

URGENT MEDICAL DEVICE CORRECTION



1 October 2025

GE HealthCare Ref. # 74084

To: Head of Ultrasound Department
Hospital Administrator
Biomedical Engineering

RE: **LOGIQ P9 and LOGIQ P10 series ultrasound systems, with software R4.5.7**

Safety Issue

GE HealthCare has become aware of an issue on certain LOGIQ P9 and LOGIQ P10 series ultrasound systems with system software version R4.5.7. The Ultrasound-Guided Attenuation Parameter (UGAP) measurement data may display inaccurate values representing liver steatosis. This could potentially lead to inappropriate clinical decisions impacting overall care.

Actions to be taken by Customer/Us er

For LOGIQ P9 and LOGIQ P10 series ultrasound systems with system **software version R4.5.7**, discontinue using the UGAP feature (please see Appendix for product identification). You may continue using other imaging features.

After the correction has been implemented, please destroy the installation media for software R4.5.7 at your site.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.74084@gehealthcare.com.

Affected Product Details

LOGIQ P9 R4.5 system (PN 5877533)
LOGIQ P10 R4.5 system (PN 5877534)
LOGIQ P10 R4.5 HD system (PN 5877535)

Intended Use: The LOGIQ P9/P10 is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal Intraoperative (abdominal, vascular)

Product Correction

GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare



Scott Kelley
Chief Medical Safety Officer
GE HealthCare

Appendix:

Part Number (PN) location and Software Version instructions for GE HealthCare LOGIQ P9 R4.5.7 and LOGIQ P10 R4.5.7

Affected Product Details

LOGIQ P9 R4.5 system (PN 5877533)
LOGIQ P10 R4.5 system (PN 5877534)
LOGIQ P10 R4.5 HD system (PN 5877535)

You can find the Part Number (PN) on the label on the side of the system. See Figure 1 below.

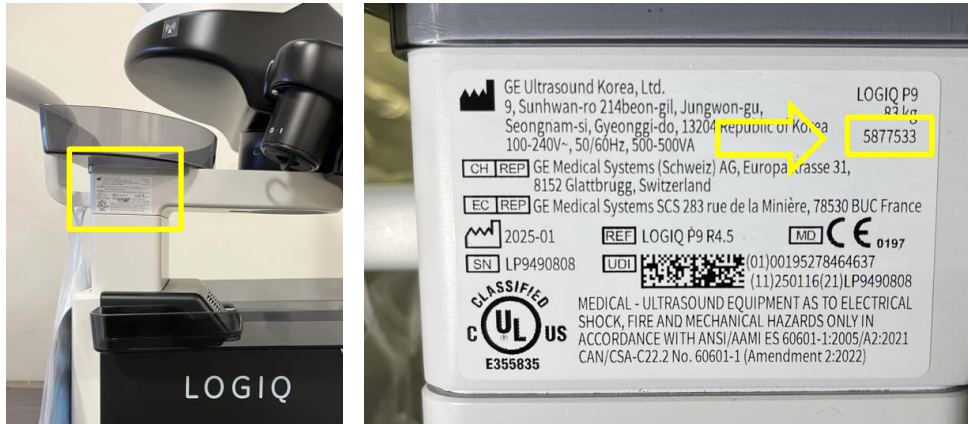


Figure 1 – Location of Label and Part Number

To confirm the **system software version**:

On the touch panel, press **Utility** and enter the **About** section on the screen. See Figure 2 below.

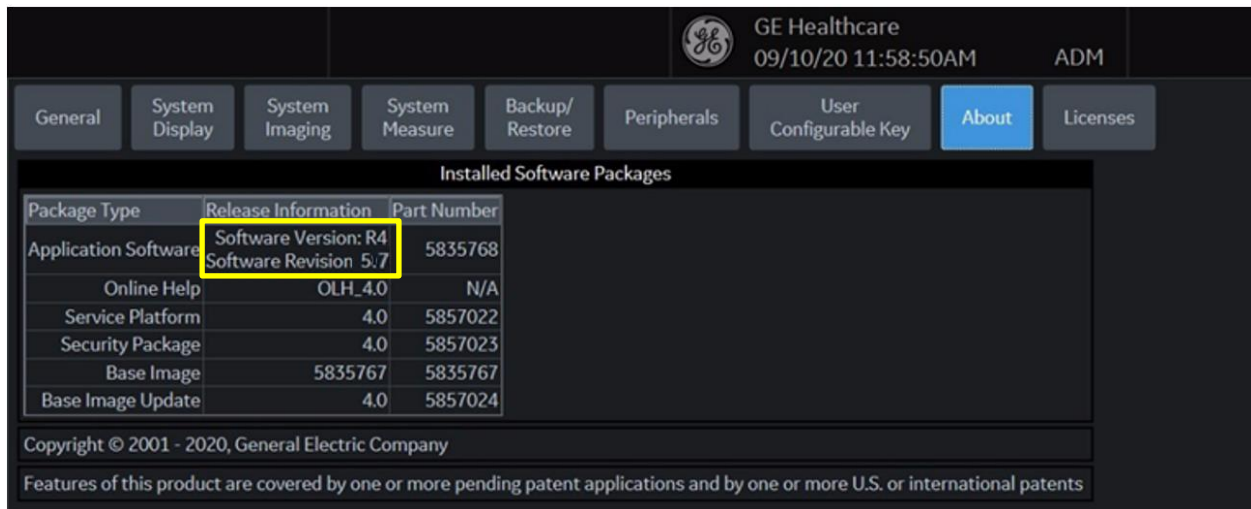


Figure 2 – Location of Software Version and Revision

If information is showing

- **Software Version: R4**, and
- **Software Revision: 5.7**,

then that system is **in scope** for this corrective action.

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

Facility Name: _____
Street Address: _____
City/State/ZIP/Country: _____
Customer Email Address: _____
Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____
Printed Name: _____
Position/Job Title: _____
Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: recall.74084@gehealthcare.com

