



# HEALTHCARE

<b>Section 4 - Healthcare</b>	<b>1</b>
<b>Medical Gases</b>	3
<b>Afrox HospitalCare</b>	4
Medical Air	4
Medical Carbon Dioxide	4
Medical Nitrous Oxide	5
Medical Oxygen	5
Entonox	6
Analgesic Demand Valve	6
Integrated Valve Regulator (IVR) - Medical Oxygen	7
Cylinder Data Sheet	8
Customer Solution Programme	10
HospitalCare Supply & Delivery Offer	10
Afrox Homecare	11
Respiratory Insufficiency - Medical Oxygen Therapy	12
Homecare Products	13
Homecare Services	19
General Information	29
Hygiene	30

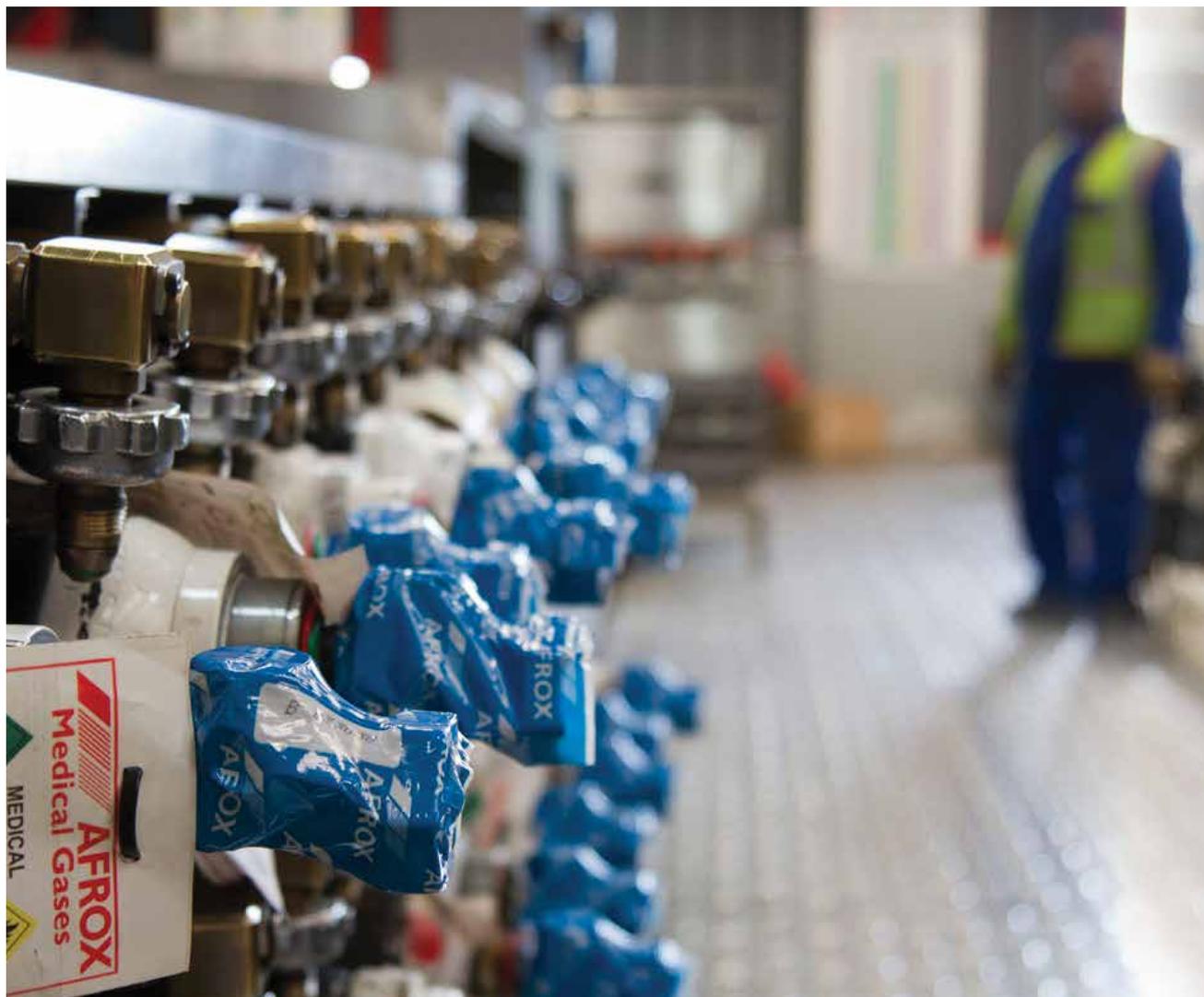
# MEDICAL GASES

Afrox is a member of The Linde Group and Afrox Healthcare forms part of the Linde's Global Healthcare strategic business unit. Afrox Healthcare is a leading supplier of medical gases and related services in the southern African region. Linde has established a global medical gases headquarters that aims to serve the medical community worldwide. With these strategic alliances, Afrox Healthcare is able to access and adopt best practices and Afrox Healthcare customers are able to enjoy local service, whilst also benefiting from valuable advice on best clinical practices across a wide range of medical gas applications.

Afrox supplies products and services to hospitals in the public and private sectors, to dentists, private doctors and veterinarians, as well as to homecare patients. One of our important guiding principles as an organisation when dealing with and handling medical gases is that of safety. This remains fundamentally critical for both our employees as well as our customers.

As a company, we recognise the responsibility and significance of ensuring a healthy nation. As such, we contribute to this by offering high quality products and services.

Medical gases are regulated by the Medicines Control Council (MCC) and all Afrox medical gases are in compliance to all applicable MCC regulations. Afrox is the first gases company in South Africa to have achieved registration of all our gases under the Medicines and Related Substances Control Act (101/1965); our customers can be assured that all medical gases purchased from Afrox Healthcare meet the requirements in terms of safety, quality and efficacy. All our gases are manufactured in ISO 9001 certified plants. We reassure our customers that all relevant handling, processing and storage of our products and equipment takes place in accordance with Good Manufacturing Practice (GMP) and the Medical Device Directive 93/42. All Afrox finished medical products and devices are subject to a rigorous quality control process, as guided by Linde safety and quality measures.



# AFROX HOSPITALCARE

## Overview

Afrox Healthcare provides a full spectrum of high quality medical gases and associated services to hospitals and clinics in both private and public sectors across southern Africa. Our gases are manufactured in ISO 9001 certified plants and are distributed to various healthcare institutions through an extensive gas distribution network in a wide range of modes from cylinders to highly specialised installations.

## Medical Air

Medical air is used:

- As a replacement for atmospheric air when the atmosphere is contaminated by noxious fumes, vapours or gases
- In anaesthesia as a carrier for volatile anaesthetic agents
- As a power source for pneumatic equipment
- In ventilators and incubators to provide uncontaminated and controlled air flow.



## Medical Carbon Dioxide

Medical carbon dioxide is used:

- To increase the depth of anaesthesia rapidly when volatile agents are being administered. It increases depth of respiration and helps to overcome breath-holding and bronchial spasm
- To facilitate blind intubation in anaesthetic practice
- To facilitate vasodilation, and thus lessen the degree of metabolic acidosis during induction of hypothermia
- To increase the cerebral blood flow in arteriosclerotic patients undergoing surgery
- To stimulate respiration after a period of apnoea
- In chronic respiratory obstruction after it has been relieved
- To prevent hypocapnia during hyperventilation
- For clinical and physiological investigation.



# Medical Nitrous Oxide

Medical nitrous oxide is used:

- For the relief of severe pain, usually in emergency situations, by inhalation with 50% oxygen
- During induction and maintenance of anaesthesia, in controlled situations
- Medical nitrous oxide is a Schedule 4 gas.



# Medical Oxygen

Medical oxygen is used:

For virtually all modern anaesthetic techniques as well as pre- and post-operative management. Oxygen provides life support by restoring tissue oxygen levels in a range of conditions, including:

- Cyanosis as a result of cardio-pulmonary disease
- Surgical trauma, chest wounds and rib fractures
- Shock, severe haemorrhage and coronary occlusion
- Carbon monoxide poisoning
- Hyperpyrexia
- Major trauma, such as road accidents and gunshot wounds
- Oxygen plays a vital role in the management of sudden cardiac and respiratory arrest - whether drug induced or traumatic - and in the resuscitation of critically ill patients when circulation is impaired. It is also used in neo-natal resuscitation
- Episodic cluster headaches.



# Entonox

## Entonox is used:

Exclusively for the relief of pain in a controlled setting by a healthcare professional. Entonox is a ready-to-use medical gas mixture consisting of 50% nitrous oxide and oxygen. The balanced nitrous oxide/oxygen ratio assures good oxygenation and minimises the risk of over-sedation.

During a painful procedure like childbirth, when the emphasis is on delivering relief from pain and discomfort with minimal sedation, Entonox is a commonly used technique. It is fast acting, self-regulated, and disperses rapidly from the body following cessation of inhalation.

Nitrous oxide exhibits classical dose-dependent analgesic effects, reducing the level of pain experienced. Entonox is fast and effective – the onset of pain relief is gained within a minute – any effects wear off rapidly.

The main advantages are:

- Non-invasive, inhaled analgesic
- Rapid onset/offset action
- Not only analgesic but contains sedative and anxiolytic properties
- Entonox can be combined with all other analgesics.

