

URGENT FIELD SAFETY NOTICE

XX July, 2012

Dear Valued Partner,

This letter is to inform you of an amendment to the field safety corrective action on the Legendair™ and Supportair™ ventilators, initiated by Covidien in March 2012, related to a potential failure of a component identified as capacitor C53.

This occurrence may result in the inability of the ventilator to switch automatically from A/C mains power to internal battery operation when the ventilator is disconnected from A/C mains during use or when there is a failure of the AC mains power during use. The ventilator will run on external battery or A/C mains power.

The affected ventilator codes are referenced below:

| Legendair™ Single Branch | | Legendair™ Double Branch | | Supportair™ | |
|--------------------------|-------------------------------|--------------------------|-------------------------------|-------------|-----------------|
| 4095700 | INTL LEGENDAIR SINGLE BRANCH | 4095900 | INTL LEGENDAIR DOUBLE BRANCH | 4096200 | INTL SUPPORTAIR |
| 4095701 | GB NO LEGENDAIR SINGLE BRANCH | 4095901 | GB NO LEGENDAIR DOUBLE BRANCH | 4096201 | GB SUPPORTAIR |
| 4095702 | DE LEGENDAIR SINGLE BRANCH | 4095902 | DE LEGENDAIR DOUBLE BRANCH | 4096202 | DE SUPPORTAIR |
| 4095705 | CA LEGENDAIR SINGLE BRANCH | 4095905 | CA LEGENDAIR DOUBLE BRANCH | | |
| 4095706 | JP LEGENDAIR SINGLE BRANCH | 4095906 | JP LEGENDAIR DOUBLE BRANCH | | |
| 4095709 | DK LEGENDAIR SINGLE BRANCH | 4095909 | DK LEGENDAIR DOUBLE BRANCH | | |
| 4095721 | AU LEGENDAIR SINGLE BRANCH | 4095921 | AU LEGENDAIR DOUBLE BRANCH | | |

According to our records, you have a ventilator that may be impacted by this issue.

Working in conjunction with several regulatory agencies, we have decided to further segment the population involved in this action into ventilator dependent and non-ventilator dependent patients. For ventilator dependent patients*, Covidien recommends replacement of the PCB (motor control board) which contains the C53 capacitor as soon as possible. Until the PCB is replaced, those patients who are equipped with the OpenPack™ or PowerPack™ external battery should keep the external battery connected at all times. Additionally, if a second ventilator has been provided per prescription, it should also be ready and available.

Attached to this field safety notice is the letter (Attachment A) we request you to send to all your end-users to inform them of the issue and to reassure them that by working with you, they can maintain proper operation of their ventilator until the PCB is replaced.

Because PCBs need to stay available for ventilator dependent patients, the replacement of the C53 capacitor for non-ventilator dependent patients needs to be included as part of the *revised* annual preventive maintenance. Replacement of the C53 component should occur no later than the next scheduled maintenance and should then be replaced annually as part of the

preventative maintenance schedule if PCBs are not available. Replacement of the PCB is the preferred action.

Instructions for replacing both the motor control board and the capacitor are provided in Attachment B. We request you to complete attached Verification Form provided in Attachment C and complete this with the serial numbers you have refurbished. If you have purchased a large number of devices, please complete this form regularly as you perform maintenance for your device and send the form back to the contact mentioned on the Verification Form.

If you do not perform your own preventive maintenance, please contact your maintenance provider to inform them of this update, or contact your local Covidien Service Center.

This notice is being distributed with the knowledge of appropriate regulatory authorities.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please do not hesitate to contact your Covidien representative or Technical Service if you have any additional questions.

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

We sincerely apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

Sincerely,



VP, Regulatory Affairs
Respiratory and Monitoring Solutions
Covidien

*Ventilator dependent patient = patient ventilated 16 or more hours/day
Non-ventilator dependent patient = patient ventilated less than 16 hours/day

Attachment A: End-User letter
Attachment B: Technical Service Bulletin
Attachment C: Verification form

Dear Valued Customer,

This letter is to inform you that Covidien, the manufacturer of the Legendair™ ventilator, has discovered that one of the components located on the Legendair™ and Supportair™ electronic Motor Control Board might exhibit degradation over time. The specific affected component is the C53 Capacitor. No failures have occurred due to component degradation but Covidien has decided to initiate action to prevent any failures from degradation over time. There are two actions that may be taken to ensure ventilators continue to function. Only one of these actions is needed address the issue:

1. Replace the affected motor board by a new board; or
2. Replace the affected C53 component yearly as part of preventive maintenance.

