



URGENT - Field Safety Notice

To all users of the **Blood Pressure Monitor YE660E**.

Re: Blood Pressure Monitor YE660E with the situation where the information of the Outdated Labelling, QR Code Discrepancy and Labelling / IFU Compliance

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the Outdated Labelling, QR Code Discrepancy and Labelling / IFU Compliance of the Blood Pressure Monitor YE660E

When does this malfunction occur and what are the potential risks?

- 1) Outdated Labelling - Existing stock in the warehouse contains outdated information on the product packaging and labels.
- 2) QR Code Discrepancy- The QR codes printed on the packaging are obsolete and do not link to the correct or updated information.
- 3) Labelling / IFU Compliance- Instructions for Use (IFU) for home-use devices must fully comply with the requirements of Act 737.

These three issues which is not conducive to the traceability of after-sales service.

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

Include as appropriate:

- 1) Site Rectification- Our personnel will conduct on-site visits to all affected retail outlets, pharmacy chains, and healthcare facilities to rectify the labelling and QR codes on existing stock.
- 2) On-Site Execution- This approach ensures that all units currently available at points of sale are brought into compliance immediately, without requiring the return of stock from retailers.
- 3) Refer to our latest version of the instruction for Use



How will the issue finally be resolved?

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO, LTD is preparing a new QR Code, Label and Malay translation of Instruction for Use, that will resolve this potential malfunction. The field modification will be available from April 15, 2026.

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

Signature

Name: Yan Xiangrong

Date: April 15, 2026

Contact person of this notification:

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Department : Overseas Business Department
Telephone : +86-18260613080
Fax :86-0511-86900859
E-mail :yan.xr@yuyue.com.cn



Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the **YUWELL Blood Pressure Monitor YE660E** with the Serial number;

GWM660E2412001-GWM660E2412400 and GWM660E25020001-

GWM660E25021000 and GWM660E25050001-

GWM660E25050400 and GWM660E25080001-

GWM660E25080500 and GWM660E26010001-GWM660E26010600

that I received the following document:

Field Safety Notice

YUWELL Blood Pressure Monitor YE660E with the situation where the information of the Outdated Labelling, QR Code Discrepancy and Labelling / IFU Compliance.

Place : _____

Date : _____

Name : _____

Signature: _____

Company stamp: