



## URGENT - Field Safety Notice

To all users of the Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523

### **Re: Discrepancies and Insufficiencies in Markings and Symbols in the User Manual, Label, and Cuff for Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523**

Dear customer,

This letter is to inform you of discrepancies and insufficiencies in the markings and symbols found in the user manual, label and cuff of the Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523.

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

ReanneQ Sdn Bhd has conducted an investigation on Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523 following announcement and instruction from the Medical Device Authority (MDA) during a market surveillance activity. The non-compliances in the affected device include issues with label on device (insufficient manufacturer information, missing lot number, symbols not according to relevant ISO standard), IFU (colours of safety sign not according to ISO 3864-1, insufficient information), and cuff (missing manufacturer information, model, batch information). After a discussion with 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 Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523 has no safety or accuracy when inspected against the relevant standards. The discrepancies and insufficiencies in the markings and symbols in the label, IFU and cuff are considered a low-risk issue, with a low likelihood of causing health consequences for users. Thus, users may continue using Ouson+ BSX523. However, users may download the revised IFU in ReanneQ's website or if they have any queries, they may contact ReanneQ directly.

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

ReanneQ Sdn.Bhd. will upload the revised IFU for the Ouson+ BSX 523 into the company's website and affected users may download them directly from there. The IFU, label and cuff with the corrected and sufficient information will be included in the next batch of products.

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 instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it 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.

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

Sincerely Yours

  
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**REANNEQ SDN BHD** (1351295-W)  
A-05-29, Kompleks Perindustrian EmiHub,  
Persiaran Surian, Kota Damansara  
47810 Petaling Jaya, Selangor, Malaysia

Carol Bong

10<sup>th</sup> April 2025

Contact person of this notification: Carol Bong

Department: Operation

Telephone: 0168960333

E-mail: carolbong@reanneq.com



## Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the *Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523* with the Serial number \_\_\_\_\_ (optional) that I received the following document:

## Field Safety Notice

Ouson+ Arm Type Electronic Blood Pressure Monitor BSX523 with Discrepancies and Insufficiencies in Markings and Symbols in the User Manual, Label, and Cuff

Place : \_\_\_\_\_

Date : \_\_\_\_\_

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

Signature: \_\_\_\_\_

Company stamp:

**REANNEQ SDN BHD** (1351295-W)  
A-05-29, Kompleks Perindustrian EmHub,  
Persiaran Surian, Kota Damansara  
47810 Petaling Jaya, Selangor, Malaysia