Fit2Fit Newsletter — December 2020

I would like to record wholehearted thanks, appreciation and respect for the incredible efforts of the RPE face fitters who served the country, above and beyond, during the height of the pandemic. The community of Fit2Fit accredited individuals did an unbelievable job supporting the healthcare professionals of this country.

When the extent of the Covid 19 pandemic started to become apparent it was, all hands to the PPE pumps to ensure that NHS and other care staff had the necessary personal protective equipment that they needed to do their jobs and save lives. Without it they were themselves in jeopardy and it is worth reminding ourselves that in fact up until July, 192 members of the NHS did lose their lives to Covid 19. As the medical emergency gained pace the number of healthcare workers now required to wear tight fitting RPE multiplied and multiplied again, often involving individuals who had never previously been required to wear a mask for their own protection. That was the first challenge – getting the individuals face fitted.

The second challenge here was continuity in supply of respirators. When the supply chains fractured the authorities first went to their pandemic stockpiles and found they were inadequate. The long and the short of it was that healthcare workers were often receiving different respirators delivery after delivery. The number of fit tests that were required was increasing all the time.

The NHS and the Department of Health and Social Care (DHSC) looked to Fit2Fit to help them prioritise and help to make fit testers available. Attempting to do this centrally was ultimately not practical and it was clear that the best way forward was direct contact from face fitters to the hospitals themselves and you did a great job.

Dentistry: As all of the fit testing was underway in Healthcare the lockdown was lifting and dentists were returning to work, but had to ensure they were Covid 19 compliant. As most dental tasks involve aerosol generating procedures this required dental staff to have RPE and have fit tests carried out.

This was the first time that this “industry” had, in the main, needed to wear RPE and it was frankly a chaotic scramble for both product and fit testing.

We also saw a significant amount of non-compliant product getting to dentistry through their normal dental supply chains. In addition we had something of a phenomenon in dentistry with examples of these suppliers setting themselves up to provide face fitting services under misleading Fit2Fit qualifications.

Between health and social care and dentistry it is a reasonable estimate to say that around a million fit tests have taken place this year, and while it is inappropriate to name individuals I would like to repeat my thanks and recognition of the heroic efforts by fit testers who were constantly in hospitals and other establishments providing this vital service.

Going forward it would be good to hear opinions and feedback on what lessons there are to be learnt from the experiences of face fitting during the pandemic. These can be fed back to HSE and could help inform future guidance.

Non-compliant RPE

From the very beginning of the year it became obvious that the threat of shortages in RPE was very real. The Covid 19 outbreak began in Wuhan, capital of China's Hubei Province, which is a global centre for the manufacturing of FFPs and filter materials, the Chinese Government began the requisitioning of factories to ensure they had adequate domestic supply. Couple this with the huge global increase in demand for RPE, the reality of shortages was fully apparent and upon us. What was not anticipated though, was the flood of non-compliant untested and potentially unsafe respirators that would get into our domestic market.

Face fitters saw more than anyone the range of utterly unfit respirators that were being presented and that you were being asked to face fit with. It was quite incredible that these respirators were getting through and it amounted to a failure of market surveillance. Perhaps the most common problem was the prevalence of KN95 product being sold. Despite the fact that it was, and is, obviously a non-compliant product it took until the summer for a Safety Alert to be produced by HSE, the PPE Market Surveillance Authority.

In the period March through July BSIF reported 300 traders to the Office of Product Safety and Standards (OPSS), HSE and Trading Standards. The vast majority of these reportings being for FFP product. In many instances we were made aware of the products by face fitters. I know these are being followed up by the authorities so please continue to report your findings of non-compliant product to BSIF and these will be sent to the appropriate regulators. Many face fitters have sent samples of questionable product to BSIF and we have in many cases sent these for testing at UKAS laboratories, most often for penetration testing, the results were at times shocking I can assure you.

Easement to conformity assessment Recommendation (EU) 2020/403: In an attempt to accelerate the availability of PPE primarily for frontline healthcare workers the EU Commission published an easement to conformity assessment which was subsequently adopted by the UK. This necessitated a series of guidance documents from OPSS in order to explain how it would work. While well motivated as an initiative the easement contributed to the widespread confusion of what a compliant product actually is. As at December 2020 the "Easement" is still in place and will be reviewed on an ongoing basis. That said part of the easement was that product could be placed on the market ahead of full conformity assessment but they must continue on with full CE conformity assessment. It would appear that in many cases this has not happened and that suppliers have ended the process once they achieved an easement certificate. We have to remain vigilant on this.

