Systems Traceability Suite V5.8.

The Customer must review, agree and approve the contents of this document before execution of the document can begin.

E-signature 1: Customer Pre-Execution Approval of the IQ/OQ Document
Date:

Document Status

Version	Date	Reason for Change	Status
V 1.0	23 Jan 2023	Final document approved	Final

Contents

1 Introduction

1.1 Purpose

This combined installation qualification (IQ) and operational qualification (OQ) document is applicable to the installation of the SG Systems V5 Traceability Suite of applications (V5.8) and to confirm that the components function in the intended manner.

The SG Systems V5.8 components will be installed and qualified remotely for the Customer via the use of a suitable remote access method.

A generic system outline configuration is shown in Section 4. This can be customized to suit a customer's individual requirements.

1.2 Referenced Documents

The following documents are referenced by this combined installation qualification / operational qualification (IQ & OQ) document.

1.2.1 SG Systems

- V5.8.0 Release – Activation Guide
- V5 Site Setup & Installation Guide - https://support.sgsystemsglobal.com/v5/v5-installation-guide/
- V5 System Requirements - https://support.sgsystemsglobal.com/v5/system-requirements/

1.2.2 Regulations

- Current Good Manufacturing Practice for Finished Pharmaceutical Products, 21 CFR 211.63
  Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and ***suitably located*** *to facilitate operations for its intended use and for its cleaning and maintenance*.
- EU / PIC/S GMP Annex 15 Clause 2.5
  Qualification documents may be combined together*, where appropriate, e.g. installation qualification (IQ) and operational qualification (OQ*).
- EudraLex - Volume 4 Good Manufacturing Practice (GMP) Guidelines, Glossary. 2004, European Commission: Brussels (Qualification definitions used in Section 2.6)

1.2.3 Industry Guidance Documents

- FDA Draft Guidance for Industry, Computer Software Assurance for Production and Quality System Software, September 2022
- GAMP 5 A Risk-Based Approach to Compliant GXP Computerized Systems, Second Edition, July 2022. International Society of Pharmaceutical Engineers, Tampa, FL.

1.2.4 Specifications of Peripheral Components

Manufacturers information and specification documents:

- Axiomtec Terminal, model GOT815-834 information and specification
- Godex RT700i/RT730i Desktop Printer information and specification
- Getac Technology Corporation T800 Tablet information and specification
- Honeywell Granit XP 1991 iSR Wireless Area-Imaging Scanner
- Honeywell Granit 1980i Full-Range Area-Imaging Scanner

2 Overview of the Integrated IQ and OQ

2.1 Rationale for the Integrated IQ and OQ Approach

This IQ & OQ is for a customer installation and integration of all V5 system components of the SG Systems Traceability Suite on a single qualified network server. The focus of the IQ to ensure that the individual applications have each been correctly installed, integrated together and work as a system.

- Set up of the server is performed by the customer
- Peripherals are installed remotely at predefined locations by SG Systems personnel.

The OQ requires a customer tester to assist the SG representative in the steps outlined in Section 7 to check that all applications and additional components are correctly installed, ready to hand over to the customer reviewer. The premise behind this approach is that if the software or components have not been installed properly, then they will not function correctly.

2.2 Responsibilities for Tasks Performed in this Qualification Document

As installation of the software and integration of peripheral components are performed remotely by SG Systems staff, there is a need for the customer to undertake preparatory work.

2.2.1 Customer Responsibilities

- Review and approve this IQ/OQ document prior to its execution.
- Provide a server meeting or exceeding recommended specifications for the installation.
- Grant access to SG Systems via a suitable remote access method. This will be done with individually named accounts.
- Connect the required peripherals (terminals, tablets, printers, scanners and scales etc.) to the customer network.
- Static IPs must be applied to all devices and appropriate peripherals.
- Provide remote access to each device for the SG Systems engineer to perform this qualification.
- Aid the SG Systems engineer in the OQ steps outlined in section 7.

- Review and approve the completed qualification document.

2.2.2 SG Systems Responsibilities

- Provide an IQ/OQ qualification document reflecting the customer needs in terms of peripherals to be connected, licensed and integrated into the V5 system.
- Access to the customer IT environment for remotely executing this qualification.
- Complete the sections of the qualification document electronically.
- Hand over the completed qualification document to the customer for review and approval.

2.3 Electronic Evidence of Qualification

The test evidence generated by executing this combined IQ/OQ document will be maintained within the customer's V5 system database.

