

Dräger Safety UK. Whitepaper review of FFP (Filtering Face Pieces) UK situation from a Manufacturer's perspective December 2021

Dräger. Technology for Life<sup>®</sup>



### INTRODUCTION AND AIM OF THIS WHITEPAPER

This present position paper is addressed to all interested parties involved with protecting people in their everyday lives against airborne transmission of SARS-CoV-2 virus with filtering face piece (FFPs) respirators. With this paper Dräger would like to contribute to the management of the pandemic caused by the SARS-CoV-2 virus by aiding the understanding of possible transmission routes and solutions and protection against such transmission with their respiratory protection equipment (RPE) portfolio of products.



# History of Pandemics 1800 to today

# **Historical Context**

Wikipedia defines a pandemic as "an epidemic of an infectious disease that has spread across a large region, for instance multiple continents or worldwide, affecting a substantial number of individuals."

Pandemics of various kinds have been occurring for centuries. Evidence suggests that the likelihood of pandemics has increased over the past century because of increased global travel and integration, urbanisation, changes in land use, and greater exploitation of the natural environment. These trends likely will continue and will intensify. Significant policy attention has focused on the need to identify and limit emerging outbreaks that might lead to pandemics and to expand and sustain investment to build preparedness and health capacity. Since the first discovery of the COVID-19 pandemic in the UK, the Government has been focused on the dual goals of protecting the general workforce from the SARS-CoV-2 virus (in addition to the wider UK population generally) and keeping the UK economy functioning at as near to full capacity as possible with respect to a wide range of sectors such as healthcare, manufacturing, industry, retail, construction, financial services and hospitality.

Today there is an emphasis on a vaccination programme to protect against the SARS-CoV-2 virus including future variants, and the wearing of face coverings to prevent the spread of the virus. FFP (Filtering Face Piece) respirators are a key element of the "prevent" strategy offering the wearer maximum protection from aerosol transmission of the virus, particularly with those FFPs with a protection factor of 3 (FFP3). This will be described in greater detail later in this paper.

# The UK and COVID-19 in 2020 and beyond

Prior to the current COVID-19 pandemic production of FFP (filtering face piece) respirators resided largely outside of the UK. The required surge requirement in UK for FFP respirators due to COVID-19 was so large that it could not be met with the limited existing domestic capacity.

Therefore it was recognised by UK Government at an early stage during the COVID-19 pandemic that new local manufacturing facilities within UK borders were required to ensure supply of PPE products was readily available, particularly FFP respirators to prevent aerosol transmission of the SARS-CoV-2 virus in healthcare environments (Hospitals). Furthermore during the COVID-19 pandemic many countries closed their borders to export of both materials to make FFPs and the finished products themselves. This is illustrated by the graphic below showing the countries with various forms of PPE export bans in place in 2020, shaded blue: There was also evidence of price surges and poor quality FFP products being offered as a result of the global increase in demand and a lack of supply availability for these lifesaving PPE items, which significantly compromised respiratory protection for the wearers in hazardous, high transmission environments such as hospitals. The UK Government however was clear in its objective which was to establish locally sourced FFPs from reputable and proven manufacturers to supply key workers in the NHS throughout the pandemic and beyond.

This would also have a further effect of improving sustainability in the sector with a lower carbon footprint due to reduced travel of the products from manufacture source to the end user.

Looking forwards, the objective of both UK Government and Dräger is to be prepared for any future pandemics and associated surges in demand for FFPs. To achieve this Dräger have introduced a series of new, innovative "Pandemic Preparedness" supply models and initiatives for Customers. Below is a typical example of the complete supply process in graphical format.





The X-plore® 1700 Series



The advantages of such flexible models are fixed prices in the event of another surge in demand, guaranteed, secured access to quality products, a forward thinking contingency plan for customers which can be activated without further negotiations and secured continuous supply whatever the situation. To ensure a total solution, Dräger can even store and manage the inventory so there is never the possibility of obsolete products or scrapping of out of date items. From a customer perspective the advantages are significant - to have guarantees of supply during any upcoming crisis as well as a defined plan in place for regular consumption, in addition to cost certainty.



# The response of Dräger to the COVID-19 pandemic

At the start of the COVID-19 pandemic the Board of Directors at Dräger responded quickly and decisively with a commitment to establish manufacturing capacity in countries across the globe that had the highest demand for FFP masks to address the surge in demand for these respirators locally. Amongst the sites chosen was one in UK which also would support a UK Government contract for supply of approximately 50 million FFP3 respirators.

