9 Centennial Drive
Suite 202
Peabody, MA 01960
Phone 781.557.3000
www.picis.com

Dec 20, 2024

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. 9 Centennial Drive Suite 202 Peabody, MA 01960 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:

Under certain circumstances, modifying the pump rate in the documentation window for a treatment which includes a unit of volume other than mL may result in inaccurate flowsheet documentation of the administered dose.

The risk is that a clinician relying solely on the flowsheet to assess the treatments received by a patient may not have accurate information for their clinical decision making.

	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*
	Customer Complaint: 'We have an order (drip) where the dose is set to 0 when the fluidrate is changed. If the dose is changed the fluidrate is updated correctly.' Note: Documentation of infusion dose administered is incorrect under circumstances where the volume is not mL and the pump rate is changed.
2.	2. Hazard giving rise to the FSCA*
	During the development of Picis v10, a line of code which supported the conversion of volume units other than mL was inadvertently omitted, causing the application to calculate a numeric dose value based on a volume of mL rather than the specified units (e.g., dL or "bag"). This issue only manifested if the pump rate is modified (resulting in inaccurate documentation of the dose administered). If the "dose administered" itself was changed, the pump rate documentation would adjust correctly.
2.	3. Probability of problem arising
	The probability of injury or death is RARE, given that the issue only affects retrospective documentation. External infusion devices or pharmacy systems are not affected or controlled by this documentation. Treatment decisions are always the responsibility of the clinical end-users and are not automated or triggered by documentation entered into the Picis software.
2.	4. Predicted risk to patient/users
	LOW: The issue affects only the documentation of administration which has already occurred and does not affect the workflow of entering a new order. The issue is confined to a small subset of order types which use a volume other than mL. The root cause identified, a missing conversion factor for a volume other than mL, has been present since the initial Picis 10 release and has only recently been noted by a customer.
2.	5. Further information to help characterise the problem
	Although the risk is low, this issue has the potential to occur at one client in Spain, one client in Portugal, three clients in Austria, one client in Denmark.
2.	6. Background on Issue
	This issue was identified by a customer in Austria.
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 or patch.	
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 Q1-2025. 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? No 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 or patch to be released in Q1-2025.	
3	6. By when should the action be completed?	Picis will make the software solution available in Q1-2025 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	**9 Centennial Drive Suite 202 Peabody, MA 01960 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 PONS COMPANY, JAIME (AUTENTICACIÓN) Digitally signed by PONS COMPANY, JAIME (AUTENTICACIÓN) Date: 2024.12.23 13:48:01 +01'00'	**Marc Lloses** **Executive Vice President** Firmado P.O. por Jaime Pons

	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.