Ambu AG
Lerzenstrasse 10
8953 Dietikon
T 044 551 97 20
F 044 551 97 21
CHE-244.930.632

www.ambu.ch
vid-ch@ambu.com

To how it may concern

20.11.2023

Urgent Field Safety Notice

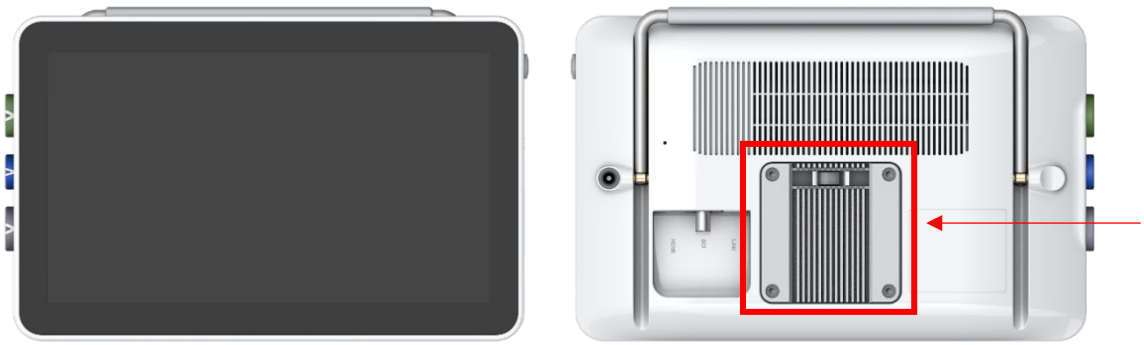
New warning in Instructions for Use for Ambu® aView™ 2 Advance

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

20.11.2023

Details on affected devices:

Model	Catalogue number	Explanation	Version no.
Ambu® aView™ 2 Advance	405011000	aView 2 Advance Gen 1, Global	All versions
	405011000US1	aView 2 Advance Gen 2, United States	
	405011000EUA1	aView 2 Advance Gen 2, Europe	
	405011000EUB1	aView 2 Advance Gen 2, Europe	
	405011000EUC1	aView 2 Advance Gen 2, Europe	
	405011000AUS1	aView 2 Advance Gen 2, Australia	
	405011000JPN1	aView 2 Advance Gen 2, Japan	
	405011000ROW1	aView 2 Advance Gen 2, Rest-of-World	
	405011000US2	aView 2 Advance Gen 2, United States	
	405011000EUA2	aView 2 Advance Gen 2, Europe	
	405011000EUB2	aView 2 Advance Gen 2, Europe	
	405011000EUC2	aView 2 Advance Gen 2, Europe	
	405011000AUS2	aView 2 Advance Gen 2, Australia	
	405011000JPN2	aView 2 Advance Gen 2, Japan	
	405011000ROW2	aView 2 Advance Gen 2, Rest-of-World	



Ambu A/S is committed to transparent communication with our customers to ensure you have timely, relevant information for managing your patients. This Field Safety Notice (FSN) provides important information regarding Ambu aView® 2 Advance™. The affected device information is listed below.

Description of the problem:

Ambu has received information on two incidents where Ambu® aView™ 2 Advance caught fire when mounted on the VESA holder of the aCart™ Compact, due to the screws used entering the lithium-ion battery of the device. No patients or staff members were harmed during the incidents.

VESA holder is a generic standard that specifies dimensions of screw-holes for mounting Ambu® aView™ 2 Advance to a cart or stand. Therefore, even though aCart™ Compact is not available in your market, any other brand medical workstations with VESA holder and longer screw lengths could be used in your market resulting in a similar fire hazard.

Packaging of aCart™ Compact includes several choices of screw lengths (12, 16, 20, 30 mm) as VESA holder is usually used for external medical monitors. In these two cases, customers mounted Ambu® aView™ 2 Advance on the VESA holder using too long screws meant for external monitors.

Upon conducting a comprehensive investigation, we have identified the root cause of these incidents. The fire hazard was a direct consequence of a battery short-circuit, which, in turn, was triggered by the use of excessively long screws to secure the device on the VESA holder. The longer screw lengths inadvertently penetrated the lithium-ion battery, leading to the fire hazard.

Since VESA option is available in the product design, we want to inform our customers of the risk of penetrating the lithium-ion battery when using too long screws for mounting. At the same time, we would like to inform our customers on how to securely fasten the Ambu® aView™ 2 Advance. In case your Ambu® aView™ 2 Advance is placed on a table or mounted on an IV pole as recommended practice there is no risk of penetrating the battery and associated fired hazards.

We urge our customers to be aware of the below Warning applicable to the *Instructions for Use* of Ambu® aView™ 2 Advance:
Use only M4 screws with the length of 14 – 16 mm when mounting Ambu aView 2 Advance on a VESA interface. Using longer screw lengths will penetrate the lithium-ion battery and result in a fire hazard and battery leakage which can cause severe burns, smoke inhalation and skin irritation. Using shorter screw lengths could result in unsecure device fastening.

The information in this Field Safety Notice is relevant for all versions of Ambu® aView™ 2 Advance.

Please communicate this information to relevant personnel within your organization. Included with the Field Safety Notice, you will find an insert for the *Instructions for Use* for Ambu® aView™ 2 Advance. The insert should be read and kept together with *Instructions for Use* you received together with your Ambu® aView™ 2 Advance. The information is also included in Appendix 2 of this notice.

Ambu A/S is not removing any Ambu® aView 2™ Advance from the field; devices remain available for use.

Advise on actions to be taken by user:
Within one month of receipt of this letter, please return confirmation of receipt of this Field Safety Notice (appendix 1).

Please familiarize yourself with the information in the insert of Instructions for Use and keep the insert together with the *Instructions for Use* booklet.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who this might concern within your organization or to any organization where the devices could have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Patient safety remains our highest priority. If you have additional questions regarding this information, please contact your local Ambu sales representative.

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

Contact reference person:
Ambu AG
Lerzenstrasse 10
CH-8953 Dietikon

vid-ch@ambu.com
Tel. +41 44 551 97 20

[redacted]

CH-REP, Country Manager

Appendix 1:

Confirmation on
Field Safety Notice RECEIVED
Return to vid-ch@ambu.com

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has received Field Safety Notice from Ambu A/S dated 20.11.2023 regarding Ambu® aView™ 2 Advance.

_____

Date

_____

Name

_____

Title

_____

Signature

Appendix 2:

Text included in the insert for the Instructions for Use

WARNING ⚠
Use only M4 screws with the length of 14 – 16 mm when mounting aView 2 Advance on a VESA interface. Using longer screw lengths will penetrate the lithium-ion battery and result in a fire hazard and battery leakage which can cause severe burns, smoke inhalation and skin irritation. Using shorter screw lengths could result in unsecure device fastening.

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