Witness Name: Richard Clack
Statement No.: First
Exhibits: RC/1 – RC/54
Dated: 14th February 2025

THE UK COVID-19 INQUIRY

Witness Statement of Richard Clack

I, Richard Clack, will say as follows:-

1. I make this statement in response to the Inquiry's formal request under Rule 9 of the Inquiry Rules 2006 (Reference: M5/RR/01), in relation to Rolls-Royce's involvement in the procurement and supply of ventilators and related medical equipment. The request relates to Module 5 of the UK Covid-19 Inquiry's ("the Inquiry") work, which will examine and make recommendations on public procurement of key equipment and supplies across the UK public sector in relation to the Covid-19 pandemic and the onwards distribution of the key equipment and supplies.

2. I have been asked to provide this statement on behalf of Rolls-Royce PLC ("Rolls-Royce"). I am currently the Head of Intellectual Property ("IP") at Rolls-Royce, a role I have held since July 2020. I am also the General Counsel for Rolls-Royce's Engineering, Technology and Safety Organisation. Prior to that, I was Chief Counsel – Head Office. In March 2020, I was asked by the Group General Counsel, Mark Gregory, to be involved in the Ventilator Challenge. I led within Rolls-Royce's general counsel function on the Ventilator Challenge and gave legal advice in relation to it, in particular on the contracts with other consortium members. I had close involvement with the Ventilator Challenge between January and July 2020, after which time Rolls-Royce's involvement in the challenge substantively came to an end.

3. As not all of the detail requested in the Inquiry's formal request for information is within my own knowledge, I have relied on some information from colleagues involved at the time, including Mark Heyman (Chief of Digital Manufacturing System), Neil Mantle (Director of Manufacturing Technology), Hannah Buller (Finance Business Partner)

and Helen Kennett (Director of UK Government Relations). We collectively identified relevant documents, as detailed in Appendix 1.

Background

4. Rolls-Royce was founded in 1906 and has a reputation for engineering excellence in the UK and globally. It develops and delivers complex power and propulsion solutions for safety-critical applications in the air, at sea and on land. It has manufacturing sites across the UK.

5. In March 2020 Rolls-Royce and other UK companies began working together to accelerate the manufacture and supply of ventilators.

Formation of VentilatorChallengeUK

6. On 16 March 2020 Boris Johnson (then UK Prime Minister) and Michael Gove (then Chancellor of the Duchy of Lancaster) led a call with over 100 representatives of industry and government. It was attended by Hamid Mughal, Rolls-Royce's then Director of Manufacturing Technology. On this call, Michael Gove urged participants to take a collective approach to raising ventilator production levels in the UK.

7. Following this call, Rolls-Royce confirmed its offer of support to HM Government (Exhibit RC/01 – INQ000536426).

8. VentilatorChallengeUK was formed on 19 March 2020. Members included Smiths Medical ("Smiths"), GKN Aerospace ("GKN"), Rolls-Royce, Thales UK Limited ("Thales"), McLaren and Siemens. Smiths Medical was at the time part of Smiths Group. It has since been acquired by ICU Medical.

9. VentilatorChallengeUK was led by Dick Elsy, the Chief Executive Officer of High Value Manufacturing Catapult ("HVMC"). HVMC is a strategic research and innovation hub for industry, commercialising the UK's most advanced manufacturing ideas. VentilatorChallengeUK was split into two groups, referred to as the 'Oyster' consortium and the 'Penguin' consortium, each working on a different ventilator design.

10. The Oyster consortium worked on a design for an intensive care ventilator from Penlon. Rolls-Royce was not part of the Oyster consortium.

11. Rolls-Royce, Smiths, GKN and Thales formed the Penguin consortium. The objective of this consortium was to assemble, test and deliver the Smiths Medical 'paraPAC plus™ P300' transport ventilator (the "Smiths Ventilator").

12. The Smiths Ventilator was already in use in the NHS. Smiths' production capacity was approximately 50 units per week and the aim was to increase this to approximately 1,000 units per week.

13. Throughout this statement, references to the 'Consortium' are references to the Penguin consortium and the group of companies involved in the manufacture, assembly and testing of the Smiths Ventilator.

The Penguin Consortium and Rolls-Royce's role in it

14. The Consortium agreed that Smiths would continue to produce ventilators as before. The increase in capacity would come from a new production capability working in parallel to Smiths' existing arrangements:

    14.1 Smiths were the experts in medical devices and therefore the obvious choice for Consortium lead. They would share their designs and technical and commercial know-how, including quality and test requirements, with the rest of the Consortium;

    14.2 Rolls-Royce and GKN would assemble and test ventilators in their factories;

    14.3 Rolls-Royce would procure materials and components and arrange logistics and IT; and

    14.4 Thales would write and deliver training to staff on ventilator manufacture and assembly processes.

15. The legal and decision-making arrangements of the Consortium are set out under the heading 'Consortium Interaction', beginning at paragraph 53 below.

