AccuSizer® System Version 3.0 Software Testing

User-friendly software package for AccuSizer SPOS Systems

The AccuSizer® system software is designed to provide a user-friendly software package for the AccuSizer family of laboratory particle size and count analyzers. The software controls the instrument, processes the data, and creates result reports. An optional add-on helps customers implement 21 CFR Part 11 compliance in their laboratories. The user interface adapts to the instrument configuration and the tasks being performed to provide an intuitive access to the available features.

The software is defined, created, and tested within a quality structure that is currently being adapted to conform to Entegris internal systems and practices. Part of this quality assurance effort includes a thorough testing of all features and operations prior to the release of version 3.0.0.0. A test plan document was defined and written by the software development team. The testing was then carried out independently by our lab chemists. The test plan document is controlled through our EtQ Reliance enterprise platform; Entegris document number 16726, Version 1 released 08/14/2019.

PURPOSE OF THE TEST PLAN DOCUMENT

The test plan describes the testing approach and overall framework that drove the testing of AccuSizer system software version 2.9.9.x-3.0.0.0. The document introduces:

- Test Strategy: rules the test will be based on, including the givens of the project (e.g., start/end dates, objectives, assumptions); description of the process to set up a valid test (e.g., entry/exit criteria, creation of test cases, specific tasks to perform, scheduling, data strategy)
- Execution Strategy: describes how the test will be performed and processed to identify and report defects, and to fix and implement fixes
- Test Management: process to handle the test logistics and all the events that come up during execution (e.g., communications, escalation procedures, risk and mitigation, team roster)

DEFECT TRACKING AND REPORTING

No software can promise to be 100% error free. What is important is to have a defined structure for documenting and fixing reported errors. Defects discovered by customers are fed via their local support contact to the product manager or software team. These defects are reviewed, and an analysis determines if a customer-specific solution or general solution is appropriate. Defects discovered internally are fed directly to the software team. The software team keeps a list of all reported defects and suggested new features. This list is prioritized and then decisions are made on which issues to address in the next release. Defects requiring fixes are corrected using the process shown in Figure 1.

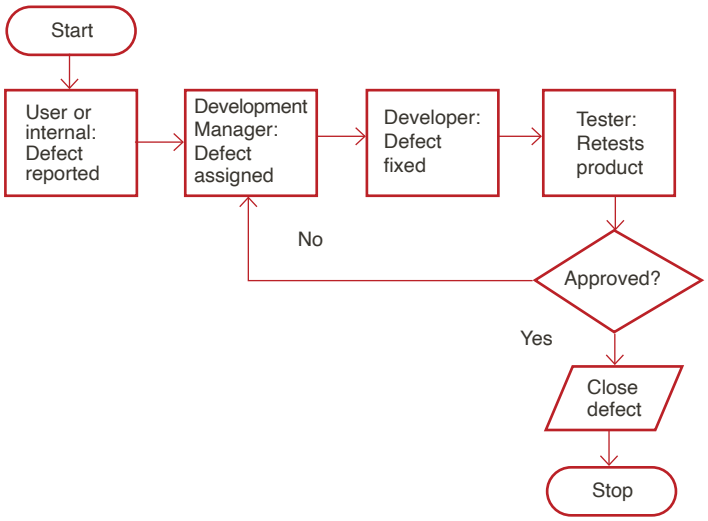

Figure 1. Defect correction plan

TEST APPROACH/PASS AND FAIL CRITERIA

The lab chemists were given the following instructions for carrying out the test plan:

- Create a test folder and copy all files into the test folder provided by software development. Unzip all files into the test folder

- Install AccuSizer system software version 3.0.0.0 contained within the testing folder
- MCPA firmware is required on all instrumentation: 1.1.3
- Legacy sensor interface firmware is required on all instrumentation: 4.0.4
- DCB firmware is required on APS and AD instrumentation: 3.0.1
- Load Testing/Validation Project into AccuSizer system from test folder (if not already present)

The test plan provides a detailed written description of the process in order to check all software functions and features. Examples are provided below. The test is recoded as "Pass" if the feature/function behaves as expected.

