

## URGENT FIELD SAFETY NOTICE

Sacci Infusion Thermo Bag article no 111521 serial no  
2017:1-XXX, 2017:2-XXX, 2018:1-XXX, 2018:2-XXX

15 May 2019

Dear customer,

The purpose of this letter is to inform you that Sacci Ryggsäckar AB is in the process of carrying out corrective actions for the infusion thermo bag. We ask our customers to follow the user instructions and check that the display is green and control the temperature by hand to ensure that it has body temperature before administration to patients.

### REASON FOR FIELD CORRECTIVE ACTION

The reason for the correction is that a component with a safety function, the overheating protection switch for the bag is set to 60 ° C instead of 45 ° C which was stated in the user manual. This component turns off the power supply to the heater if the temperature reaches 60 ° C as a precautionary measure in case of failure of the control functionality.

The reason for this corrective action is misprint in the user manual, which does not affect the function of the infusion thermo bag and have no risk for patient.

### RISK ASSESSMENT

There is no risk associated with the use of product, provided that users follows the instructions for use which prescribe that green light is lit before taking out bags to use and perform a final check of the temperature by sensing the bag by hand before administrating the infusion solution to patients.

No errors or incidents regarding overheated bags have been reported to Sacci.

### CORRECTIVE AND PREVENTIVE ACTION FOR CUSTOMER AND DISTRIBUTOR

Information goes out to customers and distributors that the overheating protection is triggered at 60 ° C instead of 45 ° C as stated in the manual. A new updated user manual will be available no later than 30 June 2019 on the website, follow the link below:

<https://www.en.sacci.se/products/healthcare/infusion-thermo-bag-ce>

**SACCI**  
SINCE 1914

## CORRECTIVE AND PREVENTIVE ACTION FOR MANUFACTURER SACCI

We apologize for any inconvenience this may have caused and we thank you for helping us filling in the response form on the next page and return it before 30 august 2019. If you have any questions, please contact Sacci or your local distributor in your region.

Sincerely,



Maria Englund, CEO Sacci AB

**SACCI**  
SINCE 1914

## Customer Response for Infusion Thermo Bag 111521

Fill in and return this form to Sacci AB by email to [info@sacci.se](mailto:info@sacci.se)

Select the appropriate box below

We have not acquired or distributed the product

OR

We have distributed the product and hereby confirm that all customers how have purchased this product have been informed and all recommended actions have been carried out.

We have the product in our possession and hereby confirm that all recommended actions have been carried out.

By entering the information below, I confirm that this message has been read, understood and that all recommended actions have been carried out.

<b>PRINT OUT the contact information and fill in this form</b>	
Name	
Title	
Customer name	
Telephone no for contact	
Date	
Signature	

