Maxtec FLOCAP

Marketing Report: Prepared for Steve Nixon

Written by Catrin Hollings

Table of Contents

Summary of Audit

The audit highlights the internal and external elements, which may affect Viamed's ability to introduce a new supplier product to the UK market as an existing distributor.

The following 12-month marketing plan uses the information gained from the audit to recommend the requirements for the launch of the Maxtec FLOCAP for the UK market.

The reason for the launch is a gap in our product range which can complement our existing offering which helps satisfy the NAP4 guidelines.

The Product

The Maxtec FLOCAP is a disposable single use colorimetric CO_2 detector used to determine the level of patients exhaled CO_2 and expiratory flow.

The $EtCO_2$ indicator visualises to the user the correct placement of the ET tube. The device can be used to satisfy the NAP4 guidelines for use in conjunction with clinical assessment.

Main Product Benefits:

- The unique flow indicator helps the caregiver identify end of exhalation which can help prevent breath stacking (incomplete expiration can result in residual air adding to the volume of the next inspiration) which can cause overdistention (excessive stretching of inflation of the lungs) and its associated health issues during resuscitation …
- The florescent orange spinner is easy to see in low light. A great training tool and verification that gas exchange is happening.
- As part of NAP4 guidelines can be used in conjunction with Capnography monitoring as the flow indicator shows end of exhalation.
- Ideal for first responders for use as indicated in the NAP4 report when capnography is not immediately available or can be used in addition to waveform CO_2 monitors by providing flow indications.
- High definition colour changing material displays CO_2; range 0-5%.
- Low-cost important back-up for every first responder's bag.
- Long life single patient product; can stay with the patient during transportation to hospital and between wards. Single patient use eliminates cross-contamination.
- Long shelf, currently tested up to 36 months.
- Suitable for patients >15kg.

Pricing

The Maxtec FLOCAP is available in a case of 24 (4 boxes of 6) and is priced at £192.00 (exc. delivery, currently).

Part Numbers

4410100	Case of 24
4430000	Single part
4430001	Sample pack
4430002	Box of 6
4490000	Leaflet

Potential Market

The Maxtec FLOCAP can be used within a number of departments and areas within NHS Ambulance and Hospital Trusts. For example: A&E, ICU/HDU, Emergency Services, Theatres and Transportation between wards/departments.

It was thought that this product could be used within the Veterinary market but after speaking with the Veterinary distributor for the UK they believe this would cause confusion in the requirements set out by their industry and would not be the product in which they thought they would be purchasing.

This product has also been discussed with University of Nottingham Veterinary School who said it was not valid for the veterinary application.

Strategic Goal

Through an integrated communications campaign, Viamed can launch the Maxtec FLOCAP into the UK market, into our existing Capnography range providing alternative cheaper, quick and easy to use solutions to our customers which help to satisfy the rules and regulations in which they are required to adhere to for patient safety i.e. NAP4 guidelines and the Resuscitation Guidelines.

Key Objectives

Unify the messaging and branding of Viamed through consistent communications, design and language, utilising existing and new product literature.
Contribute towards gaining new business by contacting key contacts within the NHS in the UK and internationally.
Create and maintain communication with existing customers and distributors to ensure they are receiving relevant, up-to-date information on Viamed.

Build, maintain and boost the web visibility of the company through a range of digital change, including social media presence of the company.

Tactics

Market research into competitors.
PR campaign targeting key publications in the relevant fields which are read by the key personnel required for this product.
Utilise video messaging provided by the manufacturer to inform customers of the products features and benefits – this can be set up on a dedicated Viamed YouTube channel.
Target current customer database with information, direct snail mail information to existing customers, engaging customers to contact us for further details and to drive them our website. This includes design, creation, editorial and sign off by director on a monthly basis (where required).
Gain further contact information from healthcare directories to utilise to contact key personnel in relevant NHS areas.
Engage with international distributor through Viamed's LinkedIn account (agreement required to be put into place with Maxtec for the UK sector first)

12 month timeline for implementation of launch

Month	Key activities	Segment	Timing	Actions	Key Tactical Action
Ongoing	Continually improve marketing function communication	Internal	Bi-Weekly	Bi-Weekly marketing meetings	Derek, Steve N discussing marketing activities and current outstanding jobs
June	Task Provided	Marketing	30/06/2015	Issue #60119	Added to job log #238
July	Market research	Marketing	Compete end Aug 2015	Research	Pricing, benefits, features & differences.
August	FAQs, application notes	Marketing/ Supplier	Before Launch	FAQs into system, application notes to L:\	In-house application notes
August	Detail sample packs and produce where required (leaflet, instructions, label)	Marketing	Before Launch	Initial stock to be ordered, production job to be added to produce 24 sample packs	Purchase Order Production Job; Appendix 11 Opera Memos
August	Design of literature; leaflet catalogue artwork	Marketing	Before Launch	Design	Appendix 5 Original Maxtec Literature Appendix 6 Viamed Leaflet Appendix 7 Catalogue Artwork
August	Website Updates	Marketing	Written before launch	Write website content – Appendix 8	Website content
October	Initial Staff product training	Internal	6th October	Provide product training to all staff	Training
September	LAUNCH PRODUCT		w/c 12th October	Website update E-shot	Website Direct Mailing: Email
October	NAP4 guidelines awareness	External	See Comms Strategy	Highlight NAP4 recommendations to end-users	Direct Mailings: Email
November	Staff recap product training	Internal	1 month after launch (w/c 16th November)	Provide product training to all staff	Training
November	NAP4 guidelines	External	See	Highlight NAP4	Direct Mailings:

	awareness		Comms Strategy	recommendations to end-users	Post
March	Sales Review	Internal	March 2016	Review sales gained, where possible show enquiries received and departments used.	Sales Report
April	NAP4 guidelines awareness	External	See Comms Strategy	Highlight NAP4 recommendations to end-users	Direct Mailings: Email repeat
May	NAP4 guidelines awareness	External	See Comms Strategy	Highlight NAP4 recommendations to end-users	Direct Mailings: Post repeat

Communications Strategy

Month	Department Target	Strategy	Timing	Media	Message
September	**Emergency Services**	Exhibition	23/24th Sept	Exhibition	Showcase Viamed products to the sector
October	**Resuscitation;** A&E, ResusResp, Ambulances	Direct Mailing Campaign	1st Sept	Direct Mail – Email	Launch of Product, unique benefits i.e. flow indicator – identify NAP4 guidelines
October	**Intubation;** ICU/HDU	Direct Mailing Campaign	1st Sept	Direct Mail - Email	
October	**Life Connections**	Exhibition	21/22nd Oct	Exhibition	Showcase Viamed products to the sector
November	**Resuscitation;** A&E, ResusResp, Ambulances	Direct Mailing Campaign	5th Oct	Direct Mail – Post	Repeat above message by post
November	**Intubation;** ICU/HDU	Direct Mailing Campaign	5th Oct	Direct Mail - Post	
April	**Resuscitation;** A&E, ResusResp, Ambulances	Direct Mailing Campaign	1st Sept	Direct Mail – Email	Launch of Product, unique benefits i.e. flow indicator –

