DYNEX TECHNOLOGIES	**Document type:** **Standard Operating Procedure**	**FSCA Reference** FSOP450-4
Urgent Field Safety Notice	**Revision** **A**	**Authored Date:** **2020-05-26**

Agility Automated ELISA System

For The Attention of: The Regulatory Affairs, Quality Assurance, Laboratory Manager or End User

Information on Affected Devices/Products	
1	**Device Type(s)**
	The Agility Analyzer is an In Vitro Diagnostic Medical Device used for automating the steps of ELISA assays.
2.	**Commercial name(s)**
	Agility
3.	**Unique Device Identifier(s) (UDI-DI)**
	5060456180058
4.	**Primary clinical purpose of device(s)**
	The Agility Analyzer is intended for automating ELISA assays. The user combines the Agility with an Assay changing the Agility intended use from an open system into a specific Analyzer for automating the steps for the assay.
5.	**Device Model/Catalogue/part number(s)**
	67000 Agility Automated ELISA System
6.	**Software version**
	Software for Agility (REF# 67800) version 1.4.3
7.	**Affected serial or lot number range**
	All Agility Analyzers that have software version 1.4.3
8.	**Associated devices**
	None identified

Reason for Field Safety Corrective Action (FSCA)	
9.	**Description of the product problem**
	We are aware of the issues of the Agility system with software version 1.4.3 and one complaint related to the problem which is described here: when the controls, standards or calibrators used in shared worklists with other assays that do not have unique names, and when the assay's controls, standards or calibrators are diluted on the instrument, there is a risk that a control from another assay's SmartKit will be used instead of the correct control for the assay being run on the Agility system. *Note*: Only diluted controls, standards or calibrators are vulnerable. Undiluted controls, standards, or calibrators will only be drawn from their own kit. This issue is caused by a feature in the Agility software v1.4.3 that allows sharing of diluents. The following conditions need to be met for the issue to occur: • Control, standard or calibrator names must be identical between two or more assays. • At least one of the assays must use Diluted controls or samples with "prepare deepwells upfront" OR sharing across assays enabled in Agility software. • The assays' reagent SmartKits must be scheduled at the same time.

Reason for Field Safety Corrective Action (FSCA)	

	• And one of the following conditions must be met:
	  ○ Fluid lot match enforcement for sharing of fluids is disabled.
	  ○ Fluid lot match enforcement for sharing of fluids is enabled but fluid lots match (e.g., both are empty).

10.	**Hazard giving rise to the FSCA**
	Agility users who batch schedule assays that do not have unique names for controls may run a risk that the same control fluids will be used on disparate assays.
11	**Probability of problem arising**
	Severity: Major If the quality control mechanism fails, the user is likely to report incorrect results due to the use of the wrong controls. Occurrence: Occasional The error is likely to occur on Agility instruments with software version 1.4.3 but only in cases where users are running multiple assays, some of which share names for controls, together in a batch. Detectability: Sometimes Users may only detect the issue if a quality control check fails. In some cases, the user may observe that control volumes used are unusual, leading them to suspect the use of only one control.
12.	**Predicted risk to patient/users**
	If the quality control mechanism fails, the user is likely to report incorrect results due to the use of wrong controls.
13	**Further information to help characterise the problem**
	If the end user is using the Agility Analyzer with an assay having diluted controls or samples with "prepare deepwells upfront" enabled, and scheduling multiple assays at the same time, they need to be aware of this issue. The issue is not directly detectable; it may manifest as an increase in Quality Control failures.
14	**Background on Issue**

	Dynex received a complaint from an end user reporting pipetting errors on the Agility Analyzer. We initialized an investigation and discovered the issue is caused by a feature in the Agility software that allows sharing of diluents. The following conditions need to be met for the issue to occur:
	• Control, standard or calibrator names must be identical between two or more assays.
	• At least one of the assays must use Diluted controls or samples with "prepare deepwells upfront" enabled in Agility software.
	• The assays' reagent SmartKits must be scheduled at the same time.
	• And one of the following conditions must also be met:
	  ○ Fluid lot match enforcement for sharing is disabled.
	  ○ Fluid lot match enforcement for sharing is enabled but fluid lots match (e.g., both are empty).

