

## **URGENT Field Safety Notice**

Trilogy Evo and Trilogy Evo O2

August 2021

**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.

Dear Customer,

This is a follow-up communication to the Philips *URGENT Field Safety Notice* for the *Trilogy Evo and Trilogy Evo O2 2017-07-A* sent in July 2021 that could pose a risk for patients or users. This notice is intended to inform you about:

- Release of software to correct the issues
- Trilogy Evo and Evo O2 Firmware Upgrade Procedure
- Business Reply Form and actions required by customers

### **1. What the problem is and under what circumstances it can occur**

Two software issues had been identified related to pressure increase. The first issue is described as *Infant/Pediatric EFS Calibration Pressure Increase* and the second issue is described as *Pressure Drift (Continuous Usage)*.

#### **Issue 1 – Infant/Pediatric EFS Calibration Pressure Increase**

An increase in the expiratory pressure (EPAP/PEEP) can occur when the pediatric/infant External Flow Sensor (EFS) is used with an Active Flow or Dual Limb circuit and a manual circuit calibration is performed. This increase in pressure will be seen shortly after starting therapy within approximately 1 to 2 minutes. The maximum expiratory pressure increase may reach up to 10 cmH<sub>2</sub>O above the set pressure. The inspiratory pressure (Pressure Support/Pressure Control/IPAP) may also be affected.

#### **Issue 2 – Pressure Drift (Continuous Usage)**

When a Trilogy Evo or Trilogy Evo O2 model is used continuously without any interruption of therapy over weeks to months, the baseline pressure (that is, the pressure initially set for the patient) may increase or decrease at a rate of up to approximately 2 cmH<sub>2</sub>O per month. This increase applies to the PEEP and the inspiratory pressure at the same rate. The maximum pressure deviation that could be seen is a 10 cmH<sub>2</sub>O shift from the baseline pressure. The pressure regulation alarms will not announce with this issue.

This issue applies to the following modes: CPAP, PSV, S/T, A/C-PC, SIMV-PC, SIMV-VC (PEEP and Pressure Support), and A/C-VC (PEEP).

The User Interface (display screen) or Care Orchestrator/Care Orchestrator Essence display the actual pressure that the patient is receiving, which will differ from the baseline setting when this condition occurs.

## 2. Describe the actions planned by Philips to correct the problem

Philips has released a software correction for this issue. The software is available via the “My Philips for Professionals” website for customers to upgrade devices.

## 3. Trilogy Evo Firmware Upgrade procedure

### A. Download of Software from MyP4P website

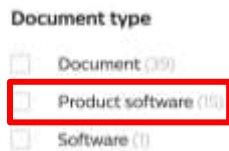
*This section will outline the steps to download the latest Trilogy Evo software on a USB stick.*

*MyP4P is not compatible with Internet Explorer. Access MyP4P using Microsoft Edge, Chrome, or Firefox browsers.*

1. Log onto <https://www.my.philips.com/> with your customer account and password.
2. Click on the Documents tab



3. Use the search tool and type: Trilogy Evo
4. Click on **Product Software** under Document Type filter on the bottom left side of the screen (below Filters)



5. Click on **Trilogy Evo** under Product filter



If your country is Japan, Singapore, Malaysia, South Korea, Brazil, Russian Federation, or China, please download version 1.05.02.00. Otherwise, please download the version 1.06.05.00.

**For United Kingdom and Ireland, please download version 1.06.05.00**

### B. Downloading Trilogy Evo SW to USB

1. Connect a USB flash drive to the PC. (Minimum memory size should be 2 GB or greater).
2. Click on the file and this will be automatically downloaded. This file is in a compressed format (.zip).

3. Save the Trilogy Evo Upgrade zip file to a known location.
4. Unzip the file and an .exe file will be available.
5. Run the .exe file to self-extract the software update file.
6. During the self-extraction, select the USB flash drive location to unzip the file to.
7. Winzip will copy the TrilogyEvo.upg file to the USB flash drive. Acknowledge the prompts and close WinZip.
8. The USB flash drive will then contain the software update file necessary to upgrade the device software.

**C. Upgrading Trilogy Evo software (USB sticks will be available for order in September 2021)**

1. Insert the USB-drive in any of the two USB ports of Trilogy Evo.
2. Go to the OPTIONS window (wrench icon) > Data Transfer
3. Trilogy Evo will recognize the USB drive and will show the Software version on the "Install Software Update" box. Click on that box.
4. Confirm that you are upgrading the device to the latest version and click YES
5. Trilogy Evo is now installing the new software. Please, wait.
6. A confirmation of Software installation complete will be shown. Press OK and turn the ventilator ON.

If you need any further information or support concerning this issue, please contact your local Philips representative or UK Philips Customer Care Service Centre on 0870 532 9741 or Ireland Philips Customer Care Service Centre on +353 1 7640229.

**Please complete the included Business Reply Form and return by fax or email within 15 days of receipt of this notification.**

Philips regrets any inconvenience caused by this problem.

Sincerely,

Rodney Mell  
Head of Quality Assurance  
Philips Sleep and Respiratory Care

## URGENT FIELD SAFETY NOTICE RESPONSE FORM

**Reference: Trilogy Evo and Trilogy Evo O2 CR# 2021-07-A**

**Instructions:** Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/Post Code/Country: \_\_\_\_\_

### Customer Actions:

- Review the enclosed serial number list that contains all of the Trilogy Evo and Trilogy Evo O2 devices you purchased that are impacted by this field action.
- Read this Urgent Field Safety Notice and update the software of all impacted devices in accordance with the software update instructions.
- Record the Serial Numbers of all corrected devices along with software version number used for the update in the table below.
- Please return the completed form by email to [safetynoticeuki@philips.com](mailto:safetynoticeuki@philips.com) within 15 business days of receipt.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this notice has been properly distributed to all users that handle the Trilogy Evo and Trilogy Evo O2 devices.

### Name of person completing this form:

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Date  
(DD/MM/YYYY): \_\_\_\_\_

Please complete and return this form within 15 business days of receipt of this notification to:  
**[safetynoticeuki@philips.com](mailto:safetynoticeuki@philips.com)**

<b>TRILOGY EVO AND TRILOGY EVO O2 DEVICES</b>				
<b>Material Number</b>	<b>Serial Number</b>	<b>Status (Select One)</b>		
		<b>Software Updated</b>	<b>Device Not Found</b>	<b>Device Destroyed</b>