Witness Name: Tom Clutton-Brock
Statement No.: 1
Exhibits: TCB/01-TCB/32
Dated:

UK COVID-19 INQUIRY

WITNESS STATEMENT OF Professor Tom Clutton-Brock **[ON BEHALF OF** The Medical Devices Testing and Evaluation Centre (MD-TEC) **]**

I, Professor Tom Clutton-Brock, will say as follows: -

The Medical Devices Testing and Evaluation Centre (MD-TEC).

1. MD-TEC was funded from January 2017 by a three-year European Regional Development Fund grant from European Strategic Investment Funds. Funding was matched by The University of Birmingham, University Hospitals NHS Foundation Trust and The University of Aston. Initially funded to support Small to Medium Enterprises in Birmingham and Solihull Local Enterprise Partnership, from January 2020 MD-TEC moved to a commercial model working with healthcare technology industries across the world.

2. The Centre is in the Institute of Translational Medicine managed by Birmingham Health Partners and is part of University Hospitals Birmingham NHS Foundation Trust (UHB). It has a fully equipped simulation suite with an operating theatre, intensive care unit, ward and outpatient areas. Core business is undertaking formative and summative usability testing to IEC 62366-1:2015 to support the regulation of medical devices and *in vitro* diagnostics.

3. MD-TEC worked very closely with the National Institute for Health and Care Research (NIHR) funded Trauma Management MedTech Cooperative (Trauma MIC) and has "state-of-the-art" simulation mannequins, audio-visual equipment and live-steaming capabilities.

4. In 2020 MD-TEC was staffed by a full-time programme manager, Sian Dunning (full time UHB employed) and a part-time clinical director, Tom Clutton-Brock (full time

University of Birmingham employed). Before COVID-19 MD-TEC work was shared with the NIHR Trauma MIC and audiovisual support was purchased from UHB as required. From the first COVID-19 lockdown introduced 23 March 2020, a decision was made to only require MD-TEC and Trauma MIC staff to attend in person if absolutely necessary to reduce potential vector spread. In 2020 other members of MD-TEC and the Trauma MIC did not have expertise in mechanical ventilation, they assisted with phone calls and deliveries, but did not take part in any ventilator testing during the "Challenge". To assist with administrative duties and to act in training videos, my two daughters, history undergraduates who had come home from university, volunteered to come into MD-TEC each day with me.

5. All the reports from MD-TEC were entirely my own work and were not reviewed externally. Feedback was received from the various manufacturing teams and factual errors corrected where appropriate. Any errors, omissions or other inaccuracies are mine alone.

6. MD-TEC received no income or inducements for any COVID-19 related work and remains independent from the UK Government and the MHRA. It did use test equipment provided through the Cabinet Office and some from generous loans from other sources. At the end of the Ventilator Challenge MD-TEC purchased approximately £ 61,418.00 worth of equipment from the Cabinet Office for £10.00. MD-TEC used this equipment to provide free-of-charge testing of COVID-19 related technology until the end of the pandemic.

7. MD-TEC is, and was not in 2020, ISO 13485 (medical device design and manufacture) or ISO 17025 (testing and calibration) approved as this is not required for the work that MD-TEC does.

MD-TEC Clinical Director, Dr (now Professor) Tom Clutton-Brock MBE MB ChB FRCP FRCA FFICM

8. I have worked as a doctor in adult intensive care since March 1982 and was made a consultant senior lecturer in 1990. I have career long experience of mechanical ventilation and the management of patients with acute respiratory distress syndrome (ARDS). I have used a very wide range of mechanical ventilators and CPAP machines from very basic designs to the latest complex machines. I spent 12 years working very part-time for the MHRA and have been a longstanding member / chair of the Interventional Procedures Advisory Committee at NICE. Although I am not a medical

device regulation expert, I have a working knowledge of the principles. In 2022 I was appointed to chair the newly formed Interim Devices Working Group at the MHRA.

