

URGENT Field Safety Notice

**3D9-3v Transducer (Accessory to Philips Ultrasound Systems:
EPIQ Elite, Affiniti 30, 50, and 70, ClearVue 850, HD15, iU22, Compact 5000)**

3D9-3v Transducer may come apart due to chassis bonding issue

June 29, 2023

**If the serial number for your 3D9-3v Transducer is listed in Appendix A:
Please immediately stop use and/or distribution of transducer listed in Appendix A.
(See also section 4 Actions to be taken by customer).**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with 3D9-3v Transducers where these transducers may come apart. This failure may occur during clinical use. This *URGENT Field Safety Notice* is intended to inform you to **immediately stop using the potentially affected 3D9-3v Transducers.**

1. What the problem is and under what circumstances it can occur.

The 3D9-3v Transducer chassis assembly consists of two parts that are bonded together. The bond between the front and rear parts of the chassis of these transducers may fail as shown in Figure 1 below.

Figure 1. Transducer Bond Failure



Philips has received complaints associated with this issue; however, there are no reports of injury or serious harm.

2. Hazard/harm associated with the issue.

If the transducer comes apart, the risk to users and patients includes tissue damage (laceration) due to contact with sharp edges and delay in diagnosis, procedure, or treatment. In addition, electric shock may occur if the transducer comes apart and the built-in safety measures to prevent electric current from reaching the patient/operator were to also fail in the transducer or the Ultrasound system. The built-in safety measures to mitigate electric current are independent mechanisms from the chassis and are not impacted if the chassis comes apart.

3. Affected products and how to identify them.

To identify your transducer serial number:

The potentially affected 3D9-3v Transducer serial numbers are listed in Appendix A. Refer to Figure 2 and Figure 3 below to locate the transducer number, device identifier and the serial number. The device identifier is 00884838061545.

Figure 2. 3D9-3v Transducer

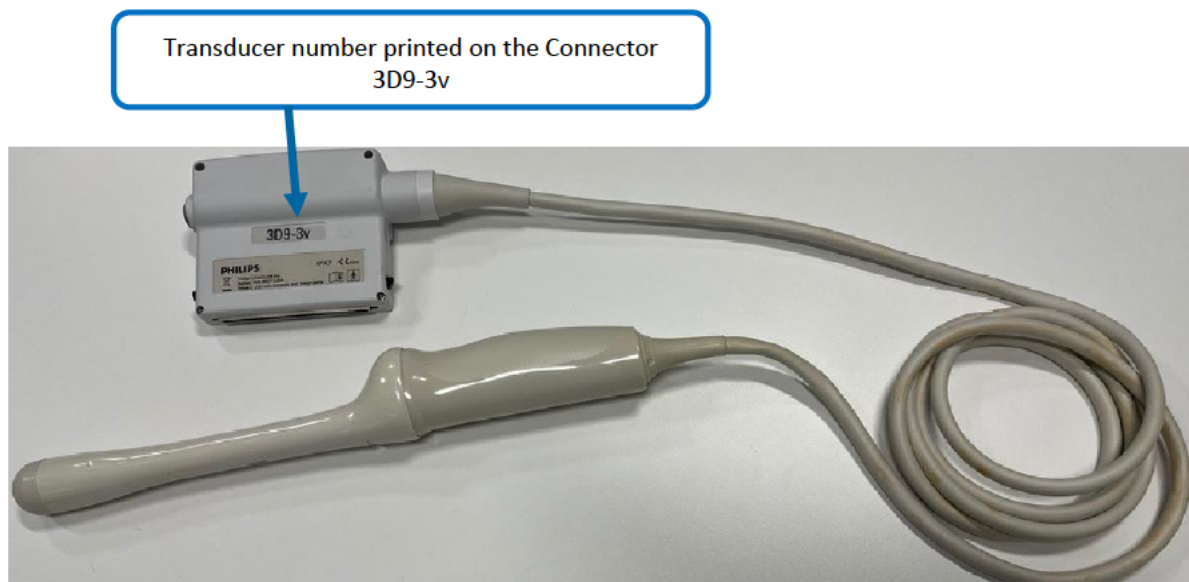


Figure 3 Device Identifier and Serial Number printed on the Connector.



Intended Use:

Ultrasound systems are intended for diagnostic ultrasound imaging or fluid flow analysis of the human body. The clinical environments where these Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users.

- **Immediately stop usage and/or distribution of the affected 3D9-3v Transducers and secure them in a location where they cannot inadvertently be used.** Transducers not included in Appendix A are not affected by this recall and can be used in accordance with the instructions for use.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.
- Circulate this Urgent Field Safety Notice to all users of this device so that they are aware of the issue. Please retain this letter with your system(s) and ensure the letter is in a place likely to be seen/viewed.

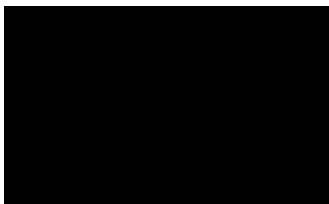
5. Actions planned by Philips to correct the problem.