April	**Intubation;** ICU/HDU	Direct Mailing Campaign	1st Sept	Direct Mail - Email	identify NAP4 guidelines
May	**Resuscitation;** A&E, ResusResp, Ambulances	Direct Mailing Campaign	5th Oct	Direct Mail – Post	Repeat above message by post
May	**Intubation;** ICU/HDU	Direct Mailing Campaign	5th Oct	Direct Mail - Post	

Marketing Budget

Department/ Area of Interest	Strategy	Recipients/Duration	Requirements	Yearly Cost
A&E (Kaltz)	Direct Mailing Campaign	79/6-monthly	Leaflet £0.18 Letter £0.07 Envelope £0.04 Postage £0.39 = £0.68 Mailing Group £300.00	£354
ResusResp (Existing Viamed Mailing Group)	Direct Mailing Campaign	334/6-monthly	Leaflet £0.18 Letter £0.07 Envelope £0.04 Postage £0.39 = £0.68	£455
ICU/HDU (Kaltz/Existing Database)	Direct Mailing Campaign	144/6-monthly	Leaflet £0.18 Letter £0.07 Envelope £0.04 Postage £0.39 = £0.68 Mailing Group £300.00	£200 + £300 Mailing group (which can be utilised for marketing)

Primary research i.e. competitors' products	Market Research	3 days	£100 per day	£300.00
Internal Staff Training	Training	1 hour sessions x 2/yearly	£50.00 per session	£100.00
Internal Staff Training; refresh course	Training	15 mins x 3/yearly (1 month after 1st session, 6-months after 2nd session)	£25.00 per session	£75.00
Bi-Weekly Meeting	Marketing Meeting	2 hours bi-weekly	£100.00 per session	£2600.00
Product Shipments; include in shipments of specific products such as Flowsensors and R-23V oxygen sensors.	Leaflet Drop	Potentially 500/yearly	£0.18 per leaflet	£90.00

Total £4,474

Marketing Audit

The purpose of this audit is to ascertain the requirements to launch the Maxtec FLOCAP Colorimetric CO_2 detector into the current market. Initially the marketing audit will cover the UK but further expanding worldwide at a later date. There is no agreement in place, currently there are no restrictions in place where we can sell FLOCAP in the UK and Europe.

There are a potential 1135 hospitals, medical centres and clinics within the UK who may have requirements for the Maxtec FLOCAP.

Predominately there are 353 NHS registered hospitals which use devices such as these.

Within these hospitals, depending on NHS foundation trust, there are departments which may purchase products in different ways. Firstly, each trust (129 in total in the UK) has a Supplies/Procurement department who purchase for all hospitals within their trust and in which the customer specifies their requirements. Secondly, the department/ward can purchase directly from Viamed and thirdly the hospitals can purchase through the NHS Supply Chain catalogue.

Viamed customers can either be end-users or distributors and the majority of accounts based in the UK are end users. Scotland is covered by an authorised Viamed distributor, Eden Medical. Viamed used to have an account to supply to the NHS Supply Chain but due to requirements set out by them and information regarding our supply chain meant this was not feasible and in the long term they would have the information to be able to purchase from our suppliers directly.

Macro Environment Analysis

Political	**Technological**
NAP4 guidelines recommend nonwaveform carbon dioxide detector devices can be used in addition to clinical assessment as alternative to the use of capnography when this is not available.	Patented flow indicator included on the FLOCAP, not available from direct comparable products
Economic	**Social**
Already purchase from Maxtec so can add to existing orders and therefore eliminate further delivery charges. Cheaper alternative to full capnography units.	Visually see the colour change on the product allowing easier understanding by the user.

SWOT Analysis

Strengths	**Weaknesses**
• Viamed known for excellent customer service. • Already an authorised distributor of Maxtec products. Maxtec is a known brand within the UK. • Maxtec FLOCAP has unique patented flow indicator allowing visualisation of patient exhaled CO_2. • Competitive pricing against competition. • Quick and easy to use.	• Viamed has a small market share. • Strong competitors brands already been sold, through NHS Supply Chain. • Flow indicator's momentum will cause the FLOCAP to spin briefly after exhalation has ceased. • Does not supply quantitative results as with a Capnograph. • Currently no alternative for competitor products for <15kg • Although colorimetric CO_2 detectors identify placement in patients with good perfusion quite well, these devices are less accurate than clinical assessment in cardiac arrest patients because pulmonary blood flow maybe so low that there is insufficient exhaled carbon dioxide. Furthermore, if the tracheal tube is in the oesophagus, six ventilations may lead to gastric distension, vomiting and aspiration. (Page 104, ERC Guidelines for Resuscitation 2010).
Opportunities	**Threats**
• Increase in exhibitions in UK allows for increased face-to-face interaction with end users. • NAP4 guidelines identify the use of colorimetric CO_2 detector as alternative to Capnography. • Paediatric/Infant Maxtec FLOCAP equivalent has not been developed yet. • Variety of department applications; A&E, ICU/HDU, Ambulances	• Competitors such as Nellcor/Covidien have a larger market share and are a well-known brand. • Paediatric/Infant Maxtec FLOCAP equivalent has not been developed yet. Nellcor already have this as do a couple of other brands.

Micro Environment Analysis

Threats to new entrants

Within the medical industry there are a number of regulations which have to be adhered to for companies to be able to sell, manufacture and distribute medical equipment and consumables. These factors are reviewed by customers such as the NHS which purchasing medical equipment as an important certification of safety and reliability.

Other marks such as CE are also required; this is a “mandatory conformance mark” to show that the product meets EU safety, health and environmental requirements. (Appendix 1 – 3)

CE0123 means we do not need to register it in the UK, we do need an agreement in place from Maxtec to allow us to sell the product in the UK and potentially Internationally.

Declaration of conformity required - requested again from Maxtec.

Bargaining power of customers

There are a number of devices which can be used to satisfy the NAP4 guidelines recommendations, the following three types of product are pitched at different price points:

1. Colorimetric CO_2 Detector:

   i.e. Maxtec FLOCAP, Nellcor Easy Cap II, Mercury Medical CO_2 detector, Portex CO_2 clip, Ambu CO_2 detector.

   Cheapest UK Pricing:

   - Maxtec - £8.00 each Viamed
   - Mercury Medical - £13.45 each
   - Nellcor Easy Cap II - £9.95 each
   - Ambu CO_2 Detector - £10.42 each

2. Capnograph without waveform i.e. Emma Capnometer

   From £775 (#53417)

3. Waveform capnograph i.e. Emma Waveform Capnograph – cheaper alternative to Viamed VM-2500 series.

   Emma (Waveform) – Estimated £1,650 (www.Boundtree.com)

   Viamed VM-2500 series £2,116.50

Competitors

	Maxtec FLOCAP	Mercury Medical	Smiths Medical Portex CO_2 Clip	Nellcor Easy Cap II	Ambu Not showing on Ambu USA website
					
Shelf Life	36 months	24 months	unknown	36 months	24 months
Use Time	24 hours	24 hours	24 hours	Up to 2 hours	unknown
Patient Size	< 15kg/33lb	NeoStat 0.25 – 2kg MiniStat 1 – 15kg StatCO2 >15kg	unknown	Pedi-Cap 1 – 15kg EasyCap >15kg	Adult and Paediatric Size available
Pricing UK	£9.00 each	£13.45 each	Not available in UK	£5.16 each	£10.42 each
Flow Indicator	Yes	No	No	No	No
Use: SPU/SU?	Single Use	Single Use	Single Use	Single Use	Single Use

The above highlights the main competitors within the market globally.