9. I have undertaken research into the function of mechanical ventilators and CPAP devices and am familiar with the methods used to assess how well they work. MD-TEC has internationally recognized expertise in assessing the usability of new technology.

10. I stopped working clinically in 2017 after a back injury, but I have kept up to date with technology advances in intensive care and anaesthesia. In July 2020 I was promoted to Professor of Anaesthesia and Intensive Care Medicine at the University of Birmingham.

Mechanical Ventilation and CPAP

11. When we breathe in normally (inhalation), signals from the brain (automatic and voluntary) make the diaphragm and rib muscles contract and a negative (sub-atmospheric) pressure is created in the lungs. Air is sucked in through the mouth and nose, passes through the voice box (larynx and vocal cords), through the windpipe (trachea) and the bronchi into the air sacs (alveoli) in the lungs. Oxygen passes from the air into the blood in very small vessels (capillaries), carbon dioxide passes the other way from the blood into the alveolar gas. Breathing out (exhalation) is passive and gas is expelled from the lungs as the muscles relax.

12. This process has been reproduced using iron lung negative pressure ventilators but has for the last 75 or so years been undertaken by a machine which blows air / oxygen mixtures under pressure into the lungs, Intermittent Positive Pressure Ventilation (IPPV). In most patients a plastic tube (endotracheal tube) is passed under general anaesthesia through the larynx and vocal cords into the trachea. An inflatable cuff on the end of the tube makes a gas tight seal in the trachea. This is commonly referred to as “invasive ventilation”. Invasive ventilation is very widely used during major surgery and in many Intensive Care Unit (ICU) patients early in their care.

13. The machine (ventilator) can be set to control many of the components of the breaths delivered. The key variables being- breath size (tidal volume), breath rate, oxygen concentration (21-100%) and maximum pressure allowed. Alveolar collapse is common in sick lungs and it is universal to apply a small amount of pressure at the end of expiration to help to prevent this, Positive End Expiratory Pressure (PEEP).

14. In simplified terms patients require mechanical ventilation in ICU either because they cannot get enough oxygen into their blood stream, or they are too weak to breathe adequately on their own. A mix of the two is common.

15. As a patient improves in ICU, they will often be allowed to start breathing for themselves through the ventilator, often with a mixture of controlled and spontaneous breaths, a process called weaning. There are many ways of doing this, all add a considerable increase in complexity of ventilator design and performance.

16. In less sick patients positive pressure can also be applied to the lungs using a tight-fitting face-mask or hood, so called "non-invasive ventilation". In one version of this the inspiratory and expiratory pressures are kept at the same level, Continuous Positive Airways Pressure (CPAP). Although simple in concept this can be difficult to achieve in practice.

Covid-19 treatment, mechanical ventilation, oxygen and syringe drivers

17. I am not a virologist nor an expert in infectious diseases. I have not cared for patients with Covid-19, although in the past I have cared for patients with severe viral lung diseases and many patients with Acute Respiratory Distress Syndrome (ARDS).

18. Covid-19 is infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Infections are typically mild and do not require any specific treatment. In a small number of patients, as the name of the virus implies, the lungs may become acutely inflamed and / or directly infected and patients are unable to get enough oxygen into their blood stream. Treatment in the early stages is with facemask oxygen but some (estimated initially to be 10%) will progress to needing invasive mechanical ventilation. Research later during the pandemic showed that treatment with CPAP could reduce the need for intubation and ventilation.

19. Publications from Italy in February 2020, Exhibit TCB/01 [INQ000503468], showed that only around 10% of patients with Covid-19 needed ICU admission but that the numbers of infected patients were rising exponentially. They predicted that all their available ventilators would be in use within two weeks. I was not involved in any decisions around the number of ventilators that could be required in the UK, but the figures coming from Italy were clearly very concerning.

