



**The Trump Administration's Failures in Contract Management and Inept Negotiation by Senior White House Officials Denied Americans Ventilators During the Coronavirus Pandemic and Squandered Up to \$504 Million in Taxpayer Funds**

**Staff Report**

**Subcommittee on Economic and Consumer Policy  
Committee on Oversight and Reform  
U.S. House of Representatives**

**July 31, 2020**

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## EXECUTIVE SUMMARY

The Subcommittee on Economic and Consumer Policy conducted an investigation to determine why the country was without adequate numbers of ventilators during the initial critical months of the coronavirus pandemic. On April 15, 2020, the Subcommittee sent a letter requesting documents and information from Philips Respironics (Philips), a leading manufacturer of ventilators that reportedly negotiated contracts with the Trump Administration.<sup>1</sup> Philips has substantially complied with the Subcommittee's requests.

This staff report is based on a review of thousands of pages of previously non-public documents, including:

- Emails and communications between Philips and the Administration regarding ventilators the country would need during a pandemic;
- Philips' original September 15, 2014 contract with the Department of Health and Human Services (HHS) for the development and purchase of 10,000 Trilogy Evo Universal ventilators for \$3,280 apiece, and the ten modifications to that contract; and
- Philips' April 7, 2020 contract for the purchase of 43,000 Trilogy EV300 ventilators for \$15,000 apiece.

These documents indicate that before and during the pandemic, inept contract management and incompetent negotiating by the Trump Administration denied the country the ventilators it needed. The Administration effectively disabled an Obama-era contract with Philips for ventilators and then struck a second contract with the company in which the Administration overpaid for nearly identical ventilators by as much as \$500 million. These are funds that could have been used for personal protective equipment (PPE) and critical medical supplies that were in short supply across the country.

## FINDINGS

- In 2014, the Obama Administration entered into a contract with Philips Respironics, a leading global manufacturer, that would have supplied the nation with 10,000 ventilators by June 2019 in case of a pandemic. Development was initially delayed, and before leaving office, the Obama Administration gave Philips an extension that would have required the company to provide all of the ventilators by November 2019—in time to be deployed for this pandemic.
- Philips' delays continued through 2017 and 2018, but the Trump Administration mismanaged Philips' repeated failures to meet contractual requirements. It gave Philips three additional extensions, the last of which allowed for final delivery of

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<sup>1</sup> Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Vitor Rocha, Chief Executive Officer, Philips North America Corporation (Apr. 15, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-15.RK%20to%20Rocha%20Philips%20re%20Trilogy%20Evo.pdf>).

the ventilators to be delayed until June 2021. Had the Trump Administration held Philips to the terms of the Obama-era contract, the country would have had 10,000 ventilators that it needed when the coronavirus crisis struck.

- On January 21, 2020, when the first coronavirus case was reported in the United States, Philips approached the Trump Administration about accelerating the delivery of ventilators under its existing contract. The Trump Administration ignored this opportunity. For six weeks, it did not respond to Philips' offer.
- Finally, in March 2020, the Trump Administration responded, but rather than demand that Philips meet the deadlines required by its existing contract, or move them up to address the pressing need, the Trump Administration agreed on March 11, 2020, to another extension, removing all delivery deadlines until September 2022. Philips secured the extension by suggesting it would actually help move up delivery. The Trump Administration failed to question Philips and granted the modification, which made the Obama-era contract useless for aiding the country during this pandemic. The Administration never asked Philips to produce more ventilators under the existing contract.
- Instead, the Trump Administration, represented by Peter Navarro and other senior officials in the White House, negotiated a new contract with Philips. It agreed to pay Philips almost five times the price than under the previous contract. The ventilators purchased under the new contract (called Trilogy EV300s) were functionally identical to those required under the previous contract (called Trilogy Evo Universals), but the Trump negotiators appeared gullible and conceded to Philips on all significant matters, including price. The documents show that the Administration accepted Philips' first offer without even trying to negotiate a lower price.
- As a result, the federal government overpaid for ventilators—no American purchaser paid more than the U.S. government. Between December 2019 and May 2020, Philips took orders for 5,339 other Trilogy EV300 ventilators from 92 different purchasers in the United States. While the Trump Administration paid \$15,000 per ventilator, some small purchasers, buying as few as one unit, were able to negotiate prices as low as \$9,327 per unit.
- The waste of taxpayer funds caused by the Trump Administration's incompetent procurement efforts for ventilators could be as much as \$500 million or more.

By taking advantage of the Trump Administration's incompetence, Philips was able to secure a financial windfall to which it clearly is not entitled, and these funds should have been dedicated to obtaining desperately needed PPE and other critical medical supplies during this pandemic. To remedy this apparent profiteering, the Trump Administration now should engage competent contracting officers at federal agencies to determine whether any of these funds can be clawed back under the provisions of the contract signed during the Obama Administration or the modifications entered into by the Trump Administration.

**I. IN 2014, THE OBAMA ADMINISTRATION ENTERED INTO A CONTRACT WITH PHILIPS THAT WOULD HAVE SUPPLIED THE NATION WITH 10,000 VENTILATORS BY JUNE 2019 IN CASE OF A PANDEMIC. BUT DEVELOPMENT WAS DELAYED, AND BEFORE LEAVING OFFICE, THE OBAMA ADMINISTRATION GAVE PHILIPS AN EXTENSION THAT WOULD HAVE REQUIRED THE COMPANY TO PROVIDE ALL OF THE VENTILATORS BY NOVEMBER 2019—IN TIME TO RESPOND TO THIS PANDEMIC.**

The Obama Administration anticipated the need for ventilators during a pandemic like the one the nation faces today. In 2011, it requested proposals for a contract to develop a “new or improved ventilator to provide life support in clinical and non-clinical environments for severe respiratory conditions resulting from influenza infections or all-hazards events.”<sup>2</sup>

Philips, a global manufacturer of medical equipment, agreed to produce those ventilators. On September 15, 2014, it entered into a contract with HHS to develop a ventilator for the Strategic National Stockpile (SNS) over the course of 36 months.<sup>3</sup> Under that contract, Philips was to receive \$13,820,069 for the development of the ventilator.<sup>4</sup> That amount was later increased to \$14,366,815 by amendment.<sup>5</sup>

Under the 2014 contract, Philips agreed to complete the development of the ventilator by September 14, 2017. The contract gave HHS the option to purchase 10,000 ventilators at a set price of \$3,280 per unit once the design obtained clearance from the Food and Drug Administration (FDA).<sup>6</sup>

The contract contemplated the following ventilator delivery schedule from the date the purchase option was exercised: 2,500 ventilators were due within nine months (by June 15, 2018), 2,500 more due four months later (by October 14, 2018), 2,500 more due four months later (by February 14, 2019), and the final 2,500 due four months later (by June 15, 2019).<sup>7</sup>

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<sup>2</sup> Biomedical Advanced Research and Development Authority, Department of Health and Human Services, *BAA-11-100-SOL-00021, BARDA Broad Agency Announcement for Advanced Research and Development of Personal Protective Equipment, Ventilators, and Diagnostics* (June 20, 2011) (online at <https://govtribe.com/opportunity/federal-contract-opportunity/barda-broad-agency-announcement-baa-for-advanced-research-and-development-of-personal-protective-equipment-ventilators-and-diagnostics-baa11100sol00021>).

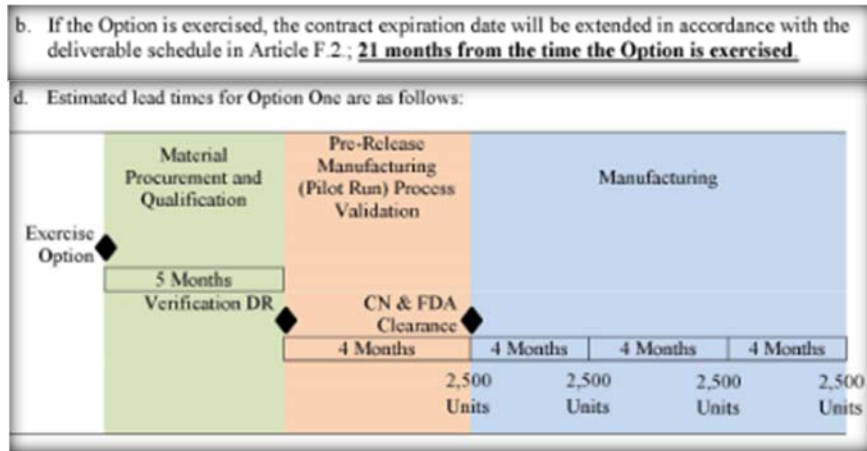
<sup>3</sup> Contract between Philips Respironics and the Department of Health and Human Services (Sept. 15, 2014) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49_Redacted.pdf)).

<sup>4</sup> *Id.*

<sup>5</sup> Modification 0005 of Contract between Philips Respironics and the Department of Health and Human Services (Sept. 6, 2017) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/192-216\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/192-216_Redacted.pdf)).

<sup>6</sup> Contract between Philips Respironics and the Department of Health and Human Services (Sept. 15, 2014) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49_Redacted.pdf)).

<sup>7</sup> *Id.*



When Philips initially fell behind in development, the Obama Administration granted one five-month extension to complete development, moving that date from September 14, 2017, to February 19, 2018.<sup>8</sup> Had development been completed by that date, the contract contemplated 2,500 ventilators being due by November 19, 2018, the next 2,500 due by March 19, 2019, the next 2,500 due by July 19, 2019, and the final 2,500 due by November 19, 2019.

Had the Trump Administration required Philips to fulfill this contract, all 10,000 ventilators would have been in the SNS prior to the pandemic hitting the country.

**II. PHILIPS' DELAYS CONTINUED THROUGH 2017 AND 2018, BUT THE TRUMP ADMINISTRATION MISMANAGED PHILIPS' REPEATED FAILURES TO MEET CONTRACTUAL REQUIREMENTS. IT GAVE PHILIPS THREE ADDITIONAL EXTENSIONS, THE LAST OF WHICH ALLOWED PHILIPS UNTIL JUNE 2021 TO DELIVER VENTILATORS. HAD THE TRUMP ADMINISTRATION HELD PHILIPS TO THE TERMS OF THE OBAMA-ERA CONTRACT, THE COUNTRY WOULD HAVE HAD 10,000 VENTILATORS THAT IT NEEDED WHEN THE CORONAVIRUS CRISIS STRUCK.**

The documents show that the Trump Administration allowed Philips' delay to become perpetual and unquestioningly granted Philips three more extensions to the development completion deadline:

- First to June 29, 2018;<sup>9</sup>

<sup>8</sup> Modification 0004 of Contract between Philips Respironics and the Department of Health and Human Services (Aug. 19, 2016) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/150-191\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/150-191_Redacted.pdf)).

<sup>9</sup> Modification 0005 of Contract between Philips Respironics and the Department of Health and Human Services (Sept. 6, 2017) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/192-216\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/192-216_Redacted.pdf)).

- Then to November 30, 2018;<sup>10</sup> and
- Then to September 30, 2019.<sup>11</sup>

On September 19, 2019, HHS finally exercised the purchase option from the last Administration's 2014 contract.<sup>12</sup>

From the date of exercise, the contract contemplated 21 months to complete delivery of the 10,000 units. By the time the Trump Administration finally exercised the option, 2,500 ventilators should have been due within nine months (by June 19, 2020), 2,500 more due four months later (by October 19, 2020), 2,500 more due four months later (by February 19, 2021), and the final 2,500 due four months later (by June 19, 2021).<sup>13</sup>

The Administration's inept management of this crucial contract deprived the country of any ventilators from Philips before the pandemic hit.

**III. ON JANUARY 21, 2020, WHEN THE FIRST CORONAVIRUS CASE WAS REPORTED IN THE UNITED STATES, PHILIPS APPROACHED THE TRUMP ADMINISTRATION TO ACCELERATE DELIVERY OF VENTILATORS UNDER ITS EXISTING CONTRACT. THE TRUMP ADMINISTRATION IGNORED THIS OPPORTUNITY. FOR SIX WEEKS, IT DID NOT RESPOND.**

On January 21, 2020, the Centers for Disease Control and Prevention (CDC) issued a press release alerting the nation to the first reported coronavirus case in the U.S.<sup>14</sup> That same day, Philips sent an email to HHS and offered to move up delivery of the Trilogy Evo Universal ventilators.<sup>15</sup>

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<sup>10</sup> Modification 0006 of Contract between Philips Respironics and the Department of Health and Human Services (June 12, 2018) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/218-224\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/218-224_Redacted.pdf)).

<sup>11</sup> Modification 008 of Contract between Philips Respironics and the Department of Health and Human Services (Apr. 26, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/228-230\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/228-230_Redacted.pdf)).

<sup>12</sup> *Modification 009 of Contract between Philips Respironics and the Department of Health and Human Services* (Sept. 19, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/231-232\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/231-232_Redacted.pdf)).

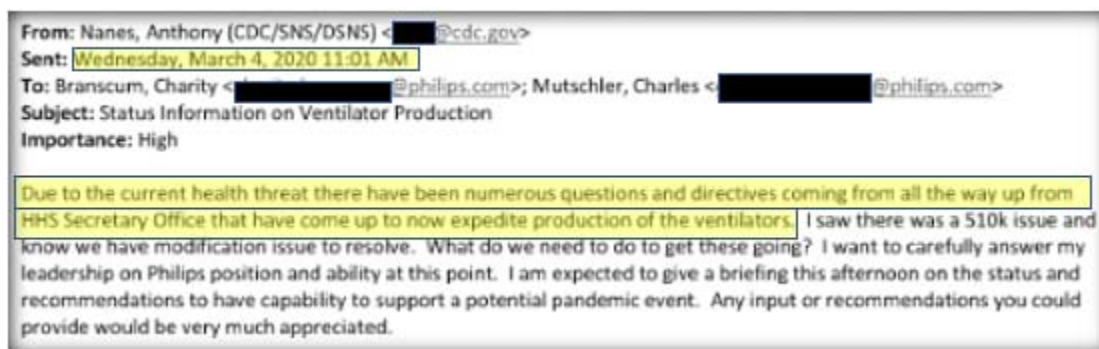
<sup>13</sup> Contract between Philips Respironics and the Department of Health and Human Services (Sept. 15, 2014) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49_Redacted.pdf)).

<sup>14</sup> Centers for Disease Control and Prevention, *Press Release: First Travel-Related Case of 2019 Novel Coronavirus Detected in United States* (Jan. 21, 2020) (online at [www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html](http://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html)).

<sup>15</sup> Email from Charles Mutschler, Senior Project Manager, Sleep and Respiratory Care, Philips, to Anthony Nanes, Logistics Management Specialist, Division of Strategic National Stockpile, Office of the Assistant Secretary for Preparedness and Response (Jan. 21, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2220\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2220_Redacted.pdf)).



Instead of seizing the opportunity to obtain the long-delayed ventilators in a time of great need, HHS did not respond. It took no actions in January or February to respond to Philips' offer to "accelerate any shipments." In fact, the Administration ignored this offer for six weeks, until March 4, 2020, when HHS finally asked Philips about expediting production of the Trilogy Evo Universal ventilators.<sup>16</sup>



**IV. RATHER THAN INSIST THAT PHILIPS MEET THE TERMS OF ITS CONTRACT, OR NEGOTIATE AN ACCELERATED SCHEDULE TO ADDRESS THE PRESSING NEED, THE TRUMP ADMINISTRATION AGREED TO A FOURTH EXTENSION, REMOVING ALL DELIVERY DEADLINES UNTIL SEPTEMBER 2022. PHILIPS SECURED THE EXTENSION BY SUGGESTING IT WOULD ACTUALLY HELP MOVE UP DELIVERY. THE TRUMP ADMINISTRATION FAILED TO QUESTION PHILIPS WHEN THE COMPANY REQUESTED MODIFICATIONS TO THE EXISTING CONTRACT, WHICH MADE THE OBAMA-ERA CONTRACT USELESS FOR AIDING THE COUNTRY DURING THIS PANDEMIC. THE ADMINISTRATION NEVER ASKED PHILIPS TO PRODUCE MORE VENTILATORS UNDER THE EXISTING CONTRACT.**

<sup>16</sup> Emails between Charity Branscum, Project Manager, Philips, Charles Mutschler, Senior Project Manager, Sleep and Respiratory Care, Philips, and Anthony Nanes, Logistics Management Specialist, Division of Strategic National Stockpile, Office of the Assistant Secretary for Preparedness and Response (Mar. 4-10, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/435-437\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/435-437_Redacted.pdf)).

On March 4, 2020, HHS finally asked Philips about expediting production of the ventilators.<sup>17</sup> Philips responded the same day, indicating support, and suggesting a contractual modification that it said would help the company accomplish that goal.<sup>18</sup>

Our team will evaluate what can be done to pull in shipments of the Trilogy Evo Universal from the current August timeframe. The current issues are also impacting our supply chain but we will explore what we can do within the bounds of the contract to expedite deliveries. **With your approval, we will move forward to make appropriate modifications to our contract to allow for the earlier shipments. We have attached a draft contract modification.** Please provide any feedback for Philips Legal approval and we will expedite the execution of this modification.

HHS agreed to the modification the next day, on March 5, 2020.<sup>19</sup>

**From:** Nanes, Anthony (CDC/SNS/DSNS) <[redacted]@cdc.gov>  
**Sent:** Thursday, March 5, 2020 10:05 AM  
**To:** Mutschler, Charles <[redacted]@philips.com>  
**Cc:** Branscum, Charity <[redacted]@philips.com>; Kelley, David (CDC/SNS/DSNS [redacted]@cdc.gov>  
**Subject:** RE: Status Information on Ventilator Production

**There are no issues with the MOD. The terms are agreeable.** please start production immediately. Once you have an idea of obtaining material and manufacturing time. Please provide it. Let me know if anything else is needed.

HHS committed a significant error, however, when it agreed to the modification without posing any questions to the company about *how* the modification would accelerate shipments or *why* the company was seeking modification.

It was only after agreeing to the modification, five days later, on March 10, 2020, that HHS finally asked Philips how much time the modifications would save.<sup>20</sup>

**From:** Nanes, Anthony (CDC/SNS/DSNS) <[redacted]@cdc.gov>  
**Sent:** Tuesday, March 10, 2020 10:43 AM  
**To:** Branscum, Charity <[redacted]@philips.com>  
**Subject:** Contract Clauses for Expedite

I want to brief leadership of options to speed up production the ventilators besides our current efforts. Can you please share the portion of the contract you spoke about how we can allocate funding to speed up production? The main response I anticipate is **how much more time will we be able to gain by executing this clause.** Can you start working out cost, quantity, and timeline for my briefing. We have some funding just made available that may be used for this.

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> Emails between Charity Branscum, Project Manager, Philips, Charles Mutschler, Senior Project Manager, Sleep and Respiratory Care, Philips, and Anthony Nanes, Logistics Management Specialist, Division of Strategic National Stockpile, Office of the Assistant Secretary for Preparedness and Response (Mar. 10-11, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/426-428\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/426-428_Redacted.pdf)).



Philips' response should have raised alarm bells for HHS—it couldn't commit to moving up delivery at all.<sup>21</sup>

We have not confirmed that we are able to provide early delivery with or without additional funding. I was just curious if the funding is available through this BAA.

