Field Safety Notice

PHILIPS

FSN: R-01-2016-A

URGENT - Field Safety Notice

Trilogy 100, Trilogy 200, Garbin, Garbin Plus, Trilogy O2, Trilogy 202, Trilogy EC

Software versions released since January 29, 2015: 13.2.04, 13.2.05, 14.0.00, and 14.1.01

Dear Customer,

Philips Respironics Trilogy devices operating with the above software versions and with dual prescriptions enabled may be susceptible to inadvertent change between active prescriptions in response to specific user interaction. This may occur without requiring user confirmation of the change. However, devices continue to accurately display the active prescription in the upper left hand corner of the display. The device does not change spontaneously.

If the user is unaware of the change between prescriptions, this could pose a risk to patients. 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 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.

We are notifying customers of this issue via this Field Safety Notification and will soon be providing a software update for affected devices. You will be notified when the software update is available.

Commented [DE1]: yes

Commented [JWD2]: Do we want to indicate here that we will be sending out a second mailing with notification of update availability?

Should you have any questions or need further information regarding this communication, please do not hesitate to contact us at (877) 387-3311 for domestic or 1-724-387-4000 for international calls.

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,

Jonathan W. Demarest,
Head of Quality & Regulatory, SRC, Philips

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AFFECTED PRODUCTS	Affected models include Trilogy 100, Trilogy 200, Garbin, Garbin Plus, Trilogy O2, Trilogy EC and Trilogy 202 units with software versions 13.2.04 or 13.2.05 or 14.0.00 or 14.1.01. These versions were introduced into production and released for upgrade to the field effective January 29, 2015.
PROBLEM DESCRIPTION	The listed Trilogy devices support dual therapy prescriptions, and two prescriptions may be programmed by a healthcare professional specific to the patient's needs as prescribed by physician. Philips Respironics has become aware that Trilogy Ventilators with software versions 13.2.04, 13.2.05, 14.0.00 or 14.1.01 are susceptible to an inadvertent change between prescriptions. This may occur under a particular set of operating conditions and after a specific sequence of key presses without requiring confirmation of the change by the user. Affected devices continue to accurately display the active prescription in the upper left hand corner of the display. As this prescription change was unintended and no confirmation was required, the user may be unaware of this change.
HAZARD INVOLVED	Should this issue occur, it is possible that patients may receive insufficient ventilation for their intended therapy session and result in patient harm.
HOW TO IDENTIFY AFFECTED PRODUCTS	Per the device's User Manual, the device software version can be obtained as follows: • After you press the power button to begin therapy, the Startup screen appears momentarily, indicating the device name and the software version. • On the Main Menu screen scroll to the Information section, press the right key, scroll to the device software version.
ACTION TO BE TAKEN BY CUSTOMER / USER	1. Complete and return the enclosed Business Reply Form 2. Affected devices can continue to be used in accordance with device Instructions for Use and this Field Safety Notice 3. Notify users with affected devices of the following: ○ Verify the appropriate prescription for their therapy session, as is displayed in the upper left corner of the Trilogy display 4. In accordance with your normal operating procedures and/or maintenance schedule, update the device software after it is made available.
ACTIONS PLANNED BY PHILIPS	We will soon release updated device software to prevent the issue described above. The updated device software will be available on my.respironics.com. Another letter will be mailed to you announcing the availability of the updated software.
FURTHER INFORMATION AND SUPPORT	Should you have any questions or need further information regarding this communication, please do not hesitate to contact us at (877) 387-3311 for domestic or 1-724-387-4000 for international calls.

Commented [APS3]: What happens if the prescription is wrong?
Follow the IFU? What does a user do?

Commented [APS4]: Do we want to commit to a letter? This could also be accomplished by phone call or via email.