



EVEREST

Where Customer Service Meets Quality™



Software
Validation

Validation Procedure

An assessment tool designed to validate the functionality of Everest - Customer Focused Quality™ for the purpose of complaint and corrective action tracking.

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Introduction

This document is intended to assist Lynk Software customers with the validation of the Everest software. The specific regulatory requirements and standard operating procedures of each company should be fully considered. Any additional requirements or validation steps should be attached.

Part IV of this procedure should be completed after the software configuration is completed. When changes are made to the Setup Menu any affected functionality should be re-validated.

This document is not legal advice or legal standard. Companies must ensure that their individual practices and procedures comply with the requirements of third party regulatory agencies. Lynk Software, Inc. assumes no responsibility or liability for the regulatory compliance of Everest users.

Part I - Functional Specification

The central purpose of Everest is to create, maintain and track concerns (customer complaints or requests, product quality issues, returns, etc.) and corrective actions for both external customers and internal areas.

Reference Document: *ProductGuide.pdf* provides an overview of the system organization and functionality.

Everest Overview

The overall scope of the Everest application includes the ability to:

1. Document, track and retrieve Concerns
2. Document, track and retrieve Actions, including Corrective Actions
3. Generate and print reports, charts and user defined queries

Specific security features include:

1. User Group access control
2. User login security
3. Concern and Corrective Action approvals
4. Required fields (to save or close a concern)
5. Audit log of all additions, changes and deletions to concern and corrective action records

Reference Document: *EverestSecurityFeatures.pdf* provides a description of the security features of Everest.

Task: Document and attach the specific requirements of the Everest system for your company if different from above.

Part I Sign Off

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Part II – Risk Analysis

It is assumed that failure of the Everest complaint management and corrective action tracking system or loss of data could result in minor business losses or have minor impacts on the safety and quality of the company's products. This document will therefore outline a minor level of validation testing directed at user needs and intended use. Validation included herein will address key risk factors as defined below.

Risk factors for use of the Everest application include:

1. Failure of the software application to save data
2. Failure of the software application to retrieve data
3. Failure of the specific security features listed above to operate properly
4. Failure of the selected configuration options to function properly

Risk factors related to the database server include:

1. Failure of server or loss of data for any reason (i.e. lost, stolen, disk failure, virus, etc.)
2. Unauthorized access or changes made to server and/or data
3. Inability to retrieve backup data

Task: Document and attach a specific risk analysis for your company if different from above.

Part II Sign Off

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Part III – Installation Qualification

1. Operating Environment and Installation

Reference Document: *EverestSystemRequirements.pdf* provides a description of the server and end user computer requirements.

1.1	Application Server specifications	
Task	Document the server(s) where the DbxServer Software and Everest web programs are installed.	
Computer Name or Id		
Hardware CPU, RAM		
Operating System and Version #		

1.2	Database Server specifications	
Task	Document the server where the database is installed (if separate from the application server).	
Computer Name or Id		
Hardware CPU, RAM		
Operating System and Version #		

1.3	Database Type	Version
Task	Document database type SQL Server	SQL Server version

1.4	End User Test System	
Task	Document the operating system of the end user computer that will be used for the validation	Note the Windows operating system name and version on this computer

1.5	End User Systems	
Task	Identify the operating system(s) where the Everest client will be installed	Confirm that all end user systems are similar in set up to the test system.*

*For example, approved windows operating system (Windows XP, 2000 or Vista.) and connecting over a LAN or WAN. Significant differences include for example connecting through a terminal services/citrix environment. In this case, a baseline level of testing should also be completed on these systems.

1.6	Installation		
Task	Confirm that the install was completed according to the installation instructions and that the software is operational.		
Initial	Pass	Fail	Comments

1.7	Additional Components		
Task	Document any add-ons to the standard product. This includes the Customer Web Portal, AIP (Automatic Import Program) or any custom integration.		

1.8	Additional Components		
Task	Confirm that any add-on products have been installed and configured prior to the validation and are operational.		
Initial	Pass	Fail	Comments

NOTE: If server security and backup procedures are documented separately, this can be attached.

2. Database Server Security

2.1		
Task	Document the following security procedures.	
Physical Security		
Operating System Security and Access		

SQL Server Security and Access	
Contingency Planning	

3. Database Backup

3.1	
Task	Document the following security procedures.
Database backup procedure	
Location of database backup	
Backup retrieval procedure	

Part III Sign Off

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Part IV – Operational Qualification

The Operational Qualification should be completed after the configuration of the Everest system.

