



# NATIONAL VENTILATOR PRODUCTION (LOCALLY MANUFACTURED VENTILATORS)

## Final Impact Report

BENEFICIARY	DESCRIPTION	FUNDING ALLOCATED	FUNDING DISBURSED
<i>National Ventilator Project (NVP)</i>	Prototype development	R9.7m	R5.1m
<i>Council for Scientific and Industrial Research (CSIR) (through NVP)</i>	Manufacturing of 18 000 ventilators	R212.1m	R176.7m
<i>South African Emergency Ventilator Project (SAVE-P) (through NVP)</i>	Manufacturing of 2 000 ventilators	R41.2m	R37.1m
<b>Total</b>		<b>R263m</b>	<b>R218.9m</b>

### 01

#### THE SOLIDARITY FUND'S HEALTH CARE MANDATE

The Solidarity Fund was established to provide a rapid and agile support mechanism for South Africa as the country battled the COVID-19 pandemic. It brings together business, civil society, and government to strengthen and augment the national pandemic response. As one of the core pillars of the Fund, the Health Pillar works to support and strengthen the national health system as it strains to cope with the added burden brought by the pandemic.

Ensuring that hospitals have an adequate supply of ventilators is crucial to fighting COVID-19. As part of the health response, the Solidarity Fund partnered with the South African government to improve the country's supply of, and access to, ventilators for those who need them. However, due to the huge demand for ventilators worldwide, South Africa was unable to source a sufficient number of ventilators from global markets to meet local demand. This resulted in the birth of the National Ventilator Project (NVP) to locally manufacture non-invasive ventilators.

### 02

#### SUPPORT FOR THE NATIONAL VENTILATOR PROJECT

The NVP was initiated by the Minister of Trade, Industry, and Competition (DTIC) under the guidance of Cabinet and the COVID-19 National Command Council. It was a coordinated national effort that involved the local design, manufacture, and supply of fit-for-purpose, non-invasive ventilators for emergency treatment.

The Project was a collaborative initiative between government and industry, and executed under the leadership of the then Minister of Health. It was established in early March 2020 at a meeting attended by Ministers and representatives of the National Department of Health (NDoH), the DTIC and the Department of Science and Innovation (DSI), as well as a range of industry stakeholders. The global shortage and escalating prices of imported ventilators at the time informed the vital need, as an urgent national priority, to develop local capacity for the manufacture of the medical devices.

The Fund and the NDoH entered into a donation agreement where it was agreed that the Fund would procure, donate, and deliver the medical devices to the NDoH and the NDoH would distribute them to the public and private health sectors as required.

The Minister of the DTIC, with the support of Minister of the Department of Higher Education, Science and Technology (DHET), mandated the South African Radio Astronomy Observatory (SARAO) to manage the project. Public and private sector clinical, health technology, and regulatory practitioners were integrally involved in leading and guiding project development and execution. Principal Specialists in critical care, pulmonology and anaesthesia advised on the requirements for the relevant treatment therapies and the apparatus required to best support such treatment in light of their first-hand experience with treating COVID-19 patients.

The Fund supported the NVP to help ensure high quality, much needed ventilators were available quickly to enable the health system to cope with the additional disease burden and demand for ventilators brought on by the pandemic and to save lives. These ventilators can also be used to help treat other respiratory health challenges, helping health facilities to save lives beyond the pandemic.

The local manufacture of the ventilators proved to be more cost effective than procuring units internationally. It further helped to develop sustainable capacity for the production of medical equipment in the country. Such capacity can be used to service both domestic and international demand in the future.

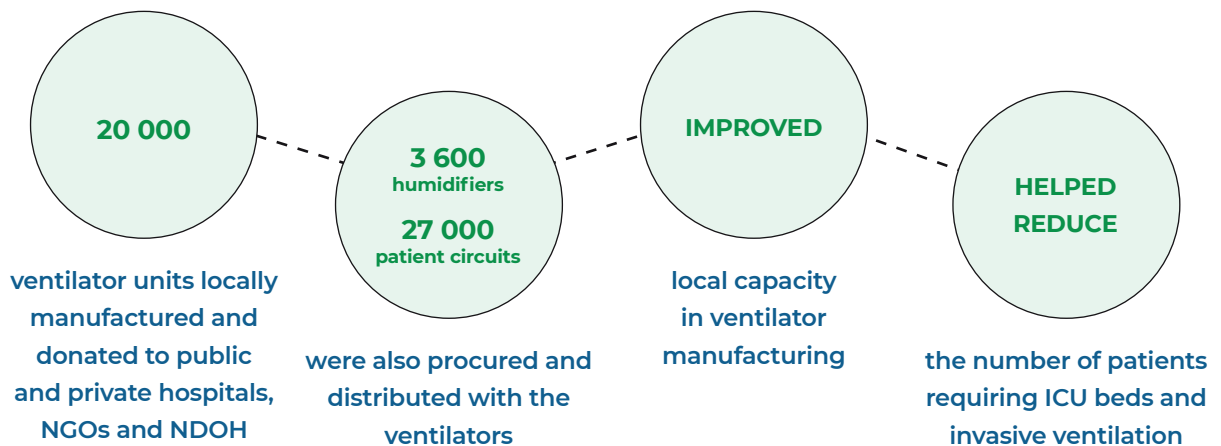
The Fund's support to the NVP was split into three grants:

1. R9.7m to fund the development of prototypes before the large-scale local production of ventilators.
2. R212.1m to fund the manufacturing of 18 000 Continuous Positive Airway Pressure (CPAP) ventilators, 27 000 patient circuits, and 3 600 humidifiers by the CSIR.
3. R41.2m to fund the manufacturing of 2 000 CPAP ventilators, that were later converted to High-Flow Nasal Oxygen (HFNO) devices, by SAVE-P.

**Through this support, 20 000 ventilators were produced locally that received** temporary section 21 licenses from the South African Health Products Regulatory Authority (SAHPRA) authorising the emergency use during the pandemic. The temporary licenses were issued for a period of 12 months renewable.

The ventilators were then distributed to public and private hospitals to provide ventilation support to hospitalised COVID-19 patients.

## IMPACT AT A GLANCE



### Distribution of ventilators

Distribution of CPAP ventilators to provinces and hospitals started just ahead of the pandemic's second wave (with high demand) and the third waves (with low demand). The task team, formed in January 2021, comprising of the Fund, the NVP Project Manager from SARAO, and the NDoH, agreed on a mechanism to enable accountability and the reconciliation of these devices via record keeping.

Of the 20 000 ventilators manufactured, 14 035 (12 888 from CSIR and 1 147 from SAVE-P) were donated by the Fund, in terms of the project, to public and private hospitals, and 5 965 remained in storage. The latter were subsequently donated to NDoH in September 2021 when the project came to a close.

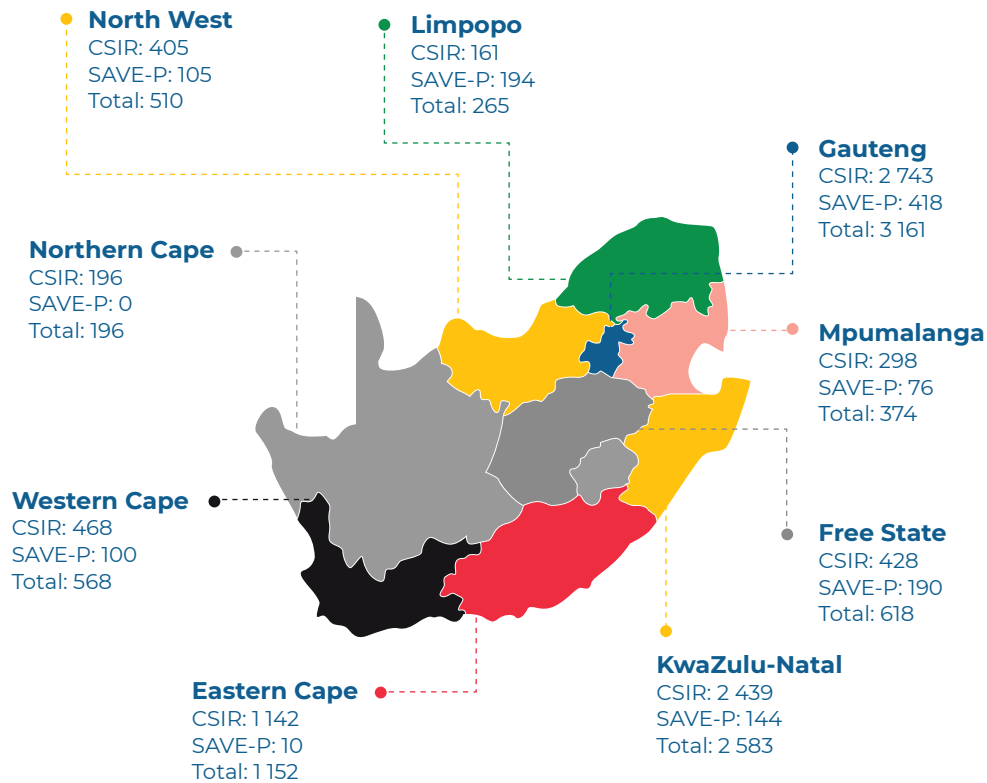
The 14 035 devices that were donated and distributed included the following donations:

- 3 100 CSIR devices donated to Gift of the Givers Foundation during the second and third waves.
- 2 415 machined configurations of the CPAP that CSIR intends to recall and dispose of in compliance with the licencing condition imposed by SAHPRA. These will be replaced by CSIR.
- The Fund further granted CSIR its request for the donation of 50 CPAP ventilators and 1 500 patient circuits on condition that CSIR undertakes to:
  - use the medical devices solely for the purpose of continuing clinical development and conducting investigation trials; and
  - comply at all times with the conditions imposed by SAHPRA in respect of its manufacturing licence, as well as any future licensing conditions which may be imposed by SAHPRA in relation to the extension of the CSIR's manufacturing licence, post the pandemic.



## Geographic distribution

(As of August 2022. CSIR Provincial numbers show public hospitals only.)



### Remaining CSIR ventilators:

Private hospitals: 1 229

Donation to NDoH: 5 112 (CSIR) 853 (SAVE-P)

Gift of the Givers Foundation: 276

To CSIR: 2 465

04

## PRINCIPLES GUIDING THE FUND'S SUPPORT OF THE NATIONAL VENTILATOR PROJECT



**Alignment with Fund's mandate and the national COVID-19 response strategy:** The Fund worked closely with relevant Government entities, particularly the NDoH and DTIC, to ensure that ventilators were given priority in the health response to the pandemic. The NDoH identified the hospitals that were in need of the ventilators and led the coordination of the public health sector distribution, whilst the Hospital Association of SA (HASA) coordinated and supported distribution to private hospitals in need.



**Impact additionality:** The Fund deploys its resources for maximum impact. Local development of ventilators brought enormous additionality to existing efforts around ventilation procurement. The availability of CPAP devices in acute and emergency units enabled early respiratory support during acute COVID-19 respiratory distress, which is believed to reduce the risk of progressing to invasive ventilation support and death, whilst also helping reduce the demand for ICU beds in the health system.



**Speed:** Rapid support to the NVP enabled the health system to address critical medical equipment needs at speed and distribution started well ahead of the Beta variant and the devastating second wave in late 2020 and early 2021.



**Price competitiveness:** The ventilators were procured at a cost of R16 487 per SAVE-P device and R7 065 per CSIR device. These costs compared favourably to international procurement alternatives.



**Supporting sustainable local manufacturing:** The NVP partnership with Department of Science and Innovation and with the CSIR was purposeful, to facilitate the establishment of sustainable, local manufacturing capacity for ventilators.



**Donation of Intellectual Property Rights:** The Fund donated the Intellectual Property rights from the development of ventilator prototypes under the NVP to the CSIR. The CSIR is South Africa's research and development institution that was established through an Act of Parliament. It is a suitable organization to hold the IP for ventilators as the public entity working with departments of higher education, science and innovation to ensure shared learning and expansion of skills in the country.

## 05

### CHALLENGES

Distribution of ventilators happened at the height of the pandemic while there was very little movement due to the lockdown restrictions. This resulted in limited physical training on the use of the devices.

The new locally manufactured devices were not well marketed to all hospitals and institutions outside the larger public sector, such as the non-governmental organisations, nursing homes etc., where they could have been of help. As a result, the demand for them was not as was anticipated and the project had to incur storage costs as these were only distributed on demand/ requests.

The reconciliation process at the end of the project challenges, in terms of tracing final destination of the devices, because there was further distribution within provinces from primary receiving hospitals to their surrounding hospitals as the need arose during the different waves. However, NDoH and the CSIR have embarked on a process to trace all ventilators in each province, working with health technology managers who are the caretakers of assets.

Not much clinical data was collected to understand the performance of these local devices and compare with the ones in the market. It is also not clear how many of the 20 000 devices actually reached bedside after being distributed to provinces. Research would need to be done to determine use and clinical performance and to determine impact in actual reduction of disease progression, demand for ICU beds, reducing hospital length of stay, and reducing death.

Lastly, engagements between the NDoH, DSI, the Solidarity Fund, and SAHPRA with CSIR as the manufacturer are required to review the devices to be decommissioned, and to develop a plan for sustaining this investment and get the devices to be fully registered, repurposed, and used for similar conditions of acute respiratory distress.

## CONCLUSION

The Fund mobilised rapidly to support the National Ventilator Project to locally develop and manufacture 20 000 ventilators, 27 000 patient circuits, and 3 600 humidifiers, benefitting public and private hospitals in all nine provinces, as per the need. This support was critical in supporting the health system that was struggling to provide ventilation support for an avalanche of COVID-19 patients in hospitals across the country. The ongoing legacy of this project has ensured a significant addition of essential equipment for the health system and developed local capacity in manufacturing these devices.