Others available in the USA include:

Fenem CO_2 Indicator
Shelf life 2 years
Patient weight >1kg
Price $20.15 each

VentLab Stat Check II CO_2 Indicator
Patient weight >2.2kg
Price $10.10 each
Source: buyemp.com

The Marketing Mix

Price

Viamed offer two different pricing structures: end-user and distributor.

Price – Maxtec Pricing

The buying price of the Maxtec FLOCAP is $144.00 box 24 (converted £91.66/£3.82 each)

UK End User has been set at £192.00 for case 24 (£8.00 each).

Price – Competitor Distributor Pricing

The prices indicated by a ± are direct equivalents to the Maxtec FLOCAP.

Mercury Medical CO_2 Detector

Manufacturer: http://www.mercurymedical.com/15_end-tidal-co2-detectors/

The Mercury Medical CO_2 Detectors are fast, durable colorimetric breath indicators for visualisation of exhaled CO_2 to assist in verifying proper intubation. StatCO2™ is designed to connect between an endotracheal tube and a breathing device. The patient's exhalation gas is led through the indicator to detect approximate ranges of end tidal CO_2 by colour comparison assisting in the verification of proper tube placement.

Features:

- Long shelf life (up to 2 years)
- Rapid Breath-to-Breath colour change (up to 24 hours)
- Convenient pull tab-once removed, it activates the device
- StatCO2 and Mini-StatCO2™ functions at relative humidity up to 100% and detects up to 50 breaths per minute
- Neo-StatCO2™ is the only CO_2 detector available for use on patients below 1 kg (between 0.25 kg to 2 kg) and detects up to 100 breaths per minute
- Cost-effective
- Single patient use-for patients with body weight greater than 15kg

UK - Source: http://medtree.co.uk/mercury-medical-co2-detector

- StatCO2 (Adult) ±
  Over 15kg of body weight
  £13.45 ex VAT (£16.14 inc. VAT)
- Mini-StatCO2 (Paediatric) £16.45 ex. VAT (£19.74 inc. VAT)
  1 – 15kg of body weight
- Neo-StatCO2 (Infant)
  0.25kg – 6kg body
  Detects CO2 to 1ml tidal volume at 100 breaths/minute
  £16.45 ex. VAT (£19.74 inc. VAT)

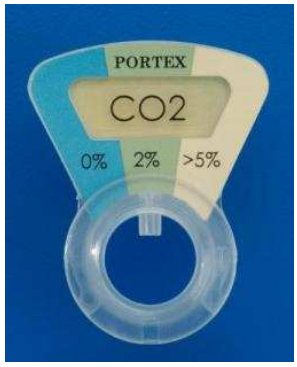
USA - Source: http://www.src-medical.com/co2_detectors1?b=1

- StatCO2 box/10 $264.95±
- Mini StatCO2 $264.95
- Neo StatCO2 $306.90

USA - Source: http://www.lifemedicalsupplier.com/co2-detectors-eid-c-557_135.html

- Mini Stat CO_2 $231.00/20
- Neo Stat CO_2 $258.00/20
- Stat CO_2 $231.00/20±

Smiths Medical - Portex CO2 Clip±



USA - Source: http://www.alphamedicalequipment.net/smithsmedicalportexco2clip.html
- $15.95 each
- $186.95, case of 12

USA - Source: http://www.acesurgical.com/portex-co2-clip-carbon-dioxide-detector.html
- $39.99 each (different image – not sure if correct)

Smiths Medical is a leading global provider of medical devices for the hospital, emergency, home and specialist environments. Their products are used during critical and intensive care, surgery, post-operative care during recovery, and in a series of high-end home infusion therapies.

The Portex CO_2 Clip Colorimetric Carbon Dioxide Detection System is a fast responding sensor that detects exhaled carbon dioxide breath-by-breath. Fast, Reliable. There when you need it!

Features:
- Weight: <.28 oz
- Dead Space: <3 mL
- Tidal Volume Range: > 150 mL
- Minute Volume Range: >3 L/minute
- Breathing Rate: <35 BPM
- Resistance to Flow: <50 Pa (0.5 cm H2O) at 60 L/minute
- Connection Ports: ISO 150 mm I.D. patient end; ISO 15 mm O.D. circuit end
- Usage Time: Up to 24 hours

Nellcor Easy Cap II Colorimetric CO2 Detector

http://www.covidien.com/rms/products/endotracheal-airway-tubes-and-accessories-for-the-operating-room/accessories/nellcor-adult-pediatric-colorimetric-co2-detector

Easy Cap® is an extra measure of safety for endo tracheal intubation. Just attach the Easy Cap® detector to the endotracheal tube and begin monitoring $EtCO_2$ levels with breath to breath response. A colour change between inspiration and expiration helps you verify proper tube placement in seconds. It also allows you to monitor $EtCO_2$ during CPR. Paediatric Pedi Cap® version also available.

- CO_2 detectors to reliably confirm correct endotracheal tube placement
- Responds quickly to exhaled CO_2 with a quick colour change from purple to yellow
- Highly visible display window provides breath to breath visual feedback

UK – Source: https://www.spservices.co.uk/item/Brand_EasyCapIIETCO2Monitor-Caseof6_57_0_3381_0.html±
- Easy Cap II $ETCO_2$ Monitor - Case of 6 £69.95 ex VAT (£5.95 delivery) - £11.66 each

- Case of 24 - £237.55 ex VAT - £9.90 each

UK - Source: https://my.supplychain.nhs.uk/Catalogue/product/ftc243 - Free Delivery
- Electrostatic Filter with Sampling Port - Adult CO_2 Detector – Oct 2011
  Price £37.14/6 inc VAT (£30.95) ± £5.16 each

UK Source: http://medtree.co.uk/easy-cap-end-tidal-co2-detector
- Adult± or paediatric £9.95 each

UK - Source: http://www.dsmedical.co.uk/pedi_cap
Delivery: minimum order £10.00 order, delivery up to 5 units £4.95, 5-10 £5.95, over £150 free delivery.
- Easy Cap End-Tidal CO_2 Detector £8.75 each±
  - Single patient use to verify endotracheal tube placement.
  Reliable carbon dioxide detectors help verify endotracheal tube placement.
  Responds quickly to exhaled CO_2 with a simple colour change from purple to yellow.
  Breath-to-breath response.
  Constant visual feedback for up to 2 hours.
  Recommended patient size: Weight over 15kg.
  Internal volume (dead space) 25cc.
  Resistance to flow 3.0cm H20 ±1.0cm @ 60L/min flow.
  Connector ports: Patient end 22mm OD/15mm ID. Circuit end 15mm OD/13mm ID.
- Pedi Cap End-Tidal CO_2 Detector £8.75 each
  - Single patient use to verify endotracheal tube placement.
  Reliable carbon dioxide detectors help verify endotracheal tube placement.
  Responds quickly to exhaled CO_2 with a simple colour change from purple to yellow.
  Breath-to-breath response.
  Constant visual feedback for up to 2 hours.
  Recommended patient size: Weight 1kg to 15kg.
  Internal volume (dead space) 3cc.
  Resistance to flow 2.5cm H20 ±0.5 cm @ 10L/min flow.
  Connector ports: Patient end 18mm OD/15mm ID. Circuit end 15mm OD/5mm ID