This document will use the default (non-customized) terminology of the Everest system. The custom terminology should be reviewed prior to completing the procedure. It may be helpful to print and attach screenshots from the following Everest Setup Menu screens:

- Configuration | Button & Tab Names
- Configuration | Data Names
- Configuration | Corrective Actions
- Configuration | Required Fields
- Configuration | Holidays
- Configuration | Other Options

The following validation steps will cover the core functionality of the Everest Web Edition as described in Part I – Functional Specification.

This validation document does NOT cover the following functionality/options:

- Configuration | Other Options | System Options | Have Action Teams
- Configuration | Other Options | System Options | Account Access by Location
- Configuration | Other Options | System Options | Internal Access by Location
- Configuration | Other Options | System Options | Auto Save Notifications
- Administration | User Information | User Groups | View Menu | Access Account Calls
- Administration | User Information | User Groups | View Menu | Access Web Concerns
- Administration | User Information | User Groups | Account Privileges
- Administration | User Information | User Groups | Area Privileges
- Administration | Imports

IMPORTANT NOTES:

Use the comment “n/a” in the “Initial” field for functionality that has been omitted in the setup menu (i.e. will not be used) or if the risk level is determined too low to warrant testing (this should be clarified in the comments section).

1. Login

1.1			
Task	Login to Everest as a user with the highest level of access privileges (system manager user group). You should have access to the entire system		
Initial	Pass	Fail	Comments

Note: Access privileges for additional user groups will be tested separately.

2. New Concerns and Corrective Actions

Focus: Testing the saving of data, specific workflow and security features.

2.1			
Account Concerns Enter a New Account			
Task	<ol style="list-style-type: none"> 1) Click on Account Concerns. 2) Click on New Account. 3) Select an Account Type. 4) Enter the Account Name as "Test Account 1". 5) Enter data in every available field for this account record including a sample contact. 6) Click on OK. 7) Search for this account in the Account List. 8) Click on Select Account. 9) Confirm that all the data was saved. 		
Initial	Pass	Fail	Comments

2.2			
Account Concerns Select Account New Concern with Actions			
Task	<ol style="list-style-type: none"> 1) Click on Account Concerns. 2) Select "Test Account 1". 3) Click on New Concern. 4) Enter sample data in every field of the concern record. 5) Add an Action for each possible action type, completing all data fields. 6) Do not close the actions or the concern record. 7) Click on OK. 8) Click on View Concern. 9) Confirm that all data was saved. 10) Print the Summary Report. 		
Initial	Pass	Fail	Comments

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2.3 Internal Areas Enter a new Internal Area			
Task	1) Click on Internal Area List . 2) Click on New Area . 3) Enter the Area Name as "Internal Test Area 1". 4) Enter data in every available field for this area. 5) Click on OK . 6) Highlight and select "Internal Test Area 1". 7) Confirm that all the data was saved.		
Initial	Pass	Fail	Comments

2.4 Internal Areas Select Internal Area New Concern			
Task	1) Click on Internal Area List . 2) Select "Internal Test Area 1" 3) Click on New Concern 4) Enter data in every available field for this area except actions. 5) Click on OK . 6) Click on View Concern . 7) Confirm that all data was saved. 8) Confirm that the Control No. has been assigned in sequential order. 9) Print the Summary Report.		
Initial	Pass	Fail	Comments

2.5 Notifications and Auto Save feature			
Task	1) Go to Open Concerns . 2) Select one of the test concerns entered above. 3) Select a New Owner and click on the Notify Owner button. 4) Send the notice by email – Click on the Email button. 5) Confirm that the notice has been received by the owner. 6) If using the Auto Save feature (Setup Configuration Other Options Auto Save Concern Notifications) then Confirm that the notice is saved as an attachment. 7) Repeat this procedure for an Action Notice.		
Initial	Pass	Fail	Comments