FFPs with Ear loops: In addition to non-compliant product we began to see, for the first time in the UK, FFPs with ear loops as opposed to head harnesses. The fact that these products could be CE marked to EN 149 was something of a surprise. However, the standard does not preclude ear loops and they can, it would appear (most commonly in the FFP 2 class) be compliant. However we know that there is significant problem with these products achieving a satisfactory face fit. Indeed the NHS will not allow the use of FFPs with ear loops because of poor face fitting results. HSE are in fact undertaking research on the effectiveness of ear loop product. These products are still circulating in the market so please feedback your findings and we will continue to provide information to the HSE which will inform future policy.

Community Face Coverings: As the market struggled to deal with the problems associated with PPE we had the requirement for face coverings to be worn in the community as an aid to reduce Covid 19 transmission, supplementing social distancing. All the authorities went to lengths to ensure that these products are not to be used as PPE (RPE) or Medical Devices. With that said they can now be produced against a CEN Workshop Agreement and in the future can claim compliance with a CEN Technical Specification (which is now in development) BSI have also launched a kite mark approval scheme. There is a danger that the purpose of these products and genuine RPE get confused, so we will watch this closely and any feedback on specific concerns you have, would be appreciated.

Fit test training

In addition to the huge amount of face fitting which was needed in health, social care and dentistry, one of the impacts of the pandemic has been the huge increase in demand for fit test training. This was driven by these users not having necessary face fitting resource available for their needs which saw them seeking to quickly train in-house staff to carry out fit testing.

There are several issues that have arisen under the heading of **fit test training** which it would be good to air here...

Online delivery of fit test training.

Along with the upsurge in demand for training came the request that, due to social distancing, this should be delivered online. Most obviously this request came from the healthcare and the dental sectors, who at the same time wanted "approved courses". There were many requests for Fit2Fit to extend course approval to online delivery but these requests were rejected. The Fit2Fit "approval" is a statement that the content of a training course matches the requirements of HSE's guidance, but there is also an implied desire to maintain quality by requiring delivery by an accredited fit tester. Fit2Fit have stated that the preference is for face to face presentation and, with an appropriate risk assessment, there appears little reason why face to face training cannot be safely undertaken. However, regardless of how training is delivered please bear in mind that training courses should only be the beginning for an individual setting out to be a fit tester. There should be mentored practise and supervision, reinforcement of learning and preferably assessment under the Fit2Fit scheme. The expectation that following a training course alone, an individual would be competent to fit test is wrong, and should be actively discouraged. There are many courses offered with a range of durations and methods of delivery, it is up to training providers to design courses as they see fit, always remembering that the training course in fit testing is only a part of the learning cycle, it is not an end point.

Remaining on the topic of fit test training, concerns have been raised over the advertising of courses and the use of accredited terminology. This is potentially misleading where buyers of training conflate this with "Approved". Please ensure that wording in the promotion and advertising of courses is clear to avoid any potential misrepresentation.

Training Course Certificates:

Following on, the practice of giving candidates a certificate following a training course, for anything other than "Attendance" should not happen and the Fit2Fit logo should not be displayed. Fit2Fit has asked all providers of "Approved" training courses to ensure that there is no mention of achievement, passing or competence anywhere on a post training course certificate. I am pleased to say that the response to these requests has been very positive and certificates have been reviewed and amended to avoid adding to the confusion of "competence". We would like to see this adopted throughout by training providers to avoid the misunderstandings by candidates of their status following a training course. Throughout 2020 we had examples of individuals complaining that they were not listed on the Fit2Fit website as accredited, when in fact all that had occurred was that they had participated in a training course.

Use of Social Media:

Social media is a communication tool that is here to stay, but I would ask that users be extremely careful of what is said and how they say it. Social media allows the widespread publication of views which are sometimes less than well informed or injudiciously expressed, further the individual's profile will often carry the Fit2Fit logo. It is not our place to censor but I would ask that users of social media do so respectfully and with caution on content especially when Fit2Fit logos are in evidence.