20. Modern ICUs and operating theatres are fitted with medical gas outlets for pressurised oxygen and Medical Air (very clean and dry) supplied by large tanks of liquid oxygen and air compressors. Most clinical staff will never consider the supply of these two gases to ever be an issue. Modern ICU ventilators typically require short bursts of very high gas flows to operate. Acute hospital wards are equipped with oxygen outlets at the bedside, but these did not, under the current NHS Health Technical Memorandum, Exhibit TCB/02 [INQ000398752], have to be able to supply the flow rates in ICU. Very few wards are equipped with Medical Air outlets.

21. Very sick patients with Covid-19 will also have other organs which do not work properly including kidneys, heart etc. All ventilated patients will require intravenous sedation, typically with two or more infusions of medicines. These are delivered from large syringes mounted in a syringe driver using a motor to push the plunger.

Normal process for mechanical ventilator, CPAP and syringe driver approvals

22. I am not a medical device regulations expert, but I did work very part-time for the MHRA for 12 years and have a working knowledge of the regulations. Mechanical ventilators, CPAP systems and syringe drivers are all medical devices, typically Class IIb devices. Since Brexit medical Devices in the UK have been regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR). In 2020, as today, the UK recognised CE marking under the EU MDD and MDR.

23. Although the MHRA oversees the regulation of medical devices it does not license devices as such. Class II devices and above are regulated by Approved Bodies in the UK (except Northern Ireland) who will issue a UKCA certificate of compliance required to place devices on the UK market. In 2020 all ventilators in use in the UK will have been CE or UKCA marked.

24. In 2020 there were no UK medical device manufacturers making ICU ventilators and only a very limited number of anaesthetic machines with ventilators were made in the UK, most with imported components.

25. Developing a new ICU ventilator from scratch takes between 5 and 7 years, regulatory approval alone 18-24 months. Most are updates of an existing model. The process involves extensive laboratory testing and (although not strictly essential) compliance to a range of international standards. ISO 80601-2-12 (ICU ventilators), ISO 18562 (breathing system components), ISO60601(Electrical safety), etc. Manufacturers will

need a Quality Management System (usually ISO 13485) for design and manufacturer and external testing in an ISO 17025 approved facility.

26. The role of usability and human factors in device design has been increasingly recognized over the last 10 years and most regulators will expect some testing of this as well as device performance. IEC 62366-1 describes methods for doing this but is not a quality management standard and a facility cannot be "approved" to this standard.

27. Having compiled all this evidence into a Technical File the manufacturer would submit this along with a review of the clinical evidence of need to an Approved Body for a UKCA certificate. A pre-regulatory, first-in-human clinical investigation, to demonstrate essential safety and performance would almost certainly be required as well.

The Ventilator Challenge and MD-TEC

28. I was not involved in any of the estimates of the numbers of ventilators, CPAP or syringe drivers potentially needed in March 2020. Subsequent reports, Exhibit TCB/03 [INQ000503467], suggested the UK was in the position of having approximately 7,400 adult ICU ventilators available. An estimated exponential surge in Covid-19 infections could result in 90,000 (subsequently reduced to 17,500) patients needing mechanical ventilation and there was no UK ICU ventilator manufacturer. The whole world would be looking to purchase ventilators from the largest manufacturers in China.

29. On the 16 March 2020 the Prime Minister launched the Ventilator Challenge as a "call to arms" to industry. The chronology of subsequent events is described in detail in the document MD-TEC Individuals Meetings Materials Module 5 of the UK Covid.docx , Exhibit TCB/04 [INQ000503604]. My first contact was with the Mayor of the West Midlands who had opened MD-TEC in 2017. This was followed by several requests for meetings with industry groups across the UK to provide expert ICU and medical device input. It was during one of these virtual meetings that I became aware of the RMVS document, Exhibit TCB/05 [INQ000503473], being developed by the MHRA.

30. I knew the Clinical Director Medical Devices at the MHRA, Dr Duncan McPherson, as we had sat on several committees together. I spoke to Duncan McPherson and offered to have some input to the RMVS if helpful. My main proposals were to include a section on usability by non-ICU staff and a short section on basic performance along the lines of ISO 80601-2-12 (ICU ventilators), accepting that full compliance was totally unrealistic.