No screen shots will be taken during the execution of this document as recommended by the GAMP 5 and the draft FDA Guidance on Computer Software Assurance (CSA) as shown in the quotations below.

GAMP 5 2nd Edition states in Section 8.5.3 on Secondary Test Evidence:

> *The generation and retention of secondary supporting hard copy or image evidence such as screen shots, in addition to the primary test result or output, is unnecessary in most cases and does not add value. It often adds significant cost without associated benefit, as well as adding unnecessary complexity. Such additional evidence should be generated and maintained only where value-added and necessary for effective testing*.

FDA's draft CSA Guidance states in lines 577 – 582:

> *Advances in digital technology may allow for manufacturers to leverage automated traceability, testing, and the electronic capture of work performed to document the results, reducing the need for manual or paper-based documentation. As a least burdensome method, FDA recommends the use of electronic records, such as system logs, audit trails, and other data generated by the software, as opposed to paper documentation and screenshots, in establishing the record associated with the assurance activities*.

2.4 Customer Prerequisites

The following special conditions apply before this combined IQ & OQ can be executed:

- The server where the software will be installed have to have been installed and qualified by the customer; any errors that occurred must have been resolved satisfactorily.
- The customer must provide remote access credentials to SG Systems using a suitable remote access method.
- The customer must provide the name of their representative who will be undertaking the Operational Qualification in Section 7.
- Prepare a controlled and uniquely numbered form to affix the labels printed from each printer during execution of Section 7.3. This will have a header 'V5 Traceability Version 5.8 IQ OQ Test Labels'.

2.5 SG Systems Prerequisites

The following special conditions apply before this combined IQ & OQ can be executed. The following actions must be completed by the SG Representative who will be undertaking the installation:

- The customer's Virtual Factory environment will be used to create the following:
  - 'Test Commodity' – a lot of this must also be created using WMS – assign a suitable quantity.
  - 'Test Formula' requiring only a small quantity of 'Test Commodity'.
  - Create a user account for the Customer Representative as required by Section 2.4, ensuring that username and password is correctly set up.
- The customer's 'Company Info' must be completed to reflect the installation location.
- The customer's database must be exported and converted for use in Microsoft SQL.
- Any customer application configurations should also be exported & username/password config applied.
- Any custom Column Definitions/other files that will be required for integration with the customer ERP must be finalized.

2.6 Definitions

The following terms and abbreviations are used in this document.

Term / Abbreviation	Definition or Meaning
Installation Qualification (IQ)	Documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations (EU GMP Annex 15)
Operational Qualification (OQ)	The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges (EU GMP Annex 15)
Qualification	Action of proving that any equipment works correctly and actually leads to the expected results (EU GMP Glossary)
WMS	V5 Application – Warehouse Management System
CC	V5 Application – Control Center
Terminal	V5 Application – Terminal
V5 App(s)/Application(s)	Refers to one, or more, of the V5 applications

2.7 Assumptions, Exclusions and Limitations

The following assumptions, exclusions and limitations apply to this combined IQ & OQ document

- The assumption behind the combined IQ and OQ approach is that the software has been extensively tested by the supplier. If not correctly installed and integrated with the utilities listed in section 6.1.1, the system will not work. The system administrator log-on is the quickest way to demonstrate this fact.

- It is assumed that the installer of the software has read the installation guide for the application and that if there any issues found during the execution of this IQ & OQ, the installer can refer to this installation guide in the first instance.
- It is assumed that any customer-provided hardware will meet the required standards to operate within the V5 environment.
- All information in Section 5 will be provided by the customer, excluding Section 5.13, which it is assumed will be undertaken by a qualified scale technician.
- V5 applications installed on the customer's server are excluded from the OQ process as the SG representative will be able to fully verify that these work as intended.
- Customer configurations of V5 applications are excluded from the IQ process and will be applied at the end of the OQ process, before the system is signed off. The rationale behind this is that configurations do not affect whether the system functions or not, rather how it functions.
- The exact version of V5 apps installed will be specified by the SG representative in Section 6 as V5.8.x.

3 Qualification Protocol Execution Instructions

3.1 Preparation for Execution

- This combined IQ/OQ must be reviewed and approved by the customer using an electronic signature before it can be executed.

3.2 Customer Pre-requisites

- The customer must complete Section 5 to confirm that the server meets recommended requirements and that all peripherals are connected to the internal IT network.
- Customers must provide desired display names for all V5 applications, scales & printers in Section 5. This will help the customer identify each device within V5.
- Customer then electronically signs the section to confirm that it is complete and correct.
- Any initial errors or defects with customer supplied hardware and network infrastructure must be resolved by the customer.
- Any initial errors or defects with hardware supplied by SG Systems must be resolved by SG Systems.