Key Suppliers to the Consortium

16. Smiths engaged PA Consulting to assist with day-to-day technical queries relating to the design of the Smiths Ventilator.

17. Rolls-Royce engaged Accenture to develop and operate a standalone Enterprise Resource Planning ("ERP") software system and provide a procurement operations

centre. Transactions with the suppliers were executed by Accenture through the ERP system. Rolls-Royce had an existing Statement of Work with Accenture (Exhibit RC/02 – INQ000536437).

18. Rolls-Royce engaged DHL Supply Chain Limited ("DHL") to provide logistics including the transport and warehousing of parts and distribution of finished goods to HM Government.

19. Rolls-Royce engaged Inspection Services Limited ("ISL") to carry out quality checks on parts received at the DHL warehouse.

20. Rolls-Royce engaged Pattonair to re-pack the parts into kits of 40, to give the assembly plants one shift's worth of material.

21. Exhibit RC/03 – INQ000536448 shows the members' roles in the Consortium and the process flow for supplier parts. Exhibit RC/04 – INQ000536459 contains a schematic of the overall supply chain.

Timeline

22. Key dates in the timeline from Rolls-Royce's perspective, relevant to the actions and/or decisions in relation to the production and procurement of ventilators, are listed below.

Date	Action
15 March 2020	HM Government circulated a draft indicative specification to outline the key requirements for a Rapidly Manufactured Ventilation System (Exhibit RC/05 – INQ000536473).
16 March 2020	Michael Gove, on a call with the Prime Minister and over 100 others including Hamid Mughal of Rolls-Royce, requested a collective approach to accelerating ventilator production.
17 March 2020	Hamid Mughal sent an email to the Executive Team of Rolls-Royce, introducing the

	Ventilator Challenge (Exhibit RC/06 – INQ000536478).
18 March 2020	Rolls-Royce submitted its response to the request from HM Government for the national effort to produce ventilators (Exhibit RC/07 – INQ000536479).
19 March 2020	The VentilatorChallengeUK steering group was launched. Nigel Pearce, as a representative from Rolls-Royce, sat on this steering committee.
22 March 2020	Hamid Mughal sent an email to the Executive Team of Rolls-Royce, introducing the engagement with Smiths.
23 March 2020	Gareth Rhys Williams, Government Chief Commercial Officer, sent a letter to Julian Fagge at Smiths, committing to purchasing 5,000 units and reserving subsequent units up to another 5,000 units (Exhibit RC/08 - INQ000536480).
24 March 2020	The Bill of Materials was issued to Rolls-Royce by PA Consulting in collaboration with Smiths.
25 March 2020	The Consortium established a team to lead on identifying the supply chain.
26 March 2020	Prime Minister's briefing, with a call to arms for 8,000 ventilators. Helen Kennett joined this call on behalf of Rolls-Royce.
27 March 2020	The first parts for the Smiths Ventilator were ordered by Rolls-Royce.

6 April 2020	The checks on Smiths' engineering drawings were finalised.
6 April 2020	The first standard parts were delivered to the DHL warehouse.
13 April 2020	2.7 million parts had been delivered, meaning 92% of the parts listed in the engineering Bill of Material had been sourced.
13 April 2020	The indemnity agreement with the Cabinet Office was executed.
16 April 2020	The first made-to-drawing parts (unique to the Smiths Ventilator) were delivered to the DHL warehouse.
17 April 2020	An issue was identified with two of the valves for the ventilator and new valves were designed by Rolls-Royce and Smiths as an alternative part.
17 April 2020	Smiths received a letter of thanks from the Cabinet Office, relating to the acceleration of the production of ventilators (Exhibit RC/09 - INQ000536481).
20 April 2020	By this date, approximately 250 technical queries had been raised with PA Consulting and concluded.
20 April 2020	The Cabinet Office sent a letter to Smiths, requiring scaling back of the production capacity (Exhibit RC/10 - INQ000536427).
23 April 2020	A sub-assembly line was built at GKN and tested successfully.

24 April 2020	The VentilatorChallengeUK steering group and HM Government took the decision to reduce the number of production lines for the Smiths Ventilator to minimise costs.
29 April 2020	The last part listed in the Bill of Materials was shipped to the build lines.
12-13 May 2020	The first Smiths Ventilator was built and tested at GKN in Luton.
14 May 2020	Smiths received a letter from the Cabinet Office, seeking to reduce the commitment to 4,000 units.
19 May 2020	Smiths responded to the Cabinet Office's letter of 14 May after consulting with the Consortium, referencing the direct and personal appeal by Cabinet Ministers to procure ventilators.
21-29 May 2020	The final Consortium agreements were finalised, including the Manufacturing Agreement and Quality Agreement.
Week commencing 1 June 2020	Delivery of Smiths Ventilators from the Filton assembly line commenced.
30 June 2020	The Cabinet Office drew the programme to a close.