## Analgesic Demand valve

Entonox is administered via a demand valve for self-administration where the patient has control of the drug intake.



Description	Item Number
Regulator - Entonox	W342229
Analgesic demand valve for cylinders	W342228
Analgesic demand valve for wall points - 3m	W342235
Analgesic demand valve for wall points - 6m	W342239
Exhalation valve pack of 100	W342231
Exhalation valve for face mask pack of 10	W342236
Exhalation valve for face mask pack of 100	W342237

# The Analgesic Demand Valve

The analgesic demand valve is intended for the self-administration of analgesic gas mixture ( $O_2/N_2O$ ) – Entonox.

Unlike conventional demand valves, the flow through the demand valve increases without a significant increase in resistance to flow. This results in an incredibly low patient effort irrespective of flow rate.

There are a number of medical applications where self-administration of medicinal gases at high flow rates:

- The exhalation valve directs exhaled gas away from the handset, eliminating the risk of cross-contamination
- State-of-the-art electrostatic viral filter allows incredibly low resistance during inhalation
- Unique one-way valve eliminates filter resistance during exhalation
- Ruby to brass valve seat eliminates the resistance to flow due to seat compliance that is suffered by conventional systems
- Unique non-linear valve actually reduces flow resistance as flow increases
- Latex-free, phthalate-free for maximum patient safety.



**Benefits of the unique exhalation valve:**

- Enables exceptionally high flows with incredibly low inspiratory effort, resulting in an unparalleled user experience
- Directs exhaled gas away from the delivery device, eliminating the risk of handset contamination
- Is a single patient use filter used with demand valves, with no risk of cross-contamination. There is no need for an expensive decontamination process after every patient use
- Incorporates a unique ultra-low resistance one-way valve. This unique valve prevents dilution of medical gas with ambient air during inhalation, only opening during exhalation to channel exhaled breath away from the handset. In contrast with conventional systems, resistance to flow at exhalation due to filter resistance is eliminated
- Is sealed securely to the handset with two snap fit clips, which when lifted, release the exhalation valve quickly and simply for disposal.

## Integrated Valve Regulator (IVR) Medical Oxygen

**The Integrated Valve Regulator (IVR):**

Designed specifically to address the needs of nurses and respiratory therapists for the administration of medical oxygen in portable cylinders. Here's how:

- The IVR is ready to use whenever it is needed; there are no separate parts to find and attach
- The valve, regulator, content gauge and flow controls are integrated into a single piece and covered by a virtually indestructible protective guard

- The live contents gauge is easy to read and always indicates how much oxygen is available
- The unique design of the IVR promotes a safer environment for hospital staff and patients
- No more need to maintain an inventory of working regulators or cylinder spanners.

These features save staff time and money.



# Cylinder Data Sheet

Dimensions exclude the cylinder valve, and are only for guidance, as the actual size/mass depends on the cylinder supplier. In the interest of product improvement, Afrox reserves the right to alter or withdraw products from the market without prior notice.

Gas Type	Contents (kg)	Valve Type	New SAP Item Number	Contents (L gas @ 1 atm. & 20°C)	Cylinder Height (mm)	Cylinder Diameter (mm)	Cylinder Material
Medical Oxygen 	0,25	PI	P101-AD-P125	187	262	90	Aluminium
	0,47	PI	101-CB-P1	352	415	100	Steel
				352	415	100	Steel
	0,49	PI	P101-BD-P1	367	405	102	Aluminium
		IVR	101-BE-IVR	420	360	102	Aluminium
	0,56	IVR	101-BE-IVR	420	400	100	Fibre Wrap
				705	755	100	Steel
	0,94	PI	101-EB-P1	705	755	100	Steel
		1,40	IVR	101-FE-IVR	1 050	880	100
	1 380				770	140	Steel
	1,84	PI	101-HB-P1	1 380	770	140	Steel
		P1 (Homecare)	101-HH-P1	1 380	470	176	Steel
4,60	BN	101-KB	3 450	1 197	176	Steel	
	PI	101-KB-P1	3 450	1 197	176	Steel	
10,20	BN	101-RC	7 650	1 422	230	Steel	

Gas Type	Contents (kg)	Valve Type	New SAP Item Number	Contents (L gas @ 1 atm. & 20°C)	Cylinder Height (mm)	Cylinder Diameter (mm)	Cylinder Material
Medical Nitrous Oxide 	1,60	PI	141-CB-P1	868	415	100	Steel
				868	415	100	Steel
	6,30	PI	141-HB-P1	3 420	770	140	Steel
		BN	141-HB	3 420	770	140	Steel
	15,70	BN	141-KB	8 525	1 197	176	Steel
	31,30	BN	141-RB	16 995	1 414	230	Steel

Gas Type	Contents (kg)	Valve Type	New SAP Item Number	Contents (L gas @ 1 atm. & 20°C)	Cylinder Height (mm)	Cylinder Diameter (mm)	Cylinder Material
 Entonox	0,79	PI	211-CB-P1	499	415	100	Steel
	3,07	PI	211-HB-P1	1 940	770	140	Steel
	7,70	PI	211-KB-P1	4 866	1 197	176	Steel
	15,40	PI	211-RC-P1	9 733	1 414	230	Steel

Gas Type	Contents (kg)	Valve Type	New SAP Item Number	Contents (L gas @ 1 atm. & 20°C)	Cylinder Height (mm)	Cylinder Diameter (mm)	Cylinder Material
 Medical Air	1,57	PI	191-HB-PI	1 303	770	140	Steel
				1 303	770	140	Steel
	3,90	BN	191-KB	3 237	1 197	176	Steel
	8,70	BN	191-RC	7 221	1 422	230	Steel
	0,78	PI	191-EB-PI				

Gas Type	Contents (kg)	Valve Type	New SAP Item Number	Contents (L gas @ 1 atm. & 20°C)	Cylinder Height (mm)	Cylinder Diameter (mm)	Cylinder Material
 Medical Carbon Dioxide	1,44	PI	201-CB-P1	783	415	100	Steel
	5,60	PI	201-HB-P1	3 046	770	140	Steel
	14,10	MALE	201-KB	7 670	1 197	176	Steel
		MALE WET	201-KB-W	7 670	1 197	176	Steel
	31,50	MALE	201-RC	17 136	1 422	230	Steel
		MALE WET	201-RC-W	17 136	1 422	230	Steel

# Customer Solution Programme

- Afrox boasts a highly competent Customer Service Centre (CSC) which operates Monday to Friday from 07h30 to 17h30. In order to ensure that our customers' needs are met at all times, a service consultant is always available to answer to your calls after hours, 7 days a week and 365 days a year
- The centre uses an event tracking system enabling and empowering our entire service and sales organisation to meet our healthcare customers' requirements
- Afrox HospitalCare's multi-skilled staff are customer service experts, offering specialised advice on all products and services that Afrox HospitalCare offers
- Throughout the country, customers can place orders, make account and general enquiries by using the shared services number 0860 020202 (Afrox HospitalCare)
- The CSC is equipped with state-of-the-art IT systems to enhance operational efficiency for the nursing services, electronic billing, electronic links for speedy authorisations and other functions. This is an effort by Afrox HospitalCare to ensure that we meet the high service levels required by our customers
- All our customer accounts are managed through the Customer Service Centre.



## Why use the Afrox eShop

- Keep track of orders and invoices
- Check order history
- Re-order from previous invoices (speeding up your order process)
- Create a custom order template (speeding up your order process)
- Manage cylinder holdings
- Manage deliveries
- View latest specials & offers
- Orders are processed in our system immediately
- No order placement queues
- Available 24/7.

# HospitalCare Supply & Delivery Offer

Afrox's medical gas and equipment distribution network is unrivalled within southern Africa. Wherever you are, we can supply.

- For the convenience and comfort of our customers, Afrox HospitalCare offers an extensive delivery service countrywide
- All deliveries are scheduled via our world-class Customer Service Centre (CSC) which can be contacted on 0860 020202
- Our CSC or your local Afrox HospitalCare representative is able to offer advice regarding lead times for our customer deliveries; however, these are naturally influenced by the proximity of our customer delivery points to Afrox distribution hubs
- Generally all orders placed and approved with the Afrox CSC will be delivered the following day provided that the purchase order has been placed the previous day before 12 noon. Bulk delivery is determined as per a telemetry system and bulk product can be delivered anytime as agreed upon with the customer
- In general, product will be delivered to a safe and convenient location, given suitable ground conditions within the standard delivery window
- Afrox will provide a customer representative with the proof of delivery (POD) collection note at the time of delivery and/or collection
- For hospitals and other large medical establishments, bulk delivery patterns are established and dependant on demand. A minimum stock of 25% or 2 days supply is generally factored in the delivery planning and scheduling
- Afrox will re-fill bulk gases as per requirements by and agreement with the customer, at any scheduled time or day of the week
- Delivery of gas other than in cylinders shall be effected at the point where it is discharged into the storage equipment at the customer site
- Delivery of gas in cylinders shall be effected at the point where the cylinders are delivered to the customer site as per the Afrox delivery matrix
- Afrox offers the convenience of a cylinder policy that operates on a "full-for-empty" basis. Extra allocations are available, subject to prior arrangement and availability
- Geographical restrictions may apply in locations that are significantly distant from an Afrox filling site.