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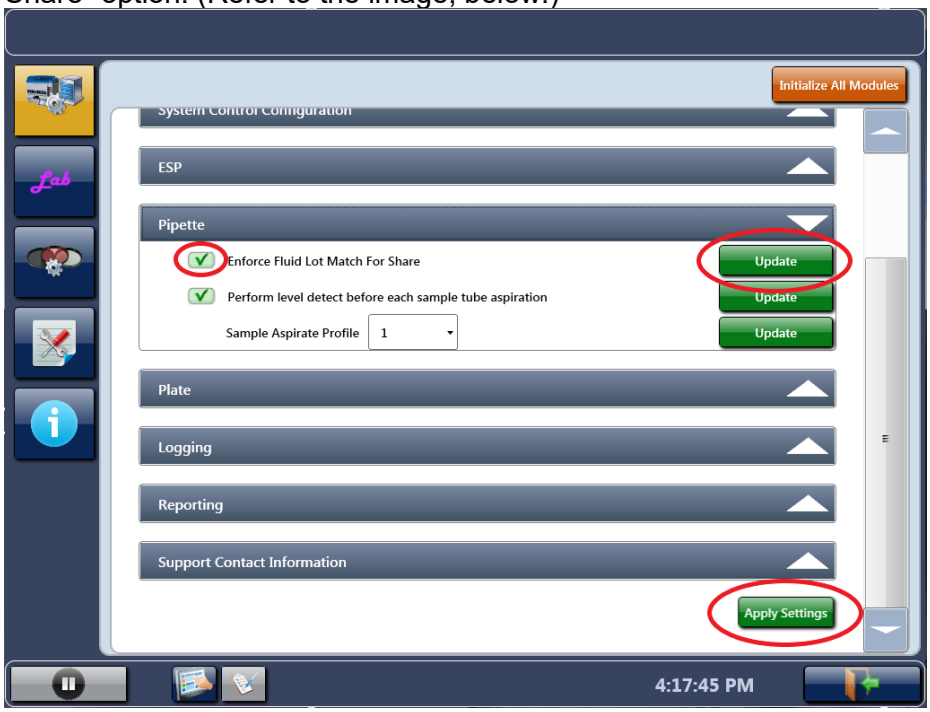
Immediate Actions to be Taken by the Customer/User

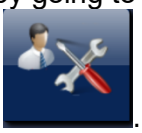
A work around has been provided to prevent the problem from occurring while the software is being improved. **Please take immediate action**:

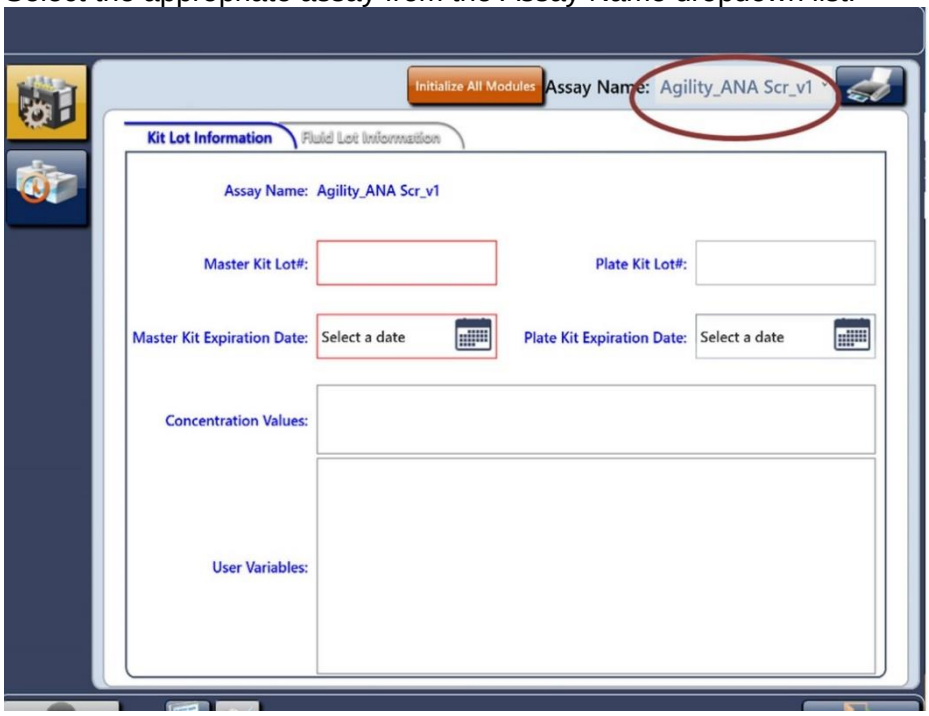
1. From the home screen in Agility, click the icon that looks like a cog wheel or gear in front of the Agility and a computer.

