
Urgent Field Safety Notice

Instruction for Use update for aView 2 Advance

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

[Date] [to be filled out by Ambu Sales or Distributor]

[Attention:] [to be filled out by Ambu Sales or Distributor]

Details on affected devices:

Model	Catalogue number	Version no.	Manufacturing date
aView 2 Advance	405011000	054 055 056 058 059	Before: October 29, 2020

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 where Ambu® aView™ 2 Advance has been dropped on the floor, short-circuited, and thereafter combusted. No patient or staff member was harmed, and the incident is regarded as an exceptionally rare case.

Regardless, we want to inform our customers that such an event – although exceptionally rare – is possible when working with devices powered by lithium-ion batteries.

Investigation has shown, that in very rare cases, multiple impacts, for example from being dropped, can cause to the Ambu® aView™ 2 Advance to short-circuit and under special circumstances make the lithium-ion battery in the device combust leading to smoke and flames.

No complaints have been received in which a patient or staff member has been reported to have been harmed.

Since launch of Ambu® aView™ 2 Advance, design changes have been implemented to avoid the risk of a short-circuit. The cause for combustion has been thoroughly investigated and the subsequent implemented changes have appropriately limited the risk of combustion of the lithium-ion.

The information in this Field Safety Notice is therefore only related to the earliest configurations (versions) of Ambu® aView™ 2 Advance as listed above.

Please communicate this information to relevant personnel within your organization. Included with the Field Safety Notice, you will find an insert for the Instruction for Use for Ambu® aView™ 2 Advance. The insert should be read and kept together with Instruction 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).

The traceability system at Ambu indicates that your institution has purchased an Ambu® aView™ 2 Advance within the affected configurations.

You should check the version number and manufacturing date (as indicated above) of your device to identify if you have a potentially affected device within your facility. In the case that your device is related to the earliest configurations of Ambu® aView™ 2 Advance, you address this by familiarizing yourself with the information in the Instruction for Use insert and keep the insert together with the Instruction for Use.

In case your device has already been returned to Ambu we apologize for the inconvenience and kindly ask you to include this information in Appendix 1.

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 on 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:
[Name / organisation, address, contact details Ambu Sales or Distributor]

[Signature Ambu Sales or Distributor]

Appendix 1:

Confirmation on
Field Safety Notice RECEIVED
Return to [filled in by Sales/Distributor]

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has received Field Safety Notice from Ambu A/S dated [date] regarding aView 2 Advance.

Version number and manufacturing date: _____

If applicable:

- The aView 2 Advance has already been returned to Ambu ☐
- The aView 2 Advance is no longer within the organization ☐

_____

Date

_____

Name

_____

Title

_____

Signature