



# trade, industry & competition

Department:  
Trade, Industry and Competition  
REPUBLIC OF SOUTH AFRICA

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Author SWP Esterhuyse/Pontsho Maruping  
Date April 2020

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### DOCUMENT APPROVALS

	Name	Capacity	Signature
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<b>Authored by</b>	Pontsho Maruping	NVP Industry Liaison	 <u>Pontsho Maruping (Apr 3, 2020)</u>
<b>Accepted by</b>	Justin Jonas	NVP Technical Advisor	 <u>Justin Jonas (Apr 3, 2020)</u>
<b>Approved by</b>	Philippa Rodseth	NVP Steering Committee Chair	 <u>P S Rodseth (Apr 3, 2020)</u>

### DOCUMENT HISTORY

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Rev 1	-	4 Apr 2020	Willem Esterhuysen	First Revision Issued to Industry in CFP

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## TABLE OF CONTENTS

<b>1. Introduction</b>	<b>4</b>
<b>2. Company Declarations and Details</b>	<b>4</b>
<b>3. Company Profile and Ability</b>	<b>5</b>
<b>4. Empowerment</b>	<b>5</b>
<b>5. Intellectual Property</b>	<b>5</b>
<b>6. Stage of development</b>	<b>5</b>
<b>7. Technical</b>	<b>6</b>
7.1. Overview of Technical Solution Proposed	6
7.2. Capacity and Capability Information	6
7.3. Operating and Maintenance Information	7
7.4. Standards and Codes	7
<b>8. Commercial</b>	<b>8</b>
<b>9. Supporting Documentation</b>	<b>8</b>

**Annexure A: Requirement Specification**

**Annexure B: SARAO mandate**



## 1. Introduction

This is a call for proposals (CFP) to identify role players to assist the Department of Trade, Industry and Competition (DTIC) on the National Ventilator Project (NVP) – referred to as “THE PROJECT”. In an effort to meet the anticipated demand for critical medical equipment such as ventilators, the DTIC is inviting companies and experts to submit their proposals in respect of the design, development, production and procurement of ventilators in South Africa.

The CFP is for a non-invasive pre-intubation ventilator solution that a clinical team has determined to be applicable to the treatment of the majority of hospitalized cases that could be developed on a short timescale.

It is important to note that the entire submission shall be electronic – this can take the format of a zip file with a clear inventory excel file indicating the submission structure. The spreadsheet provided with the CFP shall also be completed and submitted electronically.

Partial Proposals will be accepted (i.e. companies interested in providing a subset of components required by the ventilator system can respond). In this event complete the relevant sections of the CFP as far as possible. For partial proposals refer to the reference design as provided in Figure 3 of the Requirement Specification.

An evaluation of the submitted proposals will be done on Tuesday the 7th after which entities that have submitted the most promising solutions will be requested to present their solutions to the evaluation panel on Wednesday the 8th of April.

### TIMELINE

- Launch: Friday 3 April 2020 (22:00)
- Information session: Monday 6 April 2020 (10:00)
- Close : Monday 6 April 2020 (23:00)
- Evaluations: Tuesday 7 April 2020 (evaluation panel)
- Presentations: Wednesday 8 April 2020 (selected proposals)

Any queries related to the CFP can be addressed to:

- Willem Esterhuyse, [westerhuyse@ska.ac.za](mailto:westerhuyse@ska.ac.za), NVP Project Manager
- Pontsho Maruping, [umaruping@ska.ac.za](mailto:umaruping@ska.ac.za), NVP Industry Liaison

The DTIC reserves the right, in its absolute discretion, to terminate the proposal process by notice in writing to the Respondents.

## 2. Company Declarations and Details

a The DTIC requires the following information where applicable:

- i. Name of company or organization, including South African Company Registration Number or equivalent. Include type of company (e.g. private, publicly listed, Government or other);
- ii. Tax Clearance or Central Supplier Database (CSD) registration;
- iii. Names of any associated companies that may be involved in THE PROJECT (consortium and/or sub-contractor details);
- iv. Registered business address(es) (including consortium members and sub-contractors where applicable);
- v. Telephone number(s);
- vi. E-mail address(es);



- vii. Name and title of the company representative who will act as the point of contact for the company;
  - viii. If the company is Certified to ISO 9000 series, provide copies of the Certification and scope of activities of the Certification.
- b A statement authorizing submission of the response, including:
- i. an acknowledgment that the response will become the property of the DTIC on submission and will not be returned;
  - ii. any restrictions on the release of company, consortium or sub-contractor details to other parties;

### **3. Company Profile and Ability**

- a Provide details of the educational qualifications and work experience of key personnel that would be involved in managing and executing THE PROJECT.
- b Provide details of the respondent's experience and capability to undertake THE PROJECT (company involvement in relevant projects or experience in the medical or similar fields).

