Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 268 **dated** 21/12/23 **Regarding NCMDR Field Safety Notice of Ambu aView 2 Advance from (mfr: Ambu Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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سلطنة عُمان
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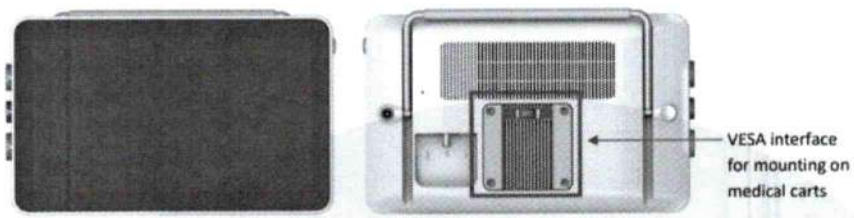
Circular No. 268/ 2023

08 -06-1445 H
21 -12-2023

Field Safety Notice of Ambu aView 2 Advance from Ambu Inc

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19811
Product	Ambu aView 2 Advance.
Description	Endoscopic video image display monitor.
Manufacturer	Ambu Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Please refer to the attachment for the affected catalogue numbers. Version No.: All
Reason	Potential for Ambu aView 2 Advance has 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.
Action	1. Please familiarize yourself with the information in the insert of Instructions for Use in the attachment and keep the insert together with the Instructions for Use booklet. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Ambu

Urgent Field Safety Notice

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

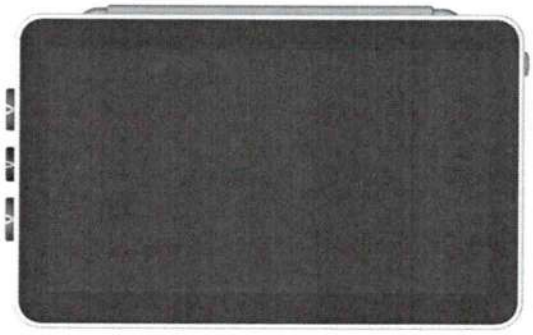
Ambu A/S - Single Registration (SRN): DK-MF-000001437

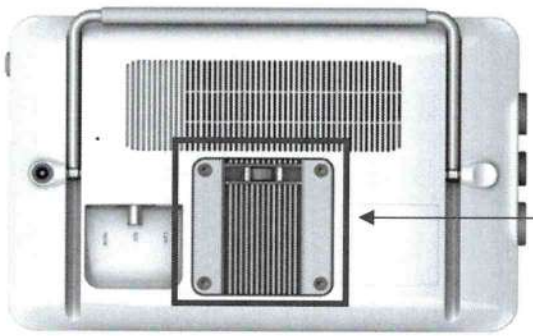
[Date] [to be filled out by Ambu Sales or Distributor]

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

Details on affected devices:

Model	Catalogue number	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:
[Name / organisation, address, contact details Ambu Sales or Distributor]

[Signature Ambu Sales or Distributor]