Participation and key decision-makers

23. A team of over 150 Rolls-Royce employees organically formed and volunteered to participate in the Ventilator Challenge. Employees involved in the Ventilator Challenge came from a range of different teams, primarily Procurement (led within the Ventilator Challenge by Warrick Matthews), Manufacturing Engineering (led by Nigel Pearce and Mark Heyman) and Quality (led by David Halpin).

24. A non-exhaustive list of key individuals at Rolls-Royce involved in the Ventilator Challenge includes:

Name	Position (as of March 2020)
Hamid Mughal	Director of Manufacturing Technology (who left Rolls-Royce in December 2020 and is no longer with Rolls-Royce).
Neil Mantle	Director of Manufacturing Technology (incoming).
Nigel Pearce	Director of Digital Manufacturing. Nigel was the main Rolls-Royce interface on the Ventilator Challenge (who left Rolls-Royce in December 2022 and is no longer with Rolls-Royce).
Mark Heyman	Chief of Digital Manufacturing System. Mark led on the supply chain and quality assurance checks.
Andy Knox	Global Supplier Operations Support Executive (who left Rolls-Royce in September 2020 and is no longer with Rolls-Royce). Andy was the Programme Director for the Rolls-Royce supply chain.
Hannah Buller	Finance Business Partner. Hannah corresponded with the Cabinet Office in relation to recovery of Rolls-Royce's costs connected to the Ventilator Challenge.
Helen Kennett	Director of UK Government Relations. Helen led on engaging with HM Government's Rolls-Royce account managers on progress with the project, and advised the Consortium

	and its advisers on engagement with the Cabinet Office.
Warrick Matthews	Chief Procurement Officer (who left Rolls-Royce in December 2022 and is no longer with Rolls-Royce).
David Halpin	Quality Executive. David provided oversight of the overall Quality Management System from a Rolls-Royce perspective.
Richard Clack	In-house lawyer. Led on the Ventilator Challenge contracts and related advice.

Procurement of parts

25. During March and early April 2020, HM Government expressed its requirement for the Consortium to produce and deliver 5,000 to 10,000 ventilators to the NHS. On 26 March 2020, the Prime Minister also sent out a call to industry for 8,000 ventilators to be available by 13 April 2020. To secure scarce components and mitigate against the risk of late delivery, the Consortium decided to procure components to produce 8,000 units. It began to do so in late March 2020 and kept HM Government updated on its progress in writing and on video or telephone calls.

26. Rolls-Royce was tasked with setting up the manufacturing supply chain for the Consortium and ensuring the quality of the parts to the build lines. Smiths, via PA Consulting Group, provided Rolls-Royce with the engineering Bill of Materials for the Smiths Ventilator, the supplier information list and ancillary information. This information (among other things) listed the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts, specifications, technical documentation and quantities for the Smiths Ventilator. The planning assumptions on the number of parts to order were agreed amongst the Consortium members on the basis of discussions between Smiths and the Cabinet Office and the commitment from the Cabinet Office to 5,000 to 10,000 ventilators.

27. Each ventilator contained 288 different components, sourced from 107 suppliers.

28. The majority of components for the Smiths Ventilator were readily available in the UK supply chain. However, the components were required in a shorter timeframe than usual and at a time when components were in high demand. Additionally, 87 of the components had to be made from raw material and were not readily available. These components were unique to the Smiths Ventilator.

29. While procuring parts, Rolls-Royce gave consideration to the availability and quality of parts. There was a need for urgency, but not at the expense of patient safety. Rolls-Royce looked at ways to mitigate risks in the supply chain and the procurement of parts, for example:

    29.1 Smiths provided its supplier information list and Rolls-Royce sought to duplicate Smiths' supply chain where possible to mitigate risks in the procurement of the components, utilising suppliers that were familiar with manufacturing the parts.

    29.2 There was a particular concern about possible challenges in the supply chain for two specific valves in the Bill of Material (the Pressure Regulator Valve and the Demand Valve). As a way to overcome any issues with the procurement of the valves, Rolls-Royce and Smiths redesigned the valves with the aim of creating a second sourcing option for the Consortium. These designs were completed as of 17 April 2020, and both valves were put through performance checks. However, in late April Smiths advised that it would not be possible to complete the regulatory approvals for the valve designs in time for the Consortium to use them.