### **4. Empowerment**

Please provide a valid B-BBEE certificate (if certification exists).

### **5. Intellectual Property**

Respondents must indicate the status of the intellectual property applied and any restrictions for access to or use of intellectual property that is required for the project.

### **6. Stage of development**

Select an appropriate stage from the list below:

- a Concept: this is the beginning of inventing a practical application of the technology. The application is speculative, and there may be no proof or detailed analysis to support the assumptions.
- b Early alpha prototype: the development process of the technology begins with the "proof of concept" stage to determine if the concept is feasible. Once the concept's positive potential is established, an alpha prototype is produced as the first version of the product. It is primarily used for testing feasibility of the main features and design aspects early in the process. Those elements that are feasible are passed on to the beta stage.
- c Beta testing: a beta prototype is a more or less functional version of the product, however, there are generally still bugs and design issues yet to be worked out at this point in the process. Beta prototype is not yet fully operational or ready for production.
- d Commercial pilot: a pilot plant is a small industrial system (typically smaller than full-scale production plant) which is operated to generate information about the behaviour of the system for use in design of larger facilities. This is a pre-commercial demonstration to prove that the technology works in its final form and under expected conditions.
- e Commercial ready – not yet deployed: the technology in its final form is ready for commercial deployment; however, the technology is not yet deployed
- f Actively deployed – the technology is launched commercially, marketed to and adopted by a group of customers.



## 7. Technical

### 7.1. Overview of Technical Solution Proposed

- a Please clearly state whether the proposed solution is aimed at meeting the entire specification or indicate interest in component supply referring to the reference design as provided in Figure 3 of the Requirement Specification
  - i In the event that the requirements are adjusted the DTIC reserves the right to make adjustments to the specification and will circulate any such changes to all parties (electronically or at the information session).
- b Respondents shall provide an overview of the technical solution proposed highlighting overall concepts, technologies, materials, performance etc. The following technical areas shall specifically be addressed:
  - i Completion of the electronic sheet indicating compliance to the requirement (using compliance codes below);
    1. **“Exceeds Requirements”**, abbreviated to “ER”, means that the condition, characteristic or performance requirement is currently fully met and is exceeded in the product offered. Details of the extent to which the product exceeds the specified requirement must be stated in an explanatory note.
    2. **“Complies”**, abbreviated to “C”, means that the condition, characteristics or performance requirement is currently fully met (Proposal Due Date) in the product offered without any additional development, redesign or rework.
    3. **“Does Not Comply”**, abbreviated to “NC”, means that the condition, characteristic or performance requirement is not fully met by the product offered, and can either not be modified or requires significant modification action to make it comply in the required timescale. Details of the extent of the non-compliance must be stated in an explanatory note.
    4. **“Not Applicable”**, abbreviated to “N/A” means that the condition, characteristic or performance requirement does not apply, as in the case where only a subset of components is covered in the proposal.
  - ii Technical description of the solution including a description of the principles of operation of the device, construction methods and materials, and a diagram showing the general arrangement of components and internal and external interfaces.

### 7.2. Capacity and Capability Information

- a Provide details of the educational qualifications and work experience of key technical appointments that could be made available for THE PROJECT.
- b Respondents shall provide information with respect to their capacity to undertake and complete THE PROJECT within the required timescales.
- c Respondents shall provide information regarding their capability to undertake the work required (design, manufacture and integration) by providing appropriate details of equipment, processes and facilities available for the execution of THE PROJECT. Typical information to be provided relates to the Product Development and in Service Deployment Processes which are to be followed and includes the following:
  - i Identification of key functional requirements driving the solution and how the concept addresses these.



