AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 4

2. AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
0004	See Block 16C		

6 ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-C
Washington DC 20201

7 ADMINISTERED BY (If other than Item 6) CODE ASPR-BARDA01

ASPR-BARDA
330 Independence Ave, SW, Rm G644
Washington DC 20201

8 NAME AND ADDRESS OF CONTRACTOR (No. street, county, State and ZIP Code)

RESPIRONICS, INC 359940
RESPIRONICS, INC. 1010 MURRY R
1010 MURRY RIDGE LN
MURRYSVILLE PA 156688525

CODE 359940 FACILITY CODE

(x) 9A AMENDMENT OF SOLICITATION NO

9B DATED (SEE ITEM 11)

X 10A MODIFICATION OF CONTRACT/ORDER NO
HHSO100201400005C

10B DATED (SEE ITEM 13)
09/15/2014

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12 ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103 (a)(3) Bilateral - to reflect other agreements of the parties modifying the contract
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not x is required to sign this document and return 1 copies to the issuing office.

14 DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: [redacted]
DUNS Number: [redacted]

PURPOSE: The purpose of this modification is to 1) REVISE Article B.2.Type of Contract and Estimated Cost 2) REVISE Article G. 4 Invoice Submission/Contract Financing Request 3) REVISE Article F.1. PERIOD OF PERFORMANCE 4) REVISE Article F.2. DELIVERABLES 4) REVISE Article G.10 Establishment of Indirect Cost Rate 5) REVISE Article G.10. ESTABLISHMENT OF INDIRECT COST RATE 6) REVISE Article H.25. Key Personnel and 7) Section J Item 1 and add the Helix Milestone Schedule

See the following pages for details:

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A NAME AND TITLE OF SIGNER (Type or print)	16A NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Elias Diacopoulos	SALIM K. ROBERTS

15B CONTRACTOR/OFFEROR	15C DATE SIGNED	16B UNITED STATES OF AMERICA	16C DATE SIGNED
(Signature of person authorized to sign)	8/19/16	(Signature of Contracting Officer)	8/22/2016

NSN 7540-01-152-8070
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

PURPOSE: The purpose of this modification is to 1) REVISE Article B.2.Type of Contract and Estimated Cost 2) REVISE Article G. 4 Invoice Submission/Contract Financing Request 3) REVISE Article F.1. PERIOD OF PERFORMANCE 4) REVISE Article F.2. DELIVERABLES 4) REVISE Article G.10 Establishment of Indirect Cost Rate 5) REVISE Article G.10. ESTABLISHMENT OF INDIRECT COST RATE 6) REVISE Article H.25. Key Personnel and 7) REVISE Section J Item 1

1. REVISE Article B.2.Type of Contract and Estimated Cost

c. ADD the following:
Incorporate page 1 of Philips Volume II: Cost Proposal dated February 26, 2014 into the contract. Attachment (1) (1 page)

d. DELETE in its entirety and REPLACE as follows:

It is estimated that the currently allotted funds will cover performance of the contract through **February 19, 2018**. Refer to Article F.1. Period of Performance.

2. REVISE ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST - is revised to include Program Support Center (PSC) as follows.

The Contractor shall submit one original and an electronic copy to the Contracting Officer (CO), an electronic copy to the Contracting Officer Representative (COR), and an electronic copy to the **Program Support Center (PSC)** as shown below:

HHS/OS/ASPR/AMCG ATTN: S. Kyle Roberts, (CO) 330 Independence Avenue, SW, Room G640 Washington, DC 20201 **HARDCOPY ORIGINAL AND** Email: [redacted]@hhs.gov	HHS/OS/ASPR/BARDA ATTN: Bonnie Shen, (COR) 330 Independence Avenue, SW, Room G640 Washington, DC 20201 Email: [redacted]@hhs.gov	Electronic Submission to: PSC_Invoices@psc.hhs.gov

3. REVISE Article F.1. PERIOD OF PERFORMANCE

REVISE and REPLACE as follows:

a. The period of performance of this contract shall be from **September 15, 2014** through **February 19, 2018**.

4. REVISE Article F.2. DELIVERABLES

DELETE in its entirety and REPLACE as follows:

Attachment (3) dated 7/8/2016 (4 pages)

5. REVISE Article G.10. ESTABLISHMENT OF INDIRECT COST RATE

DELETE in its entirety and REPLACE as follows:

In accordance with FAR Part 52.216-7(d), the Contractor shall submit its actual indirect cost rates proposal for the prior fiscal year to the Contracting Officer, no later than six months after the end of Philips fiscal year (December 31st) annually. The first required submission is due June 30, 2015 and should be submitted to the Contracting Officer.

A provisional billing rate (for fringe benefits and overhead costs) of 58.0% of total direct salaries excluding paid absences (vacation, sick, holidays), as agreed to per the Bilateral Provisional Rate Agreement between Phillips and the contracting Officer, dated December 4, 2015, has been established for interim reimbursement purposes until settlement is reached on final rates after the end of the contractor's fiscal year. Before final rates for a particular contractor fiscal year are established, the billing rate may be prospectively or retroactively revised by mutual agreement, at either the Government's or contractor's request, to prevent substantial overpayment or underpayment.

Upon approval by both parties, the final Indirect Rate Agreement for each year shall be documented and retained to support the final project reconciliation, which would occur at the conclusion of the contract. The final invoice would correct for any overpayment or underpayment of indirect expenses that may have occurred over the life of the contract.

Note: The rates agreed upon under this contract pertain to this contract only.

6. REVISE Article H.25. KEY PERSONNEL

REMOVE a dual-PI structure (Jeff Kepler and Charlie Mutschler) and REPLACE a single PI (Charlie Mutschler). Attachment (2) Organization chart attached (1 page).

7. REVISE Section J Item 1

DELETE in its entirety and REPLACE with State of Work dated 5/17/16, 32 pages.

ADD Helix Milestone Schedule, 1 page.

PHILIPS

Volume II: Cost Proposal

Philips Advanced All-Hazards Stockpile Ventilator Proposal

In Response to BARDA BAA-11-100-SOL-00021

February 26, 2014

Contact Information:
Philips Healthcare
1740 Golden Mile Highway
Monroeville, PA 15146, U.S.
[redacted] (Phone)
(Fax)
Email: [redacted]@philips.com

Attachment (1)

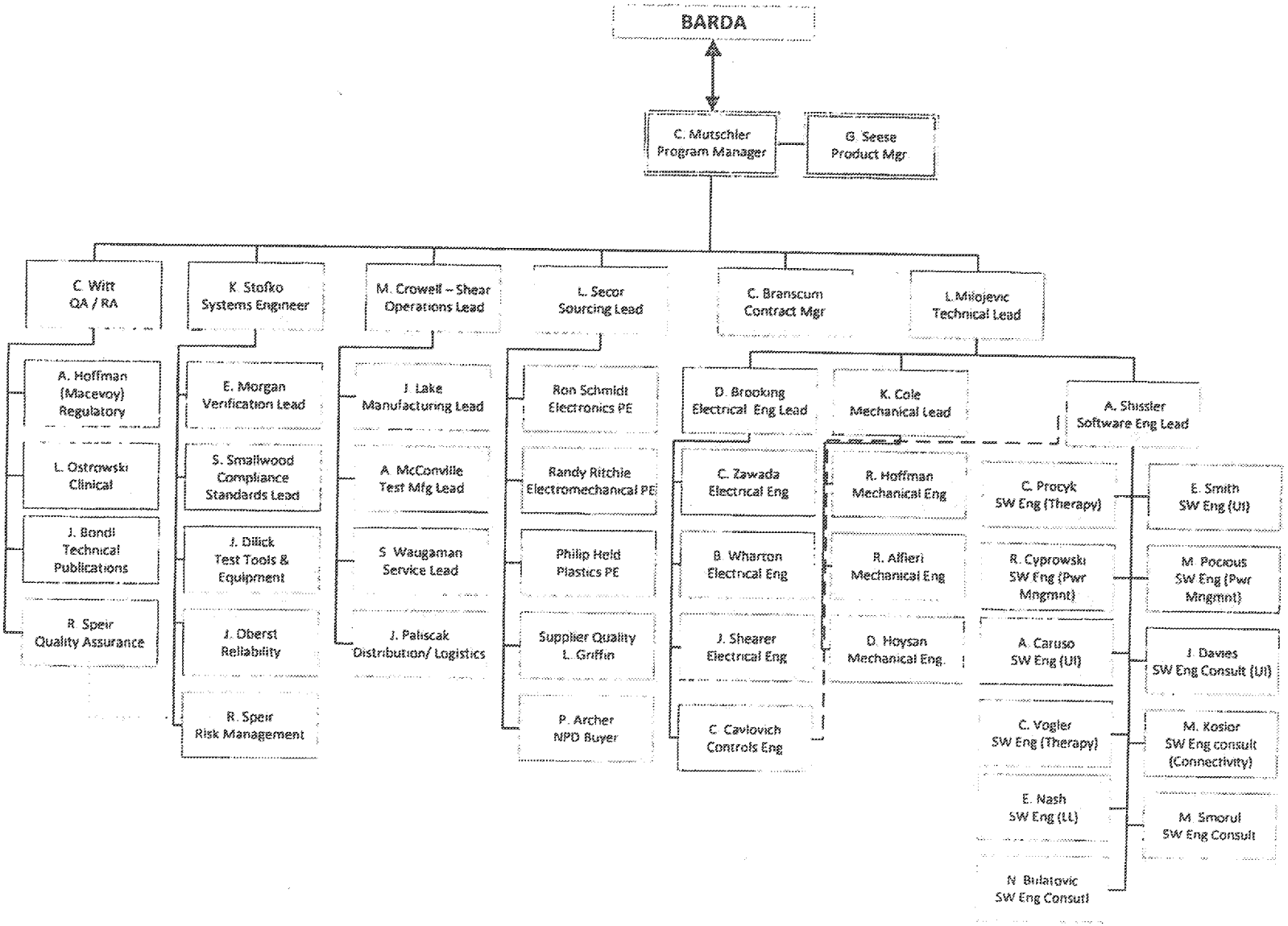
Attachment B: Cost Proposal

A. Cost Summary

Table 1 provides a cost breakdown by each Major Task by calendar year, using the same WBS numbering provided in the Technical Volume SOW.