# AFROX HOMECARE

## Overview

Afrox Homecare is committed to providing a comprehensive range of products, accessories and related services to chronic obstructive pulmonary disease (COPD) patients in the comfort of their homes. COPD is the most common cause of respiratory insufficiency. Oxygen flow rate and hours of use are prescribed by the patient's medical practitioner and Aprox Homecare ensures compliance to the prescribed regimen. Aprox Homecare actively interacts with all medical aids to assist the patient with obtaining authorisations from their medical aids for oxygen therapy.

At Aprox Homecare we pride ourselves in delivering quality products backed by outstanding services including the Aprox Homecare nursing service.

Catering for CRI (Chronic Respiratory Insufficiency) patients' homecare needs through the supply of:

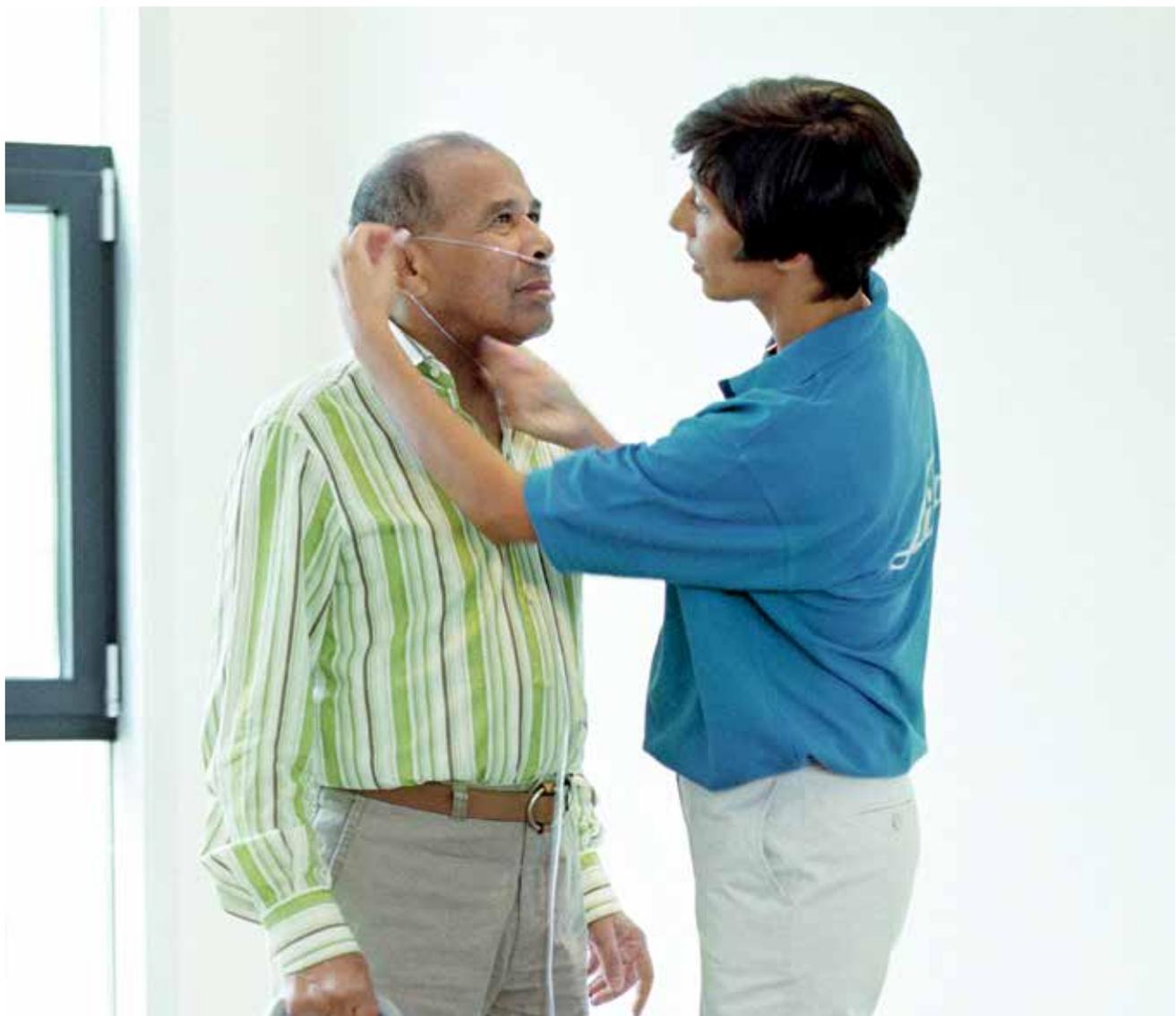
- Oxygen concentrators (stationary and portable)
- Medical oxygen cylinders
- Portable cylinder oxygen systems
- Oxygen conserving devices
- Value added services.

Customer Service Centre

Tel: 0860 030202

Fax: 011 821 3050

E-mail: [homecare@afrox.linde.com](mailto:homecare@afrox.linde.com)



# Respiratory Insufficiency - Medical Oxygen Therapy

## Definition

### Chronic Respiratory Insufficiency (CRI)

Chronic Respiratory Insufficiency (CRI) is the respiratory system's inability to oxygenate the blood. It is reflected in a fall of oxygen ( $O_2$ ) levels in the blood, sometimes linked to an increase in carbon dioxide ( $CO_2$ ) levels. These blood gases are analysed from a blood sample taken from an artery in the wrist. Blood oxygenation can be evaluated less accurately, but without a need for a blood sample, by measuring the oxygen saturation in the blood, using a saturometer placed on the end of the finger.

The main sign of respiratory insufficiency is breathlessness during activity (dyspnea). The main consequence of this chronic lack of oxygenation in the body is the development of right cardiac insufficiency, due to the gradual shrinkage of pulmonary blood vessels through which the cardiac pump must force the blood. The result is water retention with oedema of the lower limbs.

### The Main Causes of Respiratory Insufficiency

Chronic Obstructive Pulmonary Disease (COPD) is the most common cause of respiratory insufficiency. It is mainly caused by smoking. Smoke inhalation leads to inflammation of the bronchi, then their gradual shrinkage (obstruction). The alveoli can also be damaged by smoke; this is called emphysema.

At first, COPD is revealed by a chronic wet cough, then the passage of air into the bronchi becomes more difficult, which explains the breathlessness, initially on activity, then at rest. In the same way, blood oxygenation initially falls on activity, then at rest.

COPD is a common disease which affects one smoker in five after the age of 40. In France, 2,5-million people suffer from it. Of these, 30 000 are at the stage of chronic respiratory insufficiency and are treated at home with oxygen therapy or assisted ventilation. 90% of cases of COPD are due to smoking. It has been shown that at any stage of the disease, stopping smoking prevents deterioration of respiratory function and, at the same time, increases life expectancy. There are other bronchial diseases, such as asthma or cystic fibrosis.

### Other Causes

Other causes of respiratory insufficiency are represented by diseases of the lungs, thoracic wall, or respiratory pump, and these reduce the volume of air which can be taken into the lungs and hence the passage of oxygen into the blood, for example, muscular diseases (myopathies) or lung diseases such as pulmonary fibrosis.

## Diagnosis and Monitoring

Respiratory insufficiency is diagnosed and monitored jointly by the pneumologist, the GP and the physiotherapist. In the most serious cases, medical home assistance companies will be called in to administer treatments such as medical oxygen.

The pneumologist will first evaluate the condition of the respiratory tract with a Lung Function Test (LFT) which includes two types of analysis:

- Spirometry: measures respiratory capacity
- A study of blood gases.

Normal values are 75 to 100 mm of mercury for blood oxygen, between 35 and 45 mm of mercury for blood carbon dioxide and between 94 and 100% for oxygen saturation.

These examinations are often completed by a pulmonary X-ray. At the end of this first examination, the diagnosis and severity of respiratory insufficiency will be established and a programme of treatment will be proposed, followed by regular examinations (at least twice a year), to monitor treatment efficacy and progression of the respiratory insufficiency.

## Treatment

### Preventive Treatment

Preventive treatment includes stopping smoking and having an anti-flu vaccination every year and an anti-pneumococcal vaccination every four years. A change of lifestyle is often recommended: weight loss, a specific diet and regular physical exercise (after the age of 60, everyone should walk for at least 30 to 45 minutes every day).

### Treatment with Aerosol Therapy

Treatment with aerosol therapy includes the administration of drugs designed to dilate the bronchi (bronchodilators) and sometimes anti-inflammatory drugs. These drugs are taken in the form of either powder for inhalation or a spray. In some cases, these drugs are taken in the form of aerosols produced by generators.

### Respiratory Physiotherapy Sessions

Respiratory physiotherapy sessions are often prescribed to improve drainage of bronchial secretions and activity retraining.

### Oxygen Therapy

When blood oxygen levels fall during physical exercise, breathlessness on activity can be improved by administering oxygen from portable medical oxygen reserves.

When resting, blood oxygen levels are below 60 mm Hg. It is essential to administer oxygen therapy for at least 15 hours a day.

Oxygen can be administered using concentrators which produce oxygen-enriched air, or liquid or gas medical oxygen reserves.

### Ventilation

In the most severe cases of respiratory insufficiency, it is sometimes necessary to resort to mechanically assisted ventilation.