31. Duncan McPherson explained that as the conventional UKCA process would take far too long that a process of derogation under Exceptional Use Authorisation would be the only workable solution. It is important to note that only the MHRA had the authority to do this and that MD-TEC did not have, or pretend to have, any authority to approve, or not to approve, any medical devices.

32. I did also offer to do some very basic usability testing of proposed solutions at MD-TEC as this is what we were set up to do. We agreed that this would be important.

33. On 20 March 2020 I had emails from ICU consultants who had been brought together by Professor Ramani Moonesinghe asking about expert advice and usability testing. I was also contacted by Matthew Collier from PA Consulting who had been contracted to supervise the testing process.

34. It became clear during discussions with the clinical team and PA Consulting between the 23-26 March 2020 that there was a need to independently demonstrate that the proposed ventilator devices could deliver tidal volumes, rates, pressures and oxygen concentrations as specified by the MHRA RMVS. It had not been possible to identify a UK based external accredited test facility to undertake this in the timescales needed. This was most likely because the UK was not manufacturing ICU ventilators and so had no need of such a facility.

35. The preliminary testing required was not complex and used a simple ventilator tester as used by NHS Trust Clinical Engineering departments. I offered to do this in MD-TEC, but it was made absolutely clear that this was an initial performance check only and MD-TEC could not be considered an approved test facility. To obtain UKCA certification or derogation manufacturers would have to undertake extensive, internal performance testing along with external Electromagnetic compatibility (EMC) testing, biocompatibility etc. I discussed this by email with Paul Daysh (Regional Operations Manager – EU Testing Assurance & global CE Conformity Assessments, UL Solutions) who agreed that this was a suitable proposal under very difficult circumstances.

36. I was able to borrow some equipment locally but also put in a request through PA Consulting for the required test equipment. The Advanced Lung Simulator (ASL 5000), Exhibit TCB/06 [INQ000503462], along with a SimMan 3G was generously loaned by Laerdal Medical.

37. On 24 March 2020 I agreed to have an 18:00 Zoom call with PA Consulting every evening, 7 days a week, to discuss progress with the testing. These were informal updates and were not minuted.

38. The simplest (formative) usability testing requires 10-12 volunteers from representative user groups. This is not an issue for MD-TEC in normal times but recruiting clinical staff during the height of the pandemic was unrealistic. On 26 March 2020 I proposed a novel process called "Limits of Usability" to the clinical team. Here usability would be assessed by an "expert user" (myself) and "non-expert users" (my daughters). There was a very real possibility that these devices might be used by non-medical students with only basic training.

39. As well as the proposal to produce additional ventilators the Italian Covid-19 experience had found CPAP to be useful in delaying or preventing the need for intubation and invasive ventilation. Most UK ICUs had a limited supply of suitable CPAP machines and so I also assisted with the production of the Rapidly Manufactured CPAP System (RMCPAPS), Exhibit TCB/07 [INQ000503472], document from the MHRA.

40. At the beginning of the pandemic there were very mixed views about the use of CPAP in Covid-19 patients. Subsequent research did show that it had a role, Exhibit TCB/08 [INQ000503470].

41. The RMVS underwent several revisions, Exhibit TCB/09 [INQ000503474], which included the provision of some form of weaning support and continued ventilation during closed endotracheal suctioning. These would prove to be a significant challenge to industry.

Ventilator testing at MD-TEC

42. The first ventilator to be tested in MD-TEC by myself was an early version of the Penlon ESO2 on 28 March 2020. The test was conducted using a ventilator tester borrowed from Clinical Engineering at UHB along with a basic mechanical test lung. Medical grade oxygen and medical air were supplied from the medical gas outlets fitted to the 3 ICU bed spaces in MD-TEC. Initial results showed that the breath volumes supplied by the ESO2 were very different to those set on the machine. I contacted Penlon urgently and a subsequent visit found that the machine had not been calibrated before leaving their factory. A repeat test demonstrated adequate performance.