30. A summary of the supplier parts ordered and received, was sent by Nigel Pearce on 10 June 2020 (Exhibit RC/11 - INQ000536428).

Quality assurance

31. The Smiths Ventilator was already in use in the NHS with Smiths holding the relevant regulatory approvals. Smiths therefore defined the quality systems the Consortium followed when making the Smiths Ventilator. The British Standards Institution ("BSI") approved Rolls-Royce as a manufacturer of ventilators on the basis of that quality system, which was based on ISO 9001. A Quality Agreement was put in place between Smiths and Rolls-Royce (Exhibit RC/12 - INQ000536429).

32. Ventilators are intricate and highly complex pieces of medical equipment. Rolls-Royce understood the need for absolute adherence to regulatory standards to ensure patient safety and placed great emphasis on quality standards. Rolls-Royce's aim was to procure parts quickly and keep the supply chain moving with sufficient momentum, while also ensuring that parts were of the right quality and performed to the required specification. Paragraphs 33 to 51 in this statement provide an overview of the quality checks and assurances that were in place.

Quality Checks and Assurance

33. As a starting point, parts could not be shipped until supplier approval on First Article Inspection (FAI) sign off was in place. This was a process whereby a detailed examination of the 'first article' from a manufacturing run was inspected by the supplier, a step often used in manufacturing medical devices to ensure that the components produced meet the (drawing) specification. Suppliers issued a certificate of conformity, confirming that the parts met the design drawing that had been provided by Smiths. The results were then documented in a First Article Inspection Report, for review by Rolls-Royce.

34. In addition to the suppliers' own quality checks, a 'Quality Check and Quarantine' process was set up at DHL for incoming parts.

35. Some parts were identified as 'Critical Components' in the Agreement for the supply of components (the "Supply Agreement") between Rolls-Royce and Smiths, meaning any component, raw material, part or sub-assembly for incorporation into the Smiths Ventilator or use in connection with the assembly of it (including labelling) was required to be compliant with an Inspection Operation Sheet. These critical components are set out in Schedule 3 of the Supply Agreement (Exhibit RC/13 - INQ000536430). An example Inspection Operation Sheet is at Exhibit RC/14 - INQ000536431.

36. The DHL warehouse at Stirling Park had a dedicated quality check area. Incoming parts requiring a quality check were sent straight to this area for the ISL team to undertake a quality check. Clear and simple inspection procedures were provided to the ISL team and they were supported on site by three quality engineers from Smiths.

37. Those parts that were subject to a quality check by the ISL team included the parts on the Critical Component list, as well as parts for which a Quality Alert had been

issued by Rolls-Royce. Inspections were carried out on a sample basis, the size of which was determined by Smiths.

38. DHL and ISL prepared a daily quality check list which reported parts that had passed (shown in green) and failed (shown in red). The reason for the failure was recorded.

39. All parts failing the quality check were formally quarantined by DHL using a set process. Quarantined parts were physically separated at the DHL warehouse, for further inspection by Smiths quality team as to whether they could be used or rejected. 32 of the 288 parts in the Bill of Materials were recorded as having failed the quality check process. The failure rate on these parts ranged from 1% to 59%. The purpose of the quarantine process was to prevent parts that did not meet the defined specification entering the ventilator assembly line. Quarantined parts were either scrapped, reworked, or accepted on a concessional basis after advice was taken from Smiths and/or PA Consulting. I am not aware of the proportion of parts accepted after the quarantine process.

40. Once parts were delivered by DHL to the Rolls-Royce build line at Filton, the parts were subject to a further quality check. The parts went through a goods inward process, checking quantities and the relevant paperwork. The parts may have also been washed, to remove any oils applied to them for protection during transport. Operators on the build line would conduct a visual inspection and raise any quality concerns, and an investigation as appropriate would be carried out. If appropriate, Rolls-Royce approached the supplier to conduct an investigation. One example of an approach to the supplier is shown at Exhibit RC/15 - INQ000536432.

41. If parts were returned from the build factory, a standard returns label was used by the party returning the part. Returned items were then added directly to the DHL quality check quarantine list for review as to whether the parts were to be returned, replaced, scrapped or reworked by the supplier.

42. Rolls-Royce created a 'single source of truth' to help track the delivery of parts, quality checks and quarantine process. This was led by Mark Heyman, Chief of Digital Manufacturing System. He was brought into the project to lead on supply chain matters. The 'single source of truth' was the terminology used at Rolls-Royce for the creation of a single storage point for all data relating to the ventilator's Bill of Materials, quality and logistics, which was put into place approximately two weeks into the programme. This was done in response to an observation that there were multiple data sources being developed by different teams as a result of: (a) different on-

boarding dates for individuals; (b) the pace at which the programme was stood up; and (c) differing on-boarding briefs dependent on the team to which an individual was joining (e.g. purchasing, technical, logistics). The 'single source of truth' helped to ensure that those at Rolls-Royce were looking at the correct and most-up-to-date data.

