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IMPORTANT PRODUCT NOTICE

10 June 2025

RE: Circuit Selection on Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal and Trilogy EV300 Platform User Interface

Dear Customer,

When using certain circuits with Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal and Trilogy EV300 devices, Philips Respironics has become aware of a potential issue that can occur when using preset circuit calibration settings with certain Fisher & Paykel (F&P) single limb circuits. Philips Respironics has not seen issues with the quality or performance of F&P circuits as they are manufactured or supplied.

This Important Product Notice is intended to inform you about:

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

Pressure delivery may incrementally exceed the specified limits (± 2 cmH2O + 4%) for pressure control accuracy when using the following circuit configurations with preset circuit settings configured on the device User Interface:

- F&P Adult, RT202 single-limb inspiratory heated, 20 mm ID circuit, configured with the “Adult (20-22mm)” circuit setting
- F&P Adult, 900MR810 reusable single-limb Evatherm circuit, configured with the “Adult/Pediatric(19mm)” circuit setting

All other critical parameters, including Tidal Volume measurements and alarms, continue to perform as expected and are not impacted by the circuit setting.

This situation may happen when the clinician selects a preset circuit configuration based on the diameter presented in the labelling provided by the circuit manufacturer. Philips Respironics testing indicates that any potential deviation will not deviate by more than 4 cmH2O from the published accuracy specification for pressure control. All specifications are published in the device Instructions for Use.

Philips Respironics has assessed this issue and has determined that it does not result in any new or increased risk to patients because any minor deviation in pressure delivery is compensated for when setting up the patient on the circuit and ensuring their comfort and compatibility (see Calibration section for “Device Setup” and see Clinical Assessment for “Device Operation” sections of the Instructions for Use).

This issue was detected by internal testing conducted by Philips Respironics while validating system performance in all use cases. There have been no reports of this issue being observed in clinical practice or reports of it causing harm at this time.

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2. Affected products and how to identify them

This issue affects Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal and Trilogy EV300 when using the following circuits:

F&P Circuit Part Number	Philips Part Number	Part Description
RT202	1141426	Single-limb inspiratory heated, 20 mm ID circuit
900MR810	1141549	Reusable single-limb Evatherm circuit

3. The actions that you as a customer can take to minimize the effect of the issue

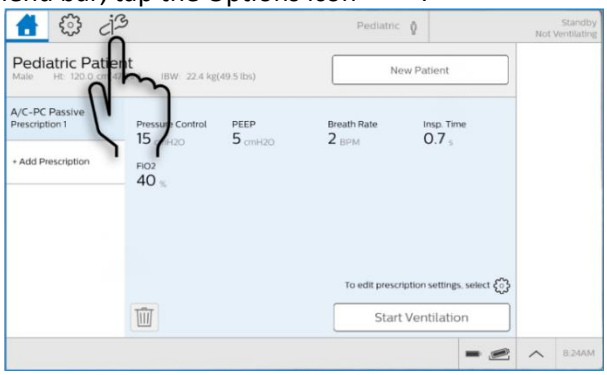
<u>To ensure variance in pressure does not occur, perform the Circuit Calibration when using F&P adult RT202 and 900MR810.</u>

Performing the following actions (see Calibration section for "Device Setup" and Clinical Assessment section for "Device Operation" of the Instructions for Use) will prevent the issue from occurring:

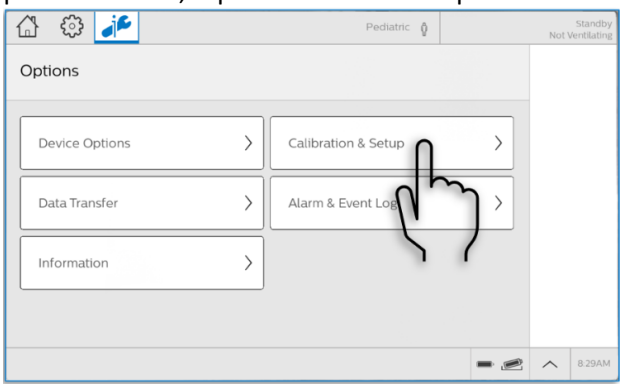
- Prior to initiating mechanical ventilation, perform a circuit calibration anytime you connect to a F&P RT202 or a 900MR810 circuit. Current guidance in the Instructions for Use define this as an optional step (see Calibration under "Device Setup"), though for these specific circuits we recommend making this a mandatory step until a solution resolving this issue is released.
- Ensure the High Tidal Volume and Low Tidal Volume alarms are set appropriately.
- If the device is currently in use with an F&P RT202 or 900MR810 circuit and a circuit calibration has not been performed, remove the patient from the device, provide an alternative means of ventilation if necessary, and perform a circuit calibration.
- Review the manual (see Calibration guidance in "Device Options" section of Instructions for Use) for guidance on how to perform circuit calibration (or see steps below).

Calibrating a Circuit: (DISCLAIMER: Photographs below are in English, however the referenced icons & buttons are equivalent in all languages for this device.)

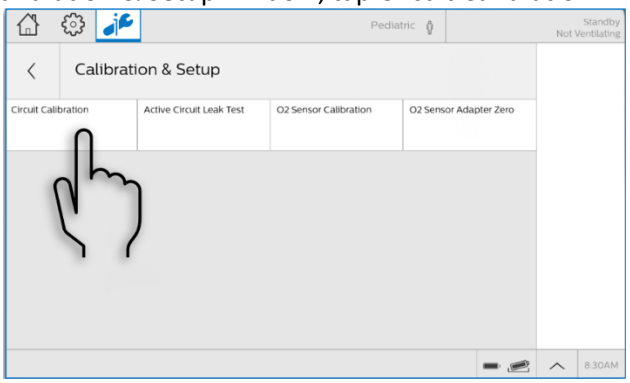
1. In the menu bar, tap the Options icon .