A Philips representative will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site, provide a replacement device, and collect the affected product (reference FCO79500565).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,



Quality Leader - Philips Ultrasound

URGENT Field Safety Notice Response Form

Reference: 3D9-3v Transducer may come apart due to chassis bonding issue (FC079500565).

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- **Immediately stop usage and/or distribution of the affected 3D9-3v Transducers and secure them in a location where they cannot inadvertently be used.** Transducers not included in Appendix A are not affected by this recall and can be used in accordance with the instructions for use.
- Circulate this Urgent Field Safety Notice to all users of this device so that they are aware of the issue. Please retain this letter with your system(s) and ensure the letter is in a place likely to be seen/viewed.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected 3D9-3v Transducers.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed form to your Philips representative.

Appendix A – Serial Numbers of the affected 3D9-3v Transducer List

B3TBRW	F01W12	F01ZG6	F01ZZ5	F024G2	F03Q35	F04DX8	F04DXC	F04DXD	F04F28
F04F29	F04F2G	F04F2H	F04F2L	F07GY0	F07VBZ	F07XRT	F07XRV	F07XRX	F07Y4Q
F083JP	F086Z5	F088QC	F08JPF	F08K4H	F08VLP	F08VLY	F08W1C	F08W1D	F08W1J
F08W1K	F08W1L	F08W1M	F08W1Q	F08WXP	F08WXY	F08WZY	F08X01	F08X02	F08X03
F08X04	F08Y2T	F08ZR3	F08ZR4	F08ZR5	F092BQ	F092BR	F092BV	F097QQ	F097QV
F097QW	F09BTB	F09BTC	F09BTD	F09BTG	F09BTH	F09BTN	F09BTP	F09C1G	F09C1H
F09C1L	F09C1M	F0BXC	F0BXT4	F0BXT5	F0BXT7	F0C3W1	F0C4DJ	F09F3R	F09F3T
F09F3V	F09F3X	F09F3Y	F09F3Z	F09F40	F09F41	F09F42	F09F43	F09F45	F09F48
F09F49	F09F4C	F09F4D	F09F4F	F09F4G	F09F4H	F09JT0	F09JT2	F09JT3	F09MH4
F09MH5	F09MH6	F09MH7	F09MH8	F09MH9	F09MHB	F09MHC	F09MHG	F09MHH	F09MHK
F09MHL	F09MHM	F09MHN	F09MHP	F09N4J	F09N4K	F09N4M	F09N4N	F09N4P	F09NLM
F09NLN	F09NLP	F09NLQ	F09NLR	F09NLT	F09V25	F09V26	F09V27	F09V28	F09V29
F09V2C	F09V2D	F09V2F	F09V2G	F09V2H	F09V2J	F09VH6	F09VH7	F09VH9	F09VHB
F09VWL	F09VWM	F09VWN	F09VWP	F09VWQ	F09XY4	F09XY5	F09XY6	F09XY7	F09XY8
F09XYB	F09XYD	F09XYF	F09XYG	F09XYH	F09YQ7	F09YQ8	F09YQ9	F09YQB	F0B16J
F0B16K	F0B16M	F0B16P	F0B1K5	F0B1K6	F0B1K7	F0B1K8	F0B1K9	F0B5KP	F0B5KQ
F0B5KR	F0B5KT	F0B5KV	F0B5KW	F0B6K9	F0B6KB	F0B6KC	F0B6KD	F0B6KF	F0B6KG
F0B7ND	F0B7NF	F0B7NG	F0B7NH	F0B7NJ	F0B7NK	F0B7NM	F0B7NN	F0B7NQ	F0B7NT
F0B7NX	F0B7NY	F0B7P0	F0B7P4	F0B7P5	F0B7X9	F0B7XC	F0B7XD	F0B7XG	F0B8G7
F0B8G8	F0B8G9	F0B8GB	F0B95D	F0B95G	F0B95H	F0BB01	F0BB02	F0BB03	F0BBGT
F0BBGW	F0BBGX	F0BBGY	F0BBGZ	F0BCFQ	F0BCFR	F0BDMQ	F0BDMR	F0BDMT	F0BDMV
F0BFK8	F0BFKB	F0BFKC	F0BFXH	F0BFXJ	F0BFXK	F0BFXM	F0BFXN	F0BFXQ	F0BFXV
F0BHWP	F0BHWQ	F0BHWR	F0BHWT	F0BHWV	F0BHWV	F0BHZP	F0BHZR	F0BHZT	F0BHZV
F0BHZW	F0BHZZ	F0BJ00	F0BJ01	F0BJ9X	F0BJ9Y	F0BJB0	F0BJB1	F0BJB2	F0BJYQ
F0BJYR	F0BL03	F0BL06	F0BMC1	F0BMC4	F0BMC5	F0BMC6	F0BN4N	F0BN4T	F0BN4V
F0BR78	F0BR79	F0BR7B	F0BR7D	F0BRMH	F0BRMJ	F0BT87	F0BT88	F0BT8B	F0BT8C
F0BVPB	F0BVPC	F0BVPF	F0BW00	F0BW01	F0BW02	F0BW03	F0BW04	F0BW05	F0BXCT
F0BXC	F0BXCW	F0BXCX							