URGENT FIELD SAFETY NOTICE

July 17, 2025

Dear Valued McKesson Customer:

Ambu Inc. has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Field Safety Notice regarding specific lots of their SPUR Resuscitator variants. This notice has been issued because Ambu received 5 complaints concerning Ambu SPUR II deviating from the design with the manometer port being blocked rendering the manometer non-functional. As a result, users are unable to use the attached manometer to monitor the patient's airway pressure. Affected product first shipped March 31, 2025.

This Urgent Field Safety Notice is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For questions regarding this notification, please contact Ambu Inc. at **(800) 262-8462**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)	
770644	523211000	RESUSITATOR, SPUR II BG RSVR ADLT (12/CS)	1001113554	1001118764
557737	530212000	SPUR II, MEDI PORT TOD MASK PEDI BAG (12/CS)	1001113557	
533885	530213000	RESUSCITATOR, SPUR II PED TOD MASK (12/CS)	1001110299	1001118767
			1001113558	1001106634
1067666	530213030	SPUR II CHILD RESC W/MANOMETER(12/CS)	2000016409	
821459	530213031	RESUSCITATOR, SPUR II BG RESVRPED (12/CS)	1001113560	1001118769
555742	530214000	RESUSCITATOR, SPUR PED BG MEDIPRT /INF/TODD (12 AMBU)	1001106636	1001113561
544776	530613000	RESUSCITATOR, SPUR W/MASK PED	1001110301	1001106637
			1001121455	1001118771
545840	531613000	RESUSCITATOR, SPUR II W/CORR TU PED MASK (6/CS)	1001118773	1001106640
			1001121460	
1205547	523611051E	RESUSCITATOR, MANUAL SPUR II ADLT MED MASK (6/CS)	2000015292	2000016401
			2000015559	
876838	530213000B	BAG, RESUSCITATION PED W/MASK (12/CS)	1001113559	

McKesson Customer Instructions:

1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no product matching the affected item(s) and lot number(s), no further action is needed

2.) A copy of the Urgent Field Safety Notice from Ambu Inc. has been included for reference.

3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days. **Please note**: Credit will only be issued for the affected Lot(s) of the product(s) listed above and entered on the reply form. **Please place a new order for replacement product if there is an immediate need**.

4.) Please dispose of any affected product in your possession in accordance with your institution's policies and procedures.

5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this Urgent Field Safety Notice.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc. July 17, 2025
Field Safety Reply Form: RC-2025-139
Ambu SPUR II Resuscitator

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____ Ship to Acct Number: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account Name: _____

Address: _____

City, State Zip: _____

☐ I acknowledge that I DO HAVE product affected by this notification and have disposed of this product in accordance with my institution's policies and procedures.

Qty	Unit of Measure	MMS #	MFG Catalog #	Description
		770644	523211000	RESUSITATOR, SPUR II BG RSVR ADLT (12/CS)
		557737	530212000	SPUR II, MEDI PORT TOD MASK PEDI BAG (12/CS)
		533885	530213000	RESUSCITATOR, SPUR II PED TOD MASK (12/CS)
		1067666	530213030	SPUR II CHILD RESC W/MANOMETER(12/CS)
		821459	530213031	RESUSCITATOR, SPUR II BG RESVRPED (12/CS)
		555742	530214000	RESUSCITATOR, SPUR PED BG MEDIPRT /INF/TODD
		544776	530613000	RESUSCITATOR, SPUR W/MASK PED
		545840	531613000	RESUSCITATOR, SPUR II W/CORR TU PED MASK (6/CS)
		1205547	523611051E	RESUSCITATOR, MANUAL SPUR II ADLT MED MASK
		876838	530213000B	BAG, RESUSCITATION PED W/MASK (12/CS)

*Return Affected lot numbers only

*** The affected lot number(s) are listed on the McKesson customer letter. Please dispose of affected product in accordance with your institution's policies and procedures.**

Credit will only be issued for product(s) listed above with affected lots.

