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Mar 16, 2023

Urgent Field Safety Notice

Nota de Seguridad de Campo Urgente (FSN)

For Attention of: Picis customers using version Picis10 of Picis Perioperative and Critical Care

Contact details of local representative (name, e-mail, telephone, address etc.)*
Picis Clinical Solutions, Inc. 100 Quannapowitt Parkway Suite 405 Wakefield, MA 01880 USA Tel: 781-557-3000 info@picis.com; Picis Clinical Solutions, S.A. Carrer del Císter, 2 08022 Barcelona, Spain Tel: +34 93 547 8300 info@picis.com

Urgent Field Safety Notice (FSN)

Risk addressed by FSN

Describe the risk that has been identified:

If a user performs specific workflow steps a possibility exists for the end user to view conflicting data (Allergies do not display in the Demographics Summary).

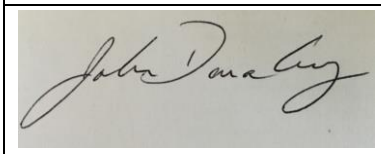
The risk is that the clinician if only viewing the Demographics Summary may not be aware of the documented allergies available within other areas of the software including the Patient Band, audit trail, and form but NOT in the Demographics Summary.

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	Picis Perioperative and Critical Care is used in the high acuity areas of the hospital for clinical documentation purposes.
1.	2. Commercial name(s)
	Picis Perioperative and Critical Care v10
1.	3. Unique Device Identifier(s) (UDI-DI)
	Perioperative / Critical Care:(01)00851831007078(11)200826(10)PPCCVersion10TPA
1.	4. Primary clinical purpose of device(s)*
	Picis Clinical Solutions' software patient information system ("software") compiles an electronic medical record utilizing commonly available hardware and is classified as a "medical device" by regulatory agencies in certain jurisdictions. The software is intended for use by healthcare professionals to aid in the calculations needed for medical treatment purposes, such as performing simple fluid rate and total dose calculations for medications based on patient weight. The medical device modules include Picis Critical Care Manager, Picis Anesthesia Manager, Picis PACU Manager, as well as Sepsis Screening and Waveform capture add-ons. A medical record is populated with information from various sources including, healthcare professionals, medical devices connected to the software, and data that arrives via hospital and laboratory information systems. The software stores this information in a database, and it may analyze and/or display the data in different formats for evaluation by healthcare professionals for informational purposes.
1.	5. Device Model/Catalogue/part number(s)*
	Picis Perioperative and Critical Care v10
1.	6. Software version
	V10
1.	7. Affected serial or lot number range
	V10
1.	8. Associated devices
	Not Applicable

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Once a patient's allergies have been documented in the Picis Perioperative and Critical Care system, AND the Demographic Summary has NOT been opened at least once, the documented allergies will appear in the Patient Band, audit trail, and form but NOT in the Demographics Summary.
2.	2. Hazard giving rise to the FSCA*
	Issue discovered internally, and under specific workflow steps, which are not recommended and are outside of the typical workflow, it is possible to have conflicting data display to end user. Out of an abundance of caution, this was considered a potential risk and warranted additional investigation/documentation
2.	3. Probability of problem arising
	Low: the workflow required to reproduce this issue is not normally followed by the clinicians using our product.
2.	4. Predicted risk to patient/users
	Issue found during internal testing-multiple opportunities exist to view correct data, however if a user performs specific workflow steps, which are not recommended and are outside of the typical workflow a possibility exists to view conflicting data. For this reason, out of an abundance of caution, this issue is being reported.
2.	5. Further information to help characterise the problem
	This issue had the potential to occur at one client in Spain, one client in Portugal and three clients in Austria as well as 4 clients in North America.
2.	6. Background on Issue
	This issue was identified internally by Picis.
2.	7. Other information relevant to FSCA
	No Additional information

	3. Type of Action to mitigate the risk*
3.	**1. 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 Picis will be providing a software solution through a service pack 10sp4.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety The software solution will be made available in Q2-2023. Picis will work with clients to implement the solution as soon as available.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Software solution being provided through a service pack 10sp4 to be released in Q2-2023	
3	6. By when should the action be completed?	Picis will make the software solution available in Q2-2023 and will work with clients to implement the solution once available.
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Picis Clinical Solutions, Inc.**
	b. Address	**100 Quannapowitt Parkway Suite 405 Wakefield, MA 01880 USA**
	c. Website address	**www.picis.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Following the regulation 2017/745 this Urgent FSN has been communicated to the pertinent National Authorities.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**John Danahey** **Executive Vice President** 

	Transmission of this Field Safety Notice

	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations 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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.