



# Clinical Review

## Oxygen Face Masks (self-supporting low/ medium concentration)

### Part 1

### Simple Face Masks, Adult

**Published: September 2018**

Must be completed and signed by a clinician

ONLY PRESCRIPTIONS OF INSULIN	
Insulin type	Dose
SC	SC

ONLY PRESCRIPTIONS OF GLUCAGON	
Medicine	Dose
Glucagon	1mg

ONLY GLUCAGON	
Medicine	Dose
Glucagon	1mg

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## **Guidance for use**

This clinical evaluation report is aimed primarily at the NHS and all those working to support patient care.

Please note that the product assessment results should only be read and used in conjunction with the full text of this clinical review.

## 1. Introduction

The NHS Clinical Evaluation Team was established in April 2016. The team's remit was to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

Everyday healthcare consumables are products that are found in the majority of Wards, Clinics, Health Centres, Treatment rooms and District Nurses' bags across the NHS. The purpose of this report is two-fold: firstly, to provide a clinical assessment of the usability and requirements from the NHS for self-supporting low/medium concentration, 'Simple' Oxygen Face Masks. This consumable is available to the NHS from the national procurement provider. The second purpose of this report is to provide a clinical statement of desired functions and properties that Clinicians in the NHS require of this product, for use in future procurement activities.

It is clear from the evidence that Oxygen Face Masks featured in this report are everyday healthcare consumables found in most clinics or ward settings and would certainly be items included in any stock list to set up a new clinical service. On that basis, the project was approved by the Clinical Reference Board, culminating in the production of this report for their approval in September 2018.

Based on 2018 data supplied by NHS Supply Chain – which holds 70% of the market share for this consumable - NHS Trusts are using over 3,000,000 Oxygen Face Masks annually with a total spend in excess of £1.75 million.

There are 1,498 different product codes in the category, via 38 different suppliers. In view of the large range of products listed, this report covers oxygen face masks classed as 'Simple Face Masks', available in April 2018. The report has been entitled Part 1 accordingly.

Intelligence about Oxygen Face Masks was gathered from a variety of sources on the current evidence available to support the way in which the devices are designed and clinically evaluated.

Following this, NHS clinical engagement sessions were held with the aim of identifying important clinical criteria for Oxygen Face. This information was used to develop clinical criteria against which all brands available from the national procurement provider in the 'Simple Face Mask' category were reviewed.

Findings from these clinical reviews are collated into a product assessment report, allowing users to identify products and see how they performed against the agreed clinical criteria.

A more detailed description of the team and our pathway approach can be found in the NHS Clinical Evaluation Team operating manual which can be found on our website at: [www.supplychain.nhs.uk/CET](http://www.supplychain.nhs.uk/CET).

## **2. Historical Context**

Oxygen, first discovered by Swedish pharmacist Karl Scheele in the early 1770's and inhaled to therapeutic effect on a tuberculosis patient, was initially administered by 'wafting oxygen from a bucket towards the patient's face' however by the late 1800's 'inhaling apparatus' had been developed. The advent of the First World War and the treatment of soldiers, suffering from chemical gas exposure, led to advances in the development of therapeutic oxygen therapy delivery using masks and nasal prongs and these methods of administration have remained broadly similar since this time (Grainge, 2004).

Nasal cannula and differing types of oxygen face mask, including Simple Face Masks, are now recommended by the British Thoracic Society (BTS, 2017) for the administration of therapeutic oxygen, in accordance with the patient's oxygen saturation levels and other significant clinical indicators (eg respiratory rates, blood gas readings, carbon dioxide retention, National Early Warning System (NEWS) Score, and pre-existing risks of respiratory conditions such as COPD etc).

## **Clinical Context**

### **3.1. Clinical Definition and Scope**

The title of this project is: Oxygen Face Masks (self-supporting low/medium concentration) Part 1, Simple Face Masks, Adult. The title reflects the focus on Oxygen therapy face masks providing a specific oxygen concentration provided by the Simple Face Mask product group. This product group will also comprise self-supporting consumables which utilise securing straps to hold the mask over the face and mouth. Adult size (excluding small and large) will be evaluated.

Collins English Dictionary defines an oxygen mask as "a device, worn over the nose and mouth, to which oxygen is supplied from a cylinder or other source: used to aid breathing".

Other oxygen therapy devices, including different types of face mask, are outside the scope of this project.

### **3.2. Clinical Use & Practice**

Simple Face Masks deliver oxygen concentrations between 40-60%. The oxygen concentration is influenced by oxygen flow rate and the patient's breathing pattern. The concentration can be changed by increasing or decreasing the flow rate between 5-10 litres per minute (L/min) (BTS, 2017). The Simple Face Mask is suitable for patients with respiratory failure without an excess of blood carbon dioxide levels (a condition which when present is referred to as 'hypercapnia').

Simple Face Masks are not suitable for patients with hypercapnic respiratory failure because the mask may deliver a high concentration of oxygen (>50%) which can result in carbon dioxide retention in some patient groups (Kane, 2011). Simple Face Masks are therefore not advised for patients who require low concentration oxygen therapy because of the risk of carbon dioxide retention.

### **3.3. Clinical Impact**

The clinical impact of Oxygen Face Mask use is well documented in the BTS Guidelines and their selection, administration and maintenance must be undertaken by a trained clinician (BTS, 2017). The primary benefit of appropriate oxygen therapy and oxygen face mask use is one of treating the symptom of hypoxia (deficiency in the amount of oxygen delivered to the lungs and body tissues) in addition to patient symptom relief. The risks known to be associated with oxygen therapy and Oxygen Face Mask use include hypercapnia and hyperoxaemia (long term inhalation of high oxygen concentrations), both of which can have a significant negative impact on patient outcomes (BTS, 2017). Additionally, efficacy is influenced by mask fit (BTS, 2017) and patient tolerance of the device (Nolan, 1993).

### **3.4. Other Clinical Considerations**

Consideration should be given to other factors relating to oxygen face masks. These include patient comfort, patient tolerance, claustrophobia, potential barriers to eating and drinking, mask positioning (which can be affected by movement of the face), inspiratory resistance, carbon-dioxide rebreathing risk and cost (BTS 2017).

The BTS (2017) also highlight that the oxygen concentration received by the patient can also be influenced by his or her physiological condition and underlying comorbidities. In light of this, it is possible that one outcome of this evaluation would be an enhanced requirement for staff development and support relating to oxygen therapy to optimise clinical application of oxygen therapy products and resulting patient outcomes. In possible association with this, it has been suggested that despite published guidelines, there may be limited uptake of widespread cultural change among practitioners, authorities, and opinion leaders which could reduce the potential for effective oxygen therapy management (Austin 2010, BMJ). Consideration of the clinical application of Oxygen Face Masks may therefore also benefit from considering the potential value of addressing this issue when looking at the overall utility of this product (**see section 7.1.3 future recommendations**).

### **3.5. Product Technical Design**

A **Simple Face Mask** is sometimes referred to as an MC Mask, Medium Concentration Mask, Mary Catterall Mask or a Hudson Mask (the latter being discouraged because the Hudson Company manufactures a variety of masks). The oxygen provided via a Simple Face Mask will be of a variable concentration depending upon oxygen flow and the patient's breathing pattern. Other types of oxygen face masks include **Venturi Masks** which utilise an adaptor to elicit accurate oxygen concentration regardless of flow rate and **High Concentration Reservoir Masks** (also called **Non-Rebreathing Masks**) which deliver oxygen at concentrations between 60-90% at a flow rate of 15L/min and are most commonly used for trauma and emergency settings.