United Kingdom Conformity Assessment (UKCA):

As a result of the UK leaving the EU we will from January 1st 2021 adopt our own conformity assessment regime to "replace" the CE conformity assessing and marking. Over the last 3 years we have moved through the change from the Directive 89/686 to Regulation 2016/425, then the "Easement" of 2020, now we will have to accommodate the changes with UKCA marking. Under this regime the UK is effectively divided into 2 markets, being GB (England, Scotland and Wales) and Northern Ireland (NI) and different rules apply. In Northern Ireland the CE regime will continue to apply as NI will remain regulatory aligned to the EU while in GB the UKCA will be required. The rules on the one hand, are quite involved and all the details can be found on the BSIF website at www.bsif.co.uk/news however, the legislation for product design and performance will remain the "same" as Regulation (EU) 2016/425 with current amendments applied to replace EU legislative references with UK references. Please visit the BSIF website to get the information that you need but please bear in mind that while UKCA applies from January 1st 2021 there is a standstill period during 2021 where CE marked product remains acceptable in the UK as long as EN and UK standards remain the same.

HSE Guidance

During the period of the pandemic the HSE produced guidance on the use of Masks and RPE, publishing a downloadable poster to illustrate proper mask donning.

https://www.hse.gov.uk/pubns/disposable-respirator.pdf

In addition HSE also put out guidance on face fitting masks during Covid 19 and how to avoid cross contamination and transmission. This guidance (last reviewed on December 1st 2020) was welcomed, but it has raised considerable discussion on how decontamination should in practice be carried out. We are still in dialogue with HSE to clarify some specific points.

https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-rpe.htm

Updating of Fit2Fit Companions: *In April 2019 Fit2Fit published "Companions" to INDG 479 covering Qualitative and Quantitative (Ambient Particle Counting) and Quantitative (Controlled Negative Pressure) methods. Work is under way to update and add content as appropriate to the Companions and I would like to suggest that you keep a watch on the Fit2Fit website so that you have the latest versions. In December 2020 there was an update to the Qualitative Companion (page 16) in order to strengthen the need for and the benefit of conducting a "reveal" test following a qualitative fit test pass.*

Additional Features:

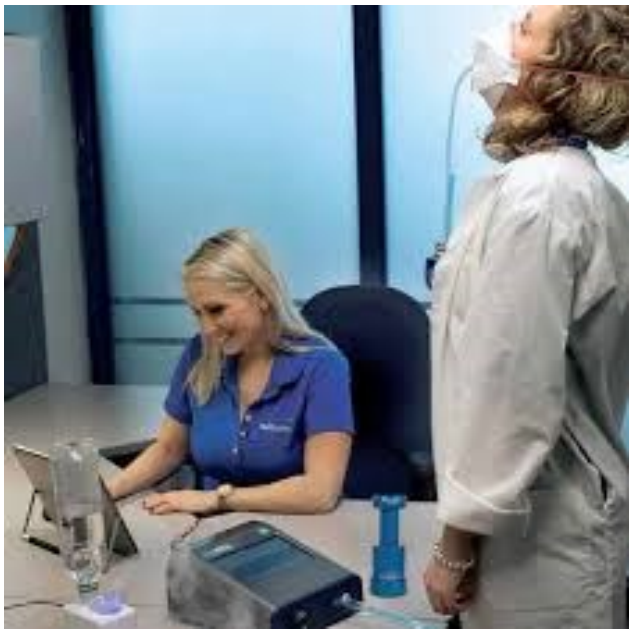
ISRP Conference 2021: *As you know the ISRP Conference had to be postponed this year. Please make a note in your diary that the Conference will now be held from the 26th to 30th of September 2021. All details can be found at* https://www.isrp.com/events/next-international-conference

The recent ISRP seminar on Covid-19 (broadcast on 3 December 2020) which features presentations on the SARS-COV-2 virus and transmission, front line healthcare experience in Italy, fit testing and face coverings can be viewed at

https://m.youtube.com/watch?feature=youtu.be&v=lyJGgZYCTAI

Thatta: *During 2020 it is fair to say that we saw the introduction of many improvised devices being used as PPE or aids to PPE. Many people will have seen the publicity around the use of the Thatta, being used by some who for religious reasons need to maintain a beard. I would like to make it clear that, despite publicity to the contrary, the use of the Thatta while wearing tight fitting RPE is* ***unacceptable*** *to the HSE.*

Webinar 2021: *We plan to run a Fit2Fit webinar in Q1 of 2021 to share news and developments in the sector. More information on this will be published shortly. We would also like to hold a physical meeting of the community next year and are looking at potential locations and timings, targeting September / October.*



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