43. The main difficulties faced when procuring parts related to their quality and availability. For example, if a part was unavailable the supplier might suggest an alternative. Due to the technical and regulated nature of ventilators, parts could not just be switched at will. They were required to pass an assessment, evaluation and approval process. These technical queries relating to the design of the Smiths Ventilator were raised with PA Consulting under delegated authority from Smiths, as designer of the ventilator and holder of the relevant regulatory approvals. Rolls-Royce would track these queries, and the response received from PA Consulting or Smiths, in a log (Exhibit RC/16 - INQ000536433, showing a list of these queries as at 25 June 2020).

44. If there was an issue with the quality of a part discovered on any build line, a 'Quality Alert' was raised and issued to operators for awareness. Approximately 30 Quality Alerts were raised by Rolls-Royce and circulated to the Consortium (Exhibit RC/17 - INQ000536434). Actions taken following the issue of these quality alerts may have included segregating loose stock and inspecting stock against the Quality Alert to identify and quarantine non-compliant stock.

45. If the part failed to conform to quality standards an investigation would where necessary be carried out to understand why. Key members of the Consortium were kept updated and outcomes of the investigation process were shared with the Consortium for awareness and learning. As an example of how this communication worked in practice, please see Exhibit RC/18 - INQ000536435.

46. On 23 and 24 May 2020, a 'stop and fix' was put in place regarding the quality of shipments, storage and picking of materials following issues at both the GKN and Rolls-Royce assembly lines. This is a common engineering practice, dedicating all resource to fixing an issue, and was felt necessary as the most efficient way to resolve the outstanding quality issues. The purpose of the 'stop and fix' was to identify conformity of the machined parts that had not been subject to batch spot checks at DHL and to re-inspect known parts that had been subject to a Quality Alert. Approximately 15 Quality Alerts were active at this time. A root cause analysis into the issues was undertaken and corrective actions put in place, with assembly re-

commencing on 24 May 2020. An email chain in relation to this analysis and the parts to be quarantined is exhibited a **Exhibit RC/54 INQ000574181 Exhibit RC/54a INQ000574182**

47. In May 2020, prior to the Consortium starting wide-scale build of the Smiths Ventilators at Rolls-Royce and GKN, Smiths in Luton carried out two trial builds to assess any potential issues with the assembly of the ventilators.

48. Once built, finished ventilators underwent a rigorous testing process, defined by Smiths, before delivery to the NHS.

49. Consortium members resolved any issues through frequent communication. In addition to daily emails, the following meetings were held:

    49.1 A daily stand-up meeting, led by Rolls-Royce, to handle any ongoing issues across all assembly areas. Example minutes from these daily stand-up meetings are exhibited at Exhibits RC/19 – RC/25 (INQ000536436 - INQ000536443).

    49.2 A steering committee, made up of consortium members, also met virtually once a week.

    49.3 Members of the Consortium also held daily calls at 19:00 hours. These calls focused on practical issues including engineering and procurement and during these calls, Consortium members were open about any challenges encountered and their impact.

50. It may be of assistance to the Inquiry for me to give an example of an issue that was encountered and how this was resolved. One issue which came up was whether glues and greases needed to be refrigerated during transport and storage. To resolve this issue, advice on refrigeration was sought from Smiths and the part manufacturers. More glues were then sourced, which were easier to handle. **Irrelevant & Sensitive**

Irrelevant & Sensitive

51. Rolls-Royce is aware that a supplier non-conformance notification was raised in July 2020 after production stopped as, during a review of the ventilators manufactured, it was noted that there were duplications in the certificate of conformity and delivery notes provided by Rolls-Royce. Two ventilators had been labelled with the same serial

number, and one of these ventilators was then over-labelled with a new serial number. The documentation had been updated with the new serial number and the labels were re-printed. Post-completion of the production run, all serial numbers were reviewed and this was the sole instance of duplication identified through that activity.

52. I think it is important for me to make the Inquiry aware that otherwise, as far as Rolls-Royce is aware, there have been no issues with the quality, safety, appropriateness or effectiveness of any of the Smiths Ventilators produced.

Consortium interaction

53. Whilst the Consortium operated in a highly collaborative manner and to some extent like one entity, the legal construct was that Smiths sold ventilators to HM Government and Rolls-Royce provided manufacturing and procurement services to Smiths. Relationships between Consortium members were governed by contract. Rolls-Royce entered into:

53.1 A non-disclosure agreement with Smiths;

53.2 A Procurement Agreement in which Rolls-Royce sells procurement services and components to Smiths;

53.3 A Manufacturing Agreement (and related quality agreement) in which Rolls-Royce sells assembly services to Smiths (Exhibit RC/26 - INQ000536444);

53.4 A Side Letter setting out mitigation actions and responsibility for paying the cost of surplus components;

53.5 A Consortium Agreement pulling together administrative and generic terms (for example, confidentiality);

53.6 A Service Agreement with DHL dated 9 April 2020, for transport and warehousing of components and finished product distribution services (Exhibit RC/27 - INQ000536445).

