Date: 2024-09-05

Urgent Field Safety Notice (FSN)

ARGUS 717V (REF 601268)

and

ARGUS 718V (REF 601349)

For Attention of: **customer service department / service provider.**

Contact details of local representative
Distributor name
Distributor Contact Person
Distributor Address
Distributor E-Mail
Distributor Phone number

CODAN ARGUS AG • Oberneuhofstrasse 10 • CH-6340 Baar

CODAN ARGUS AG
Oberneuhofstrasse 10
CH-6340 BAAR
Switzerland

Urgent Field Safety Notice (FSN)

ARGUS 717V (REF 601268)

and

ARGUS 718V (REF 601349)

Therapy interruption / delay continuation of therapy

1 Information on Affected Devices	
1.1	**Device Type(s)**
	ARGUS 717V Volumetric Pump (discontinued in 2017) and ARGUS 718V Volumetric Pump (discontinued in 2017) 
1.2	**Commercial name(s)**
	ARGUS 717V and **ARGUS 718V**
1.3	**Primary clinical purpose of device(s)**
	The volumetric pumps ARGUS 717V and ARGUS 718V are purposed to deliver fluids and medications through any clinically accepted route of administration connected to a patient in a predefined way.
1.4	**Device Model/Catalogue/part number(s)**
	REF 601268 and **REF 601349**
1.5	**Affected serial number range**
	All

2 Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem

This problem involves the power board/mainboard female-on-board Micro-Match connector, the flat ribbon cable, and the Micro-Match male connector. If any of these components are defective, the connection between the mainboard and the power board can be compromised.

The flat ribbon cable and connectors are particularly vulnerable to damage if the cable is pulled out by tugging on the wires during servicing.

Additionally, during a Standard Safety Check (SSC) or repairs, if the back and front parts of the A71XV are opened too far without disconnecting the cable, it can create tension on the cable and connectors. This excessive mechanical stress can damage the crimping between the male connector and the cable, leading to a compromised connection between the mainboard and power board.

In case this problem happens, the device could in rare cases unexpectedly shutdown and generates a technical error TE-8131 and/or TE-18028.

2.2 Hazard giving rise to the FSCA

Therapy interruption or delay of continuation of therapy.

2.3 Probability of problem arising

Unlikely

2.4 Predicted risk to patient/users

Therapy interruption or delay of continuation of therapy is effectively an underdosing and/or an underinfusion. The potential severity of harm depends on the duration of the interruption in relation to the pharmacokinetics of the intervention that is interrupted.

2.5 Further information to help characterise the problem

The problem is detected by internal self-tests, leading to technical errors: TE-8131 and/or TE-18028.

2.6 Background on Issue

An investigation into a defective ARGUS 717V revealed that a damaged flat ribbon cable (601342 - flat ribbon cable 24-pole) was responsible for error messages TE-8131 and TE-18028. These errors can occur when the connection between the mainboard and the power board is lost or unstable.

CODAN ARGUS AG • Oberneuhofstrasse 10 • CH-6340 Baar

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 • the flat ribbon cable (REF: 601342 - flat ribbon cable 24-pole) shall always be removed from the female connector by holding and pulling the male connector, not by tugging on the wires. • if the cable of the identified device has been subjected to high mechanical stress at any point during the pump's lifetime, either through stretching during repairs or improper disconnection, the cable should be replaced with a new one (REF: 601342 - flat ribbon cable 24-pole). • in the case of any future service, it is recommended to replace the flat ribbon cable with a new one (REF: 601342 - flat ribbon cable 24-pole), once it has been disconnected from the power board/mainboard.	
3.2	**By when should the action be completed?**	See point 3.1.
3.3	**Is customer Reply Required?** **(If yes, form attached specifying deadline for return)**	Yes
3.4	**Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Service technicians / service providers information through this FSN.	
3.5	**Is the FSN required to be communicated to the patient / lay user?**	No

CODAN ARGUS AG • Oberneuhofstrasse 10 • CH-6340 Baar

4 General Information		
4.1	**FSN Type**	New
4.2	**Further advice or information already expected in follow-up FSN?**	No
4.3	**Manufacturer information** (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**CODAN ARGUS AG**
	b. Address	Oberneuhofstrasse 10, CH-6340 Baar, Switzerland
	c. Website address	www.codancompanies.com
4.4	**The Competent (Regulatory) Authority of your country has been informed about this communication to customers.**	
4.5	List of attachments/appendices:	FSCA001_2024_FSN Customer Reply
4.6	Name/Signature	Luca Pedrinis / CODAN ARGUS AG PRRC

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action till medical device disposal, to ensure effectiveness of the corrective action.

If you have given the ARGUS 717V and ARGUS A718V volumetric infusion pump(s) to third parties, please ensure that all such users are also informed, receive the relevant safety information in this FSN and take the measures specified in this FSN.

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.

CODAN ARGUS AG • Oberneuhofstrasse 10 • CH-6340 Baar

Customer Reply Form

Medical Device Notification Acknowledgement

Please complete this form and return it to CODAN ARGUS AG promptly upon receipt and no later than 30 days after receipt.

1. Field Safety Notice (FSN) information	
FSN Reference number	FSCA001 2024
FSN Date	2024-09-05
Product/ Device name	ARGUS 717V and ARGUS 718V
Product Code(s)	601268 and 601349
Batch/Serial Number (s)	all

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

*Mandatory fields are marked with **

CODAN ARGUS AG • Oberneuhofstrasse 10 • CH-6340 Baar

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 to complete or enter N/A*
☐	The information and required actions have been brought to the attention of all relevant users and executed.	*Customer to complete or enter N/A*
☐	I do not have any affected devices.	*Customer to complete or enter N/A*
☐	I have a query please contact me (e.g. need for replacement of the product).	*Customer to enter contact details if different from above and brief description of query*
Print Name*		*Customer print name here*
Signature*		*Customer sign here*
Date*		

4. Return acknowledgement to sender (per E-mail or Letter)	
Email	support@codanargus.com
Customer Helpline	+41 (0) 41 785 09 44
Postal Address	CODAN ARGUS AG Product Management Oberneuhofstrasse 10 CH-6340 Baar, Switzerland
Deadline for returning the customer reply form	No later than 30 days after receipt

*Mandatory fields are marked with **

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.