# Homecare Products

At Afrox Homecare, we pride ourselves in delivering quality products backed by outstanding service.



## Oxygen Concentrator

- Ideal solution for patients requiring oxygen in the comfort of their homes
- Oxygen is always available, no refilling required
- Concentrator is quiet and aesthetically appealing.



## Oxygen Devices

- The oxymatic conserving device can extend the average usage time of an oxygen cylinder by five times.



## Medical Oxygen Cylinders

- Used for intermittent oxygen usage
- Backup system (power failures are a reality).

## Oxygen Concentrators (Stationary)

Oxygen concentrators are electrically operated devices that concentrate the oxygen content of normal room air to approximately 90% at flow rates up to 5 l/min. Concentrators are convenient, cost effective, do not require refills and are aesthetically attractive. Of all the delivery systems used by oxygen-dependent patients, oxygen concentrators are the most common and usually the most economical method to provide oxygen therapy at home. An oxygen concentrator uses sieve-bed technology to extract oxygen from the surrounding air. This oxygen is then delivered to the patient using a plastic tube connected to a nasal cannula or face mask. The advantages of a concentrator over other forms of oxygen supply are:

- Concentrators provide a continuous supply of oxygen, while requiring very low maintenance
- The concentrator stays in the room in which it is placed and the person using the device can use a longer length of oxygen tubing (15 m of tubing is provided free of charge) to move around the house without having to move the concentrator
- A concentrator can be combined with a medical oxygen cylinder as a backup in case of power outages
- Concentrators are highly cost-efficient.

Because concentrators operate solely on electricity, it is critical that they are always supplied with a backup cylinder to ensure uninterrupted oxygen supply, even during power failure.



Description	Item Number
Millenium Concentrator, 220 V	W342104
Everflo Concentrator	W004011

## Oxygen Concentrator (High Flow Oxygen Concentrator)

**AirSep High Flow Concentrator** combines high pressure with high flow to create the premium 10 l/min oxygen concentrator. It is uniquely designed to meet oxygen patients' high flow needs while providing the essential outlet pressure to drive special respiratory accessories, including large-volume jet nebulisers, venti-masks, and medication nebulisers. The high pressure from the concentrator also easily powers long oxygen tubing runs.

The 10 l/min oxygen concentrator simplifies a tracheostomy setup by eliminating the need for a separate external compressor. Administer humidified oxygen to a trach by connecting a jet neb bottle directly to Intensity's O<sub>2</sub> outlet. The unit can reduce both equipment needs and overall power consumption through the delivery of oxygen to two patients simultaneously up to combined total flow of 10 l/min with one unit.



## Oxygen Concentrator (Portable Oxygen Concentrator)

The **Inogen One**<sup>®</sup> concentrator is designed to provide active oxygen users unparalleled freedom and independence and an ability to live life without the restraints imposed by traditional oxygen therapy devices. It's approved for stationary, portable, and travel use, for daytime and night time. The concentrator is made to make your life easier. There are no regulators to switch or portable tanks to refill or replace, just a couple of buttons. That's it. Inogen One<sup>®</sup> delivers the independence of our original oxygen concentrator, but it's smaller, lighter, and makes more oxygen with a longer battery life.



Description	Item Number
AirSep High Flow Concentrator	W342127

Description	Item Number
Inogen One <sup>®</sup> G3 System - 16 cell	W342054
Inogen One <sup>®</sup> G3 System - 8 cell	W342055
Inogen One <sup>®</sup> G2 System - 24 cell	W342082
Inogen AC Power Supply G2	W342025
Inogen AC Power Supply G3	W342058
Inogen G3 16 Cell Battery	W342079
Inogen G3 8 Cell Battery	W342071
Inogen One G2 EXT Battery Charger	W342085
Inogen One G3 Carry Bag	W342073
Inogen One G3 DC Power Cable	W342077
Inogen One G3 EXT Battery Charger	W342074

## SimplyGo Mini

The SimplyGo Mini portable oxygen concentrator (POC) offers true reliability that today's patients demand in a POC. With up to 9 hours battery autonomy and the ability to deliver nearly 20% more oxygen output than the nearest competitive POC, SimplyGo Mini has the highest oxygen output of any POC weighing 2,3 kg or less.

Description	Item Number
SimplyGo Mini Standard Battery	W342137
SimplyGo Mini Extended Battery	W342169

## Oxygen Vitapak System

Travelling with medical oxygen can be difficult. Oxygen Vitapak System is designed to take care of all medical oxygen needs throughout the journey, freeing patients from worry and the need to make arrangements with different authorities in different countries or regions.

With Oxygen Vitapak System, Afrox Homecare combines our expertise in technology and logistics to create a truly life-enhancing service for oxygen-dependent patients. We work in cooperation with international partners, coordinating the delivery of medical oxygen at every step of the journey. Patients have the freedom to plan an extensive itinerary, safe in the knowledge that their vital supply of oxygen will be there, when and where they need it.

This system consists of a small portable cylinder, an Oxymatic® unit, a carry pouch and a nasal cannula. The Oxymatic® oxygen conserver extends the life of the oxygen cylinder by as much as seven times. Oxygen cylinders, used in combination with the Oxymatic® unit, provide a cost-effective solution to the patient. Small lightweight cylinders fit neatly into a backpack, permitting valuable freedom of movement away from the patient's home oxygen source for reasonably long periods of time, thus allowing the patient to get out into the community, to shop, visit friends or family, or get to their doctor for a checkup. The availability of mobile oxygen has a direct impact on patients' quality of life.



Conserving device

Oxygen, Vitapak

Description	Item Number
Oxymatic® Device with Carry Bag	W340575
Oxygen, Vitapak, 0,25 kg Medical Oxygen Cylinder	W342113

## Medical Oxygen Cylinders

Afrox medical oxygen cylinders are registered as medicines with the South African Medicines Control Council under the Medicines and Related Substances Control Act (101 of 1965). This means that the manufacturing process has to comply with Good Manufacturing Practice, ensuring that Afrox medical oxygen is fit for its intended use, is safe, is of appropriate quality, and performs as expected so as not to place patients at risk.

Cylinders are widely available in many different sizes, flexible in their use, provide high purity oxygen of 99,5% and can deliver flow rates in excess of 5 l/min, which making them suitable for nebulisation.

For short burst oxygen therapies, or where high flow rates are prescribed, cylinders are used as the main source of medicinal oxygen.

For homecare, medical oxygen cylinders are primarily used as a backup for oxygen concentrators, in case of power failures, for example.

Lightweight cylinders increase patient mobility, paired with an oxygen-conserving device and a backpack to increase ease-of-use. The oxygen-conserving device usually enables a cylinder to last approximately 5 times as long as a stand-alone cylinder.



Description	Item Number
Oxygen, Medical, Cylinder Rental	W321052
Oxygen, Medical, 1,84 kg, PI Refill	W340284
Oxygen, Medical, (1 360 l) 1,84 kg, PI Refill	W340679

## Nebuliser Mini-Plus

- The Mini-Plus is a compressor nebuliser designed for easy portability, especially for people on the move.
- Chronic respiratory problems are unpredictable and it is important for people to have their treatment devices close at hand.
- The compact size, lightweight and convenient carrying handle of the Mini-Plus facilitate portability and allow each person to keep their Mini-Plus accessible at all times.

### Features and Benefits

- Reliable piston-driven motor
- Compact size
- Tubing holder design.

## Finger Monitor SB100

Fingertip SpO<sub>2</sub> incorporates the electronics and sensor into one unit that provides a cost-effective solution for spot-checks and short-term monitoring. Fingertip SpO<sub>2</sub> is not influenced by a patient's motion; therefore, it gives patients the freedom of having their physical checkup taken anywhere and anytime they want including having it incorporated into an athletic activity.

### Features and Benefits

- Delivers accurate pulse rate and blood saturation in seconds
- One-touch keypad for easy operation
- Big and bright LED display
- Compact and light for mobility
- Two AAA alkaline batteries for easy power supply
- Automatic power-off after 10 seconds in idling.

**Size:** 63,5 mm (h) x 34 mm (w) x 36 mm (d)

**Weight:** 37 g

## Vac Pump Vac Pro

The VAC-series pump is Afrox Homecare's new portable suction unit and has been designed by Apex to combine function with aesthetic appeal and meet the needs of today's hygiene and infection control requirements. The VacMaxi suction unit is a powerful, fast and effective aspirator ideal for use in high vacuum, high flow applications.

### Features and Benefits

- Lightweight for easy portable use
- Integrated canister holder
- Ergonomic easy to carry handle
- Easy to adjust pressure regulator
- Smooth ABS hygienic finish, easy to clean
- Detachable power cord for quickly change.

**Size:** 352 mm (l) x 206 mm (w) x 192 mm (d)

**Weight:** 2,8 kg

### Free Accessories

Mouthpiece set

**Size:** 14 cm (w) x 18,8 cm (d) x 10 cm (h)

**Weight:** 1,6 kg



Description	Item Number
Nebuliser Mini-Plus	W342912



Description	Item Number
Finger Monitor SB100	W342913



Description	Item Number
Vac Pump Vac Pro	W342914

## Regulators and other accessories

Afrox provides a wide range of medical regulators to use with medical gas cylinders.

### ALPINOX Pin Index Medical Oxygen Regulator with Flow Selector

Pin index oxygen gas regulator is used for homecare, emergency and hospital oxygen therapy.

