

FIELD SAFETY NOTICE

Mercury Advance V1 Control Unit

Affected Devices: **Mercury Advance V1 control units** manufactured and sold between 2011 and 2015 and identified as follows:



Figure 1: Front panel showing artwork on the Mercury Advance V1



Figure 2: On-product label showing format of serial number on the Mercury Advance V1

Please note that this Field Safety Notice DOES NOT in any way relate to the Mercury Advance V2 control unit manufactured and sold since 2015 and identified as follows:

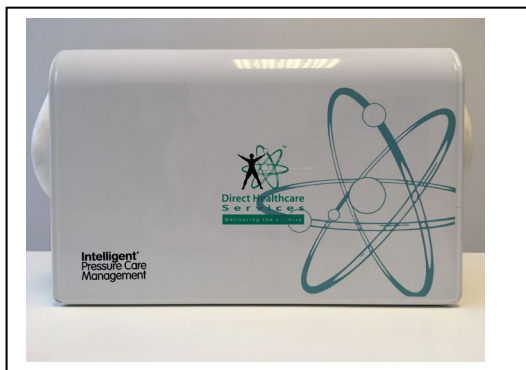


Figure 1: Front panel showing artwork on the Mercury Advance V2



Figure 2: On-product label showing format of serial number on the Mercury Advance V2

Date: 15 March 2019
Attention: All Customers and End-users
Reason: In response to a Potential Concern reported to the MHRA under reference number MHRA AI 2018-010-010-206-001

Dear Valued Customer:

The purpose of this letter is to advise you that Direct Healthcare Group Limited (DHG) is executing a Field Safety Notice for the Mercury Advance V1 control unit. This Field Safety Notice describes below the immediate action advised to be taken by you.

- Remove from use the Mercury Advance V1 control unit as soon as practicably possible
- Contact DHG representative to upgrade to the Mercury Advance V2 control unit

Description of Issue

The control unit may stop alternating due to failure of the geared components of the air distribution valve, with no alarm to indicate that the patient is not receiving alternating pressure treatment. This aspect has been designed out of the Mercury Advance V2 control unit which has been manufactured and sold since 2015.

Actions to be taken by the user of the device

- Remove from use all Mercury Advance V1 control units as soon as practicably possible and place them into quarantine or in an area where they cannot be accessed for use
- Contact your DHG representative or the DHG Head Office on 0800 043 0881 to upgrade to the Mercury Advance V2 control unit

Transmission of this Field Safety Notice

Please assure within your organisation that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them also, informing them of the below mentioned contact person.

Please maintain awareness on this notice for an appropriate period to ensure effectiveness of the above actions.

A copy of this Field Safety Notice has been provided to the MHRA who is aware of these actions.

Confirmation

Please complete and return the attached Confirmation Form and table (see Appendix) via email to jo.campbell@directhealthcaregroup.com to confirm that the above actions have been taken.

Contact reference person

For questions regarding this Field Safety Notice, please contact:

Stuart McAllister (Director),
Direct Healthcare Group Ltd.,
Withey Court, Western Industrial Estate,
Caerphilly, CF83 1BF
Tel: 0800 043 0881
Email: stuart.mcallister@directhealthcaregroup.com

— Thank you for your cooperation in this matter. Direct Healthcare Group is committed to providing quality products and service to its customers and we apologise for any inconvenience this situation may have caused.

Yours faithfully,



Jo Campbell
QARA Director



Stuart McAllister
Director

Enclosures:

Appendix: [Confirmation Form and Table](#)

Appendix

Field Safety Notice – Confirmation Form

Product Name: **Mercury Advance V1 control unit**
MHRA Report Number: **MHRA AI 2018-010-010-206-001**
Date: **15 March 2019**
Type of Action: **Removal from use**

- I have read and understood the contents of this Field Safety Notice and confirm that our Mercury Advance V1 control unit inventory has been checked and I have recorded the status of each device in the attached table:

Hospital / Facility Name	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	Date:

Example:

Control Unit Serial Number	Status
987654321	Not Located
135792468	Disposed of
246813579	Removed from use

Please return by **30 April 2019** to:

Jo Campbell
Direct Healthcare Group Ltd.,
Withey Court, Western Industrial Estate,
Caerphilly, CF83 1BF

Email: jo.campbell@directhealthcaregroup.com

Field Safety Notice – Confirmation Form Table

Control Unit Serial Number	Status	Control Unit Serial Number	Status