Table 1: Project Cost Summary by Major Category and Year

	Year 1	Year 2	Year 3	Year 4	Total
Labor Grade M/SE (Hrs)	12,470.8	6,262.9	4,309.9	1.7	23,045.3
Labor Grade M/SE (Rate)	*$65.70*	*$67.67*	*$69.70*	*$71.79*	
Labor Grade E (Hrs)	34,811.8	28,697.4	17,607.1	11.3	81,127.6
Labor Grade E (Rate)	*$46.73*	*$48.13*	*$49.58*	*$51.06*	
Labor Grade T (Hrs)	4,673.0	3,047.8	771.2	0.0	8,492.0
Labor Grade T (Rate)	*$26.99*	*$27.80*	*$28.63*	*$29.49*	
Direct Labor Costs	**$2,572,211**	**$1,889,805**	**$1,195,374**	**$699**	**$5,658,090**
Material Costs	$195,121	$2,399,879	$360,000	$0.00	$2,955,000
Travel Costs	$0	$0	$0	$0	$0
Other Direct Costs	$414,854	$235,146	$70,000	$0	$720,000
Consultant Costs	$538,969	$371,497	$181,660	$0	$1,092,126
Total Direct Costs	**$3,721,155**	**$4,896,327**	**$1,807,034**	**$699**	**$10,425,216**
Indirect Costs	**$1,543,327**	**$1,133,883**	**$717,225**	**$419**	**$3,394,854**
Total Costs	$5,264,482	$6,030,210	$2,524,259	$1,118	$13,820,069
Fixed Fees	$0	$0	$0	$0	$0
Total Project Cost	**$5,264,482**	**$6,030,210**	**$2,524,259**	**$1,118**	**$13,820,069**



Attachment (2)

BARDA AAHSV
Deliverable List
Contract No. HHSO100201400005C
Date: August 17, 2016

ATTACHMENT 3

DELIVERABLES LIST

SOW Ref	Revised Due Date (from CA)	Deliverable	Description
3.1.1	3mo	Product Requirements Document	Specific product functional, environmental, safety, and regulatory requirements.
3.1.1	3mo	Quality Information	Historical quality information of related products, including CAPAs, MDRs, complaints, etc. Design Quality Engineering will work with Quality Systems to obtain the appropriate information.
3.2.1	3mo	Project Plan	Provides design and development plans, and captures strategies of functional groups.
3.2.2	3mo	Risk Assessment - Initial Hazards Analysis	Identifies potential harms, hazards, and risks which are classified by severity.
D.2.2.1.1	4mo	Requirements and Planning Review Minutes	Review held at the end of the Requirements and Planning phase.
4.1.1	5mo	System Architecture Document	Specifies the major components in the product and the external interfaces to other products, accessories, and/or users in their environments.
4.3.2	6mo	Hardware Specification Documents	Specifies electrical and mechanical sub- system requirements, including test and acceptance criteria where necessary.
4.1.2	6mo	User Interface Document	Describes the initial user interface with the device controls and displays.
4.3.3	6mo	Software Requirement Specification	Provides requirements associated with ventilator software, including details for test planning
Deliverable removed. Connectivity requirements are included in the PRD.			
Deliverable removed. Internal process documentation.			
This is part of our review process of the system architecture and will be referenced and captured as part of the formal technical review. This is not a standalone deliverable			
Output of document is captured in our PRD and other requirement documentation. This is not a standalone deliverable			
4.3.1	5mo	Risk Assessment - Detailed Hazards Analysis	Review and update the Risk Assessment from the previous phase to incorporate additional risks and control measures defined during system design activities.
4.4.1	6mo	Software Development Plan	Describes how engineering will develop software, including iteration plans, configuration management, and software quality assurance
4.4	6mo	Design Verification Plan	Describes the approach and specific testing that will be conducted for appropriate V&V and compliance testing. Will identify 3rd party test approach and gain BARDA approval
4.4	6mo	Reliability Plan	Sets out the reliability assurance activities that will be undertaken in conjunction with the development team to assure that that the design meets or exceeds its specified reliability goals
4.4	6mo	Risk Management Plan	Defines the specific project activities that will capture and assess safety risks, define and verify control measures.
4.4	6mo	Regulatory Plan	Presents the approach that will be taken to obtain any necessary regulatory approvals
4.4.1	6mo	Labeling Plan	Presents the approach to assure proper labeling and language translations for the anticipated market.
Deliverable removed. Optional informal internal documentation.			
4.4.1	6mo	Clinical Plan	Presents the general approach that will be used in the clinical analysis of the product.
4.4.1	6mo	Global Sourcing Plan	Plans for new suppliers, new 7.9, and/or new technologies.
4.4.1	6mo	Manufacturing Plan	Defines the plans for manufacturing to include activities for developing the facilities, processes, and equipment for production.
4.4.1	6mo	Service Plan	Plan to handle technical service for the products, including field repairs, spare parts, and service manuals. Includes development of training for service technicians. May also include product support.
4.4.1	6mo	Customer Support and User Training Plan	Provides initial plans for product launch to establish special requirements related to training materials for clinician and inexperienced care providers with limited or no respiratory training. .
4.4	6mo	Human Factors / Validation Plan	The Human Factors plan presents the planned human factors engineering (HFE) activities the project Planned activities are designed to ensure that the product is safe and effective for its intended use and ensure the usability of the product
D.2.2.1.2	6mo	Initial Product Cost Target Allocation	Captures initial product cost targets and allocates budget percentage across major architectural components.
D.2.2.1.2	6mo	System Design Review Minutes	Reviews the results of all the activities and issues associated with System Design to assure that the project is prepared to proceed into detailed design.
Removed because this is to verify that the BOM is properly loaded into SAP.			
This is part of the overall Build Report information and not a standalone deliverable.			
This is part of the overall Build Report information and not a standalone deliverable.			
5.1.3	12mo	EB1 Engineering Build Package & Report	Provides record of the configuration of engineering or pre-production devices, including design drawings, assembly process information, supply, and people considerations.
5.2.3	28mo	EB2 Engineering Build Package & Report	Provides record of the configuration of engineering or pre-production devices, including design drawings, assembly process information, supply, and people considerations.
5.3.4	28mo	EB3 Engineering Build Package & Report	Provides record of the configuration of engineering or pre-production devices, including design drawings, assembly process information, supply, and people considerations.
EB4 Design Approach Build should have been removed from the original contract SOW. There will be three Engineering Builds in the Detailed Design phase.			

BARDA AAHSV
Deliverable List
Contract No. HHSO100201400005C
Date: August 17, 2016

ATTACHMENT 3

DELIVERABLES LIST

SOW Ref	Revised Due Date (from CA)	Deliverable	Description
5.3.2	32mo	Software Design Descriptions	Describes the detailed design of the ventilator software including the definition of modules and their interfaces, including the Communication Means Device (CMD)
Design description included in the SDD. This is not a standalone deliverable.			
Build prodecures are part of the build or test reports. This is not a standalone deliverable.			
Build prodecures are part of the build or test reports. This is not a standalone deliverable.			
Release notes are part of the build reports. This is not a standalone deliverable.			
Release notes are part of the build reports. This is not a standalone deliverable.			
Duplicate. Formal Technical Design Review Records will be provided at the end of each build			
D.5.1	13mo	EB1 Technical Design Review Records	Documents the results of reviews, including a summary of what reviews were conducted (files, reviewers, issues). Includes code review meeting minutes
D.5.2	26mo	EB2 Technical Design Review Records	Documents the results of reviews, including a summary of what reviews were conducted (files, reviewers, issues). Includes code review meeting minutes
Deliverable removed. EB3 Technical Design Review is part of the Detail Design Review.			
EB4 Design Approach Build should have been removed from the original contract SOW. There will be three Engineering Builds in the Detailed Design phase.			
Code Review Meeting Minutes are included as part of the Technical Design Review Records. This is not a standalone deliverable.			
5.3.1	32mo	Hardware Design Descriptions	Describes the detailed design of the ventilator hardware including the definition of components, sub-assemblies and their interfaces.
5.1.1	32mo	Detailed Design Analysis (DFMEA for each sub-component identified)	Documents the analysis of the detailed designs, components, etc. May include multiple deliverables to cover electrical and mechanical analyses such as dFMEAs.
Removed deliverable. This is an internal check to verify that the return codes are loaded into SAP.			
5.6.2	32mo	Risk Assessment - Detailed Hazards Analysis and Mitigation Control Measures	Captures all risk controls identified in detailed design phase. Includes the following: Risk Matrix; Key Components List; Usability File; Product Security Risk Assessment, and Privacy Impact Assessment.
These are part of the Final Design Package and are not a standalone deliverable			
These are part of the Technical Design Reviews and are not standalone deliverables.			
These are part of the Technical Design Reviews and are not standalone deliverables.			
5.6.3	32mo	Design V&V Test Procedures	Documents the test procedures that will be used to verify product requirements. Add rows as necessary.
5.6.3	32mo	Design V&V Trace Matrix	Provides trace matrix between requirements and V&V activities, test procedures, reports. Add rows as necessary.
Reliability test results will be captured as part of the overall Verification test reports. This is not a standalone deliverable.			
Internal process to define format for DHR.			
D.5.5.1	32mo	Process Analysis (Process FMEA)	Identifies and assess potential manufacturing process risks as input to process validation plan and manufacturing quality plan. Detection methods are identified as part of the manufacturing procedures and instructions
D.5.5.1	32mo	Process Master Validation Plan (MVP)	Documents the process flow and the test requirements to validate the manufacturing equipment, process and instructions. It also includes the aspects related to the servicing process, equipment and instructions
D.5.5.1	32mo	High Volume Surge Capable Mfg. Plan	Document includes plans to prepare facilities, tooling, and capabilities to meet the surge capacity demand of 1,700 units per month and deliver 10,000 units in 6- months.
Documentation that would be included as part of the Pre-Pilot build report and final Device Master Record. This is not a standalone deliverable.			
Documentation that would be included as part of the Pre-Pilot build report and final Device Master Record. This is not a standalone deliverable.			
Documentation that would be included as part of the Pre-Pilot build report and final Device Master Record. This is not a standalone deliverable.			
Documentation that would be included as part of the Pre-Pilot build report and final Device Master Record. This is not a standalone deliverable.			
Deliverable removed this is an internal process.			
This will be provided in association with each build report package. This is not a standalone deliverable.			
These are provided as part of the final design package. This is not a standalone deliverable.			
5.4	48mo	Lay Caregiver & Clinical Training Materials (Marketing Literature)	Captures literature that complies with all applicable requirements with regard to legibility, accuracy, product claims, educational materials, and user understanding.
5.4	36mo	Manual / Instructions for Use (Labeling)	Review and approve device and packaging labels, artwork, and drawings, manuals, inserts, etc.
5.5.3	36mo	Service and SNS Maintenance Manual and Plan	Provides the technical information for how to service and repair the device.
Duplicate. Labeling is captured in Product Structure and BOM			
Captured as part of DHF. This is not a standalone deliverable.			
Deliverable removed. Internal process documentation.			
Deliverable removed. Internal process documentation.			
D.2.2.2.3	32mo	Product Cost Estimates	Captures estimated component and assembly costs based on design documentation produced in the detailed design phase.