54. Smiths held the contract with the HM Government for the sale of the ventilators. Smiths then placed an Order with Rolls-Royce, subject to the terms of the Manufacturing Agreement, for Rolls-Royce's entire volume of Smiths Ventilators manufactured and dispatched prior to 30 June 2020, subject to a maximum amount of 1,600 units. Rolls-Royce was to use reasonable endeavours to manufacture and

dispatch as many units as operationally practicable (subject to the maximum amount) on or before 30 June 2020.

Liability

55. HM Government recognised the exceptional circumstances in which the Consortium was operating and agreed to indemnify Consortium members against losses arising from product failures or intellectual property rights ("IPR") infringement.

56. On 13 April 2020, the Consortium members executed a Deed of Indemnity (Exhibit RC/28 - INQ000536446) with the Minister for the Cabinet Office. The indemnity was not absolute, and Rolls-Royce was at risk if it failed to use reasonable skill and care or work to the agreed quality systems. I provided legal advice to Rolls-Royce's Board on the terms of the indemnity, the contents of which are privileged. Key terms of this indemnity included:

56.1 Rolls-Royce's liability was capped at I&S of the contract value and its obligations for the work as part of the Consortium was limited to:

56.1.1 Undertaking ventilator consortium activities with reasonable skills and care in the circumstances;

56.1.2 Flowing down its obligations to the supply chain as appropriate;

56.1.3 Procuring parts and carrying out assembly as required by the Smiths design;

56.1.4 Working to the quality standards agreed with Smiths.

56.2 HM Government's indemnity covered:

56.2.1 **Irrelevant & Sensitive**

56.2.2 Claims that the ventilators are defective or not fit for purpose;

56.2.3 **Irrelevant & Sensitive**

57. Rolls-Royce was not indemnified against tax compliance, employee claims or data protection.

58. This indemnity was then passed down to some suppliers. There were two different categories of suppliers. Contracts with suppliers were entered into on the basis of Smiths' standard terms and conditions, where those suppliers were acting as part of

their normal course of business (referred to in Exhibit RC/13 - INQ000536430). However, suppliers who were being asked to manufacture a component that was not part of their normal course of business or on unusual terms (for example, without profit), received an adapted version of the Smiths' standard terms that passed down the benefit of the HM Government indemnity.

59. Standalone agreements were negotiated by Rolls-Royce with DHL and Pattonair for their services.

60. Rolls-Royce called off a new statement of work under its framework agreement with Accenture. The expectation was that the ERP system used as part of the Smiths ventilator sprint would be handed over to Smiths at the conclusion of the sprint phase of activity without any future liability or recourse into Rolls-Royce or Accenture.

61. The major risks identified by Rolls-Royce as part of the ventilator project included safety, regulatory compliance and cost recovery.

62. The Cabinet Office had committed to purchase ventilators from the Consortium. Rolls-Royce would not usually commence work without a formal contract in place. However, these were unprecedented times and there was a personal plea from the Prime Minister and Cabinet Office ministers for assistance in the production and procurement of ventilators.

63. Rolls-Royce wanted to help during the pandemic in any way it could. The Consortium was set up in a matter of days and agreements between Consortium members were negotiated and finalised within a short period of time, despite their complexity. Given the urgency of the situation, Consortium members continued to work together in good faith to progress with the procurement of parts and build of the assembly lines while agreements were being finalised.

Government interaction

64. At the outset of the VentilatorChallengeUK Consortium during initial briefing calls with the Cabinet Office, the Cabinet Office offered "whatever support" that was required for the collective effort to produce ventilators in the UK (Exhibit RC/6 - INQ000536478).

65. Such support included practical support. For example, a letter dated 25 March 2020 from the Department for Business, Energy and Industrial Strategy stated that employees working for the Consortium were permitted to travel to work despite

lockdown restrictions (Exhibit RC/29 - INQ000536447). Another example is a letter from the Chancellor of the Duchy of Lancaster, dated 30 March 2020, which stated that the Government would do everything in its power to support ventilator production (Exhibit RC/30 - INQ000536449).

66. On 31 March 2020, Smiths as Consortium lead presented to the Cabinet Office a plan to 'ramp up' production of ventilators to deliver 8,000 ventilators from three assembly sites, with an option to grow beyond that to more sites.