USA - Source: http://www.beesmed.com/covidien-nellcor-easy-detectors-p-2319.html
- Easy Cap II CO_2 Detectors $97.72/6±

USA - Source: http://www.sedationkit.com/Anesthesia-CO2_Detectors.html
- MAL-EasyCapII-MP - CO_2 Detector Easy Cap 20/Case $199.00±
- MAL-Pedicap-MP - CO_2 Detector Pedi Cap 20/Case $199.00
- MAL- EasyCapII6PK-MP - CO_2 Detector Easy Cap II Box of 10 $115.00±
- MAL-PediCap6-MP - CO_2 Detector Pedi Cap Box of 10 $115.00

USA - Source: http://www.emsprofessionals.net/CO2-detector-Nellcor-Easy-Cap-II.html
- CO_2 detector, Nellcor Easy Cap II $13.56 each±

USA - Source: http://www.lifemedicalsupplier.com/co2-detectors-eid-c-557_135.html
- Easy cap CO_2 detector Latex Free $13.40 each±
- Pedi cap CO_2 detector $15.12 each

USA - Source: http://www.firstinmedical.com/Easy_Cap_CO_Detector_Adult_p/se-n7697.htm
- Easy Cap CO_2 Detector $15.17 each±

USA - Source: http://statesurgicalsupply.com/covidien-respiratory-monitoring-co2-detector-easycap-ii-6.html±

- Case 24 - $187.40
- Case 6 - $101.09
- $16.85 each

Distributors with no pricing:

- USA - https://www.mooremedical.com/index.cfm?/Easy-Cap-CO2-Detector/&PG=CTL&CS=HOM&FN=ProductDetail&PID=1684&spx=1
- USA - https://www.mooremedical.com/index.cfm?/Pedi-Cap-CO2-Detector/&CS=HOM&FN=ProductDetail&PG=CTL&PID=1685&spx=1
- http://products.covidien.com/pages.aspx?page=ModelDetail&id=103451&cat=Enteral%20Feeding&cat2=Model

Ambu CO2 Disposable Detector

The Ambu CO_2 Detector is a carbon dioxide detector designed to detect CO_2 in the exhaled breath of a patient. It provides colorimetric indication of end-tidal CO_2 by changing from violet at ambient levels of CO_2 to yellow at normal respiratory levels. The Ambu CO2 Detector is used during mechanical ventilation to assist in the placement of an endotracheal or nasotracheal tube, or to verify the condition of a patient airway. The detector may be used for up to two hours of continuous use.

UK - Source: http://medtree.co.uk/ambu-co2-detector-case-of-12

- Adult ± or paediatric: £124.95 case of 12

Source: http://www.ccrmed.com/store/products_detail.php?ProductID=961

- Adult ± or child $110.00

Source: http://www.acesurgical.com/portex-co2-clip-carbon-dioxide-detector.html

- $39.99 each (branded as Portex but think possibly incorrect) ±

Promotion

Viamed do not carry out promotions such as buy one get one free but complete marketing activities such as:

- Advertising
- Direct mailings
- Telesales
- Demos
- Exhibitions
- Quantity discounts – some Viamed products have quantity discounts, can appraise after the launch and feedback.
- Free UK mainland postage

Place

Selling to the NHS hospitals and ambulance trusts can take two avenues dependant on location in the UK.

- Direct selling
- Through designated distributors

There are a number of key channels that need to be addressed to highlight this new product. As stated above advertising, direct mailings, telesales and product demos can be utilised to highlight the range.

For Viamed direct mailigs are main marketing activities for a new product such as Maxtec FLOCAP we are able to utilise existing sanitised mailing groups but would also be beneficial to purchase for departments we currently do not have up-to-date information for.

Source of mailing groups include (Quotes in appendix 4):

- Binleys - £2,718
- Kaltz - £795 for NHS (updated 6 monthly) and £795 for Emergency Services (updated yearly).

People

Viamed provide excellent customer service. This is vital to the success of the business as they need to inform customers of the full process from enquiry to delivery of the product.

Excellent product knowledge is fundamental to the success of the range – this will include jargon busting literature.

As front line staff the office administration team are required to have basic knowledge of the product and understand its uses to be able to answer queries from customers.

Physical Evidence

It is vital to have consistency of all aspects of the company which customers interact with e.g. product packaging, advertising, offices – to reinforce Viamed's quality and professional image.

Although this product will not be branded Viamed it still is required to be packaged correctly and boxed effectively so that no damage occurs to the product or packaging.

Packaging is suitable, received from Maxtec in good condition see below.

This case contains 4 dispensing boxes of 6 FLOCAPs.

Inside each inner box is 6 FLOCAPs.

Each outer case is labelled with the below label and is taped up with the Maxtec tape shown overleaf.

Pre-barcoding instructions

Viamed blue reorder label to be ideally added to each individual product as well as the inner box and case where applicable – ISO dependant.

To reorder contact:
Viamed Ltd
Tel: +44 (0)1535 634542
Email: orders@viamed.co.uk

Sample pack products require “Not for clinical use” labels adding, not supplied in original, packaging in accordance with ISO and CE. (Stickers to be ordered for all sample pack stock)

Not for clinical use
for demonstration only
Viamed Ltd Tel: +44 (0)1535 634542

Conclusion

In conclusion, this product is a viable option for first responders and hospital staff to accurately measure the amount of CO_2 being exhaled from the patient. It is a cost effective solution allowing CO_2 monitoring to be completed when Capnograph is unavailable. We do not suggest that customers replace their capnographs with this device but using this device first can help a patient’s survival whilst either waiting for capnography to be used or when transporting between departments. With the launch of this product within our range Viamed are providing alternative solutions for our customers which are cost effective and timely.

Appendices

Appendix 1: FAQs

(Added to Intrastats for review)

1. *What do the different colour changes mean?*

   Purple (0%).....No carbon dioxide detected
   Beige (1-2%).....Exposed to CO_2, approx. 1% to 2%
   Yellow (5%)..... Exposed to 5% or greater CO_2

2. *What does the flow indicator spinner readings mean?*

   Spinning*.....Patient is exhaling
   Not Spinning.....Exhalation flow < 1 LPM

* At end of the exhalation, the flow indicators momentum will cause it to spin briefly after exhalation has ceased.

3. *What patient weight can the Maxtec FLOCAP be used on?*

   For patients greater than 15kg (33lbs)

4. *How long can the Maxtec FLOCAP be used for?*

   For use for up to 24 hours continuously on a single patient.

5. *How often can the product be used?*

   The Maxtec FLOCAP is for single use and can be used for a maximum of 24 hours on a single patient.

6. *What is the connector size?*

   Connector Port (Patient End): 15 mm Inner Diameter/22 mm Outer Diameter
   Connector Port (Ventilator End): 15 mm Outer Diameter

Appendix 2: Application Notes

Below is the enhanced versions of the Maxtec Operator Manual (Appendix 10)

Indications for use

The FLOCAP is used to provide a semi-quantitative visualisation of the CO_2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.