2. On the next screen, which is the lab information screen, click on the same icon as before. This will open the Agility's configuration screen.
3. Make sure that the checkbox next to "Enforce Fluid Lot Match For Share" is checked.
4. Click on the "Update" button alongside the "Enforce Fluid Lot Match For Share" option. (Refer to the image, below.)



5. Scroll down to the bottom of the configuration screen to click on the "Apply Settings" button.
6. Select the "Dashboard" icon on the bottom of the screen to return to the "Home" screen

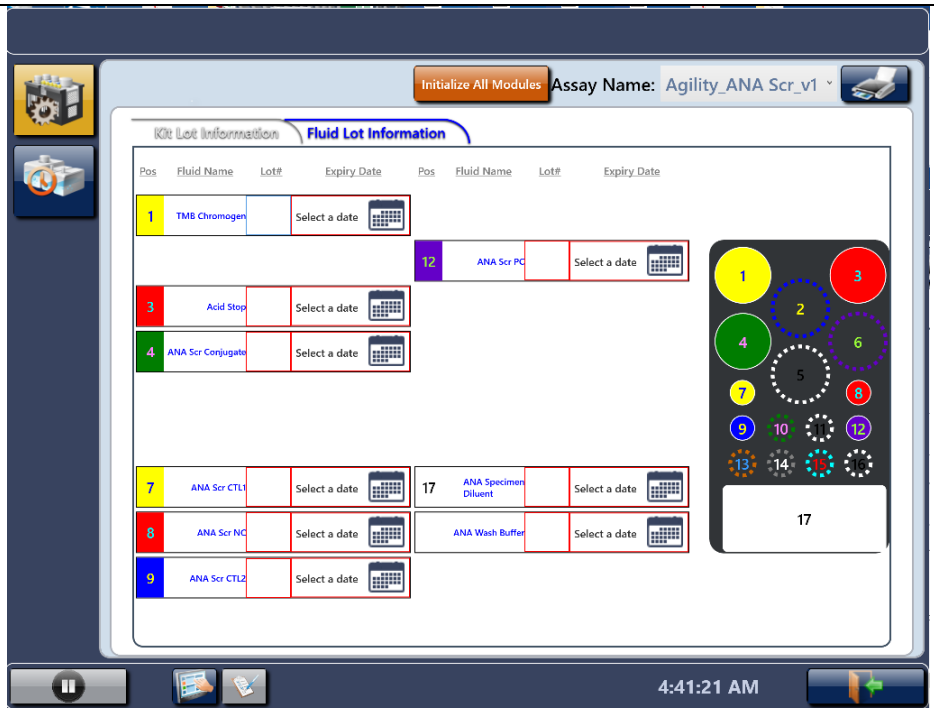
7. SmartKit barcodes can be printed by going to the “Home” icon,  , then the Tools button by selecting  .
8. Select the appropriate assay from the Assay Name dropdown list.



9. Input SmartKit information for the barcode label to be printed.

⚠	**Enter the Master kit lot, Plate Kit Lot, as well as expiry dates for both.**

10. For assays that need updating of concentrations of standards and/or user variables, update these as well.
11. Next, select the “Fluid Lot Information” tab to enter the lot number and expiration dates for standards, controls, and reagents. All of these tabs must be added before the SmartKit barcode is printed.



12. After all of the lot specific information has been entered, print the barcode (Make sure the printer is powered on) by clicking on the printer icon in the upper right corner.