In some instances Oxygen Face Masks are also used for the management of non-invasive ventilation (eg in some patients with COPD) and utilise a process known as positive airway pressure to promote optimal respiratory function. Nasal Cannula can be used to deliver low and medium concentration oxygen to patients via prongs inserted into the nostrils (BTS 2008, 2017).

## **4. Pathway Methods**

The evaluation followed the process given in the CET operating manual and as approved by the overseeing Clinical Reference Board. This can be found in the CET Operating Manual on our website: [www.supplychain.nhs.uk/CET](http://www.supplychain.nhs.uk/CET)

### **4.1. Intelligence Gathering**

In preparation of the criteria, account has been taken of academic and related clinical evidence, known guidance and nationally recognised publications as further described in this section.

#### **4.1.1 Literature search**

A literature search has been undertaken to establish what current academic knowledge exists on the products for evaluation. It should be noted that the team have not conducted a comprehensive or systematic review of literature. However, the team have interrogated the information to look for common themes which supported the development of the clinical criteria.

Initially, an evidence search was performed across the NICE service:

<https://openathens.nice.org.uk/> This suggested best practice considerations in the use of oxygen face masks and oxygen therapy.

The search terms used (Figure 1) generated many returns, however, there was little new information generated.

**Figure 1**

Search criteria	Databases searched
<ul style="list-style-type: none"> <li>Oxygen Face Masks</li> <li>Oxygen Therapy</li> </ul>	<ul style="list-style-type: none"> <li><b>NICE website Evidence search</b> <a href="https://www.evidence.nhs.uk/">https://www.evidence.nhs.uk/</a></li> <li><b>NICE website journals and databases</b> <a href="https://openathens.nice.org.uk/">https://openathens.nice.org.uk/</a> (using Healthcare databases advanced search tool – AMED, EMBASE, HMIC, BNI, Medline, PsycInfo, CINAHL, HEALTH BUSINESS ELITE databases searched)</li> </ul>
Date Range	Since 2007
Language	English

Figure 1 Literature and other sources searches – **Oxygen Face Masks**

#### 4.1.2 National procurement provider specification

As the national procurement provider, NHS Supply Chain manages a framework of suppliers who are then listed in the national catalogue. The framework covers a wider selection of products than just Simple Face Masks.

The specification used by the national provider (NHS Supply Chain) has been reviewed to understand what has previously been asked of suppliers of these devices and with reference to Simple Face Masks, no additional standards with the exception of Medical Device Directive 93/42/EEC, CE marking is mentioned.

The previous procurement specification used by the national provider (NHS Supply Chain) was reviewed by the clinical evaluation team. The team believed that the specification did not include sufficient clinical criteria.

#### 4.1.3 National and international safety and quality standards

Account has also been taken of appropriate international and other standards as they pertain to the devices (e.g. from the International Organisation for Standardisation (ISO), European Standards (EN) and/or British Standards Institution (BSI).

Medical Device Directive 93/42/EEC as amended, currently in transition to the new Medical Device Regulation MDR 2017/745

Standard /Certification
All products classified as a Medical Device must have their CE marking clearly evident on the product and/or packaging and meet the requirements set out within the standard(s) related to labelling.

A review of Medicines & Healthcare products Regulatory Agency (MHRA) alerts has also been performed. The MHRA website (<https://www.gov.uk/drug-device-alerts>) returned no product alerts relating to this product category against the search terms previously described. Alerts relating to high concentration and resuscitation oxygen masks, tubing, humidification, ventilation, tracheal tubes and nebulisers were noted

#### 4.1.4 Product suppliers and manufacturers

All suppliers listed within the national framework were invited to submit relevant evidence, product information and testing data to help support the review.

Some suppliers provided a range of information from product brochure through to technical datasheets.

#### 4.1.5 Quality of evidence

Hierarchy of evidence

Levels of evidence sometimes referred to as hierarchy of evidence are assigned to studies based on the methodological quality of their design, validity, and applicability to patient care (Figure 2).

In relation to Oxygen Face Masks, evidence to level 7 was found during literature search or suppliers' submissions. This most notably related to The British Thoracic Society Guidelines (2017).

**Figure 2**

Hierarchy ranking	Description
Level 1	A systematic review of all relevant randomised controlled trials (RCT) or evidence-based clinical practice guidelines based on systematic reviews of RCT evidence
Level 2	Evidence from at least one well designed RCT
Level 3	Evidence from well-designed controlled trials; non-randomised, quasi experimental
Level 4	Well-designed case control & cohort studies
Level 5	Systematic reviews of descriptive and qualitative studies
Level 6	Evidence from a single, descriptive or qualitative study
Level 7	Evidence from the opinion of authorities and/or reports of expert committees

Figure 2 – Hierarchy ranking: Evidence based practice in nursing & healthcare: a guide to best practice” (B.M. Melnyk & E. Fineout-Overholt; 2005; p10)

## **5. NHS Clinical Engagement**

In order to develop a shared vision of what is required from Oxygen Face Masks several methods of engagement were used.

Clinical engagement events were used to formulate thoughts, ideas and needs from different clinicians familiar with the products. Clinicians were able to identify both their own expectation(s) of their patient group and intended patient outcome.

Mapping exercises were undertaken to determine specific personnel that should be involved and/or consulted regarding these products. This stage of the report focused on clinical staff that are:

- a) recognised as subject experts, and/or
- b) recognised regular users of the devices in their clinical practice.

Various methods of engagement were undertaken to ensure these clinical opinions were robust, and validated by peers from around the country, options of engagement included:

- Regional and national face-to-face events with NHS clinical colleagues
- Focussed visits to NHS clinicians regional and national face-to-face events
- Website subscription
- Attendance at specialist network events
- Attendance at NHS Business Services Authority events
- Web-based surveys and e-engagement tools (e.g. email, WebEx, portal based surveys)

### **5.1. Clinical Conversations**

To build a broad group of attendees at our events letters were sent inviting Trusts to nominate clinical colleagues to attend a series of regional group events. These were hosted by NHS organisations throughout England to enable the widest possible access for all invited. This set aside any pre-existing regional variance.

Details of the discussion outcomes were recorded online from the open events and then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product has been tested.

### **5.2. Clinical Criteria and Rationale**

The data received from all the NHS clinical conversation events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria.

A clinical criterion is defined for the purposes of this report as a principle or standard by which products may be evaluated. It is a statement which describes the clinician's requirements for the product.

The proposed criteria were validated by workshop attendees and all other clinical experts engaged in the development process. In addition, other clinical experts who are likely to add further useful insight were also included, leading to the finalised clinical criteria listed in Figure 3.