#### Key advantages:

- New generation of medical regulator with high flow precision and continuous flow between settings
- Ergonomic, intuitive design is easy to use and ensures safer, more accurate dosing
- Single-stage piston regulator technology ensures a long lifetime
- CE certified according to MDD 93/42/EEC
- Compliant with EN ISO 10524.

#### Applications:

- Emergency solutions / regulators / cylinder regulator
- Homecare solutions / regulators / cylinder regulator
- In-hospital therapy / flowmeters / cylinder regulators.



#### Specifications Ordering Codes

Gas Type	Oxygen
Inlet Pressure	200 bar 2 900 PSI
Outlet Pressure	4,5 bar 58 PSI
Flow Settings	0-1/2-1-2-3-4-5-6-7-9-12-15, 0-1/4-1/2-1-2-3-4-6-12-15-25 litres/minute
Gauge Face	0-315
Body Material	White coated brass
Seat Material	Nylon
O-ring Material	EPDM

### MINIOX Medical Gas Regulator

Compact cylinder regulator is used for homecare, hospital and emergency oxygen therapy.

#### Key advantages:

- Precise gas flow and pressure control for safe and accurate oxygen therapy
- More accurate flow control reduces gas wastage and reduces operating costs
- Complies with national standards
- Available in single outlet, double outlet or flowmeter configurations
- Compact, economical design

#### Applications:

- Emergency solutions / regulators / cylinder regulator
- Homecare solutions / regulators / cylinder regulator
- In-hospital therapy / flowmeters / cylinder regulators.



### Specifications Dimensional Drawing Ordering Codes

Gas Type	Oxygen, Air, N <sub>2</sub> O
Filter Material	Sintered bronze 20 µm
O-ring Material	EPDM
Diaphragm Material	EPDM
Seat Material	PA 6.6
Body Material	Chrome-plated brass
Upper Operating Temperature Limit	60 Celsius 140 Fahrenheit
Lower Operating Temperature Limit	-20 Celsius -4 Fahrenheit
Flow Rate	0-18 slpm
Outlet Connection	National standards
Inlet Connection	National standards
Outlet Pressure	3,5 bar 43,5 PSI
Inlet Pressure	200 bar 2 900 PSI
Weight	0,640 grams

Description	Inlet Connection	Item Number
BPR Medical Oxygen Regulator PI	Pin Index	W039015
BPR Medical Air Regulator PI	Pin Index	W039017
Rotarex Medical Oxygen Regulator PI	Pin Index	W039022
Alpinox Medical Oxygen Regulator PI	Pin Index	W039025



### Dial Flow Regulators

Dial flow regulators are supplied with either a bullnose or pin index fitting, and can be fitted to all cylinder types. They have a tolerance accuracy of +/-10% for 1 litre per minute flow rates and above, providing more accurate delivery. Dial flow regulators are designed to be smaller and more compact. With less protruding parts, and with an all-metal construction, they are less prone to accidental damage.

Description	Inlet Connection	Item Number
Dial Flow Medical Oxygen Regulator PI	Pin Index	W039011

### Accessories and Consumables

Afrox Homecare offers a range of accessories and consumables for the delivery of medical gases in homecare, including regulators, cannulae and face masks.

Description	Item Number
Medical Regulator Monthly Rental	W342080
Oxygen Medical Regulator PI (Saleable)	W039009
Oxygen Medical Regulator BN (Saleable)	W039010
Oxygen Humidifier Bottle	W342030
Adult Oxygen Face Mask	W342036
Adult Oxygen Nasal Cannula	W342037
Nipple & Nut Connector	W342038
Twist & Pull Connector	W342044
Oxygen 15 m Tubing	W342046
Paediatric Nasal Cannula	W342032
Paediatric Oxygen Mask	W342034
Paediatric Nebuliser Mask	W342135
Paediatric Flowmeter	W342136
Cylinder Trolley 1,84 kg	W340646
Nebuliser (Medicine Aerosol Therapy)	W342049

# Homecare Services

## Delivery

- A 24-hour Customer Service Centre (0860 030202)
- Medical aid authorisation and claims on your behalf
- Initial delivery of Afrox Homecare equipment (concentrator, cylinder, etc.) free of charge anywhere in South Africa
- Education and assistance on how to use the concentrator and cylinders
- Refilling of cylinders, if and when required, including collection and delivery
- Emergency deliveries at a fee.

## Homecare

- Patients will be visited by a qualified nurse, as per agreed terms
- All accessories will be supplied at a reasonable cost to meet patients' needs.



## Prescribing Information

### Scheduling Status

Not scheduled

### Proprietary Name

Afrox Compressed Medical Oxygen

### Composition

Oxygen 99,5% min

### Maximum Impurities

Carbon dioxide 300 vpm

Carbon monoxide 5 vpm

Moisture 60 vpm

Nitrogen & argon 0,5%

### Pharmacological Classification

A34 Other. Medical Gases

### Pharmacological Action

Oxygen is present in the atmosphere at 21%.

The basal oxygen consumption in man is about 250 ml/min for a body surface of 1,8 m<sup>2</sup>. It is reduced by about 10% during anaesthesia and natural sleep, and by about 50% for a 10°C fall in body temperature.

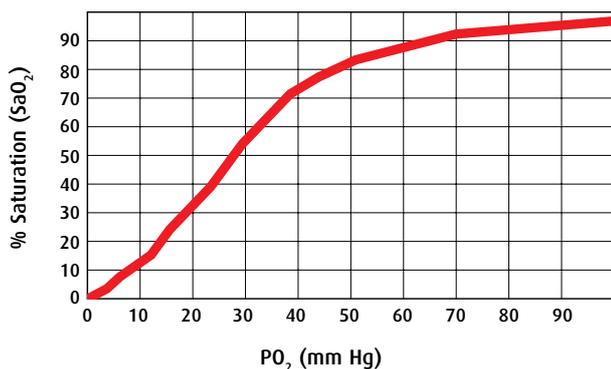
### Pharmacokinetic particulars

The uptake of oxygen by the blood in the lungs, and discharge to the tissues is determined by the oxygen dissociation curve. The characteristic sigmoid shape ensures that, at tensions between 5 kPa (40 mm Hg), and 2 kPa (15 mm Hg), the oxygen carried in the blood from the lungs can be readily given up to the tissues.

The uptake from the lungs is rapid because blood flow through the capillaries, where exchange takes place, occurs in about 0,5 seconds. The uptake of oxygen is favoured by the simultaneous loss of carbon dioxide which is then excreted in the expired air. Conversely, the entry of carbon dioxide into the blood from the tissues facilitates oxygen transfer to the cells.

At rest, mixed venous blood returning to the lungs contains 13-14 ml of oxygen per 100 ml, but with severe exercise, the oxygen content may fall to 3-4 ml. In very active tissue, almost complete extraction occurs.

### Oxyhaemoglobin dissociation curve



### Indications

Oxygen is used for the prevention and treatment of hypoxia.

### Contra-Indications

- (i) There are no absolute contra-indications to the use of oxygen but the inspired concentration should be limited in the case of premature infants and those patients with chronic bronchitis and emphysema. (See Side Effects and Special Precautions).
- (ii) Oxygen supports combustion and smoking should be prohibited when oxygen is in use, and no naked flame should be allowed.

### Warnings

- (i) Special care is needed when oxygen is administered and careful monitoring is required:
  - To chronic respiratory failure patients
  - In hyperbaric chambers in the management of conditions such as carbon monoxide poisoning, anaerobic infections and acute ischaemic disease. Convulsions and other central nervous system effects may occur at 2 atmospheres or more, after a few hours' exposure to pure oxygen. At higher pressures, more rapid onset of central nervous system effects may occur.
- (ii) Too high an oxygen tension in the treatment of an acute exacerbation of chronic respiratory failure may arise, for instance, as a result of pulmonary infection in an elderly patient with bronchitis and emphysema. In such a patient the arterial PO<sub>2</sub> may be of the order of 35 mm, and the PCO<sub>2</sub> about 75 mm, with the stimulus to ventilation being primarily hypoxic. If high tensions of oxygen are administered, the hypoxic drive is removed, ventilation is reduced and the PCO<sub>2</sub> may rise sufficiently high to produce coma. Under these conditions, the hypoxaemia can be reduced by quite small increments in the concentration of inspired oxygen. This should never exceed 35% at the beginning of treatment; an initial concentration of 25% will produce considerable improvement, subsequent increments being permissible provided the PCO<sub>2</sub> does not rise further.

### Dosage and Directions for Use

#### Recommended doses and dosage schedules:

- (i) Distinguish between adults, children and the elderly and between different clinical indications.
- (ii) There is no distinction generally between the use of oxygen in any age group.
- (iii) The fundamental indication is the presence of hypoxia due to an unknown cause.
- (iv) Modern oxygen usage requires separate devices for administering the gas in high and in low concentrations. The lowest concentration should not fall below that present in ambient air (20,9%).
- (v) The concentration should be increased to a level that provides a satisfactory oxygen partial pressure in arterial blood.

**Routes of administration:**

Oxygen is usually administered through the lungs by inhalation. The major exception is when a metered supply is fed into the oxygenator of an extracorporeal circulation of a cardio-pulmonary by-pass system.