- ii. Prototype models and development tests conducted to assess compliance against specifications and to identify key risks.
  - iii. Industrialisation planning to indicate use of various production methods to start production at a low rate and ramp to maximum rate in the shortest possible time with well defined maturity checkpoints during the early (pre-production) phase.
  - iv. Qualification testing for specific safety and reliability requirements and planning of these to ideally run in parallel with production.
  - v. Change management processes to ensure that qualification failures are rectified in a structured fashion and impacted production items can be withdrawn or rectified by means of serial number tracking.
  - vi. Quality management processes to prevent substandard supplier delivered materials, components or manufactured parts to be introduced into the production line and to allow in the field failures to be assessed and product recalls or modifications to be implemented with immediate effect.
  - vii. Acceptance test processes to allow release into service of each of the produced items.
  - viii. Configuration management processes to ensure that all production units are aligned with the latest qualification standard of the design.
- d Minimum production targets to be as follows:
- i. Start production as soon as possible (latest end of April 2020)
  - ii. Providing a minimum of 1500 units by the end of May 2020
  - iii. Providing a minimum of 10 000 units by end of June 2020
  - iv. Ability to scale manufacturing to 50 000 units or more if required

### **7.3. Operating and Maintenance Information**

Respondents shall provide a brief description of the complexity of the operation of the system and state the training personnel will require in order to be able to use the system.

### **7.3. Operating and Maintenance Information**

Respondents shall provide a brief description of the complexity of the operation of the system and state the training personnel will require in order to be able to use the system.

### **7.4. Standards and Codes**

Suppliers are requested to provide full details of the standards and codes they intend to comply to. In the event where certifications are required, this shall be clearly stated and estimated timescales for said certifications shall be provided.



## 8. Commercial

Provide a ROM price for the proposal. This should be broken down to the bill of materials (BOM) and should be consistent with the information supplied in the electronic submission sheet on tab "BOM of Solution Offered". VAT should be included in the estimated prices stated on the sheet. The following detail should be supplied per component:

- BOM Item #
- Part Number
- Description
- QTY/Units
- Cost/Unit
- Total Cost
- Supplier for prototype unit (if applicable)"
- Supplier for mass manufacture
- Supplier Details

## 9. Supporting Documentation

Respondents should include any necessary supplementary documentation that they feel is relevant to the submission.





## Annexure A: Requirement Specification



**the dti**

Department:  
Trade and Industry  
**REPUBLIC OF SOUTH AFRICA**

# **NATIONAL VENTILATOR PROJECT**

## **NON-INVASIVE VENTILATION SYSTEM (NVS)**

### **REQUIREMENTS SPECIFICATION**

Document number ..... SSA4003-0009-000

Revision ..... 1





Classification..... Unclassified

Prepared By..... T Küsel

Date ..... 3 April 2020

Non-Invasive Ventilation System Specification	Doc No:	<b>SSA4003-0009-000</b>
	Rev No:	1

### DOCUMENT APPROVALS

	Name	Capacity	Signature
<b>Authored by</b>	T. Küsel	NVP Systems Engineer	<i>T. Küsel</i>
<b>Accepted by</b>	O. Smith	NVP Medical Representative	 <u>Oliver Smith (Apr 3, 2020)</u>
<b>Accepted by</b>	K. Roper	NVP Specialist Adviser	
<b>Accepted by</b>	W. Esterhuyse	NVP Project Manager	
<b>Approved by</b>	P. Rodseth	NVP Steering Committee Chair	 <u>P S Rodseth (Apr 3, 2020)</u>

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Publish in eB and Distribute to all signatories on the document.
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**TABLE OF CONTENTS**

**1 INTRODUCTION ..... 4**

**1.1 Background ..... 4**

**1.2 Purpose of this document..... 4**

**1.3 Reference Documents ..... 4**

**2 REQUIREMENTS ..... 5**

**2.1 System Description..... 5**

**2.2 System Boundary and External Interface Requirements..... 5**

**2.3 System Functions and Functional Requirements ..... 7**

**2.4 Other System Requirements..... 8**

**2.5 Assumptions ..... 9**

**3 APPENDIX A: REFERENCE DESIGN ..... 10**

**LIST OF TABLES**

Table 1: NVS external interface requirements ..... 6

Table 2: NVS functional requirements..... 7

Table 3: NVS non-functional requirements ..... 8

**LIST OF FIGURES**

Figure 1: NVS boundary and external interfaces ..... 5

Figure 2: NVS main functions..... 7

Figure 3: Reference design of NVS system ..... 10

**ABBREVIATIONS**

EMC	Electromagnetic Compatibility
CMH2O	Centimetres of water pressure
DTIC	Department of Trade, Industry and Competition
HMEF	Heat and Moisture Exchange Filter
NVP	National Ventilator Project
NVS	Non-invasive Ventilation System

