



Compower® 厦门康勃医疗科技有限公司

ADD: UNIT 301, NO. 16, XIANGHONG ROAD, XIANG'AN TORCH INDUSTRIAL ZONE, XIAMEN
361101, CHINA.

TEL: 0086- 592-5799319

FAX: 0086- 592-5796765

Web: www.cpmedi.com Email: Info@cpmedi.com

FSN Ref: CP 2023-1_ Compower PVC Manual Resuscitator

FIELD SAFETY NOTICE- Compower Silicone Manual Resucitator:

Dear Sir or Madam,

Xiamen Compower Medical Tech. Co., Ltd. is initiating a Field Safety Notice for the product listed below. This letter contain important information that needs your immediate attention.

IDENTIFIED CODE	AFFECTED BATCH
TDM-RES-1500W	20000752
	21005072
	22003432
	23000262
	24005702
TDM-RES-1500	20000852
	22003532
	24005802

Identified Product:

Affected BVM stock in the scope of this FSN are devices with a non-coloured product label and does not having a circular Red dot on the packaging. About the identification of product, please refer to ***Appendix 1_ TDM-RES-1500 - 1500W Identificaion.***

ISSUE:

BVM patient valve worked loose. This caused the device to fall apart,including the internal diaphragm.

RISK TO HEALTH:

It will result in a delay of lung ventilation on patient.

ACTIONS TO BE TEAKEN BY THE CUSTOMER OR USER:

Any unopened affected stock must be returned to your distributor. Used and opened devices should be disposed of in accordance with your local procedures.

Please share this information with your distributer and user and retain this notification as part of your Quality system documentation. If you have forwarded



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Compower® Xiamen Compower Medical Tech. Co., Ltd.

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any of the affected product(s) listed above to another distributor or user, please
provide them a copy of this letter.

**Please complete and return the enclosed vigilance response form within 10 days so
that we are assured you have received this important communication.**

If you have any questions regarding this notice, please contact the Customer Support
Hotline at +86-592-5799319 or info@cpmedi.com.

We apologise for the inconvenience that this caused your.

Yours sincerely,

Frank Lin 2023-8-16.


Frank Lin

General Manager

Xiamen Compower Medical Tech. Co., Ltd.

Tel: +86-592-5799319/+86-13306000583

Enclosed: Vigilance Response Form

 厦门康勃医疗科技有限公司 Xiamen Compower Medical Tech. Co., Ltd.	Document: Vigilance Response Form	Document #: CP-VRF-0001 Revision: 01 Effective date: 2023-07-06
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Please complete the appropriate sections below and fax back to Compower:
 +86-5796765 or email to: info@cpmedi.com.

This form is to confirm receipt of the enclosed Compower Field Safety Notice dated _____, which provides information regarding the dispose of Compower PVC Manual Resuscitator.

Please complete the below form.

Site Name: _____

Name of contact person: _____

Telephone number of
contact person: _____

Email address of contact
Person: _____

- ☐ (1): I confirm this notice has been read, understood and that all recommended actions have been implemented as required.
- ☐ (2): I confirm this notice has been read and understood. But all recommended action will not be implemented as required until _____.
- ☐ (3): I have not received affected Compower PVC Manual Resuscitator.

Customer Name: _____

Customer Signature: _____

Date (DD/MM/YY): _____

Thank you for your kind cooperation.

Appendix 1 TDM-RES-1500/1500W identification document:

Introduction

This document is meant to aid in identification of the faulty BVM's.

Method

If the BVM's are marked with **white labels with red dot** shown in figure 1 or with fully coloured **blue labels** shown in figure 2, then this is a PASS. The product with marked red dot are not covered by the FSN.



Image 1 – Pass



Image 2 – Pass

If the BVM's are marked with only a **white label** shown in figure 3, then this is a potential FAIL.

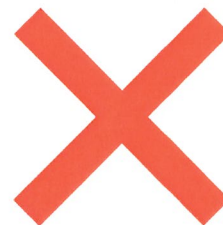
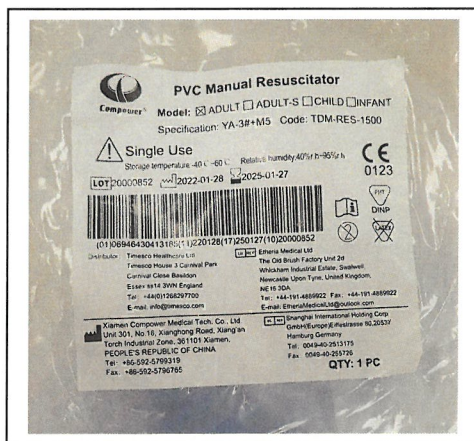


Image 3 – Fail

No other test or identification is required.