The objective of the Dräger Board of Directors was opening the factory in such short timescale was to react quickly to the pandemic situation with significant investment at a local country level in UK to ensure all NHS staff were (and still are) protected from airborne aerosol transmission of the SARS-CoV-2 virus through wider provision and use of respiratory protective equipment (RPE). A new Dräger manufacturing facility was established in Follingsby Gateshead, in close proximity to the already existing manufacturing site in Blyth. Dräger sourced, refurbished, equipped, and opened a factory dedicated to producing FFP masks in less than twelve weeks from inception to commencing manufacture. This would have been considered impressive in normal times, however during a pandemic was testament to the hard work and commitment of all involved working towards a clear goal of achieving production as soon as possible of the FFP masks.

The factory was opened to ensure Dräger could be considered as a credible "Made in Britain" Supplier of FFP masks and give confidence to customers in the face of export bans by Countries and the unquantified risk posed by Brexit. The factory is highly mechanised to ensure the possibility of human error is minimised and productivity and output is maximised. The option of continuous running day and night resilience was

also integrated at the planning stage to ensure flexibility and variable output levels with the option of supplying the global network of Dräger customers overseas at some point in the future if necessary.





# A history of RPE (Respiratory Protective Equipment) product development - 100 years in the making

Since 1889 Dräger has designed, innovated, and manufactured products which protect and save lives. The X-plore® 1730 C Series mask manufactured in the UK was originally designed and developed approximately twenty years ago and has continued to undergo refinement and upgrading as new materials became available and experience has led to design developments to increase comfort and fit. Today the X-plore<sup>®</sup> 1730 C Series FFP mask design is considered one of the cornerstones of the complete Dräger RPE range currently available.

However, Dräger doesn't just manufacture FFPs. There is a complete range of RPE products designed to combat a range of hazards and work in different applications and situations. The range includes half and full-face masks and Powered Air Purifying Respirators (PAPR). This comprehensive range of RPE products has been developed using the same expertise and attention to detail as the FFPs and is designed to ensure any user has the right product and level of protection to safeguard against the particular respiratory hazard faced. Working across numerous industries and scenarios the range is one of the largest and most comprehensive offered by any manufacturer globally and leverages the long heritage and history Dräger has in the application field.





# **Approvals and Testing**

Dräger recognise the importance of all FFP masks being independently tested and approved by relevant Authorities and having valid certificates. All manufacturers of FFP half masks must have their products tested in accordance with the mandatory EN 149:2001+A1:2009 standard before these are placed on the European market. Dräger has undertaken this independent testing and verification and has passed with all their product range offered.

The user can ensure they have a tested and approved FFP mask from Dräger by looking for the CE mark, the four-digit Notified Body Number of the testing laboratory and the applicable standard, e.g. EN 149:2001 all printed on the products and packaging. All Dräger FFPs including the UK manufactured X-plore® 1730 C Series have this information clearly printed on each mask in a prominent position for added reassurance.





# FFP respiratory product design and innovation

Dräger manufacture a range of FFP respirators to suit many applications. There are three specific models – the X-plore® 1300 series, a moulded cup shaped FFP. The X-plore<sup>®</sup> 1700 series – a fold flat FFP and the X-plore<sup>®</sup> 1900 series, a trifold version FFP. All FFP series are available in FFP1, FFP2 and FFP3 protection classifications. The X-plore® 1900 series FFP even has two sizes (S and M-L) available to ensure a leak-free, tight fit even with smaller faces.

Each mask has specific design features unique to its design and these can be summarised using the following graphical illustrations:

# Dräger X-plore<sup>®</sup> 1300 Series



CoolSAFE<sup>™</sup> filter material High filter performance Low breathing resistance No clogging under high exposure to dust (dolomite dust test)



CoolMAX<sup>™</sup> exhalation valve (optional) Very low breathing resistance Releases humid air Easy and comfortable breathing

Hypoallergenic inner layer Comfortable to wear



With additional activated carbon layer which filters out unpleasant nuisance odours

Colour coding Fast recognition of protection class





Individual adjustment of length/ tension

VarioFLEX<sup>™</sup> head harness FFP1/2: continuous looped textile strap

FFP3: variable 4-point adjustment Easy donning and doffing Sits comfortably without any pressure





Flexible nose clip Great fit to the face

High sealing performance in the critical areas around the nose

Molded mask body

Classic, ergonomic shape High inner space volume Extra re-inforcement ribbing for stability







# Dräger X-plore<sup>®</sup> 1700 Series



Comfortable flexible nose clip Great fit around the nose due to the combination of nose pad and nose clip



CoolSAFE<sup>™</sup> filter material Minimal breathing resistance and high filter performance due to special filter material



CoolMAX<sup>™</sup> exhalation valve (optional) No heat build-up underneath the mask due to exhalation valve



High Comfort Soft inner lining made from moisture-resistant material for long-lasting comfort



VarioFLEX<sup>™</sup> head harness Easy to put on / take off with continuous loop head harness