**These devices have been classified as follows:**

Fixed Performance Systems (patient independent)

- High flow – venti masks
- Low flow – anaesthetic circuits.

In all these systems, the oxygen concentration is pre-determined by the clinician.

Variable Performance Systems (patient dependent)

- Without re-breathing – catheters and cannulae
- With re-breathing through a face mask.

These systems only function by means of the patient who creates the inspired mixture by the act of breathing.

Various patients and device factors influence the result.

**Side Effects and Special Precautions**

- (i) Oxygen toxicity depends on both the inspired pressure (a function of concentration and barometric pressure), and the duration of exposure, the safe duration decreasing as the pressure increases.

At lower pressures of up to 2 atmospheres absolute, pulmonary toxicity occurs before central nervous system toxicity. At higher pressures the reverse applies.

Symptoms of pulmonary toxicity include a decrease in vital capacity, cough and substernal distress.

Symptoms of central nervous system toxicity include nausea, mood changes, vertigo, twitching, convulsions and loss of consciousness.

- (ii) High concentrations of oxygen should be avoided in patients whose respiration is dependent upon hypoxia drive, otherwise carbon dioxide retention and respiratory depression may ensue.
- (iii) Any fire or spark is highly dangerous in the presence of increased oxygen concentrations, especially when oxygen is used under pressure. Cylinders containing oxygen should be fitted with an approved regulator by which the rate of flow can be controlled. It is important that the regulator be free from oil or grease, otherwise a violent explosion may occur.
- (iv) Care should be taken in the handling and use of medical oxygen gas cylinders.

**Other Undesirable Effects (Frequency and Seriousness)**

Oxygen toxicity can occur as manifested by:

- (i) Retinopathy of prematurity has been associated in some premature infants with excessive oxygen therapy.
- (ii) Central nervous system toxicity including dizziness, convulsion and loss of consciousness after only 2-3 hours of exposure to pure oxygen at 2 or more atmospheres, e.g. sports and deep sea diving.

- (iii) Retrosternal soreness associated with coughing and breathing difficulties, made worse by smoking and exposure to cold air after breathing pure oxygen at atmospheric pressure for several hours.

**Identification**

- All cylinders containing compressed medical oxygen shall be colour-coded in accordance with SABS 06-1957
- The cylinder shall have a black body, with the shoulder being painted white. The symbol 'O<sub>2</sub>' shall be stencilled in white on the side of the body.

**Presentation**

- All cylinders having a water capacity of more than 10 l shall have valve protection guards fitted, the only exceptions being cylinders manufactured before 1985, as they have no provision for the fitting of guards
- Chevron labels, stating the name 'Oxygen' and the masses/volumes of the contents, shall be fitted to the shoulders of the cylinders in line with the valve outlet socket
- A 'Tickopress' label stating the expiry date, the name of the filling site, and carrying the sequential number shall be affixed to the shoulder of the cylinder
- A heat-shrink seal shall be fitted to the valve of the cylinder confirming that the cylinder has been properly filled and has passed the leak-test.

**Storage Instructions**

- Never permit oil, grease, or any other readily combustible substance to come into contact with high pressure oxygen
- Full and empty cylinders should be segregated
- Use a 'first-in – first-out' inventory system to prevent full cylinders being stored for excessive periods of time
- Keep out of reach of children.

**Registration Number**

290037

**Name and Business Address of the Applicant**

African Oxygen Limited  
23 Webber Street  
Selby  
Johannesburg  
2001

## Prescribing Information

### Scheduling Status

Not scheduled

### Proprietary Name

Afrox Compressed Medical Air

### Composition

Oxygen	20,5	-	21,5%
Nitrogen & Inerts	78,5%	-	79,5%

### Maximum Impurities

Carbon Dioxide	500 vpm
Carbon Monoxide	10 vpm
Moisture	25 vpm
Odour	Nil

### Pharmacological Classification

A34 OTHER. MEDICAL GASES

### Indications

Air is used :-

- As a replacement for atmospheric air when the atmosphere is contaminated by noxious fumes, vapours or gases
- In anaesthesia as a carrier for volatile anaesthetic agents
- As a power-source for pneumatic equipment
- In ventilators and incubators to provide uncontaminated and controlled air flows.

### Contra-Indications

Compressed air is contra-indicated where oxygen or other gaseous combinations would be indicated. (Airways obstruction, pneumonia, and a myriad of cardio-respiratory conditions.

### Warnings

- Compressed air should never be given if it contains less than 21% oxygen
- Care should be taken in the handling and use of medical air cylinders.

### Dosage and Directions for Use

- Distinguish between adults, children and the elderly, and between different clinical conditions. The clinical indication would not be whether to use air for use in breathing apparatus, anaesthetic equipment or incubators, but whether to change the formulation of air, e.g. to add more oxygen, depending on the clinical condition
- For breathing purposes, air is administered by various means, commonly by self-contained, or compressed air line breathing apparatus
- In anaesthesia, air is administered via a cylinder and valve assembly through a face mask or endotracheal tube.

### Side Effects and Special Precautions

- Oxygen toxicity depends on both the inspired pressure (a function of concentration and barometric pressure), and the duration of exposure, the safe duration decreasing as the pressure increases.

At lower pressures of up to 2 atmospheres absolute, pulmonary toxicity occurs before central nervous system toxicity. At higher pressures the reverse applies. Symptoms of pulmonary toxicity include a decrease in vital capacity, cough and substernal distress.

Symptoms of central nervous system toxicity include nausea, mood changes, vertigo, twitching, convulsions and loss of consciousness

- Retinopathy of prematurity has been associated in some premature infants with excessive oxygen therapy
- Facilities or practices in which medical air is breathed in a high pressure environment should be prepared to deal with illnesses associated with decompression (Bends or Caisson disease).

### Known Symptoms of Overdosage and Particulars of its Treatment

- Treatment is symptomatic and supportive
- See "Side Effects and Special Precautions."

### Identification

All cylinders containing compressed medical air shall be colour-coded in accordance with SABS 06-1957.

The cylinder shall have a French grey body, with the shoulder being painted with white and black quadrants. The word "Air" shall be stencilled in black on the cylinder.

### Presentation

All cylinders having a water capacity of more than 10 litres shall have valve protection guards fitted, the only exceptions being cylinders manufactured before 1985, as they have no provision for the fitting of guards.

Chevron labels, stating the name "Air" and the masses/volumes of the contents, shall be fitted to the shoulders of the cylinders in line with the valve outlet socket.

A "Tickopress" label stating the expiry date, the name of the filling site, and carrying the sequential number, shall be affixed to the shoulder of the cylinder.

A heat-shrink seal shall be fitted to the valve of the cylinder confirming that the cylinder has been properly filled and has passed the leak-test.

### Storage Instructions

Never permit oil, grease, or any other readily combustible substance to come into contact with high pressure air.

Full and empty cylinders should be segregated.

Use a "first-in - first-out" inventory system to prevent full cylinders being stored for excessive periods of time.

Keep out of reach of children.

## Prescribing Information

### Scheduling Status

Not scheduled

### Proprietary Name

Afrox Medical Carbon Dioxide

### Composition

Constituent		Purity Minimum	Active or Inactive	Purpose if Inactive
Chemical Name	Approved Name	99,0%	Active	N/A
Carbon Dioxide	Medical Carbon Dioxide			

### Pharmacological Classification

A34 OTHER. MEDICAL GASES

### Pharmacological Action

The effect of inhaling carbon dioxide, or of its accumulation in the body through ventilation defects, varies with the tension achieved in the blood, the duration and condition of the exposure, and the susceptibility of the individual concerned.

### Indications

- Increase the depth of anaesthesia rapidly when volatile agents are being administered. It increases depth of respiration and helps to overcome breath-holding and bronchial spasm
- Facilitates blind intubation in anaesthetic practice
- Facilitates vasodilation, and thus lessen the degree of metabolic acidosis during induction of hypothermia
- Increases the cerebral blood flow in arteriosclerotic patients undergoing surgery
- Stimulates respiration after a period of apnoea
- In chronic respiratory obstruction after it has been relieved
- Prevents hypocapnia during hyperventilation
- For clinical and physiological investigations.

### Contra-Indications

- The use of carbon dioxide is not recommended in pregnancy, and the safety in lactation has not been established.

### Warnings

- Carbon dioxide is stored in high pressure gas cylinders as a liquid under pressure. Rapid opening of the valve can cause the discharged gas to re-liquefy. This liquid can cause cold burns if in contact with the skin. Cylinders should only be used in the vertical position with the valve uppermost
- Care is needed in the handling and use of Medical carbon dioxide gas cylinders.

### Dosage and Directions for Use

Carbon dioxide should only be given under the direct supervision of a clinician. Except under special circumstances (e.g. physiological investigations), the inspired concentration should not exceed 5%. However, 100% carbon dioxide may be insufflated into the abdominal cavity to distend it, to allow the investigation and treatment of intra-abdominal disease, particularly of a gynaecological nature.

### Routes of Administration

The major exception is when a metered supply is fed into the oxygenator of an extracorporeal circulation of a cardio-pulmonary by-pass system.