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

Ambu Inc.
6721 Columbia Gateway Drive, Suite 200
Columbia, MD 21046
P. 800-262-8462, F. 800-262-8673

Urgent Field Safety Notice
Removal of Ambu® SPUR® Resuscitator variants with Blocked Manometer Port

This document contains important information for the safe and effective use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

July 08, 2025

Commercial name: **Ambu® SPUR® II**

Device type: **Manual Pulmonary Resuscitator**
Sterility information**: Non-sterile devices**

Dear Valued Partner:

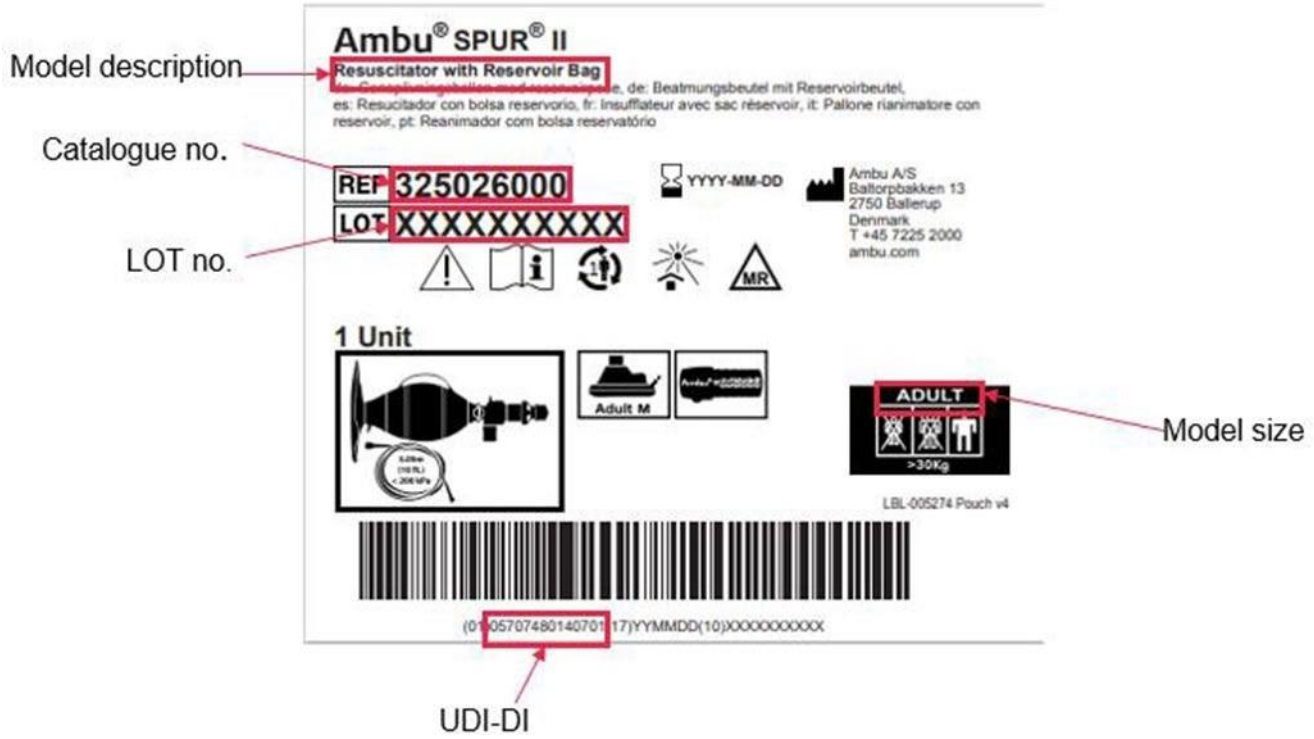
Ambu has received complaints concerning Ambu® SPUR® II deviating from the design with the manometer port being blocked rendering the manometer non-functional. This defect can lead to an increased risk of barotrauma and delayed ventilation, since the ventilation pressure applied with Ambu® SPUR® II cannot be read on the manometer.