BARDA AAHSV **ATTACHMENT 3**
Deliverable List
Contract No. HHSO100201400005C
Date: August 17, 2016

DELIVERABLES LIST

SOW Ref	Revised Due Date (from CA)	Deliverable	Description
D 2.2.2 3	32mo	Detailed Design Review Minutes	Reviews items associated with Detailed Design phase.
6 1	36mo	PP1 Engineering Build Report	Provides record of materials used, procedures, personnel involved, dates, and traceability information for engineering pre-production devices. Include production equivalency analysis?
6.2	36mo	PP1 Design Verification Report	Provides a record of all verification testing, including configurations tested, as run procedures, results, and conclusions. Add rows as necessary to identify the deliverables/reports. Testing completed by agreed USG upon independent third party testing facility
6.2	36mo	PP1 Validation and Human Factors Test Report	Presents the results of Validation and Human factors testing as captured in the V&V and Human Factors plan.
D 6.2	36mo	PP1 Validation and Human Factors Test Report	Presents the results of Validation and Human factors testing as captured in the V&V and Human Factors plan.
This is part of the Final PP1 Verification Report and is not a standalone deliverable.			
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This is part of the Final PP1 Verification Report and is not a standalone deliverable.			
6.7.2	42mo	Risk Assessment Hazards Analysis and Verification	Risk Matrix; Update Key Components List; Update Usability File, Product Security Risk Assessment, Privacy Impact Assessment
D.2.2.1.4	40mo	Updated Cost Estimates	Captures updated estimated component and assembly costs based on design documentation updates produced in the verification design phase
D.2.2.1.7	40mo	Verification Review Meeting Minutes	Reviews items associated with Design Verification phase.
D.6.6.2.4	41mo	Process Validation Records	Protocols and reports that validate the manufacturing equipment, procedures and process (IQ, OQ, and PQ)
Deliverable removed. Internal process documentation.			
6.6.2	41mo	Design Validation Report	Documents the results of validation activities. Add rows as necessary to identify the deliverables/reports
Deliverable removed. Clinicals will not be conducted on this program.			
6.7.2	42mo	Final Risk Assessment	Risk Matrix; Update Key Components List; Update Usability File, Product Security Risk Assessment, Privacy Impact Assessment
D.2.2.1.4	42mo	Validation Review Meeting Minutes	Review meeting minutes held at the end of Design Validation phase.
D6	42mo	Final Device Master Record	Documents that captures full published technical and performance specifications of the ventilator system. Sub set of product requirements document. Typically captured as part of the operators manual.
D.2.2.1 5	42mo	List of Known/ Deferred Defects	Documents the known defects that are deferred and the rationale for releasing product with these defects.
These are part of the DMR and are not a standalone deliverable.			
D.6.6.3.4	42mo	Process Master Validation Report	MVP report to include status of all process validation activities.
Deliverable removed. This is not needed for domestic release.			
D.5.6	42mo	Design History File Index	Index of all design history file documents
Deliverable removed. Internal process documentation.			
Deliverable removed. Internal process documentation.			
This has been removed because this already exists in the negotiated option to purchase 10,000 units.			
D.2.2.1 5	42mo	Final Design Review Meeting Minutes	Document meeting minutes of Final Design Review held at the end of the Design Transfer phase
D.2.1	42mo	Final Report	Final program report to BARDA. Summary of all relevant project deliverables, actual project budget, and actual project schedule.

n/a	42mo	Device Master Record	Full Recipe to build device – Reference Drawings, Assy, Test
5.1.4	16mo	One Ventilator Prototype	EB2 Prototype Unit
6 1	29mo	One Ventilator Prototype	PP1 Production Prototype Unit
6.6.2	42mo	One Ventilator Prototype	Released Patient Ready Prototype Unit Fully Kitted Final Configuration

ATTACHMENT 4

Statement of Work

Philips Advanced All-Hazards Stockpile Ventilator

A. Background

Philips will develop the AAHSV based on its' FDA-cleared Trilogy platform, approved for facility and home use, while integrating an advanced suite of features to meet BARDA needs. Philips has proven experience in developing portable ventilators based on its market-leading Trilogy ventilator platform. Trilogy offers many of the capabilities required by BARDA, and demonstrates Philips' capabilities not only in feature delivery, but also advanced design, development, validation, and full-scale deployment.

The following table summarizes these changes:

Improved Blower design	WIFI Compatible
Simplified architecture and PCA reduction	Dual Limb Compatibility
Enhanced Li-Ion Batteries with increased battery life	Wider Temperature Range
Integrated Oxygen Blender Module (OBM)	Lower Tidal Volume Range
Capnostat Connectivity Packaging enhancements	Touchscreen User Interface

B. Introduction

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to Broad Agency Announcement (BAA) BARDA 11-21.

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. Because of the nature of this (R&D) contract and complexities inherent in this and prior programs, at designated milestones of the government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. In any event, the Government reserves the right to change product, process, schedules, or event to add or delete part of all of these elements as the need arises.

The PDP development process and Philips' quality system meets the requirements of 21 CFR Part 820 Quality System Regulation, Good Manufacturing Practice for Medical Devices.

C. Scope

The scope of the BARDA funded R&D effort to develop the AAHV begins initial planning (phase III), and quickly moves to focus on the Product Realization stage (Phases IV-VI) of Philips' PDP. The goal of this project is to create a ventilator design that meets all BARDA requirements, establish manufacturing capability to produce the ventilator, and secure FDA clearance for the device. Production tooling and manufacturing facilities to produce the

AAHSV will be funded and owned by Philips. Several tasks in Phases II and III will be completed prior to project inception.

The proposed work plan is divided into phases that correspond with the PDP (Table 11). The specific tasks, milestones, and deliverables for each of the Phases to be performed in this BARDA project are detailed below.

Phase III	Phase IV	Phase V	Phase VI
Requirements & Planning	System Design	Detailed Design	Verification & Validation (V&V)

Table 11: The Work Phases of Philips AAHSV BARDA Project

D. Task Area Breakdown

The tasks contained in this Statement of Work are classified according to Philips PDP:

ID	Task Name	Year 1												Year 2												Year 3												Year 4		
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
2	Program Management																																							
2.1	Program Management																																							
2.2	Technical Direction																																							
3	Phase 3 Requirements & Planning																																							
3.1	Product Requirements & Risk Assess																																							
3.2	Project Planning Development																																							
4	Phase 4. System Design																																							
4.1	Preliminary System Investigations																																							
4.2	Project Planning																																							
4.3	System Architecture																																							
4.4	System Req and Risk Assessment																																							
5	Phase 5 Detail Design																																							
5.1	EB1 Initial Design																																							
5.2	EB2 Detailed Design																																							
5.3	EB3 Final Engineering Build																																							
5.4	Manuals & Labeling																																							
5.5	Quality & Regulatory																																							
5.6	Operations Development																																							
5.7	Supply Chain Development																																							
5.8	Reliability																																							
5.9	System Engineering																																							
6	Phase 6: Design V&V and Transfer																																							
6.1	V&V Engineering Support																																							
6.2	PP1																																							
6.3	PP2 Supplier Process Qual Build																																							
6.4	510(k)																																							
6.5	Final Design Verification																																							
6.6	Pilot Build																																							

WORK BY SCHEDULE

WBS 3: Phase 3 Requirements & Planning:

Product Requirements:
Contractor will deliver a Product Requirements Document (PRD). The objective of the PRD is to capture the design input for the product design which would be the basis for required verification & validation activities. The PRD will capture all required industry standards and directives necessary to support regulatory submittals; international registrations (if required); North America safety agency listings; and European CE marking requirements (if required) for the product. Key inputs to the Product Requirements document are BARDA BAA-11-100-SOL-00021, Philips Advanced All-Hazards Stockpile Ventilator Full Proposal, and Historical Quality Information on Ventilator devices.

Requirements Review:
Contractor will conduct reviews of the product requirements document with BARDA and provide a final draft document for formal review and approval. The objective of this review is to assure that BARDA and Philips are aligned with the intended product scope and to address incomplete, ambiguous, or conflicting requirements. Key inputs to this review would be the Product Requirements Document.

Project Plan:
Contractor will generate a Project Plan. The objective of the project plan is to describe the design and development activities and define responsibility for implementation. This initial release of the project plan will establish a top-down schedule based on the Philips Advanced All-Hazards Stockpile Ventilator SOW and known product requirements. Initial resource and budgets requirements will be allocated across identified work breakdown structures.

Initial Risk Analysis:
Contractor will generate an initial risk analysis document. The objective of the initial risk analysis document is to identify potential hazards and risk classified by severity. The contractor's process in completing this deliverable will comply with ISO 14971 Medical devices – Application of risk management to medical devices. Key inputs to the Initial Risk Analysis are the Product Requirements Document.

WBS 4: Phase 4 Design & Development:

System Architecture:
The contractor will generate a system architecture document. The objective of the system architecture is to specify the major components in the product and the external interfaces to other products, accessories, and / or users in their environments. Key inputs to the system architecture are a completed product requirements document.

System Design Approach:

Contractor shall complete a sub-system design of major architectural components, an initial product form, and initial User Interface. The objective of the initial system design approach is a risk reduction activity to confirm that major architectural decisions made can meet the product requirements within budget and schedule constraints. Key inputs to the System Design Approach are the System Architecture Document, Product Requirements document, and Project Plan.

Safety & Reliability:
Contractor will generate a system level failure mode effects analysis (FMEA) and detailed hazard analysis. The objective of the system level FMEA is to describe the failure modes, effects, and criticality of the major architectural components as defined in the System Architecture document. The process will be used to help identify risks and additional controls needed at a system level. The objective of the detailed hazard analysis is to incorporate additional risks and control measures defined during system design activities. The risk assessment is updated with specific events that would expose hazardous situations that would cause the Harms. The contractor's process in completing this deliverable will comply with ISO 14971. Key inputs for both the System FMEA and Detailed Hazard Analysis are the System FMEA and initial design approach.

Hardware Requirements:
Contractor will generate detailed sub-system hardware requirements. The objective of the sub-system hardware requirements is to establish allocation of key product requirements to the appropriate sub-system. The document provides design direction and basis for verification for specified subsystems. Key inputs to the hardware requirements are the PRD, Risk Assessment, and System Architecture. Contractor will provide BARDA a draft for review and comment.

Software Requirements:
Contractor will generate detailed software requirements. The objective of the software requirements is to establish allocation of key product requirements to the appropriate software modules. The document provides design direction and basis for verification for specified software modules. Software requirements will be generated in compliance with IEC 62304 Medical device software – Software lifecycle processes. Key inputs to the software requirements are the PRD, Risk Assessment, and System Architecture. Contractor will provide BARDA a draft for review and comment.

PRD Updates and Sub-System Trace Analysis:
Contractor will update and release Product Requirements Document (PRD) for detailed design phase and generate a trace matrix that provide links from PRD requirements to sub-system requirements. The objective of this PRD release is to update the document with specified controls as identified by the risk process, clarifications from generation of sub-system requirements, and any new requirements as identified during the system design phase. The trace matrix will assure that there are clear links and allocations of system

requirements to the subsystems. Key inputs are the initial PRD, Risk Assessment, and initial sub-system requirements.