Despite that lack of assurance, HHS still executed the contractual modification the next day, on March 11, 2020. The modification cancelled the scheduled delivery obligations which had required benchmarks to be hit, and partial fulfillments to be delivered, throughout the contract. The Administration relieved Philips of any obligation to deliver even a single ventilator before September 29, 2022, when all 10,000 would come due.<sup>22</sup>

Delivery and payment schedule for CLIN003:

Philips will deliver an indefinite quantity of Part Number DS2000X11B Trilogy Evo SP Ventilators on a periodic basis until delivery of 10,000 units is complete on or before September 29, 2022.

Such quantity of Part Number DS200X11B is defined as noted below:

Philips will notify ASPR of delivery quantity and delivery date no less than 45 days prior to delivery.

ASPR will notify Philips of delivery location no less than 30 days prior to the delivery date provided per Philips delivery notification.

Philips will invoice 30 days in arrears of such delivery at the rate of \$3,280 per unit.

Philips appears to have duped the Administration into thinking that this amendment, which permits a lengthy delay, was necessary for it to expedite production. When questioned about the deal, an HHS spokesman indicated that Philips would be making the ventilators “as soon as possible.”<sup>23</sup> However, Philips dispelled that notion by stating that “the company has no plan to even begin production anytime this year.”<sup>24</sup> Philips also touted the fact that it was free to sell its ventilators abroad instead of delivering the ventilators to HHS because “its contract with HHS gave the company until 2022 to produce the cheaper stockpile version.”<sup>25</sup>

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<sup>21</sup> *Id.*

<sup>22</sup> Modification 00010 of Contract between Philips Respironics and the Department of Health and Human Services (Mar. 10, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/432-434\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/432-434_Redacted.pdf)).

<sup>23</sup> *Taxpayers Paid Millions to Design a Low-Cost Ventilator for a Pandemic. Instead, the Company is Selling Versions of it Overseas.*, ProPublica (Mar. 30, 2020) (online at [www.propublica.org/article/taxpayers-paid-millions-to-design-a-low-cost-ventilator-for-a-pandemic-instead-the-company-is-selling-versions-of-it-overseas-](http://www.propublica.org/article/taxpayers-paid-millions-to-design-a-low-cost-ventilator-for-a-pandemic-instead-the-company-is-selling-versions-of-it-overseas-)).

<sup>24</sup> *Id.*

<sup>25</sup> *A Company Promised Cheap Ventilators to the Government, Never Delivered, and is Now Charging Quadruple the Price for New Ones*, ProPublica (Apr. 8, 2020) (online at [www.propublica.org/article/a-company-promised-cheap-ventilators-to-the-government-never-delivered-and-is-now-charging-quadruple-the-price-for-the-new-ones](http://www.propublica.org/article/a-company-promised-cheap-ventilators-to-the-government-never-delivered-and-is-now-charging-quadruple-the-price-for-the-new-ones)).

The pressure of this Subcommittee’s investigation may have encouraged Philips to deliver some ventilators to the U.S., even though the Trump Administration’s contract did not. Philips reported to the Subcommittee that it delivered 200 Trilogy Evo Universal ventilators to HHS in June, about six weeks after the Subcommittee had formally initiated its probe.<sup>26</sup> However, had the Trump Administration not suspended the contract’s partial fulfillment obligation, Philips would have been required to deliver at least 2,500 ventilators by June 19, 2020.

In a response to the Subcommittee, Philips reiterated that it is not obligated to complete delivery of the ventilators until September 2022, but it also claimed that it is “working with the SNS to accelerate delivery of the 10,000 unit production by the end of 2021.”<sup>27</sup> Even if true, that is more than six months later than the June 19, 2021 deadline to complete delivery prior to the ill-conceived contractual modification. The Trump Administration’s agreement to suspend contractual obligations required by the Obama-era contract ensured that Philips is not obligated to provide ventilators to help Americans in the throes of this pandemic.

**A. The Administration Never Asked Philips to Make More Ventilators Under the Existing Contract**

The Obama-era contract provides that the “Government reserves the right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise.”<sup>28</sup> The need for more of these ventilators arose when the pandemic was overwhelming American hospitals, which were running short of ventilators.<sup>29</sup>

HHS knew that the original contract gives it the power to increase its order in times of need. When HHS exercised the option to purchase 10,000 ventilators under the Obama-era contract on September 19, 2019, HHS conducted a site visit of Philips’ manufacturing facility. The minutes of that September visit made clear the purpose of the contract was to be able to quickly make the ventilators available in the case of a pandemic:<sup>30</sup>

• SNS wants to maximum uptime and availability of units at time of a pandemic situation

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<sup>26</sup> Email from Counsel to Philips North America Corporation to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (July 10, 2020).

<sup>27</sup> Letter from Counsel to Philips North America Corporation to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 26, 2020).

<sup>28</sup> Contract between Philips Respironics and the Department of Health and Human Services (Sept. 15, 2014) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1-49_Redacted.pdf)).

<sup>29</sup> *There Aren’t Enough Ventilators to Cope with the Coronavirus Crisis*, New York Times (Mar. 18, 2020) (online at [www.nytimes.com/2020/03/18/business/coronavirus-ventilator-shortage.html](http://www.nytimes.com/2020/03/18/business/coronavirus-ventilator-shortage.html)).

<sup>30</sup> Email from Charles Mutschler, Senior Project Manager, Sleep and Respiratory Care, Philips, to Anthony Nanes, Logistics Management Specialist, Division of Strategic National Stockpile, Office of the Assistant Secretary for Preparedness and Response (Nov. 5, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/485-489\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/485-489_Redacted.pdf)).

Indeed, on March 19, 2020, in one of Philips' first communications with White House negotiators about acquiring more ventilators, Philips brought up the \$3,280 Trilogy Evo Universal, attaching the following spec sheet to an email about an upcoming sales meeting:<sup>31</sup>

<b>PHILIPS</b>		Trade Agreements Act / Buy American Act / Origin Determination Form	
Form #4954		Ver. 00	
		Page 1 of 2	
ER # _____			
<b>COMPLETE FOR ALL DETERMINATIONS (TAA / BAA / Origins)</b>			
Part Number(s)	DS2000X118		
Product Name(s)	Trilogy Evo Universal Ventilator		
Product Category	Device		
Device Type	Ventilator		
Plant Name / Location	RUSM		
Intended Use of Main Device			
<p>The Trilogy Evo Universal ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo Universal is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO2, FIO2, CO2, and pulse rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional and hospital settings and non-emergency transport settings; for example, wheelchair. It may be used for both invasive and non-invasive ventilation.</p>			
Description of Part (if different than main device)			
Essential Component and its Function	Motor/Blower ASSY		
CoO of Essential Component	USA		
Ctry of Substantial Transformation	USA		
Bill of Materials	Refer to 2nd tab		
Recommended CoO of FGD	USA		
<b>COMPLETE FOR TAA/BAA DETERMINATIONS ONLY</b>			
FDA 510(k) Number	K181170		
Number of Components	Refer to 2nd tab		
List or Attach Operational Methods Sheets for Final Substantial Transformation Process			
ER 2230328 Master Validation Plan			
See above MVP			
Number of Assembly Steps	22		
Assembly Time	345.6		

On March 23, 2020, Philips' Chief Executive Officer (CEO) touted in an email to HHS Secretary Alex Azar and HHS Assistant Secretary for Preparedness and Response Robert Kadlec that through "co-development with BARDA, Philips has developed the best solution to confront exactly the pandemic we are facing."<sup>32</sup>

However, the point escaped the White House negotiators. The Administration did not exercise this option, and the documents show no evidence that it even discussed the possibility of Philips producing more ventilators under the Obama-era contract. As a result, the Trump Administration squandered the ability to buy more of the "best solution to confront exactly the pandemic that we are facing." Instead, it negotiated a new contract to purchase a much pricier option.

<sup>31</sup> Emails between Nick Padula, Vice President, Health and Human Services, Philips, and Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 18-19, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/857-862\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/857-862_Redacted.pdf)).

<sup>32</sup> Email from David Shoultz, Head of Government Affairs (U.S.), Philips, to Alex M. Azar II, Secretary, Department of Health and Human Services (Mar. 23, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038_Redacted.pdf)).

Despite rhetoric from the President about the Defense Production Act—claiming that “if people don’t give us what we need for our people, we’re going to be very tough, and we’ve been very tough”—the Trump Administration never used the Defense Production Act to compel more production of ventilators under the original contract.<sup>33</sup>

**V. THE TRUMP ADMINISTRATION, REPRESENTED BY PETER NAVARRO AND OTHER SENIOR OFFICIALS IN THE WHITE HOUSE, NEGOTIATED A NEW CONTRACT WITH PHILIPS. IT AGREED TO PAY PHILIPS ALMOST FIVE TIMES THE PRICE REQUIRED UNDER THE PREVIOUS CONTRACT. ALTHOUGH THE NEW VENTILATORS WERE FUNCTIONALLY IDENTICAL, THE TRUMP NEGOTIATORS APPARENTLY WERE GULLIBLE AND CONCEDED TO PHILIPS ON ALL SIGNIFICANT MATTERS, INCLUDING PRICE. THE DOCUMENTS SHOW THAT THE ADMINISTRATION ACCEPTED PHILIPS’ FIRST OFFER WITHOUT EVEN TRYING TO NEGOTIATE A LOWER PRICE.**

**A. A New Contract Was Negotiated by High-Level Administration Officials from President Trump’s Inner Circle**

After the Trump Administration relieved Philips of any obligation to provide ventilators under the Obama-era contract for two more years, top Administration officials negotiated a new contract. Persons involved in the negotiations included:

- Peter Navarro, Assistant to the President, Director of Trade and Manufacturing Policy, was chief negotiator;
- Jared Kushner, Senior Advisor to the President, participated in a telephone call with Philips’ CEO on March 18, and at least two other telephone calls with Philips on March 30 and April 1,<sup>34</sup>
- Adam Boehler, Jared Kushner’s former college roommate and current CEO of the U.S. International Development Finance Corporation, assigned an HHS contract officer to formalize the deal already negotiated by the White House,<sup>35</sup>

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<sup>33</sup> The White House, *Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing* (Apr. 4, 2020) ([www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-19/](http://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-19/)).

<sup>34</sup> Emails from Hailey Hart, Associate Director, Office of Public Liaison, The White House, to David Shultz, Head of Government Affairs (U.S.), Philips (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2056\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2056_Redacted.pdf)); Emails between Hailey Hart, Associate Director, Office of Public Liaison, The White House, and David Shultz, Head of Government Affairs (U.S.), Philips (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2063\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2063_Redacted.pdf)); Letter from Counsel to Philips North America Corporation to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 26, 2020).

<sup>35</sup> Emails from Nick Padula, Vice President, Health and Human Services, Philips, to Colonel James P. Work, and Adam Boehler, Chief Executive Officer, U.S. International Development Finance Corporation (Mar. 27, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1250\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1250_Redacted.pdf)); Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 26, 2020) (online at

- HHS Secretary Alex Azar participated in teleconferences with Philips on March 22 and March 28;<sup>36</sup>
- HHS Assistant Secretary for Preparedness and Response, Robert Kadlec participated in a teleconference with Philips on March 22,<sup>37</sup> and
- Members of the National Security Council and National Economic Council participated in a March 17 teleconference with Philips.<sup>38</sup>

Philips suggested talking points to be included in President Trump's announcement of the deal:<sup>39</sup>

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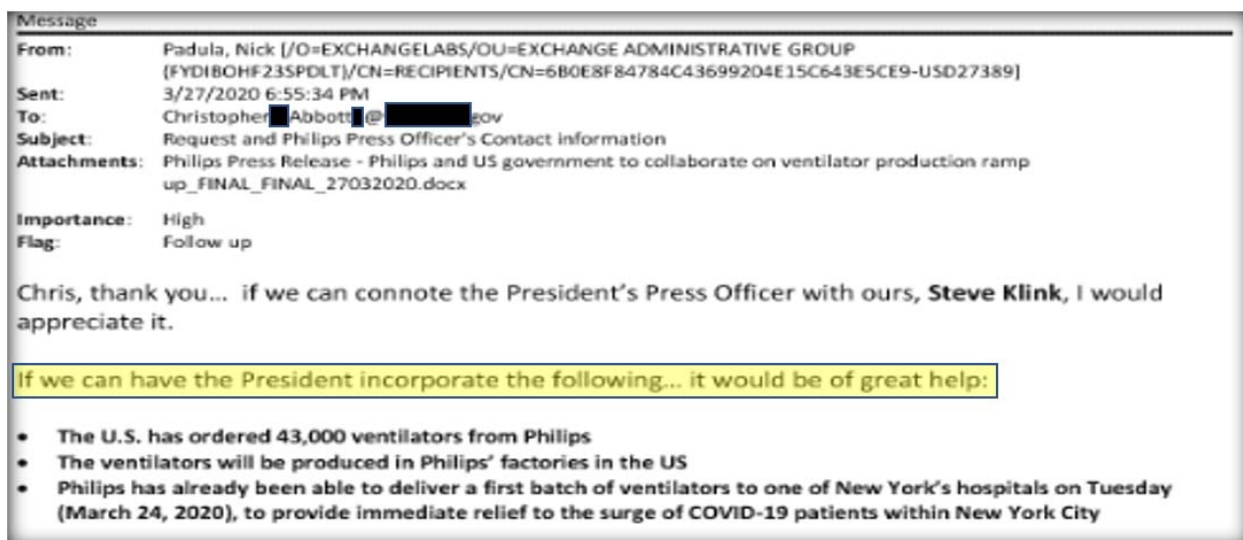
([https://oversight.house.gov/sites/democrats.oversight.house.gov/files/285-292\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/285-292_Redacted.pdf)); Email from Adam Boehler, Chief Executive Officer, U.S. International Development Finance Corporation, to Nick Padula, Vice President, Health and Human Services, Philips (Mar. 27, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1067-1068%20Redacted.pdf>); Email from Nick Padula, Vice President, Health and Human Services, Philips, to Adam Boehler, Chief Executive Officer, U.S. International Development Finance Corporation (Mar. 26, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1211\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1211_Redacted.pdf)).

<sup>36</sup> Email from David Shoultz, Head of Government Affairs (U.S.), Philips, to Alex M. Azar II, Secretary, Department of Health and Human Services (Mar. 23, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038_Redacted.pdf)); Email from John Groetelaars, President and Chief Executive Officer, Hillrom Holdings, Inc., to Arwenithia Ford-Barnes, Executive Assistant, Office of the Secretary, Department of Health and Human Services (Mar. 16, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/787\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/787_Redacted.pdf)); Email from David Shoultz, Head of Government Affairs (U.S.), Philips, to Alex M. Azar II, Secretary, Department of Health and Human Services (Mar. 23, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2028-2030%20Redacted.pdf>); Letter from Counsel to Philips North America Corporation to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 26, 2020).

<sup>37</sup> Emails between David Shoultz, Head of Government Affairs (U.S.), Philips, Alex M. Azar II, Secretary, Department of Health and Human Services, and Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services (Mar. 28, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2010-2022%20Redacted.pdf>); Email from David Shoultz, Head of Government Affairs (U.S.), Philips, to Alex M. Azar II, Secretary, Department of Health and Human Services (Mar. 23, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038_Redacted.pdf)); Email from David Shoultz, Head of Government Affairs (U.S.), Philips, to Alex M. Azar II, Secretary, Department of Health and Human Services (Mar. 23, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2028-2030%20Redacted.pdf>).

<sup>38</sup> Emails from Nick Padula, Vice President, Health and Human Services, Philips, to David Shoultz, Head of Government Affairs (U.S.), Philips, Hailey Hart, Associate Director, Office of Public Liaison, The White House, and Monica Volante, Director, Federal Government Affairs, Philips (Mar. 17-18, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/877-879Redacted.pdf>).

<sup>39</sup> Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 27, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/383\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/383_Redacted.pdf)).



The chief “negotiator” for the White House was Peter Navarro, Assistant to the President and Director of Trade and Manufacturing Policy. In a March 19, 2020, email to Navarro’s staff, Philips’ Vice President of Health and Human Services identified Peter Navarro as “on point, and we are in process now,” while discussing multiple negotiations meetings with Peter Navarro.<sup>40</sup> Philips confirmed in a letter to the Subcommittee that “From March 17 until the contract was signed on April 7, Philips participated in several teleconferences, chiefly with Dr. Navarro ... to discuss and finalize the terms of the April 2020 contract.”<sup>41</sup>

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<sup>40</sup> Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/857-862\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/857-862_Redacted.pdf))

<sup>41</sup> Letter from Counsel to Philips North America Corporation to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 26, 2020); Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 24, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/870\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/870_Redacted.pdf)); Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House, Mark Sebastiaan Anthony Stoffels, Senior Vice President, Business Leader Connected Care North America, Philips, Trina Eaddy, Senior Counsel and Compliance Officer, Philips, and John Frank, Business Group Leader, Sleep and Respiratory Care, Philips (Mar. 25, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/301\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/301_Redacted.pdf)).

Appointment

**From:** Padula, Nick [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B0E8F84784C43699204E15C643E5CE9-USD27389]  
**Sent:** 3/24/2020 1:57:26 PM  
**To:** Padula, Nick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b0e8f84784c43699204e15c643e5ce9-usd27389]; Christopher [REDACTED] [REDACTED]@ [REDACTED].gov  
**Subject:** Dr. Navarro - Philips Meeting  
**Location:** Skype Meeting  
**Start:** 3/24/2020 8:30:00 PM  
**End:** 3/24/2020 9:00:00 PM  
**Show Time As:** Busy

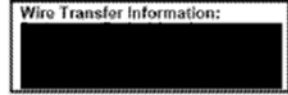
Appointment

**From:** Padula, Nick [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B0E8F84784C43699204E15C643E5CE9-USD27389]  
**Sent:** 3/24/2020 10:59:38 PM  
**To:** Abbott, Christopher J. EOP/WHO [REDACTED] [REDACTED]@ [REDACTED].gov; Stoffels, Mark Sebastiaan Anthony [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db506e23a9a140dab31c768db8318fe3-NLY07943]; Eddy, Trina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca75dd32b5d74d6fba38eee42c7a9040-310108355]; Frank, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90c3057023fb4b4fba6fb7d8867f8831-usd37915]  
**Subject:** Dr. Navarro and Philips Re-Group  
**Location:** Skype Meeting  
**Start:** 3/25/2020 3:00:00 PM  
**End:** 3/25/2020 4:00:00 PM  
**Show Time As:** Tentative  
**Importance:** High

Philips even addressed the invoice for 42,900 of the 43,000 units to Peter Navarro (reflecting the final cost per unit on March 25, 2020—13 days before a final contract was executed).<sup>42</sup>

<sup>42</sup> Invoice for Trilogy EV300 Bundle from Philips Respironics, to Peter Navarro, Assistant to the President and Director of the Office of Trade and Manufacturing Policy, The White House (Mar. 25, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/298-299\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/298-299_Redacted.pdf)).

# Invoice Trilogy EV300 Bundle



Toll Free: 1-800-345-6443  
 Fax: 1-888-558-6632  
 Email: [respironics.homecare.customerservice@philips.com](mailto:respironics.homecare.customerservice@philips.com) - [Nick.Padula@Philips.com](mailto:Nick.Padula@Philips.com)

Invoice Date: 03/25/2020

P.O:

**INVOICE DUE DATE:**

Fifty Percent (50%) advance of the total contract value upon receipt of Philips Invoice; thereafter, Philips will bill 30 Days in arrears for 50% of the previous month's billing cycle, delivery quantity.