Affected devices and how to identify them:

The device is a disposable resuscitator which is provided unsterile. Refer to **Table 1** for the SPUR® II devices affected including model description, size, catalog number, lot number and UDI-DI.

Note: The product configuration will be different depending on the variant you have. The photos provided here show where manometer port is located on the Ambu® SPUR® II resuscitator, and where the manometer is attached/can be attached.

Example of product label:



*Note: Several Ambu® SPUR® variants are affected. The product label will be different depending on the variant you have. This example is to show how you identify the affected item based on Table **1** and the information on the product label.*

Intended Use:

The Ambu SPUR II Resuscitator is a single patient use resuscitator intended for pulmonary resuscitation

Description of the problem:

Ambu received 5 complaints concerning Ambu® SPUR® II deviating from the design with the manometer port being blocked rendering the manometer non-functional. As a result, users are unable to use the attached manometer to monitor the patient's airway pressure.

While none of the complaints involved patients and no harm or injuries have been reported, Ambu has assessed that the blocked manometer port increases the risk of patient harm.

Hazard/harm associated with the issue:

This defect can lead to an increased risk of barotrauma, since the ventilation pressure applied with SPUR II cannot be read on the manometer. In addition, if the user feels uncertain using a device with a non-functional manometer, the defect may also lead to an increased risk of delayed ventilation.

The preliminary root cause investigation for the blocked manometer port identified a manufacturing problem (molding tool). The root case will be further investigated and documented in CA-000948. The damaged molding tool has been repaired, and a delivery stop has been initiated for the affected items.

Photo of blocked manometer port

Actions that should be taken to prevent risks to patients or users:

Our records indicate that you have purchased the Ambu® SPUR® II products, and you may have affected devices in stock.

Please read this entire Field Safety Notice (FSN). You must identify if any of your Ambu® SPUR II products belong to the affected lots listed on **Table 1.**

~~You must complete and return **APPENDIX 1** of this FSN~~:

- ~~Confirm that you have received the FSN~~
- ~~Confirm the number of affected items in your possession, at the time of receiving this FSN~~
- ~~Confirm that you have discarded the affected items in your possession, and whether you would like a refund or replacement for the discarded items~~.

~~**Please return your confirmation on the actions described in the FSN within 2 weeks of receiving this letter.**~~

Transmission of this Field Safety Notice:

This notice needs to be communicated to all those who need to be aware within your organization or to any organization where the devices could have been transferred.

Please forward this notice to other organizations that may be impacted by this FSN.

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

Below, you will find links to report adverse events to the FDA MedWatch.

https://www.accessdata.fda.gov/scripts/medwatch/

https://www.fda.gov/media/76299/download

Ambu confirms that this notice has been provided to the appropriate Regulatory Agency.
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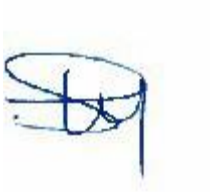
Should you have additional questions, please do not hesitate to contact undersigned or Tammy Groff at tfey@ambu.com

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

Sincerely,



Sanjay Parikh
Senior Director, QA/RA
sap@ambu.com

Table 1:

List of affected Ambu® SPUR® II Catalog Numbers

Model (description and size)	Catalog Number	UDI-DI	Lot number

SPUR® II Adult Resuscitator, Adult	523211000	05707480152193	1001113554 1001118764
SPUR® II Adult Resuscitator, Single Patient Use Resuscitator, Adult	523611057	05707480038688	2000015876
SPUR® II Adult Resuscitator, Single Patient Use Resuscitator, Adult	523611051E	05707480154135	2000015292 2000015559 2000016401
SPUR® II Adult Resuscitator, Single Patient Use Resuscitator, Adult	524611000	05707480152278	1001110297
SPUR® II Adult Resuscitator, Single Patient Use Resuscitator, Adult	524611051	05707480154395	2000015969 2000016252
SPUR® II Adult Resuscitator w/Mercury Filter, Adult	523611051	05707480149513	2000015874
SPUR® II Adult Resuscitator, Pop-off open 40”, w/PEEP Valve 20, Adult	524611001	05707480149698	2000015881
SPUR® II Adult Resuscitator w/PEEP Valve 20, Adult	524611011	05707480149711	2000015882
SPUR® II Adult Resuscitator w/Pressure Limiting Valve, Adult	524611031	05707480149735	2000015884 2000015968
SPUR® II Adult Resuscitator w/Pressure Limiting Valve, Adult	524611047	05707480149759	2000016102

SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530212000	05707480152353	1001113557

Model (description and size)	**Catalog Number**	**UDI-DI**	**Lot number**
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530212001	05707480149797	2000016408
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530213000	05707480152377	1001110299 1001113558 1001118767 1001106634
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530213000B	05707480153534	1001113559
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530213001	05707480152391	1001106635
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530213011	05707480152438	1001118768
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530213031	05707480152452	1001113560 1001118769
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530213048	05707480154159	2000016529 2000016410

SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530214000	05707480152490	1001106636 1001113561
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530613000	05707480152612	1001110301 1001121455 1001106637 1001118771
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530613071	05707480150298	2000015574

Model (description and size)	Catalog Number	UDI-DI	Lot number
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530614017	05707480150397	2000015440
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	530619031	05707480150595	2000016761
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531613000	05707480152773	1001118773 1001121460 1001106640
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531613001	05707480152797	1001106641 1001110305 1001113567 1001118774
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531613010	05707480152810	1001113568
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531613031	05707480150717	2000015182 2000015731 2000015896 2000016112 2000016263

SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531613047	05707480150755	2000015444 2000015580 2000015897 2000015982
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531613051	05707480154470	2000016825

Model (description and size)	**Catalog Number**	**UDI-DI**	**Lot number**
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531614026	05707480150854	2000016265 2000016612
SPUR® II Pediatric Resuscitator, Single Patient Use Resuscitator, Pediatric	531638000	05707480150878	2000015184 2000015583
SPUR® II Pediatric Resuscitator w/10 O2 tube & Manometer	530200016	05707480149773	2000014933 2000015857
SPUR® II Pediatric Resuscitator w/Manometer & PEEP Valve 20, Pediatric	530613031	05707480150212	2000015889
SPUR® II Pediatric Resuscitator w/PEEP Valve 20, Manometer & CO2 Detector, Pediatric	530613831	05707480150373	2000015179 2000015726 2000015891

SPUR® II Pediatric Resuscitator w/Manometer, Pediatric	530213030	05707480149858	2000016409
SPUR® II Pediatric Resuscitator w/Manometer, Pediatric	530614030	05707480150410	2000014938 2000015299
SPUR® II Pediatric Resuscitator w/CO2 Detector, Pediatric	530614800	05707480150434	2000015098
SPUR® II Pediatric Resuscitator, INF&TOD W/Manometer, Pediatric	530615030	05707480150472	2000015893
SPUR® II Pediatric Resuscitator w/Expiratory Filter, Manometer PEEP Valve, Pediatric	531600051	05707480163441	2000015181 2000015577

~~Appendix 1:~~

~~Confirmation that the FSN has been read and the affected items have been discarded.~~

~~Confirmation on~~
~~Field Safety Notice Completed~~
~~Return to Tammy Groff at tfey@ambu.com~~

~~The undersigned person hereby confirms that~~

_____

~~Name/Address of Hospital/ Clinic/ Emergency Center~~

~~Has completed the actions describes in the Field Safety Notice from Ambu A/S dated July 08, 2025. Regarding **Ambu® SPUR® II.**~~

~~If applicable:~~

~~•The Ambu® SPUR® II is no longer within the organization~~ ☐

~~•The Organization has the Ambu® SPUR® II in stock and will discard affected product~~ ☐