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URGENT Field Safety Notice

Trilogy Evo and Trilogy Evo O2

XX-Jul-2021

To: <Name / Title / Customer Name>
<Street Address>
<City, State, Zip Code>

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 Philips *URGENT Field Safety Notice* for the *Trilogy Evo and Trilogy Evo O2* that could pose a risk for patients or users. This notice is intended to inform you about:

- what the problems are and under what circumstances they can occur,
- the actions that should be taken by the customer/user in order to prevent risks for patients, and
- the actions planned by Philips to correct the problem.

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

Two software issues have 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_2O 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 cmH2O 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 cmH2O shift from the baseline pressure. The pressure regulation alarms will not annunciate 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 hazard/harm associated with the issue

Issue 1 – Infant/Pediatric EFS Calibration Pressure Increase

There is potential for inappropriate therapy to be provided when the EFS is used with manual calibration.

Harms that could occur as a result of an increase in delivered pressure include:

- Barotrauma (an injury to the lungs because of too much pressure)
- Hypotension (a decrease in blood pressure)

If the expiratory pressure (EPAP/PEEP) increases but the inspiratory pressure (Pressure Support/Pressure Control/IPAP) remains unchanged, the following harm could occur:

- Hypercarbia (too much carbon dioxide in the blood)

Issue 2 – Pressure Drift (Continuous Usage)

There is potential for inappropriate therapy to be provided to a patient if there is a pressure increase or decrease from the baseline pressure settings without alarm.

Harms that could occur as a result of pressure drift *increase* over time include:

- Barotrauma (an injury to the lungs as a result of too much pressure). The potential occurrence of barotrauma related to this issue is considered to unlikely; however, if it were to occur, it may be a serious injury.
- Hypotension (a decrease in blood pressure). The potential occurrence of hypotension related to this issue is considered to be occasional.

Harms that could occur as a result of pressure drift *increase* over time, and then abruptly reverting therapy (pressure settings) back to the initial prescribed settings, include:

- Dyspnea (a sensation of shortness of breath)
- Hypoxemia (a low amount of oxygen in the blood)

Harms that could occur as a result of pressure drift *decrease* over time include:

- Hypoxemia (a low amount of oxygen in the blood)

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3. Affected products and how to identify them

Product name	Product number
Trilogy Evo	BL2110X15B, CA2110X12B, DE2110X13B, DS2110X11B, EE2110X15B, ES2110X15B, EU2110X15B, FR2110X14B, GB2110X15B, IA2110X15B, IN2110X15B, IT2110X21B, KR2110X15B, LA2110X15B, LD2110X23B, ND2110X15B, RDE2110X13B, UDS2110X11B
Trilogy Evo O2	DE2100X13B, DS2100X11B, EE2100X15B, ES2100X15B, EU2100X15B, FR2100X14B, FX2100X15B, IA2100X15B, IN2100X15B, IN2100X19, IT2100X21B, JP2100X16B, LA2100X15B, ND2100X15B, RDE2100X13B, SP2100X26B

Trilogy Evo and Trilogy Evo O2 devices with software versions 1.02.01.00, 1.03.05.00, 1.03.07.00, 1.04.02.00, 1.04.06, 1.05.01 and 1.06.02 are impacted.

To check the software version, tap the Options icon  located on the top left side of the screen. Choose "Information" to find the software version.

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

Issue 1 – Infant/Pediatric EFS Calibration Pressure Increase

Please take the following actions until the upcoming software fix is implemented on your device.

If you are using the infant/pediatric EFS, **do not perform a manual circuit calibration**. Instead, **use the default calibration**. The pressure increase will not occur if the default circuit calibration is used.

As stated in the Clinical Manual, the ventilator is optimized for circuits that are within the specifications shown in "Circuit Requirements" section of the Clinical Manual, which are listed below. When using the default circuit calibration settings, ensure that you are using a circuit with these specifications:

- Inspiratory/expiratory resistance: up to 5 cmH2O at:
  - 15 L/min for pediatric (14 to 16 mm)
  - 2.5 L/min for infant (9 to 13 mm) circuit size
- Compliance: up to 4 ml/cmH2O

