



Date: December 15, 2022

**Re: HRC Patient Interface & Mask Availability Update – North America Hospital Customers**

Dear Valued Philips Customer,

We want to follow up on our recent communication with additional information about the biocompatibility evaluation requirement (ISO 18562) for medical devices.

As we've communicated, manufacturing of affected products is paused while products are evaluated. We have restarted production of the Performax Pediatric masks for the United States and Canada. Inventory will be available in early January 2023. Validation of other products are ongoing.

As a reminder, many of our other products are not impacted by this evaluation gap, including all ventilators, PerformaTrak masks (US only), Trilogy EV300 circuits, AC611 high-flow nasal cannula, and AF541 masks sold in the US and Canada.

Our inventory of V60 / V60 Plus single-limb passive circuits is depleted, and we cannot resume manufacturing until the biocompatibility evaluation is completed. We are unable to give a firm date as to when manufacturing will resume. While we are unable to directly fulfill your circuit needs, there are other potential options for single-limb, non-heated circuits with proximal pressure lines. Our preferred master distributor, Tri-Anim, has an alternative circuit, and other manufacturers provide similar options.

Please note that ISO 18562 evaluations are a regulatory requirement, and these evaluations are not related to a quality issue. These evaluations are not related to the June 14, 2021, Philips Respironics voluntary medical device recall/field safety notification and will not have any impact on the pace of the remediation, which continues to progress. The ISO 18562 evaluations that have been completed to date give us confidence that the evaluations of the remaining products will also be successful.

Again, we regret the impact this may have on your business and the inconvenience it may cause your patients. If you have any questions, or if there are other ways we can support you, please connect with your Philips representative or call our customer service at 1-800-722-9377.

Sincerely,

*Jeff Ward*

Business Sales Leader, Hospital Respiratory Care, North America



## Appendix: Suggested Alternatives

Table 1: Hospital Respiratory Care products awaiting ISO 18562 validation

Products requiring validation	Substitute option
AF531 Leak 1 Global Parts	US: Shift to Domestic part numbers; see Table 2 Canada: Shift to AF541
AF531 Leak 2 and SE	US: AF531 Leak 1 with replacement elbow, PerformaTrak or AF541 Canada: Shift to AF541
PerformaTrak (Canada only)	Consider AF541 Masks
PerforMax XL	Consider an alternative Mask Line, such as AF541 or PerformaTrak
Contour Deluxe Petite Only	Consider an alternative Mask Line, such as AF541 or PerformaTrak
AP111	Consider an alternative Mask Line, such as AF541 or PerformaTrak
AF811	Consider an alternative Mask Line, such as AF541 or PerformaTrak
V60 and BiPAP Circuits	Consider an alternative circuit

Table 2: United States AF531 Leak 1 alternative part list

Global Parts		Product Description	US Equivalent	
12 Digit PN	7 Digit PN		12 Digit PN	7 Digit PN
989805628751	1072629	L AF531 EE LEAK1 CAP STRAP, SU, 10 PACK	989805635021	1072620
989805628741	1072628	M AF531 EE LEAK1 CAP STRAP, SU, 10 PACK	989805635011	1072619
989805628731	1072627	S AF531 EE LEAK1 CAP STRAP, SU, 10 PACK	989805635001	1072618
989805628691	1072623	L AF531 EE LEAK1 4PT HDG, SU, 10 PACK	989805634991	1061735
989805628681	1072622	M AF531 EE LEAK1 4PT HDG, SU, 10 PACK	989805634981	1061734
989805628671	1072621	S AF531 EE LEAK1 4PT HDG, SU, 10 PACK	989805634971	1061733