- The FLOCAP has a visual indicator to visually detect the end of exhalation
- For use up to 24 hours
- For patients greater than 15 kg (33 lbs)

- Environment of use – hospital, sub-acute, pre-hospital, transport

Contraindications:

- DO NOT use the FLOCAP for the detection of Hypercapnia/Hypercarbia (CO_2 retention in the blood)
- DO NOT use the FLOCAP for the detection of main-stem bronchial intubation
- DO NOT use the FLOCAP during mouth to tube ventilation
- DO NOT use the FLOCAP to detect oropharyngeal tube placement (used to maintain or open a patient's airway)

• Standard clinical assessment must be used

When low pulmonary perfusion (blood flow through the blood vessels) coincides with accidental esophageal intubation (incorrect ET tube placement), colorimetric CO_2 indication cannot be properly interpreted. However, if proper tube placement is ascertained by independent means, then the FLOCAP may be used to help assess the progress of positive pressure ventilation as evidenced by an increase in end-tidal CO_2.

Warnings:

- DO NOT use if you have blue-yellow colour blindness.
- DO NOT use on patients with body weight less than 15kg (33lbs) due to the potential for rebreathing exhaled CO_2.
- DO NOT use the FLOCAP with devices that elevate humidity such as nebulizers or heated humidifiers.
- DO NOT use in the presence of the following agents: atropine, infasurf, naloxone, intratracheal epinephrine, trichloroethylene, chloroform.
- DO NOT use the FLOCAP for a duration of more than 24 hours.

• For use with air and oxygen only; chemical interactions will affect device accuracy.
• Read the entire contents of the operating manual before using the FLOCAP.

Periodic colour changes reflect the breathing pattern of the patient. However, a permanent purple to purple-beige colour indicates a lack of exhaled carbon dioxide, the cause of which requires immediate attention. If the purple-beige colour does not appear during a breathing cycle, this may indicate a significant degree of carbon dioxide rebreathing and should also be of immediate concern.

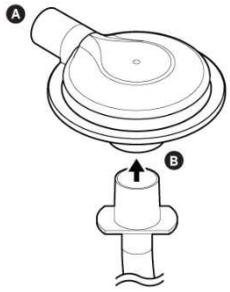
Cautions:

- Single use only, discard after use.
- Interpreting colour change before 6 complete breaths may lead to a false result.
- Excessively low cardiac output will result in low CO_2 content in the lungs.
- Excessive CO_2 in the stomach may cause erroneous colour change.
- Contamination, liquid water or excessive moisture may cause poor visibility, limit litmus function or inhibit spinner motion; causing functionality issues. The FLOCAP should be replaced immediately if this occurs.
- Reflux of any kind into the FLOCAP may compromise its accuracy or performance. The FLOCAP should be replaced immediately if this occurs.
- The FLOCAP is an adjunct (in addition) assessment tool and should not be relied upon as the sole means of verifying proper intubation. Follow your institutional guidelines for verifying proper intubation in addition to use of the FLOCAP.
- During cardiac arrest, CO_2 levels in the lungs may be too low to affect a colour change in the FLOCAP. Re-establishment of pulmonary blood flow is required for the FLOCAP to function properly.
- Storage for extended periods at temperatures above 25°C may result in reduced shelf life.
- Do not use if the package is already unsealed.

- Do not open the pouch until ready to use, prolonged exposure to ambient air may affect accuracy or performance.
- The bright coloured vane of the flow indicator is not intended to be a quantitative flow meter.
- At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.
- Do not use in an environment with insufficient lighting.
- Inspect the FLOCAP for damage prior to use.
- Do not use in the presence of acidic liquid or medication.
- Avoid exposure to strong sunlight and other sources of ultraviolet light.
- The FLOCAP does not take the place of traditional end tidal CO_2 monitoring which remains necessary to provide quantitative measurements and patient alarms.

Appendix 3: Instructions for Use

1. To open: Open the pouch, remove and inspect the FLOCAP. Ensure the element inside the housing is still purple. If its colour looks to be closer to beige the device should be discarded. Some yellowing around the edge is permissible.



2. To connect: Attach the FLOCAP securely between the ventilation source and the mask or endotracheal tube, by pushing together and rotating slightly, as illustrated here:
   A. Connect to breathing device here.
   B. Connect to endotracheal tube here.
3. For CO_2 Detection: Ventilate the patient with 6 complete breaths. At the end of the 6 breath cycles, check the colour of the FLOCAP indicator.
   - If the colour of the indicator is yellow, continue to ventilate the patient and monitor clinical cues for adequate ventilation.
   - If the colour of the indicator is beige, continue to ventilate with 6 additional breaths and recheck. If the colour has not moved towards yellow, this indicates insufficient exhaled CO_2. This requires immediate attention. Employ your institution's protocol to verify proper tube placement and adequate gas exchange.
   - If the colour remains purple, or a colour similar to purple, the patient may not have a patent airway or the endotracheal tube may not be positioned correctly. This requires immediate attention. Employ your institution's protocol to verify proper tube placement and adequate gas exchange.
   - Continue to monitor the colour of the CO_2 indicator throughout the entire time the device is in use. Do not exceed 24 hours of use.
   - During the course of ventilation, if the FLOCAP returns to and remains purple or beige coloured, this indicates insufficient exhaled CO_2. This requires immediate attention.
4. Not intended to be a quantitative indicator. Follow your institution's guidelines for breath frequency and tidal volume during resuscitation and for avoiding auto-PEEP (gas trapped in the alveoli in the lungs at the end of exhalation) during resuscitation. At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.

Appendix 4: Maxtec CE Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 15 03 45041 017

Manufacturer:	**Maxtec** 2305 South 1070 West Salt Lake City UT 84119 USA
EC-Representative:	**QNET BV** Hommerterweg 286 6436 AM Amstenrade THE NETHERLANDS
Product Category(ies):	**Electrochemical Oxygen Sensors, Analyzers, Monitors, Air/Oxygen Blenders, Flowmeters and CO2 Indicators**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72103033

Valid from: 2015-04-13
Valid until: 2016-12-18

Date, 2015-04-14

Hans-Heiner Junker

628136

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

Appendix 5: Maxtec ISO 13485:2012 Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS CRT2 / 10.13

Product Service

CERTIFICATE

No. Q1N 15 03 45041 016

Holder of Certificate: **Maxtec**
2305 South 1070 West
Salt Lake City UT 84119
USA

Facility(ies): Maxtec
2305 South 1070 West, Salt Lake City UT 84119, USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Servicing of Electrochemical Oxygen Sensors, Analyzers, Monitors, Air/Oxygen Blenders, Flowmeters and CO2 Indicators**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72103033

Valid from: 2015-04-13
Valid until: 2017-08-31

628138

Date, 2015-04-14

Hans-Heiner Junker

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Appendix 6: Maxtec ISO 13485:2013 CMDCAS Certificate

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. QS1 15 04 45041 018

Certificate Holder: Maxtec
2305 South 1070 West
Salt Lake City UT 84119
USA

Certification Mark:

Scope of Certificate: Design, Development, Manufacture, Distribution and Servicing of Electrochemical Oxygen Sensors, Analyzers, Monitors, and Air / Oxygen Blenders, Flowmeters and CO2 Indicators