**Figure 3**

CLINICAL CRITERIA AND RATIONALE FOR INCLUSION	
Packaging Criteria	Rationale
The product name and type is displayed on the outer packaging	Clinicians have indicated clearly displayed name of product category (eg simple face mask) should be on packaging to facilitate safe and speedy product selection.
The product name and type is displayed on the inner packaging.	Clinicians have indicated clearly displayed name of product category (eg simple face mask) should be on packaging to facilitate safe and speedy product selection.
Adult/Child indicated on inner packaging	Indicated by clinicians as essential for safe product selection.
Simple Face Mask (including mask) also contains tubing?	Clinicians have advised these items should ideally be provided in one bag for ease of use
Oxygen range per flow rate displayed on inner packaging	Oxygen flow rate was indicated by clinicians as essential <b>See section 7.1.3 future recommendations</b>
Sterile/non-sterile displayed on the inner packaging	Indicated by clinicians as essential for appropriate and safe product selection.
Single Use / Single Patient Use documented on inner packaging	Indicated by clinicians as essential to ensure correct infection prevention measures are maintained.
Product can be seen through packaging	Indicated by clinicians as essential to ease speed of selection.
Opening and Preparation Criteria	Rationale
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	Indicated by clinicians as essential to aid appropriate packaging opening.

Inner packaging tab, perforations / dotted lines are easy to tear	Indicated by clinicians as essential to ease opening of the packaging.
The apparatus can be assembled without contact with interior of mask or connection points	Indicated by clinicians as essential to reduce cross infection risk.
<b>Clinical Use Criteria</b>	<b>Rationale</b>
The assembled apparatus can be self-administered without wearer touching interior of mask	Indicated by clinicians as essential to reduce cross infection risk
Mask is a comfortable fit for the wearer (ie, no desire to self-reposition whilst wearing)	Indicated by clinicians as essential - patient comfort when wearing mask highlighted
Pressure to bridge of nose minimised	Indicated by clinicians as essential as risk of pressure damage to bridge of nose highlighted
Pressure to skin above ear strap minimised	Indicated by clinicians as essential as risk of pressure damage to skin above ears highlighted
Seal around face optimised	Indicated by clinicians as essential to minimise oxygen leakage
Straps supporting mask are robust	Indicated by clinicians as essential i.e. straps do not pull out of mask easily
<b>Disposal Criteria</b>	<b>Rationale</b>
Packaging describes disposal advice eg clinical waste, recyclable, biodegrade	Indicated by clinicians as essential to aid appropriate waste stream choice.

### 5.2.1 Criteria explanation- Exclusion

To capture true representation of clinical opinion, this report also aims to capture criteria that were raised, but not included as final criteria when the evaluation of Exclusions (Figure 4).

**Figure 4**

Excluded Criteria	Rationale for exclusion
<b>Clinical Use Criteria</b>	<b>Rationale</b>
Face Mask Fit prevents leaking of oxygen around seal	Clinicians have stated that this information would facilitate effective functioning of the oxygen mask however currently there is no identified standardised rating for the Simple Face Mask. Obvious gaps on wearing were therefore assessed at evaluation but no absolute assessment of leakage evaluated. <b>See section 7.1.3 future recommendations</b>
User involvement in design of mask	Some clinicians stated it would be useful to ensure oxygen masks are designed following extensive user involvement however such data was not available for all of the products currently supplied by NHSSC for evaluation. <b>See section 7.1.3 future recommendations</b>
<b>Disposal Criteria</b>	<b>Rationale</b>
Disposal of the oxygen face mask after use	The used mask itself is healthcare waste – follow local policy ( <b>see section 7.1.4 future recommendations</b> )

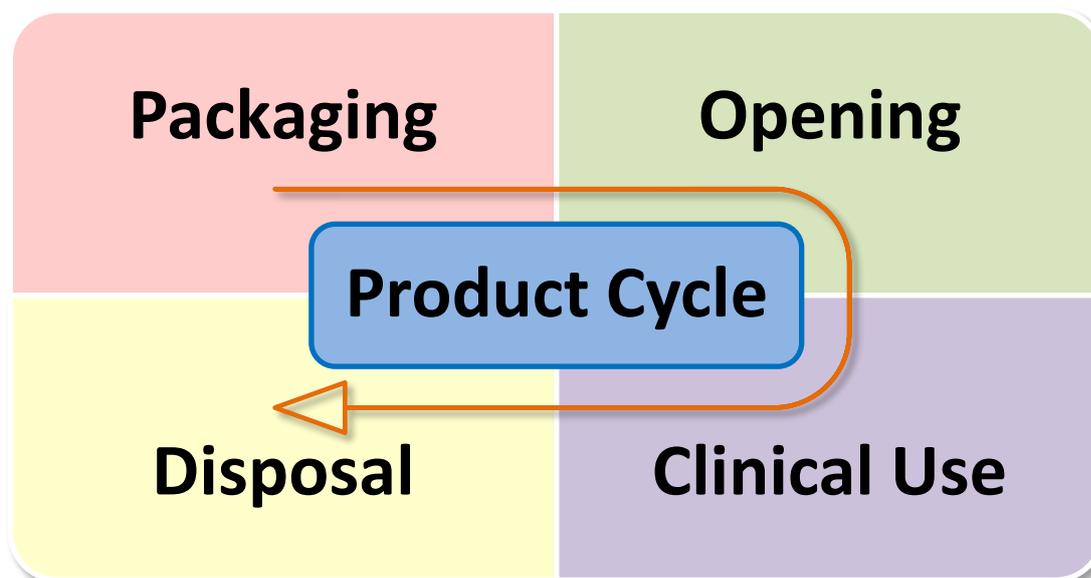
### 5.3 Product Evaluation

Evaluation methodologies are defined for each and every clinical criterion. They reflect a simulated clinical environment.

Wherever possible, products were supplied in a ‘ward ready’ unit of issue as would be found by clinical staff on accessing a store area in their clinical environment. Where this has not been possible it was acknowledged as part of the product assessment results matrix.

The tests were formulated to move through the key aspects of product use using the NHS Clinical Evaluation Team product cycle:

**Figure 5 – NHS Clinical Evaluation Team Product Cycle**



The evaluation product was ordered and picked from the NHS distribution centres. Products evaluated have been stored post evaluation for a period of three months after publication of this review.

Practicing NHS clinical staff were invited to review the products in accordance with the developed criteria. It was not possible to ‘blind’ the evaluations; in the sense that the evaluators were aware of the product brand; however, the product to be evaluated was independently picked in accordance with the product selection criteria in Section 2 and prepared for evaluation by colleagues who were not otherwise involved in the process.

Each clinical evaluator entered data independently and without inter-rater comparison into their own electronic dataset. These were then collated, reviewed and summarised by the clinical specialist lead for the project.

As part of the evaluation preparation, each evaluator was a more detailed and product specific definition for each of the scores.