3.3 SG Systems Salesforce

- The hardware information detailed in Section 5 will be used to set up the service contract and the License Key generated. This step must be completed prior to Section 6.

3.4 SG Systems Engineer

- The SG Systems engineer checks that the protocol has been approved by the customer and that the pre-requisites section has been completed fully and approved by the customer
- Use two screens to complete this work: one for execution of the work and the second for contemporaneously completing this IQ/OQ protocol

- If either of these have not been performed, then the engineer cannot execute the qualification protocol
- A trained SG Systems engineer will execute the tasks in this IQ/OQ protocol remotely.
- A customer will review the completed protocol work to confirm that the work has been completed satisfactorily and any deviations are recorded and resolved.
- The SG Systems engineer documents the results of qualification at the end of each test procedure.
- The SG Systems engineer documents a summary of the qualification in Section 9 of the protocol.
- Any issues that arise during execution of the IQ must be resolved between the SG and customer representatives.

3.5 Instructions for Completing the Test Steps

- Carry out the test steps in strict order, from the beginning to the end of each section.
- It is acceptable for SG representatives to hand over the IQ/OQ process to another trained individual at any given time due to shift time constraints. The change will be documented by a different electronic signature on the executed IQ/OQ protocol.
- If there are any problems encountered, enter the issue in the first available Deviation Note (e.g. D1, D2 etc.) and complete the corresponding number in section 8.
- Execution must be halted if the observed difference is critical (i.e. if it is not possible to follow the test instructions any further), and results in failure.
- Raise a Deviation Note in Section 8 and document any corrective action taken.

3.6 Documented Evidence

- The following records will be used as the primary record of work performed in this qualification protocol:
    - The activation of the V5 system and who performed the activation will be stored in the customer's V5 database
    - The first successful connection of each V5 app, who performed this action, as well as the software version installed, will be stored in the customer's V5 database
- As documented in Section 2.3 no printouts of these electronic records will be made
- The reviewer needs to access the electronic records to confirm that work has been performed. This can be done via the customer's V5 database, hosted on their server.

3.7 Acceptance Criteria for each Test Procedure

- The acceptance criteria for each test procedure are listed at the end of the section for each test.
- The tester must review the Acceptance Criteria, determine whether they were met by the test, and whether each one has a Pass, Conditional Pass or Fail status.
- If the acceptance criterion is met, 'PASS' is recorded for the related test steps using DocuSign.
- If 'Conditional Pass' has been assigned against the related test steps, then type 'CONDITIONAL PASS'.
- If 'Fail' have been assigned against any related test step, then type 'FAIL'
- The Tester identifies any deviations associated with the test procedure from Section 8

- If 'Pass' is recorded for all acceptance criteria, then write 'PASS' in the space provided for the whole test procedure.
- If 'Conditional Pass' has been assigned against any acceptance criterion, then write 'CONDITIONAL PASS' in the space provided for the whole test procedure.
- If 'Fail' has been assigned against any acceptance criterion, then write 'FAIL' in the space provided for the whole test procedure.
- The tester then electronically signs the procedure entries in the space provided.

3.8 Documenting Qualification Deviations

- Any deviation from the instructions in this qualification document must be recorded in the Deviation section (Section 8).
- Details of the problem must be recorded against the first available Log number, (prefaced 'D'), e.g. D1.
- Reference the assigned Log number in the IQ or OQ Section where the deviation occurred.
- Each Deviation entry must be electronically signed by the SG Engineer.
- At the end of the Qualification, if there are no deviations or deviations not required, the SG Engineer must type into each unused deviation note, not applicable and electronically sign each one.