Project Management & Planning:
Contractor will make an update to the project plan and generate the following detailed functional plans prior to closure of the System Design phase:

- Design Verification & Validation Plan
- Risk Management Plan in accordance with ISO 14971 Medical devices - Application of risk management to medical devices
- Software Development Plan in accordance with IEC 62304 Medical device software - Software lifecycle processes
- Regulatory Plan
- Clinical Plan
- Global Sourcing & Manufacturing Plan
- Service Plan
- Human Factors Plan in accordance with IEC 62366 Medical devices - Application of usability engineering to medical devices
- Reliability Plan
- Labeling Plan

The objective of the project plan updates and initial functional plans are to finalize a bottoms-up schedule, generate an engineering build plan, and capture activities associated with the detailed design phase of development. The engineering build plan will describe the functional requirements planned for each build and an initial estimate of the quantity of units and sub-systems needed for each build. Key inputs are the PRD, Sub-System Requirements, and System Architecture Document. BARDA will be provided opportunity to review and approve plans prior to closure of the System Design Phase.

WBS 5: Detailed Design:

WBS 5.1 EB1: Initial Design & Subsystem Prototype

EB1 Hardware Design:
Contractor will generate updated hardware requirements and initial hardware design documentation per the engineering build plan. Objective is to release documentation that will be used to procure components for Engineering Build 1. Key inputs are the engineering build plan and hardware requirements.

EB1 Software Design:
Contractor will generate updated software requirements and initial documented software design and code per the engineering build plan. Objective is to release software

documentation and code that will be used to support the EB1 and EB2 builds. Key inputs are the engineering build plan and software requirements. Contractor will provide BARDA a draft for review and comment.

EB1: Sub-System Prototype Build:
Contractor will build physical sub-system prototypes per the engineering build plan for EB1. The objective of this build is to provide sub-systems and prototypes that will be used for EB1 engineering testing. Key inputs are the Initial Software and Hardware design documentation.

EB1 Engineering Testing:
Contractor will perform and generate test results for functional testing, reliability testing and human factors formative testing per the engineering build plan for EB1 phase. The objective of engineering testing is to reduce technical risk by supporting early verification as the design evolves. Key inputs are the EB1 subsystems, Software Code, and Engineering test protocols.

PRD Updates and SRD Updates:
Contractor will update and release Product Requirements Document (PRD) and System Requirements Document (SRD). The objective of these releases is to update the document with specified controls as identified by the risk process, clarifications from generation of sub-system requirements, and any new requirements as identified during the detail design phase. The trace matrix will assure that there are clear links and allocations of system requirements to the subsystems. Key inputs are the initial PRD, initial SRD, Risk Assessment, and initial sub-system requirements.

Design V&V and Reliability Support:
Contractor will generate a master verification and validation plan, usability specification, reliability testing, and security assessment. The objective of the master verification and validation plan is to outline all required test activities for the formal V&V phase 6. Key inputs are PRD and SRD.

WBS 5.2 EB2: Initial Design & Subsystem Prototype

EB2 Hardware Detailed Design:
Contractor will generate updated hardware design documentation for defect resolution and new design documentation per the engineering build plan. The objective is to release documentation that will be used to procure components for Engineering Build 2. Key inputs are the engineering build plan, hardware requirements, and defects found in EB1 Testing.

510 (k) Software Detailed Design:
Contractor will generate updated documented software design and code for defect resolution and new code per the engineering build plan. Objective is to release software

documentation and code that will be used to support the 510(k) testing. Key inputs are the engineering build plan, software requirements and defects found in EB1 testing.

EB2 System Integration Build:
Contractor will build system prototypes per the engineering build plan for EB3. The objective of this build is to provide systems and sub-systems that will be used for Engineering and V&V Testing. Key inputs are the EB1 Software and EB2 Hardware design documentation.

EB2 Engineering Testing:
Contractor will perform and generate test results for functional testing and engineering clinical testing per the engineering build plan for EB2 phase. The objective of engineering testing is to reduce technical risk by supporting early verification as the design evolves. Key inputs are the EB2 subsystems, Software Code, and Engineering test protocols.

WBS 5.3 EB3: Initial Design & Subsystem Prototype

EB3 Hardware Detailed Design:
Contractor will generate updated hardware design documentation for defect resolution and new design documentation per the engineering build plan. The objective is to release documentation that will be used to procure components for V&V Testing. Key inputs are the engineering build plan, hardware requirements, and defects found in EB2 Testing.

EB3 Final Engineering Build:
Contractor will build production equivalent systems and accessories per the engineering build plan for EB3. The objective of this build is to provide systems and accessories that will be used for EB3 engineering testing. Key inputs are the EB1 Software, 510(k) Software and Hardware design documentation.

EB3 Engineering Testing:
Contractor will perform and generate test results for functional testing; initial standards, safety & EMC testing; reliability testing; human factors formative testing; and engineering clinical testing per the engineering build plan for EB3 phase. The objective of engineering testing is to reduce technical risk by supporting early verification as the design evolves. Key inputs are the EB3 subsystems, Software Code, and Engineering test protocols.

Contractor will generate final engineering design documentation that will address remaining defects from all engineering testing. Engineering documentation will be used to build (or update) systems for official phase 6 verification and validation activities.

WBS 5.4 Manuals & Labeling

Manual & Labeling Development:
Contractor will generate clinical and lay caregiver training materials, instructions for use, quick start guides, device labels, and packaging labels. Device instructions for use, device labels, and packaging labels will meet requirements and standards as identified in the PRD. Training materials will be developed to support the specific needs of the BARDA product and identified end users. Key inputs will be the PRD and clinical support.

WBS 5.5 Quality & Regulatory

Regulatory & Clinical Support:
The contractor will provide regulatory review and approval of specified documentation and clinical support as needed throughout the project. This task captures the effort needed to maintain these reviews and approvals. No specific deliverable is captured in this WBS element.

WBS 5.6 Operations Development

Philips will fund Operations & Manufacturing activities for procurement of production tooling, procurement of fixtures and manufacturing line.

WBS 5.7 Supply Chain Development

Supply Chain Development:
Contractor will assure that all identified suppliers are qualified and all component parts have key process characteristics and initial material qualification agreements in place. The objective of this task is to ensure that all procured material conforms to specified requirements. Key inputs are Component Specifications. Contractor's process will comply with 21 CFR Part 820.50.

WBS 5.8 Reliability

Reliability:
Contractor will generate a reliability plan. The objective of the reliability plan is to outline all required test activities to verify reliability. Key inputs are complete requirement documentation.

WBS 5.9 System Engineering

Risk Assessment: Mitigation Control Measures:

Contractor will generate an updated risk assessment including required mitigation control measures and develop necessary complaint handling codes. The objective of the risk assessment updates are to assure that controls are in place and verified for any risks determined to be unacceptable. All risk controls are considered design input requirements and will be linked to a requirements document to assure full verification. Key inputs to this task are the final requirement specifications to assure coverage.

Design V&V and Reliability Support:
Contractor will generate a master verification and validation plan, V&V protocols, and Design V&V Trace Matrix. The objective of the master verification and validation plan is to outline all required test activities for the formal V&V phase 6. The design V&V Trace matrix will assure full coverage of all requirements to specified test protocols. Key inputs are complete requirement documentation.

Product Requirements and System Requirements Updates:
Contractor will update a Product Requirements Document (PRD) and System Requirements Document (SRD). The objective of these documents is to capture the design input for the product and system design which would be the basis to for required verification & validation activities. The PRD will capture all required industry standards and directives necessary to support regulatory submittals; international registrations (if required); North America safety agency listings; and European CE marking requirements (if required) for the product. Key inputs to the Product Requirements document are BARDA BAA-11-100-SOL-00021, Philips Advanced All-Hazards Stockpile Ventilator Full Proposal, and Historical Quality Information on Ventilator devices.

Requirements Review:
Contractor will conduct reviews of the product requirements document with BARDA and provide a final draft document for formal review and approval. The objective of this review is to assure that BARDA and Philips are aligned with the intended product scope and to address incomplete, ambiguous, or conflicting requirements. Key inputs to this review would be the Product Requirements Document.

WBS 6: Verification & Validation:

Software Design:
Contractor will generate updated documented software design and code per the engineering build plan. Objective is to release software documentation and code that will be used to support final V&V testing. Key inputs are the engineering build plan, software requirements and defects found in V&V testing.

PP1: Pre-Pilot Build #1:
Contractor will execute a Pre-Pilot Build (PP1) to support verification and validation activities. The objective of the PP1 build is to product production equivalent units for the

purpose of formal product V&V testing. Key inputs are a V&V plan, production equivalent devices, and a validated manufacturing process.

PP1 Design Verification & Validation Testing:
Contractor will deliver a Design Verification Report and a Design Validation Report. The objective of these reports is to demonstrate that the design complies with all product requirements (note: the V&V test results may be combined into a single report). Key inputs are V&V Test Plans and Test Procedures. Contractor's process for this testing will comply with 21 CFR Part 820.30.

PP1 Design Iterations and Defect Resolution:
Contractor will establish a process to manage issues that arise during the Verification & Validation (V&V) of the product. The objective of this process is to ensure that all issues identified during V&V testing are adequately resolved or otherwise disposition prior to product release. Design documentation will be updated as needed. Key inputs are a V&V test plans, and a process for tracking and closing issues identified during V&V testing.

PP2: Pre-Pilot Build #2:
Contractor will build updated production equivalent units based on design iterations required to resolve defects identified during testing of PP1 units. The objective of this build is to provide production equivalent units for the purpose of formal product V&V testing. Key inputs to the PP2 build are a V&V plan, production equivalent devices, and a validated manufacturing process.

PP2 Final Design Verification & Validation Testing:
If design changes are made after PP1 V&V testing is completed, Contractor will execute an additional round of V&V Testing (PP2) and deliver a Final Design Verification Report and a Design Validation Report (note: the V&V test results may be combined into a single report). The objective of this report is to demonstrate that the design complies with all product requirements. Key inputs are V&V Test Plans and Test Procedures. Contractor's process for this testing will be in compliance with 21 CFR Part 820.30.

Supply Chain Qualification:
Contractor will execute agreements with subcontractors providing material to support the Pilot Build of the product. The agreements will outline deliverables and activities required to demonstrate the subcontractor's ability to provide conforming product on a reliable basis. Key inputs are Sourcing Plan and Component Specifications. The contractor's process will comply with 21 CFR 820.50.

Pilot Build & Process Qualification:
Contractor will conduct a Pilot Build and qualify the processes required to support that build. The objective of the Pilot Build is to demonstrate readiness to transfer the design from Engineering to a manufacturing organization and to confirm that the manufacturing process generates products that complies with requirements.

Key inputs are a verified and validated design, and process validation plans. Contractor's process will comply with 21 CFR 820.70.

Regulatory Approval:
Contractor will prepare, submit and gain 510(k) clearance for ventilator and system accessories. Contractor will obtain regulatory approval of the device. The objective of the plan is to gain 510(k) clearance of for the ventilator and system accessories. Key inputs are the product requirements document, Regulatory Plan, and V&V Test Reports.

