



MEDICAL DEVICE FIELD SAFETY NOTICE

LEGENDAIR® Ventilator

May XX, 2011

Dear Valued Customer,

This letter is to inform you of a field safety notice on the LEGENDAIR® ventilator related to potential failure of audible backup alarms in the event of power loss to the ventilator. Codes for affected products are referenced below.

4095700	INTL LEGENDAIR SINGLE BRANCH X1
4095701	GB NO LEGENDAIR SINGLE BRANCHX1
4095702	DE LEGENDAIR SINGLE BRANCH X1
4095705	CA LEGENDAIR SINGLE BRANCH X1
4095706	JP LEGENDAIR SINGLE BRANCH X1
4095709	DK LEGENDAIR SINGLE BRANCH X1
4095900	INTL LEGENDAIR DOUBLE BRANCH X1
4095901	GB NO LEGENDAIR DOUBLE BRANCHX1
4095902	DE LEGENDAIR DOUBLE BRANCH X1
4095905	CA LEGENDAIR DOUBLE BRANCH X1
4095906	JP LEGENDAIR DOUBLE BRANCH X1
4095909	DK LEGENDAIR DOUBLE BRANCH X1
4095921	AU LEGENDAIR DOUBLE BRANCH X1

We have found that a capacitor in the Central Processing Unit (CPU) printed circuit board (PCB) used on the Legendair® to power the backup battery alarm in the case of loss of power may degrade. This could lead to a decreased time of audible sound, less audible or no audible alarm at all in the event of power loss to the ventilator. Current information indicates the lifetime of these capacitors may be affected by usage temperature. Investigation is continuing to further define the details of the capacitor life.

According to our records, you have a ventilator which may be impacted by this issue. **During the next scheduled preventive maintenance cycle, an additional test of the ventilator must be conducted.** This will determine whether the audible backup alarm would function properly in the event of total power loss. How to conduct this test is clearly outlined in the attached Service Manual Addendum.

Covidien will provide an initial inventory of PCBs to support the results of testing conducted during preventive maintenance. If testing determines that the PCB needs to be replaced, please place the tested PCB in the shipping container of the replacement PCB, complete the included documentation and labels, package the replaced PCB in the shipping container of the replacement PCB, and return it to Covidien at the address provided.

Upon receipt of the tested PCBs, Covidien will dispatch to you new or refurbished PCBs equal in number to those returned, for use in subsequent board replacements. This procedure will cover one (1) PCB per

Legendair and for a period not exceeding one (1) calendar year from the date of reception of this letter. PCBs returned to Covidien that are found to pass the screening test, or are faulty for reasons not related to the alarm test specified, will not be eligible for replacement under this procedure.

If results of testing do not indicate the PCB needs to be replaced, no further action is required.

Until the scheduled preventive maintenance has been completed, the ventilator must be operated primarily under mains power and with a fully-charged internal battery, as currently specified in the Service and Operators Manual.

If you do not currently conduct your own preventive maintenance, please contact your maintenance provider to inform them of this update, or your local Covidien Service Center at the number provided (attached).

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

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

Sincerely,

Frances E. Harrison

Vice President, Regulatory Affairs

Respiratory and Monitoring Solutions

Covidien, formerly known as Tyco Healthcare

Attachment – Manual Addendum



COVIDIEN

Date 11/05/2011

**Maintenance File Revision B Addendum
Legendair™ Portable Ventilator
Involuntary Stop Alarm Test**

The following test should be performed during your annual service to ensure the performance of the audio alarm when all power is lost or a complete failure of the system and software.

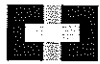
- Switch the device on using the mains switch at the rear.
- Connect a patient circuit and test lung
- Start the ventilation
- Leave unit to ventilate for a minimum of 10 minutes.
- Set the AC mains switch to the off position
- The device will turn off and the alarm should be active
- Confirm that the alarm sounds for at least 15 seconds.
- Set the mains switch to the on position.
- Then stop ventilation with the ⓘ key, by pressing and holding for 3 seconds and then releasing the key when prompted on the screen.

Kind regards

Frances E. Harrison

Vice President, Regulatory Affairs

Respiratory and Monitoring Solutions
Covidien, formerly known as Tyco Healthcare



COVIDIEN

[Please insert date the form was sent]

URGENT MEDICAL DEVICE FSCA Légendair ventilators

VERIFICATION FORM

Customer Contact Details	Covidien Contact Details
Hospital Name:	To: <i>[please insert name Covidien commercial office]</i>
Address:	Address: <i>[please insert Covidien address]</i>
Telephone n°:	Telephone n°: <i>[please insert Covidien telephone number]</i>
Fax n°:	Fax n°: <i>[please insert Covidien fax number]</i>
E-mail:	E-mail: <i>[please insert contact e-mail address]</i>

Please test all devices and complete attached forms as indicated below.

Option 1: The alarm functions correctly and sounds for 15 seconds

⇒ Please complete form 1

Option 2: The alarm function does not sound or sounds less than 15 seconds

⇒ Please complete form 2

Name:
(please print)

Signature:

Date:

FORM 1 **The alarm sounds for 15 seconds**

FORM 1 **The alarm sounds for 15 seconds**

Please fax the form back to: [enter fax number]

[illegible]

FORM 2

[illegible]