PHILIPS

FSN: 2019-11-A

URGENT - Field Safety Notice

Trilogy Evo, Garbin Evo, LifeVent Evo 2

Released Software Versions SW 1.00.05, SW 1.01.09.00, SW 1.01.10.00, and SW 1.01.11.00

Dear Customer,

During engineering testing, Philips became aware of two (2) unlikely scenarios that result in the Trilogy Evo failing to alarm immediately and persistently after a loss of therapy event. The failure to alarm as designed is the result of the software on impacted Trilogy Evo devices not reacting properly to these events.

Patients may be at risk should this problem occur while the patient is not being actively monitored. There have been no reports of harm or injury associated with this issue.

Affected devices can continue to be used in accordance with this Field Safety Notice.

This Field Safety Notice informs you of the following:

- Description of the issue and the circumstances under which it can occur
- Customer/user actions that are required to prevent risks for patients
- Philips Respironics actions to resolve the issue

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Should you have any questions or need further information regarding this communication, please do not hesitate to contact us:

This notice has been reported to the appropriate regulatory agencies.

We appreciate your support in reacting to this Field Safety Notice and sincerely regret any inconvenience that this action may cause you.

Sincerely,

Rodney Mell,
Head of Quality & Regulatory, SRC, Philips

AFFECTED PRODUCTS	Affected models include Trilogy Evo, Garbin Evo, LifeVent Evo 2 units with software versions 1.00.05, 1.01.09.00, 1.01.10.00, and 1.01.11.00. These software versions represent all Trilogy Evo software versions introduced into production and released for upgrade to the field for the life of the device.
PROBLEM DESCRIPTION	The Trilogy Evo is designed to maintain an immediate alarm for two minutes when a loss of therapy or power failure event is detected. During engineering testing Philips became aware of two unlikely scenarios that result in the Trilogy Evo failing to alarm immediately and persistently after a loss of therapy event. The failure to alarm as designed is the result of the software on impacted Trilogy Evo devices not reacting properly to these events. These failures have not been reported from the field and were only observed during device testing in a controlled environment designed to force the failures to occur. The failures are unlikely to occur outside of the testing environment. In cases where a remote alarm or nurse call normally closed (NC) alarm system is in use, the Trilogy Evo appropriately signals the accessory alarms to annunciate.
HAZARD INVOLVED	Should this problem occur, it is possible that caregivers could be delayed in responding to patients receiving insufficient ventilation for their intended therapy session, resulting in patient harm.
HOW TO IDENTIFY AFFECTED PRODUCTS	Affected models include Trilogy Evo, Garbin Evo, LifeVent Evo 2 units with software versions 1.00.05, 1.01.09.00, 1.01.10.00, and 1.01.11.00. Per the device's User Manual, the device software version can be viewed as follows: • In the menu bar, tap the Options icon. • In the device Options window, tap Information • Software Version Number is listed here
ACTION TO BE TAKEN BY CUSTOMER / USER	1. Affected devices can continue to be used in accordance with device Instructions for Use and this Field Safety Notice until it is possible to update the device software 2. Until the software is updated, users should do the following: o **Use the Trilogy Evo device only in cases where an accessory remote alarm or nurse call normally closed (NC) system is in use and/or;** o **An additional physiological monitoring alarm is in place on the patient (e.g. SPO2) as recommended in device labeling** o **The Trilogy Evo device should be removed from use in any case where the above mentioned monitoring and alarms are not in place** 3. Update the device software as soon as possible. The updated device software is available on my.respironics.com 4. Download the software to a USB drive from my.respironics.com and follow your device user manual to install. 5. If you have any problems downloading and installing the updated software from my.respironics.com, please contact our Customer Service Department at [Insert local customer service phone number] 6. Return the Business Reply Form (BRF) confirming that device software has been updated

ACTIONS PLANNED BY PHILIPS	Philips Respironics will send follow up communications in fifteen (15) days if we do not receive confirmation that your device has been updated.
FURTHER INFORMATION AND SUPPORT	Should you have any questions or need further information regarding this communication, please do not hesitate to contact us at [Insert local customer service phone number]

Business Reply Form

Philips Respironics

2019-11-A

TRILOGY EVO SOFTWARE ISSUE
FIELD ACTION

«Account_Number»

«Name_1»

«Street»

«Address_2»

«City» **«STATE»** **«Postal_Code»**

«Telephone_1»

PLEASE COMPLETE THE FOLLOWING ACTIONS

INSTRUCTIONS:

1) **Review the enclosed list that details all of the Trilogy Evo, Garbin Evo, or LifeVent Evo2 devices you purchased that are impacted by this field action.**
2) **Read the enclosed Field Safety Notice and update the software of all impacted devices in accordance with the instructions.**
3) **Record the Serial Numbers of all corrected devices along with software version number used for the update.**
4) **Please return the completed form by email to [Insert Market Group specific email address] within 15 business days of receipt.**

It is necessary that Philips receive timely response to this Notice; please respond within 15 business days of receipt. If you have any questions or concerns, please contact Philips Respironics at [Insert Market Group Specific Customer Service Phone Number] for international calls.

Your signature below acknowledges that you have received the enclosed notice and have accurately indicated the devices updated on the included page.

FORM COMPLETED BY (PRINT NAME): _____

SIGNATURE: _____ **DATE:** _____

PLEASE COMPLETE AND RETURN THIS FORM WITHIN 15 BUSINESS DAYS OF RECEIPT OF THIS NOTIFICATION TO PHILIPS RESPIRONICS:
BY EMAIL: [INSERT LOCAL EMAIL]

Business Reply Form

Philips Respironics

2019-11-A

TRILOGY EVO SOFTWARE ISSUE
FIELD ACTION

Please update the devices that you have purchased as soon as possible and indicate the software version number that was used for the update:

☐ **All purchased devices have been updated with software version _____.**

☐ **A portion of purchased devices have been updated with software version _____. The serial numbers of these devices are listed below.**

Trilogy Evo, Garbin Evo, or LifeVent Evo2 Serial Numbers:	