43. Between 28 March 2020 and 22 May 2020, 43 separate ventilator reviews were conducted by me at MD-TEC and reports returned to PA Consulting. Details of the devices tested and report dates are in the spreadsheet CV19 Vent Testing Diary.xlsx. Exhibit TCB/10 [INQ000503598]. The format of the testing day did change somewhat during that period as new test equipment and software arrived but generally the procedure was as follows:

    a. 06:00-09:00 Device delivered to MD-TEC, inventory completed, certificate of "not used in patients" checked.
    b. 09:00-10:00 Device set up in ICU bed space 1, connected to medical gases and 240v power, correct ventilator tubing selected with Heat & Moisture Exchange Filter (HMEF) and Bacterial Filters (BF), connected via PF300 analyser to test lung (ASL 5000), video camera and computer screen streaming set up. Exhibit TCB/11 [INQ000503605].
    c. 10:00-11:00 Zoom call with manufacturing team to confirm correct ventilator set up and operation of controls.
    d. 11:00-15:00 Test schedule run and results recorded, range of rates, tidal volumes, PEEP, oxygen as in RMVS. Function of alarms tested.
    e. 15:00-17:00 Still images and video of set up and basic operation recorded for use in report and in "Bite-Sized" education material.
    f. 18:00-19:00 Zoom update call with PA Consulting
    g. 05:00-07:00 Report written and emailed to PA Consulting.

44. Most of the newly developed ventilators were provided in several versions as development continued. Typically, one or two "Preliminary Reports" Exhibit TCB/12 [INQ000503600], Exhibit TCB/13 [INQ000503594], Exhibit TCB/14 [INQ000503595], were produced as Word documents with accompanying spreadsheets. Final versions were called "Final RMVS Tests", Exhibit TCB/15 [INQ000503601], Exhibit TCB/16 [INQ000503602].

CPAP testing at MD-TEC

45. Although simple in concept, CPAP is both more challenging to generate mechanically and to test. It requires a test lung that can "breathe", the ASL 5000 can do this.

46. In March 2020 a CPAP device, the Ventura, based on a reverse engineered version of a previously CE marked system, the WhisperFlow Exhibit TCB/17 [INQ000503475],

was proposed by a team from University College London and Mercedes AMG. Before having a device to test at MD-TEC, I did have email and telephone discussions around the need for safety blow-off valves in the breathing system and concerns over its ability to use very high volumes of oxygen when in use. Subsequent testing in May 2020 confirmed good CPAP pressures but with high oxygen usage, Exhibit TCB/18 [INQ000503608], Exhibit TCB/19 [INQ000503609].

47. A second, fan based, CPAP system developed in Wales was also tested and found to generate effective pressures but again with high oxygen usage. Exhibit TCB/20 [INQ000503596], Exhibit TCB/21 [INQ000503597].

MD-TEC and the MHRA, TDA, Cabinet Office, DHSC, devolved nations and industry

48. Most communications during the ventilator challenge were handled through PA Consulting. There were 3 or 4 informal virtual discussions with the ICU clinicians group led by Ramani Moonesinghe and 2 or 3 meetings with the MHRA early in the process. I was invited to attend the beginning of a COVID-19 Daily Procurement Meeting chaired by Lord Agnew on the 22 April 2020 to explain the testing being done at MD-TEC, Exhibit TCB/22 [INQ000503464]. I also attended the first half of a TDA meeting on the 21 May 2020 with a final summary of the testing done, Exhibit TCB/23 [INQ000503593]. I was, correctly, not copied into agendas or minutes from these meetings.

49. I was not at the COVID-19 Strategy Ministerial Group Meeting on 27 March 2020 as MD-TEC had not started testing then and did not attend subsequent meetings.

50. The final reports to Cabinet Office (CO) of the 12 designs tested are in the Word document MD-TEC CO Reports v3.4.docx, Exhibit TCB/24 [INQ000503603], submitted via PA Consulting.

51. The only direct communications with Cabinet Office were at the end of the Challenge when arrangements were made for MD-TEC to purchase surplus test equipment.