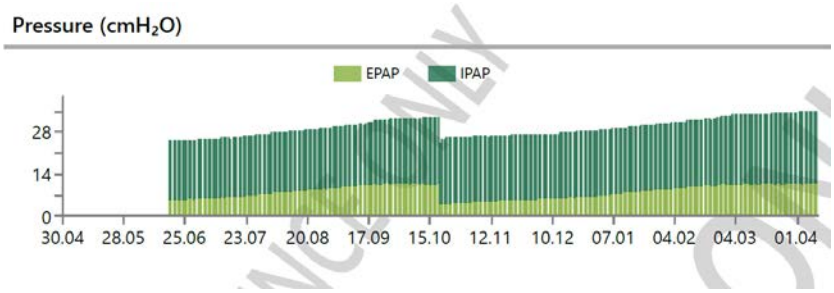
If your circuit does not meet these criteria, then seek other options as stated in the Clinical Manual. When setting volumes that are greater than or equal to 50 ml, passive and active PAP circuit types may be used.

If, the above options are not clinically appropriate, then seek an alternative ventilator.

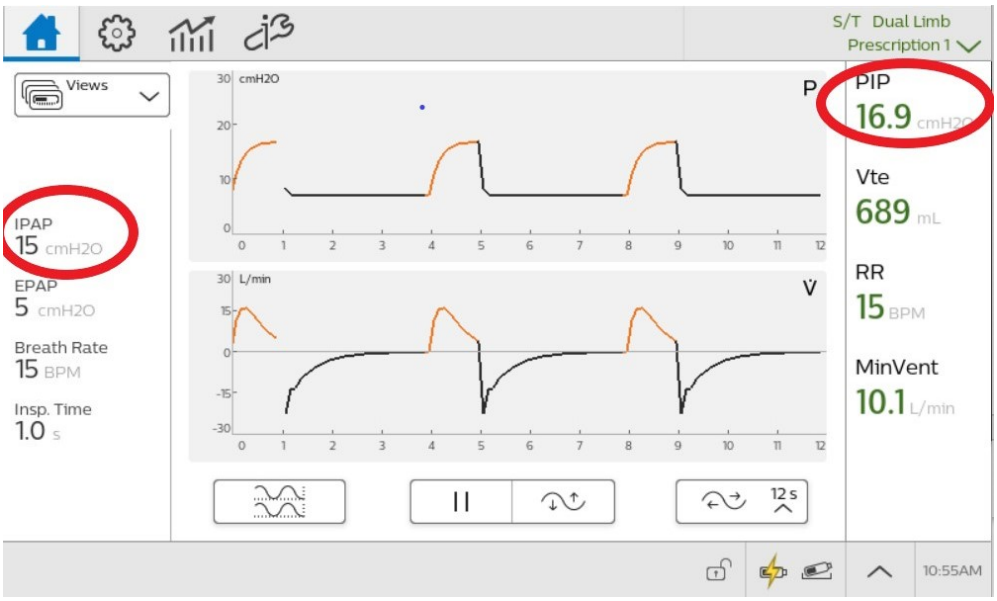
Issue 2 – Pressure Drift (Continuous Usage)

The following methods should be used to inspect the device to determine if a pressure drift has occurred as the pressure alarms will not detect it:

i. The Respiratory clinician or Physician can detect the increase/decrease in pressure by observing the pressure Trend report in Care Orchestrator/Care Orchestrator Essence as shown below.



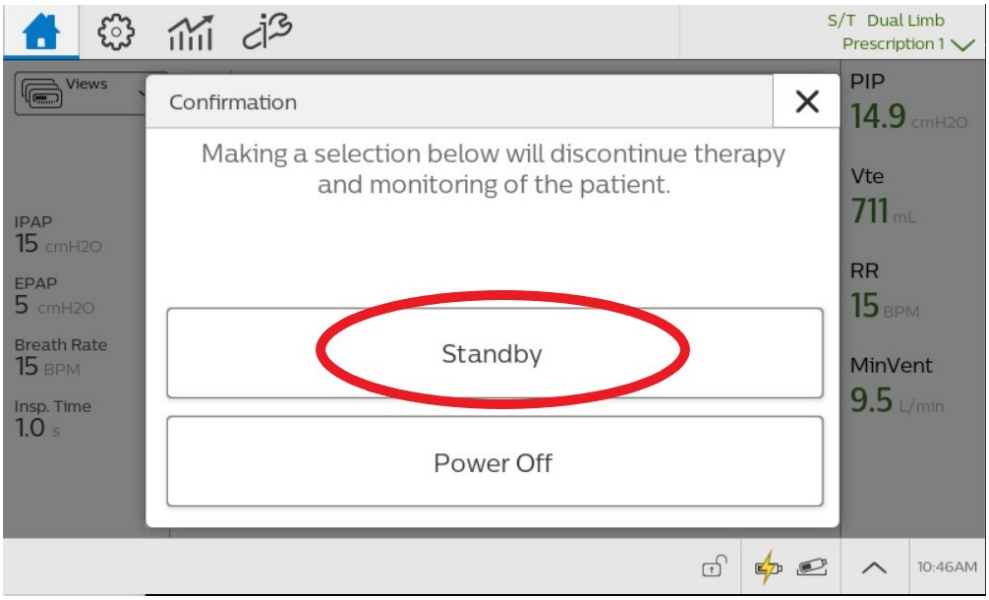
ii. The caregiver can detect the increase in pressure by observing the measured parameters on the device's screen (measured PIP value or pressure waveform as shown below where the IPAP is set to 15 cmH2O but because of the pressure increase the actual delivered pressure is 16.9 cmH2O).