In addition, extensive testing was performed on calculated and reported results. For these tests result data was exported and then imported into an Excel spreadsheet. Calculations were made using Excel spreadsheets and compared to results in the AccuSizer software. The test is recorded as a "Pass" if the two results match. The calculation validation testing procedure is shown below:

- Perform database export of sample data
  Note: The database export function was tested to assure values within the software matched exported values.
- Generate a report for each report listed within section 14.2
- Manually calculate the values that are contained in each report within section 14.2
- Verify calculated results match report

The complete Test Plan AccuSizer system software 3.0.0.0 document is 282 pages long and completely covers all software features, functions, and report calculations. The purpose of this short document is to provide an overview of the testing procedures used and reported results. The complete test plan is considered Entegris intellectual property and is kept confidential.

EXAMPLES

Test Case 1: Passwords

From the AccuSizer System Manual: ***Password Format***

The password format must be defined to the software. Only the administrator has access to the password settings for the software, therefore it is their responsibility to protect access to the software. Information such as the length of the password, the number of attempts that may be made to login into the software, and the expiration of the password itself must be defined. In addition, password options must also be defined as to the structure of the password itself. Special characters, upper or lowercase letter requirements, and number involvement must be defined.

Access to the Security Settings window is obtained by selecting "Security Settings" from the Options pull-down menu. Once all the fields are completed, click "OK". From this point on, all of these requirements must be adhered to when defining a new user to the system. Remember the values that display in the fields of the following window are only there as an example. These values are predicated upon the internal SOPs of the worksite.

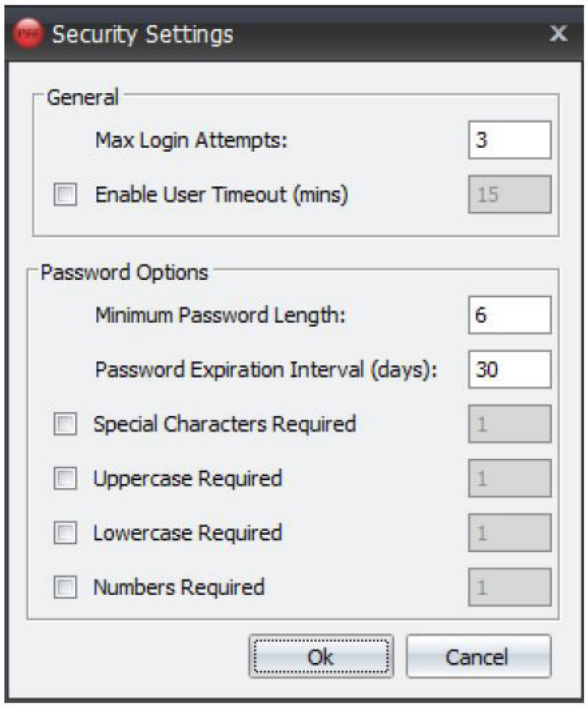

Figure 2: AccuSizer system manual section and software settings on passwords

The password security settings were tested and documented in the AccuSizer System Test Plan as shown below:

6.5.4.7 Security Settings saved correctly

6.5.4.7.1 PROCEDURE:

- Enter the appropriate value type for the field name and follow the test criteria
- Make sure every value persists when saving it

Field Name	Value type	Test Criteria	Pass/Fail
Max Login Attempts	Numerical	Set a number, save and retrieve.	
Enable User Timeout (mins)	Boolean	Check/uncheck box, save and retrieve.	
Enable User Timeout (mins)	Numerical	Set a number, save and retrieve.	
Minimum Password Length	Numerical	Set a number, save and retrieve.	
Password Expiration Interval (days)	Numerical	Set a number, save and retrieve.	
Special Characters Required	Boolean	Check/uncheck box, save and retrieve.	
Special Characters Required	Numerical	Set a number, save and retrieve.	
Uppercase Required	Boolean	Check/uncheck box, save and retrieve.	
Uppercase Required	Numerical	Set a number, save and retrieve.	
Lowercase Required	Boolean	Check/uncheck box, save and retrieve.	
Lowercase Required	Numerical	Set a number, save and retrieve.	
Numbers Required	Boolean	Check/uncheck box, save and retrieve.	
Numbers Required	Numerical	Set a number, save and retrieve.	