Non-invasive Ventilation System Specification	Doc No:	SSA4003-0009-000
	Rev No:	1

# 1 INTRODUCTION

## 1.1 BACKGROUND

The outbreak of the COVID-19 pandemic has placed a severe burden on the national health care system and has resulted in shortages of medical supplies and equipment. One of the identified shortages is the availability of ventilation systems appropriate for the treatment of the majority of patients presenting at health facilities. The National Ventilator Project (NVP) was launched in an attempt to rapidly develop and produce ventilation solutions for the pandemic. The requirements in this document have been developed for this purpose.

The requirements in this document have used [2] as a source document. The requirements were then further developed through a process of requirements analysis and consultation with expert medical professionals. The requirements were then formally reviewed by a panel appointed by the National Ventilator Project Steering Committee, under the auspices of the DTIC.

## 1.2 PURPOSE OF THIS DOCUMENT

The purpose of this document is to specify the minimum requirements for a rapidly developed non-invasive ventilation systems. The purpose of this specification is to enable a fast track development, industrialisation and production of a ventilation system as defined in the Project Execution Plan [1].

The requirements contained in this document will form the basis for selecting design options, verification of the design and verification of the delivered production products.

**Note:** these requirements represent a minimal standard, specifically developed for the COVID-19 pandemic and should not be used outside of this context. The requirements have been kept at a minimum to enable the selection of products that allow for a very high speed development and production acquisition process.

## 1.3 REFERENCE DOCUMENTS

The following documents are referenced for context and clarifications.

[1] T. Kusel, “*National Ventilator Project Execution Plan*”, SSA4003-0009-001, Rev1.

[2] UK Medicines & Healthcare products Regulatory Agency, “Rapidly Manufactured CPAP Systems (RMCPAPS) Specification”, version 1.5, 29 March 2020.

## 2 REQUIREMENTS

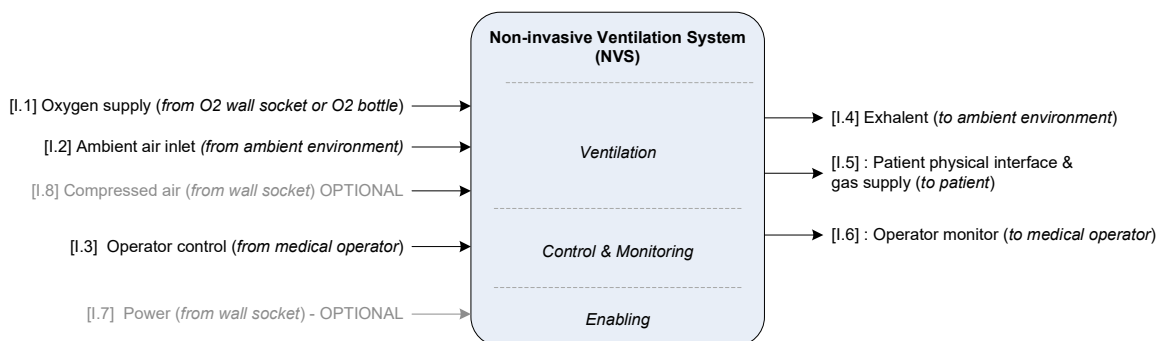
### 2.1 SYSTEM DESCRIPTION

The Non-invasive Ventilation System (NVS) supplies a pressurised mixture of air and oxygen to the patient through a mask or hood. The pressurised gas helps the patient by supplying a higher level of oxygen and by keeping the airway and lung pressure elevated above ambient air pressure throughout the breathing cycle to keep the lung alveoli recruited and operating effectively. The medical operator can adjust the inspired oxygen proportion (FiO<sub>2</sub>) of the gas supplied to the patient and can adjust the elevated pressure to the required level. The achieved pressure can be monitored by the medical operator. Infection control is critical to prevent the spread of the virus in the health care facility. For this reason the management of exhaled air and proper sealing of the mask/hood is important. The preferred hood or mask system is less likely to interfere with other medical equipment, is likely to be more comfortable for the patient and is considered to be more effective at infection control.

A reference design is described in Appendix A. Note that this reference design is not prescriptive, however, it represents a likely scenario for a cost effective and simple solution that meets all the requirements.