2.6			
Concern Category workflow – default owner, due days, required actions			
Task	<ol style="list-style-type: none"> 1) Click on Account Concerns. 2) Select "Test Account 1". 3) Click on New Concern. 4) Select a Concern Type and Category that has workflow defined in the Setup Menu (i.e. default owner, due days, required actions) 5) Confirm the default owner, due days and required actions. 6) Click on OK. 7) Click on View Concern. 8) Confirm that all data was saved. 9) Print the Summary Report. 		
Initial	Pass	Fail	Comments

2.7			
Fields required to Save a Concern			
Task	<ol style="list-style-type: none"> 1) Click on Account Concerns. 2) Select "Test Account 1". 3) Click on New Concern. 4) Attempt to save the Concern (by clicking on OK) without any of fields required to save a concern completed. 5) Confirm that Everest does not allow you to save the concern. 6) Enter data for one of the fields required and attempt to save the concern again. 7) Repeat this process until all of the required fields have been tested. 8) Print the Summary Report. 		
Initial	Pass	Fail	Comments

2.8			
Fields required to Close a Concern			
Task	<ol style="list-style-type: none"> 1) Click on Account Concerns 2) Select "Test Account 1". 3) Click on New Concern. 4) Enter some data, include data required to Save a concern, but do not include data required to close a concern. 5) Attempt to close the concern by clicking on the 'closed' radio button on the Concern Tab. 6) Confirm that Everest does not allow you to close the concern. 7) Enter data for one of the fields required and attempt to save the concern again. 8) Repeat this process until all of the required fields have been tested. 9) Print the Summary Report. 		

Initial	Pass	Fail	Comments

2.9	Fields required to Close a Corrective Action
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Task	<ol style="list-style-type: none"> 1) Click on Account Concerns 2) Select "Test Account 1". 3) Select one of the test Concerns entered above. 4) Add a corrective action. 5) Confirm that the corrective action cannot be closed unless the required sections are completed (as specified under Setup Configuration Corrective Actions).
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Initial	Pass	Fail	Comments

2.10	Corrective Action Approvals, Electronic Signatures and Dual Passwords
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Task	<p>Everest can be configured with three levels of approvals for corrective actions.</p> <p><u>Approvals:</u> A check box will be enabled on the Corrective Action Tab. This box can be checked by any user that is in a User Group with 'Perform Approval' privileges. The system will display the name of the user and the date. The Corrective Action can then be closed. The Corrective Action can only be un-approved by a user with the same privilege.</p> <p><u>Approvals with Electronic Signatures:</u> This will require that the user enter their password when approving a corrective action.</p> <p><u>Approvals with Electronic Signatures and Dual Passwords:</u> This will require that a user maintain a separate password for approving corrective actions or concerns. This can be maintained in Setup User Information Users or under User Change Password.</p> <p>Note:</p> <p>This step should be completed to the level that your system is configured. If testing Electronic Signatures, the logged in user must have a password. If checking Dual Passwords, the logged in user must have a dual password.</p> <ol style="list-style-type: none"> 1) Click on Account Concerns. 2) Select "Test Account 1". 3) Click on New Concern. 4) Enter some data, include all data required to save or close a concern. 5) Add a corrective action and fill in any required fields. 6) Check the 'Response Complete' box. 7) Check the 'Approved' box. Enter a password or dual password as required by the system. 8) Confirm that the system is functioning as configured. For example, if
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	you have the system configured for dual passwords, confirm that the system requires this second and unique password to complete the approval. 9) Login as a user that does not have 'Perform Approval' privileges. Confirm that this user cannot re-open a concern. 10) Print the Summary Report		
Initial	Pass	Fail	Comments

2.11	Concern Approvals, Electronic Signatures and Dual Passwords		
Task	<p><u>Approvals:</u> A check box will be enabled on the Concern Tab. This box can be checked by any user that is in a User Group with 'Perform Approval' privileges. The system will display the name of the user and the date. The Concern can then be closed. The Concern can only be un-approved by a user with the same privilege.</p> <p><u>Approvals with Electronic Signatures:</u> This will require that the user enter their password when approving a concern.</p> <p><u>Approvals with Electronic Signatures and Dual Passwords:</u> This will require that a user maintain a separate password for approving corrective actions or concerns. This can be maintained under User Change Password.</p> <p>Note:</p> <p>This step should be completed to the level that your system is configured. If testing Electronic Signatures, the logged in user must have a password. If checking Dual Passwords, the logged in user must have a dual password.</p> <ol style="list-style-type: none"> 1) Click on Account Concerns. 2) Select "Test Account 1". 3) Click on New Concern. 4) Enter some data, include all data required to save or close a concern. 5) Close any actions that are open. 6) Check the 'Approved' box on the Concern Tab. Enter a password or dual password as required by the system. 7) 'Close' the Concern. 8) Confirm that the system is functioning as configured. For example, if you have the system configured for dual passwords, confirm that the system requires this second and unique password to complete the approval. 9) Login as a user that does not have 'Perform Approval' privileges. 10) Confirm that this user cannot re-open a concern. 11) Print the Summary Report. 		
Initial	Pass	Fail	Comments