Figure 3: Password testing #1

6.5.4.7.2 TEST PASS/FAIL CRITERIA:

PASS: See table for each field test criteria and apply it.

FAIL: Values not conforming or failing to test criteria or unexpected results.

6.5.4.7.3 TEST DELIVERABLES

- Attach the test results to the test plan in pdf format

6.5.4.8 Security Settings functionality

Item	Test Description	Test Date	Pass/Fail	Tested By (Initials)
1	Verify Max Login Attempts			
2	Verify User Timeout			
3	Verify all Password Options			

Item	Test Description	Test Date	Pass/Fail	Tested By (Initials)
1	Verify Max Login Attempts	10/29/19	Pass	S.L
2	Verify User Timeout	10/29/19	Pass	S.L
3	Verify all Password Options	10/29/19	Pass	S.L

Figure 4: Password testing #2; above in original format, below signed and dated by tester

6.5.4.8.1. Max Login Attempts

6.5.4.8.1.1 PROCEDURE:

- Log off AccuSizer system if not already logged off
- Attempt to log in with the wrong password

6.5.4.8.1.2 TEST PASS/FAIL CRITERIA:

PASS: User gets locked out of AccuSizer system after the maximum login attempts set under Security Settings.

FAIL: User is never locked out of AccuSizer system or user gets locked out after several attempts different than the one determined under Security Settings.

6.5.4.8.1.3 TEST DELIVERABLES

- Attach the results of the test to the test plan in pdf format

6.5.4.8.2 Enable User Timeout

6.5.4.8.2.1 PROCEDURE:

- Check "Enable user timeout" and set it to 10 minutes
- Do not interact with AccuSizer system, make sure it is automatically logged off after 10 minutes

6.5.4.8.2.2 TEST PASS/FAIL CRITERIA:

PASS: User gets logged off after 10 minutes.

FAIL: User does not get logged off after 10 minutes.

6.5.4.8.2.3 TEST DELIVERABLES

- Attach the results of the test to the test plan in pdf format

6.5.4.8.3 Password Options

6.5.4.8.3.1 PROCEDURE:

- Set the password option requirements and confirm that they are enforced when creating, updating, and deleting a user under User Management
- Set the password option requirements and confirm that they are enforced when updating a password
- Fields to set:

Password requirement	Value type	Pass/Fail
Minimum Password Length	Numerical	
Password Expiration Interval (days)	Numerical	
Special Characters Required	Boolean	
Uppercase Required	Boolean	
Lowercase Required	Boolean	
Numbers Required	Numerical	

Figure 5: Password testing #3

6.5.4.8.3.2 TEST PASS/FAIL CRITERIA:

PASS: Program only allows passwords that conform to the set requirements.

FAIL: Program allows passwords that do not conform to the set requirements.

6.5.4.8.3.3 TEST DELIVERABLES

- Attach the results of the test to the test plan in pdf format

Test Case 2: Features Specific to 21 CFR Part 11 Features

Note: In this example only selected final results are shown for the sake of brevity.

Item	Test Description	Test Date	Pass/Fail	Tested By (Initials)
1	Verify correct search range			
2	Verify audit tree			
3	Verify Print Preview / Export			
4	Verify Audit dialog filters work			

Item	Test Description	Test Date	Pass/Fail	Tested By (Initials)
1	Verify ability to add a user			
2	Verify ability to edit a user			
3	Verify ability to enable and disable a user			

Figure 6: Excerpts from test plan on 21 CFR part 11 features

Test Case 3: Size Calculations

The ability to accurately calculate the mean, median, mode, and standard deviation was verified by comparing the results in a software report to calculations made in an Excel file from the same raw data. The comparison of results is shown below.