52. I had a small number of email and virtual discussions with NHS supplies around choosing the correct single use components for the ventilators. I had no discussions with the devolved nations.

53. Discussions with industry did take place directly at the beginning of the Challenge but were subsequently handled through PA Consulting. I think at times that industry was under the impression that I played a much greater role in the decisions not to proceed with proposed designs than was the case. I was asked to produce Red-Amber-Green style reports of device performance against the RMVS, including usability. These will have inevitably been part of the decision-making process, but it was always clear that the final decisions would be made by the TDA.

54. Costs, manufacturing ability and supply chain analysis were not part of the MD-TEC assessments. MD-TEC was not involved in any procurement activity.

55. From my perspective interactions with clinicians, the MHRA, PA Consulting, CO / TDA, the DHSC and industry were conducted professionally and with a very high degree of mutual respect. There was an intense feeling of pressure and potential catastrophic loss of life if the wrong decisions were made.

56. I was approached by the press and news outlets to discuss the Ventilator Challenge, I did not engage in any of this type of activity.

Educational material, Quick Start Guides, Bite-Size videos

57. From the beginning of the Ventilator Challenge it was clear that these devices might have to be used by clinical staff not familiar with ICU ventilation. Considerable effort was made to make designs as usable as possible, but instructions and demonstrations of initial set-up would be required.

58. MD-TEC has simulation facilities ideally suited to the production of this material. Following the preliminary function testing, images and videos were taken of the designs submitted. These were sent to the educational team at PA Consulting and with input from the clinical team and the e-Learning for Health team these were used to produce printed "Quick-Start" guides, Exhibit TCB/25 [INQ000503471], Exhibit TCB/26 [INQ000503599] and "Bite-Size" videos, these remain available on the e-learning for health portal http://portal.e-lfh.org.uk/Component/Details/620844 . The videos cannot be downloaded from the e-learning for health portal and were created by the e-learning for health team. I have included some representative screen shots taken from the videos, Exhibit TCB/27 [INQ000498536].

Post Ventilator Challenge testing at MD-TEC

59. Although the Ventilator Challenge had finished with the selection of the Penlon ESO2 to go forwards to high volume manufacturing, there remained a considerable demand from manufacturers for simple function and usability testing of ventilator, CPAP and PPE designs. MD-TEC agreed with CO that having purchased test equipment at such a low price it would continue to support Covid-19 related device development free-of-charge.

60. Designs tested included, protective enclosures and hoods, facemasks, CPAP systems (including a design with carbon dioxide absorption), communication systems and viricidal sprays. Most of the testing was usability. MD-TEC also tested ventilator designs from overseas, Switzerland, South Africa and Bosnia and Herzegovina, Exhibit TCB/28 [INQ000503607]. MD-TEC has the equipment to test syringe drivers, but this was not used.

61. The Penlon ESO2 also underwent further testing of weaning modes in support of it obtaining a UKCA certificate.

62. As part of ventilator procurement DHSC had purchased significant quantities of ICU and transport ventilators from China. Although all were CE marked, there were concerns about function and usability. Using protocols developed for RMVS testing these devices were also assessed and reports provided to DHSC, Exhibit TCB/29 [INQ000503606]. For two devices educational material was also produced and a live online training session provided for the VG70.

Equality and Diversity

63. The "Equity in medical devices: independent review", published March 2024, Exhibit TCB/30 [**INQ000438237**], highlights the dangers of ignoring the differences in device function between population groups. The effect of skin colour on the measurements made by pulse oximeters are an important example and were relevant during the Covid-19 pandemic.

64. Ventilator design and settings are primarily determined by lung volumes and gas transfer functions. Lung volume is a function of lean body mass and height and so is different on average between males and females. Gas transfer is a function of physics and physiology and is similar in all mammals. Some modern ICU ventilators allow users to input lean body mass, height and sex to generate initial settings. This was not a

requirement in the RMVS and the proposed initial settings would have been safe, if not ideal, across a very wide range of adult patients.