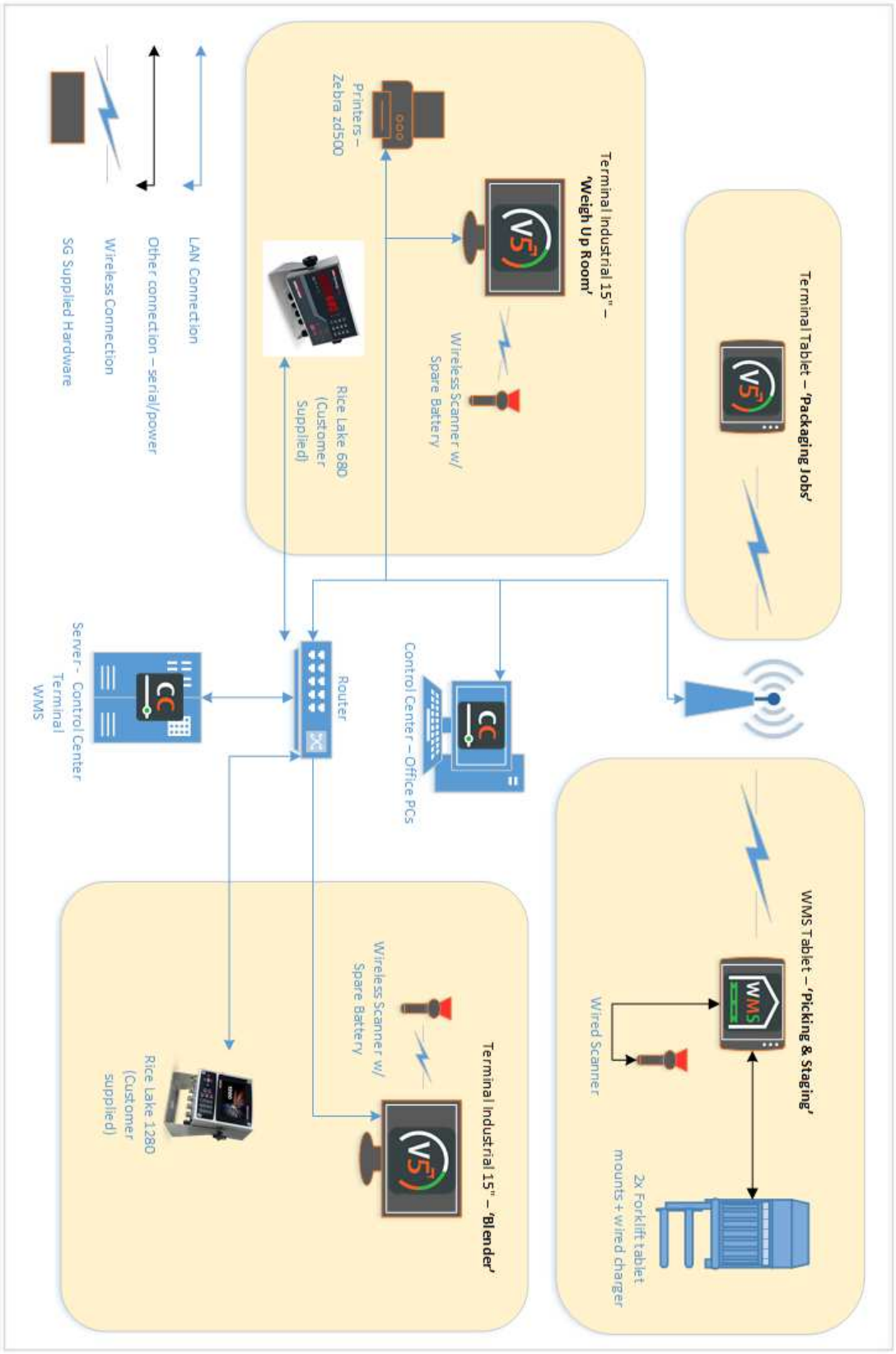
3.9 IQ/OQ Protocol Approval

- The SG Systems representative must complete the statement in Section 9 that the system has Passed, Conditionally Passed or Failed the qualification by selecting the applicable option.
    - PASS should be recorded if all test procedures in the test script have passed.
    - CONDITIONAL PASS should be recorded where one or more test procedures have been assigned a Conditional Pass, but no 'Fails' have been recorded.
    - FAIL should be recorded where the system fails one or more test procedures.

3.10 Document Review

- A reviewer from the customer checks the test script for accuracy and completeness after the customer tester has finished and signed off their work. The role of the reviewer is to ensure:
    - All sections of the test script have been completed.
    - The reviewer agrees with the conclusions reached by the SG and customer testers at the end of each test.
- The reviewer checks the test log to confirm each table has been completed correctly. When necessary, deviations should be read and understood.
- At the end of the script, the reviewer signs off Section 10 to confirm the conclusions of the tester.

4 System Configuration



5 Confirmation of Customer Pre-Installation Checks

This section must be completed by the customer before later sections of the document can commence.