Mean: 204.060 µm
Mode: 298.312 µm
Median: 295.030 µm
Standard Deviation: 132.786 µm

Figure 7: Results from AccuSizer system software report

Calculated Values		
		% Error
Mean	204.0598593	0.00%
Mode	298.311757	0.00%
Median	295.0296915	0.00%
Standard Deviation	132.7856918	0.00%

Figure 8: Results from Excel spreadsheet

Test Case 4: USP 729 PFAT 5 Calculation

A measurement was performed following typical USP 729 testing protocol. The testing results are shown in Figure 9. In this case, the raw counts were exported and then imported into a spreadsheet and comparisons were made between calculations from the spreadsheet to results reported in the AccuSizer system software. An example is shown in Figure 10. This testing was performed using multiple AccuSizer systems; the AccuSizer A2000, AD, and APS systems.

Flow rate: 30.0 mL/min
Number sized (≥ 0.5): 78126
DF: 1.651
Sample volume: 30.0 mL
Measurement time: 60 seconds
Report date/time: 14:39, 09/18/2019

Sample: Kodak Run 1 75ul
Comment:
Run Date/Time: 13:56, 07/11/2018

Fat Concentration (mass %)	Oil Density (g/mL)	$PFAT_5$
30.0	0.9213	0.00886

TEST Criteria	RESULT
PFAT5 < 0.05% (PASS)	PASS

Figure 9: USP 729 AccuSizer system software report

Reported Values	
Fat Concentration(ma	Oil Density(g/mL
30.0	0.9213
TEST Criteria	RESULT
PFAT5 < 0.05% (PASS)	PASS
Calculated Values	
Abs Vol	2.1639E-06
Total Vol	0.024422012
PFAT5	0.00886%
PFAT5 < 0.05% (PASS)	Pass
	Value
Vessel Volume (mL)	30
Project	Software testing
Protocol	USP 729
Injection Volume (uL)	75
Sample ID	a91a00e6-742c-414b
Run Name	729 1 75ul
Volume To Run Start (mL)	1.2730000019
Volume to Run End (mL)	31.273000717
Volume Sampled (mL)	30.000000715
PreDF	1
RSF	1.6505498336
DF	1.6505498336
Injection Volume (uL)	75
Injection Volume (mL)	0.075
V1	30
Va	1.2730000019
Vb	31.273000717
e^-(va/V1)	0.95845436
e^-(vb/V1)	0.352595646
=B33-B34	0.605858714
Calc RSF	1.650549834
% Error	0.00%

Figure 10: USP 729 Excel calculations

Test Case 5: USP 788 LVI Testing

Measurements were performed following typical (but lower sample volume) USP 788 LVI testing protocol. The testing results are shown in Figures 11 and 12. This testing was performed using multiple samples; the AccuSizer SIS, A2000, AD, and APS systems.

Sample	Run Date/Time	Sample Vol. (mL)	Pre DF	≥ 10 um (#/mL)	≥ 25 um (#/mL)
HCl Sample 3 Rep. 2	14:32 12/08/2017	0.2	1.00	300	65
HCl Sample 3 Rep. 3	14:33 12/08/2017	0.2	1.00	375	65
HCl Sample 3 Rep. 4	14:33 12/08/2017	0.2	1.00	350	95
			Mean	341.7	75

TEST Criteria	RESULT
(Mean #/mL ≥ 10 um) ≤ 25/mL AND (Mean #/mL ≥ 25 um) ≤ 3/mL (PASS)	FAIL

Figure 11: USP 788 LVI software report

Reported Data				
Sample	Run Date/Time	Sampl	≥ 10 um	≥ 25 um
HCl Sample 3 Rep. 2	14:32 12/08/2017	0.2	300	65
HCl Sample 3 Rep. 3	14:33 12/08/2017	0.2	375	65
HCl Sample 3 Rep. 4	14:33 12/08/2017	0.2	350	95
			341.7	75
TEST Criteria	RESULT			
Test Result	(Mean/mL ≥ 10um)≤ 25/mL & (Mean/mL ≥ 25um)≤ 3/m			
	Fail			
Calculated Values				
	≥10um	≥ 10 u	≥ 25um	≥ 25 um
Rep 2	60	300	13	65
Match		Pass		Pass
	≥ 10um	≥ 10 u	≥ 25um	≥ 25 um
Rep 3	75	375	13	65
Match		Pass		Pass
	≥ 10um	≥ 10 u	≥ 25um	≥25 um
Rep 4	70	350	19	95
Match		Pass		Pass
	≥ 10 um(#)	≥ 10 um	≥ 25 um	≥ 25 um
Match	68.3	341.7	15	75
		Pass		Pass