The defined criteria either prompted a ‘yes/no’ answer, which has been represented with a ✓ / X, or a score was given between 0 and 3, or 0 and 2 as follows:

**Figure 6 – NHS Clinical Evaluation Team scoring methods**

Score	Meaning
0	This does not meet the criteria
1	This partially meets the criteria
2	This meets the criteria

<b>3 This exceeds the criteria</b>
------------------------------------

These numerical scores across all evaluators were totalled and a mean value determined. The mean values convert to a star rating in accordance with Figure 7:

**Figure 7 – conversion of mean scores to star rating**

<b>Point scored</b>	<b>Star value</b>
<b>0 to 0.99</b>	<b>0 stars</b>
<b>1 to 1.24</b>	<b>1 Star</b>
<b>1.25 to 1.74</b>	<b>1.5 Stars</b>
<b>1.75 to 2.24</b>	<b>2 Stars</b>
<b>2.25 to 2.74</b>	<b>2.5 Stars</b>
<b>2.75 to 3.00</b>	<b>3 Stars</b>

The above scoring mechanisms will not be followed where the criterion identified by the CET cannot reasonably exceed expectations. For example, if the clinical criterion was whether ‘the product can be seen through packaging’, then it cannot reasonably be expected that a product could exceed that criteria. Therefore, in such circumstances, the relevant criteria will be based on the scoring regime of:

- a. If the criterion is a Yes/No response, the responses will be converted into aggregate percentages and then star ratings as follows:

**Figure 8 – Percentage scores to star rating**

<b>Percentages (Yes)</b>	<b>Star value</b>
<b>0% to 24.99%</b>	<b>0 star</b>
<b>25% to 49.99%</b>	<b>1 star</b>
<b>50% to 74.99%</b>	<b>1.5 stars</b>
<b>75% to 100%</b>	<b>2 stars</b>

- b. For other subjective criteria, the responses will be converted into mean scores and then star ratings as follows:

**Figure 9 – Points scores to star rating**

<b>Point scored</b>	<b>Star value</b>
<b>0.00 to 0.99</b>	<b>0 star</b>
<b>1.00 to 1.24</b>	<b>1 star</b>
<b>1.24 to 1.74</b>	<b>1.5 stars</b>
<b>1.75 to 2.00</b>	<b>2 stars</b>

On the basis that clinical evaluators will be providing scores as follows:

- 0 stars – Does not meet the criteria
- 1 star – Partially meets the criteria
- 2 stars – Meets the criteria

All supplemental products used in the evaluation are in NHS use and available through the national catalogue.

Evaluators were also encouraged to record comments where they felt it necessary to provide rationale for their scoring and answers.

The results obtained have been validated by the NHS Clinical Evaluation Team moderation committee for consistency of scoring and interpretation. These results are presented in the product assessment reports herein.

## **6. Product Assessment Results**

The following product assessment results pages show the tested clinical criteria listed vertically on the left-hand side of the page with the tested device found horizontally across the top of the matrix. The accompanying photographs were taken during evaluation. These photographs are of sample products provided for evaluation. Lot numbers were recorded and samples have been retained in storage following the completion of evaluation.

The products represented are the range of suppliers and brands available through the NHS national procurement provider's framework as of April 2018.

Results can be seen within the product matrix. Each clinical product has been given a star rating and the evaluator's collated comments are included in the matrix.

	AFP MEDICAL LTD
<b>OXYGEN THERAPY</b> <b>Simple Oxygen Face masks</b> 	
NPC	FDD3266
MPC	X12
BRAND	Oxygen Facemask Medium Concentration
BASE DESCRIPTION	Adult with headstrap
UNITS PER BOX	100 units in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	Product not available for evaluations
The product name and type is clearly displayed on the inner packaging.	
Adult/Child clearly indicated on inner packaging	
Simple Face Mask contains tubing?	
Oxygen range per flow rate clearly displayed on inner packaging	
Sterile/non sterile clearly displayed on the inner packaging	
Single Use / Single Patient Use documented on inner packaging	
Packaging transparent and product clearly visible	
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	
Inner packaging is easy to open	
The apparatus can be assembled without contact with interior of mask or connection points	
The assembled apparatus can be self-administered without wearer touching interior of mask	
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	
Pressure to bridge of nose minimised	
Pressure to skin above ear strap minimised	
Seal around face optimised	
Straps supporting mask are robust	
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	

\*Maximum number of 2 stars attainable

<b>ALBERT WAESCHLE LTD</b>	
<b>OXYGEN THERAPY</b> <b>Simple Oxygen Face masks</b> 	
<b>NPC</b>	FDQ3374
<b>MPC</b>	gs2020.0
<b>BRAND</b>	Guardian
<b>BASE DESCRIPTION</b>	Oxygen Facemask Medium Concentration
<b>UNITS PER BOX</b>	100 in box
<b>NHS CET PRODUCT ASSESSMENT CRITERIA</b>	<b>Evaluation Scores</b>
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	☆☆ (0.00)*
The product name and type is clearly displayed on the inner packaging.	☆☆☆ (1.50)*
Adult/Child clearly indicated on inner packaging	✓
Simple Face Mask contains tubing?	✓
Oxygen range per flow rate clearly displayed on inner packaging	✗
Sterile/non sterile clearly displayed on the inner packaging	✓
Single Use / Single Patient Use documented on inner packaging	✓
Packaging transparent and product clearly visible	☆☆☆ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	☆☆ (0.00)*
Inner packaging is easy to open	☆☆ (0.67)*
The apparatus can be assembled without contact with interior of mask or connection points	☆☆☆☆ (1.86)
The assembled apparatus can be self-administered without wearer touching interior of mask	☆☆☆ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	☆☆☆ (1.40)*
Pressure to bridge of nose minimised	☆☆☆ (1.33)*
Pressure to skin above ear strap minimised	☆☆☆ (1.60)*
Seal around face optimised	☆☆☆ (1.50)*
Straps supporting mask are robust	☆☆☆ (1.83)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### CAIRN TECHNOLOGY LIMITED



NPC	FDQ3314	FDQ3315	FDQ3316
MPC	DOM9082	DOM9080	DOM9080A
BRAND	Fairmont	Fairmont	Fairmont
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration
UNITS PER BOX	100 in box	100 in box	100 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (1.86)*	★★ (2.00)*	Product not available for evaluations
The product name and type is clearly displayed on the inner packaging.	★★ (1.71)*	★★ (1.86)*	
Adult/Child clearly indicated on inner packaging	✓	✓	
Simple Face Mask contains tubing?	✓	✗	
Oxygen range per flow rate clearly displayed on inner packaging	✗	✗	
Sterile/non sterile clearly displayed on the inner packaging	✓	✓	
Single Use / Single Patient Use documented on inner packaging	✓	✓	
Packaging transparent and product clearly visible	★★ (2.00)*	★★ (1.86)*	
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	☆☆ (0.00)*	☆☆ (0.00)*	
Inner packaging is easy to open	☆☆ (0.50)*	☆☆ (0.50)*	
The apparatus can be assembled without contact with interior of mask or connection points	N/A	Not Tested	
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ (1.93)*	★★ (1.93)*	
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★ (1.57)*	★★ (1.57)*	
Pressure to bridge of nose minimised	★★ (1.52)*	★★ (1.52)*	
Pressure to skin above ear strap minimised	★★ (1.83)*	★★ (1.83)*	
Seal around face optimised	★★ (1.62)*	★★ (1.62)*	
Straps supporting mask are robust	★★ (1.85)*	★★ (1.85)*	
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	✗	