5.1 Server

Recommended Specification	Actual	
Make and Model		
Physical or Virtual Server		
Windows Server 2016 or later		
64-bit architecture		
2.8GHz Processor (Quad Core)		
500GB Hard Disk Space		
16 GB Ram		
Network Connection		
IP Address		
MAC Address		
Required Software Modules	Control Centre ☑	
	WMS ☑	
	Terminal ☑	
V5 App Names	Control Centre	
	WMS	
	Terminal	
Remote Access Method		
Login details sent to SG? (Y/N)		

E-signature 2: Customer Confirmation of Server Pre-requisites

5.2 Office

5.2.1 Office PC

Make and Model	
Serial No	
Windows 10 or later	
64-bit architecture	
2.8GHz Processor (Quad Core)	
10GB Hard Disk Space	
8 GB Ram	
Network Connection	
IP Address	
MAC Address	
Required Software Module(s)	Control Centre ☑ WMS ☒ Terminal ☒
V5 App Name – Control Center	

E-signature 3: Customer Confirmation of Office Pre-requisites

5.3 Weigh Up Room

5.3.1 Device Information

Make and Model	Axiomtec GOT815-834
Serial No	
IP Address	
MAC Address	
Network Connection	
Required Software Module(s)	Control Centre ☒ WMS ☒ Terminal ☑
V5 App Name – Terminal	

5.3.2 Peripherals

Make and Model	Serial No	IP Address	V5 Name
Printer: Godex RT700i		IP:	
Wireless Scanner: Honeywell Grant XP 1991iSR		N/A	N/A
Rice Lake 680		IP:	

E-signature 4: Customer Confirmation of Weigh-up Room 1 Pre-requisites

5.4 Blender

5.4.1 Device Information

Make and Model	Axiomtec GOT815-834
Serial No	
IP Address	
MAC Address	
Network Connection	
Required Software Module(s)	Control Centre ☒ WMS ☒ Terminal ☑
V5 App Name – Terminal	

5.4.2 Peripherals

Make and Model	Serial No(s)	IP Address(es)	V5 Name(s)
Wireless Scanner: Honeywell Grant XP 1991iSR		N/A	N/A
Rice Lake 1280		IP:	

E-signature 8: Customer Confirmation of Blender 1 Pre-requisites

5.5 Packaging Jobs

5.5.1 Device Information

Make and Model	Getac T800
Serial No	
IP Address	
MAC Address	
Network Connection	
Required Software Module(s)	Control Centre ☒ WMS ☒ Terminal ☑
V5 App Name – Terminal	

E-signature 10: Customer Confirmation of Packaging Job 1 Pre-requisites

5.6 Picking & Staging

5.6.1 Device Information

Make and Model	Getac T800
Serial No	
IP Address	
MAC Address	
Network Connection	
Required Software Module(s)	Control Centre ☒ WMS ☑ Terminal ☒
V5 App Name – WMS	

5.6.2 Peripherals

Make and Model	Serial No	IP Address	V5 Name
Wired Scanner: Honeywell Grant XP 1980i		N/A	N/A

E-signature 12: Customer Confirmation of Picking and Staging 1 Pre-requisites

5.7 Additional Scale Information

SG Systems will require additional information to complete the configuration of each scale that is to be utilized in the V5 system. This should be provided below by the customer or their qualified scale technician.

Scales **must** be set to continuous output once correctly calibrated in order to correctly function with the V5 system.

Model	Serial #	Units	Capacity	Decimals	Databits	Baud rate	IP Address	Network Port
RL 680								
RL 1280								

E-signature 14: Customer Confirmation of Additional Scale Information

5.8 Confirmation that Installation Pre-Requisites Are Completed Correctly

The SG Systems Engineer confirms that all installation pre-requisites have been completed correctly by the customer and that the Installation Qualification can begin.

E-Signature 15: SG Systems Engineer E-signature / Date

6 Installation Qualification

6.1 Installation & Activation of V5 on Customer Server.

6.1.1 Server Installation Procedure

1. Confirm that, per Section 5, the customer has installed a remote access tool and has provided relevant login details which allow SG support representatives access to a Windows account on the customer's server with Administrator privileges.
2. Remotely log in to this account and install the following software: in the following order:
   - SQL Database - MSSQL Server 2017.
   - SQL Database Management Studio 18.
   - The customer's database from the Virtual Factory / Consultancy Period phase.
   - TIBCO JasperReports Server for electronic reporting – v7.1.0 + SG configuration (bundles with Apache TomCat)
   - Java Runtime Environment (JRE) 1.8 – 64bit update 144.
   - UltraVNC viewer 1.2.10 or above.
3. Use the 'SG Installer' to install all required V5 applications. The SG Representative must specify the exact version of each installed V5 application.
4. Activate V5 using Control Center. All MAC address and V5 device names should be provided by the customer in section 5 and input into Salesforce prior to this step.
5. Update Column Definitions that are required to make the SG Gateway function with external ERP (Baan).