**CURRENCY:** USD

**BILL TO:**

Dr Peter Navarro  
 White House, Eisenhower Bldg  
 1650 Pennsylvania Ave NW  
 Washington DC 20502

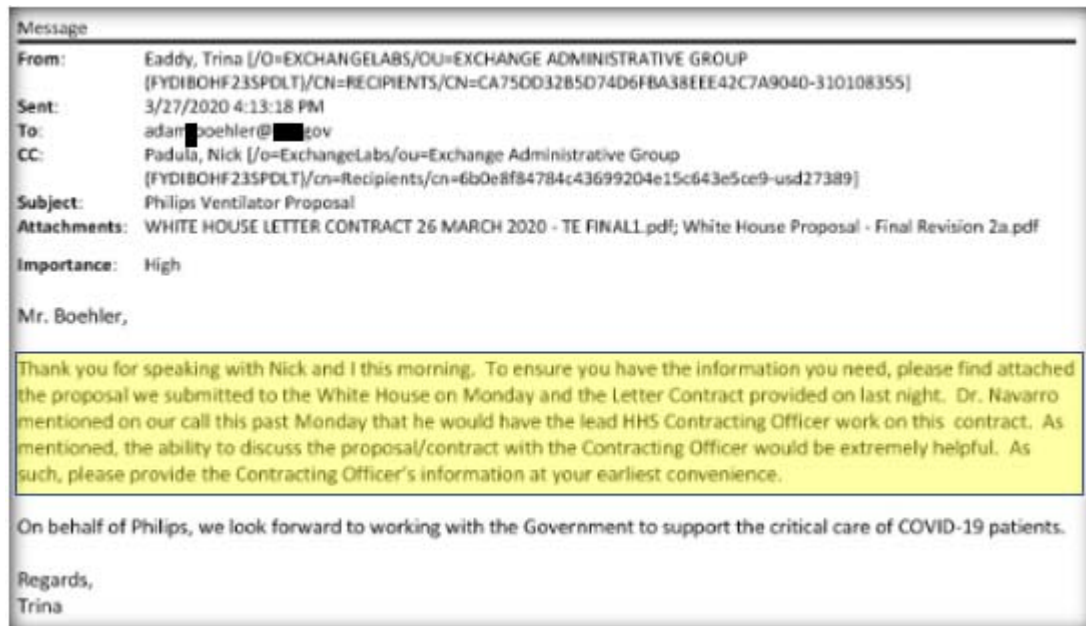
Item Number	Description	Item Total
DS2200X11Bundle	<b>Trilogy EV300 Bundle:</b> <b>Includes</b> <ul style="list-style-type: none"> <li>• DS2200X11B-Trilogy EV300, US</li> <li>• Includes Oxygen Blending Module</li> <li>• 1141765-SPRS-2 Roll Stand, H-111 cm, EV300 Mount</li> <li>• 1131463 Kit, Cyl mount, 108mm 4.25in (SPRS-2)</li> <li>• 1109602 Kit, O2 Transport Cart, MTG, DISS-M</li> <li>• 332497-Circuit Support Arm</li> <li>• 1132106- External Flow Sensor Cable w/1 Adult/Ped flow sensor</li> <li>• 1139436-Dual Limb AEV, 10pk</li> <li>• 1127306-Disp, Adult, Dual Limb Circuit, 10pk</li> <li>• 1132340- Disp, 22mm, Adult, Non-Htd Passive Circuit, 10pk</li> <li>• Circuit pack includes filter</li> </ul>	<b>\$15,000.00</b>
	<b>Quantity : 42,900</b> <ul style="list-style-type: none"> <li>• April 2020 : 1,100 units</li> <li>• May 2020 : 1,300 units</li> <li>• June 2020 : 1,500 units</li> <li>• July 2020 : 3,500 units</li> <li>• August 2020 : 4,800 units</li> <li>• September 2020 : 5,700 units</li> <li>• October 2020 : 8,000 units</li> <li>• November 2020 : 8,000 units</li> <li>• December 2020 : 9,000 units</li> </ul>	<b>Order Total</b> \$643,500,000.00  \$16,500,000.00 \$19,500,000.00 \$22,500,000.00 \$52,500,000.00 \$72,000,000.00 \$85,500,000.00 \$120,000,000.00 \$120,000,000.00 \$135,000,000.00

HHS professional contract officers were excluded until the last moment. By then, the generous terms of the contract had already been agreed to by the White House.

After Peter Navarro agreed to Philips' terms, Philips sent a "Letter Contract" reflecting those terms (cost, number of ventilators, delivery schedule, and contract clauses) to Jared



Kushner's former college roommate, Adam Boehler, asking at Peter Navarro's behest, to be assigned an HHS contract officer to "negotiate" the already-agreed-upon contract.<sup>43</sup>



Adam Boehler did what the Philips official asked. Philips' email introduction to the HHS contract officer reveals that any negotiation by professional staff would be a mere formality—attached to the introduction email was the Letter Contract reflecting the terms that were already agreed upon with Peter Navarro.<sup>44</sup>

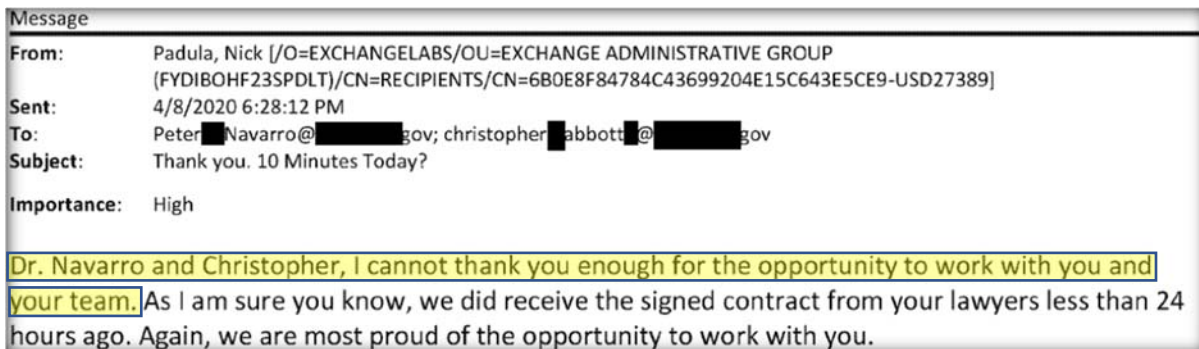
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<sup>43</sup> Email from Trina Eaddy, Senior Counsel and Compliance Officer, Philips, to Adam Boehler, Chief Executive Officer, U.S. International Development Finance Corporation (Mar. 27, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/960-989%20Redacted.pdf>).

<sup>44</sup> Email from Trina Eaddy, Senior Counsel and Compliance Officer, Philips Adam Boehler, Chief Executive Officer, U.S. International Development Finance Corporation (Mar. 27, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/992-1021\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/992-1021_Redacted.pdf)).



After the final contract was in hand, Philips thanked Mr. Navarro.<sup>45</sup>



**B. The Trump Administration Paid Nearly Five Times the Price Per Ventilator Than the Obama Administration Negotiated**

The ventilator purchased under the Obama-era contract is the Trilogy Evo Universal, at a cost of \$3,280 per unit.<sup>46</sup>

<sup>45</sup> Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House, and Peter Navarro, Assistant to the President and Director, Office of Trade and Manufacturing Policy, The White House (Apr. 8, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/393\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/393_Redacted.pdf)).

<sup>46</sup> Modification 008 of Contract between Philips Respironics and the Department of Health and Human Services (Apr. 26, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/228-230\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/228-230_Redacted.pdf)).

New Model Initial Production Fully Kitted FDA-Approved AAHSV Ventilator plus Rugged Basic Pulse Oximeter and Colorimetric Co2 Intubation Monitor Obligated Amount: \$32,800,000.00	10000	EA	3,280.00	32,800,000.00
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On April 7, 2020, Philips was awarded a second contract to deliver 43,000 Trilogy EV300 ventilators to HHS. Under that contract, HHS agreed to pay Philips \$15,000 per ventilator (\$645,000,000). The contract also included some component parts, bringing its total value to \$646,683,750.<sup>47</sup>

Item No.	Description	Quantity	Unit	Unit Price	Total Amount
1	Trilogy EV300	43,000	ea.	\$15,000.00	\$645,000,000.00
2	Circuits- Consumables Disp, 22mm. Adult, Non- Htd Passive Circuit, 10pk	11,550	ea.	\$125.00	\$ 1,443,750.00
3	Filters –Consumables Bacterial/Viral Filter, 10pk	3,000	ea.	\$80.00	\$240,000.00
	<b>Total</b>				<b>\$646,683,750.00</b>

Philips also sells an identical model to commercial customers, called the Trilogy Evo, at a market list price (not the government price) of \$11,167.<sup>48</sup>

**C. Had the White House Negotiators Asked Basic Questions of Philips, They Would Have Discovered that the Ventilators Purchased Under the New Contract Were Functionally Identical to the Ventilators Under the Prior Contract**

Aside from price, there is no discernable difference in either appearance or functionality between the Trilogy Evo Universal, the Trilogy Evo, and the Trilogy EV300. For a comparison showing that the features and specifications of the three models are the same, see **Appendix A**.

Philips seemed to concede the similarities between models in a March 18, 2020, email to the White House, in which it referred to the Trilogy Evo and the Trilogy EV300 as one ventilator:<sup>49</sup>

<sup>47</sup> Contract between Philips Respironics and the Department of Health and Human Services (Apr. 17, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/236-258\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/236-258_Redacted.pdf)).

<sup>48</sup> Commercial Market List Prices for Philips Ventilators (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1151.pdf>).

<sup>49</sup> Emails between Nick Padula, Vice President, Health and Human Services, Philips, and Hailey Hart, Office of Public Liaison, The White House (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125_Redacted.pdf)).

The EV300 (hospital) and EVO (Home-Care) were specifically designed in conjunction with the Bio-Medical Advanced Research and Development Authority (BARDA) for a new "stockpile" ventilation platform. Philips was awarded the contract in 2014 to design and manufacture a ventilator capable of Invasive and Non-Invasive ventilation, Infant-Adult and, Acute-Care through Home-Care. The result was the launch of the Trilogy EVO platform. The EVO was designed for Home-Care use and was released in Dec 2019 while the EV300 was designed for institutional use and was released on March 1, 2020.

The Trilogy Evo and EV300 ventilator delivers enhanced performance in noninvasive (NIV) and invasive (IV) ventilation, so patients can be treated with a single device throughout their hospital stay, regardless of changing conditions. Comprehensive, advanced NIV auto-titrating therapy modes include AVAPS-AE, and invasive ventilation is available with single- and dual-limb circuits and leak compensation. The Trilogy Evo and EV300 ventilators are designed to treat the varying needs of respiratory insufficiency throughout the patient's stay. The platform boasts an industry leading 15-hr battery and unprecedented 70,000 hr blower replacement making it the best in class for transport and cost-of-ownership.

The Trilogy Evo Universal is the name that Philips calls the ventilator it sold to HHS under the Obama-era contract. HHS was intimately familiar with the functionality and appearance of that model since it co-developed it with Philips and drafted the specifications. Further, the purchase option in the first contract was contingent on Philips receiving FDA 510(k) approval to market the ventilator. Philips submitted 510(k) applications for both the Trilogy Evo Universal and the Trilogy Evo at the same time. On the same day, FDA granted both applications and issued nearly identical authorizations, using the same words and specifications to describe both ventilators.<sup>50</sup> For a comparison of the Trilogy Evo Universal and Trilogy Evo 510(k) approvals, see **Appendix B**.

**D. The White House Negotiators Failed to Discern Differences Between Ventilator Models, and Missed Obvious Signals to Purchase Cheaper Option**

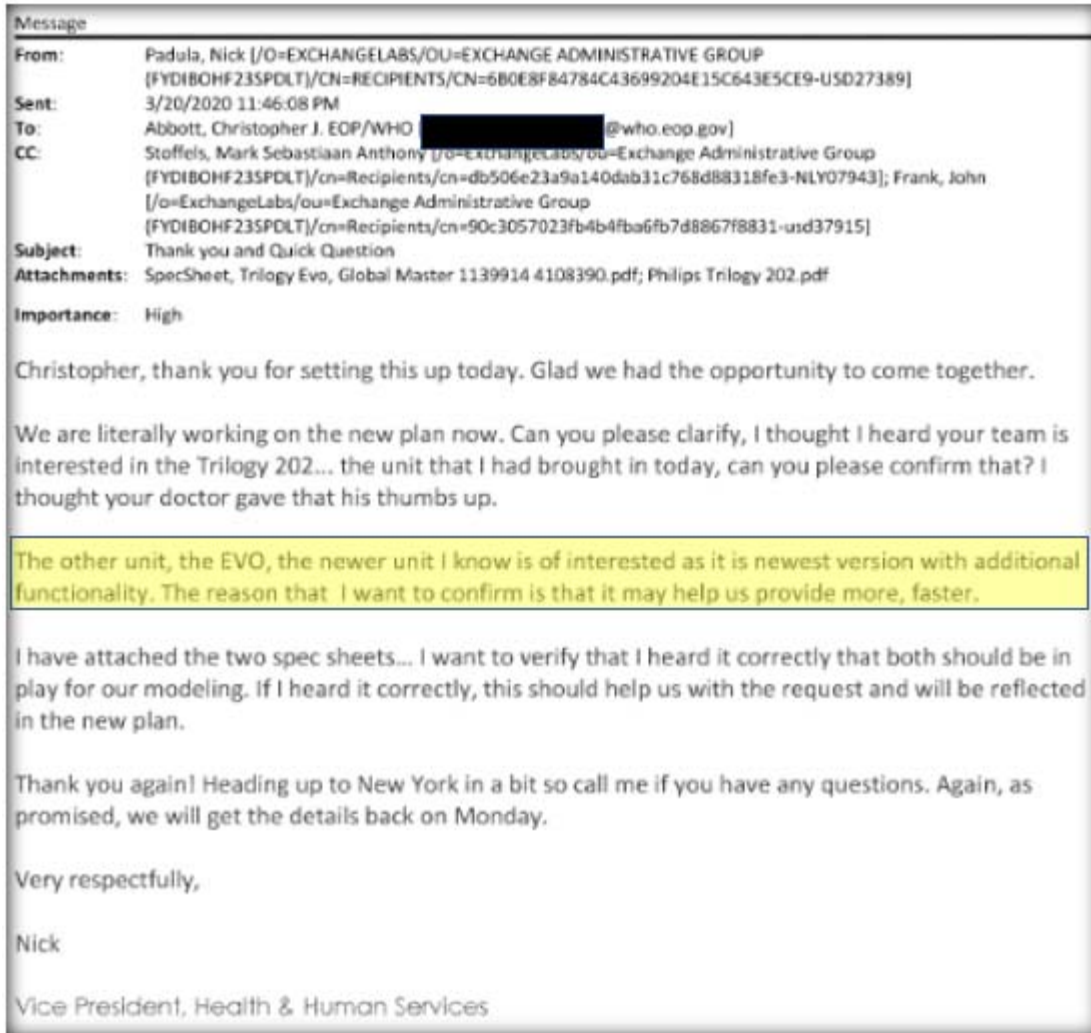
Philips initially suggested selling the same model to the Trump Administration that the Obama Administration had purchased for \$3,280 each: the Trilogy Evo Universal.<sup>51</sup> Then Philips suggested that the Administration buy the middle-priced Trilogy Evo.<sup>52</sup>

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<sup>50</sup> Food and Drug Administration, Center for Devices and Radiological Health, Trilogy Evo Ventilator (K181166) 510(k) approval letter (Jul. 18, 2019) (online at [www.accessdata.fda.gov/cdrh\\_docs/pdf18/K181166.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf18/K181166.pdf)); Food and Drug Administration, Center for Devices and Radiological Health, Trilogy Evo Universal Ventilator (K181170) 510(k) approval letter (Jul. 18, 2019) (online at [www.accessdata.fda.gov/cdrh\\_docs/pdf18/K181170.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf18/K181170.pdf)).

<sup>51</sup> Emails between Nick Padula, Vice President, Health and Human Services, Philips, and Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 18-19, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/857-862\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/857-862_Redacted.pdf)) (In a March 19, 2020, pitch to the White House, Philips presented the \$3,280 Trilogy Evo Universal ventilator as an option for the upcoming contract, attaching a Trilogy Evo Universal specification sheet to the email to White House negotiators about an upcoming sales meeting).

<sup>52</sup> Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 20, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/780-786\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/780-786_Redacted.pdf)).



Philips pitched the Trilogy Evo as the best option to Secretary Azar and Assistant Secretary Kadlec on March 23, 2020.<sup>53</sup>

<sup>53</sup> Email from David Shoultz, Head of Government Affairs (U.S.), Philips, to Alex M. Azar II, Secretary, Department of Health and Human Services (Mar. 23, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2031-2038_Redacted.pdf)).

Message

**From:** Shoultz, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E0CF5FDACFE43D29250F1COA7DDD376-USD24339]  
**Sent:** 3/23/2020 6:02:40 PM  
**To:** alex.azar@█.gov  
**CC:** robert.kadlec@█.gov; Houten, Frans van [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=011f6b4ad83940f4b1890c35c152a260-nly40790]; Beck, Gary (OS/IEA) (FYDIBOHF23SPDLT)/cn=Recipients/cn=011f6b4ad83940f4b1890c35c152a260-nly40790]; bryan.shuy@█.gov; jonathan.hayes@█.gov  
**Subject:** Philips COVID-19 Ventilator Response Deck  
**Attachments:** Philips Evo ramp up plan 23.03.20 V4 legal.pptx  
**Flag:** Follow up

Mr. Secretary –

At the request of Philips CEO, Frans van Houten, I am sending you the attached deck. This deck describes the Philips COVID-19 Response for ventilators. Per our conversation yesterday, this is the deck that my team will be sharing with Dr. Peter Navarro this afternoon. We believe this reflects Philips’ sincere interest in helping American patients and patients around the world at this time of crisis.

Summary 

- As a leading global ventilator provider, Philips is significantly scaling up our global manufacturing capacity (x2 in 8 weeks, x4 in Q3 2020 of global capacity, tens of millions USD invested), leveraging our global supply chain & partners (15% market share, 60% supply sourced globally)
- Through our co-development with BARDA, Philips has developed the best solution to confront exactly the pandemic that we are facing\* Our Trilogy Evo ventilator is made & approved for this. As requested by Dr. Navarro last week Friday, we have been working 24x7 to come up with what we believe is the best approach to confront the crisis: **Fastest possible ramp-up** looking at all scenarios available to get **maximum amount of right ventilators** to serve **maximum amount of US patients**.

\*FDA approved portable life support ventilator capable of delivering invasive therapy (with filtration, long battery use if required and integrated high concentrations of oxygen) when required for wide age range of patients experiencing respiratory compromise related to the virus

Yet, the Administration did not buy either of those less expensive models; it purchased the Trilogy EV300. In arriving at that selection, the Administration never requested, and never received, a side-by-side comparison of the three models of ventilators. But it did see a narrative comparison of the Trilogy Evo and the Trilogy EV300. In that comparison, the two ventilators are referred to as a single ventilator:<sup>54</sup>

<sup>54</sup> Emails between Nick Padula, Vice President, Health and Human Services, Philips, and Hailey Hart, Office of Public Liaison, The White House (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125_Redacted.pdf)).

The EV300 (hospital) and EVO (Home-Care) were specifically designed in conjunction with the Bio-Medical Advanced Research and Development Authority (BARDA) for a new “stockpile” ventilation platform. Philips was awarded the contract in 2014 to design and manufacture a ventilator capable of Invasive and Non-Invasive ventilation, Infant-Adult and, Acute-Care through Home-Care. The result was the launch of the Trilogy EVO platform. The EVO was designed for Home-Care use and was released in Dec 2019 while the EV300 was designed for institutional use and was released on March 1, 2020.