Your homecare provider will contact you to organize this modification.

The function of the C53 Capacitor is to switch the ventilator operation from main electric power to battery operation when the electrical plug is removed from the electrical wall outlet.

If the capacitor fails due to degradation, the switch from main electric power to battery operation might not occur, resulting in the ventilator ceasing to function. In this event an audible, non-resettable audible alarm will sound for a minimum of 10 seconds.

For this reason Covidien recommends following the precautions until your home care provider exchanges the board or replaces the component as part of preventive maintenance.

- 1) Make sure that the ventilator's internal battery is fully charged and functional before the ventilator is used, even if the ventilator will be plugged into the wall. If you unplug the ventilator from the wall outlet, please assess and confirm the continuation of the ventilator operation.
- 2) If you own an OpenPack™ or PowerPack™ external battery pack, leave the ventilator connected to the external battery pack at all times. Those battery packs will manage the ventilator power supply. See User's Manual for operating parameters.
- 3) Even when the patient is not connected to the ventilator, it is recommended to keep the ventilator plugged to the battery pack and into the wall outlet, so that the external battery is being continually recharged. Also, if the ventilator has been stored for a period of time, it is recommended that you recharge the internal battery before the ventilator is used.
- 4) If you own a second ventilator, make sure it is available and ready for use. It is recommended to keep the ventilator plugged into the wall outlet, so that the internal battery is being recharged. Also, if the ventilator has been stored for a period of time, it is recommended that you recharge the internal battery before the ventilator is used.
- 5) The Legendair ventilator continuously and automatically controls the state of the internal battery, even if the ventilator is being operated on wall power. However, it is recommended that you check the charge status of the internal battery once each month. This is a simple procedure that is described in the "Internal Battery Maintenance" section of the User's Manual.



Should you have any questions regarding this letter, please contact our office at [phone number]. .

Sincerely,

Home Healthcare Provider

**TSB1000014-01 Rev. B
ECO-R206600****International Technical Service Bulletin, Portable Ventilators,
Legendair and Supportair
Revised -Addendum to the Fields Safety Corrective Action**

This Technical Service Bulletin details the different actions that may be necessary to take in relation to the Urgent Field Safety Notice dd June 2012.

The affected devices cover the following legacy ranges:

Airox Legendair™ Single Branch
Airox Legendair™ Double Branch
Airox Supportair™

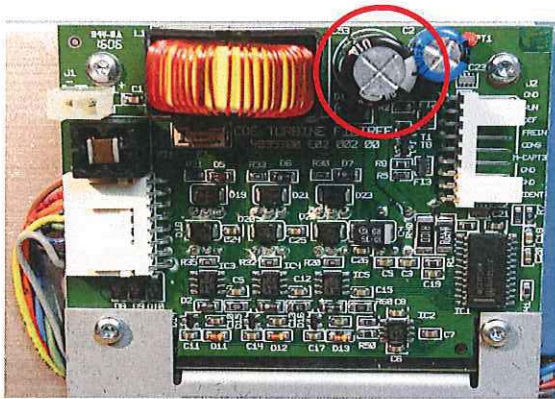
The change is focused on the Turbine Controller Printed Circuit Board fitted within these devices and specifically on the replacement of capacitor C53.

The following options will aid you in replacing the C53 or updating your device:

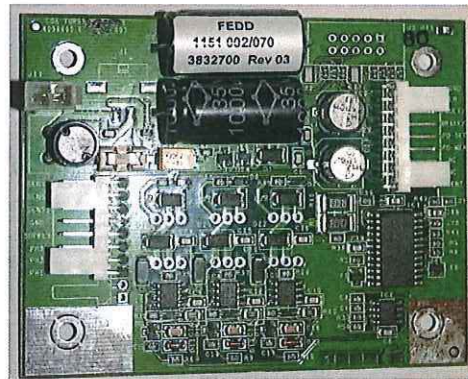
1. The New PCB 3832799 can be installed as per the service manual
 - Legendair Service Manual Rev B. Chapter 5 page 11
 - Supportair Service Manual Rev A. Chapter 5 page 12
2. Replacement of the existing 3812799 PCB that contains a new C53 component, is done following the above mentioned service manual references.
3. Replacement of the C53 capacitor on the existing PCB can be performed by the HCP or at a Covidien Technical Services location.

The capacitor has been released as a spare part to allow replacement of this capacitor, part number 10049759, which will be available for order in a pack containing 10 capacitors.