Final Risk Assessment: Hazard Analysis and Verification:
Contractor will provide a final risk assessment that verifies and ensures all final mitigation controls (design and/or manufacturing process). Contractor will update the initial risk analysis document to a final state. The objective of the final risk analysis document is to ensure all final risk mitigations and controls are in place. The contractor's process in completing this deliverable will comply with ISO 14971 Medical devices – Application of risk management to medical devices. Key inputs to the Initial Risk Analysis are the Product Requirements Document and System Architecture Document.

WORK BY FUNCTION

D2. Program Management

Philips intends to provide all administration and operations responsibilities required to support the AAHSV development project throughout its duration. This includes, but is not limited to the following tasks across the entire project:

- Delivery of all required BARDA Reporting
- Facilitator of Internal Milestone & Gate Meetings
- Contract Management & Administration
- Engineering Documentation Services

D.2.1. BARDA Reporting

Philips will comply with the finalized reporting requirements associated with the AAHSV development project. Philips will appoint an experienced, government reporting manager. The Government reporting manager will be charged with managing and tracking BARDA requirements including communications and reporting. In addition, the Program Manager for the AAHSV program will support this function.

- Monthly Earned Value Management Report
- Monthly Technical Progress Reports
- Monthly BARDA Update Meetings
- In Process Review Meetings (IPRs)

- Yearly Program Report
- Final Program Report

D.2.2. Internal Milestones and Phase Gate Meetings

As described in our previous submission the Philips Product Development Process (PDP) includes several project phases. Each project phase has specific objectives, deliverables and requirements that establish criteria for completion and mark progress towards achieving the key development objectives. Each phase of the Program includes a milestone design review and ends or is closed out with a Formal Gate Review. During this review a cross-functional team evaluates progress against plan and confirms the quality and completeness of the phase deliverables.

D.2.2.1. Internal Reviews

D.2.2.1.1. Requirements & Planning Design Review

During the Requirements and Planning Design Review, the overall risk of the program is assessed and throughout the program risks are continuously identified, assessed, and catalogued. Any factors that are considered high-risk are immediately brought to the attention of program managers and addressed immediately. However, at this design review, the overall spectrum of risks are assessed as a whole and evaluated. Each risk is linked to overall program objectives and assessed according to impact on the requirement, severity, and timing. Although not all risks must be resolved at this phase, the overall risk profile must be judged acceptable. If any core requirement appears to be at risk of being met, additional technical development or non-technical mitigation steps, such as resourcing, planning, or training, will be performed to resolve the issue.

D.2.2.1.2. System Design Review

The first system design review is designed to verify the prototype proof-of-concept relative to system requirements. By breaking down and assessing the performance of each subsystem as well as analyzing the general approach, an assessment is made of the likelihood of delivering the top-level specifications and program objectives. This assessment is based on a formal gap analysis relative to project objectives and system requirements. If any major objectives, including cost, quality, and schedule are not being met, Phase IV tasks will be revisited until objectives are met, or a decision to terminate the project is made.

D.2.2.1.3. Detailed Design Review

Creation of the detailed design is an iterative process, and represents one of the most substantial individual tasks in the program. Whereas many subsystems and the engineering build prototypes may still exist in breadboard format, in this stage, the complete device package is designed and developed. The detailed design includes many sub-tasks, including optimizing subsystems for costs, manufacturability, and quality.

In Detailed Design Review, a *Design Freeze* indicates when the formal design process is complete. This means that engineering has demonstrated that the design meets all project requirements and objectives. After the Design Freeze, a formal Design Change Tracking process will be initiated to track the justification and impact of design changes through full launch.

D.2.2.1.4. Design Verification & Validation (V&V) Review

A preliminary design review is performed to assess the EQT data and determine if the design is ready to transition into V&V. A V&V equivalent set of testing protocols must be developed and successfully executed to pass the design review. If any failed requirements or other risks are identified, additional iterations of EB, EQT, and DR will be performed.

During the Verification and Validation (V&V) review, the team reviews the results of V&V activities, and ensures that all V&V activities are complete. Successful completion of this review initiates the Pilot Run.

D.2.2.1.5. Final Design Review

A final design review is performed once the full set of documentation for Phase V is collected and reviewed. This formal design review captures the reasons and justification for approving production. The final design review entails a full, complete assessment of device functionality and quality. Based on the detailed design package, updated Risk Register, and detailed business case, the team will approve capital allocation for manufacturing and initiation of V&V.

In this review, the team also verifies that all defects have been resolved. A complete program review is conducted to verify all program objectives have been met. This design review is intended to assess readiness prior to product launch. This review will show that the battery of testing is appropriate, complete, and correctly implemented/performed.

D.2.2.2. Gate Meetings

D.2.2.2.1. GATE 3: Project Approval

The program will pass through this gate when product requirements and the Project Plan are established and when they balance technical feasibility and program objectives with an acceptable level of risk. Risks must be appropriate given the stage of development. If any objectives are not met, or if any risks rise above an acceptable level, prior steps or deliverables in Phase III will be repeated or refined until objectives are met.

D.2.2.2.2. GATE 4: System Design Approval

The preliminary system design review assesses the deliverables and any new risks or other issues to determine if the overall business case justifies continuing the project. The program may pass through this gate when it is suitably demonstrated that the design meets system and subsystem requirements as well as aligns with project objectives around cost, quality, and schedule. Risks are again assessed to ensure an appropriately low risk burden is being carried forward. If any objectives are not met, or if any risks rise above an acceptable level, prior steps or deliverables will be repeated or refined until objectives are met.

D.2.2.2.3. GATE 5: Detailed Design Approval

Approval of the design launches formal V&V efforts. Complete EQT test data in conjunction with completion of the full list of Phase V deliverables provide assurance that the device is ready for formal V&V.

This formal design review captures the reasons and justification for approving production. The final design review entails a full, complete assessment of device functionality and quality. In this review, the team verifies that all defects have been resolved. A complete program review is conducted to verify all program objectives have been

met. This design review is intended to assess readiness prior to product launch. This review will show that the battery of testing is appropriate, complete, and correctly implemented/performed.

D.2.2.2.4. GATE 6: Production Approval

Formal full market release may not occur immediately. A limited launch, such as for one specific customer, one country, or one market, may precede full market release. Pilot units may be delivered to the launch segment to gather additional feedback. Gate 6 is then used to review the data and approve full launch. Given the transition from R&D to acquisition contracting for BARDA, this is a likely route for launch.

D.2.3. Contract Management & Administration

This work element captures the time allocation for all necessary administrative support functions throughout the duration of the Program.

D.2.4. Engineering Documentation Services

As listed in the Deliverables Scheduled found in Section VI, several documents are required throughout the project. The primary function of this work element is to support the creation and updating of these documents through the Program. This task ensures all program documents, such as the bill of materials, design documents, testing results, etc. are linked together.

In addition, the Engineering Change Order (ECO) Release is the administrative product release. It serves as a checklist and, after launch, is the repository for any documents associated with development of the product. Release of the ECO includes independent reviews to ensure documentation is in order and complete. A regulatory checklist is also performed to ensure that all files are updated, complete, and accurate. Effectively, the ECO release is a documentation audit. After ECO release, the product is officially launched, and an acquisition contract would trigger the product build.

D3. Phase III: Requirements and Planning

Please Note: A complete breakdown of all Phase III Program Deliverables has been provided in Section V: Deliverables Schedules.

During Phase III, Philips will create a detailed project plan including formal, testable product requirements, functional plans for regulatory approval (FDA and worldwide), as well as clinical strategies. Parts of Phase III have been completed to support generation of Philips' full BARDA submission. Additional steps are currently underway.

D.3.1. Product Requirements Document

Philips will generate a Product Requirement Document (PRD) for BARDA's approval. This document will serve as the master document of the product design requirements that are traced to verification and validation. A formal review with BARDA will be conducted to facilitate the approval of the final PRD. D.3.2. Project Planning Development

The Project Plan provides specific tracking metrics, milestones, review and documentation plans, communication strategies and detailed strategies that outline Regulatory, Reliability, Sourcing, Verification and Validation (V&V), Clinical, Manufacturing and Engineering objectives/activities. Concurrently, the design team initiates design and testing activities to establish proof of concept prototypes aimed at proving concepts and identifying and mitigating risks. The Planning Phase closes with the completion of the Requirements and Planning Design Review.

Additionally, the Initial Risk and Hazards Analysis are completed during this task. The core philosophy is based on assessing and reducing program risk. Tasks are organized according to their risk profiles in order to mitigate risk as quickly as possible. This is consistent with Philips' philosophy of designing-in quality, rather than to develop a project and then test-in quality later. Once the overall development program is created, top-level requirements are linked to the plan. The project plan is built around the development strategy.

D4. Phase IV: System Design

Please Note: A complete breakdown of all Phase III Program Deliverables has been provided in Section VI: Deliverables Schedules.

In Phase IV, the development team considers multiple design approaches then creates a System Architecture that breaks down the high-level requirements into specific sub-system requirements. A preliminary system design is chosen which forms the baseline for the detailed design in Phase V. Bottom-up engineering technical testing plans are created to verify the design. Sub-system technical reviews also occur, which enable architecture reviews for each subcomponent.

D.4.1. System Architecture and Requirements

D.4.1.1. System Architecture Document

Philips will create a System Architecture Document which specifies the major components in the product and the external interfaces to other products, accessories, and/or users in their environments.

D.4.1.2. System Design Approach

This task begins the formal device development work. The system is broken down into architectural components and sub-systems. Engineering teams will consider multiple approaches to meet both product and sub-system requirements. Subsystem teams are defined during Phase IV, and may include:

- Pneumatic Control & Delivery Design Approach
- Connectivity & Logging Design Approach
- Power Management Design Approach
- Therapy Design Approach
- Enclosure & Mechanical Packaging Design Approach
- Product Industrial Design & Human Factors (GUI Design Approach, Physical Interface Design, and Human Factors Task Analysis)

D.4.2. Sub-System Requirements and PRD Updates

In this task, the technical teams take the top level requirements found in the PRD and break them down into subsystem requirements. The outcome of this task is a series of subsystem specification documents that are traceable to the top-level PRD. Specification documents are created in parallel with preliminary design efforts. The technical staff collaborates with subsystem architects to develop working prototypes in parallel with defining and refining subsystem specifications.

D.4.2.1. Safety & Reliability

During this phase, the following safety reliability activities occur:

- Development, Review, and Approval of the System Level FMEA
- Risk Assessment: Detailed Hazard Analysis from previous Phases

These safety assessments of the system design drive additional control measures that are captured in the PRD and sub-system requirements.

D.4.2.2. Hardware Requirements Specification

Philips will provide a Hardware Requirement Specification that details the electrical and mechanical sub- system requirements, including test and acceptance criteria where necessary.

D.4.2.3. Software Requirements Specification

Philips will provide a Software Requirement Specification that lists all requirements associated with software, including details for test planning.

