

Ambu A/S
Baltorpbakken 13
D-2750 Ballerup
Denmark
T +45 72 25 20 00
F +45 72 25 20 50
ambu@ambu.com
www.ambu.com
CVR. nr. 63644919
06 September 2024

Urgent Field Safety Notice

Ambu® VivaSight™ 2 DLT

Ambu A/S - Single Registration (SRN): DK-MF-000001437

16/09/2024

Details on affected devices:

Model	Catalog Number	Affected Expiration dates and LOTs:
Ambu® VivaSight™ 2 DLT Kit 35 Fr	412351000	30-08-2026 to 26-06-2027, LOT no.1000883048 to 1001021855
Ambu® VivaSight™ 2 DLT Kit 37 Fr	412371000	30-08-2026 to 24-06-2027, LOT no. 1000883059 to 1001021861
Ambu® VivaSight™ 2 DLT Kit 39 Fr	412391000	02-09-2026 to 26-06-2027, LOT no. 1000883071 to 1001021917
Ambu® VivaSight™ 2 DLT Kit 41 Fr	412411000	04-09-2026 to 05-06-2027, LOT no. 1000883080 to 1001011434



Expiration date

Ambu® VivaSight™ 2 DLT Kit 35 Fr - LEFT

Kit - Double lumen endobronchial tube with camera
DE: Set - Doppellumentubus mit Kamera, ES: Kit - Tubo de doble luz con cámara, FR: Kit - Sonde double lumière avec camera, IT: Kit - Tubo endotracheale a lume doppio con videocamera, PT: Kit - Tubo endobronquial de duplo lúmen com cámara

REF 412351000

LOT XXXXXX

YYYY-MM-DD



US: Rx LOT no.

Description of the problem:

Ambu has received complaints regarding the design of the product Ambu® VivaSight™ 2 DLT, specifically referring to a hyper angulation of the distal end of the double lumen tube. This hyper angulation can potentially lead to an increased risk of complications during intubation and potential airway injury.

A root cause investigation has indicated that the hyper angulation deviation is linked to a manufacturing issue that occurred during a specific timeframe in the production of the product. The findings furthermore conclude that not all products are impacted by this issue. Thus, the majority of Ambu® VivaSight™ 2 DLTs available are not affected by this deviation.

Following the investigation, Ambu has immediately implemented a correction in the manufacturing process to resolve the issue.

Advise on actions to be taken by users:

The tracking system at Ambu indicates that your institution has purchased the Ambu® VivaSight™ 2 DLT products and that there may be affected devices in your stock.

Please identify if any of your Ambu® VivaSight™ 2 DLT products belong to the affected expiration dates and LOT numbers listed on page 1 of this Field Safety Notice. If so, you should not use the product and you must discard the identified products.

Ambu will compensate you by either replacing the units with a new Ambu® VivaSight™ 2 DLT product or an Ambu® aScope™ 4 Broncho Slim, which can be used with a conventional DLT, or by providing a refund.

Please return your confirmation of the actions described in the Field Safety Notice (Appendix 1) within 2 weeks of receiving of this letter.

Transmission of this Field Safety Notice:

This Field Safety Notice must be passed on to all relevant personnel within your organisation or to any other organisations where the devices may have been transferred. Therefore, please forward this notice to other organisations that may be impacted by this issue.

Also, please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologise for any inconvenience and thank you in advance for your cooperation.

Ambu confirms that this notice has been notified to the appropriate Regulatory Agency.

Contact reference person:

Jennifer Gregory

Product Manager, Pulmonary

jejr@ambu.com

07436 230 961

Ambu Limited, Incubator 2, Alconbury Weald Enterprise Campus, Cambridgeshire, PE28 4XA

Appendix 1:

Confirmation on Field Safety Notice Completed

Return to:

Jennifer Gregory
Jegr@ambu.com

The undersigned person hereby confirms that

has completed the actions described in the Field Safety Notice from Ambu A/S dated 16/09/2024 regarding.
Ambu® VivaSight™ 2 DLT

Total number of products discarded: _____

Please fill in Table 1 if your organisation has discarded Ambu® VivaSight™ 2 DLT

or

The organisation has not identified any deform VivaSight 2 DLT:

Date

Name

Title

Signature

E-mail

Table 1 Overview of discarded affected items at your organization.

Model	Catalogue number	Quantity
Ambu® VivaSight™ 2 DLT Kit 35 Fr	412351000	
Ambu® VivaSight™ 2 DLT Kit 37 Fr	412371000	
Ambu® VivaSight™ 2 DLT Kit 39 Fr	412391000	
Ambu® VivaSight™ 2 DLT Kit 41 Fr	412411000	