67. Rolls-Royce attended weekly calls with Gareth Rhys Williams, GKN and Smiths to discuss progress.

68. On 17 April 2020, HM Government confirmed its requirement for 5,000 ventilators but refused to make any commitment to reimburse the cost of parts beyond those required for the 5,000 units ordered. It was accepted by the Cabinet Office that it was reasonable for more than 5,000 of each of the parts to be purchased, as there would likely be an element of scrap/damage. There was therefore an agreement with the Cabinet Office for reimbursement of the cost of parts for 5,750 units. As referred to above in paragraph 25, parts were ordered on an assumption that 8,000 ventilators were required, and as such the Consortium did not receive reimbursement for all parts ordered.

69. The majority of the correspondence with the Cabinet Office was directed through Smiths. On occasion, in light of time pressures, individuals from Rolls-Royce would make a direct approach to the Cabinet Office to discuss costs. An example of this is exhibited at Exhibit RC/31 - INQ000536450, following an issue with the quality of three parts of the Smiths Ventilator. To control costs, interim orders for smaller quantities of the parts were made to avoid stopping the production lines while a decision was taken on how many parts were ultimately required.

70. HM Government agreed to buy as many ventilators as the Consortium could deliver by 30 June 2020, up to a maximum of 4,418. HM Government agreed to buy a further 582 ventilators made by Smiths, bringing the overall maximum to 5,000.

71. Smiths and the Cabinet Office met regularly to discuss costs and timescales for delivery. Rolls-Royce, and other Consortium members, worked hard to ramp up production, against a backdrop of starting manufacturing lines from scratch and the need to ensure stringent adherence to quality, training and safety protocols. Some of the detail of this correspondence between the Cabinet Office and Smiths, including in

relation to mitigating costs, is included in Exhibits RC/32 to RC/37 (INQ000536451 - INQ000536456).

72. It was a term of the contract that Smiths held with HM Government that Consortium members evidenced all costs which they sought to recover.

73. The Cabinet Office had appointed Deloitte and the Cost Assurance and Analysis Service ("CAAS"), who conducted audits and assurance on Rolls-Royce. While the majority of this liaison on costs was via Smiths, at times Rolls-Royce spoke directly with the Cabinet Office on costs. For example, Exhibit RC/38 - INQ000536457 shows a liaison between Rolls-Royce and the Cabinet Office on the calculation of costs.

74. When submitting invoices, Rolls-Royce responded to audit queries and was asked for sample supplier invoices by Deloitte or CAAS. For example, please see Exhibit RC/39 - INQ000536458. Rolls-Royce's finance team also pulled together an analysis of the Bill of Materials from the Accenture ERP system, to calculate the theoretical Bill of Materials order value of 5,750 units as opposed to the actual order value (Exhibit RC/40 - INQ000536460).

75. The Cabinet Office raised particular queries in relation to VAT, DHL storage costs, Accenture's costs, labour and overhead charges and cost of delays. The Consortium's position was that it strongly believed these were reasonably incurred in line with the contractual agreement and provided evidence to the Cabinet Office to demonstrate this. Exhibit RC/41 - INQ000536464 and Exhibit RC/42 - INQ000536465 provides a summary overview of the position on costs and a presentation on Accenture's role in the Consortium.

76. The final Rolls-Royce invoice was submitted to Deloitte on 11 September 2020 and no further queries on costs were received.

77. In its Rule 9 request, the Inquiry has asked Rolls-Royce whether the fact that the UK did not join an EU procurement scheme for ventilators in the early stages of the pandemic had any impact on Rolls-Royce's work as part of the VentilatorChallengeUK Consortium or in the Ventilator Challenge. Rolls-Royce has no experience of EU medical device procurement or the EU procurement scheme for ventilators and as such is unable to draw any conclusions on the impact of the UK not joining an EU procurement scheme for ventilators in the early stages of the pandemic.

<u>Consultation with the TDA, MHRA and NHS</u>

78. Smiths was the product designer and held the relevant regulatory approvals for the ventilator. As such, any discussions with the Technical Design Authority ("TDA"), Medicines and Healthcare products Regulatory Agency ("MHRA") and the NHS in relation to the Smiths Ventilator would have been with Smiths.

79. Rolls-Royce understands that the MHRA issued an exceptional use authorisation to Smiths, dated 27 May 2020, permitting Smiths to apply the relevant conformity mark (the CE mark) to the Smiths Ventilator subject to the terms and conditions set out in that correspondence.

Costs

80. Rolls-Royce participated in the VentilatorChallengeUK Consortium on a 'not-for-profit' basis and did not profit from its participation. This was communicated to the public, such as through media coverage from the VentilatorChallengeUK Consortium (Exhibit RC/43 - INQ000536466).