Standard(s): ISO 13485:2003

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M1536

Effective Date: 2015-04-17
Expiry Date: 2017-09-20

Gary Minks
Vice President, Regulatory Affairs

Page 1 of 1

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®

SCC Accredited CB-MS OCSM Accrédité CCN

UCB_F_12.04 2012-02

Appendix 7: Database Quotations

Binleys ICU

Section 3: Costs

Data Costs

Single Use	
Single mailing:	£505
Single email (Managed Service Only):	£376
Multiple Use	
12 months licence – Mailing, Telemarketing & Email	£1,239
Additional Charges	
Delivery:	£20
Service/Selection Charges:	£0
Additional Data Fields:	£0
Additional Users:	£0

All prices exclude VAT

Binleys Accident and Emergency

Section 3: Costs

Data Costs

Single Use	
Single mailing:	£625
Single email (Managed Service Only):	£445
Multiple Use	
12 months licence – Mailing, Telemarketing & Email	£1,479
Additional Charges	
Delivery:	£20
Service/Selection Charges:	£0
Additional Data Fields:	£0
Additional Users:	£0

All prices exclude VAT

Kaltz

The National NHS Trust Procurement Directory – September & March http://www.kaltz.co.uk/downloads/nhsmediapack.pdf
The Emergency Services Procurement Directory – May http://www.kaltz.co.uk/downloads/esmediapack.pdf

Nationally the following positions are available.

Full Page £1495
Half Page £795

If taking representation in multiple publications a 15% discount will apply and a further 5% discount for payment within 30 days with immediate access to the databases, this will then be updated on publication.

On taking the representation with us you are provided with;

A hard copy of each directory you appear in, which obviously lists the names of all the key decision makers, buyers and specifiers within each sector such as Accident & Emergency , ICU/HDU (Intensive care) units, Antenatal Care, Nursing, Midwifery, Procurement, Supplies & Purchasing, Fleet Supplies, Patient Care, Resourcing, Emergency Response, Rehab etc etc

We will provide accurate electronic databases for each publication you appear in with all the relevant contact names, addresses and contact details for your communication and marketing purposes

Your advert will also appear free of charge in the online versions of each directory you appear in, I can include a hyper-link to your own website from here.

You are entitled to choose your own five categories for the index to products and services and we also provide a complimentary artwork service.

Finally, payment is not expected until after each distribution date, or a further 5% discount is given for payment within 30 days of booking.

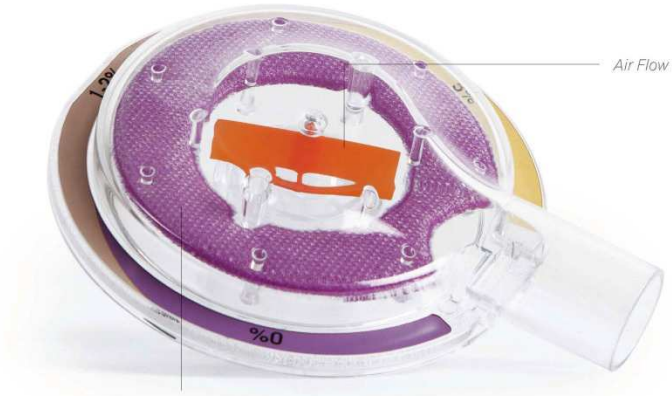
Appendix 8: Original Maxtec Literature

SENSING. ANALYSIS. DELIVERY.

FLOCAP® Flow Indicator & $EtCO_2$ Detector

maxtec

FLOCAP®



High-Definition Indication of Exhaled CO_2

WORDS FROM AN EXPERT!

"The new CPR guidelines recommend a slower ventilation rate and one of the reasons for this change is to assure that a more complete exhalation takes place during CPR thus reducing the risk of overdistention of the lungs."

FLOCAP Flow Indicator

The ***FLOCAP***® is a single-use $EtCO_2$ & flow indication device designed for visualization of a patient's exhaled CO_2 and expiratory flow. The $EtCO_2$ indication will assist the user in verifying proper ET tube placement. The flow indicator helps the caregiver identify end of exhalation which may help prevent breath stacking or overdistention and its associated health issues during resuscitation.

Part Numbers

FLOCAP 24/pk R500P21

The ventilatory effects of auto-positive end-expiratory pressure development during cardiopulmonary resuscitation.

Wioda RP, Dzwonczyk R, Bernacki BL, Cannion M, Lynn L. Crit Care Med. 1999 Oct;27(10):2212-7.

Multi-Colored Indicator Shows Exhaled CO_2

TOP 10
REASONS TO BUY FLOCAP®

WORDS FROM AN EXPERT!

"It's one thing to place a mask over a person's face, and another to objectively know you are actually ventilating them; Thus the FloCap"

-Anesthesiologist

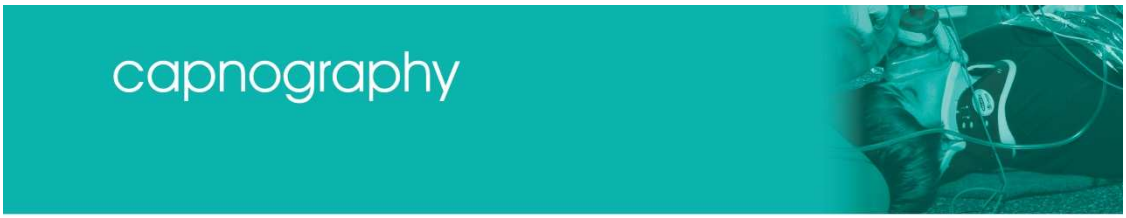
1. The florescent orange spinner is easy to see in low light and works indefinitely. A great training tool and verification that gas exchange is happening.
2. The flow indicator adds value when using a mask as well as on a patient that has been intubated.
3. Made in the USA.
4. A low cost important back-up in every bag.
5. Helps reduce air stacking by knowing the end of exhalation.
6. Has value even when CO_2 and waveform monitoring is present because the flow indicator shows end of exhalation.
7. High Definition color changing material displays CO_2 %.
8. Extremely long life; The product can stay with the patient after having been opened to go from OR or ED to PACU or ICU and still be used if an event or transport is needed.
9. Incredibly long shelf life, currently tested at 36 months.
10. A strong way to discern end expiratory breath in addition to wave form CO_2 monitors.

REMEMBER – FLOCAP can be used on patients down to a 33 LB body weight.

maxtec®

6526 South Cottonwood Street | Salt Lake City, Utah | 84107
800.748.5355 *(toll free)* | 801.266.5300 *(international)* | 801.270.5590 *(fax)*
www.maxtec.com

Appendix 9: Viamed First Draft - Maxtec FLOCAP Leaflet



FLOCAP®

Flow Indicator & $EtCO_2$ Detector

maxtec

- Long shelf life, currently tested to 36 months
- High definition colour changing material displays CO_2 %
- Patented flow indicator spinner
- Highly visible
- A quick way to determine end expiratory breath in addition to waveform CO_2 monitors
- If "waveform CO_2 monitors are not available, a nonwaveform carbon dioxide detector device in addition to clinical assessment is an alternative" hence the Maxtec FLOCAP

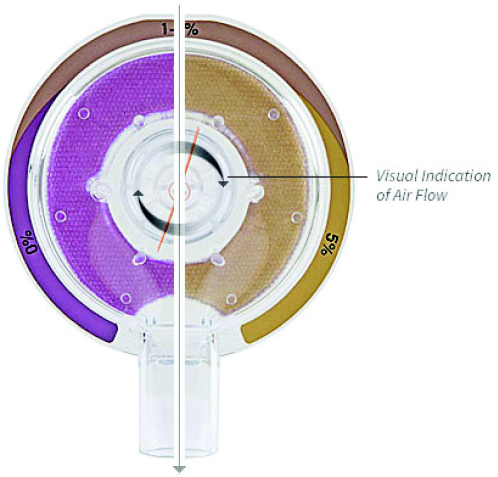
Source: NAP4 Report 4th National Audit Project of The Royal College of Anaesthetists

The FLOCAP is a single-use $EtCO_2$ & flow indication device designed for visualisation of a patient's exhaled CO_2 and expiratory flow. The $EtCO_2$ indication assists the user in verifying proper ET tube placement. The flow indicator helps the caregiver identify end of exhalation which may help prevent breath-stacking or overdistention and its associated health issues during resuscitation.