The Trilogy Evo and EV300 ventilator delivers enhanced performance in noninvasive (NIV) and invasive (IV) ventilation, so patients can be treated with a single device throughout their hospital stay, regardless of changing conditions. Comprehensive, advanced NIV auto-titrating therapy modes include AVAPS-AE, and invasive ventilation is available with single- and dual-limb circuits and leak compensation. The Trilogy Evo and EV300 ventilators are designed to treat the varying needs of respiratory insufficiency throughout the patient’s stay. The platform boasts an industry leading 15-hr battery and unprecedented 70,000 hr blower replacement making it the best in class for transport and cost-of-ownership.

There is no record that the Administration asked if there were differences between the models. The Administration did not request or receive any data on Philips’ cost of production.

Philips did provide the Administration with the list of commercial market prices for Philips’ ventilators. That document showed that Philips charged thousands more for a Trilogy EV300 than for a Trilogy Evo.<sup>55</sup>

Nevertheless, the contract HHS signed on April 7, 2020, committed to purchasing 43,000 ventilators from Philips: 100 Trilogy Evos followed by 42,900 Trilogy EV300s. The Administration agreed to pay as much for the Trilogy Evos as the Trilogy EV300s (\$15,000 each), even though the commercial market list price of the Trilogy Evo is only \$11,167.<sup>56</sup>

Philips appears to have duped the Administration, which failed to ask any relevant questions about the differences between ventilator models, into buying the priciest model, the \$15,000 Trilogy EV300, and in paying over list price for the middle-level model.

#### **E. The White House Negotiators Were Easily Steered into the Priciest Option and Failed to Question the False Reason Philips Gave for It to Be Selected**

A single email may explain how the Administration was steered into the most expensive option, the Trilogy EV300. On May 25, 2020, Philips sent an email to the White House negotiators, stating:<sup>57</sup>

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<sup>55</sup> Commercial Market List Prices for Philips Ventilators (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1151.pdf>).

<sup>56</sup> *Id.*

<sup>57</sup> Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 25, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/303\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/303_Redacted.pdf)).

As promised, we spoke with our product specialists and they recommended that you select the EV300 for the more clinician-friendly screens.

There is no evidence that the Administration ever questioned Philips’ assertion that the Trilogy EV300’s screen was “more clinician-friendly” or why that purported feature justified an extra \$11,720 per ventilator (the cost difference between the Trilogy Evo Universal and the Trilogy EV300)—over \$500 million extra cumulatively.

Had the Administration asked how the screen was different, it would have discovered that the screens on the Trilogy EV300 are identical to the screens on the less expensive Trilogy Evo and Trilogy Evo Universal Models:

Trilogy Evo Universal <sup>58</sup>	Screen dimensions	8", 20.32 cm
	Ingress protection	IP22: protection against finger-sized objects and protected against dripping water when tilted up to 15 degrees.
Trilogy Evo <sup>59</sup>	Screen dimensions	8", 20.32 cm
	Ingress protection	IP22: protection against finger-sized objects and protected against dripping water when tilted up to 15 degrees.
Trilogy EV300 <sup>60</sup>	Screen dimensions	8", 20.32 cm
	Ingress protection	IP22: protection against finger-sized objects and protected against dripping water when tilted up to 15 degrees.

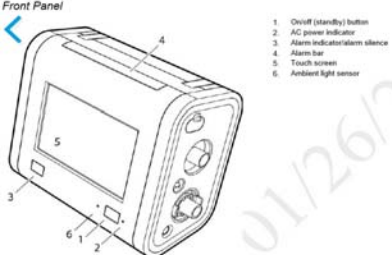


<sup>58</sup> Philips Trilogy Evo Universal Instructions for Use Manual--Page 89, ManualsLib (Jan. 26, 2018) (online at [www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=89#manual](http://www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=89#manual)).

<sup>59</sup> Specification sheets for Trilogy EV300 and Trilogy Evo Ventilators (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1134-1137.pdf>).

<sup>60</sup> *Id.*



## View of the Screens of the Three Ventilators

<p>Trilogy Evo Universal<sup>61</sup></p>	<p>Parts of Trilogy Evo Universal</p>  <p>1. On/off (standby) button          2. AC power indicator          3. Alarm indicator/alarm silence          4. Alarm bar          5. Touch screen          6. Ambient light sensor</p>				
<p>Trilogy Evo<sup>62</sup></p>	<p>The future of respiratory care is here</p> <p>Choose Trilogy Evo to help provide smooth transitions across your patients' changing environments and as their disease progresses</p> <ul style="list-style-type: none"> <li>✓ <b>Simple</b> Easy-to-use user interface, configurable to the care environment</li> <li>✓ <b>Connected</b> Providing timely care information to the bedside wherever it is</li> <li>✓ <b>Portable</b> The ease of setting the supply results in unobstructed, and free a convenient carrying bag that lets you see the screen and alarms</li> <li>✓ <b>Adaptable</b> Works with various air flow care settings and masks change</li> <li>✓ <b>Reliable</b> The most robust and durable device we've ever created</li> </ul> <p>Ordering information</p> <table border="0"> <tr> <td style="font-size: small;">Description</td> <td style="font-size: small;">Part number</td> </tr> <tr> <td>Trilogy Evo, USA</td> <td>0427100108</td> </tr> </table> 	Description	Part number	Trilogy Evo, USA	0427100108
Description	Part number				
Trilogy Evo, USA	0427100108				
<p>Trilogy EV300<sup>63</sup></p>	 <ul style="list-style-type: none"> <li>✓ <b>Simple</b> Easy-to-use user interface, configurable to the care environment</li> <li>✓ <b>Portable</b> The ease of setting the supply results in unobstructed, and free a convenient carrying bag that lets you see the screen and alarms</li> <li>✓ <b>Adaptable</b> Works with various air flow care settings and masks change</li> <li>✓ <b>Reliable</b> Durable rugged design to support use throughout the hospital</li> </ul>				

<sup>61</sup> Philips Trilogy Evo Universal Instructions for Use Manual—About Trilogy Evo Universal; Parts of Trilogy Evo Universal, ManualsLib (Jan. 26, 2018) (online at [www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=12#manual](http://www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=12#manual)).

<sup>62</sup> Trilogy Evo Quick Start Guide for Clinicians, Philips Respironics (Nov. 13, 2019) (online at [https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZWl1bnQiOiBbeyJSZXNvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWhlMDEuY2xvdWRmcm9udC5uZXQvcGhpbCUyRjElMkZmaWxlcUyRjEwMDA2JTJGMtk3NjclMkZmaWxllwiQ29uZG10aW9uIjp7IkRhdGVMZXRyZGVhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjp7IkFXUzpTb3VyY2VJcCI6IjAuMC4wLjAvMCMjOj9fX1dfQ\\_\\_&Signature=Wv3qc6arlyMKbOr4Nrk-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYZOR-fvsev1xmacLxyN6XNGEzIETmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKhlq7NRykBV5HskjyvRqPQoeya2TUKKLvPHM\\_&Key-Pair-Id=APKAJTOZQY4H2RTLVOYA](https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZWl1bnQiOiBbeyJSZXNvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWhlMDEuY2xvdWRmcm9udC5uZXQvcGhpbCUyRjElMkZmaWxlcUyRjEwMDA2JTJGMtk3NjclMkZmaWxllwiQ29uZG10aW9uIjp7IkRhdGVMZXRyZGVhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjp7IkFXUzpTb3VyY2VJcCI6IjAuMC4wLjAvMCMjOj9fX1dfQ__&Signature=Wv3qc6arlyMKbOr4Nrk-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYZOR-fvsev1xmacLxyN6XNGEzIETmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKhlq7NRykBV5HskjyvRqPQoeya2TUKKLvPHM_&Key-Pair-Id=APKAJTOZQY4H2RTLVOYA)).

<sup>63</sup> Continuum of Care. Simplified Workflow. Introducing Trilogy EV300, Philips Respironics (Jan. 2020) (online at <https://philipsproductcontent.blob.core.windows.net/assets/20200214/a05bc42d33834d0e89c9ab61013d781a.pdf>).

In fact, Philips explained to the White House in a March 18, 2020, email that the user interface was consistent across the platform.<sup>64</sup>

The user interface on the Evo and EV300 ventilators was designed to be consistent across the platform while customized to the specific care environment in which its being used. The Evo

The Administration’s willingness to spend hundreds of millions of extra dollars for non-existent “more clinician-friendly screens” constitutes waste.

**F. After the Sale Was Completed, Philips Misleadingly Claimed That the Trilogy EV300 Was Selected Because It Was Available, and Other Models Were Not. That Statement is Inaccurate, Yet the Administration Repeated It**

There is no evidentiary record that the Administration probed Philips’ production capability for the company’s various models or that it factored that into its selection of the EV300.

After the second contract became public, Philips issued a public statement that the \$15,000 ventilators were available, and the \$3,280 models were not. Philips claimed that it “had only made the stockpile version in small batches and didn’t want to ramp up production on a ventilator that it hadn’t mass produced, a slower process than increasing production of other models.” An HHS statement at the time was lent in support of that assertion: “the agency purchased ‘what was immediately available.’”<sup>65</sup>

The implication in Philips’ post-hoc justification—that Philips was already selling the Trilogy EV300—is inaccurate. The statement offered by the Trump Administration is also false.

The ventilator that the Trump Administration purchased was not on the market. The following chart shows that Philips did not begin rolling out the Trilogy EV300 until March 2020, when the Trump Administration agreed to buy them.<sup>66</sup>

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<sup>64</sup> Emails between Nick Padula, Vice President, Health and Human Services, Philips, and Hailey Hart, Office of Public Liaison, The White House (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125_Redacted.pdf)).

<sup>65</sup> *A Company Promised Cheap Ventilators to the Government, Never Delivered, and is Now Charging Quadruple the Price for New Ones*, ProPublica (Apr. 8, 2020) (online at [www.propublica.org/article/a-company-promised-cheap-ventilators-to-the-government-never-delivered-and-is-now-charging-quadruple-the-price-for-the-new-ones](http://www.propublica.org/article/a-company-promised-cheap-ventilators-to-the-government-never-delivered-and-is-now-charging-quadruple-the-price-for-the-new-ones)).

<sup>66</sup> Philips Ventilator Sale Chart (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2241.pdf>).

Philips' Hospital Ventilator Sales (September 2019-May 2020)												
Ventilator Models	Sep	Oct	Nov	Dec	2019 Total	Jan	Feb	Mar	Apr	May	2020 Total	Grand Total
BIPAP V30 AUTO, DOMESTIC	5	10	23	19	57	4	15	24	371	-136	278	335
TRILOGY 202 VENTILATOR U.S.A	33	37	39	35	144	11	18	234	-214	3	52	196
TRILOGY EV300, USA					0			5359	42926	983	49268	49268
V30 AUTO MOBILITY	200	241	118	370	929	147	142	364	-5	37	685	1614
V60 STD DOM, VENT, CART, ARM, NIC ASSM					0			1			1	1
V60 STD DOM, VENT, CART, ARM, NIC UNASSM	23	24		19	66	7			-5	2	4	70
V60 TRSPT DOM, CART, ARM, 02 MAN, NIC ASSM	87	96	54	275	512	29	55	1108	1141	-698	1635	2147
V60 TRSPT DOM, CART, ARM, 02 MAN, NIC UNAS	161	138	108	699	1106	136	132	976	1093	-140	2197	3303
V60 VENTILATOR, ENGL OPT: CFLEX, AVAPS	0	-1	0	2	1	11	0	-1	-1	10	19	20
E30	0	0	0	0	0	0	0	0	1547	3331	4878	4878
<b>Grand Total</b>	<b>509</b>	<b>545</b>	<b>342</b>	<b>1419</b>	<b>2815</b>	<b>345</b>	<b>362</b>	<b>8065</b>	<b>46853</b>	<b>3392</b>	<b>59017</b>	<b>61832</b>

Note: The order amounts shown herein are the net per month. There are negative order amounts due to cancelled orders or revised orders. If a customer decides to revise its order from one product to another, the initial order is still considered cancelled, resulting in a negative number.

The Administration knew this. In a March 18, 2020 email to the White House, Philips explained that the Trilogy EV300 was a new product being introduced and that it would take time to build up inventory.<sup>67</sup>

Since this is a new product introduction, we are currently building inventory for the product "release" for sale at the end of March/ beginning of April. This is an estimate but we believe the time from order to receipt of product will be 10 to 12 weeks for the EV300 platform from order to delivery. These will also be managed on a FIFO basis.

By selecting the \$15,000 model, the Administration demonstrated that it either failed the most basic duty of reading what Philips sent it or that it was not concerned about overpaying.

**G. The Administration Took Philips' First Offer—There is No Evidence It Even Tried to Negotiate a Lower Price for the Ventilators**

Contrary to President Trump's rhetoric, the Administration's conduct in negotiations with Philips reveals a complete failure to attempt to secure a better price.

On March 18, 2020, President Trump invoked the Defense Production Act (DPA) and issued an Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19.<sup>68</sup>

<sup>67</sup> Emails between Nick Padula, Vice President, Health and Human Services, Philips, and Hailey Hart, Office of Public Liaison, The White House (Mar. 18, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1122-1125_Redacted.pdf)).

<sup>68</sup> Executive Order 13909, *Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19* (Mar. 18, 2020) (online at [www.federalregister.gov/documents/2020/03/23/2020-06161/prioritizing-and-allocating-health-and-medical-resources-to-respond-to-the-spread-of-covid-19](http://www.federalregister.gov/documents/2020/03/23/2020-06161/prioritizing-and-allocating-health-and-medical-resources-to-respond-to-the-spread-of-covid-19)).

In the negotiations for ventilators, the Administration did not use that leverage to negotiate a better price.

Philips' first proposal to the Administration, dated March 24, 2020, offered to provide 43,000 ventilators for \$15,000 per ventilator, and \$1,683,750 worth of circuits and filters, for a total contract price of \$646,683,750.<sup>69</sup>

## Ventilator Proposal

### United States Government

March 24, 2020

**SECTION C. DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

**PERIOD OF PERFORMANCE:** March 22, 2020 – March 21, 2021

**CONTRACT TYPE:** Firm Fixed-Price Contract

**DELIVERABLES:** 4 CLINs (see below)

**CLIN 1: Trilogy EVO**

Description	Item Total
Trilogy Evo, OBM Bundle: Includes	\$15,000 x 100 units
Trilogy Evo Roll Stand	
Disp, Adult, Dual Limb Circuit, 10pk	
Disp, 22mm, Adult, Non-Htd Passive Circuit, 10pk	
External Flow Sensor Cable w/1 Adult/Ped flow sensor	
Dual Limb AEV, 10pk	
FIO2 Sensor Assembly	
Oxygen Blending Module	
Delivery	Quantity
March 2020	100 Units
CLIN 1 Price	Price
	\$1,500,000.00
	\$1,500,000.00

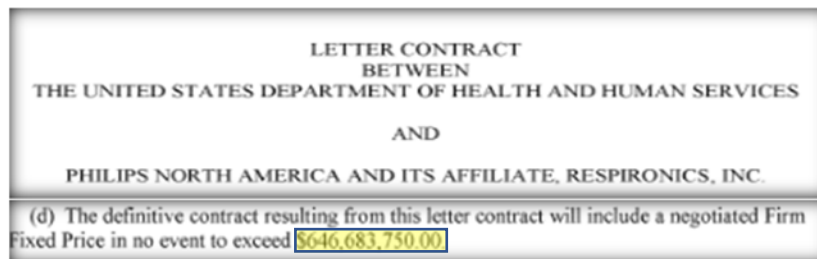
**CLIN 2: Trilogy EV300**

Description	Item Total
Trilogy EV300 OBM Bundle: Includes	\$15,000 x 42,900 total units
Trilogy EV300, US	
Oxygen Blending Module (OBM)	
SPRS-2 Roll Stand, H-111 cm, EV300 -Mount Kit, Cyl mount, 108mm 4.25in(SPRS2)	
Kit, O2 Transport Cart, MTG, DISS-M Circuit Support Arm	
External Flow Sensor Cable w/1 Adult/Ped flow sensor Dual Limb AEV, 10pk	
Disp, Adult, Dual Limb Circuit, 10pk	

<sup>69</sup> Email from Trina Eaddy, Senior Counsel and Compliance Officer, Philips, to Adam Boehler, Chief Executive Officer, U.S. International Development Finance Corporation (Mar. 27, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1251-1280\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1251-1280_Redacted.pdf)).

Disp, 22mm, Adult, Non-Htd Passive Circuit, 10pk Circuit pack includes filter		
Month of Delivery	Quantity	Price
April 2020	1,100 units	\$16,500,000.
May 2020	1,300 units	\$19,500,000.
June 2020	1,500 units	\$22,500,000.
July 2020	3,500 units	\$52,500,000
August 2020	4,800 units	\$72,000,000.
September 2020	5,700 units	\$85,500,000.
October 2020	8,000 units	\$120,000,000.
November 2020	8,000 units	\$120,000,000.
December 2020	9,000 units	\$135,000,000.
CLIN 2 Price		\$643,500,000.00
<b>CLIN 3 – Circuits (Consumables)</b>		
<b>Description</b>		<b>Item Total</b>
Disp, 22mm, Adult, Non-Htd Passive Circuit, 10pk		\$125.00 x 11,550 units
Month of Delivery	Quantity	Price
May	1,800	\$225,000
June	3,750	\$468,750
July	6,000	\$750,000
CLIN 3 Price		\$1,443,750.00
<b>CLIN 4 – Filters (Consumables)</b>		
<b>Description</b>		<b>Item Total</b>
Bacterial/Viral Filter, 10pk		\$80.00 x \$240,0000 units
Month of Delivery	Quantity	Price
May	1000	\$80,000
June	1000	\$80,000
July	1000	\$80,000
CLIN 4 Price		\$240,000.00
<b>TOTAL CONTRACT PRICE (CLINS 1-4)</b>		<b>\$646,683,750.00</b>

Two days later, on March 26, 2020, Philips had a letter contract in hand for its requested amount: \$646,683,750:<sup>70</sup>



On March 30, HHS gave Philips a formal authorization to proceed on those terms.<sup>71</sup>

<sup>70</sup> Email from Nick Padula, Vice President, Health and Human Services, Philips, to Christopher Abbott, Associate Director, Office of Trade and Manufacturing Policy, The White House (Mar. 26, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/285-292\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/285-292_Redacted.pdf)).

<sup>71</sup> Email from Annette Wright, Contracting Officer, Centers for Disease Control and Prevention, to Trina Eaddy, Senior Counsel and Compliance Officer, Philips (Mar. 30, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2163-2166\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2163-2166_Redacted.pdf)).

