DXC.technology Healthcare and Lifesciences

Urgent Field Safety Notice

Date: 26/06/2018
Unique FSN ID: FSN ID 916002
Unique PAN ID: PAN ID iLAB 006-00
MHRA reference number: 2017/002/014/701/015

ILAB AKI 2.1 Build 5

To: All Organisations using ILAB AKI 2.1 Build 5

FAO: Medical Device Safety Officer and Clinical Safety Officer

***Please Note** – this Field Safety Note refers to an historical incident managed through PAN ID iLAB 006-00. This incident has been closed and no further action is necessary. However, following a discussion with the UK Competent Authority we have been advised to reissue the notification as a Field Safety Notice in compliance with European vigilance requirements - MEDDEV 2.12/1 rev 8.*

Issue:

Under certain circumstances the AKI algorithm is not returning the expected AKI stage. Where results sit below "S" status these will not be used by the system to calculate AKI stage on any subsequent requests on the same patient. Instead the system will use the most appropriate creatinine at status "S" according to the rules of the algorithm.

Action Required by Customer:

Where there may be a delay in raising creatinine results to status "S" and there are multiple requests on the same patient please ensure that results are authorised in chronological order and force the system to recalculate the AKI stage on subsequent requests for the same patient.

Transmission of this Notice

This notice should be passed on to all those who need to be aware within your organisation. Please maintain awareness on this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

DXC is vigilant with regard to potential service issues that could impact upon patient safety. A DXC Safety Notice is issued when we identify a risk to patient safety and identify that you should immediately adopt a work-around and/or a fix should be installed as a matter of urgency.

If there is a workaround included please put this into place immediately and implement the fix as soon as it is available. If you are a managed site, please request DXC to install the fix in the same way you request an install for any other fixes.

For regulatory and safety enquiries please contact ukclinsafe@dxc.com

For enquiries relating to this product contact your usual product representative.

We confirm that the appropriate Regulatory Agencies will be notified.

PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS NOTICE

Reply to the same email address that sent you this notice, (not ukclinsafe@dxc.com), stating you have read and understood it.

Dear Customer

DXC regards patient safety of paramount importance. As part of our clinical risk and major incident handling procedures and processes, we have developed this notice. Notices may be sent to you if DXC becomes aware of any issues which may affect patient safety in your health care practice.

This is a Field Safety Notice, (which incorporates the same content as a Product Alert Notice), which advises you that there is a risk to patients associated with a Software Medical Device product you are using. It describes the characteristics of the risk, as well as other details, and informs you of the actions you can take to mitigate this risk.

Kind regards

Product Manager

Issue ID(s): iAssist 916002

Clinical Risk Class: Medium

Product	ILAB AKI 2.1		
Build	Build 5	**Version**	
Summary of Issue	Patient should have been scored as AKI stage 2, but has not.		
Date Identified	5th Dec 2016	**Issue number (for internal use only)**	iAssist 916002
Issuing Officer*	Contact your DXC representative.		
Further Details	Under certain circumstances the AKI algorithm is not returning the expected AKI stage. Where results sit below "S" status these will not be used by the system to calculate AKI stage on any subsequent requests on the same patient. Instead the system will use the most appropriate creatinine at status "S" according to the rules of the algorithm.		
DXC Clinical Safety Assessment	**Description of Hazard and ID**	LAB-008 Clinical calculations may produce an inaccurate result.	
	Clinical Risk Impact	Information which is presented to the user must at all times be calculated correctly. Any discrepancies / inaccuracies may pose a risk to patients due to incorrect decision making.	
	Clinical Safety Officer	Contact your DXC representative.	
Recommended Workaround/ Remedial Action	Where there may be a delay in raising creatinine results to status "S" and there are multiple requests on the same patient please ensure that results are authorised in chronological order and force the system to recalculate the AKI stage on subsequent requests for the same patient.		
Proposed Technical Resolution/	Under investigation [The resolution has been managed by issuing a Product Bulletin in April 2017]		

Corrective Action		
Resolution available from*	**Available from**	[The resolution has been managed by issuing a Product Bulletin in April 2017]
DXC's nominated contacts*	Contact your DXC representative.	
Next steps	Customers to immediately inform all users of the details covered in this document please.	

*Terms Defined	
Term	**Description**
Issuing Officer	This will be the Product Owner in the Country of Origin
Resolution available from	This will explain what the Customer needs to do to implement a fix
DXC's nominated contacts	This will be the Product Owner in the Country of Origin