### 2.2 SYSTEM BOUNDARY AND EXTERNAL INTERFACE REQUIREMENTS

The NVS system boundary and external interfaces are shown in Figure 1 below. The NVS plugs into the oxygen supply system provided in the facility where it is used. There is an option for an oxygen bottle in cases where centralised wall oxygen is not available. The baseline specification assumes an ambient air inlet, but allows for an optional compressed air connection. The mask/hood and the pipes leading to the patient are assumed to be part of the system. The Exhalent is assumed to go to the ambient environment, but shall be filtered or sterilised. The baseline specification assumes that no electrical power supply is needed because a purely mechanical system is preferred (see reference design), however, and optional power supply interface is included.



**Figure 1: NVS boundary and external interfaces**

**Note: Preference will be given to solutions that are able to operate without the optional interfaces.**

Non-invasive Ventilation System Specification	Doc No:	SSA4003-0009-000
	Rev No:	1

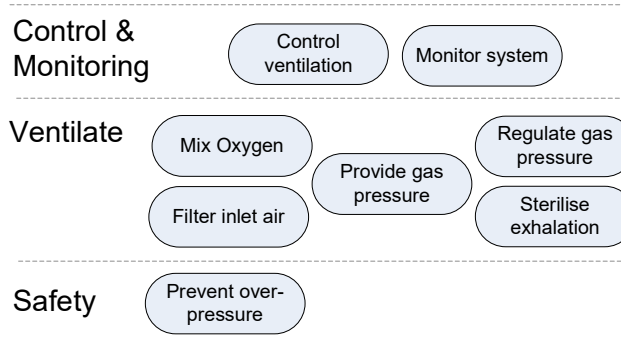
The external interface requirements are defined in Table 1 below:

**Table 1: NVS external interface requirements**

<b>Interface</b>	<b>ID</b>	<b>Requirement</b>
I.1: Oxygen supply	R.I.1	All gas connectors and hoses must use standard non-interchangeable connectors and be colour coded according to recognised medical standards.
	R.I.2	The NVS Oxygen inlet shall connect to standard South African hospital wall Oxygen supply or Oxygen bottle interfaces.
	R.I.3	The NVS shall regulate the supplied Oxygen pressure as needed to operate effectively.
1.2: Ambient air inlet	<i>requirements covered in R.F.1</i>	
I.3: Operator control	<i>requirements covered in R.F.2 &amp; R.F.4</i>	
I.4: Exhalent	R.I.4	All parts coming into contact with the patient's breath must be either disposable or able to be decontaminated between patients.
	R.I.5	The exhaled gas shall be filtered with an easily replaceable HMEF viral filter
I.5: Patient physical interface and gas supply	R.I.6	The mask or hood shall have a sealing mechanism to prevent the escape of exhaled air and fluids (to prevent contamination)
	R.I.7	The hood/mask and all gas supply pipes shall be made from medically approved materials.
	R.I.8	The device shall be usable with the patient in seated or lying down positions.
	R.I.9	The hood/mask shall have an anti-asphyxiation mechanism to allow for additional ambient air to enter the mask in case the inhalation gas volume exceeds the gas supply volume.
I.6: Operator monitoring	<i>requirements covered in R.F.5 &amp; R.F.9</i>	
I.7 Power	R.I.10	The NVS shall connect to standard 240V, 50 Hz South African wall power socket. <i>[only required if power interface is used]</i>
	R.I.11	If the NVS function is dependent on electrical power, it shall automatically provide backup power for a period of 30 minutes or longer in case the main power supply fails.
I.8 Compressed air	R.I.12	The NVS compressed air inlet shall connect to a standard South African hospital wall compressed air supply point. <i>[only required if compressed air interface is used]</i>

## 2.3 SYSTEM FUNCTIONS AND FUNCTIONAL REQUIREMENTS

The main NVS system functions are shown in Figure 2 below.