On April 7, 2020, the final contract was awarded for the purchase of 43,000 ventilators for \$15,000 per ventilator and \$1,683,750 worth of circuits and filters, for a total contract price of \$646,683,750.<sup>72</sup>

Item No.	Description	Quantity	Unit	Unit Price	Total Amount
1	Trilogy EV300	43,000	ea.	\$15,000.00	\$645,000,000.00
2	Circuits- Consumables Disp. 22mm, Adult, Non- Htd Passive Circuit, 10pk	11,550	ea.	\$125.00	\$ 1,443,750.00
3	Filters -Consumables Bacterial/Viral Filter, 10pk	3,000	ea.	\$80.00	\$240,000.00
	<b>Total</b>				<b>\$646,683,750.00</b>

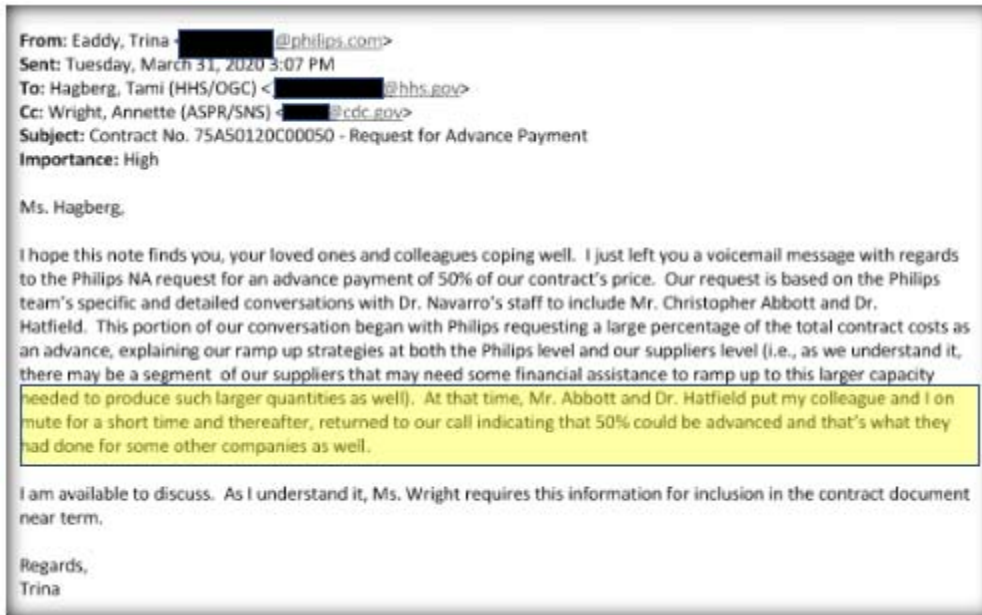
The documents show no attempt by Administration to negotiate a lower price.

**H. Peter Navarro Promised 50% Prepayment (\$323,341,875) Before the Delivery of a Single Ventilator, Which Was Later Reduced to 10% By HHS Professional Staff**

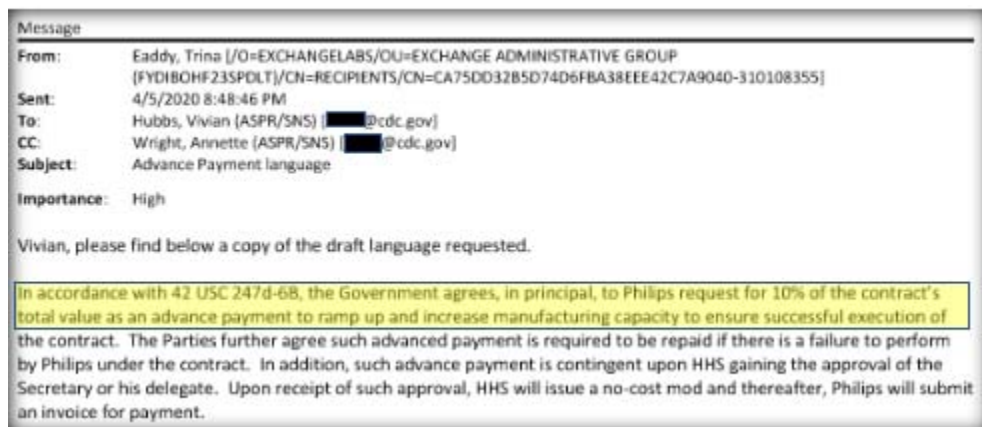
Peter Navarro failed to discover that he was buying ventilators identical to the Trilogy Evo Universals at almost five times the price, and he accepted without negotiation Philips’ opening offer on cost. Beyond that, he promised Philips a 50% prepayment, which would have amounted to a \$323,341,875 prepayment to a company that had not yet delivered a single ventilator on a contract from 2014. His staff told Philips he had done this for other companies as well.<sup>73</sup>

<sup>72</sup> Contract between Philips Respironics and the Department of Health and Human Services (Apr. 17, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/236-258\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/236-258_Redacted.pdf)).

<sup>73</sup> Emails between Trina Eaddy, Senior Counsel and Compliance Officer, Philips, and Tami Hagberg, Acting Assistant Deputy Associate General Counsel, Department of Health and Human Services (Mar. 31-Apr. 1, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1414-1417\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1414-1417_Redacted.pdf)).



Fortunately, in this instance, Mr. Navarro's promise was later reduced by HHS professional staff to 10%, which still amounts to \$64,668,375:<sup>74</sup>



**VI. THE ADMINISTRATION DRASTICALLY OVERPAID FOR VENTILATORS—NO AMERICAN PURCHASER PAID MORE THAN THE ADMINISTRATION. BETWEEN DECEMBER 2019 AND MAY 2020, PHILIPS TOOK ORDERS FOR 5,339 OTHER TRILOGY EV300 VENTILATORS FROM 92 DIFFERENT PURCHASERS IN THE UNITED STATES. SOME SMALL PURCHASERS, BUYING AS FEW AS ONE UNIT, WERE ABLE TO NEGOTIATE PRICES AS LOW AS \$9,327, COMPARED TO \$15,000 PAID BY THE TRUMP ADMINISTRATION.**

<sup>74</sup> Email from Trina Eddy, Senior Counsel and Compliance Officer, Philips, to Vivian Hubbs, Chief Contracting Officer, Centers for Disease Control and Prevention (Apr. 5, 2020) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1847\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1847_Redacted.pdf)).

While the Administration failed to attempt to negotiate price, other U.S. purchasers successfully did. Between December 18, 2019, and May 27, 2020, Philips sold 5,339 other Trilogy EV300 ventilators to 92 different purchasers in the United States. None of them paid more per ventilator than HHS. The prices were subject to negotiation. For example, one Missouri purchaser, acquiring just a single Trilogy EV300, secured it for just \$9,327. A New Jersey purchaser acquiring only two ventilators was able to purchase them for \$10,573 each. A buyer in Florida making a larger purchase of 155, got them for \$10,400 each.<sup>75</sup>

Model	Ship to State	Customer Identifier	Sales Doc Number	Sales Order Date	March-20	April-20	May-20	June-20	Grand Total	Price Per Unit
TRILOGY EV300, USA	North Carolina	94015857	6305610344	3/26/2020	50		-15	-12	23	\$12,133
TRILOGY EV300, USA	North Carolina	94015857	6305670065	5/4/2020			5		5	\$12,133
TRILOGY EV300, USA	North Carolina	94015857	6305689688	5/18/2020			10		10	\$12,133
TRILOGY EV300, USA	North Carolina	94015857	6305696846	5/21/2020			2		2	\$12,133
TRILOGY EV300, USA	California	94017630	6305605469	3/24/2020	40		-40		0	\$12,133
TRILOGY EV300, USA	California	94017630	6305682360	5/12/2020			6		6	\$12,133
TRILOGY EV300, USA	California	94017630	6305688137	5/15/2020			34		34	\$12,133
TRILOGY EV300, USA	Vermont	94020717	6305616856	3/30/2020	200	-200			0	\$12,059
TRILOGY EV300, USA	Pennsylvania	94020721	6600463904	2/7/2020	2				2	\$10,746
TRILOGY EV300, USA	Pennsylvania	94020721	6600471858	4/17/2020			19		19	\$12,133
TRILOGY EV300, USA	Missouri	94021056	6305610827	3/26/2020	3				3	\$12,133
TRILOGY EV300, USA	Washington	94026264	6305662070	4/29/2020		2			2	\$12,133
TRILOGY EV300, USA	Wyoming	94027652	6600474233	5/1/2020			2		2	\$11,786
TRILOGY EV300, USA	Wyoming	94027668	6305606141	3/24/2020	3				3	\$12,133
TRILOGY EV300, USA	Wyoming	94027668	6305609910	3/25/2020	1				1	\$12,133
TRILOGY EV300, USA	Wyoming	94027668	6305614045	3/27/2020	2				2	\$12,133
TRILOGY EV300, USA	Colorado	94027992	6305615113	3/28/2020	3				3	\$12,133
TRILOGY EV300, USA	Louisiana	94028043	6305615114	3/28/2020	2				2	\$17,333
TRILOGY EV300, USA	Nebraska	94030131	6305616842	3/30/2020	1				1	\$12,133
TRILOGY EV300, USA	Florida	94030685	6305597128	3/19/2020	10		-5		5	\$12,133
TRILOGY EV300, USA	Florida	94030685	6305670050	5/4/2020			5		5	\$12,133
TRILOGY EV300, USA	Arkansas	94030749	6305611726	3/26/2020	2				2	\$12,133
TRILOGY EV300, USA	Massachusetts	94030871	6305584831	3/13/2020	0				0	\$17,333
TRILOGY EV300, USA	Florida	94031186	6600469055	3/27/2020	5				5	\$12,133
TRILOGY EV300, USA	Missouri	94032947	6305665476	4/30/2020		1			1	\$9,327
TRILOGY EV300, USA	Oregon	94034015	6305642190	4/14/2020	1				1	\$12,133
TRILOGY EV300, USA	Massachusetts	94034035	6305636312	4/9/2020		3			3	\$11,440
TRILOGY EV300, USA	Illinois	94034370	6305635024	4/8/2020		2			2	\$12,133
TRILOGY EV300, USA	Ohio	94034523	6305632772	4/7/2020		1			1	\$12,133
TRILOGY EV300, USA	New York	94034813	6600475540	5/13/2020			2		2	\$11,786
TRILOGY EV300, USA	Colorado	94036513	6600474324	5/5/2020			1		1	\$12,133
TRILOGY EV300, USA	Massachusetts	94036833	6305616812	3/30/2020	100	-100			0	\$12,133
TRILOGY EV300, USA	Kansas	94037809	6305652753	4/21/2020		1			1	\$10,818
TRILOGY EV300, USA	Massachusetts	94038626	6305634433	4/8/2020		10	-10		0	\$12,133
TRILOGY EV300, USA	Massachusetts	94038626	6305672050	5/5/2020		2			2	\$12,133
TRILOGY EV300, USA	Massachusetts	94038678	6305652724	4/21/2020		10	-5		5	\$11,180
TRILOGY EV300, USA	Massachusetts	94038678	6305672770	5/6/2020			5		5	\$11,180
TRILOGY EV300, USA	Massachusetts	94038689	6305619786	3/31/2020	40	-40			0	\$12,133
TRILOGY EV300, USA	Massachusetts	94038689	6305640204	4/13/2020		5			5	\$12,133
TRILOGY EV300, USA	Pennsylvania	94039367	6305674420	5/6/2020			2		2	\$12,133
TRILOGY EV300, USA	Pennsylvania	94039600	6305632727	4/7/2020		0			0	\$12,133
TRILOGY EV300, USA	Maryland	94039835	6600475543	5/13/2020			30	0	30	\$11,786
TRILOGY EV300, USA	Illinois	94040761	6305683007	5/12/2020			4		4	\$12,133
TRILOGY EV300, USA	Ohio	94041395	6305617694	3/30/2020	2				2	\$12,133
TRILOGY EV300, USA	Minnesota	94041862	6305626727	4/3/2020		1			1	\$12,133
TRILOGY EV300, USA	New Jersey	94045023	6305599515	3/20/2020	14				14	\$11,960

<sup>75</sup> Table Listing Sales of All EV300 Ventilators to Purchasers in the United States Between December 19, 2019 and May 27, 2020 (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2242-2248.pdf>).



Model	Ship to State	Customer Identifier	Sales Doc Number	Sales Order Date	March-20	April-20	May-20	June-20	Grand Total	Price Per Unit
TRILOGY EV300, USA	Kentucky	94045269	6305650581	4/20/2020		5	-3		2	\$12,133
TRILOGY EV300, USA	Kentucky	94045269	6305683399	5/13/2020			3		3	\$12,133
TRILOGY EV300, USA	Iowa	94045375	6305704899	5/27/2020			1		1	\$12,133
TRILOGY EV300, USA	Missouri	94045657	6305613378	3/27/2020	4				4	\$11,383
TRILOGY EV300, USA	Colorado	94047008	6600473417	4/28/2020		2			2	\$12,133
TRILOGY EV300, USA	New Jersey	94047018	6305647311	4/16/2020		2			2	\$10,573
TRILOGY EV300, USA	Michigan	94047060	6305592038	3/17/2020	12	-3			9	\$11,266
TRILOGY EV300, USA	Michigan	94047060	6305642354	4/14/2020		3			3	\$11,266
TRILOGY EV300, USA	Florida	94048249	6305685755	5/14/2020			1		1	\$10,671
TRILOGY EV300, USA	Wisconsin	94048975	6305629285	4/6/2020		20	-15		5	\$12,133
TRILOGY EV300, USA	Wisconsin	94048975	6305671590	5/5/2020			5		5	\$12,133
TRILOGY EV300, USA	Wisconsin	94048975	6305682610	5/12/2020			5		5	\$12,133
TRILOGY EV300, USA	Wisconsin	94048975	6305688171	5/15/2020			5		5	\$12,133
TRILOGY EV300, USA	North Carolina	94049607	6305616871	3/30/2020	50		-25		25	\$12,133
TRILOGY EV300, USA	North Carolina	94049607	6305682387	5/12/2020			10		10	\$12,133
TRILOGY EV300, USA	North Carolina	94049607	6305701632	5/26/2020			15		15	\$12,133
TRILOGY EV300, USA	Florida	94051908	6305605279	3/24/2020	5				5	\$12,133
TRILOGY EV300, USA	Michigan	94052520	6305609926	3/25/2020	3				3	\$12,133
TRILOGY EV300, USA	Pennsylvania	94055878	6600471858	4/17/2020		24	-24		0	\$12,133
TRILOGY EV300, USA	Louisiana	94068434	6600470682	4/7/2020		4			4	\$12,133
TRILOGY EV300, USA	California	94078522	6305603563	3/23/2020	250			-250	0	\$11,093
TRILOGY EV300, USA	California	94094926	6305647760	4/17/2020		2			2	\$12,133
TRILOGY EV300, USA	Minnesota	94119484	6305648749	4/17/2020		1			1	\$12,133
TRILOGY EV300, USA	Maryland	94119713	6305603193	3/23/2020	25				25	\$11,093
TRILOGY EV300, USA	Georgia	94126087	6305677964	5/8/2020			40		40	\$12,133
TRILOGY EV300, USA	Georgia	94126087	6305691004	5/18/2020			10		10	\$12,133
TRILOGY EV300, USA	Kansas	94126442	6305681953	5/12/2020			81	-50	31	\$12,133
TRILOGY EV300, USA	Kansas	94126442	6305690789	5/18/2020			40		40	\$12,133
TRILOGY EV300, USA	Kansas	94126442	6305703679	5/27/2020			29		29	\$12,133
TRILOGY EV300, USA	Colorado	94147526	6600471638	4/14/2020		17	-17		0	\$12,133
TRILOGY EV300, USA	Missouri	94155123	6305646261	4/16/2020		1			1	\$12,133
TRILOGY EV300, USA	Arizona	94187393	6305671530	5/5/2020			4		4	\$12,133
TRILOGY EV300, USA	New Mexico	94201897	6305697564	5/21/2020			4		4	\$12,133
TRILOGY EV300, USA	Virginia	94220318	6305606292	3/24/2020	8		-4		4	\$10,998
TRILOGY EV300, USA	Virginia	94220318	6305670053	5/4/2020			4		4	\$10,998
TRILOGY EV300, USA	West Virginia	94227329	6305685100	5/14/2020			3		3	\$12,133
TRILOGY EV300, USA	Illinois	94227979	6305614075	3/27/2020	4		-3	-1	0	\$12,133
TRILOGY EV300, USA	Illinois	94227979	6305671199	5/5/2020			2		2	\$12,133
TRILOGY EV300, USA	Illinois	94227979	6305688180	5/15/2020			1	-1	0	\$12,133
TRILOGY EV300, USA	West Virginia	94231670	6305625119	4/2/2020		7	-3		4	\$12,133
TRILOGY EV300, USA	West Virginia	94231670	6305671540	5/5/2020			3		3	\$12,133
TRILOGY EV300, USA	North Carolina	94273957	6600458651	12/18/2019		3			3	\$11,769
TRILOGY EV300, USA	Pennsylvania	94313256	6600471858	4/17/2020			5		5	\$12,133
TRILOGY EV300, USA	Massachusetts	94346289	6305619790	3/31/2020	50		-9	-41	0	\$12,133
TRILOGY EV300, USA	Massachusetts	94346289	6305684121	5/13/2020			5		5	\$12,133
TRILOGY EV300, USA	Indiana	94357693	6305618096	3/30/2020	1,200				1,200	\$12,133

Model	Ship to State	Customer Identifier	Sales Doc Number	Sales Order Date	March-20	April-20	May-20	June-20	Grand Total	Price Per Unit
TRILOGY EV300, USA	Georgia	94384638	6305627444	4/3/2020		2			2	\$12,133
TRILOGY EV300, USA	New Jersey	94388654	6600469020	3/26/2020	60	0	0		60	\$12,133
TRILOGY EV300, USA	Georgia	94472710	6305626682	4/3/2020		10			10	\$12,133
TRILOGY EV300, USA	Georgia	94472710	6305638744	4/10/2020		10			10	\$12,133
TRILOGY EV300, USA	Texas	94483379	6305600637	3/20/2020	100	-100			0	\$11,613
TRILOGY EV300, USA	Texas	94483379	6305642381	4/14/2020		0			0	\$11,613
TRILOGY EV300, USA	Texas	94483379	6305707251	5/28/2020			15		15	\$12,133
TRILOGY EV300, USA	Alaska	94488922	6305617698	3/30/2020	4				4	\$12,133
TRILOGY EV300, USA	New Jersey	94497556	6600467564	3/19/2020	1				1	\$10,746
TRILOGY EV300, USA	Michigan	94505997	6305632263	4/7/2020		10	-4		6	\$12,133
TRILOGY EV300, USA	Michigan	94505997	6305672038	5/5/2020			2		2	\$12,133
TRILOGY EV300, USA	Michigan	94505997	6305693064	5/19/2020			2		2	\$12,133
TRILOGY EV300, USA	New Jersey	94538936	6600470865	4/6/2020		3			3	\$12,133
TRILOGY EV300, USA	Michigan	94558278	6305611627	3/26/2020	30				30	\$10,400
TRILOGY EV300, USA	Michigan	94558278	6305611964	3/26/2020	30				30	\$10,400
TRILOGY EV300, USA	Michigan	94558278	6305703683	5/27/2020			100	-100	0	\$10,400
TRILOGY EV300, USA	New York	94559652	6305603165	3/23/2020	16	-8			8	\$12,133
TRILOGY EV300, USA	New York	94559652	6305642377	4/14/2020		8			8	\$12,133
TRILOGY EV300, USA	Texas	94560956	6305608392	3/25/2020	72	-12	-60		0	\$12,133
TRILOGY EV300, USA	Texas	94560956	6305642380	4/14/2020		7			7	\$12,133
TRILOGY EV300, USA	Pennsylvania	94563924	6305638058	4/10/2020		35	-25		10	\$12,133
TRILOGY EV300, USA	Pennsylvania	94563924	6305672091	5/5/2020		0			0	\$12,133
TRILOGY EV300, USA	Pennsylvania	94563924	6305684141	5/13/2020		5			5	\$12,133
TRILOGY EV300, USA	Pennsylvania	94563924	6305687299	5/15/2020			10		10	\$12,133
TRILOGY EV300, USA	Pennsylvania	94563924	6305688173	5/15/2020			10		10	\$12,133
TRILOGY EV300, USA	Texas	94582197	6305645548	4/16/2020		10			10	\$10,671
TRILOGY EV300, USA	New Jersey	94640045	6600477539	5/29/2020			1		1	\$11,613
TRILOGY EV300, USA	Nebraska	94650159	6305604428	3/23/2020	5				5	\$12,133
TRILOGY EV300, USA	New York	94651312	6305599635	3/20/2020	500		-50		450	\$11,613
TRILOGY EV300, USA	New York	94651312	6305703666	5/27/2020			50		50	\$11,613
TRILOGY EV300, USA	New Jersey	94651380	6305629399	4/6/2020		200	-200		0	\$17,333
TRILOGY EV300, USA	Illinois	94651415	6305632280	4/7/2020		1			1	\$12,133
TRILOGY EV300, USA	Washington	94651485	6305607120	3/24/2020	300		-111	-15	174	\$12,192
TRILOGY EV300, USA	Washington	94651485	6305670061	5/4/2020			20		20	\$12,192
TRILOGY EV300, USA	Washington	94651485	6305684625	5/13/2020			15		15	\$12,192
TRILOGY EV300, USA	Washington	94651485	6305689684	5/18/2020			46		46	\$12,192
TRILOGY EV300, USA	Washington	94651485	6305701645	5/26/2020			30		30	\$12,192
TRILOGY EV300, USA	Florida	94651528	6305611616	3/26/2020	1,000	-1,000			0	\$12,133
TRILOGY EV300, USA	Oregon	94651549	6305606560	3/24/2020	150			-150	0	\$11,093
TRILOGY EV300, USA	New York	94651937	6305616834	3/30/2020	850		-20		830	\$12,133
TRILOGY EV300, USA	New York	94651937	6305616835	3/30/2020	150				150	\$12,133
TRILOGY EV300, USA	New York	94651937	6305684610	5/13/2020			10		10	\$12,133
TRILOGY EV300, USA	New York	94651937	6305689693	5/18/2020			10		10	\$12,133
TRILOGY EV300, USA	Florida	94652239	6305616861	3/30/2020		290	-110	-135	45	\$10,400
TRILOGY EV300, USA	Florida	94652239	6305691024	5/18/2020			10		10	\$10,400
TRILOGY EV300, USA	Florida	94652239	6305703683	5/27/2020				100	100	\$10,400