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### CAREFUSION UK 306 LTD



	FAG3604	FDD2075	FDD5051	FDB916	FAG1653
NPC	FAG3604	FDD2075	FDD5051	FDB916	FAG1653
MPC	1202	1200	1206	1201	M1047597
BRAND	AirLife	AirLife	AirLife	Airlife	Vital Signs
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Facemask aerosol adult	Facemask Medium Concentration	Oxygen Facemask Medium Concentration
UNITS PER BOX	50 in box	50 in box	50 in box	50 in box	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	Product not available for evaluations	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	Product not available for evaluations
The product name and type is clearly displayed on the inner packaging.		★★ (1.91)*	★★ (1.91)*	★★ (1.91)*	
Adult/Child clearly indicated on inner packaging		✓	✓	✓	
Simple Face Mask contains tubing?		✗	✗	✓	
Oxygen range per flow rate clearly displayed on inner packaging		✗	✗	✗	
Sterile/non sterile clearly displayed on the inner packaging		✓	✓	✓	
Single Use / Single Patient Use documented on inner packaging		✓	✓	✓	
Packaging transparent and product clearly visible		★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)		☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*	
Inner packaging is easy to open		★☆☆ (1.00)*	★☆☆ (1.00)*	★☆☆ (1.00)*	
The apparatus can be assembled without contact with interior of mask or connection points		Not Tested	Not Tested	N/A	
The assembled apparatus can be self-administered without wearer touching interior of mask		★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)		★☆☆ (1.43)*	★☆☆ (1.43)*	★☆☆ (1.43)*	
Pressure to bridge of nose minimised		★☆☆ (1.58)*	★☆☆ (1.58)*	★☆☆ (1.58)*	
Pressure to skin above ear strap minimised		★★ (1.82)*	★★ (1.82)*	★★ (1.82)*	
Seal around face optimised		★☆☆ (1.67)*	★☆☆ (1.67)*	★☆☆ (1.67)*	
Straps supporting mask are robust		★★ (1.83)*	★★ (1.83)*	★★ (1.83)*	
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade		✗	✗	✗	

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### CLEMENT CLARKE INTERNATIONAL LTD



	FDD2285	FDD273	FDD254	FDD536	FDD449	FDD694
NPC						
MPC	L2017	L2009	L2010	L3000	L2007	L2000
BRAND	Lifecare	Lifecare	Lifecare	Lifecare	Lifecare Duomask	Lifecare Duomask
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Facemask aerosol adult	Facemask combination adult	Facemask combination adult
UNITS PER BOX	50 in box	1 in pack	1 in box	1 in box	1 in box	1 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★★ (1.52)*	★★★ (1.52)*	★★★ (1.52)*	★★★ (1.52)*	★★★ (1.52)*	★★★ (1.52)*
The product name and type is clearly displayed on the inner packaging.	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*
Adult/Child clearly indicated on inner packaging	✓	✓	✓	✓	✓	✓
Simple Face Mask contains tubing?	✗	✗	✓	✗	✗	✗
Oxygen range per flow rate clearly displayed on inner packaging	✓	✓	✓	✗	✓	✓
Sterile/non sterile clearly displayed on the inner packaging	✗	✗	✗	✗	✗	✗
Single Use / Single Patient Use documented on inner packaging	✓	✓	✓	✗	✓	✓
Packaging transparent and product clearly visible	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Inner packaging is easy to open	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*
The apparatus can be assembled without contact with interior of mask or connection points	Not Tested	Not Tested	★★★ (2.00)	Not Tested	Not Tested	Not Tested
The assembled apparatus can be self-administered without wearer touching interior of mask	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*
Pressure to bridge of nose minimised	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.43)*
Pressure to skin above ear strap minimised	★★★ (1.46)*	★★★ (1.46)*	★★★ (1.46)*	★★★ (1.46)*	★★★ (1.46)*	★★★ (1.46)*
Seal around face optimised	★★★ (1.42)*	★★★ (1.42)*	★★★ (1.42)*	★★★ (1.42)*	★★★ (1.42)*	★★★ (1.42)*
Straps supporting mask are robust	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.57)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	✗	✗	✗	✗	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### DRAEGER MEDICAL



NPC	FDQ3325	FDQ3361
MPC	MP01921	MP01926
BRAND	O2star	
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Facemask combination adult
UNITS PER BOX	50 in box	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (0.00)*	★★ (0.00)*
The product name and type is clearly displayed on the inner packaging.	★★★ (1.57)*	★★★ (1.57)*
Adult/Child clearly indicated on inner packaging	✗	✗
Simple Face Mask contains tubing?	✓	✗
Oxygen range per flow rate clearly displayed on inner packaging	✗	✗
Sterile/non sterile clearly displayed on the inner packaging	✓	✓
Single Use / Single Patient Use documented on inner packaging	✓	✓
Packaging transparent and product clearly visible	★★★ (2.00)*	★★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★★ (1.86)*	★★★ (1.86)*
Inner packaging is easy to open	★★★ (1.83)*	★★★ (1.83)*
The apparatus can be assembled without contact with interior of mask or connection points	★★★ (1.86)	Not Tested
The assembled apparatus can be self-administered without wearer touching interior of mask	★★★ (2.00)*	★★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (2.00)*	★★★ (2.00)*
Pressure to bridge of nose minimised	★★★ (2.00)*	★★★ (2.00)*
Pressure to skin above ear strap minimised	★★★ (1.83)*	★★★ (1.83)*
Seal around face optimised	★★★ (1.71)*	★★★ (1.71)*
Straps supporting mask are robust	★★★ (1.71)*	★★★ (1.71)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### FLEXICARE MEDICAL LTD



NPC	FDD981	FDD191	FDE101	FDD539
MPC	032-10-013	032-10-001	032-10-002	032-10-006
BRAND	Venticaire	Venticaire	Venticaire	Venticaire
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Facemask aerosol adult
UNITS PER BOX	1 in box	1 in box	1 in box	1 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★★ (1.93)*	★★★ (1.93)*	★★★ (1.93)*	★★★ (1.93)*
The product name and type is clearly displayed on the inner packaging.	★★★ (1.73)*	★★★ (1.73)*	★★★ (1.73)*	★★★ (1.73)*
Adult/Child clearly indicated on inner packaging	✓	✓	✓	✓
Simple Face Mask contains tubing?	✗	✗	✗	✗
Oxygen range per flow rate clearly displayed on inner packaging	✓	✓	✓	✗
Sterile/non sterile clearly displayed on the inner packaging	✗	✗	✗	✗
Single Use / Single Patient Use documented on inner packaging	✓	✓	✓	✓
Packaging transparent and product clearly visible	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★★ (1.86)*	★★★ (1.86)*	★★★ (1.86)*	★★★ (1.86)*
Inner packaging is easy to open	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
The apparatus can be assembled without contact with interior of mask or connection points	Not Tested	Not Tested	★★★ (2.00)	Not Tested
The assembled apparatus can be self-administered without wearer touching interior of mask	★★★ (1.97)*	★★★ (1.97)*	★★★ (1.97)*	★★★ (1.97)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.67)*	★★★ (1.67)*	★★★ (1.67)*	★★★ (1.67)*
Pressure to bridge of nose minimised	★★★ (1.77)*	★★★ (1.77)*	★★★ (1.77)*	★★★ (1.77)*
Pressure to skin above ear strap minimised	★★★ (1.78)*	★★★ (1.78)*	★★★ (1.78)*	★★★ (1.78)*
Seal around face optimised	★★★ (1.77)*	★★★ (1.77)*	★★★ (1.77)*	★★★ (1.77)*
Straps supporting mask are robust	★★★ (1.79)*	★★★ (1.79)*	★★★ (1.79)*	★★★ (1.79)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	✗	✗	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### GE HEALTHCARE