**Figure 2: NVS main functions**

The requirements relating to the NVS functions are defined in Table 2 below:

**Table 2: NVS functional requirements**

Function		ID	Requirement
Ventilate	Filter inlet air	R.F.1	The NVS shall filter the ambient air inlet to a suitable breathing air standard.
	Add oxygen	R.F.2	The NVS shall enable the operator to control the inspired oxygen proportion (FiO2) of the gas supplied to the patient to a value from 30% to 100% as set by the operator, either in 10% increment steps, or on a continuous scale, with an accuracy of +5%.
	Regulate pressure	R.F.3	The NVS shall maintain a constant minimum positive airway pressure at all times during the breathing cycle, as set by the operator.
		R.F.4	The NVS shall enable the operator to regulate minimum positive airway pressure to a value from 5 to 25 cmH2O above ambient air pressure.
	Sterilise exhalation	<i>requirements covered in R.1.5</i>	
Monitor & Control	Monitor pressure	R.F.5	The NVS shall display the achieved airway pressure.
	Control ventilation	R.F.7	The operator shall be able to turn the patient gas supply on and off (for fitting the device and taking it off) <i>[other control requirements covered in R.F.2 and R.F.4]</i>
Safety	Prevent over-pressure	R.F.8	The NVS shall have a mechanism to ensure that the patient airway is never exposed to a gas pressure of more than 40cmH2O
	Pressure loss alarm	R.F.9	The NVS should have an alarm if there is a failure of the pressurised gas supply to the mask/hood. <i>[Note that this is not a mandatory requirement, but would be an advantage]</i>



## 2.4 OTHER SYSTEM REQUIREMENTS

All other NVS requirements are defined in Table 3 below:

**Table 3: NVS non-functional requirements**

<b>Category</b>	<b>ID</b>	<b>Requirement</b>
Electromagnetic compatibility	R.O.1	The NVS shall comply with IEC 60601-1-2 or equivalent EMC standard. <i>[only applicable if electronic components are used]</i>
Sanitation	R.O.2	All external surfaces must be able to be sanitised, without damage to the device. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.
Labelling	R.O.3	The NVS shall provide clear permanent labelling for all external interfaces.
	R.O.4	The NVS shall provide clear permanent labelling for all monitor and control points.
Ergonomics	R.O.5	The NVS shall be floor standing and mounted on a wheel base that is easy to move, and bed mountable to standard hospital bed configuration.
	R.O.6	The NVS shall be easy and intuitive to use and should require minimum training.
	R.O.7	The NVS shall provide controls and monitoring in a location that is convenient for the operator to use.
	R.O.8	The NVS controls shall be placed in such a way that they are not adjusted inadvertently.
	R.O.9	The NVS shall provide gas connection points locations that are convenient to connect and disconnect.
	R.O.14	The NVS system shall be delivered with operating and maintenance instructions.
Reliability	R.O.10	The NVS shall operate without failure or need for maintenance for a period of 14 days.
Maintainability	R.O.11	Following a block of 14 days, the NVS shall be maintained to allow returning to service within 1 hour.
	R.O.12	Consumable spares (o-rings, seals, washers, filters) shall be provided with the NVS to allow a 1 hour turnaround time and a total of 10 blocks of use.
	R.O.15	The NVS shall be delivered with operating and maintenance instructions.
Manufacturability	R.O.13	The NVS shall be manufactured using parts and materials that are readily available in large quantities on the commercial market or can be manufactured locally in South Africa.

Non-invasive Ventilation System Specification	Doc No:	SSA4003-0009-000
	Rev No:	1