Model	Ship to State	Customer Identifier	Sales Doc Number	Sales Order Date	March-20	April-20	May-20	June-20	Grand Total	Price Per Unit
TRILOGY EV300, USA	Massachusetts	94652311	6305619797	3/31/2020		95	-30		65	\$11,631
TRILOGY EV300, USA	Massachusetts	94652311	6305642339	4/14/2020		5			5	\$11,631
TRILOGY EV300, USA	Massachusetts	94652311	6305684616	5/13/2020			7		7	\$11,631
TRILOGY EV300, USA	Massachusetts	94652311	6305690714	5/18/2020			23		23	\$11,631
TRILOGY EV300, USA	Louisiana	94652590	6600470141	4/1/2020		75	-64	0	11	\$12,680
TRILOGY EV300, USA	Louisiana	94652590	6600474085	5/6/2020			15		15	\$12,038
TRILOGY EV300, USA	Louisiana	94652590	6600475026	5/13/2020			4		4	\$12,038
TRILOGY EV300, USA	Louisiana	94652590	6600476520	5/20/2020			45		45	\$12,038
TRILOGY EV300, USA	New York	94652866	6305635019	4/8/2020		500	-104	-50	346	\$12,133
TRILOGY EV300, USA	New York	94652866	6305675571	5/7/2020			4		4	\$12,133
TRILOGY EV300, USA	New York	94652866	6305682624	5/12/2020			54		54	\$12,133
TRILOGY EV300, USA	New York	94652866	6305689690	5/18/2020			46		46	\$12,133
TRILOGY EV300, USA	Ohio	94655129	6305708650	5/29/2020			1,000	-224	776	\$12,133

The prices of Trilogy EV300 ventilators were subject to negotiation. It would stand to reason that a purchaser of 43,000 units would be able to negotiate a better deal than a purchaser of a single unit. However, that did not happen—the Trump Administration, with all its purchasing power, paid the highest price among American purchasers.

The Subcommittee requested the same information on Philips’ foreign ventilator sales during this time period, but Philips has refused to produce it.

**VII. THE TRUMP ADMINISTRATION'S INCOMPETENT PROCUREMENT EFFORTS FOR VENTILATORS SQUANDERED UP TO \$500 MILLION OR MORE. PHILIPS TOOK ADVANTAGE OF THE TRUMP ADMINISTRATION'S INEPTNESS AND SHOULD RETURN EXCESS TAXPAYER FUNDS.**

If the Trump Administration had purchased 43,000 Trilogy Evo Universals for the same price that the Obama Administration had negotiated, it would have spent \$503,960,000 less in taxpayer dollars.

There is no indication that the units the Administration purchased provide any benefit over the Trilogy Evo Universals, which were designed specifically for use in a pandemic.

The Trump Administration's efforts constitute over half-a-billion dollars of waste, fraud, or abuse. Philips should return the excess so that it may aid the nation's response to the coronavirus pandemic.


# **APPENDIX A**

## Front View of Each Ventilator, Showing No Differences

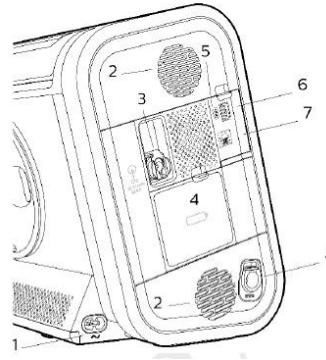
<p>Trilogy Evo Universal<sup>76</sup></p>	<p><b>Parts of Trilogy Evo Universal</b></p> <p><i>Front Panel</i></p>  <ol style="list-style-type: none"> <li>1. On/off (standby) button</li> <li>2. AC power indicator</li> <li>3. Alarm indicator/alarm silence</li> <li>4. Alarm bar</li> <li>5. Touch screen</li> <li>6. Ambient light sensor</li> </ol>				
<p>Trilogy Evo<sup>77</sup></p>	<p>The future of respiratory care is here</p> <p>Choose Trilogy Evo to help provide smooth transitions across your patients' changing environments and as their disease progresses</p> <ul style="list-style-type: none"> <li> <b>Simple</b> Easy-to-learn user interface, configurable to the care environment</li> <li> <b>Connected</b> Providing timely care information to the people who need it</li> <li> <b>Portable</b> 15 hours of battery life, easily mounts on wheelchairs, and has a convenient carrying bag that lets you see the screen and alarms</li> <li> <b>Adaptable</b> Stays with patients as their care settings and needs change</li> <li> <b>Reliable</b> The most robust and durable device we've ever created</li> </ul>  <p><b>Ordering information</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Description</th> <th style="text-align: left;">Part number</th> </tr> </thead> <tbody> <tr> <td>Trilogy Evo, USA</td> <td>D52110X11B</td> </tr> </tbody> </table>	Description	Part number	Trilogy Evo, USA	D52110X11B
Description	Part number				
Trilogy Evo, USA	D52110X11B				

<sup>76</sup> Philips Trilogy Evo Universal Instructions for Use Manual—About Trilogy Evo Universal; Parts Of Trilogy Evo Universal, ManualsLib (Jan. 26, 2018) (online at [www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=12#manual](http://www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=12#manual)).

<sup>77</sup> Trilogy Evo Quick Start Guide for clinicians, Philips Respironics (Nov. 13, 2019) (online at [https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZW11bnQiOiBbeyJSZXRvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWhlMDEuY2xvdWRmcm9udC5uZXQvcGhpCUyRjElMkZmaWxlcUyRjEwMDA2JTJGMtk3NjcIMkZmaWxliwiQ29uZGI0aW9uIjpw7IkRhdGVMZXRyZGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjpw7IkFXUzpw7I3VyY2VJcCI6IjAuMC4wLjAvMCI9fX1dfQ\\_\\_&Signature=Wv3qc6arlyMKbOr4Nrk-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYzOR-fvsev1xmacLxyN6XNGEzIETmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKHIq7NRykBVs5HskjyvRqPQoeya2TUKKLvPHM\\_&Key-Pair-Id=APKAJTZOZQY4H2RTLVOYA](https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZW11bnQiOiBbeyJSZXRvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWhlMDEuY2xvdWRmcm9udC5uZXQvcGhpCUyRjElMkZmaWxlcUyRjEwMDA2JTJGMtk3NjcIMkZmaWxliwiQ29uZGI0aW9uIjpw7IkRhdGVMZXRyZGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjpw7IkFXUzpw7I3VyY2VJcCI6IjAuMC4wLjAvMCI9fX1dfQ__&Signature=Wv3qc6arlyMKbOr4Nrk-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYzOR-fvsev1xmacLxyN6XNGEzIETmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKHIq7NRykBVs5HskjyvRqPQoeya2TUKKLvPHM_&Key-Pair-Id=APKAJTZOZQY4H2RTLVOYA)).

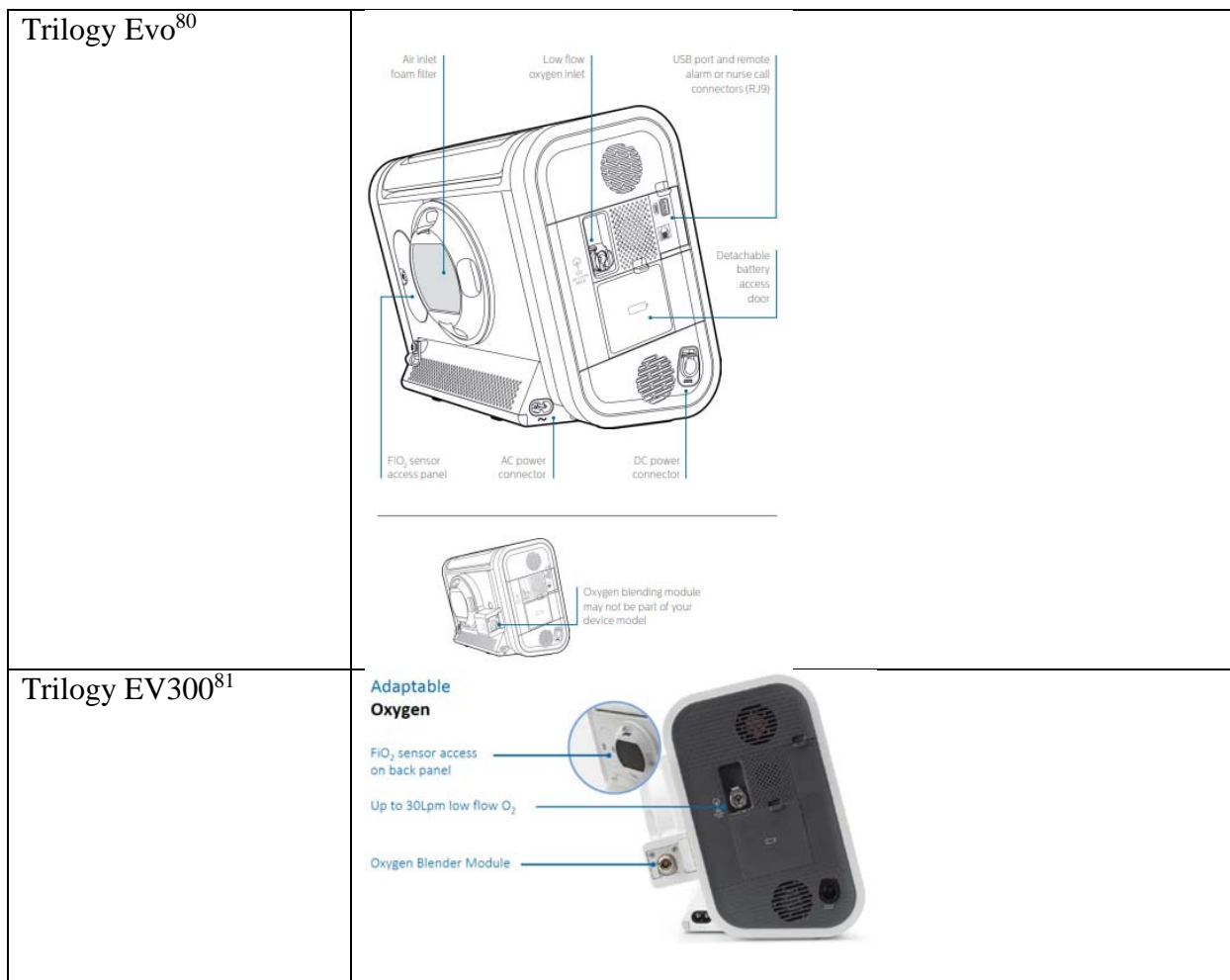
<p>Trilogy EV300<sup>78</sup></p>	<div style="display: flex; align-items: center;"> <div style="flex: 1; padding-right: 10px;"> <p><b>Simple</b> Easy-to-learn user interface, configurable to the care environment</p> <p><b>Portable</b> 15 hours of battery life* to enable on-the-go use</p> <p><b>Adaptable</b> Stays with patients throughout the hospital as their needs change</p> <p><b>Reliable</b> Durable, rugged design to support use throughout the hospital</p> </div> <div style="flex: 1;">  </div> </div>
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**Utility Panel View of Each Ventilator, Showing No Differences**

<p>Trilogy Evo Universal<sup>79*</sup></p>	<div style="display: flex; align-items: center;"> <div style="flex: 1;"> <p><i>Utility Panel</i></p>  </div> <div style="flex: 1; padding-left: 20px;"> <ol style="list-style-type: none"> <li>1. AC power connector</li> <li>2. Air vents</li> <li>3. Low flow oxygen inlet</li> <li>4. Detachable battery access door</li> <li>5. Micro USB Port for device service</li> <li>6. Accessory USB Port (USB external storage device, communication cables)</li> <li>7. Remote alarm or nurse call connector (RJ9)</li> <li>8. DC power connector</li> </ol> </div> </div>
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<sup>78</sup> *Introducing Trilogy EV300*, Philips Respironics (Jan. 2020) (online at <https://philipsproductcontent.blob.core.windows.net/assets/20200214/a05bc42d33834d0e89c9ab61013d781a.pdf>).

<sup>79</sup> *Philips Trilogy Evo Universal Instructions for Use Manual—Page 13*, ManualsLib (Jan. 26, 2018) (online at [www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=13#manual](http://www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=13#manual)).

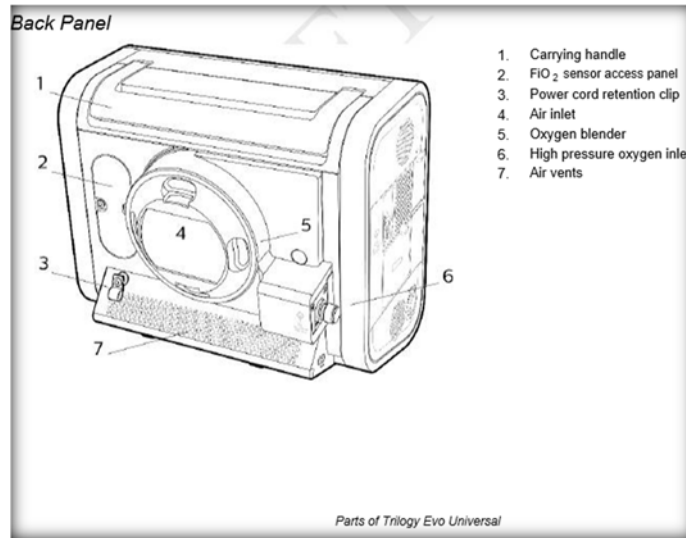


Although it is not pictured in the Trilogy Evo Universal diagram, that model comes equipped with an oxygen blender module—shown in this diagram from an alternate angle.<sup>82</sup>

<sup>80</sup> *Trilogy Evo Quick Start Guide for Clinicians*, Philips Respironics (Nov. 13, 2019) (online at [https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZW1lbnQiOiBbeyJSZXRvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWhlMDEuY2xvdWRmcm9udC5uZXQvcGhpbCUyRjEIMkZmaWxlcUyRjEwMDA2JTJGMtk3NjclMkZmaWxliwiQ29uZGI0aW9uIjpw7IkRhdGVMZXNzVGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjpw7IkFXUzpw7Tb3VyY2VJcCI6IjAuMC4wLjAvMCI9fX1dfQ\\_\\_&Signature=Wv3qc6arlyMKbOr4NrK-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYzOR-fvsev1xmacLxyN6XNGEzIETmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKHLq7NRykBV5SHskjyvRqPQoeya2TUKKLvPHM\\_&Key-Pair-Id=APKAJTOZQY4H2RTLVOA](https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZW1lbnQiOiBbeyJSZXRvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWhlMDEuY2xvdWRmcm9udC5uZXQvcGhpbCUyRjEIMkZmaWxlcUyRjEwMDA2JTJGMtk3NjclMkZmaWxliwiQ29uZGI0aW9uIjpw7IkRhdGVMZXNzVGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjpw7IkFXUzpw7Tb3VyY2VJcCI6IjAuMC4wLjAvMCI9fX1dfQ__&Signature=Wv3qc6arlyMKbOr4NrK-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYzOR-fvsev1xmacLxyN6XNGEzIETmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKHLq7NRykBV5SHskjyvRqPQoeya2TUKKLvPHM_&Key-Pair-Id=APKAJTOZQY4H2RTLVOA)).

<sup>81</sup> *Trilogy EV300 Evolution of Care: Simple, Portable, Reliable, Adaptable*, Philips Respironics (Feb. 2020) (online at [www.usa.philips.com/c-dam/b2bhc/master/landing-pages/experience-catalog/sleep-and-respiratory-care/how-philips-is-globally-addressing-the-coronavirus-covid-19/clinical-resources/trilogy-ev300-clinical-presentation.pdf](http://www.usa.philips.com/c-dam/b2bhc/master/landing-pages/experience-catalog/sleep-and-respiratory-care/how-philips-is-globally-addressing-the-coronavirus-covid-19/clinical-resources/trilogy-ev300-clinical-presentation.pdf)).

<sup>82</sup> *Philips Trilogy Evo Universal Instructions for Use Manual—Page 13*, ManualsLib (Jan. 26, 2018) (online at [www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=13#manual](http://www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=13#manual)).



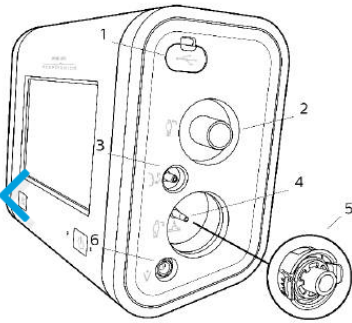
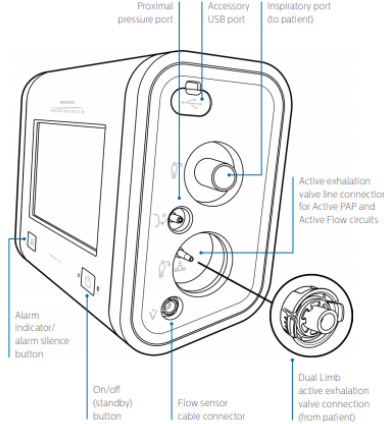
The Trilogy Evo Universal's oxygen blender module is also described in a June 26, 2020, letter from Philips to the Subcommittee:<sup>83</sup>

Philips and BARDA executed the contract to develop the Stockpile Ventilator on September 15, 2014. The September 2014 contract included the option to purchase 10,000 ventilators at the negotiated cost of \$3,280 per ventilator once the design had obtained FDA clearance. As mentioned, Philips would research and design and, upon 510(k) clearance and the exercise of the option, manufacture the Stockpile Ventilator, which included certain accessories and components that were unique to the needs of the SNS and ultimately included packaging enhancements; adult and pediatric circuitry to fit a wide-range of patients; **integrated oxygen blender module**; enhanced battery life; wireless remote monitoring; dual limb compatibility; and a touchscreen user interface, among other features.