Type of Action to mitigate the risk		
16	**Action to Be Taken by the User** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions for Use (IFU) ☒ Other ☐ None Immediate action to be taken as defined in Section 15 or upgrade the Agility Analyzer to software version 1.4.7 and above.	
	By when should the action be completed?	The action should be completed by 2022-07-15.
	Particular considerations for:	Agility Systems with software version 1.4.3 used in Clinical Laboratories
	Is follow-up of patients or review of patients' previous results recommended?	Yes - If the use of incorrect controls has been identified.
17	**Action Being Taken by DYNEX** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None <u>Release of updated Agility software v1.4.7 in August 2020</u>	
	By when should the action be completed?	The updated Agility software version 1.4.7 has been released in August 2020. DYNEX will continue to contact each affected customer/user about the correcting Agility software versions and complete the action by 2022-07-30.
	Is the FSN required to be communicated to the patient /lay user?	No
	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	Not applicable

General Information			
18	**FSN Type**		Update
19	**For updated FSN, reference number and date of previous FSN**		00227497
20	**For Updated FSN, key new information as follows:** - Update Section 6 to specify the software version that has issues - Update Section 15 to give a timeline for actions to be completed by the customer/user - Update Section 16 to give a timeline for actions to be completed by DYNEX - Update Section 22 to refence the Technical Bulletin - Update Section 23 to give a timeline for follow-up FSN - Update Section 24 for company's website address and telephone number - Update Section 25 to inform the submission of FDA Form 806 to the authority - Update Section 27 for the Name/Tile of the contact person who is responsible for conducting the correction		
21	**Further advice or information already expected in follow-up FSN?**		Yes
22	**If follow-up FSN expected, what is the further advice expected to relate to:**		
	A Technical Bulletin has been sent out for the release of the Agility Software v1.4.7 (TB394)		
23	**Anticipated timescale for follow-up FSN**		2022-07-30
24	**Manufacturer information**		
	a. Company Name		DYNEX Technologies, Inc.
	b. Address		14340 Sullyfield Circle, Chantilly, Virginia, USA 20151
	c. Website address		www.dynextechnologies.com
	d. Telephone number		703-631-7800
25	**The Competent (Regulatory) Authority of your country has been informed about this communication to customers.** Since 2020-07-06 DYNEX has not been aware of any incorrect patient results that have been used to make clinical determinations due to this issue. FDA form 806 (Device Correction/Removal Report Model for Industry) has been submitted to the authority on April 7, 2022 (Report of Corrections and Removal number: FEI -04/07/2022 – 1117676).		

26	**List of attachments/appendices:**	FSOP450-5 Acknowledgement Form
27	**Authorized by:** Signature:	Name/Title: Jeff Fisher VP of Quality Assurance & Regulatory Affairs
	Date	2022-06-13

Transmission of this Field Safety Notice	
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

DYNEX TECHNOLOGIES	**Document type:** **Standard Operating Procedure**	**Document Number:** **FSOP450-5**
Title: Field Safety Notice Customer Reply Form	**Revision** **A**	**Authored Date:** **2020-05-22**

Please complete sections 2, 3

1. Field Safety Notice (FSN) information	
FSN Reference number*	00227497
FSN Date*	2022-06-10
Product/ Device name*	Agility Software
Product Code(s)	67800 Agility Software v1.4.3

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer notes or comments or N/A
☐	I performed all actions requested by the FSN.	Customer notes or comments or N/A
☐	I do not have any affected devices.	Customer notes or comments or N/A
Print Name*		
Signature*		
Date*		

Please complete sections 2, 3

4. Return acknowledgement to sender	
Email	dynexra@dynex.com
Customer Helpline	phone +1 (703) 803-1202
Postal Address	DYNEX Technologies, Inc. 14340 Sullyfield Circle Chantilly, VA 20151
Fax	+1 (703) 803-1441
Deadline for returning the customer reply form*	2022-07-15

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the Field Safety Notice (FSN) and confirms that you have received the FSN.

Your organization's reply is the evidence that we use to monitor the progress of the corrective actions.