

Field Safety Information No. 4 / 2014

Manufacturer: CODAN ARGUS AG

Product: Syringe pump:
green stream SY-P ARGUS 600, Firmware version 1.00 – 1.51
ARGUS 600, Firmware version 3.01 – 4.32

Subject: Missing “syringe alarm” due to wrong replacement parts

Date: November 2014

ATTENTION: Distributors, Clinical Customer, Service Companies, Risk Managers

Dear Customers,

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

This safety information is regarding a missing pump alarm related to syringe recognition and identification caused by incorrect pump maintenance of ARGUS 600 syringe pump.

ARGUS 600 was produced in three firmware (FW) versions:

- Version FW1: green stream SY-P ARGUS 600, firmware version 1.00 – 1.51.
- Version FW3 and FW4: ARGUS 600, firmware version 3.01 – 4.32.

The differences between CODAN ARGUS 600 Version FW1 and Version FW3/FW4 included mechanical, electronical and further logical changes. As there are design differences between FW1 and FW3/FW4, several mechanical parts inside the driver head are not interchangeable across the FW versions – although they are a similar shape.

Investigation of an adverse event revealed that FW3/FW4 clamps were used in one European hospital as replacements for broken FW1 clamps resulting in the “syringe alarm” not activating – even though the syringe was mounted improperly it was possible to start the infusion.

This lack of infusion control / delay of therapy is associated with the risk of under infusion of medication with a potential harm of pain, serious injury or death to patient.

Customers' corrective and preventive actions

Check the compatibility of firmware and clamps by visual inspection described in the following:



Software release display and display test
 Switch off the pump.
 Keep the key "MODE" pressed and press the key "ON/OFF".
 The left hand display shows "600",
 the right hand display "rx.xx" (firmware version) during 3 sec.

<p>The pump green stream SY-P ARGUS 600, firmware version 1.00 – 1.51 must be equipped with clamps (grey parts) as shown in the figure below.</p>	<p>The pump ARGUS 600, firmware version 3.01 – 4.32 must be equipped with clamps (grey parts) as shown in the figure below.</p>
	
<p>If clamps match with FW Continue to use the pump. If a defect occurs until June 2016, remove the device and dispose of it according to WEEE Regulations 2013.</p>	<p>If clamps match with FW Continue to use the pump. Perform the Standard Safety Check according to the maintenance specification by the manufacturer.</p>
<p>If clamps do not match with FW Remove the pump from service and dispose of it according to WEEE Regulations 2013.</p>	<p>If clamps do not match with FW Remove the pump from service and replace the entire housing drive unit followed by a Standard Safety Check. The housing drive unit is designated as part number 10.152 (also known as 600937).</p>
<p>Dispose of all available non preassembled clamps Plan for decommissioning of the pumps in June 2016.</p>	<p>Dispose of all available non preassembled clamps Plan for decommissioning of the pumps in 2019.</p>

User manuals: 14.184.C_A600 en.V3.0X
 14.195.D_A600 en.V4.3X
 Service manuals: 14.188.D_A600 en.SM.V3.0X
 14.194.E_A600_S_en.SM.V4.3X

Spare parts for the pump ARGUS 600, firmware version 3.01 – 4.32 are still available as listed in the service manual above. The spare part list can be downloaded in the login area at codanargus.com or is available from your local area representative

Please contact us for any questions at +41 (0)41 785 09 44 or codan@codanargus.com, or contact your local distributor for assistance.

Thank you for your support.

Kind regards,
CODAN ARGUS AG



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Quality Assurance