

## **Urgent Field Safety Notice**

**Diacon P**

**FSCA-Identifizier: Diacon P 2019-09**

**Correction of values for Cooper and Zine for Lot 0821901, Exp.: 2021- 08-31**

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Date	25.09.2019
Attention	Distributors and users of below listed products

### **Details on affected devices:**

Product:	<b>Diacon P</b>
Catalogue Number:	<b>D98482, D14482, D9848ZSV</b>
Lo :	<b>0821901</b>

### **Description of the problem:**

The values for parameters Zine an Cooper of the package insert of the concerned lot of control show wrong data. It is unlikely that the error leads to a false report of patient values, as the measured values would fall outside the assigned range. The FSN should be discussed with the head of laboratory.

### **Advise on action to be taken by the user:**

Update existing stock with the attached amended instructions for use.

Please fill out the attached Confirmation Form and send it back to us until **25.10.2019**.

### **Transmission of this Field Safety Notice:**

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

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

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

### **Contact Reference Person:**

Mag. Lorenz Miller, Safety Officer, DIALAB GmbH  
Phone: +43 2236 660910-48, e-mail: miller@dialab.at

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

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Mag. ...  
Safety Officer, DIALAB GmbH

## Confirmation Form

**Diacon P**

**FSCA-Identifizier: Diacon P 2019-09**

**Urgent Customer Information**

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Distributor/Customer Details:

Company Name	
Address	

The undersigned confirms that all required actions have been implemented for and all concerned parties have been made aware of this Field Safety Notice.

Completed By	
Telephone / E-Mail	
Date	
Signature	

Please complete this form and send it via e-mail until **25.10.2019** to [office@dialab.at](mailto:office@dialab.at).

Thank you for your efforts!