6.1.2 Server Installation Log

Software	Version	Installation successful? ('Y'/'N')
1. SQL Database	MSSQL Server 2017	
2. SQL Database Management Studio	MSSM 18	
3. Customer database	N/A	
4. TIBCO JasperReports Server + Tomcat	7.1.0	
5. Java Runtime Environment (JRE)	1.8 – 64bit update 144	
6. UltraVNC viewer	1.2.10 or above	
7. SG Control Center		
8. SG Terminal		
9. SG WMS		
10. Column Definitions updated	N/A	

6.1.3 Activating V5 on the Customer Server

1. Note the assigned License Key from Salesforce: .....
2. Open the server Control Center module.
3. Select the 'Update License' option.
4. Select the 'Activate Online' option.
5. Enter the License Key and confirm.
6. Upon first entry of the license key, a dialogue box will appear, into which the SG technician will input their name. This information, along with activation timestamp, will be held in the database.
7. The list of contract items will be pulled from Salesforce and be displayed.
8. Control Center will then close and should be reopened again to use.
9. Once activation is complete, the SG representative will export a PDF of the 'system.statics' table from the MSSQL database. This can be done by viewing the table, right clicking and printing to PDF. This will be called 'V5 version 5.8 Activation.pdf' and kept on the customer's server desktop for the Quality Department to transfer to secure network storage.

E-signature 16: Installation & Activation of V5 on the customer server performed by & date:

6.2 Installation of Additional V5 Applications

6.2.1 Installation Procedure

1. The customer will be required to provide one-time access to each device using a Logmein123 remote support session.
2. The SG representative will then install the required software:
   i. Java Runtime Environment (JRE) – 1.8 – 64bit update 144
   ii. UltraVNC Server 1.2.10 or above (excludes CC devices)
   iii. The appropriate V5 apps for each device, specified in section 5, using the 'SG Installer'. The SG Representative must specify the exact version of each installed V5 application.
   iv. Teraterm scale application (v4.91) for the V5 apps that will be using scales.
3. The SG representative will run each V5 app once to confirm connection to the server.
   A dialogue will be presented upon the initial database connection for each unique V5 application install. The SG representative will input their name here and this, along with a timestamp, will be stored in the database against that app.
   They **cannot** sign this install off until connection can be established.
4. The SG representative will confirm VNC connection to each device from the server (if applicable). They **cannot** sign this install off until connection can be established.
5. Once installation of all V5 apps is complete, the SG representative will export a PDF of the 'terminals' table from the MSSQL database. This can be done by viewing the table, right clicking and printing to PDF. This will be called 'V5 Version 5.8 Terminals.pdf' and kept on the customer's server desktop.

6.2.2 Office PC Installation Log

Software	Version	Installation successful? ('Y'/'N')
1. Java Runtime Environment (JRE)	1.8 – 64bit update 144	
2. SG Control Center		
E-signature 17, Installation performed by & date		

6.2.3 Weigh Up Room Installation Log

Software	Version	Installation successful? ('Y'/'N')
1. Java Runtime Environment (JRE)	1.8 – 64bit update 144	
2. SG Terminal		
3. UltraVNC server	1.2.10 or above	
4. Teraterm	4.91	
E-signature 18, Installation performed by & date		

6.2.4 Blender Installation Log

Software	Version	Installation successful? ('Y'/'N')
1. Java Runtime Environment (JRE)	1.8 – 64bit update 144	
2. SG Terminal		
3. UltraVNC server	1.2.10 or above	
4. Teraterm	4.91	
E-signature 22, Installation performed by & date		

6.2.5 Packaging Jobs Installation Log

Software	Version	Installation successful? ('Y'/'N')
1. Java Runtime Environment (JRE)	1.8 – 64bit update 144	
2. SG Terminal		
3. UltraVNC server	1.2.10 or above	
E-signature 24, Installation performed by & date		

6.2.6 Picking & Staging Installation Log

Software	Version	Installation successful? ('Y'/'N')
1. Java Runtime Environment (JRE)	1.8 – 64bit update 144	
2. SG WMS		
3. UltraVNC server	1.2.10 or above	
E-signature 26, Installation performed by & date		

6.3 Installation of Printers

6.3.1 Printer Installation Procedure

1. Confirm that the customer has provided all relevant information for each printer in section 5.
2. Check connection to each printer's IP using a suitable web browser.
3. Use Control Center on the customer's server to add the required number of printers to the V5 system.