<sup>83</sup> Letter from Counsel to Philips North America Corporation to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 26, 2020).



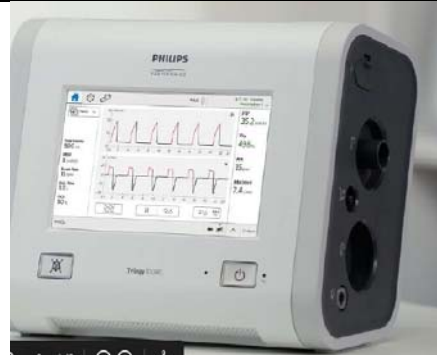
## Patient Panel View of Each Ventilator, Showing No Differences

<p>Trilogy Evo Universal<sup>84</sup></p>	<p style="text-align: right;">Instructions for Use   About Trilogy Evo Universal</p> <p><b>Patient Panel</b></p>  <ol style="list-style-type: none"> <li>1. Accessory USB port (pulse oximeter, CO<sub>2</sub> monitor)</li> <li>2. Inspiratory port (to patient)</li> <li>3. Proximal pressure port</li> <li>4. Active exhalation valve line connection for ActivePAP and Active Flow circuits</li> <li>5. Dual limb active exhalation valve connection (from patient)</li> <li>6. Flow sensor cable connector</li> </ol>
<p>Trilogy Evo<sup>85</sup></p>	<p><b>Overview</b></p>  <p>Proximal pressure port    Accessory USB port    Inspiratory port (to patient)</p> <p>Alarm indicator/ alarm silence button    On/off (standby) button    Flow sensor cable connector</p> <p>Active exhalation valve line connection for Active PAP and Active Flow circuits</p> <p>Dual Limb active exhalation valve connection (from patient)</p>

<sup>84</sup> Philips Trilogy Evo Universal Instructions for Use Manual—Page 13, ManualsLib (Jan. 26, 2018) (online at [www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=13#manual](http://www.manualslib.com/manual/1571575/Philips-Trilogy-Evo-Universal.html?page=13#manual)).

<sup>85</sup> Trilogy Evo Quick Start Guide for Clinicians, Philips Respironics (Nov. 13, 2019) (online at [https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZW11bnQiOiBbeyJSZSNvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWlMDEuY2xvdWRmcm9udC5uZXQvcGhpCUyRjElMkZmaWxlcYUyRjEwMDA2JTJGMtk3NjclMkZmaWxliwiQ29uZG10aW9uIjpb7IkRhdGVmZXNzVGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjpb7IkFXUzpTb3V5Y2VJcCI6IjAuMC4wLjAvMCI9fX1dfQ\\_\\_&Signature=Wv3qc6arlyMKbOr4Nrk-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYzOR-fvsev1xmacLxyN6XNGEzIEtmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKHIq7NRykbV5HskjyvRqPQoeya2TUKKLvPHM\\_&Key-Pair-Id=APKAJTOZQY4H2RTLVOA](https://d1oohiyvdehe01.cloudfront.net/phil%2F1%2Ffiles%2F10006%2F19767%2Ffile?Policy=eyJTdGF0ZW11bnQiOiBbeyJSZSNvdXJjZSI6Imh0dHBzOi8vZDFvb2hpeXZkZWlMDEuY2xvdWRmcm9udC5uZXQvcGhpCUyRjElMkZmaWxlcYUyRjEwMDA2JTJGMtk3NjclMkZmaWxliwiQ29uZG10aW9uIjpb7IkRhdGVmZXNzVGhhbiI6eyJBV1M6RXBvY2hUaW1lIjoxNTk0NDEzMDY5fSwiSXBBZGRyZXNzIjpb7IkFXUzpTb3V5Y2VJcCI6IjAuMC4wLjAvMCI9fX1dfQ__&Signature=Wv3qc6arlyMKbOr4Nrk-AWrLjLytXpgvjfdAsimxUcuSygsmTX6~YcizYAWhaP5vcOpzifmouXYzOR-fvsev1xmacLxyN6XNGEzIEtmdufPwY8zOZlplfIREQxhtqv6RFVpcCIFKHIq7NRykbV5HskjyvRqPQoeya2TUKKLvPHM_&Key-Pair-Id=APKAJTOZQY4H2RTLVOA)).

Trilogy EV300<sup>86</sup>



Philips has repeatedly compared the Trilogy Evo and the Trilogy EV300 without demonstrating any difference in the models. And according to Philips' specification sheets, there is no difference between those models (except that the less expensive Trilogy Evo model actually has *two more* ventilation modes).<sup>87</sup>

Trilogy Evo	Trilogy EV300
<p><b>Ventilation modes</b></p> <p>A/C-PC: Assist control (pressure control)</p> <p>A/C-VC: Assist control (volume control)</p> <p>CPAP: Continuous positive airway pressure</p> <p>PSV: Pressure support ventilation</p> <p>S/T: Spontaneous/timed ventilation</p> <p>SIMV-PC: Synchronized intermittent mandatory ventilation (pressure control)</p> <p>SIMV-VC: Synchronized intermittent mandatory ventilation (volume control)</p> <p>AVAPS-AE</p> <p>MPV-PC: Mouthpiece ventilation (pressure control)</p> <p>MPV-VC: Mouthpiece ventilation (volume control)</p>	<p><b>Ventilation modes</b></p> <p>A/C-PC: Assist control (pressure control)</p> <p>A/C-VC: Assist control (volume control)</p> <p>CPAP: Continuous positive airway pressure</p> <p>PSV: Pressure support ventilation</p> <p>S/T: Spontaneous/timed ventilation</p> <p>SIMV-PC: Synchronized intermittent mandatory ventilation (pressure control)</p> <p>SIMV-VC: Synchronized intermittent mandatory ventilation (volume control)</p> <p>AVAPS-AE</p>
<p><b>Physical</b></p> <p>Weight: 5.2 Kg (11.5 lbs) device 5.8 Kg (12.7 lbs) with detachable battery 6.3 Kg (13.8 lbs) with oxygen blender and detachable battery</p> <p>Size: Without oxygen blender: 16.5 cm D x 28.6 cm W x 24.5 cm H 6.48" D x 11.25" W x 9.65" H With oxygen blender: 19.3 cm D x 28.6 cm W x 24.5 cm H 7.6" D x 11.25" W x 9.65" H</p> <p>Screen dimensions: 8", 20.32 cm</p> <p>Ingress protection: IP22: protection against finger-sized objects and protected against dripping water when tilted up to 15 degrees.</p>	<p><b>Physical</b></p> <p>Weight: 5.8 Kg (12.7 lbs) with detachable battery 6.3 Kg (13.8 lbs) with oxygen blender and detachable battery</p> <p>Size: With oxygen blender: 19.3 cm D x 28.6 cm W x 24.5 cm H 7.6" D x 11.25" W x 9.65" H</p> <p>Screen dimensions: 8", 20.32 cm</p> <p>Ingress protection: IP22: protection against finger-sized objects and protected against dripping water when tilted up to 15 degrees.</p>
<p><b>Oxygen</b></p> <p>Low flow: 0 to 30 l/min, maximum 10 psi</p> <p>High pressure: 280 to 600 kPa (41 to 87 psi)</p>	<p><b>Oxygen</b></p> <p>Low flow: 0 to 30 l/min, maximum 10 psi</p> <p>High pressure: 280 to 600 kPa (41 to 87 psi)</p>

<sup>86</sup> *Trilogy EV300 Evolution of Care: Simple, Portable, Reliable, Adaptable*, Philips Respironics (Feb. 2020) (online at [www.usa.philips.com/c-dam/b2bhc/master/landing-pages/experience-catalog/sleep-and-respiratory-care/how-philips-is-globally-addressing-the-coronavirus-covid-19/clinical-resources/trilogy-ev300-clinical-presentation.pdf](http://www.usa.philips.com/c-dam/b2bhc/master/landing-pages/experience-catalog/sleep-and-respiratory-care/how-philips-is-globally-addressing-the-coronavirus-covid-19/clinical-resources/trilogy-ev300-clinical-presentation.pdf)).

<sup>87</sup> Specification Sheets for Trilogy EV300 and Trilogy Evo Ventilators (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/1134-1137.pdf>).

Measured and displayed patient parameters		Measured and displayed patient parameters	
Tidal volume (Vt or Vte)	0 to 2000 ml	Tidal volume (Vt or Vte)	0 to 2000 ml
Minute ventilation (MinVent)	0 to 30 L/min	Minute ventilation (MinVent)	0 to 30 L/min
Leak	0 to 200 L/min	Leak	0 to 200 L/min
Respiratory rate (RR)	0 to 90 BPM	Respiratory rate (RR)	0 to 90 BPM
Peak inspiratory flow (PIF)	0 to 200 L/min	Peak inspiratory flow (PIF)	0 to 200 L/min
Peak inspiratory pressure (PIP)	0 to 90 cmH <sub>2</sub> O	Peak inspiratory pressure (PIP)	0 to 90 cmH <sub>2</sub> O
Mean airway pressure	0 to 90 cmH <sub>2</sub> O	Mean airway pressure	0 to 90 cmH <sub>2</sub> O
Percentage spontaneous triggered breaths (%Spont Trig)	0 to 100%	Percentage spontaneous triggered breaths (%Spont Trig)	0 to 100%
I:E ratio	0.9:1 to 1:9.9	I:E ratio	0.9:1 to 1:9.9
Dynamic compliance (Dyn C)	1 to 100 ml/cmH <sub>2</sub> O	Dynamic compliance (Dyn C)	1 to 100 ml/cmH <sub>2</sub> O
Dynamic resistance (Dyn R)	5 to 200 cmH <sub>2</sub> O/L/sec	Dynamic resistance (Dyn R)	5 to 200 cmH <sub>2</sub> O/L/sec
Dynamic plateau pressure (Dyn Pplat)	0 to 90 cmH <sub>2</sub> O	Dynamic plateau pressure (Dyn Pplat)	0 to 90 cmH <sub>2</sub> O
Auto-PEEP	0 to 20 cmH <sub>2</sub> O	Auto-PEEP	0 to 20 cmH <sub>2</sub> O
FiO <sub>2</sub> with FIO <sub>2</sub> sensor	21% to 100%	FiO <sub>2</sub> with FIO <sub>2</sub> sensor	21% to 100%
SpO <sub>2</sub> with pulse oximeter accessory	0 to 100%	SpO <sub>2</sub> with pulse oximeter accessory	0 to 100%
Pulse rate with pulse oximeter accessory	18 to 321 beats per minute	Pulse rate with pulse oximeter accessory	18 to 321 beats per minute
ETCO <sub>2</sub> with CO <sub>2</sub> accessory	0 to 150 mmHg	ETCO <sub>2</sub> with CO <sub>2</sub> accessory	0 to 150 mmHg
<b>Electrical</b>		<b>Electrical</b>	
AC Input voltage	100V - 240V, 50/60 Hz, 1.7 - 0.6A	AC Input voltage	100V - 240V, 50/60 Hz, 1.7 - 0.6A
DC Input voltage	12/24V 6.5A	DC Input voltage	12/24V 6.5A
Internal and detachable Li-ion batteries	15 hours' nominal total run time per method in IEC 60601-2-72 (7.5 hours each battery)	Internal and detachable Li-ion batteries	15 hours' nominal total run time per method in IEC 60601-2-72 (7.5 hours each battery)
Charge time for detachable and internal battery	from 0% to 80%: 2.5 hours from 0% to 100%: 3.5 hours	Charge time for detachable and internal battery	from 0% to 80%: 2.5 hours from 0% to 100%: 3.5 hours
<b>Alarms</b>		<b>Alarms</b>	
Inspiratory Pressure	1 - 90 cmH <sub>2</sub> O	Inspiratory Pressure	1 - 90 cmH <sub>2</sub> O
Tidal Volume	OFF, 10 - 2000 ml	Tidal Volume	OFF, 10 - 2000 ml
Minute Ventilation	OFF, 0.2 - 30 L/min	Minute Ventilation	OFF, 0.2 - 30 L/min
Respiratory Rate	OFF, 1 - 90 BPM	Respiratory Rate	OFF, 1 - 90 BPM
Circuit Disconnection	OFF, 5 - 60 sec	Circuit Disconnection	OFF, 5 - 60 sec
Apnea Interval	5 - 60 sec	Apnea Interval	5 - 60 sec
No trigger	OFF, 0.5 - 15 min (Only in MPV)		
<b>Environmental</b>		<b>Environmental</b>	
Operating	Temperature: 0°C to 40°C Relative humidity: 5% to 90% RH, non-condensing Atmospheric pressure: 62 to 106 kPa Altitude: -1261 to 12,971 feet Battery charging temperature: 5°C to 40°C	Operating	Temperature: 0°C to 40°C Relative humidity: 5% to 90% RH, non-condensing Atmospheric pressure: 62 to 106 kPa Altitude: -1261 to 12,971 feet Battery charging temperature: 5°C to 40°C
Transient operating temperature	-20°C to 50°C	Transient operating temperature	-20°C to 50°C
Storage temperature	Temperature: -25°C to 70°C Relative humidity: 5% to 93% RH, non-condensing	Storage temperature	Temperature: -25°C to 70°C Relative humidity: 5% to 93% RH, non-condensing

Controls		Controls	
AVAPS with passive circuit	PSV, S/T, and A/C-PC modes only	AVAPS with passive circuit	PSV, S/T, and A/C-PC modes only
Tidal volume	35 - 2000 ml on Dual Limb and Active Flow circuits, 50 - 2000 ml on passive and active PAP circuits	Tidal volume	35 - 2000 ml on Dual Limb and Active Flow circuits, 50 - 2000 ml on passive and active PAP circuits
Breath rate	0 - 80 BPM	Breath rate	0 - 80 BPM
PEEP	0 - 35 cmH <sub>2</sub> O for active circuits 3 - 25 cmH <sub>2</sub> O for passive circuits	PEEP	0 - 35 cmH <sub>2</sub> O for active circuits 3 - 25 cmH <sub>2</sub> O for passive circuits
EPAP/CPAP	3 - 25 cmH <sub>2</sub> O	EPAP/CPAP	3 - 25 cmH <sub>2</sub> O
IPAP	3 - 60 cmH <sub>2</sub> O	IPAP	3 - 60 cmH <sub>2</sub> O
Pressure support/pressure control	0 - 60 cmH <sub>2</sub> O	Pressure support/pressure control	0 - 60 cmH <sub>2</sub> O
Inspiratory time	0.3 - 5.0s	Inspiratory time	0.3 - 5.0s
Rise time	0 - 6	Rise time	0 - 6
Triggering and cycling	Off, Auto-Track, Sensitive Auto-Track, and Flow Trigger	Triggering and cycling	Off, Auto-Track, Sensitive Auto-Track, and Flow Trigger
Flow trigger sensitivity	0.5 - 9 l/min	Flow trigger sensitivity	0.5 - 9 l/min
Flow cycle sensitivity	10% - 90% of peak flow	Flow cycle sensitivity	10% - 90% of peak flow
Flow pattern	Square, Ramp	Flow pattern	Square, Ramp
FiO <sub>2</sub>	21% - 100%	FiO <sub>2</sub>	21% - 100%
Inspiratory time min/max	0.3 - 3.0 sec	Inspiratory time min/max	0.3 - 3.0 sec
Backup ventilation	ON - OFF	Backup ventilation	ON - OFF





The only reason that Philips appears to charge different prices for identical ventilators appears to be the intended buyer. The following Philips specification sheet highlights the identical functionality between the Trilogy Evo and the Trilogy EV300 but indicates that they are intended to be sold for different intended care settings. In a comparison chart of Philips' ventilation solutions, the Trilogy EV300 is listed as a hospital-only solution, while the Trilogy Evo is listed for either hospital or home.<sup>88</sup>



## Philips Hospital Ventilation Solutions



Models supporting both Invasive and Non-invasive ventilation

	Max Inspiratory Pressure	Respiratory Rate	Modes		Oxygen	Battery Time	Connectivity
			Pressure	Volume			
 E30 <sup>1</sup>	30 cmH <sub>2</sub> O	0 to 30bpm	CPAP, S, S/T, PC	N/A	Device Inlet Port: 60lpm max Circuit Bleed In: 30lpm max	N/A	N/A
 Trilogy 202	50 cmH <sub>2</sub> O	0 to 60 bpm (volume modes) 0 to 40 bpm (AVAPS-AE) 1 to 60 bpm (all other modes)	CPAP, S, S/T, PC, PC-SIMV, T, AVAPS-AE, PC-MPV	SIMV, AC, CV, AC-MPV	High Pressure: (40 to 87 psi) FiO <sub>2</sub> : 21 - 100%	6 hours	Optional SpO <sub>2</sub> monitoring, IntelliVue /Capsule connectivity
 Trilogy EV300	60 cmH <sub>2</sub> O	0 to 80 bpm	CPAP, PSV, S/T, SIMV-PC, A/C-PC, AVAPS-AE	A/C-VC, SIMV-VC	Low Flow: 0-30lpm max High Pressure: (41 to 87 psi) FiO <sub>2</sub> : 21-100%	15 hours	Bluetooth and WiFi Optional SpO <sub>2</sub> , EtCO <sub>2</sub> and FIO <sub>2</sub> monitoring Touchscreen Care Orchestrator OmniLab Direct Capsule/IntelliVue connectivity
 V60, V60 Plus	40 cmH <sub>2</sub> O	4 to 60 bpm	HFT <sup>2</sup> , CPAP, S/T, PCV, AVAPS, PPV (optional)	N/A	High Flow: 10-80lpm <sup>2</sup> High Pressure: (40 to 87 psi) FiO <sub>2</sub> : 21-100%	6 hours	IntelliVue connectivity via RS232



<sup>88</sup> Philips Ventilation Solutions Datasheet, Philips Respironics (online at [www.philips.com/c-dam/b2bhc/master/Products/Category/ventilation/group/philips-ventilation-specifications-comparison-chart.pdf?\\_ga=2.251455040.772752659.1594060554-879679223.1594060554](http://www.philips.com/c-dam/b2bhc/master/Products/Category/ventilation/group/philips-ventilation-specifications-comparison-chart.pdf?_ga=2.251455040.772752659.1594060554-879679223.1594060554)).



