
April 18, 2019

Urgent Field Safety Notice:

Disposable Expiratory Filter included in Ambu® SPUR® II Disposable Resuscitator kit

Dear Customer,

Details on affected devices:

Product name: Disposable Expiratory Filter (included in Ambu SPUR II Disposable Resuscitator kit)

Catalog Number: See Appendix 2

Lot Number: See Appendix 2

Products delivered from March 2018 to February 2019 are without indication of expiry date (of the filter).

Description of the problem:

You have received Ambu SPUR II Disposable Resuscitator kit where the expiry date of Disposable Filter is not indicated. Total 456 pcs were distributed without the expiry date information.

Shelf life of the filter is 5 years. Therefore, there is no immediate risk of the filter being expired.

The expiry date of the filter you have received is 2022-03-17 (March 17, 2022).

Advise on actions to be taken by user:

Please be aware of the expiry date of your filter. The filter should not be used after this date.

Transmission of this Field Safety Notice:

Pass this notice to all those who need to be aware within your organisation or to any organisation where the devices could have been transferred/distributed, shipped or sold.

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.

We sincerely apologize for any inconvenience that this action may cause and thank you in advance for your cooperation.

Please complete appendix 1 within 30 days and forward it to Shelby Mitchell at shmi@ambu.com

Should you have any questions regarding this notice, please do not hesitate to contact the undersigned.

Sincerely,



Sanjay Parikh
Director QA/RA
sap@ambu.com
800 262 8462

Enclosures:
Appendix 1 Field Safety Notice Receipt Confirmation
Appendix 2 Lot number and qty Listing

Appendix 1:

Confirmation on
Field Safety Notice Received
Return to Shelby Mitchell (shmi@ambu.com)
Fax 800 262 8673 or via phone call 800 262 8462 x 1114

The undersigned person hereby confirms that I have received Field Safety Notice from Ambu dated April 08, 2019 regarding information about the expiry date of Disposable Filter (Disposable filter included in Ambu® SPUR® II Disposable Resuscitator kit).

Name/Address of Customer:

Did you further distribute this product? _____

If the product was further distributed, please forward this Field Safety Notice to all customers you distributed to.

Date

Name

Title

Signature

Appendix 2: Catalog Number, Lot Number and Qty Listing

Item number	Lot number	Qty
530213034	1000126689	12
530213034	1000180442	12
530213034	1000104454	12
530213034	1000126689	12
530213034	1000172174	12
530213034	1000180442	6
530213034	1000104454	24
530213034	1000126689	12
530213034	1000172174	24
530213034	1000126689	12
530213034	1000172174	12
530213034	1000104454	12
530214034	1000104455	12
530214034	1000178342	12
530214034	1000104455	24
530214034	1000178342	12
530214034	1000104455	12
530613034	1000106535	96
530613034	1000169579	54
530613034	1000190716	60
530613034	1000123855	12

Urgent Field Safety Notice

Thursday, April 18, 2019

Dear Valued Life-Assist Customer,

According to our records you may have purchased a product that is affected by the enclosed manufacturer Field Safety Notice. Please examine your inventory to determine if you have the following product(s), with an affected lot number in your possession.

AMBU® SPUR II® Resuscitator w/HEPA Filter, Pedi

Life-Assist, Inc. Product Code	Product Description	Manufacturer Product Code	Lot #s
OM4300H	AMBU® SPUR II® Resuscitator w/HEPA Filter, Pedi	530 213 034	1000126689, 1000180442, 1000104454, 1000172174

This table contains only product codes and lots that Life-Assist purchased from the manufacturer. See Appendix 2 of the enclosed manufacturer notification for complete list of affected products and lot numbers.

Reason for the Notification:

Ambu has issued the enclosed Field Safety Notice regarding Ambu SPUR II Disposable Resuscitator kits where the expiry date of the disposable filter is not indicated. The shelf life of the filter is 5 years. The expiry date of the filters identified in this notice are March 17, 2022 (03-17-2022).

Please read the enclosed notice from the manufacturer for more information.

Action Required:

1. Immediately forward this notification to any pertinent personnel, department, and/or location within your organization.
2. Check your inventory for the specific product/lot number(s) identified in this notice.
3. Be aware of the expiry date of the filter on affected product is March 17, 2022 (03-17-2022).
4. Complete Appendix 1 within 30 days and forward it, along with any questions regarding this notice, to Shelby Mitchell at shmi@ambu.com.

We apologize for any inconvenience.