6.3.2 Printer Installation Log

Printer	Serial #	IP Address	V5 Name	Setup Complete ('Y'/'N')
Godex RT700i				
E-signature 28, Installation performed by & date				

6.4 Installation of Scales

6.4.1 Scales Installation Procedure

1. Confirm that the customer has provided all relevant information for each scale in section 5.13.
2. Gain access to each device that requires scale attachment via UltraVNC.
3. Using the information provided by the scale tech, configure the relevant scale settings files.

6.4.2 Scales Installation Log

Make/Model	Serial #	IP Address	V5 App Assignment(s)	Setup Complete ('Y'/'N')
Rice Lake 680				
Rice Lake 1280				
E-signature 29, Installation performed by & date				

6.5 Installation of Wired/Wireless Scanners

6.5.1 Scanner Installation Procedure

1. The customer is responsible for ensuring that scanners are connected to the correct devices, as per Section 5
2. The SG Representative will confirm the V5 app assignment for each scanner
3. The SG representative will send the appropriate barcode for a customer representative to scan in section 7

6.5.2 Scanner Installation Log

Scanner	Serial #	V5 App Assignment	Setup Complete ('Y'/'N')
1911i Wireless			
1911i Wireless			
1980i Wired			
E-signature 30, Installation performed by & date			

6.6 Acceptance Criteria for the Installation Qualification

Test Acceptance Criteria	Pass/CP/Fail
1. Installation of all required, non-V5 software on the customer server is successful.	
2. Installation of server V5 Applications is successful	
3. V5 Activation is successful.	
4. Installation of additional 'Control Center' modules is successful.	
5. Installation of all 'Terminal' modules is successful.	
6. Installation of all WMS modules is successful.	
7. Installation of all printers is complete.	
8. Installation of all scales is complete.	
9. Installation of all scanners is complete.	
10. Export of 'System Statics' table is complete. This will show the date/time of V5 activation and the SG tech who did it.	
11. Export of 'Terminals' table from customer database is complete. This will show the date/time of each V5 application's initial boot and the SG tech who did it.	
Test Procedure Passes, Conditionally Passes, or Fails.	
E-signature 31, Installation Qualification Performed by & date	
E-signature 32, Installation Qualification Customer Reviewed by & date	

7 Operational Qualification

7.1 Prerequisites to OQ Process

- The SG Representative must have successfully completed and signed off the Installation Qualification of the System components in Section 6 prior to starting the Operational Qualification.

7.2 Confirmation of Correct Installation of V5 Applications

7.2.1 Test Procedure

1. The SG Representative will provide a username and password for the customer tester to log in to V5, as outlined in Section 2.5.
2. The Customer will log on to each V5 app and confirm that it can connect to the server.
3. Correct setup is confirmed once username and password entry has been accepted and the V5 app's home window is shown. The customer can now log out of the software using the red x in the bottom left (Terminal), the exit symbol in the top left (WMS), or by logging out of Control Center under the 'Home' header at the top left.
4. ***It is assumed here that any server installed V5 apps have been installed and tested correctly by the SG Representative.***

7.2.2 Test Log

Location	V5 App	V5 App Name	Successful Login (Y/N)
Office PC	Control Center		
Weigh Up Room	Terminal		
Blender	Terminal		
Packaging Jobs	Terminal		
Picking & Staging	WMS		
E-signature 33, Customer SG Software Checkout performed by & date			

7.3 Confirmation of Correct Installation of Printers

7.3.1 Test Procedure

1. The SG Representative will print a test 'stock' label for a lot of 'Test Commodity' to each printer from the server's Control Center.
2. Each printed label will contain each printer's individual V5 name provided in Section 5. The SG representative should make these changes to the label between test prints.
3. Once all printers have had a test label sent, the Customer Representative will confirm that the label has printed with the correct V5 printer name
4. Stick all the labels to the controlled form defined in Section 2.4 called 'V5 Traceability Version 5.8 IQ OQ Test Labels'.

7.3.2 Test Log

Printer Serial #	Printer V5 Name	Successful Test Print (Y/N)

E-signature 34, Printer OQ Performed by & date

7.4 Confirmation of Correct Installation of Scales

7.4.1 Test Procedure

1. The Customer Representative will log in to each V5 app that will be using a scale using the username and password provided by the SG representative.
2. They will select the appropriate scale (if multiple scales are set up for 1 device) within the V5 app using the scale select screen. If the app is only using 1 scale, this will be selected by default.
3. They will then use 'Scale Only' mode in V5 Terminal to weigh a known quantity/calibration weight on the appropriate scale.
4. Test is a success if the correct weight is shown.

