

MEDICAL LABELING CORRECTION

Electronic Instructions for Use (eIFU) missing on the Medtronic Manual Library website

eIFU for the following products:		
Country	Product Name(s)	Model #/CFN
Malaysia	Micra™ AV	MC1AVR1
	Azure™ XT DR MRI SureScan™	W2DR01
	Azure S DR MRI SureScan	W3DR01

26 July 2023 | 03:28 PDT

Dear Customer:

Medtronic is addressing several instances of missing electronic Instructions for Use (eIFU) on the Medtronic Manual Library website for the Medtronic products identified above. **Medtronic is not requesting any return of product from your facility**, nor does this issue impact any function or therapy delivery of any Medtronic device.

During a routine review, Medtronic discovered instances of eIFU not posted within the specific country section of the online Medtronic Manual Library. Based on an internal investigation and risk assessment, the issue has negligible or no impact on patient safety. **The missing eIFU are now available in the Medtronic Manual Library**: please visit <http://manuals.medtronic.com> to access.


Customers are asked to share this information with clinicians in your facility who implant or provide follow-up care for patients with the above-identified products, and complete the enclosed Confirmation Form and hand or scan then email back to your local Medtronic field representative.

Medtronic is communicating this information to the appropriate regulatory agency in your country.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic field representative.

Sincerely,

DocuSigned by:
Soon Yee Chow

 Signer Name: Soon Yee Chow
Signing Reason: I approve this document
Signing Time: 26 July 2023 | 03:28 PDT
1E2740387A274E0090C4FDEFC815685A

Quality and Regulatory Affairs Lead
Malaysia

Medtronic

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Customer Confirmation Form

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For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately

Customer Contact Details		Medtronic Contact Details	
Distributor/Hospital/Clinic/Patient name:		Name:	
Address:		Contact:	
Phone no:	Email:	Email:	

By signing this form, I confirm that I have read the Electronic Instructions for Use (eIFU) missing on the Medtronic Manual Library Website. Notification Letter, dated 26 July 2023 | 03:28 PDT and taken the actions identified in the letter.

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic field representative.

Name (print): _____ Signature: _____ Stamp: _____ Date:

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For questions, contact your local Medtronic field representative.