D.4.2.4. PRD Updates and Final Sub-System Trace Analysis

After each review of a document, all updates are incorporated into the appropriate documents and then a final Sub-System Design Trace Matrix is approved.

D.4.3. Project Management & Planning

D.4.3.1. Functional Support Plans

Detailed Functional Support Plans are generated in order to define and detail the steps necessary to be taken to successfully launch. This includes both design and validation tasks. In particular, manufacturing plans and supplier requirements and validation must be tightly integrated to ensure efficient transition from design to manufacturing. The following plans are developed during this task:

- Engineering Development Plan
- Software Development Plan
- Design Verification and Validation Plan
- Reliability Plan

- Risk Management Plan
- Regulatory /Labeling Plan
- Standards Requirements
- Industrial Design Plan
- Clinical Plan
- Sourcing Plan
- Manufacturing Plan
- Defect Investigation Plan * Service and Support Plan
- Initial Launch Plan

D.4.3.2. Engineering Build & Detailed Design Planning

In preparation for the next phase, Philips will capture all activities associated with the technical detail design efforts. As result, an Engineering Build Plan will be created and updates will be made to the overall Program Plan.

D5. Phase V: Detailed Design

Please Note: A complete breakdown of all Phase III Program Deliverables has been provided in Section VI: Deliverables Schedules.

The purpose of Phase V is to develop, iterate, and test detailed designs to demonstrate that the product will comply with the requirements. The project team details and finalizes the system design, culminating in a production-equivalent AAHSV prototype. Design closure documents are generated, including the final bill of materials, formal subsystem specifications, traceability matrix, and purchasing documentation. The team generates qualification plans for components, and works with suppliers to get Component Specification Sheets based on the systems' Key Component/Process Characteristics which are critical to quality or function. Supplier requirements are based on the Key Component/Process Characteristics (KCPCs).

Phase V includes multiple testing phases. User tests on interface and function are central elements of Phase V. Safety testing informs field testing with actual users. Philips also employs bench top testing and simulation units, including simulated lungs, simulated snoring, and other biomimetic technologies. Reliability testing and safety testing includes humidity, vibration, drop tests, shipping, and storage tests. EMI and RFI testing is performed for single and double-fault, water ingress testing, full shipping testing and storage testing. All testing plans established during Phase IV are executed in Phase V. Phase III establishes overall goals and specifications for testing. Phase V compares its results to Phase III – where
not successful, re-design and re-testing iteration occurs.

Phase V includes design-for-manufacturability (DFM) reviews to reduce cost and increase quality and improve production efficiency for BARDA. The team will determine manufacturing test specifications, for suppliers, in-process, and post-manufacturing quality assurance. This will accelerate Philips' ability to transition into full manufacturing and provide the most accurate final cost estimate. Phase V also includes traceability plans for lot tracking, and establishing component and device traceability.

D.5.1. Engineering Build (EB) #1: Initial Design & Sub-System Prototypes

The objective of EB1 is to develop the necessary sub-system and partial system test beds to prove fundamental pneumatic control and delivery. EB2 includes prototypes of final enclosures to ensure all parts have proper shape, form factor, mounting configurations, and other geometric considerations. These features are particularly important for design-for-manufacturability.

EB1 is still assembled in the engineering lab (no production line exists at this stage); however, the engineering team will invite operations personnel, such as assemblers and quality assurance personnel, to provide feedback on manufacturability and quality at this stage. This feedback is delivered to the engineering design team to incorporate into the detailed design and to resolve any issues discovered.

D.5.1.1. EB1 Initial Hardware Design

Philips will provide documented hardware designs that will be used for the EB1 Sub-System build. This will include the initial development of the Hardware Design Document (HDD) and updates to the Hardware Requirements Specification (HRS). It will also include the hardware component & sub-system design reviews.

In order to complete the EB1, design documentation for the following major hardware elements are required:

- Initial Enclosure Design
- Initial Motor Blower Design and Integration
- Initial Patient Circuits
- Initial Internal Airpath/Pneumatic Interface
- User Interface Display Selection & Evaluation
- System PCA
- Display PCA
- Interconnect PCA
- Power Supply and Batteries
- Internal Cables & Wire harnesses

The initial hardware design will be closed with a series of formal technical reviews. Completion of the formal technical reviews gives approval to release prototype tooling and designs to support procurement for EB1. At this stage of development Philips will rely on quick tools and rapid prototyping efforts. Individual FTRs may be held for specific sets of tools. For example, one FTR may focus on mechanical enclosures and another on blower/impeller parts, as these require different sets of tools. Each FTR is specific to the tool being procured.

D.5.1.2. Initial Software Design

Philips will provide a documented software design along with code that can be used for the EB2 Sub- System build. This will include the initial development of the Software Design Document (SDD) and updates to the Software Requirements Specification (SRS). This also includes the Software Detailed Design Documentation, Unit Test Procedures, Software Unit Tests, Code Reviews for each software element captured.

Software elements Include:

Display Board Software

- User Interface
- Data Logging
- Connectivity & External Communication
- SW Upgrade
- Inter Processor Communication
- Monitoring Process
- Display Board SW Support and Drivers

System & Therapy Board Software

- Control & Delivery
- Therapy
- Power Management
- Communications
- SW Upgrades
- System Diagnostics
- Therapy Board Support SW and Drivers

The initial software design will be closed with a series of formal code reviews. Completion of the formal code reviews will give approval to release the software code to support the engineering builds.

D.5.1.3. EB1 Sub-System Prototype Build

Tooling for each subsystem approved by FTR is procured in EB1. Initial system test beds are built to prove out fundamental pneumatic control & delivery and long term component reliability set ups are built. Product models and UI prototypes are created to drive initial human factor evaluations. An engineering build report is generated to document the configuration of all components used during this build.

D.5.1.4. EB1 Engineering Qualification Testing (EQT)

Engineering Qualification Testing (EQT) is a detailed set of testing of all specifications and requirements. EQT is intended to mirror the detail and specificity of full Verification & Validation (V&V), although unlike V&V, EQT is performed by the engineering staff. The goal of EQT is to make sure there are no surprises during formal V&V. Philips will perform engineering testing and evaluation of the EB1 units against the requirements provided in the individual design documentation. As a result of this testing, EB1 Engineering Test Procedures and Test Report documentation will be provided.

- **Functional Verification Testing** – Testing of EB1 units against PRD and subsystem requirements
- **Reliability & Robustness Testing** – Captures the component reliability and robustness testing of EB1
- **Human Factors Formative Testing** – Includes Human Factors and Use Testing of EB1

D.5.2. Engineering Build (EB) #2: Detailed Design and System Prototype

The intention of EB2 is to design, build and test a fully integrated ventilator against product requirements. EB2 will create refined ventilator system prototypes. Based on feedback from the assembly and operation of EB1, the team conducts a second series of formal technical reviews. The feedback is broken down and fed back into individual subsystem designs.

Overall feedback is aggregated and compared to the baseline specifications and objectives. The team assesses if the design is meeting requirements and is on schedule. EB2 will include a second round of formal design-for-manufacturability assessments based on feedback from EB1. All cross-functional teams, such as service, defect investigation, and manufacturing teams, provide feedback on EB1. Inclusion of this feedback is intended to mitigate risks associated with transitioning from R&D into full production, and is consistent with Philips' desire to design-in quality rather than to test-in quality.

The data generated in this design phase is intended to substantially reduce the risk associated with verification and validation (V&V). The test data generated is designed to give the highest confidence possible that V&V will conclude successfully. The goal is to minimize as much as possible the issues uncovered during V&V, and instead catch them during engineering qualification.

D.5.2.1. EB2 Hardware Detailed Design

The primary focus of the EB2 hardware detailed design is to fix open hardware defects from EB1 and provide the required documented hardware designs and bill of materials (BOM). The following actions and documents are necessary to complete the EB3 System Prototype build:

- Update Design to resolve EB2 defects
- Update Design to support main ventilator functionality
- Creation of Bill of Materials for Ventilator
- Update Hardware Design Description Documentation
- Key Characteristics of each component identified
- Update Final Hardware Requirement Specifications
- Completed Detailed Design Analysis (DFMEA) for each sub-component identified

In order to produce the EB2 prototype, design documentation with the necessary defect resolution updates are required for each of the following components:

- Detailed Enclosure Design
- Detailed Motor Blower Design and Integration
- Detailed Patient Circuits (includes design of new passive exhalation device to allow for prototype tooling to support EB2)
- Initial Internal Airpath / Pneumatic Interface
- System PCA
- Display PCA
- Interconnect PCA
- Power Supply and Batteries
- Internal Cables & Wire harnesses

- External Interconnect Cables

D.5.2.2. 510(k) Software Detailed Design

The primary focus of the 510(k) Software Detail Design is the documentation of both the design and code for all the Display Board Software Components and System & Therapy Board Software Components. These documents are listed as follows:

- Code Review Meeting Minutes
- Controlled SW release and release notes
- SW Build Procedure
- Final SRS with updates

D.5.2.3. EB2 System Integration Build

EB2 Build will include updates to previous EB1 systems test beds based on any hardware changes made. The updated test beds allow for increased testing of new functionality designed at this stage. Initial ventilator prototypes are also built using low volume prototype enclosures. Ventilator prototypes will capture majority of all internal HW components, but not all SW functionality at this time. Systems will allow for initial Standards, Safety & EMC testing, Human Factors Formative testing, and support initial Engineering Clinical Studies.

D.5.2.4. EB2 Engineering Qualification Testing

Philips will perform EQT and evaluation of the EB2 units against requirements. Upon completion of these tasks Philips will provide the documented EB2 Test Procedures and Reports.

Philips will perform the necessary Functional Verification Testing against the PRD and Sub-System requirements. These tests include thermal testing, sound testing, new EB1 defect testing and EB2 functionality testing.

The following provides more details of the tasks to be performed per test:

- **Functional Verification Testing** – Testing of new EB2 Functionality and EB1 Defects
- **Initial Standards, Safety & EMC Testing** – Captures testing against known standard and regulatory requirements
- **Reliability & Robustness Testing** – Captures the system reliability and robustness testing of EB2 units.
- **Human Factors Formative Testing** – Includes Human Factors and Use Testing of EB2 systems
- **Engineering Clinical Testing** – Captures the results of clinical testing.

D.5.3. Engineering Build (EB) #3: Final Engineering System & Accessory Build

The final outcome of EB3 is a Final Detailed Design that is ready for formal Verification & Validation.
EB3 is an important gate to engineering qualification testing (EQT). This is the main and final engineering build prior to V&V testing. During this build, Philips will design, build, and test a fully integrated ventilator, system accessories, and Patient Monitoring SW against product requirements.

D.5.3.1. Final Hardware Detailed Design

The task includes incorporating the necessary updates to address all known engineering defects. All supporting documentation will be updated appropriately to address these findings. Philips will also provide all required drawings and hardware specifications for all components utilized. These documents and actions include the following:

- Final Component Specification, Hardware Design Descriptions, and Drawings are required to support the EB3 and ensure the full configuration control for the Pre-Pilot build. Lead times for the Pre-Pilot are procured from these deliverables.
- SNS Packaging Design will document system packaging design for stockpile and long term storage.
- Pulse Oximetry, Capnography, & Any Other Accessory Integration design work will be completed by Philips in support of the EB3.