### Side Effects and Special Precautions

- Above a concentration of 6%, carbon dioxide gives rise to headache, dizziness, mental confusion, palpitations, hypertension, dyspnoea, increased depth of rate of respiration, and depression of the central nervous system
- Concentrations of about 30% may produce convulsions. Higher concentrations are depressants; inhalation of 50% carbon dioxide is reported to produce central effects similar to anaesthetics
- The inhalation of high concentrations may produce respiratory acidosis
- Abrupt withdrawal of carbon dioxide after prolonged inhalation commonly produces pallor, hypertension, dizziness, severe headache and nausea or vomiting.

### Known Symptoms of Overdosage and Particulars of its Treatment

- Overdose of carbon dioxide stimulates breathing. If excessive this may cause extreme respiratory difficulty, raise the blood pressure and lead to nausea and vomiting, and occasionally unconsciousness
- Treatment is symptomatic and supportive.

### Identification

All cylinders containing medical carbon dioxide shall be colour-coded in accordance with SABS 06-1957.

The cylinder shall have a green body with a French grey shoulder. The symbol "CO<sub>2</sub>" and the name "CARBON DIOXIDE"

shall be stencilled in black on the shoulder and body of the cylinder respectively.

### Presentation

All cylinders having a water capacity of more than 10 litres shall have valve protection guards fitted, the only exceptions being cylinders manufactured before 1985, as they have no provision for the fitting of guards.

Chevron labels, stating the name "Medical carbon dioxide" and the masses/volumes of the contents, shall be fitted to the shoulders of the cylinders in line with the valve outlet socket.

A "Tickopress" label stating the expiry date, the name of the filling site, and carrying the sequential number, shall be affixed to the shoulder of the cylinder.

A heat-shrink seal shall be fitted to the valve of the cylinder confirming that the cylinder has been properly filled and has passed the leak-test.

### Storage Instructions

Medical carbon dioxide cylinders should be stored:

- Under cover, kept dry and clean
- Away from stocks of material and not subjected to extremes of heat
- Stored separately from industrial and other non-medical cylinders
- Full and empty cylinders stored separately.
- Keep out of reach of children.

## Prescribing Information

### Scheduling Status

Schedule: 4

### Proprietary Name

Afrox Medical Nitrous Oxide

### Composition

Nitrous Oxide 99,0% min

### Maximum Impurities

Carbon Dioxide 100 vpm

Carbon Monoxide 10 vpm

Moisture 50 vpm

Nitrogen Oxides 2 vpm

Oxygen & Nitrogen 1,0%

### Pharmacological Classification

A34 OTHER. MEDICAL GASES

### Pharmacological Action

- Nitrous oxide is eliminated unchanged from the body mostly by the lungs
- Induction with nitrous oxide is relatively rapid, but a concentration of about 70% is needed to produce unconsciousness at sea level. At higher altitudes, unconsciousness will not be produced in healthy robust patients
- Nitrous oxide is a low potency inhalation anaesthetic and not readily soluble. High concentrations, not greater than 70%, are used for induction of anaesthesia and recovery occurs quickly.

### Indications

Nitrous oxide is used:-

- For the relief of severe pain, usually in emergency situations, by inhalation with 50% oxygen
- Only during induction and maintenance of anaesthesia, in controlled situations.

### Contra-Indications

- Nitrous oxide should not be used with any condition where air is entrapped within a body and where its expansion might be dangerous e.g.
  - Artificial, traumatic or spontaneous pneumothorax
  - Air embolism
  - Decompression sickness
  - Following a recent dive

- Following air encephelography
- Severe bullous emphysema
- Use during myringoplasty
- Gross abdominal distension
- The safety in pregnancy and lactation has not been established
- Nitrous oxide should not be used as an analgesic anaesthetic agent for more than 24 hours without monitoring of peripheral blood for features of megaloblastic anaemia and leukopenia.

### Warnings

- Administration of nitrous oxide, more frequently than every 4 days, should be accompanied by routine blood cell counts for evidence of megaloblastic change in red cells and hypersegmentation of neutrophils
- Nitrous oxide should never be given with less than 21% oxygen. A minimum of 30% oxygen should be used during anaesthesia. At high altitudes and in the presence of disorders affecting oxygenation, higher concentrations of oxygen will be needed
- Scavenging of waste nitrous oxide gas should be used to reduce operating theatre and equivalent treatment room levels to a level below 200 ppm of ambient nitrous oxide
- At the end of a nitrous oxide/oxygen anaesthesia, withdrawal of the mask leads to an outpouring of nitrous oxide from the lungs and consequent dilution of oxygen in incoming air. This results in "diffusion hypoxia" and is counteracted by giving 100% oxygen for a few minutes when the flow of nitrous oxide is stopped
- EFFECTS ON ABILITY TO DRIVE AND TO USE MACHINES  
Nitrous oxide is rapidly eliminated but driving, use of machinery and other psycho-motor activities should not be undertaken until 12 hours have elapsed after nitrous oxide anaesthesia
- Care should be taken in the handling and use of nitrous oxide gas cylinders.

### Dosage and Directions for Use

- Distinguish between adults, children and the elderly and between different clinical indications
- For the production of general anaesthesia nitrous oxide is administered by inhalation through a suitable anaesthetic apparatus in concentrations up to 70% with oxygen as the balance
- In neonates and elderly patients, an increased susceptibility to anaesthesia may be observed
- There are no essential differences between the adult and child.

### Routes of Administration

Nitrous oxide is administered through a face mask or tracheal tube by means of an anaesthetic apparatus. The gas is breathed in by the patient and absorbed through the lungs.

### Side Effects and Special Precautions

- Anaesthetic agents should be used with caution in patients with cardiac, respiratory, renal, or hepatic impairment
- Hypoxic anaesthesia is dangerous, and nitrous oxide should always be administered with oxygen
- Nitrous oxide diffuses into gas-filled body cavities, and care is essential when using it in patients at risk from such diffusion, such as those with abdominal distension, pneumothorax, or similar cavities in the peritoneum or pericardium.

### Other Undesirable Effects (Frequency & Seriousness)

- The use of nitrous oxide causes inactivation of vitamin B12 which is a co-factor of methionine synthase. Folate metabolism is consequently interfered with and DNA synthesis is impaired following prolonged nitrous oxide administration. These disturbances result in megaloblastic marrow changes. Exceptionally heavy occupational exposure and addiction have resulted in myeloneuropathy and subacute combined degeneration
- In patients with normal bone marrow, stores of mature granulocytes will normally be adequate to prevent leucopenia during exposure for up to 3 days : in patients exposed to nitrous oxide for longer periods of time, leucopenia will develop, and exposure for 4 days or longer can result in agranulocytosis
- Repeat exposure to nitrous oxide at intervals of less than 3 days will have a cumulative effect on DNA synthesis, and megaloblastic marrow changes have been reported following multiple short-term exposures
- Depletion of methionine has been implicated in the neurological deficit seen in chronic abusers of nitrous oxide
- Oxygen should be administered during emergence from prolonged anaesthesia with nitrous oxide to prevent diffusion, hypoxia where the alveolar oxygen is diminished
- Nitrous oxide is known to have an ozone depleting potential. It is a "greenhouse gas" and may contribute to global warming.

### Known Symptoms of Overdosage and Particulars of its Treatment

- Inapplicable, unwitting or deliberate inhalation of nitrous oxide will result in unconsciousness, passing through stages of increasing light-headedness and intoxication, and, if the victim were to be within a confined space, death from anoxia could result. The treatment is removal to fresh air, and if necessary, the use of an oxygen resuscitator.

### Identification

All cylinders containing compressed nitrous oxide shall be colour-coded in accordance with SABS 06-1957.

The cylinder shall have a French Blue shoulder and body, with the symbol "N<sub>2</sub>O" and the name "NITROUS OXIDE" stencilled in white on the shoulder and body of the cylinder respectively.

### Presentation

All cylinders having a water capacity of more than 10 litres shall have valve protection guards fitted, the only exceptions being cylinders manufactured before 1985, as they have no provision for the fitting of guards.

Chevron labels, stating the name "Nitrous Oxide" and the masses/volumes of the contents, shall be fitted to the shoulders of the cylinders in line with the valve outlet socket.

A "Tickopress" label stating the expiry date, the name of the filling site, and carrying the sequential number, shall be affixed to the shoulder of the cylinder.

A heat-shrink seal shall be fitted to the valve of the cylinder confirming that the cylinder has been properly filled and has passed the leak-test.

### Storage Instructions

Never permit oil, grease, or any other readily combustible substance to come into contact with high pressure nitrous oxide.

Full and empty cylinders should be segregated.

Use a "first-in - first-out" inventory system to prevent full cylinders being stored for excessive periods of time.

Keep out of reach of children.

## Prescribing Information

### Scheduling Status

Schedule: 4

### Proprietary Name

Entonox

### Composition

Oxygen	48% min
Nitrous oxide	52% max

### Maximum Impurities

Moisture	50 vpm
----------	--------

Only oxygen and nitrous oxide that conform to their individual specifications shall be used for the filling of Entonox cylinders.

### Pharmacological Classification

A34 OTHER. MEDICAL GASES

### Pharmacological Action

- Nitrous oxide is eliminated unchanged from the body mostly by the lungs
- Induction with nitrous oxide is relatively rapid, but a concentration of about 70% is needed to produce unconsciousness at sea level. At higher altitudes, unconsciousness will not be produced in healthy robust patients

### Indications

Entonox is used exclusively for the relief of pain in a controlled setting by trained personnel.

