



# Urgent Field Safety Notice No. 1 / 2016

Manufacturer: CODAN ARGUS AG  
Product: ARGUS 717 V / ARGUS 718 V  
Subject: Bolus setup in combination with ARGUSmedDB  
Type of Action: Advice regarding the use  
Date: August 2016

## ATTENTION: Distributors, Clinical Customers

Dear distributors, dear customers,

We kindly ask you to distribute this information to all affected personnel responsible for the clinical use of the products listed above.

### Details on affected devices:

CODAN ARGUS identified a design deficiency in ARGUS 717 V / ARGUS 718 V in relation with the use of ARGUSmedDB.

### Purpose:

This is a preventive notification to avoid any harm to patients and provide you with remedy instructions. It contains advice regarding the correct use and will be followed by a resolution to be implemented as a part of a mandatory ARGUS 717 V / ARGUS 718 V firmware release update, which is currently in development.

### Description of the problem:

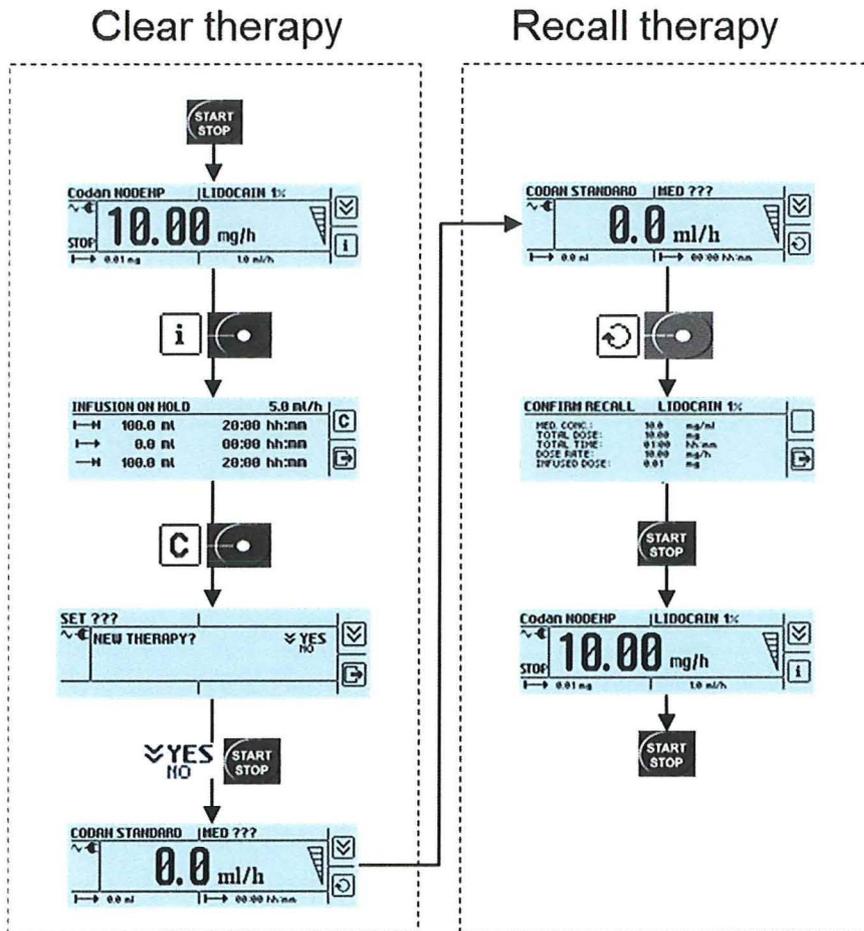
When restarting a finished therapy, ARGUS 717 V and ARGUS 718 V reset the Bolus values, which are defined in ARGUSmedDB, to the system default values for the IV-set defined on the pump. This behavior is incorrect and could cause patient hazard in certain instances.

### Advice on action to be taken by the user:

When using ARGUSmedDB, the predefined Bolus parameters for each medication are only correctly set by clearing and recalling the therapy each time before starting a therapy.



Following workflow demonstrates the advised user action:



Additionally, CODAN ARGUS advises to verify the Bolus parameters every time before applying a Bolus.

BOLUS MENU		MED ???
START		
BOLUS RATE:	1200.	ml/h
BOLUS MAX:	10.0	ml
MODE:	MANUAL	

### Transmission of this Field Safety Notice:

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

### Contact reference person:

If you have further questions, please contact your local distributor or us directly using +41 (0)41 785 09 44 or codan@codanargus.com.



Thank you for your support.

Kind regards,

Oliver Ullmann  
General Manager

Richard Jansky  
Head of Quality Management

Jochen Kurze  
Product Management

The undersigned confirm that the relevant National Competent Authorities have been informed of the FSCA.