Masks are folded flat (boxes of 20 without valves and 10 with valves)



Hygienic Masks are individually packed



**Colour coding** Fast recognition of protection class



# Dräger X-plore<sup>®</sup> 1900 Series



VarioFLEX<sup>™</sup> head harness Tear-resistant VarioFLEX<sup>™</sup> head straps make the mask easy to don and doff



#### High Comfort Soft inner lining made from moisture-resistant material f

moisture-resistant material for long-lasting comfort



Tri-fold design For optimal adjustment to the face and stable positioning

### CoolSAFE<sup>™</sup> filter material Specially developed filter material for high filtration efficiency and low breathing resistance



#### Flexible nose clip Flexible nose clip and soft nose pad for a secure seal

SmartFold Design Provides increased breathing

space and a sturdy mask body

CoolMAX<sup>™</sup> exhalation valve (optional) Effectively releases humid and warm air

Size variation

Two sizes (S and M/L) for an optimal fit for virtually every face

Colour coding and individually packaged

Colour coding to easily identify protection classes Masks are individually packed for hygiene













### How do FFPs work?

Particulate filters are usually made of "nonwoven" material. "Nonwovens" are networks of three-dimensionally arranged fibres. Aerosol particles are separated in filters by different mechanisms. However, particulate filters do not function like "sieves". Very small particles are filtered out with high efficiency due to their Brownian molecular movement. If an aerosol flows through the open areas between the fibres in a filter. three different mechanisms lead to the separation of particles on the fibres: impaction, interception, and diffusion. These three mechanisms have different effects on particles of different sizes. Impaction (inertial separation of particles) is the main separation mechanism for very small particles.

The influence of interception grows with increasing particle size. Conversely, the diffusion due to Brownian molecular movement increases with decreasing particle size. As soon as a particle hits a fibre it sticks to it. It is largely impossible for particles separated in a filter or on other surfaces to detach again. This is why FFP masks are effective with differing sizes of particulates.

However, a thicker denser or more multi-layer filter medium is required to achieve a higher degree of separation. But this also increases the flow resistance of the filter and therefore the breathing resistance. Therefore, some FFP models offer a valve to assist with exhaled breath ventilation. All FFP masks are tested against breathing resistance limits to ensure the user is not restricted with air intake and exhalation.

Another feature of the nonwoven material is their fibres are electrically charged during manufacture. Some airborne particles carry a natural electrical charge and can thus be removed from the air better than with solely mechanical filtration. However, uncharged particles are also polarised in the resulting electrical field within the filter and are also increasingly separated. The introduction of electrically charged fibres has no influence on the pressure drop making this particularly effective as a dual cause of particle capture. All Dräger FFPs use electrostatically charged nonwoven material as integral filter material.



Respiratory protection is our core competence Passionate, well-qualified employees guarantee production according to highest quality standards.



**180 countries** Dräger equipment is used every day in over 180 countries globally.

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**Dedicated UK Factory** Manufacturing the X-plore® 1700 C Series FFP masks for UK use in all Industries.



### 100 years of experience in respiratory protection

Founded in Lubeck, Germany in 1889. Now in its fifth generation as a family run business with over 15,000 employees globally and +600 in UK.

# Why Dräger?

Dräger is an international leader in the fields of medical and safety technology. The family-owned company was founded in Lübeck, Germany, in 1889. Over the past five generations, Dräger has evolved into a publicly traded, worldwide group. The company's long-term success is based on the four key strengths of its value-driven culture: customer intimacy, professional employees, continuous innovation, and a commitment to outstanding quality.

Dräger locations worldwide

"Technology for Life" is the guiding philosophy. Whether in Hospitals or Industry or emergency response services, Dräger products protect, support, and save lives.

Customers trust Dräger's products to protect them and allow them to focus on the job task safe in the knowledge their products will work when required.

Dräger has more than 15,000 passionate, wellqualified employees worldwide offering expertise and trusted advice and has equipment in use every day in more than 180 countries protecting and saving human lives globally. The company has sales and service subsidiaries in over 50 countries. Its development and production facilities are based in UK, Germany, Norway, Sweden, South Africa, the USA, Brazil, Chile, the Czech Republic, and China.

With a global network of manufacturing and service / supply centres throughout the world (see graphic below) customers trust Dräger to provide and maintain products that protect and save lives.

- Headquarters
- Production sites
- Logistics centres
- Sales and service locations



### CONCLUSION

Dräger has been very proud to have contributed to the efforts both nationally in UK and globally in combatting the threat of COVID-19 by opening a new factory in UK to manufacture FFP masks. Dräger will continue to develop and manufacture new innovative products such as the X-plore<sup>®</sup> 1730 C model FFP in this fight and are committed to saving and protecting lives both now and in the future.

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