VIAMED

FLOCAP®

Flow Indicator & $EtCO_2$ Detector



Multi-colored Indicator Displays Exhaled CO_2

Colour indications

Purple (0%)
No carbon dioxide detected

Beige (1-2%)
Exposed to CO2 approx 1-2%

Yellow Beige (2-5%)
At intermediate CO2 concentrations of 2-5%

Yellow (5%)
Exposed to 5% or greater CO2

Permanent Yellow
A damaged indicator

Spinning*
Patient is exhaling

Not spinning
Exhalation flow < 1 LPM

* At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.

Flow Sensitivity	1 LPM
CO_2 detection	0%, 1-2%, >5%
Use duration	24 hours
Storage temperature	5°C (41°F) to 25°C (75°F)
Use temperature	10° C (50°F) to 40°C (104°F)
Internal volume	<25ml
Leak rate according to ISO 9360-1	0.00 ml/min
Compliance according to ISO 9360-1	0.44 ml/kPa
Device weight	23g
Pressure drop	0.7 cmH_2O @ 30 LPM, 2.7 cmH_2O @ 60 LPM, 5.7 cmH_2O @ 90 LPM
Connector port (patient end)	15 mm Inner Diameter/22 mm Outer Diameter
Connector port (ventilator end)	15 mm Outer Diameter
Patient size	>15 Kg (33 lbs)
Part Number Maxtec FLOCAP: Pack of 24	4410100

Specifications Subject to Change

CE 0123

Distributed by:

VIAMED

Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634 542 Fax: +44 (0)1535 635 582
Email: info@viamed.co.uk Website: www.viamed.co.uk

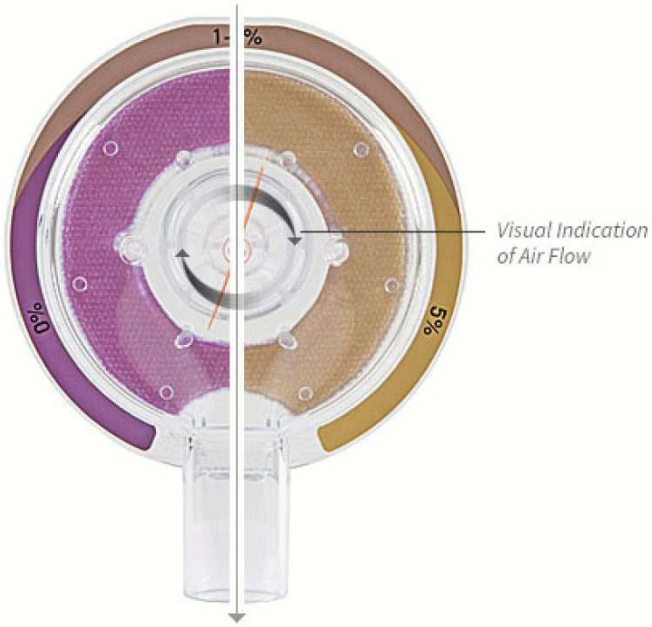
Part Number: 4490000
Date: 09/15

Appendix 10: Viamed First Draft – Catalogue Artwork

- Long shelf life, currently tested to 36 months
- High definition colour changing material displays CO_2 %
- Patented flow indicator spinner
- Highly visible
- A quick way to determine end expiratory breath in addition to waveform CO_2 monitors
- If "waveform CO2 monitors are not available, a nonwaveform carbon dioxide detector device in addition to clinical assessment is an alternative" hence the Maxtec FLOCAP

Source: NAP4 Report 4th National Audit Project of The Royal College of Anaesthetists

The FLOCAP is a single-use $EtCO_2$ & flow indication device designed for visualisation of a patient's exhaled CO_2 and expiratory flow. The $EtCO_2$ indication assists the user in verifying proper ET tube placement. The flow indicator helps the caregiver identify end of exhalation which may help prevent breath-stacking or overdistention and its associated health issues during resuscitation.



CE 0123

Appendix 11: Viamed First Draft – Website Artwork/Text

Part number **4410100**
Product name Maxtec FLOCAP EtCO2 Detector

The FLOCAP is a single-use EtCO2 & flow indication device designed for visualisation of a patient's exhaled CO2 and expiratory flow. The EtCO2 indication assists the user in verifying proper ET tube placement. The flow indicator helps the caregiver identify end of exhalation which may help prevent breath-stacking or overdistention and its associated health issues during resuscitation.

More Information

Part number 4410100
Product name Maxtec FLOCAP EtCO2 Detector

The FLOCAP is a single-use EtCO2 & flow indication device designed for visualisation of a patient's exhaled CO2 and expiratory flow. The EtCO2 indication assists the user in verifying proper ET tube placement. The flow indicator helps the caregiver identify end of exhalation which may help prevent breath-stacking or overdistention and its associated health issues during resuscitation.

Pack of 24

- Long shelf life, currently tested to 36 months
- High definition colour changing material displays CO2 %
- Patented flow indicator spinner
- Highly visible
- A quick way to determine end expiratory breath in addition to waveform CO2 monitors
- If "waveform CO2 monitors are not available, a nonwaveform carbon dioxide detector device in addition to clinical assessment is an alternative" hence the Maxtec FLOCAP

  Source: NAP4 Report 4th National Audit Project of The Royal College of Anaesthetists

Full specification information available upon request.

Appendix 12: GBP End User Price List

Viamed Limited
15 Station Road, Cross Hills, Keighley
West Yorkshire, BD20 7DT, U.K.
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582
Email: info@viamed.co.uk
Website: www.viamed.co.uk

GBP Price List

Reference	Description	Price
4410100	Maxtec FLOCAP - CO2 & Flow Indication Device	£192.00

Prices exclude VAT and delivery.
No minimum order charge.
Currency: GBP
Prices effective: 05 August 2015

Appendix 13: Maxtec Operator Manual

FLOCAP™

OPERATING MANUAL & INSTRUCTIONS FOR USE

R500P21

1.0 SYSTEM OVERVIEW

1.1 Description:

The FLOCAP is a simple, disposable, single-use CO_2 and flow indication device designed for placement between a breathing device and a patient's endotracheal tube or mask for visualization of exhaled CO_2 and to give a visual indication of the presence of expiratory flow. The CO_2 indicator will assist the caregiver in verifying proper ET tube placement. A lack of color change may indicate improper intubation. Exhaled gas passes through the device and indicates a range of end-tidal CO_2. The flow indicator allows the caregiver to visually detect if the patient is still exhaling.