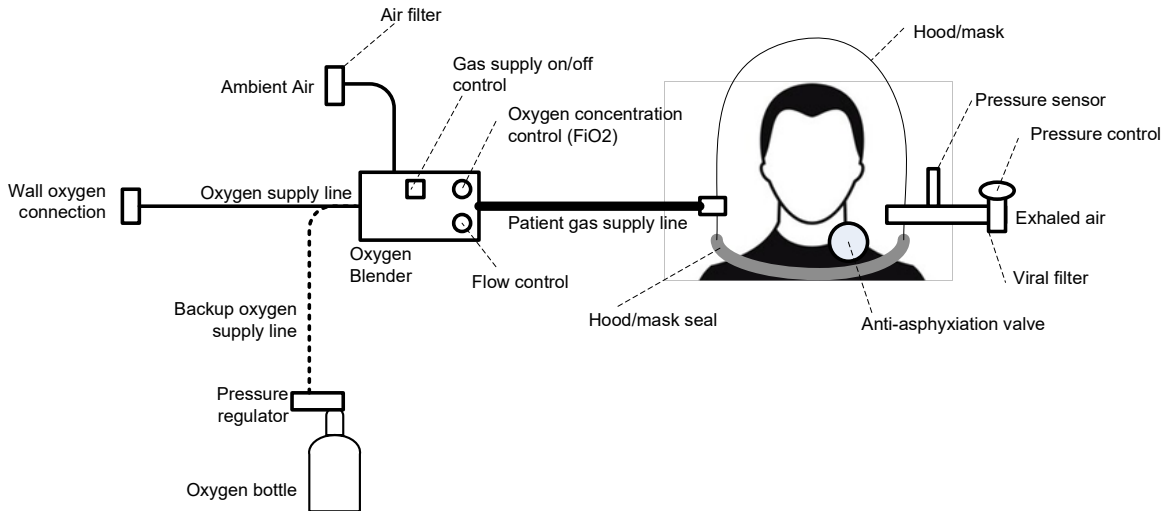
## 2.5 ASSUMPTIONS

The following assumptions apply to this specification:

- a) It is assumed that oxygen level monitoring is not an essential requirement for the NVS because oxygen intake will be monitored on the patient directly using a fingertip blood oxygen meter.
- b) It is assumed that humidification of the patient gas supply is not an essential requirement if the mask/hood concept is implemented, because the humidity is maintained through the mask/hood environment combined with the appropriate filters and flow control.
- c) It is assumed that the NVS operates in an environment where ambient air is refreshed at a sufficient rate to meet medical standards.

### 3 APPENDIX A: REFERENCE DESIGN

A reference design is shown in Figure 3 below. Note that this design is not prescriptive, but shows one possible design option that is capable to meet all the requirements.



**Figure 3: Reference design of NVS system**

This design uses a mechanical Oxygen blender to mix the pressurised Oxygen supply with ambient air to the desired inspired Oxygen proportion ( $FiO_2$ ). The operator can control the oxygen proportion at the blender. The hood is strapped down onto the patient's shoulders with under-arm straps. The pressure in the hood is controlled through the exhalent outlet valve, which is also fitted with a viral filter and acts as an over-pressure safety mechanism. A pressure indicator shows the achieved pressure in the hood/mask. An anti-asphyxiation valve acts as a mechanism to allow additional ambient air to enter the mask in case the inhalation gas volume exceeds the gas supply volume, and also acts as a safety measure in case the inlet gas supply fails.



## Annexure B: SRAO Mandate



MINISTER  
TRADE, INDUSTRY AND COMPETITION  
REPUBLIC OF SOUTH AFRICA

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1 April 2020

Dr Rob Adam  
Managing Director  
**The South African Astronomy observatory (SARAO)**

Dear Dr Adam

**Mandating SARAO to manage the development/manufacturing process for ventilators to deal with the Corona Virus situation**

The Department of Trade, Industry and Competition (DTIC) has been inundated by proposals of companies and individuals who wish to provide solutions for the ventilator shortage that will likely be experienced in the near future due to the corona virus outbreak. It is clear that we need to have a structured process to 1) define a specification for what is required and 2) to manage the process of developing and manufacturing/procuring a solution that will meet this requirement.

I have requested Dr Bernie Fanaroff, who is my Facilitator for the steel and metal fabrication Master Plan, to engage with industry on the matter.

Due to the severity of the situation, and following consultation with Minister Blade Nzimande, we decided to appointed an entity to support the DTIC in this development process. This also has the support of the Director General Dr Phil Mjwara.

This letter serves to confirm that SARAO (South African Radio Astronomy Observatory), a business unit of the National Research Foundation, has been mandated by me to manage this process based on the experience they have gained in development of complex systems for the MeerKAT radio telescope. They will work with Dr Fanaroff.



**MINISTER  
TRADE, INDUSTRY AND COMPETITION  
REPUBLIC OF SOUTH AFRICA**

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www.thedtic.gov.za

In prior discussions with my Special Advisor Mr Harald Harvey, you have indicated that in particular the following people from SARAO will be involved, in addition to others who may be identified from time to time:

- Willem Esterhuysen: Project Manager
- Thomas Kusel: Process Control
- Pontsho Maruping: Industry Liaison
- Justin Jonas: Technical advisor

In order to rapidly converge on a suitable solution for the ventilators, I am requesting all stakeholders to provide the above mentioned team with all the support they can muster, without regard for personal gain, in order to save lives and minimize the effect of the Corona virus on the people and economy of South Africa.

Your Sincerely

**Ebrahim Patel  
Minister of Trade, Industry and Competition**

**Cc Minister BE Nzimande  
Minister of Higher Education, Science, and Technology**












# SSA4003-0009-002 Rev 1 CFP for NVP

Final Audit Report

2020-04-03

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