### Contra-Indications

- Entonox should not be used in any condition where air is entrapped within a body and where its expansion might be dangerous, e.g.
  - Artificial, traumatic or spontaneous pneumothorax
  - Air embolism
  - Decompression sickness
  - Following a recent dive
  - Following air encephelography
  - Severe bullous emphysema
  - Use during myringoplasty
  - Gross abdominal distension
- The safety in pregnancy and lactation has not been established.
- Entonox should not be used for more than twenty-four hours without monitoring blood for features of megaloblastic anaemia and leukopenia.

### Warnings

- Administration of Entonox more frequently than every 4 days should be accompanied by routine blood cell counts for evidence of megaloblastic change in red cells and hypersegmentation of neutrophils
- Thorough ventilation or scavenging of waste gases should reduce operating theatre and equivalent treatment room levels of ambient nitrous oxide to a level below 200 ppm. Entonox is non-flammable but strongly supports combustion (including some materials which do not normally burn in air). It is highly dangerous when in contact with oils, greases, tarry substances and many plastics
- A slight, but quantified impairment in driving ability was found up to 30 minutes following 15 minutes inhalation of nitrous oxide/oxygen mixtures
- Care should be taken in the handling and use of Entonox gas cylinders.

### Dosage and Directions for Use

- Distinguish between adults, children and the elderly and between different clinical indications
- Doses are self-regulated in nearly all cases by the use of a face mask connected through a demand valve to the Entonox cylinder
- Entonox may be administered by personnel trained in its use (obstetric units, accident units and accident ambulances).

### Routes of Administration

Entonox is administered through a face mask. The mask is connected to an Entonox supply through a demand valve system. The valve is operated by the act of inhalation of the patient and closes down when the patient ceases to inhale.

In nearly all cases, Entonox is self-administered, but it may be administered by attendant medical personnel. Since pain is usually relieved by a concentration of 25% nitrous oxide, continued inhalation does not occur. However, should inhalation continue, light anaesthesia supervenes and the mask drops away as the patient relaxes, or is removed if administration has been by attendant personnel.

### Side Effects and Special Precautions

Prolonged analgesia may theoretically result in bowel distension, middle ear damage and rupture of ear drums.

### Other Undesirable Effects (Frequency & Seriousness)

- Entonox should not be employed for analgesia in patients with head injuries with impairment of consciousness, maxillo-facial injuries, decompression sickness, or those heavily sedated
- Nitrous oxide diffuses into gas-filled body cavities, and care is essential when using it in patients at risk from such diffusion, such as those with abdominal distension, pneumothorax, or similar cavities in the pericardium or peritoneum
- The use of nitrous oxide causes inactivation of vitamin

B12 which is a co-factor of methionine synthase. Folate metabolism is consequently interfered with and DNA synthesis is impaired following prolonged nitrous oxide administration. These disturbances result in megaloblastic marrow changes. Exceptionally heavy occupational exposure and addiction have resulted in myeloneuropathy and subacute combined degeneration

- In patients with normal bone marrow, stores of mature granulocytes will normally be adequate to prevent leucopenia during exposure for up to 3 days : in patients exposed to nitrous oxide for longer periods of time, leucopenia will develop, and exposure for 4 days or longer can result in agranulocytosis
- Repeat exposure to nitrous oxide at intervals of less than 3 days will have a cumulative effect on DNA synthesis, and megaloblastic marrow changes have been reported following multiple short-term exposures
- Depletion of methionine has been implicated in the neurological deficit seen in chronic abusers of nitrous oxide
- Hypoxic anaesthesia is dangerous, and nitrous oxide should always be administered with oxygen
- Cylinders containing Entonox should be fitted with an approved regulator by which the rate of flow can be controlled. It is important that the regulator be free from all traces of oil or grease, otherwise a violent explosion may occur
- Nitrous oxide is known to have an ozone depleting potential. It is a "greenhouse gas" and may contribute to global warming.

#### **Known Symptoms of Overdosage and Particulars of its Treatment**

Inapplicable, unwitting or deliberate inhalation of Entonox will ultimately result in unconsciousness, passing through stages of increasing light-headedness and intoxication, and, if the victim were to be within a confined space, death from anoxia could result. The treatment is removal to fresh air, and if necessary, the use of an oxygen resuscitator.

#### **Identification**

All cylinders containing Entonox shall be colour-coded in accordance with SABS 06-1957.

The cylinder shall have a French Blue body, with the shoulder being painted with blue and white quadrants. The symbols "N<sub>2</sub>O and O<sub>2</sub>" shall be stencilled in black on a white quadrant.

The name "Entonox" shall be stencilled in white on the body of the cylinder.

#### **Presentation**

All cylinders having a water capacity of more than 10 litres shall have valve protection guards fitted, the only exceptions being cylinders manufactured before 1985, as they have no provision for the fitting of guards.

Chevron labels, stating the name "Entonox" and the masses/ volumes of the contents, shall be fitted to the shoulders of the cylinders in line with the valve outlet socket.

A "Tickopress" label stating the expiry date, the name of the filling site, and carrying the sequential number, shall be affixed to the shoulder of the cylinder.

A heat-shrink seal shall be fitted to the valve of the cylinder confirming that the cylinder has been properly filled and has passed the leak-test.

#### **Storage Instructions**

Never permit oil, grease, or any other readily combustible substance to come into contact with high pressure Entonox.

Full and empty cylinders should be segregated.

Use a "first-in - first-out" inventory system to prevent full cylinders being stored for excessive periods of time.

Keep out of reach of children.

# General Information

## Medical Oxygen

Oxygen is colourless, odourless and tasteless, so a super-oxygenated atmosphere cannot be detected by normal human senses.

In a super-oxygenated atmosphere, objects and especially organic materials (fabrics, wood, paper, etc.) which do not normally burn in air, may ignite violently at the slightest spark or contact with a source of fire (cigarettes, for example). Fatty substances (oils, greases, etc.) ignite spontaneously in contact with oxygen.

## Safety Regulations

Oxygen is one of the elements in the triangle of fire.

The higher the concentration of oxygen, the greater the risk.

Oxygen is heavier than air. Therefore, the most common risks linked to super-oxygenation are on the floor or low down.

Oxygen represents 21% of the composition of ambient air. It is an oxidising agent, i.e. it maintains and activates the combustion of any combustible material.

Oxygen activates the combustion of any inflammable material. To avoid any risk of fire, follow the instructions in this section carefully.



## General Instructions\*

- 1** Eliminate any inflammable sources close to your source of oxygen. Your source of oxygen must be stored and used more than two metres away from any device which produces flames (fireplace, cooker, stove, water-heater, etc.).



- 2** Do not use or store your oxygen therapy equipment close to machinery which produces sparks (electrical appliances, friction or ignition toys, etc.).



- 3** Do not use aerosol sprays (lacquer, deodorant, etc.), solvent (alcohol, petrol, etc.) on the equipment or even close to it.



- 4** Use medical oxygen only for the treatment prescribed by your physician.

- 5** Do not smoke or allow others to smoke in the room where your oxygen therapy equipment is stored and used.



- 6** Do not grease or lubricate your equipment, tubes or oxygen goggles. Make sure your hands are clean when handling the equipment. Do not use near oil, grease, hand or face cream, etc.

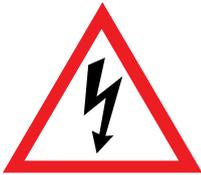


- 7** High concentrations of oxygen are dangerous: aerate the room where you use the oxygen source; do not store empty or full oxygen tanks in a cupboard, a car boot, etc.



**\* Consult the medication instruction leaflet before use.**

## Installation



- Keep the equipment more than three metres away from any source of ignition
- Do not smoke or allow others to smoke near the equipment during handling
- Keep at least 15 cm space around the device to allow air to circulate
- Do not cover or place it behind curtains
- Do not use aerosol sprays (lacquer, deodorant, etc.) when the equipment is in operation
- Aerate the room in which you use the equipment
- Do not install the equipment in a garage or kitchen where oils and greases are used
- Do not install the equipment in a bathroom or wet area
- The equipment must be used vertically
- Use the electric cable supplied with the equipment to connect it
- Use a dedicated power outlet
- If an electrical extension or multiple adaptor has to be used, make sure it is standard equipment: (cable H05VVF 220-240 V 50/60 Hz 10 A)
- Place the equipment in a place where you can hear the alarm.

### Warning



- Pets may damage the tubing
- Do not step on the tubing
- Bleach, chlorine, alcohol and scented oils must not be used to wash the equipment or consumables (mask, goggles or tubes). These solutions could damage your equipment and reduce its lifetime.

## Hygiene

### Precautions for Use

Wash your hands before any intervention.

### Servicing

Before starting any cleaning procedure, set the switch to '0' and disconnect the mains lead.

Do not apply any liquid directly onto the equipment casing.

Use a damp cloth or sponge with gentle household cleaner and dry it.

The oxygen concentrator must be dusted regularly and the dust filter must be cleaned every week (wash it in soapy water, rinse, leave to dry and put back in place).

To avoid any risk of electric shock, do not remove the concentrator casing. Only the technician is authorised to do this.

### Consumables

Average consumption is about two sets of oxygen goggles or masks per month.

The end-pieces of the goggles must be rinsed under the tap every day and the goggles changed if they are damaged.