

## **URGENT – Field Safety Notice**


To all users of the NovoPlus Neuw Upper Arm Blood Pressure Monitor NBP100

### **Re: Discrepancies and Insufficiencies in Markings and Symbols in the User Manual, Rating Label, and Cuff**

Dear customer,

This letter is to inform you of discrepancies and insufficiencies in the markings and symbols found in the user manual, rating label, and cuff of the NovoPlus Neuw Upper Arm Blood Pressure Monitor NBP100 (Lot No.: OBNC005, OBND001, OBNG004, OBNH004, OBNJ007, OBOB006). These issues do not fully comply with certain requirements of the applicable ISO 80601-2-30 standard.

### **What are the discrepancies and insufficiencies in the information, and what are the potential risks?**

Revo Healthcare has conducted an investigation on the NBP100 and its accessories in response to the instruction from the Medical Device Authority (MDA) during a market surveillance activity. The non-compliances in the NBP100 include issues with the rating label (incorrect color for the ISO 7010-M002  symbol), user manual (incorrect colors for the ISO 7010-M002 and warning symbols, insufficient description for the batch code symbol, and incomplete symbol used for the serial number), and cuff (insufficient manufacturer information, missing lot number, and missing ISO 7010-M002 and crossed-out wheeled bin symbols). After a discussion with the MDA, it was concluded that the discrepancies and insufficiencies in the information have a low probability of causing health consequences for users.

### **What steps can the user take to avoid the potential risk of this issue?**

The NBP100 Blood Pressure Monitor has no safety or accuracy issues when inspected against the aforementioned standard. The discrepancies and insufficiencies in the markings and symbols in the user manual, rating label, and cuff are considered a low-risk issue, with a low likelihood of causing health consequences for users. Thus, users may continue using the NBP100 according to the accompanying user manual. However, users may contact Revo Healthcare if they have any queries regarding the markings and symbols or if they wish to obtain an updated user manual for the NBP100.

**How will the issue finally be resolved?**

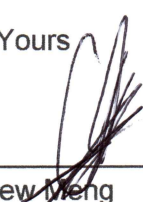
Revo Healthcare Sdn. Bhd. will provide the updated user manual for the NBP100 to affected users upon request. The user manual, rating label, and cuff with the corrected and sufficient information will be included in the next batch of products, as agreed upon by the MDA.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instruction for use. Your personnel should maintain awareness over an appropriate defined period. If you have sold this medical device and is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

Should you have any further queries regarding the Field Safety Notice, please do not hesitate to contact Revo Healthcare Sdn. Bhd. at 04-3059560 / 012-4538640 and/or via email (enquiry@revohealthcare.com). Kindly acknowledge the notification of this field safety notice by completing the "Field Safety Notice Response Form" and reverting it to email (enquiry@revohealthcare.com) or facsimile (04-8298640).

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours

  
Cheah Chew Meng  
Managing Director  
11 March 2025



**Contact person of this notification:**

Name: Liz Lee

Establishment: Revo Healthcare Sdn. Bhd.

Department: RA/QA

Telephone: 04-305 9560 / 012-453 8640

Email: liz.lee@revohealthcare.com



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## Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the NovoPlus Neuw Upper Arm Blood Pressure Monitor NBP100 with the Lot / Serial number \_\_\_\_\_ (optional) that I received the following document:

## Field Safety Notice

**NovoPlus Neuw Upper Arm Blood Pressure Monitor NBP100 with Discrepancies and Insufficiencies in Markings and Symbols in the User Manual, Rating Label, and Cuff (Ref: REVO/FSN/2025/01)**

Received by:

\_\_\_\_\_  
Name:

Position:

Address:

Date:

Company Stamp

**PLEASE RETURN THE COMPLETED RESPONSE FORM TO:**

Revo Healthcare Sdn. Bhd.

Email: enquiry@revohealthcare.com

Facsimile: 04-8298640