

Name: [To be completed by Distributor](#)
Address: [to be completed by Distributor](#)

URGENT FIELD SAFETY NOTICE

Product Name: Cap Diaphragm - 3100A and 3100B circuit accessory
Product Reference: See attached list in Appendix 1
Lot Numbers: See attached list in Appendix 1
FSCA Identifier: RES-2013-3100AB-01
Date: 11 March 2013
Type of Action: Field Safety Notice

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel; and Distributors, Sales Representatives, Commercial and Operation Managers Distributing CareFusion Cap/Diaphragms Assemblies

Details on Affected Devices

Refer to attached list in Appendix 1

Description of the Problem

CareFusion is issuing a Field Safety Notice as a result of reports from hospitals in the UK of failures of cap diaphragms used on the 3100A or 3100B high frequency oscillatory ventilators.

Specific lots of cap/diaphragm assemblies for use with 3100A or 3100B high frequency oscillatory ventilators could fail reaching the targeted mean airway pressure (39-43 cm H₂O) during pre-use calibration checks.

This document is intended to alert all users of the potential issue until a permanent correction can be implemented.

Safety Risks:

The system may fail during the patient circuit calibration prior to use on patients. The device may not pressurize sufficiently to pass the Circuit Calibration and/or the Performance Verification check.

If a pre-use calibration is not performed, affected cap/diaphragms may not be identified leading to a possible instability of Mean Airway Pressure and/or loss of amplitude.

Other Risks:

Inventory deficiency

It is recommended to ensure that stock levels are adequate to meet clinical demands.

Root cause of the problem:

The malfunction identified is an apparent leak through the Cap/Diaphragm Assembly (Part number: 766896) see picture 1 below.

Failures due to leaky Cap/Diaphragms are identified during the ventilator set-up procedures. The failures manifest themselves as the inability to achieve the targeted Mean Airway Pressure (the circuit pressure will be low).

There are two causes for leaking Cap/Diaphragms. Both were the result of the Cap/Diaphragm body being loose in the cap. The first was due to wear on the molding insert from the injection molding process which reduced the clamping force holding the body in place. The second cause was the result of an incorrect preventive maintenance of an insert pin in the tool used to mold the part. These conditions may allow the body to move and leakage to occur in the Cap/Diaphragm.



Picture 1 – Cap/Diaphragm Assembly



Actions Required:

Distributors

1. Perform an inventory check and identify the list of customers in which the affected lots were distributed.
2. Distribute this Field Safety Notice to all affected customers.
3. Return the Response Form (Appendix 3) to CareFusion when completed.

End Users

1. Perform an inventory check and locate any affected lots.
2. Complete and return the response form (Appendix 3) to your distributor.
3. Follow the instructions listed below when using the product:

- a. Identification of affected Cap/Diaphragms

Perform pre-use checks prior to use. Pre-use checks include Patient Circuit Calibration and Performance Verification. These procedures are described in the Operator's Manual as well as in the labeling on the 3100A/B itself. A summary of these procedures is given in appendix 2.

- b. Troubleshooting of the failure

If the 3100A or 3100B fail either of these procedures, normal troubleshooting of the failure should be performed. This includes verification of flow and other ventilator settings, checking for loose connections and bypassing the humidifier chamber.

- c. If at the end of this process the cap/diaphragm is suspected, replace all three cap/diaphragms and repeat the pre-use checks. If the 3100A or 3100B still fails the pre-use checks, CareFusion technical support should be contacted.

CareFusion technical support may be reached at the following phone numbers or email address:

+49.931.4972.393
+1.714.283.2228

support.cc.eu@carefusion.com



Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

Your competent authority has already been notified of this Field Safety Notice by CareFusion's Authorised EU Representative.

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local CareFusion representative.

CareFusion apologizes for the inconvenience that this action may have caused.

Sincerely,

To be signed by Distributor

CareFusion Representative

Appendix 1: Catalogue Numbers and Lot Numbers of affected products (to be completed by Distribution Partner)

Appendix 2: Pre-use Checks

The information below is provided to give the operator the sequence for performing pre-use patient circuit calibration and performance verification check. Refer to the 3100A or 3100B Operator's Manuals for full set up and operation information.

Patient Circuit Calibration

Patient circuit calibration screw adjusts the maximum mean pressure that can be obtained with a specific Patient Circuit. The screw adjustment is used to calibrate the maximum mean pressure after the Patient Circuit is changed or the Mean Airway Pressure () control diaphragm is changed.

Before use on a patient, each patient circuit must be calibrated to the 3100A and 3100B by following the instructions in the label shown on the equipment and as shown below.

<p style="text-align: center;">PATIENT CIRCUIT CALIBRATION PROCEDURE OFF-PATIENT</p> <p>IMPORTANT - Before use on a patient, each patient circuit must be calibrated to the Model 3100 by following this procedure:</p> <ol style="list-style-type: none">1. Insert stopper in Patient Circuit "Y" and turn on Bias Flow gas.2. Rotate Mean Pressure LIMIT and ADJUST controls to "Max".3. Adjust Bias Flow to 20 LPM.4. Depress and hold RESET (Oscillator OFF).5. Observe Mean Pressure display and adjust Patient Circuit Calibration screw for a reading of 39-43 cm H₂O. <p style="text-align: right;">P/N 765759F</p>

3100A

<p style="text-align: center;">PATIENT CIRCUIT CALIBRATION PROCEDURE OFF-PATIENT</p> <p>IMPORTANT—Before use on a patient, each patient circuit must be calibrated to the Model 3100B by following this procedure:</p> <ol style="list-style-type: none">1. Insert stopper in Patient Circuit "Y" and turn on Bias Flow gas.2. Rotate Mean Pressure ADJUST control to "Max."3. Set Max P_{aW} Alarm to 59 cm H₂O.4. Adjust Bias Flow to 20 LPM.5. Depress and hold RESET (Oscillator OFF).6. Observe Mean Pressure display and adjust Patient Circuit Calibration screw for a reading of 39-43 cm H₂O. <p style="text-align: right;">P/N 772754A</p>
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3100B