7.4.2 Test Log

Make/Model	Serial #	V5 Name	V5 App Assignment(s)	Correct Weight (Y/N)
Rice Lake 680				
Rice Lake 1280				

E-signature 35, Scale OQ checks performed by & date

7.5 Confirmation of Correct Installation of Scanners

7.5.1 Test Procedure – V5 Terminal

1. The Customer Representative will make use of the stock barcodes printed for Section 7.3.
    i. Another label can be printed here if needed.
2. They will log in to Terminal using the username and password code provided by SG.
3. Under the 'All Formulas' tab, they will navigate to 'Test Formula' and run it.
4. On the following 'Lot Select' screen for 'Test Commodity', they will scan the provided label.
5. If the scanner is functioning correctly, the lot will be selected and Terminal will proceed to the weigh screen.
6. The Customer Representative should then abort the batch and return to the Terminal main screen and exit the app.

7.5.2 Test Log

Scanner	Serial #	V5 Terminal Assignment	Successful Scan (Y/N)
1911i Wireless			
1911i Wireless			

E-signature 36, Scanner OQ performed by & date

7.5.3 Test Procedure – V5 WMS

1. The Customer Representative will make use of 1 of the stock barcodes printed for Section 7.3.
    i. Another label can be printed here if needed. The customer representative should inform the SG representative if this is the case.
2. They will log in to WMS using the username and password provided by SG.
3. They will scan the provided label.
4. If successful, this will open the commodity manager for that lot of 'Test Commodity'.

7.5.4 Test Log

Scanner	Serial #	V5 Terminal Assignment	Successful Scan (Y/N)
1980i Wired			

E-signature 37, Scanner OQ performed by & date

7.6 Confirmation of Correct App Configuration Assignments

7.6.1 Test Procedure – V5 App Configurations

1. The SG representative will apply all relevant application configuration settings from the server's Control Center. These will be sourced from the customer's virtual factory environment.
2. The SG representative will make note of the applied configuration for each V5 app.
3. Copies of the predefined configuration files will be left on the customer's server.
4. The SG representative will confirm successful application of the settings by connecting to each device and logging in once.

7.6.2 Test Log

Location	V5 App Name	V5 Type	Configuration File	Config Applied/Login successful (Y/N)
Server - CC		CC		
Server - Terminal		Terminal		
Server - WMS		WMS		
Office PC		CC		
Weigh Up Room		Terminal		
Blender		Terminal		
Packaging Jobs		Terminal		
Picking & Staging		WMS		

E-signature 38, App Configuration OQ performed by & date

7.7 Operational Qualification Acceptance Criteria

Test Acceptance Criteria	Pass/CP/Fail
1. Customer is able to log on to all V5 applications on all devices	
2. Customer confirms correct test print to each printer	
3. Customer confirms scales work for each designated device	
4. Customer confirms the scanners work for each designated device	
5. SG engineer confirms that all correct app configurations have been applied	
Test Procedure Passes, Conditionally Passes, or Fails.	
E-signature 39, SG Operational Qualification completed by & date	
E-signature 40, Customer Operational Qualification approved by & date	

8 Deviations

No	Deviation Description and Resolution	E-Sign & Date
D1		Esign
D2		Esign
D3		Esign
D4		Esign

No	Deviation Description and Resolution	E-Sign & Date
D5		Esign
D6		Esign
D7		Esign
D8		Esign

9 Qualification Summary Report and Release for Customer Validation

The SG Systems V5 System Installation Qualification has:

- Passed
- Conditionally Passed
- Failed

The SG Systems V5 System Operational Qualification has:

- Passed
- Conditionally Passed
- Failed

The system:

- **Is** released for customer validation
- **Is not** released for customer validation

If all previously reported deviations have been resolved, the SG representative will confirm this section as 'not applicable' and sign the document. The customer will also sign to confirm this.

If there are any deviations reported that cause a conditional pass to be recorded for any aspects of the system, the system can still be released for customer validation provided these deviations do not impact the functioning of the system and do not impact either product quality or data integrity.

	Esign SG Esign Customer

E-Signature 41 SG Systems Engineer completing the IQ/OQ and date
E-Signature 42 Customer reviewing and approving the IQ/OQ and date