2. In the Options window, tap Calibration & Setup.

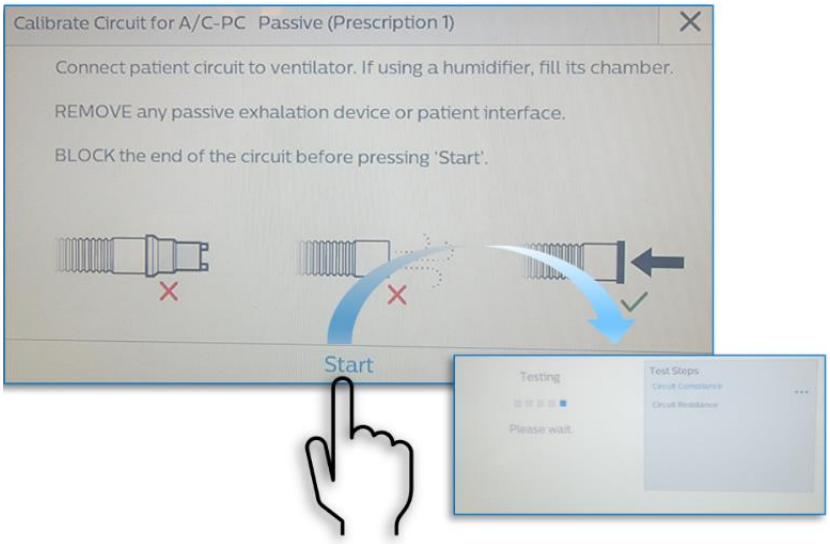


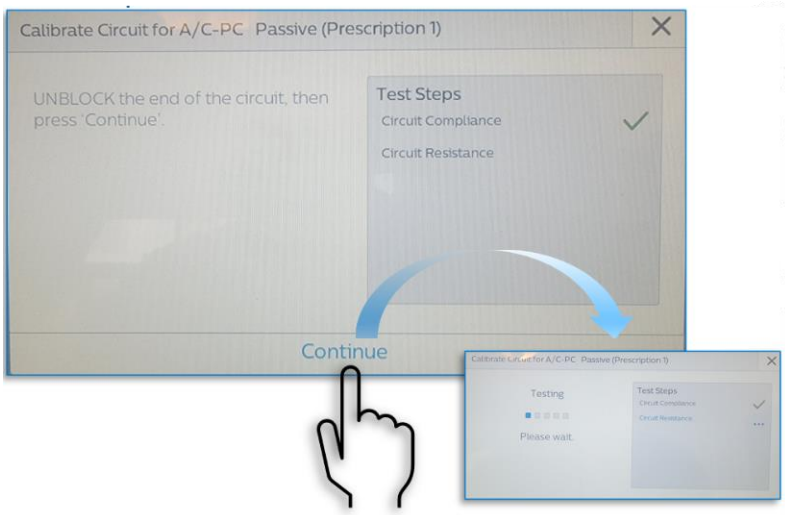
3. In the Calibration & Setup window, tap Circuit Calibration.



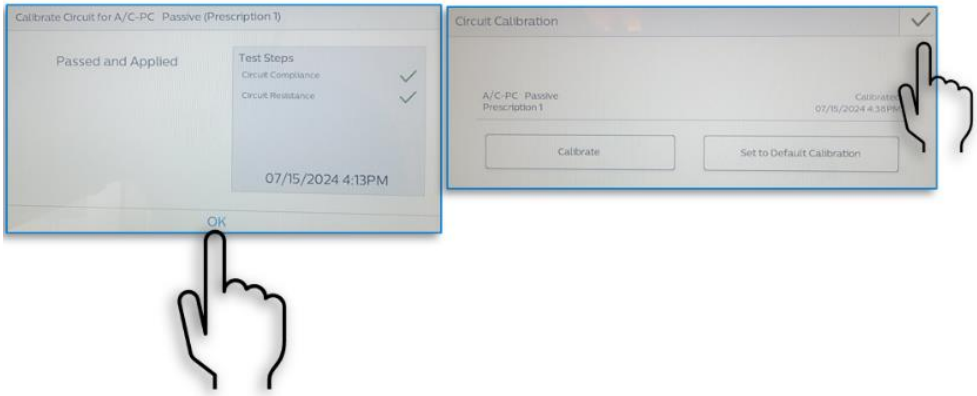
4. In the Calibrate Circuit window in the Current Prescriptions list, tap the prescription you want to calibrate and then tap Calibrate.

5. Follow the instructions on the screen.





- Confirm successful circuit calibration:



- If any part of the test fails, correct the issue suggested on the screen and then tap Retest to continue the test.
- To cancel the test, tap **Exit.**

4. The actions planned by Philips

Philips Respironics is currently working on a solution to resolve this issue. A separate notification will be provided when a solution is available.

5. Additional Information and Support

If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI : +448000260086
NI: +448000260430
ROI: +3531800832340

Email: UKFCO@philips.com

Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Tracie Capozzio
Head of Quality Therapy Platforms

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IMPORTANT PRODUCT NOTICE RESPONSE FORM

Reference: Circuit Selection on Trilogy Evo Platform User Interface Trilogy Evo, Trilogy Evo O2, Trilogy Universal, and Trilogy EV300, 2024-CC-SRC-012

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Important Product Notice, understanding of the issue, and required actions to be taken. This form can be completed by filling out the required fields, scanning, and emailing to **uki_quality_CR@philips.com**

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Read and Acknowledge the Important Product Notice.
- You may complete this form and return it to **uki_quality_CR@philips.com**

We acknowledge receipt and understanding of the accompanying Important Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle the Trilogy Evo, Trilogy Evo O2, Trilogy Universal and Trilogy EV300.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to **UKI_Quality_CR@philips.com**