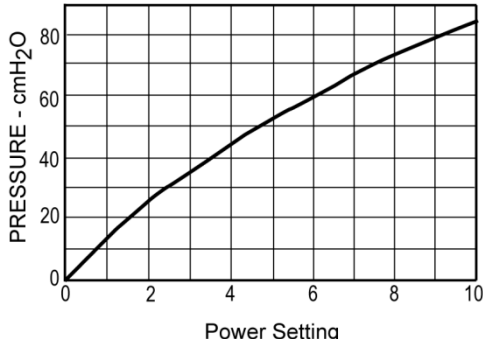
Performance Verification

The two figures below are intended to help ascertain that the 3100A and/or the 3100B are performing in a typical fashion without problems.

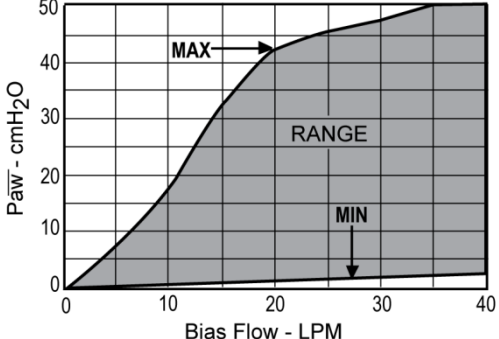
VENTILATOR PERFORMANCE CHECKS

OFF-PATIENT
These graphs illustrate the typical performance to be expected from the Model 3100A:

Minimum ΔP vs POWER



Range of Static MEAN Pressure vs BIAS FLOW



OFF-PATIENT

1. Insert Stopper in Patient Circuit "Y", and turn on both gas sources.
2. Set BIAS FLOW for 20 LPM and rotate MEAN PRESSURE LIMIT to "MAX".
3. Pressurize system by pressing and holding "RESET", and "ADJUST" for a Mean Pressure of 19-21 cmH₂O.
4. Set "FREQUENCY" to 15, "% I-Time" to 33, and press "START/STOP" to start the oscillator.
5. Set "POWER" to 6.0 and "center the piston".
6. Observe the following parameters, at the altitude range of your facility, and verify that they fall within the specified ranges:

<u>ALTITUDE (FT)</u>	<u>MEAN (cmH₂O)</u>	<u>ΔP (cmH₂O)</u>
0-2000	15-23	56-75
2000-4000	15-23	52-70
4000-6000	15-23	48-65
6000-8000	15-23	44-60
8000-10,000	15-23	41-56

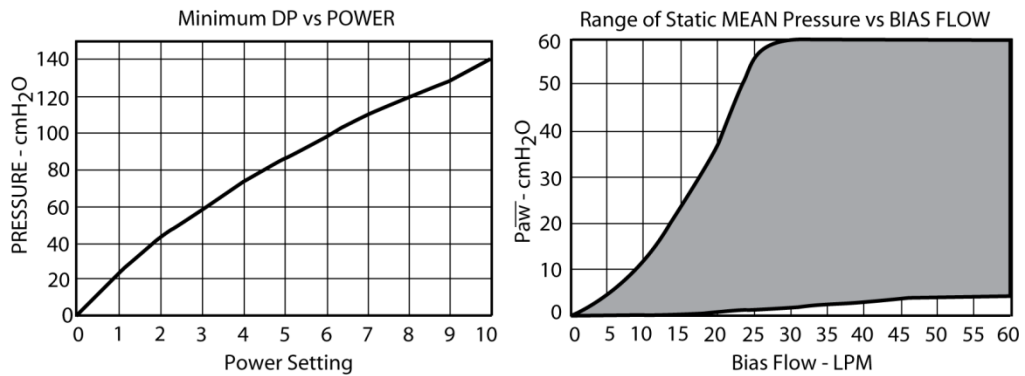
767129-101E

3100A

VENTILATOR PERFORMANCE CHECKS

OFF-PATIENT

These graphs illustrate the typical performance to be expected from the Model 3100B:



OFF PATIENT

1. Insert Stopper in Patient Circuit "Y", and turn on both gas sources.
2. Rotate Mean Pressure ADJUST knob to 12 o'clock position.
3. Set "BIAS FLOW" for 30 LPM.
4. Pressurize system by pressing and holding "RESET", and "ADJUST" for a Mean Pressure of 29-31 cmH₂O.
5. Set "FREQUENCY" to 6, "% I-Time" to 33, and press "START/STOP" to start the oscillator.
6. Set "POWER" to 6.0
7. Observe the following parameters, using the appropriate altitude range and verify that they fall within the specified ranges.

<u>ALTITUDE (FT)</u>	<u>MEAN (cmH₂O)</u>	<u>DP(cmH₂O)</u>
0-2000	26-34	113-135
2000-4000	26-34	104-125
4000-6000	26-34	95-115
6000-8000	26-34	86-105

767165-101L

3100B

Appendix 3

URGENT FIELD SAFETY NOTICE – Verification Form

Product Name: Cap Diaphragm - 3100A and 3100B accessory

Product Reference: Refer to Appendix 1

Lot Numbers: Refer to Appendix 1

FSCA Identifier: RES-2013-3100AB-01

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- I have read and understand the content of this Field Safety Notice and confirm that I have distributed this notice to all those who need to be made aware.*

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

Please return to your local CareFusion representative or distributor.