3. Login Security and User Group Access

Focus: Testing password settings and access privileges.

3.1 Setup Configuration Other Options Password Expire Days			
Task	Everest can be configured with a 'Password Expire Days'. This feature can be tested with the following procedure: <ol style="list-style-type: none"> 1) Close the Everest software 2) Change the date on your operating system 3) Go to Control Panel <ol style="list-style-type: none"> a. Select Date, Time, Language, Regional Options b. Set the Date in the future past the date when a password should expire 4) Logon to Everest 5) Confirm that Everest prompts you to re-set your password 6) Close the Everest software 7) Re-set the date on your operating system 		
	Pass	Fail	Comments

3.2 Setup Configuration Minimum Password Size			
Task	<ol style="list-style-type: none"> 1) Go to User Change Password. 2) Attempt to enter a Password that is smaller than the Minimum Password Size. 3) Confirm that Everest requires the Minimum Password Size. 		
Initial	Pass	Fail	Comments

3.3 User Group Access Privileges			
Task	<ol style="list-style-type: none"> 1) Login as a user under each User Group and confirm controlled access as specified in the Setup Menu. 		
Initial	Pass	Fail	Comments

4. View Menu

Focus: Testing the retrieval of data from View Menu Options

4.1 View Menu Concerns By Owner			
Task	1) Confirm that open or closed concerns can be retrieved. Printed Summary Reports can be used as a log of entered data. 2) Confirm the concerns can be retrieved under all sorting options 3) Confirm that a concern can be retrieved by entering a specific Control Id.		
Initial	Pass	Fail	Comments

4.2 View Menu Actions by Owner			
Task	1) Confirm that open Actions can be retrieved. Printed Summary Reports can be used as a log of entered data. 2) Confirm that Actions can be retrieved under all sorting options. 3) Confirm that an Action can be retrieved by entering a specific Action Id.		
Initial	Pass	Fail	Comments

4.3 View Menu Search Concerns			
Task	1) Confirm that all entered Concerns can be retrieved under the various filtering options.		
Initial	Pass	Fail	Comments

4.4 View Menu Return Authorizations			
Task	1) Confirm that any entered Returns can be retrieved. 2) Confirm that Actions can be retrieved under all sorting options. 3) Confirm that an Action can be retrieved by entering a specific Action Id.		
Initial	Pass	Fail	Comments

5. Reports Menu

Focus: Testing the generation and accuracy of reports, charts, user defined queries and Audit Reports.

5.1 Reports Concern Reports			
Task	1) Confirm that reports can be generated and are accurate. Test all sorting and filtering options that will be used to analyze quality data.		
Initial	Pass	Fail	Comments

5.2 Reports Charts			
Task	1) Confirm that charts can be generated and are accurate. Test all sorting and filtering options that will be used to analyze quality data.		
Initial	Pass	Fail	Comments

5.3 Reports Queries			
Task	1) Create a Query for each major section of the queries data fields, i.e. Account, Concern, Product, Defect, Returns, Repairs, Actions. 2) For each Query, include all the fields within that section. 3) Run each Query and verify the data.		
Initial	Pass	Fail	Comments

5.4 Reports Audit Reports			
Task	1) Confirm that the Audit Report contains the additions, changes and deletions for at least one Concern (sort by Control Id). If necessary, add, change and delete data from a new Concern for testing. Note: Within the Audit Report, 1 = Yes (is selected) and 0 = No (is not selected). Therefore, if a field goes from a 1 to a 0, then the selection has been deleted.		
Initial	Pass	Fail	Comments

Note: All test data should be deleted following the validation procedure.

Part IV Sign Off

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____

Print Name: _____

Title/Role: _____

Sign Name: _____

Date: _____