# Philips Hospital/Home Ventilation Solutions



Models supporting both Invasive and Non-invasive ventilation

	Max Inspiratory Pressure	Respiratory Rate	Modes		Oxygen	Battery Time	Connectivity
			Pressure	Volume			
 Trilogy 100 Trilogy 200	50 cmH <sub>2</sub> O	0 to 60 bpm (volume modes) 0 to 40 bpm (AVAPS-AE) 1 to 60 bpm (all other modes)	CPAP, S, S/T, PC, PC-SIMV, T, AVAPS-AE, PC-MPV	SIMV, AC, CV, AC-MPV	Low Flow: 15lpm max	6 hours	Bluetooth Optional SpO <sub>2</sub> monitoring, Care Orchestrator PC Direct IntelliVue /Capsule
 Trilogy Evo Trilogy Evo O2	60 cmH <sub>2</sub> O	0 to 80 bpm	CPAP, PSV, S/T, SIMV-PC, A/C-PC, AVAPS-AE, MPV-PC	A/C-VC, SIMV-VC, MPV-VC	Low Flow: 0-30lpm max High Pressure: (41 to 87 psi) <sup>1</sup> FIO <sub>2</sub> : 21-100% <sup>2</sup>	15 hours <sup>2</sup>	Bluetooth and WiFi Optional SpO <sub>2</sub> , EtCO <sub>2</sub> and FIO <sub>2</sub> monitoring Care Orchestrator OmniLab Direct IntelliVue /Capsule

In a brochure for the Evo model, Philips emphasized the models' similarities with the headline: "Different care settings. Same clinical technology." The functionality of the models is the same; the differences are based entirely on the care environment for which they are being sold.<sup>89</sup>

<sup>89</sup> *Trilogy Evo Product Brochure*, Philips Respironics (online at <https://philipsproductcontent.blob.core.windows.net/assets/20191028/752f8345d10143f380ccaaf400e7d93d.pdf>).

## Different care settings. Same clinical technology.

Trilogy EV300 and Trilogy Evo were developed specifically for use in their respective environments. They deliver enhanced performance in noninvasive and invasive ventilation, so patients can be treated with a single device through their hospital stay and as they transition home. Both Trilogy EV300 and Trilogy Evo feature Philips proprietary algorithms AVAPS-AE and digital auto-trak, and invasive ventilation is available with single- and dual-limb circuits and leak compensation. Every Trilogy EV300 and Trilogy Evo includes pressure and volume modes and optional SpO<sub>2</sub> and CO<sub>2</sub> monitoring.

### Trilogy EV300 and Trilogy Evo have the same core functionality with the user experience optimized for the care environment.

- Patient experience is the same with every Trilogy EV300 or Trilogy Evo model.
- Easy to use and teach for both hospital and home
- Learn one device and easily operate any device

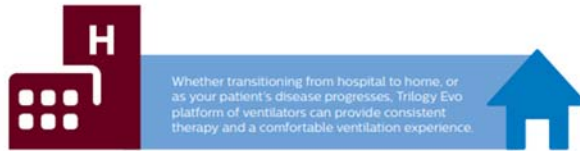
#### Trilogy EV300

- Clinician-friendly user interface
- Clinician interface built to optimize in-hospital ventilator use
- Patient demographic default settings and alarms
- Dedicated ventilation modes for hospital environment
- Field serviceability with standard service tools



#### Trilogy Evo

- Patient/caregiver-friendly user interface
- Patient limited access setting
- Adjustable patient view
- Ability to save multiple prescriptions
- Dedicated ventilation modes for home environment



Whether transitioning from hospital to home, or as your patient's disease progresses, Trilogy Evo platform of ventilators can provide consistent therapy and a comfortable ventilation experience.

## **APPENDIX B**

The FDA’s 510(k) approvals show that the Trilogy Evo Universal and the Trilogy Evo are identical. The Evo and Evo Universal Ventilators were deemed substantially equivalent to legally marketed predicate devices after review of their respective Section 510(k) premarket notifications of intent to market on the same day. The 510(k) summaries for each model are substantially identical:<sup>90</sup>

Trilogy Evo Universal 510(K) from FDA	Trilogy Evo 510(K) from FDA
<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>Indications for Use</b></p> <p>Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below.</p> <p>510(k) Number (if known) K181170</p> <p>Device Name Trilogy Evo Universal Ventilator</p> <p><b>Indications for Use (Describe)</b> The Trilogy Evo Universal ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo Universal is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO<sub>2</sub>, FIO<sub>2</sub>, CO<sub>2</sub>, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional/hospital settings and non-emergency transport settings for example wheelchair. It may be used for both invasive and non-invasive ventilation.</p>	<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>Indications for Use</b></p> <p>Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below.</p> <p>510(k) Number (if known) K181166</p> <p>Device Name Trilogy Evo Ventilator</p> <p><b>Indications for Use (Describe)</b> The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO<sub>2</sub>, FIO<sub>2</sub>, CO<sub>2</sub>, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and non-invasive ventilation.</p>
<p><b>Trilogy Evo Universal Ventilator</b> <span style="float: right;"><b>Traditional 510(k)</b></span></p> <p style="text-align: center;"><b>Section 6: 510(k) Summary</b></p> <p><b>Device Description</b> The Trilogy Evo Universal ventilator is a microprocessor controlled blower based pressure support, pressure control or volume controlled ventilator intended for the care of individuals who require mechanical ventilation. The ventilator is intended to provide continuous or intermittent ventilatory support. The ventilator is suitable for use in institutional/hospital settings and non-emergency transport settings for example wheelchair. It is applicable for adults and pediatric patients weighing at least 2.5 kg who require the following types of ventilatory support:</p> <p><b>Control Modes</b></p> <ul style="list-style-type: none"> <li>A/C-PC: Assist control</li> <li>A/C-VC: Assist control</li> </ul> <p><b>Spontaneous modes</b></p> <ul style="list-style-type: none"> <li>CPAP: Continuous positive airway pressure</li> <li>PSV: Pressure support ventilation</li> </ul> <p><b>Mixed modes</b></p> <ul style="list-style-type: none"> <li>S/T: Spontaneous/timed ventilation</li> <li>SIMV-PC: Synchronized intermittent mandatory ventilation (pressure control)</li> <li>SIMV-VC: Synchronized intermittent mandatory ventilation (volume control)</li> </ul> <p>In addition to the therapy modes, the Trilogy Evo Universal provides the following major functions:</p> <ul style="list-style-type: none"> <li>Therapy Features including Backup Ventilation, Inspiratory Time Min/Max and Sigh</li> <li>Power Management of various power sources (AC, internal and detachable Li-Ion batteries and external Pb-Acid battery)</li> <li>Physiological alarms</li> <li>Graphical User Interface using a touch screen display, status LEDs and dedicated keys for user input</li> <li>Bluetooth and USB Communications</li> <li>Compatibility with various patient interfaces and multiple circuit types</li> <li>Connectivity with hospital monitors</li> <li>Capability to connect, display and alarm SpO<sub>2</sub>, FIO<sub>2</sub> and ETCO<sub>2</sub> monitors</li> <li>Ventilation with supplemental low flow oxygen or oxygen blender</li> </ul> <p>The associated accessories include:</p> <ul style="list-style-type: none"> <li>Bacteria Filter</li> <li>Circuits, including Passive, Active and Dual Limb</li> <li>FIO<sub>2</sub> Sensor</li> <li>Active Exhalation Valves</li> <li>Leak Device</li> <li>Heat and Moisture Exchangers (HME's)</li> <li>Oximeter and Sensors</li> <li>Capnography Sensors and cable</li> <li>Flow Sensors</li> <li>Detachable Battery and Battery Cables</li> <li>Roll Stand</li> <li>Mounting Bracket</li> </ul> <p><b>Indications for Use</b> The Trilogy Evo Universal ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo Universal is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO<sub>2</sub>, FIO<sub>2</sub>, CO<sub>2</sub>, and Pulse Rate data when integrated with the appropriate accessories. The ventilator</p> <p>Respironics Inc. <span style="float: right;">Page 6-2</span></p>	<p><b>Trilogy Evo Ventilator</b> <span style="float: right;"><b>Traditional 510(k)</b></span></p> <p style="text-align: center;"><b>Section 6: 510(k) Summary</b></p> <p><b>Device Description</b> The Trilogy Evo ventilator is a microprocessor controlled blower based pressure support, pressure control or volume controlled ventilator intended for the care of individuals who require mechanical ventilation. The ventilator is intended to provide continuous or intermittent ventilatory support. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It is applicable for adults and pediatric patients weighing at least 2.5 kg who require the following types of ventilatory support:</p> <p><b>Control Modes</b></p> <ul style="list-style-type: none"> <li>A/C-PC: Assist control</li> <li>A/C-VC: Assist control</li> </ul> <p><b>Spontaneous modes</b></p> <ul style="list-style-type: none"> <li>CPAP: Continuous positive airway pressure</li> <li>PSV: Pressure support ventilation</li> </ul> <p><b>Mixed modes</b></p> <ul style="list-style-type: none"> <li>S/T: Spontaneous/timed ventilation</li> <li>SIMV-PC: Synchronized intermittent mandatory ventilation (pressure control)</li> <li>SIMV-VC: Synchronized intermittent mandatory ventilation (volume control)</li> </ul> <p><b>AVAPS-AE modes</b></p> <ul style="list-style-type: none"> <li>AVAPS-AE with PC Breath enabled, with auto backup</li> <li>AVAPS-AE with PC Breath enabled, without auto backup</li> <li>AVAPS-AE with PC Breath disabled, with auto backup</li> <li>AVAPS-AE with PC Breath disabled, without auto backup</li> </ul> <p>The AVAPS-AE mode is intended for noninvasive use in adult and pediatric patients weighing over 10kg with Respiratory Insufficiency or Respiratory Failure.</p> <p>In addition to the therapy modes, the Trilogy Evo provides the following major functions:</p> <ul style="list-style-type: none"> <li>Therapy Features including Backup Ventilation, Inspiratory Time Min/Max and Sigh</li> <li>Power Management of various power sources (AC, internal and detachable Li-Ion batteries and external Pb-Acid battery)</li> <li>Physiological alarms</li> <li>Graphical User Interface using a touch screen display, status LEDs and dedicated keys for user input</li> <li>Bluetooth and USB Communications</li> <li>Compatibility with various patient interfaces and multiple circuit types</li> <li>Remote alarm and nurse call capability</li> <li>Connectivity with hospital monitors</li> <li>Capability to connect, display and alarm SpO<sub>2</sub>, FIO<sub>2</sub> and ETCO<sub>2</sub> monitors</li> <li>Ventilation with supplemental low flow oxygen or oxygen blender</li> </ul> <p>The associated accessories include:</p> <ul style="list-style-type: none"> <li>Filters</li> <li>Circuits, including Passive, Active and Dual Limb, and Mouth Piece Ventilation</li> <li>FIO<sub>2</sub> Sensor</li> <li>Active Exhalation Valves</li> <li>Leak Device</li> <li>Oximeter and Sensors</li> <li>Capnography Sensors and cable</li> <li>Flow Sensors</li> <li>Detachable Battery and Battery Cables</li> </ul> <p>Respironics Inc. <span style="float: right;">Page 6-2</span></p>

<sup>90</sup> Food and Drug Administration, Center for Devices and Radiological Health, *Trilogy Evo Ventilator (K181166) 510(k) Approval Letter* (July 18, 2019) (online at [www.accessdata.fda.gov/cdrh\\_docs/pdf18/K181166.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf18/K181166.pdf)); Food and Drug Administration, Center for Devices and Radiological Health, *Trilogy Evo Universal Ventilator (K181170) 510(k) Approval Letter* (July 18, 2019) (online at [www.accessdata.fda.gov/cdrh\\_docs/pdf18/K181170.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf18/K181170.pdf)).



<p><b>Trilogy Evo Universal Ventilator</b> <span style="float: right;"><b>Traditional 510(k)</b></span></p> <p style="text-align: center;"><b>Section 6: 510(k) Summary</b></p> <p>is suitable for use in institutional/hospital settings and non-emergency transport settings for example wheelchair. It may be used for both invasive and non-invasive ventilation.</p> <p>The Intended Use of the Trilogy Evo Universal is the same as compared to the primary predicate, Trilogy Series of Ventilator with Oximetry, K111610, to provide invasive and noninvasive positive pressure ventilation. The Indications for Use for the Trilogy Evo Universal is not identical to the predicate device, Trilogy Series of Ventilator with Oximetry, K111610; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.</p> <p><b>Comparison of Technological Characteristics with the Predicate Device</b> The Trilogy Evo Universal ventilator is similar to the Primary Predicate Device, Trilogy Series of Ventilator with Oximetry that was cleared under K111610. The Trilogy Evo ventilator has the same intended use and similar indications for use, operating principles, technologies and manufacturing processes as the predicate device. See table below for a comparison of the Trilogy Evo Universal ventilator to the primary predicate device, Trilogy Series of Ventilator with Oximetry.</p>	<p><b>Trilogy Evo Ventilator</b> <span style="float: right;"><b>Traditional 510(k)</b></span></p> <p style="text-align: center;"><b>Section 6: 510(k) Summary</b></p> <ul style="list-style-type: none"> <li>• Nurse Call cables</li> <li>• Roll Stand</li> <li>• Mounting Bracket</li> </ul> <p><b>Indications for Use</b> The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO<sub>2</sub>, FIO<sub>2</sub>, CO<sub>2</sub>, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and non-invasive ventilation.</p> <p>The Intended Use of the Trilogy Evo is the same as compared to the primary predicate, Trilogy Series of Ventilator with Oximetry, K111610, to provide invasive and noninvasive positive pressure ventilation. The Indications for Use for the Trilogy Evo is not identical to the predicate device, Trilogy Series of Ventilator with Oximetry, K111610; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.</p> <p><b>Comparison of Technological Characteristics with the Predicate Device</b> The Trilogy Evo ventilator is similar to the Primary Predicate Device, Trilogy Series of Ventilator with Oximetry, K111610. The Trilogy Evo ventilator has the same intended use and similar indications for use, operating principles, technologies and manufacturing processes as the predicate device. See table below for a comparison of the Trilogy Evo ventilator to the primary predicate device, Trilogy Series of Ventilator with Oximetry, K111610.</p>
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The comparisons of technological characteristics with the predicate device are particularly telling, as both models share a primary predicate device: Trilogy Series Ventilator with Oximetry (K111610).<sup>91</sup>

<p><b>Trilogy Evo Universal Ventilator</b> <span style="float: right;"><b>Traditional 510(k)</b></span></p> <p style="text-align: center;"><b>Section 6: 510(k) Summary</b></p> <p><b>Comparison of Technological Characteristics with the Predicate Device</b></p> <table border="1"> <thead> <tr> <th>Characteristic</th> <th>Subject Device: Trilogy Evo Universal Ventilator Manufacturer: Resprionics</th> <th>Predicate Device: Trilogy Series Ventilator with Oximetry (K111610) Manufacturer: Resprionics</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td><b>Intended Use</b></td> <td>The Trilogy Evo Universal ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo Universal is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO<sub>2</sub>, FIO<sub>2</sub>, CO<sub>2</sub>, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional/hospital settings and non-emergency transport settings for example wheelchair. It may be used for both invasive and non-invasive ventilation.</td> <td>The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric through adult patients weighing at least 5kg (11lbs). The Oximetry interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate. The device is intended to be used in the home, hospitals and institutions, and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation. It is not intended to be used as a transport ventilator.</td> <td>Substantially equivalent to K111610. Patient weight expanded from 5.0 kg to 2.5 kg. Comparison testing with predicate ventilator demonstrates substantial equivalence.</td> </tr> <tr> <td><b>Patient Population</b></td> <td>Pediatrics and Adults</td> <td>Pediatrics and Adults</td> <td>Substantially equivalent</td> </tr> <tr> <td><b>Principle Of Operation</b></td> <td>Microprocessor controlled Electronically powered Software driven</td> <td>Microprocessor controlled Electronically powered Software driven</td> <td>Substantially equivalent</td> </tr> <tr> <td><b>Performance</b></td> <td>Met ISO 80601-2-12 requirements on essential performance of ventilators</td> <td>Met ISO 80601-2-12 requirements on essential performance of ventilators</td> <td>Substantially equivalent</td> </tr> <tr> <td><b>Waveform Comparison</b></td> <td>Comparable waveform results</td> <td>Comparable waveform results</td> <td>Substantially equivalent</td> </tr> </tbody> </table> <p style="text-align: right;">Page 6-4</p>	Characteristic	Subject Device: Trilogy Evo Universal Ventilator Manufacturer: Resprionics	Predicate Device: Trilogy Series Ventilator with Oximetry (K111610) Manufacturer: Resprionics	Comments	<b>Intended Use</b>	The Trilogy Evo Universal ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo Universal is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO <sub>2</sub> , FIO <sub>2</sub> , CO <sub>2</sub> , and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional/hospital settings and non-emergency transport settings for example wheelchair. It may be used for both invasive and non-invasive ventilation.	The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric through adult patients weighing at least 5kg (11lbs). The Oximetry interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate. The device is intended to be used in the home, hospitals and institutions, and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation. It is not intended to be used as a transport ventilator.	Substantially equivalent to K111610. Patient weight expanded from 5.0 kg to 2.5 kg. Comparison testing with predicate ventilator demonstrates substantial equivalence.	<b>Patient Population</b>	Pediatrics and Adults	Pediatrics and Adults	Substantially equivalent	<b>Principle Of Operation</b>	Microprocessor controlled Electronically powered Software driven	Microprocessor controlled Electronically powered Software driven	Substantially equivalent	<b>Performance</b>	Met ISO 80601-2-12 requirements on essential performance of ventilators	Met ISO 80601-2-12 requirements on essential performance of ventilators	Substantially equivalent	<b>Waveform Comparison</b>	Comparable waveform results	Comparable waveform results	Substantially equivalent	<p><b>Trilogy Evo Ventilator</b> <span style="float: right;"><b>Traditional 510(k)</b></span></p> <p style="text-align: center;"><b>Section 6: 510(k) Summary</b></p> <p><b>Comparison of Technological Characteristics with the Predicate Device</b></p> <table border="1"> <thead> <tr> <th>Characteristic</th> <th>Subject Device: Trilogy Evo Ventilator Manufacturer: Resprionics</th> <th>Predicate Device: Trilogy Series Ventilator with Oximetry (K111610) Manufacturer: Resprionics</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td><b>Intended Use</b></td> <td>The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. 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Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO <sub>2</sub> , FIO <sub>2</sub> , CO <sub>2</sub> , Respiratory Rate, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and non-invasive ventilation.	The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric through adult patients weighing at least 5kg (11lbs). The Oximetry interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate. 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The mode is limited to that intended patient population.	<b>Patient Population</b>	Pediatrics and Adults	Pediatrics and Adults	Substantially equivalent	<b>Principle Of Operation</b>	Microprocessor controlled Electronically powered Software driven	Microprocessor controlled Electronically powered Software driven	Substantially equivalent	<b>Performance</b>	Met ISO 80601-2-12 and 80601-3-72 requirements on essential performance of ventilators	Met ISO 80601-2-12 and 80601-3-72 requirements on essential performance of ventilators	Substantially equivalent	<b>Waveform Comparison</b>	Comparable waveform results	Comparable waveform results	Substantially equivalent
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<b>Intended Use</b>	The Trilogy Evo Universal ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo Universal is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO <sub>2</sub> , FIO <sub>2</sub> , CO <sub>2</sub> , and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional/hospital settings and non-emergency transport settings for example wheelchair. It may be used for both invasive and non-invasive ventilation.	The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric through adult patients weighing at least 5kg (11lbs). The Oximetry interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate. The device is intended to be used in the home, hospitals and institutions, and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation. It is not intended to be used as a transport ventilator.	Substantially equivalent to K111610. Patient weight expanded from 5.0 kg to 2.5 kg. Comparison testing with predicate ventilator demonstrates substantial equivalence.																																														
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