D.5.3.2. Final Software Detailed Design

The task includes incorporating the necessary updates to address all known engineering defects. All supporting documentation will be updated appropriately to address these findings. The documents include:

- Final Software Release Notes
- Software Build Procedure
- Final Software Design Descriptions
- Final Code Review Meeting Minutes

D.5.3.3. EB3 Final Engineering Build

The objective of EB3 is to design and build fully integrated ventilator systems, including all system accessories, and Patient Monitoring SW. Full ventilator systems and accessories are built to support testing of all external system interfaces. The result of this build will be a final detailed design that is ready for formal verification and validation.

D.5.3.4. EB3 Engineering Testing

Philips will perform final EQT and evaluation of the EB3 units against requirements. Upon completion of these tasks Philips will provide the documented EB3 Test Procedures and Reports.

D.5.4. Manual & Labeling Development

Philips will develop and provide all manuals and labels in support of this Program to assure proper labeling and language translations for the anticipated market. This includes:

- Manual / Instructions for Use
- Device Labeling
- Clinical Training Materials
  - Lay Caregiver and Clinical Training Materials
  - Quick Start Guide
  - Customer Support Plan

D.5.5. Operations Development

The primary purpose of the function is document all Operations related tasks/activities required to support the commercialization of the product

D.5.5.1. Manufacturing Development

The following sections outline the Manufacturing related tasks/activities associated with assembly, test, and packaging the product.

- **Manufacturing Assembly & Process Development** will outline how product will be built, tested, packaged, and labeled. Outline the tasks required to prepare Operations to produce the product after release.
- **Manufacturing Test Development** will outline how the product will be tested to confirm compliance with requirements outlined in the ERS (Equipment Requirements Specification). These include:
  - Manufacturing Test Plan
  - Manufacturing Equipment Requirements Specification
  - System Calibration Procedures
  - Manufacturing Equipment Functional Specifications
- **Manufacturing Final Packaging Process Development** will outline how the final fully kitted system ventilator would be packaged and determine required shipping and logistic process needed to support.
- **Manufacturing Process Analysis & FMEA** will be completed to identify potential failure modes that could occur during the manufacturing process and prevent products form meeting requirements.
- **Process Master Validation Plan** will confirm that the manufacturing and test processes developed for producing the product are capable of consistently producing a product that meets requirements.
- **High Volume Surge Capable Manufacturing Plan** will include plans to prepare facilities, tooling, and capabilities to meet the surge capacity demand of 1,700 units per month and deliver 10,000 units in 6-months.

D.5.5.2. Supply Chain Development

This task captures all the required supply chain development activities to support the detailed design phase. These items include:

- Supplier Identification and Qualification
- Initial Material Qualification Agreements & Key Component/Process Characteristics
- Bill of Materials Creation/Cost Estimate

D.5.5.3. Service

This task captures all the required service development activities to support the detailed design phase. These items include:

- Service & Preventative Maintenance Manual will capture all unique service requirements for the strategic national stockpile.
- Service Process Analysis & FMEA will be completed to identify potential failure modes that could occur during recommended service and prevent products form meeting requirements
- Service Equipment Requirements Specifications
- Service Equipment Functional Specifications

D.5.6. Quality & Regulatory

Philips will identify the regulatory, clinical, and quality time required to support detailed design and knowledge needed to prepare for V&V activities. This information is obtained thorough the following:

D.5.6.1. Regulatory & Clinical Support

- Review and approval of documentation
- Clinical planning activities

D.5.6.2. Risk Assessment - Mitigation Control Measures

- Project Audits and process review
- Generation of Catalogue Profile and Customer Complaint Codes
- Design Verification & Validation (V&V) and Reliability Support

D.5.6.3. Development of V&V Master Plan

- V&V Protocol Development and Engineering Test Support
- Reliability Analysis
- Reliability protocol development and test support

If a pre-submission meeting is deemed necessary during the contract performance period BARDA will be provided the opportunity to review draft materials prior to such meeting. In addition, BARDA will be provided the opportunity to review and approve the listed Regulatory Deliverables.

Table 13: Regulatory Deliverables

Quality System Procedure	Deliverable
QSP 7.9-093: Execute Regulatory Plan	• Regulatory Plan • Labeling Plan • Standards Requirements Document
QSP 7.9-067: Premarket Notifications – 510(k)	• Abbreviated 510(k)
QSP 7.3-024: Product Labeling	• Instructions for Use

	• Device Label • Packaging Label

Quality System Procedure	Deliverable
QSP 7.3-282: Establishing Design History File	• Design History File Index
QSP 7.9-066: Establishment Registration and Device Listing	• FURLS database update for Device Listing • Establishment Registration Assessment and FURLS database update (if necessary)

D6. Phase VI: Design Verification & Transfer

Philips will conduct formal verification & validation activities on production-equivalent product and to transfer the products Device Master Record. The outcome of this phase is that all design input requirements have been successfully verified & validated, all operational activities are fully qualified, and necessary regulatory approvals are obtained.

D.6.1. PP1: Pre-Pilot Build #1

The first pre-pilot build will produce a sufficient quantity of units to support planned V&V and clinical activities. This is the first build that occurs after the design freeze and represents the first full, final- design configuration build. The primary purpose of PP1 is to support the first V&V test cycle. PP1 is based on a production-style assembly line and full production the following:

D.6.2. PP1 Design Verification & Validation (V&V) Testing

Verification demonstrates that the design of the PP1 units complies with all requirements. Validation focuses on documenting that the device meets the needs of the customer. The testing is performed by an independent review organization within Philips (QA group) in a formal, pre-approved process. These tests include, but are not limited to the following:

- Standards, Safety, & EMC Testing
- Functional Verification Testing
- Reliability Testing
- Human Factors and Validation Testing

Philips will provide all documentation in support of every test completed.

D.6.3. PP1 Design Iterations and Defect Resolution

All design iterations and defect resolution discovered during PP1 V&V testing will be documented. Final Ventilator system & accessory specifications will be complete.

D.6.4. PP2: Pre-Pilot Build #2 (optional)

After V&V and user trials are performed, a second pre-pilot build may be performed to fix any issues found during the trials. A range of defect resolutions may be incorporated at this stage, from major faults to minor improvements. If only easily solvable improvements are found, a limited PP2 may be performed; if no issues are found, PP2 is not required. A limited PP2 build with updates to PP1 units is assumed.

D.6.5. PP2 Final Design Verification & Validation Testing

In the second cycle of V&V testing, the team will test of any of the new items built into PP2. A subset of the V&V is performed based on the changes made. In this round of V&V, the team must also evaluate items impacted by change, not just the direct items changed.

D.6.6. Operations Qualification

D.6.6.1. Supply Chain Qualification

Supplier qualification is a part of Philips' Quality System. In this task, each supplier is confirmed to have the capability to deliver a quality product. The material qualification agreement (MQA) is the master document that governs how to create requisite installation qualification (IQ), operational qualification (OQ), and process qualification (PQ) documents. The more critical the parameter, the higher level of stringent testing is performed during IQ/OQ/PQ.

IQ involves verifying that the equipment is set up suitably (e.g. has proper utility service, etc.) and is capable of performing its task.

At a high level, the OQ verifies that parts meet their specifications and that the supplier can build them reliably. OQ commonly entails high-low sampling to test operating limits and measuring process robustness or process sensitivity to variations in quality of parts. In OQ, the team sets up control limits (e.g. pressure/temp ranges, acceptable levels) to qualify the overall manufacturing process on the supplier side.

PQ confirms the supplier can build the requisite number of parts, all with sufficient quality. PQ testing spans multiple production shifts. The PQ generates CPK data (Process capability index), a part of six sigma practice. PQ also verifies that the critical quality parameters found in the MQA can be met.

D.6.6.1. Supplied Part Qualification

Supplier is confirmed to have the capability to deliver a quality product. Supplied Part Qualification assures and documents the results of qualification of all supplier provided parts and components.

D.6.6.2. Pilot Build & Process Qualification

D.6.6.2.1. Manufacturer Assembly and Test Equipment Qualification

Validation of the final assembly process results in production of fully sellable parts that can be delivered to BARDA for acceptance testing or stakeholder evaluation. This step includes an initial pilot run (PR1). This step will evaluate line

quality and perform defect investigation of any issues found. Impacts and causes will also be assessed. A sampling of the units produced will be sent to the V&V lab for destructive evaluation to detect assembly faults or any other issue that might impact the functionality of the device.

Production process validation also includes an independent, external assessment of overall product quality assessment. This evaluator will perform the same steps completed in the technical assessment, while reviewing the original assessment and any fixes.

The pilot run closes out the production process validation and generates sellable units. These units may be delivered to BARDA, other customers, or other stakeholders for further evaluation or clinical use.

D.6.6.2.2. Pilot Build

The intention of the Pilot Build is to build production units with fully qualified test equipment to support final design validation and process qualification activities. This task captures all support activities required to order, prepare and build Pilot units. This build will include the building of a fully integrated and packaged ventilator, including system accessories.

D.6.6.2.3. Final System Validation Testing

The Final System Validation Testing confirms that units build under final controlled and qualified processes satisfy all requirements.

D.6.6.2.4. Process Master Validation & Report

The Process Master Validation & Report will include status of all process validation activities.

D.6.7. Regulatory, Clinical & Quality

D.6.7.1. Regulatory Approval

Regulatory Approval includes generating and submitting a complete 510(k) package and securing FDA clearance.

D.6.7.2. Final Risk Assessment: Hazard Analysis and Verification

The Final Risk Assessment: Hazard Analysis & Verification will document the design quality and final risk assessment identifying any potential harms, hazards, and risks, classified by severity, of the Program.