Figure 12: USP 788 LVI Excel calculations

All reports including calculated results were tested using this procedure. The reports tested following this procedure are:

AS 4059 Cumulative
Cumulative Particle Count Data Sheet (DS-2)

AS 4059F Cumulative
Cumulative Particle Count Data Sheet (DS-2) Without Pass/Fail

AS 4059 Fluid Cleanliness
Fluid Cleanliness Differential Data Sheet (DS-1)

AS 4059F Fluid Cleanliness
Fluid Cleanliness Differential Data Sheet (DS-1) Without Pass/Fail

ChP 2015 2.2 1.A
Chinese Pharmacopoeia Small Volume Injectables

ChP 2015 2.3 1.B
Chinese Pharmacopoeia Large Volume Injectables

ChP 2015 Clean Glassware
Chinese Pharmacopoeia Clean Glass

EP 2.9.19 1A
European Pharmacopoeia Small Volume Injectables

EP 2.9.19 1.B
European Pharmacopoeia Large Volume Injectables

ISO 4406
Hydraulic Fluid Power Method for Coding the Level of Contamination by Solid Particles

JP XVII 1.A
Japanese Pharmacopoeia Large Volume Injectables

JP XVII 1.B
Japanese Pharmacopoeia Small Volume Injectables

Multi-Region Report
Report Showing Data in Several Diameter Ranges

NAS 1638
Aerospace Cleanliness Classification for Hydraulic Fluids

NAS 1638 Without Pass/Fail
NAS 1638 *Without Pass/Fail*

NAVAIR 01-1A-17
Navy Standard for Hydraulic Fluids

NAVAIR Without Pass/Fail
Navy Standard for Hydraulic Fluids Without Pass/Fail Criteria.

Sensor Calibration
Sensor Calibration Report

USP 1788
Sensor Resolution Report

USP 1788
Particle Counting Accuracy

USP 729
Globule Size Distribution in Lipid Injectable Emulsions

USP 786
Particle Sizing by Analytical Sieving

USP 786 European
Particle Sizing by Analytical Sieving

USP 786 Japan
Particle Sizing by Analytical Sieving

USP 786 R20
Particle Sizing by Analytical Sieving

USP 786 R20/3
Particle Sizing by Analytical Sieving

USP 786 R40/3
Particle Sizing by Analytical Sieving

USP 786 Recommended
Particle Sizing by Analytical Sieving

USP 786 US

Particle Sizing by Analytical Sieving

USP 788 2005 LVI

USP 788 2005 Large Volume Injectables

USP 788 2005 SVI

USP 788 2005 Large Volume Injectables

USP 788 2014 1.A

USP 788 2005 Large Volume Injectables

USP 788 2014 1.B

USP 788 2005 Large Volume Injectables

USP 788 2014 Clean Glass

USP 788 2005 Large Volume Injectables

WHO 2012 QAS/11.405 5.7.1. Test A.1

WHO 2012 Large Volume Injectables

WHO 2012 QAS/11.405.5.7.1. Test A.2

WHO 2012 Small Volume Injectables

CONCLUSIONS

This document is only a brief overview of the complete topic of software quality, control, testing, and validation. Complete test results are securely stored at our main office in Port Richey, Florida and securely off-site. The complete test plan document is considered Entegris intellectual property and is not available for customer review.

Customers interested in additional details can contact Mark Bumiller, Entegris technology manager, at mark.bumiller@entegris.com. Service fees may be associated with support requests depending on the nature and depth of the efforts required to respond to customer questions. Entegris will provide additional support to any customer requiring more information due to an FDA audit, or questions asked by representatives from the FDA.

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