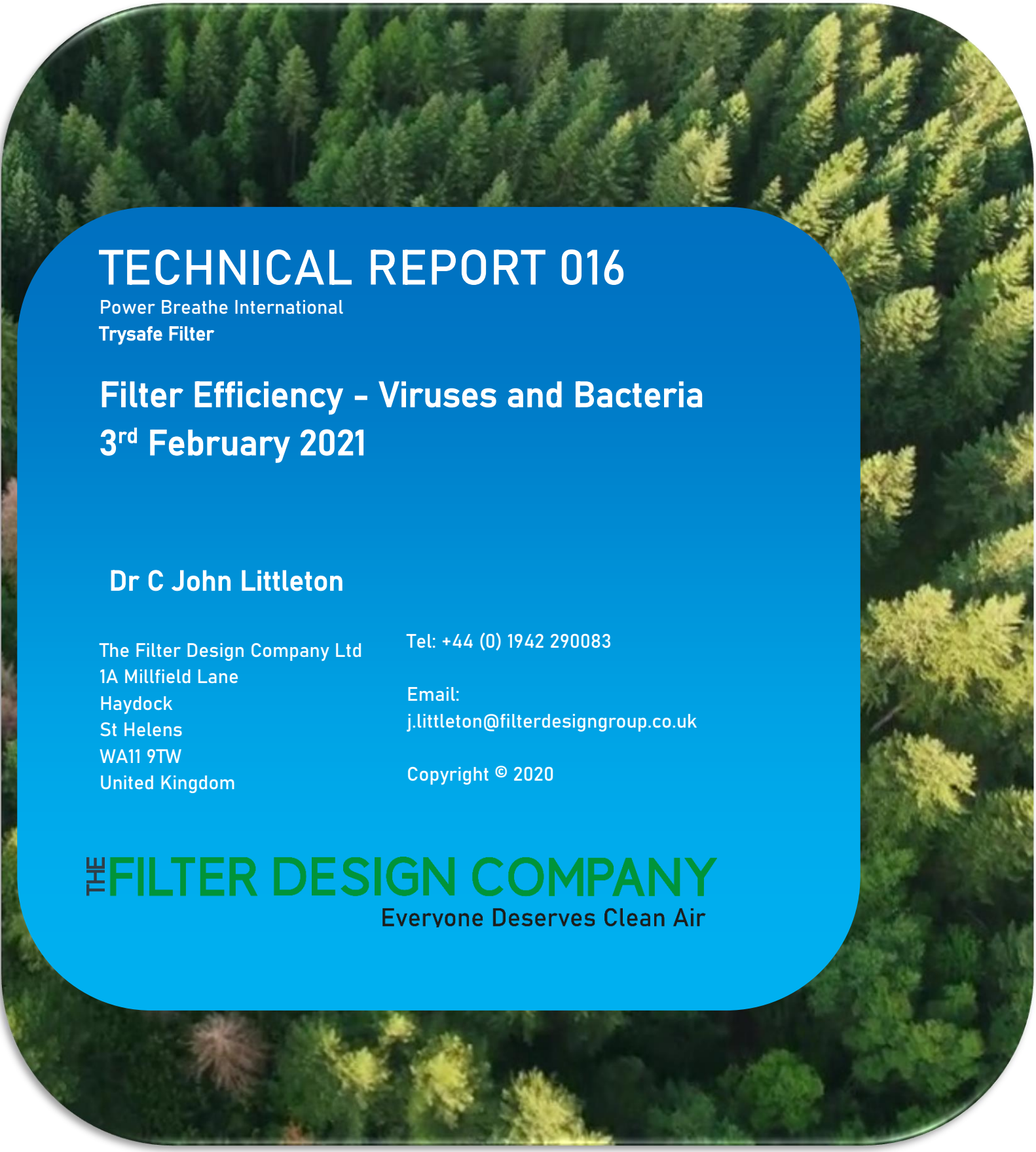

TECHNICAL REPORT 016

Power Breathe International

Trysafe Filter

Filter Efficiency – Viruses and Bacteria

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Dr C John Littleton

The Filter Design Company Ltd
1A Millfield Lane
Haydock
St Helens
WA11 9TW
United Kingdom

Tel: +44 (0) 1942 290083

Email:
j.littleton@filterdesigngroup.co.uk

THE FILTER DESIGN COMPANY

Everyone Deserves Clean Air

Filter Efficiencies – Viruses and Bacteria.

INTRODUCTION

Particulate material including dust, fume (thermally generated particulate), mist, airborne fibres, bacteria and viruses come in many different varieties, shapes and materials. These range from greater than 50 microns (the width of a human hair) down to nano particles. As a simplification, the smaller the particle, the more likely it is to penetrate the filter material.

Industrial filter standards need to be able to cover the whole spectrum of particulate materials and so a worst-case situation is chosen as the test method. There are two tests chosen and both generate a polydisperse particulate challenge (meaning that there is a wide range of particle sizes in the challenge air). As an example, one challenge is common salt (NaCl) particles where the particles generated are in the size range ~0.03 μm to ~1 μm. The **Trysafe Filter** has an efficiency at 30 l/min of around 95% when tested with this challenge.

It is well understood that viable virus aerosols are greater than 1 μm in size (typically around 3 μm in size). This work sets out to determine the efficiency of the **Trysafe Filter** against bacteria and viruses. Since the filter could work in both directions, both the circular and the oval inlet orientation have been tested.

EXPERIMENTAL

The filters in question (**Trysafe Filter**) have been tested against the highest challenge level of bacteriophage that can be generated as a test aerosol. This was introduced into a specially adapted filter with an adaptor supplied by FDC to allow the challenge concentration to be introduced onto the inlet side of the filter. Both the circular and oval inlets were used as the inlet in this work.

This test procedure was performed to evaluate the Viral Filter Efficiency (VFE) of **Trysafe Filter** at an increased challenge level. A suspension of ΦX174 bacteriophage was delivered to the test article at a challenge level of greater than 10^6 plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a sixstage, viable particle, Andersen sampler for collection. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101. This test procedure was modified from the, standard VFE test procedure in order to employ a more severe challenge than would be experienced in normal use. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

The Challenge concentration was 6.4 x 10^6 PFU (Plaque Forming Units - PFU)

Table 1 – Experimental Parameters

Number of filters tested	**Tested in Triplicate**
Side Tested	Circular Port (CJL-FDC-001 and CJL-FDC-002) Oval Port (CJL-FDC-003)
Challenge Flow Rate	30 LPM
Area Tested	Entire Filter
Challenge Level	7.2 x 10^6 PFU (Plaque Forming Units - PFU)
Mean Particle Size	~2.9 µm

RESULTS

Live virus testing was performed on 3 off filters, with the following results:

Table 2 - Results

Sample Number	Plaques Detected	Filter Efficiency
Sample CJL-FDC-001	7600 PFU	>99.89%
Sample CJL-FDC-002	8000 PFU	>99.89%
Sample CJL-FDC-003	5700 PFU	>99.921%
Test Results		Acceptable

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} x\ 100$$

Where: C = Challenge Level
T = Total PFU recovered downstream of the test article

CONCLUSIONS

1. The average filter efficiency of the **Trysafe Filter** is in excess of 99.9%
2. The efficiency results against Viral / bacterial challenge for the **Trysafe Filter** are significantly above the efficiencies obtained using "standard EN14387" test methods used in measuring Respiratory Protective Equipment.

Dr C John Littleton
Technical Manager
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