This change is limited to the devices with either Turbine Controller PCB 3812700 or 3812799 installed, and once the device has the new version Turbine Controller PCB 3832799 installed, no further action is required.

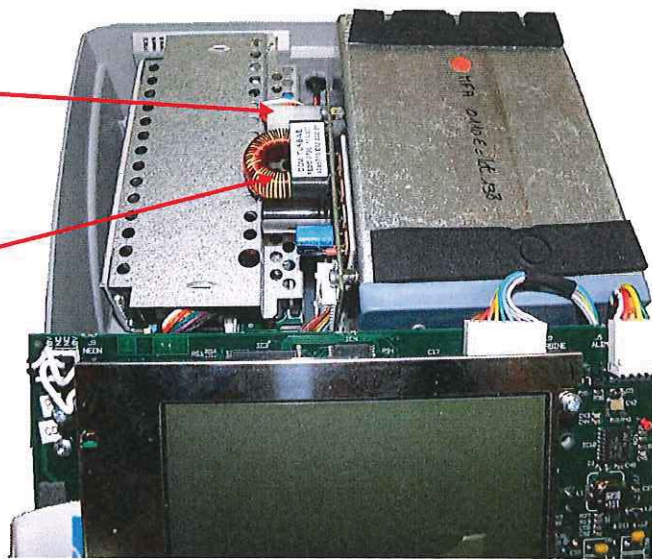


This PCB needs C53 replaced



This PCB requires no action

With the top cover removed the Turbine Controller PCB is located here.



The C53 is located here

This matrix shows which device and printed circuit board combination is impacted by this improvement.

If your device shows "Yes" you will need to replace the C53 as detailed below.

If your device has "No" within the matrix no action is required.

| | Turbine Controller PCB Installed | | |
|------------|----------------------------------|---------|---------|
| Device | 3812700 | 3812799 | 3832799 |
| Legendair | Yes | Yes | No |
| Supportair | Yes | Yes | No |

The updated preventative maintenance schedule is detailed below, only applies to devices with 3812700 or 3812799 installed.

This schedule replaces the one detailed in Chapter 2 of both the Legendair revision B and Supportair revision A Service Manuals.

Legendair

| Interval | Prefix |
|---------------|--------|
| Every Year | V3 |
| Every 3 years | V4 |
| Every 6 years | V5 |

| Operation | V3 | V4 | V5 |
|--|----|----|----|
| Checking user/machine interfaces, adjustment and calibration | X | | |
| Intentional vent stop alarm test | X | | |
| Flow laminator cleaning | X | | |
| Replacement of C53 capacitor | X | | |
| Replacement of internal battery | | X | |
| Replacement of turbine box | | | X |

Supportair

| Interval | Prefix |
|---------------|--------|
| Every Year | V2 |
| Every 3 years | V3 |
| Every 6 years | V4 |

| Operation | V2 | V3 | V4 |
|--|----|----|----|
| Checking user/machine interfaces, adjustment and calibration | X | | |
| Inspection date of oxygen hose | X | | |
| Replacement of C53 capacitor | X | | |
| Replacement of internal battery | | X | |
| Flow Laminator cleaning | | X | |
| Checking, adjustment and calibration O2 | | X | |
| Replacement of pilot solenoid valve | | X | |
| Replacement of complete O2 block | | | X |
| Replacement of cooling fan | | | X |
| Replacement of turbine box | | | X |

This change should be made with immediate effect.



EMEA Technical Product Manager
 Covidien

URGENT MEDICAL DEVICE FSCA VERIFICATION FORM

| Customer Contact Details | Covidien Contact Details |
|---|--|
| Hospital / HCP: Covidien Account Number: | To: [please insert name Covidien commercial office] |
| Address: | Address: [please insert Covidien address] |
| Telephone n°: | Telephone n°: [please insert Covidien telephone number] |
| Fax n°: | Fax n°: [please insert Covidien fax number] |
| E-mail: | E-mail: [please insert contact e-mail address] |

I acknowledge receipt of the Field Safety Notice regarding Legendair™ and Supportair™ C53 FSCA _____ (signature)

Please complete below column, indicating all serial numbers you have serviced and indicate whether the C53 capacitor or Motor Control Board (MCB) was replaced.

| Serial numbers Legendair™ or Supportair™ ventilator | C53 component replaced on board (P/N 100049759) Yes/No | MCB with new C53 (P/N 3812799) Yes/no | New revision MCB (P/N 3832799) Yes/No |
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Please fax this form to the fax number referenced at the top of this form.

Name: _____ Signature: _____ Date: _____
 (please print)