NPC	FAG1652
MPC	M1047600
BRAND	Vital Signs
BASE DESCRIPTION	Oxygen Facemask Medium Concentration
UNITS PER BOX	100 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (2.00)*
The product name and type is clearly displayed on the inner packaging.	★★ (2.00)*
Adult/Child clearly indicated on inner packaging	✓
Simple Face Mask contains tubing?	✗
Oxygen range per flow rate clearly displayed on inner packaging	✓
Sterile/non sterile clearly displayed on the inner packaging	✗
Single Use / Single Patient Use documented on inner packaging	✓
Packaging transparent and product clearly visible	★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★ (0.00)*
Inner packaging is easy to open	★ (1.00)*
The apparatus can be assembled without contact with interior of mask or connection points	★★★ (2.00)
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.50)*
Pressure to bridge of nose minimised	★★★ (1.67)*
Pressure to skin above ear strap minimised	★★★ (1.67)*
Seal around face optimised	★★★ (1.67)*
Straps supporting mask are robust	★★★ (1.83)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### GBUK HEALTHCARE

NPC	FDQ3432	FDQ3436
MPC	8115-0-50	1102-7-50
BRAND	Salter labs	Salter Labs
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration
UNITS PER BOX	50 in box	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (1.86)*	Product not available for evaluations
The product name and type is clearly displayed on the inner packaging.	★★ (1.71)*	
Adult/Child clearly indicated on inner packaging	✓	
Simple Face Mask contains tubing?	✗	
Oxygen range per flow rate clearly displayed on inner packaging	✓	
Sterile/non sterile clearly displayed on the inner packaging	✗	
Single Use / Single Patient Use documented on inner packaging	✓	
Packaging transparent and product clearly visible	★★ (2.00)*	
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	☆☆ (0.00)*	
Inner packaging is easy to open	★★ (1.00)*	
The apparatus can be assembled without contact with interior of mask or connection points	Not Tested	
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ (1.86)*	
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★ (1.86)*	
Pressure to bridge of nose minimised	★★ (1.86)*	
Pressure to skin above ear strap minimised	★★ (1.86)*	
Seal around face optimised	★★ (1.57)*	
Straps supporting mask are robust	★★ (1.71)*	
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### INTERSURGICAL LTD



NPC	FDD3711	FDD4322	FAG3064	FDD112	FDD5144
MPC	1135015	1136015	1188015	1116000	1115000
BRAND	Intersurgical	Intersurgical	Intersurgical	Intersurgical Ltd	Intersurgical Ltd
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Facemask aerosol adult	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration
UNITS PER BOX	40 in box	1 in box	1 in pack	1 in pack	1 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★★ (1.86)*	Product not available for evaluations	★★★ (1.86)*	★★★ (1.86)*	★★★ (1.86)*
The product name and type is clearly displayed on the inner packaging.	★★★ (1.86)*		★★★ (1.86)*	★★★ (1.86)*	★★★ (1.86)*
Adult/Child clearly indicated on inner packaging	✓		✓	✓	✓
Simple Face Mask contains tubing?	✓		✗	✗	✓
Oxygen range per flow rate clearly displayed on inner packaging	✓		✗	✓	✓
Sterile/non sterile clearly displayed on the inner packaging	✗		✗	✗	✗
Single Use / Single Patient Use documented on inner packaging	✓		✓	✓	✓
Packaging transparent and product clearly visible	★★★ (2.00)*		★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★★ (0.00)*		★★★ (0.00)*	★★★ (0.00)*	★★★ (0.00)*
Inner packaging is easy to open	★★★ (1.00)*		★★★ (1.00)*	★★★ (1.00)*	★★★ (1.00)*
The apparatus can be assembled without contact with interior of mask or connection points	★★★ (1.93)		Not Tested	Not Tested	★★★ (1.81)
The assembled apparatus can be self-administered without wearer touching interior of mask	★★★ (1.71)*		★★★ (1.71)*	★★★ (2.00)*	★★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.79)*		★★★ (1.79)*	★★★ (1.54)*	★★★ (1.54)*
Pressure to bridge of nose minimised	★★★ (1.86)*		★★★ (1.86)*	★★★ (1.79)*	★★★ (1.79)*
Pressure to skin above ear strap minimised	★★★ (1.71)*		★★★ (1.71)*	★★★ (1.92)*	★★★ (1.92)*
Seal around face optimised	★★★ (1.86)*		★★★ (1.86)*	★★★ (1.93)*	★★★ (1.93)*
Straps supporting mask are robust	★★★ (2.00)*		★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗		✗	✗	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



**ISKUS HEALTH UK LTD**



NPC	FDQ3463
MPC	01.000.08.110
BRAND	Dahlhausen
BASE DESCRIPTION	Facemask combination adult
UNITS PER BOX	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (1.86)*
The product name and type is clearly displayed on the inner packaging.	★★ (1.86)*
Adult/Child clearly indicated on inner packaging	✓
Simple Face Mask contains tubing?	✓
Oxygen range per flow rate clearly displayed on inner packaging	✗
Sterile/non sterile clearly displayed on the inner packaging	✓
Single Use / Single Patient Use documented on inner packaging	✓
Packaging transparent and product clearly visible	★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	☆☆ (0.00)*
Inner packaging is easy to open	★★ (1.33)*
The apparatus can be assembled without contact with interior of mask or connection points	N/A
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ (1.86)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★☆☆ (1.17)*
Pressure to bridge of nose minimised	★★ (1.33)*
Pressure to skin above ear strap minimised	★★ (1.71)*
Seal around face optimised	★★ (1.57)*
Straps supporting mask are robust	★★ (1.86)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗

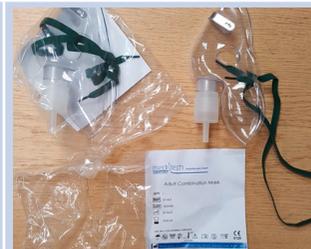
\*Maximum number of 2 stars attainable

		LYALL WILLIS & CO LTD					
<b>OXYGEN THERAPY</b> Simple Oxygen Face masks 							
NPC	FDQ3492	FDQ3493	FDQ3494	FDQ3491	FDQ3499	FDQ3500	FDQ3502
MPC	130M-110	130M-110-E	130M-110-N	130M-110-T	130-103	130-103-E	130-106
BRAND	Fairmont		Plastimed	Plastimed			
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Facemask combination adult	Facemask combination adult	Facemask aerosol adult			
UNITS PER BOX	100 in box	100 in box	100 in box	100 in box	125 in box	125 in box	100 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores						
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	Product not available for evaluations						
The product name and type is clearly displayed on the inner packaging.							
Adult/Child clearly indicated on inner packaging							
Simple Face Mask contains tubing?							
Oxygen range per flow rate clearly displayed on inner packaging							
Sterile/non sterile clearly displayed on the inner packaging							
Single Use / Single Patient Use documented on inner packaging							
Packaging transparent and product clearly visible							
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)							
Inner packaging is easy to open							
The apparatus can be assembled without contact with interior of mask or connection points							
The assembled apparatus can be self-administered without wearer touching interior of mask							
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)							
Pressure to bridge of nose minimised							
Pressure to skin above ear strap minimised							
Seal around face optimised							
Straps supporting mask are robust							
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade							

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### MEDITECH SYSTEMS LTD (DORSET)

