
Urgent Field Safety Notice

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

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

This letter is to notify you of a potential safety issue related to Ambu® A valve. Ambu® A valve is an anesthesia valve designed for use in anesthesia breathing systems as a non-rebreathing or single directional valve.

Details on affected devices:

Product Name	Catalogue number
Ambu® A valve	A019 001 000

Description of the problem:
Ambu has received an incident report following use of Ambu® A valve from a French hospital, where the patient involved was diagnosed with barotrauma following incorrect use of the A valve.

For safe use of the Ambu® A valve in anesthesia systems it is required that the device is used in combination with a pressure limiting valve.

During investigation and evaluation of the incident, it has been concluded that from a clinical perspective, the users may not recognize the importance of placing and/or correct mounting of a pressure limiting valve as stated in the Instruction for Use. This may be due to use of more modern anesthesia systems which has built-in safety features. The Ambu®A valve was developed more than 20 years ago and is no longer state-of the-art and the product does not have built-in safety features to mitigate the risk.

Advise on actions to be taken by user:
Within 1 week 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 the Ambu® A valve device and there may be devices in your stock. You should address this by discontinue use and discarding your Ambu® A valve device according to local regulations.

Within one month of receipt of this letter, please return your confirmation of actions described in Field Safety Notice Completed (appendix 2).

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

Please transfer this notice to other organisations 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.

We sincerely apologise for any inconvenience and thanking you in advance for your cooperation. Ambu confirms that this notice has been notified to 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 MM-DD-2020 regarding Ambu® A valve.

_____

Date

_____

Name

_____

Title

_____

Signature

Appendix 2:

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

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has completed the actions described in Field Safety Notice from Ambu A/S dated MM DD, 2020 regarding Ambu® A valve.

Number of products discarded: _____

Or

The organisation has previously ceased use of Ambu® A Valve and all devices have been discarded:
YES ☐ NO ☐

_____

Date

_____

Name

_____

Title

_____

Signature