1.2 Indications for use:

The FLOCAP is used to provide a semi-quantitative visualization of the CO2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.

The FLOCAP has a visual indicator to visually detect the end of exhalation.

For use up to 24 hours.

For patients greater than 15 kg (33 lbs.)

Environment of use – hospital, sub-acute, pre-hospital, transport

R500M21 REV.D

1.3 Contraindications:

- DO NOT use the FLOCAP for the detection of Hyperacpnia/Hypercarbia.
- DO NOT use the FLOCAP for the detection of main-stem bronchial intubation.
- DO NOT use the FLOCAP during mouth to tube ventilation.
- DO NOT use the FLOCAP to detect oropharyngeal tube placement.
- Standard clinical assessment must be used.

When low pulmonary perfusion coincides with accidental esophageal intubation, colorimetric CO_2 indication cannot be properly interpreted. However, if proper tube placement is ascertained by independent means, then the FLOCAP may be used to help assess the progress of positive pressure ventilation as evidenced by an increase in end-tidal CO_2.

1.4 Warnings:

- DO NOT use if you have blue-yellow color blindness.
- DO NOT use on patients with body weight less than 15kg (33lbs) due to the potential for rebreathing exhaled CO_2.
- DO NOT use in the presence of the following agents: atropine, ifasufr, naloxone, intratracheal epinephrine, trichlorethylene, chloroform.
- DO NOT use the FLOCAP for a duration of more than 24 hours.
- For use with air and oxygen only; chemical interactions will affect device accuracy.
- Read the entire contents of this operating manual before using the FLOCAP.

Periodic color changes reflect the breathing pattern of the patient. However, a permanent purple to purple-beige color indicates a lack of exhaled carbon dioxide, the cause of which requires immediate attention. If the purple-beige color does not appear during a breathing cycle, this may indicate a significant degree of carbon dioxide rebreathing and should also be of immediate concern.

1.5 Cautions:

- Single use only, discard after use.
- Interpreting color change before 6 complete breaths may lead to a false result.
- Excessively low cardiac output will result in low CO_2 content in the lungs.
- Excessive CO_2 in the stomach may cause erroneous color change.
- Contamination, liquid water or excessive moisture may cause poor visibility, limit litmus function or inhibit spinner motion. The FLOCAP should be replaced immediately if this occurs.
- Reflux of any kind into the FLOCAP may compromise its accuracy or performance. The FLOCAP should be replaced immediately if this occurs.
- The FLOCAP is an adjunct assessment tool and should not be relied upon as the sole means of verifying proper intubation. Follow your institutional guidelines for verifying proper intubation in addition to use of the FLOCAP.
- During cardiac arrest, CO_2 levels in the lungs may be too low to affect a color change in the FLOCAP. Re-establishment of pulmonary blood flow is required for the FLOCAP to function properly.
- Storage for extended periods at temperatures above 25°C may result in reduced shelf life.
- Do not use if the package is already unsealed.
- Do not open the pouch until ready to use, prolonged exposure to ambient air may affect accuracy or performance.
- The bright colored vane of the flow indicator is not intended to be a quantitative flow meter. At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.
- Do not use in an environment with insufficient lighting.
- Inspect the FLOCAP for damage prior to use.
- Do not use if the presence of acidic liquid or medication.
- Avoid exposure to strong sunlight and other sources of ultraviolet light.
- The FLOCAP does not take the place of traditional end tidal CO_2 monitoring which remains necessary to provide quantitative measurements and patient alarms.

2.0 INSTRUCTIONS FOR USE:

1. To open: Open the pouch, remove and inspect the FLOCAP. Ensure the element inside the housing is still purple. If its color looks to be closer to beige the device should be discarded. Some yellowing around the edge is permissible.
2. To connect: Attach the FLOCAP securely between the ventilation source and the mask or endotracheal tube, by pushing together and rotating slightly, as illustrated here:

Ⓐ Connect to breathing device here.

Ⓑ Connect to endotracheal tube here.

3. For CO_2 Detection: Ventilate the patient with 6 complete breaths.
   At the end of the 6 breath cycles, check the color of the FLOCAP indicator.
   - If the color of the indicator is yellow, continue to ventilate the patient and monitor clinical cues for adequate ventilation.
   - If the color of the indicator is beige, continue to ventilate with 6 additional breaths and recheck. If the color has not moved towards yellow, this indicates insufficient exhaled CO_2. **This requires immediate attention.** Empiry your institution's protocol to verify proper tube placement and adequate gas exchange.
   - If the color remains purple, or a color similar to purple, the patient may not have a patent airway or the endotracheal tube may not be positioned correctly. **This requires immediate attention.** Empiry your institution's protocol to verify proper tube placement and adequate gas exchange.
   - Continue to monitor the color of the CO_2 indicator throughout the entire time the device is in use.
   - Do not exceed 24 hours of use.
   - During the course of ventilation, if the FLOCAP returns to and remains purple or beige colored, this indicates insufficient exhaled CO_2. **This requires immediate attention.**
4. For Exhalation Monitoring: Monitor the rate at which the flow indicator rotates during exhalation to visually observe the patient's exhalation and detect when exhalation is complete. The FLOCAP is not intended to be a quantitative indicator. Follow your institution's guidelines for breath frequency and tidal volume during resuscitation and for avoiding auto-PEEP during resuscitation. At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.

3.0 COLOR & FLOW INDICATOR INTERPRETATION:

Note that the detector color will continue to fluctuate from inspiration to expiration for up to twenty-four hours. When the gas contains CO_2 (i.e., expired gas from the patient), the indicator color will change. Following are the color indications of the FloCap indicator device.

Purple (0%)	No carbon dioxide detected
Beige (1-2%)	Exposed to CO_2, approx. 1% to 2%
Yellow Beige (2-5%)	At intermediate CO_2 concentrations of 2%-5%
Yellow (5%)	Exposed to 5% or greater CO_2
Permanent Yellow	A damaged indicator

Spinning*	Patient is exhaling
Not Spinning	Exhalation flow < 1 LPM

*At the end of exhalation, the flow indicator's momentum will cause it to spin briefly after exhalation has ceased.

4.0 MECHANICAL SPECIFICATIONS:

Internal Volume:	< 25 ml
Pressure Drop according to ISO 9360-1:	
at 30 LPM	0.7 cmH2O
at 60 LPM	2.7 cmH2O
at 90 LPM	5.7 cmH2O
Leak rate according to ISO 9360-1:	0.0 ml/min
Compliance according to ISO 9360-1:	0.44 ml/kPa
Device Weight:	23 grams
Connector ports according to ISO 5356-1:	
Patient end	15mm I.D./22mm O.D.
Ventilator end	15mm O.D.

5.0 SYMBOL GUIDE:

Maxtec
6526 South Cottonwood Street
Salt Lake City, Utah 84107
USA

TEL: 1 (800) 748.5355
FAX: 1 (801) 270.5590
EMAIL: sales@maxtec.com
WEBSITE: www.maxtec.com

EC REP QNET BV
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

Appendix 14: Sample Pack Contents

1. Leaflet - Maxtec FLOCAP (Appendix 9)
2. Product - 4430000 FLOCAP Single
3. Price List - GBP End User (Appendix 12)
4. Operator Manual - FLOCAP Operator Manual (Appendix 13)
5. Label – Outer Sample Pack