	FDD3236	FDD2128	FDD2108	FDD2104
NPC	FDD3236	FDD2128	FDD2108	FDD2104
MPC	221421	22142004	221462	221426
BRAND	Meditech	Medi-Tech	Medi-Tech	Medi-Tech
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Facemask combination adult	Facemask aerosol adult
UNITS PER BOX	50 in box	50 in box	50 in box	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
The product name and type is clearly displayed on the inner packaging.	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Adult/Child clearly indicated on inner packaging	✓	✓	✓	✓
Simple Face Mask contains tubing?	✓	✓	N/A	✗
Oxygen range per flow rate clearly displayed on inner packaging	✗	✗	✗	✗
Sterile/non sterile clearly displayed on the inner packaging	✗	✗	✗	✗
Single Use / Single Patient Use documented on inner packaging	✓	✓	✓	✓
Packaging transparent and product clearly visible	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Inner packaging is easy to open	★★ (0.50)*	★★ (0.50)*	★★ (0.50)*	★★ (0.50)*
The apparatus can be assembled without contact with interior of mask or connection points	★★★ (2.00)	★★★ (2.00)	Not Tested	Not Tested
The assembled apparatus can be self-administered without wearer touching interior of mask	★★★ (2.00)*	★★★ (1.57)*	★★★ (2.00)*	★★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.53)*	★★ (0.43)*	★★★ (1.53)*	★★★ (1.53)*
Pressure to bridge of nose minimised	★★★ (1.71)*	★★★ (1.29)*	★★★ (1.71)*	★★★ (1.71)*
Pressure to skin above ear strap minimised	★★★ (1.71)*	★★ (0.14)*	★★★ (1.71)*	★★★ (1.71)*
Seal around face optimised	★★★ (1.75)*	★★★ (1.71)*	★★★ (1.75)*	★★★ (1.75)*
Straps supporting mask are robust	★★★ (1.71)*	★★ (0.57)*	★★★ (1.71)*	★★★ (1.71)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	✗	✗	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



**PROACT MEDICAL LTD**



NPC	FDD2252
MPC	Pb-23101
BRAND	PRO-Breathe
BASE DESCRIPTION	Oxygen Facemask Medium Concentration
UNITS PER BOX	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★★ (2.00)*
The product name and type is clearly displayed on the inner packaging.	★★ (1.86)*
Adult/Child clearly indicated on inner packaging	✓
Simple Face Mask contains tubing?	✓
Oxygen range per flow rate clearly displayed on inner packaging	✓
Sterile/non sterile clearly displayed on the inner packaging	✓
Single Use / Single Patient Use documented on inner packaging	✓
Packaging transparent and product clearly visible	★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★ (2.00)*
Inner packaging is easy to open	★★ (2.00)*
The apparatus can be assembled without contact with interior of mask or connection points	★★★ (2.00)
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.43)*
Pressure to bridge of nose minimised	★★★ (1.71)*
Pressure to skin above ear strap minimised	★★ (1.86)*
Seal around face optimised	★★ (1.86)*
Straps supporting mask are robust	★★ (1.86)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



<b>NPC</b>	<b>FDD4182</b>
<b>MPC</b>	<b>1126</b>
<b>BRAND</b>	<b>Portex first breath</b>
<b>BASE DESCRIPTION</b>	
<b>UNITS PER BOX</b>	<b>50 in box</b>
<b>NHS CET PRODUCT ASSESSMENT CRITERIA</b>	<b>Evaluation Scores</b>
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	★ ★ (0.00)*
The product name and type is clearly displayed on the inner packaging.	★★ ★ (1.86)*
Adult/Child clearly indicated on inner packaging	✓
Simple Face Mask contains tubing?	✗
Oxygen range per flow rate clearly displayed on inner packaging	✗
Sterile/non sterile clearly displayed on the inner packaging	✓
Single Use / Single Patient Use documented on inner packaging	✓
Packaging transparent and product clearly visible	★★ ★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	★★ ★ (2.00)*
Inner packaging is easy to open	★★ ★ (2.00)*
The apparatus can be assembled without contact with interior of mask or connection points	Not Tested
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ ★ (1.86)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★ ★ (1.33)*
Pressure to bridge of nose minimised	★★ ★ (1.50)*
Pressure to skin above ear strap minimised	★★ ★ (1.67)*
Seal around face optimised	★★ ★ (1.67)*
Straps supporting mask are robust	★★ ★ (1.67)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗

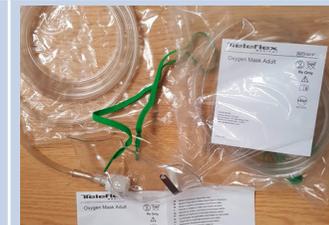
\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



### TELEFLEX MEDICAL (RUSCH & PILLING WECK)



NPC	FDD042	FDD479	FDD500	FDD2756
MPC	1049	1041	Hu1083	1041P
BRAND	Hudson	Hudson	Hudson	Teleflex Medical
BASE DESCRIPTION	Oxygen Facemask Medium Concentration	Oxygen Facemask Medium Concentration	Facemask aerosol adult	Oxygen Facemask Medium Concentration
UNITS PER BOX	50 in box	50 in box	50 in box	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathable)	★★ (2.00)*	Product not available for evaluations	★★ (2.00)*	★★ (2.00)*
The product name and type is clearly displayed on the inner packaging.	★★ (1.85)*		★★ (1.85)*	★★★ (1.71)*
Adult/Child clearly indicated on inner packaging	✓		✓	✓
Simple Face Mask contains tubing?	✗		✗	✓
Oxygen range per flow rate clearly displayed on inner packaging	✗		✗	✗
Sterile/non sterile clearly displayed on the inner packaging	✓		✓	✗
Single Use / Single Patient Use documented on inner packaging	✓		✓	✓
Packaging transparent and product clearly visible	★★ (2.00)*		★★ (2.00)*	★★ (2.00)*
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	☆☆ (0.00)*		☆☆ (0.00)*	☆☆ (0.00)*
Inner packaging is easy to open	★★★ (1.50)*		★★ (1.00)*	☆☆ (0.42)*
The apparatus can be assembled without contact with interior of mask or connection points	Not Tested		Not Tested	N/A
The assembled apparatus can be self-administered without wearer touching interior of mask	★★ (2.00)*		★★ (2.00)*	★★ (2.00)*
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	★★★ (1.62)*		★★★ (1.62)*	★★★ (1.86)*
Pressure to bridge of nose minimised	★★★ (1.57)*		★★★ (1.57)*	★★★ (1.57)*
Pressure to skin above ear strap minimised	★★★ (1.96)*		★★★ (1.96)*	★★★ (1.96)*
Seal around face optimised	★★★ (1.75)*		★★★ (1.75)*	★★★ (1.86)*
Straps supporting mask are robust	★★★ (1.85)*		★★★ (1.85)*	★★★ (1.85)*
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗		✗	✗