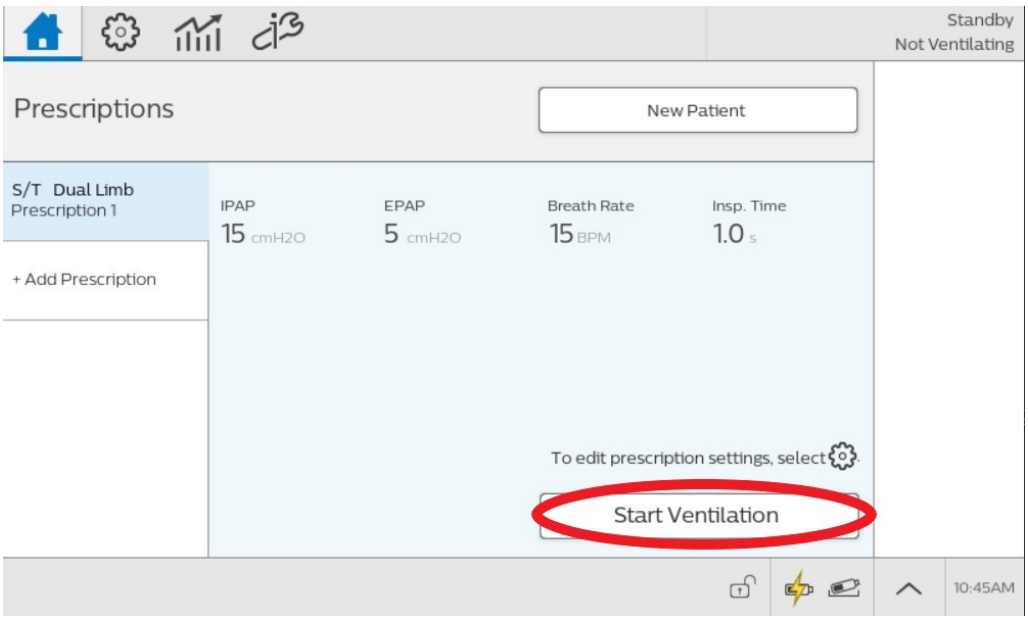
If a pressure drift is detected, the decision to reset the device and return to its original, intended settings MUST be made in consultation with a clinician. Take steps to support the patient during a brief interruption in therapy, as needed.

The following actions can be taken to reset the device back to the original settings:

i. Press Start/Stop, which brings user to the Confirmation Screen (see below). In the Confirmation Screen, choose “Standby.”



ii. Once Standby is selected, the user will see the Standby screen. Next, quickly touch “Start Ventilation” to resume therapy without delay.



Philips recommends that users periodically (monthly) perform the steps above to prevent the pressure from drifting.

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5. Describe the actions planned by Philips to correct the problem

Philips will be releasing a software correction for this issue. The software will be made available via the "My Philips for Professionals" website for customers to upgrade devices. Philips will be contacting Trilogy Evo and Trilogy Evo O2 customers when the software is released.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market>*

Please complete, sign, and return the acknowledgment and receipt form at the end of this letter.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Rodney Mell
Head of Quality Assurance
Philips Sleep and Respiratory Care

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Trilogy Evo and Trilogy Evo O2 (2017-07-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/Postal Code/Country: _____

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

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD/MM/YYYY): _____

Complete and sign response card and return to Philips by either of the following methods:

1. Email - enter local email
2. Fax – enter local fax number