Helix SP Technical Specification

*** text contained within [brackets] indicates a design goal *****

Patient Range	
	Newborn (≥2.5kg) to Adult
Ventilation Types	
	Volume control, pressure control, bi-level and back-up ventilation, invasive or non-invasive ventilation
Ventilation Modes	
Pressure Control	CPAP+PS, PC, S/T, SIMV-PC
Volume Control	AC, SIMV-VC
Controls[2]	
Delivered Tidal Volume	35 – 1,200 ml
Breath Rate	0 – 80 BPM
PEEP and CPAP	0 – 35 cm H_2O for active exhaust circuits 3 – 25 cm H_2O for passive circuits
Pressure support breaths (differential)	0 – 60 cm H20 Patient pressure limited to 60cmH_2O
Inspiratory time	0.3 – 5.0s constrained to prohibit an inverse I:E ratio
Pressure support Rise time	0 - 6
Triggering and Cycling	AutoTrak, Sensitive AutoTrak, and Flow Trigger
Flow trigger sensitivity	0.5 – 9 l/min
Flow cycle	10% – 90% of peak flow
Back-up ventilation rate	4 – 80 BPM
Flow Pattern	Square, Ramp
FiO_2	21% – 100%
Other Controls & Features	Sigh, 100% O_2, Manual Breath

User Settable Patient Alarms	
Circuit Disconnect	OFF, 5 to 60 seconds in increments of 5 seconds
Apnea Interval	OFF, 5 to 60 seconds in 5 second increments
High PIP	PEEP+10 to 80 cmH2O in increments of 1 cmH2O
Low PIP	PEEP+1 to 80 cmH2O in increments of 1 cmH2O.
High/Low Tidal volume	OFF, 10 to 2000 ml in increments of 5 ml
Low Minute Ventilation	OFF, 0.3 to 99 lpm in increments of 0.1 lpm from 0.3 lpm to 9.9 lpm and 1 lpm for settings ≥10 lpm
High Minute Ventilation	OFF, 1 to 99 lpm in increments of 0.1 lpm
High/Low Respiratory Rate	OFF, 1 to 80 BPM in increments of 1 BPM
High FiO_2 with O_2 Sensor	OFF, 27 to 100% in increments of 1%
Low FiO_2 with O_2 Sensor	OFF, 21 to 95% in increments of 1%
High etCO2 with etCO2 Accessory	OFF, 1 to 100 mmHg in increments of 1 mmHg
Low SpO_2 with Pulse Oximeter Accessory	OFF, 50 to 95% in increments of 1%
High SpO_2 with Pulse Oximeter Accessory	OFF, 90 to 100% in increments of 1%
Low Heart Rate with Pulse Oximeter Accessory	OFF, 18 to 300 in increments of 1 beat per minute
Measured and Displayed Patient Parameters[2]	
Tidal volume (Vti or Vte)	0 to 2000 ml with a resolution of 1 ml
Minute ventilation	0 to 25 l/min with a resolution of 0.1 l/min
Leak rate	0 to 200 l/min with a resolution of 0.1 l/min
Respiratory rate	0 to 80 BPM with a resolution of 1 BPM
Peak inspiratory flow	0 to 200 l/min with a resolution of 0.1 l/min
Peak inspiratory pressure	0 to 90 cmH2O with a resolution of 0.1 cmH2O
Mean airway pressure	0 to 90 cmH2O with a resolution of 0.1 cmH2O
Percentage patient triggered breaths	0 to 100% with a resolution of 1%
I:E ratio	1:99 to 1:9.9
Dynamic Lung Compliance	0.5 to 200 ml/cmH2O with a resolution of 0.1 ml/cmH2O
Dynamic Lung Resistance	5 to 200 cmH2O/l/sec with a resolution of 0.1 cmH2O/l/sec
Plateau Pressure	0 to 90 cmH2O with a resolution of 0.1 cmH2O
Auto-PEEP	0 to 90 cmH2O with a resolution of 0.1 cmH2O
FiO_2	21% to 100% with a resolution of 0.1%

SpO2 with Pulse Oximeter Accessory	0 to 100% with a resolution of 1%
Heart rate with Pulse Oximeter Accessory	25 to 240 BPM with a resolution of 1 BPM
etCO2 with End Tidal CO2 Accessory	0 to 150 mmHg with a resolution of 1 mmHg
Indicators	
AC power	LED
Battery capacity	Indicated on graphical user interface
Alarm	LED, High visibility Light bar, audible and relay contact
Environmental	
Operating	0°C to 40°C 5% to 90% RH, non-condensing 106 to 62 kPa atmospheric pressure
Transient Operating Temperature, excluding high pressure oxygen blending	-20°C to 50°C
Storage	-25°C to 70°C 5% to 90% RH, non-condensing
Physical	
Weight	14.1 lbs, (6.4 kg)
Size	TBD, Nominal 6.8"D x 11.5"W x 9.5"H
Ingress Protection	IP22 [IP33]
Electrical	
AC Input Voltage	Nominal Range 100- 240 V AC, 50/60Hz, ~2.5A
DC Input Voltage (External battery)	12VDC and 24VDC (10.5 to 30.3 VDC), 10A fuse rating
Type of Protection Against Electric Shock	Class II/Internally powered equipment
Degree of Protection against Electric Shock:	Type BF Applied Part
On-Board Batteries	2 Li-Ion batteries 8 [10] hr total run time per method in IEC 80601-2-72 4 hr nominal recharge time[3]
Nurse Call/Remote Alarm	Form C relay output
Oxygen	
Low Flow	0 to 30 l/min; maximum 50 psi
High Pressure	280 to 600 kPa (41 to 87 psi).

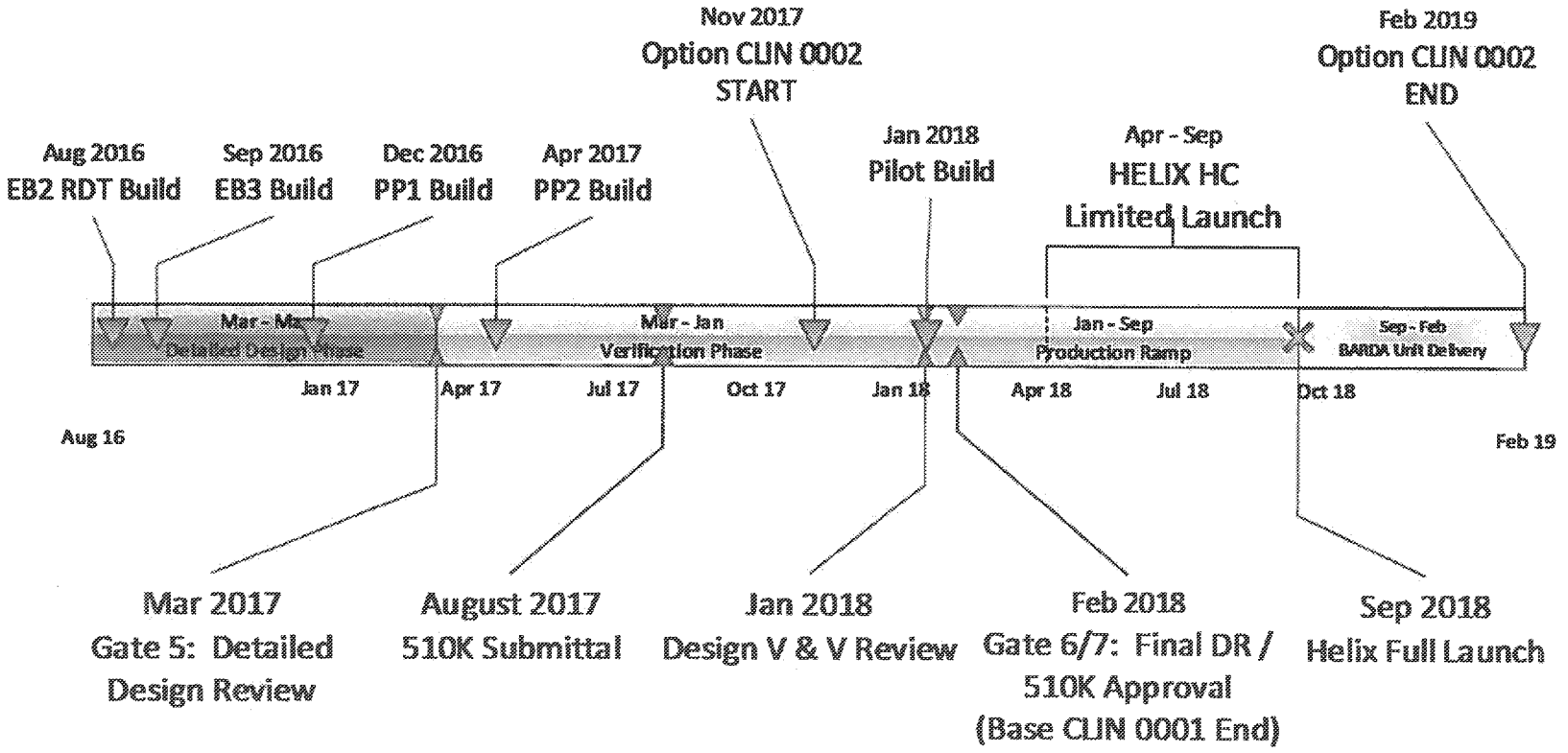
Pneumatic System	
	Turbine
Control Accuracy[1]	
Pressure	±(2 cmH2O + 4% of the setting)
Tidal Volume	±(4 ml + 15% of setting) for volumes > 50 ml [±(4 ml + 15% of setting) for volumes ≤ 50 ml]
FiO2	±5 % FiO2
Monitored Parameter Accuracy[1]	
Airway Pressure	±(2 cmH2O + 4% of actual)
Tidal Volume	±(4 ml + 15% of actual) for volumes ≥ 35 ml ± 10 ml for volumes < 35 ml
FiO2	±(2.5% FiO2 + 2.5% of actual reading) within a 24-hour 2-point calibration period
User Interface Features	
Graphical User Interface Features	Configurable Setup based on user inputs (Patient Demographic defaults) Numerical data (see Measured and Displayed Parameter section) Time based waveforms Pause/Freeze controls: Patient airway pressure, Flow, CO_2
Connectivity Capability	Wi-Fi, USB, Bluetooth, NFC
Patient Circuits	
	Passive exhaust Dual Limb, Active exhaust Active with Flow Active with PAP
Filtration	
Device inlet	Includes high efficiency inlet filter Accepts NATO CBRN filter
Device outlet and Expiratory limb	Accepts 22 mm commercial bacteria filter

Standards	
General	IEC 60601-1-1
Collateral	IEC 60601-1-11 Home Health Care Environment according to transit-operable usage
Particular	IEC 80601-2-12 Critical Care Ventilator IEC 80601-2-61 Pulse oximeter IEC 80601-2-55 Respiratory Gas Monitors (includes Oxygen and CO2 monitoring)
Mechanical Vibration	[MIL-STD 810G, Method 514.6, Procedure 1, Category 24]
Mechanical Shock	[MIL-STD 810G, Method 516.6, Procedure 1, Functional Shock – 40 g, 11 ms.]
Airworthiness	[IEC60601-1-12 Emergency Medical Services (EMS) Environment EN 13718-1 Medical devices used in air ambulances RTCA DO-160G Environmental Conditions and Test Procedures for Airborne Equipment Section 7 Operational Shocks and Crash safety, Category A Section 8 Vibration, Category U/U2 Section 20 Radio Frequency Susceptibility (radiated and Conducted), Category S Section 21 Emission of Radio Frequency Energy, Category M]

Notes:

1. Accuracies stated are based on specific environmental conditions. For stated accuracy, the environmental conditions are: Temperature: 25°C; Humidity: 50 %RH; Altitude: 380 meters above sea level nominal. Stated accuracy is based on successful completion of Calibrate Circuit.
2. All flows and volumes are expressed in BTPS.
3. On-board battery charging enabled for battery temperatures greater than 0°C.

Helix Milestone Schedule



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