65. Adjustments are made from measurements of oxygen and carbon dioxide in arterial blood and although normal values do vary with age, appropriate target levels in mechanically ventilated patients appear to be valid across the whole range of population groups.

66. Labelling, both physical and electronic, in medical devices in the UK is always in English and units of measurement are standardised for safety. Some imported ventilators could be set to alternative languages, but this is not used, again on safety grounds. Some ventilators, both existing ICU and Challenge designs, are heavy and require mounting on a suitable trolley.

67. In the NHS, staff come from a very wide range of backgrounds, the need to ensure that new medical device designs are safely usable is a key factor in modern device design and played a pivotal role in the Ventilator Challenge.

Conclusions and lessons learnt

68. The Covid-19 pandemic was an extraordinary global event with ramifications that will stretch long into the future. Any review of actions undertaken must be wary of the benefits of hindsight. The estimates of the number of patients with Covid-19 that would potentially need mechanical ventilation were based on the best available information from other countries and the nature of pandemic spread.

69. The UK estimates were wrong and little, if any, of the >£200m spent on the Ventilator Challenge benefitted patients at that time. Some of the CE marked ventilators purchased by DHSC have presumably gone into NHS stock and so the money has not been wasted. The Penlon ESO2, whilst the best choice in very difficult circumstances, is not a readily usable ICU or anaesthesia ventilator. If stocks have been maintained (I have no knowledge of this) then a simple hands-on training programme should be developed so they can be used in the future if required.

70. In my opinion we can never be fully prepared for another pandemic like event. The investment required would strip resources from an already embattled NHS. Many of the patients with Covid-19 lung disease required much more intensive care support than just mechanical ventilation, Exhibit TCB/31 [INQ000503463]. Worldwide it was recognised that all ventilated patients would require additional equipment such as

syringe drivers for drug delivery, vital signs monitors and the staff trained to use them, Exhibit TCB/32 [INQ000498537]. Additional equipment could, and was, borrowed from other areas in hospitals, operating theatres, wards etc. Ventilators however are not used outside of intensive care, anaesthetic rooms, operating theatres and for transport.

71. Covid-19 demonstrated just how dependent the UK is on the overseas manufacturing of medical devices and the risks that this entails. The Ventilator Challenge and the wider procurement activity placed huge demands on UK manufacturing which were met with courage, ingenuity and hard work. It was a huge privilege to have been able to play a small role in that exercise.

72. The UK continues to invest in medical device development, MD-TEC has expanded and continues to support UK industry across a very wide range of projects. The NIHR Trauma MIC finished in April 2024, but we have become one of the 14 NIHR HealthTech Research Centres, focusing on Devices, Digital and Robotics.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: ___ **Personal Data**

Dated: ____October 31, 2024

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TCB/01	jama_grasselli_2020_vp_200049.pdf
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TCB/04	MD-TEC Individuals Meetings Materials Module 5 of the UK Covid.docx
TCB/05	RMVS001 v3.1[1] TCB.pdf
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TCB/07	RMCPAPS001.pdf
TCB/08	News- RECOVERY-RS trial finds continuous positive airway pressure (CPAP) reduces need for invasive ventilation in hospitalised COVID-19 patients | NIHR Compressed.pdf
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TCB/15	Dyson TTP CC Vent Final Report V2.0.docx
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TCB/22	CO MD-TEC Briefing Note 21042020.pdf
TCB/23	20200521_Summary TDA Meeting Outcomes 21 May_v1.0.pdf
TCB/24	MD-TEC CO Reports v3.4.docx
TCB/25	PENLON ESO 2 Quick Start Guide V2 .pdf
TCB/26	DRAFT CoVent_V8[1] Quick Start Guide - TCB.pptx
TCB/27	MD-TEC Screen shots from NHS e-lfh Penlon ESO 2
TCB/28	TMD Preliminary Report November 2020 V1.0c.pdf
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TCB/31	bmj.m1201.full.pdf
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