\*Maximum number of 2 stars attainable

# OXYGEN THERAPY

## Simple Oxygen Face masks



	UNOMEDICAL (CONVATEC)				
	FDC1285	FDC1286	FDC1291	FDC1292	FDC1354
NPC	FDC1285	FDC1286	FDC1291	FDC1292	FDC1354
MPC	93-103MM	93-102MM	93-103MMV	93-102MMV	9-102MM
BRAND	Unomedical	Unomedical	Unomedical	Unomedical	Unomedical
BASE DESCRIPTION	Facemask oxygen medium concentration adult				
UNITS PER BOX	50 in box	50 in box	50 in box	50 in box	50 in box
NHS CET PRODUCT ASSESSMENT CRITERIA	Evaluation Scores				
The product name and type is clearly displayed on the outer packaging (e.g. oxygen mask – non rebreathe)	☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*	Product not available for evaluations
The product name and type is clearly displayed on the inner packaging.	☆☆☆ (1.85)*	☆☆☆ (1.85)*	☆☆☆ (1.85)*	☆☆☆ (1.85)*	
Adult/Child clearly indicated on inner packaging	✓	✓	✓	✓	
Non Rebreathe Mask (incorporating mask & bag) also contains tubing?	N/A	N/A	N/A	N/A	
Simple Face Mask contains tubing?	✗	✓	✗	✓	
Oxygen range per flow rate clearly displayed on inner packaging	✗	✗	✗	✗	
Sterile/non sterile clearly displayed on the inner packaging	✗	✗	✗	✗	
Single Use / Single Patient Use documented on inner packaging	✗	✗	✗	✗	
Packaging transparent and product clearly visible	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	
The inner packaging has clear information on where and how to open (i.e. arrow, tab or perforations)	☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*	
Inner packaging is easy to open	☆☆ (0.50)*	☆☆☆ (1.00)*	☆☆ (0.50)*	☆☆☆ (1.00)*	
The apparatus can be assembled without contact with interior of mask or connection points	Not Tested	☆☆☆☆ (2.00)	Not Tested	☆☆☆☆ (2.00)	
The assembled apparatus can be self-administered without wearer touching interior of mask	☆☆☆ (1.92)*	☆☆☆ (1.92)*	☆☆☆ (1.92)*	☆☆☆ (1.92)*	
Mask is a comfortable fit for the wearer (i.e., no desire to self-reposition whilst wearing)	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	
Pressure to bridge of nose minimised	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	
Pressure to skin above ear strap minimised	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	
Seal around face optimised	☆☆☆ (1.92)*	☆☆☆ (1.92)*	☆☆☆ (1.92)*	☆☆☆ (1.92)*	
Straps supporting mask are robust	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	☆☆☆ (2.00)*	
Packaging clearly describes disposal advice e.g. clinical waste, recyclable, biodegrade	✗	✗	✗	✗	

\*Maximum number of 2 stars attainable

## **7. Using the Product Assessment Results Matrix**

The clinical criteria displayed are designed to capture key clinical elements that health professionals may wish to consider when reviewing/selecting products for their own clinical practice. The report is intended as a guidance tool to aid product selection and is not intended to be a universal determination of the clinical effectiveness of any particular product. Each clinical practitioner should therefore make their own assessments taking into account all relevant considerations for their particular situation.

Not all clinical criteria cited in the report will be relevant or important in all environments, i.e. 'Pressure to skin above ear strap minimised' will not be relevant in clinical settings using masks which have straps designed to be worn below the ears.

Likewise not all clinical criteria will be relevant or important for all patient groups; i.e. 'assembled apparatus can be self-administered without wearer touching interior of mask' will not apply for patients who do not self-administer their oxygen face mask.

Clinicians may identify the criteria that most represent their clinical environment and patient demographic, and may choose to build their own hierarchy of importance to aid product selection for patient outcome goals using the matrix presented in this report, their own clinical knowledge, as well as any other resources (including publications) to provide informed choice and transparency of their decision for the product being used.

## **8. Further Considerations and Recommendations**

### **8.1. Future recommendations**

#### **8.1.1 Packaging**

Several observations have been made towards the packaging.

- Clear labelling of name and type of product on the packaging
- Clear description of the contents of the packaging, i.e mask with or without tubing to facilitate clinical organisation and need in line with the setting.
- Sterile/non sterile and single patient use clearly visible
- Future product development and evaluation may also benefit from considering product information detailing cleaning and maintenance to align with health and safety, and infection control guidelines.

#### **8.1.2 Opening**

- Clear packaging to enable the final product to be seen, this also includes correct position of labels relating to perforations and access.
- Packaging that can be opened easily without spilling the packet contents

- The apparatus can be assembled without contact with interior of mask or connection points
- Oxygen flow rate was indicated by clinicians *as an essential feature to be documented on the packaging of oxygen face masks. BTS (2017) guidelines clearly indicate that Simple Face Masks will deliver oxygen concentrations between 40-60% and the concentration can be changed within these parameters by increasing or decreasing the flow rate between 5-10 litres per minute (L/min).*

### **8.1.3 Clinical Use**

- The risk of unnecessary oxygen leakage around gaps between face and mask was highlighted and although assessment for this was raised by clinicians, there is currently no identified standard test for this, relating to Simple Face Masks. Consideration regarding this issue would therefore be a recommendation in future research and development for this product.
- Information gathered from our Clinical Conversations indicates that clinicians believe that oxygen mask use and further development would be enhanced through greater user involvement. This would therefore be a recommendation when considering product use and development in the future.

### **8.1.4 Disposal**

- Recycling of packaging is important and needs to be clearly displayed.
- Disposal of the used oxygen face mask should be undertaken in accordance with local clinical waste policy and recycling considered where appropriate.

## **8.2. Barcodes**

The CET are aware of the Scan4Safety project and are aligned with the ambitions of the programme, which will deliver significant benefits in terms of patient safety and efficiency, to the NHS. The adoption of standards, driven by Scan4Safety, enables patient, product and location identification and traceability from the supply chain to the patient.

Adoption of these standards has also been shown to improve the quality of care by minimising the risk of human error.

The CET will be considering the inclusion of an evaluation criteria relating to the presence of GS1 compliant barcodes in future reports, as following our clinical conversations we have seen clinical staff asking for it to be included, but further information will be issued by the CET on this to stakeholders in advance.

## **9. Acknowledgements**

On behalf of the Clinical Reference Board and the NHS Clinical Evaluation Team, we would like to acknowledge the support, help and advice given by our colleagues across a range of organisations. We would particularly like to thank the Department of Health and Social Care, NHS Business Services Authority and their Communications team along with publishing partners The APS Group and, most importantly, our NHS colleagues who have supported our work.

The team would also like to acknowledge the inspiration of Mandie Sunderland who saw this opportunity and who, through her personal drive and enthusiasm, has ensured that the clinical voice and the need for quality, safety and value throughout the NHS has been heard.

## **10. Disclaimer**

Reports published by the NHS Clinical Evaluation Team represent general guidance and the team's opinions on products are based on the clinical evaluations undertaken, using the information and clinical criteria generated from extensive stakeholder engagement in line with the team's requirements and evaluation pathway. Reports will be reviewed and updated at the team's discretion as deemed appropriate to reflect any changes.

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Reports are accurate at the time of publication, any recommendations or best practice guidance should be checked for updates.

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<https://www.supplychain.nhs.uk/CET>

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**‘Quality, safety and value are at the heart of our work and it’s important that we use our clinical experience to deliver high standards of care while reducing cost and waste in the NHS.’**

Mandie Sunderland  
Chair, Clinical Reference Board  
(Governing body of the NHS Clinical Evaluation Team)