81. An Estimated Cost Model for the Consortium's participation in the Ventilator Challenge was provided to the Cabinet Office through Smiths. This was not priced on a cost per ventilator basis, but as a one-off cost. As new assembly lines for ventilators were being set up, there were initial fixed set up costs.

82. As well as operating on a not-for-profit basis, Rolls-Royce took the decision to operate on a 'cash neutral' basis, meaning that there would be sufficient capital upfront from the Consortium/the Cabinet Office to cover the supplier invoices, preventing the account balance going below zero. A deposit from the Cabinet Office, via Smiths, of £10,712,500 was received on 3 April 2020 for the Bill of Material costs, which was used to pay suppliers and ensure Rolls-Royce remained cash neutral.

83. A separate bank account was set up by Rolls-Royce for the payment of suppliers, which worked with the new ERP system. A Finance Business Partner at Rolls-Royce was seconded onto the project full time to track and manage costs and communicate the costs to HM Government.

84. If parts could not be used in the assembly of a ventilator because of their quality or because they did not fit the design brief, Rolls-Royce aimed to mitigate costs. For example, quarantined parts may have been returned to the supplier to be reworked to make them suitable for use.

85. As mentioned earlier in this statement, the Consortium decided to procure components on the basis of the demand signal from HM Government of a need to produce 8,000 units. Later, HM Government committed to reimbursing the costs for procuring components for 5,000 units. The approximate 3,000 sets of surplus components cost £1.7 million. Under a Side Letter dated 29 May 2020 (Exhibit RC/44 - INQ000536467) Rolls-Royce, GKN, Smiths and the High Value Manufacturing Catapult agreed to work together to mitigate the loss. A 'Mitigation Steering Committee' was set up, which met once a week, to agree a plan mitigate costs, such as to generate income from the return, sale or use of the components over and above those for 5,000 units. The residual liability was then split between Rolls-Royce and Smiths, with GKN also making a contribution of £200,000.

86. Overall, Rolls-Royce spent £16,764,188.15 million on the ventilator project, of which £14,262,542.74 million was funded by the Cabinet Office. The costs included the cost of legal advice, Pattonair, Accenture, DHL, labour and the Bill of Materials (which formed the largest majority of the costs). Smiths, GKN and Rolls-Royce agreed an arrangement to share the loss of £2.5 million.

87. At the end of the Ventilator Challenge, the Consortium assessed options for the use of any leftover parts, such as returning these to the supplier, selling them or selling the parts for scrap. However, the cost for the transport of the parts was often higher than the recovery. Some of the remaining Bill of Materials was bought by Smiths at cost price as stock for use in its future manufacturing lines. Rolls-Royce made no profit from this.

Transparency

88. The Cabinet Office provided a copy of the guidance in relation to the publication of tender documentation and the publication of contracts (the "Transparency Guidance") and Rolls-Royce was required, by virtue of the agreements entered into with Smiths, to co-operate with HM Government to publish the Supply Agreement and comply with the Transparency Guidance if and when applicable.

89. VentilatorChallengeUK promoted awareness by issuing a number of press releases to keep the public updated on the progress of the production and procurement of ventilators during the pandemic. Media enquiries were routed through VentilatorChallengeUK. VentilatorChallengeUK circulated weekly newsletters to its participants, an example from 12 June 2020 is exhibited at Exhibit RC/45. Exhibit

RC/46 accompanied the newsletter and provides for talking points and communications on the winding down of the Ventilator Challenge, circulated amongst the Consortium by VentilatorChallengeUK. This messaging had been agreed with the Cabinet Office communications team.

90. The High Value Manufacturing Catapult also released press releases, examples of which are exhibited at Exhibit RC/47 - INQ000536470 and RC/48 - INQ000536471.

91. Rolls-Royce also informed the public of the progress of the production and procurement of ventilators during the pandemic, through press releases, an example of which is available on Rolls-Royce's website at https://www.rolls-royce.com/media/our-stories/discover/2020/behind-the-scenes-of-the-ventilator-challenge.aspx (Exhibit RC/49 - INQ000536472). This includes a video of the assembly line and personal stories of why Rolls-Royce's personnel participated in the Ventilator Challenge.

92. General media reports were made on the VentilatorChallengeUK, such as the article by Paul Fanning published in Eureka! on 11 May 2020, exhibited at Exhibit RC/50 - INQ000536474.

93. In the Inquiry's formal request under Rule 9 of the Inquiry Rules 2006, reference is made to an article by Rob Davies, published by the Guardian newspaper on 4 May 2020, entitled 'The inside story of the UK's NHS coronavirus ventilator challenge', which states:

"*The inside story of what happened in this period is one of early panic and confusion, of companies with expertise clashing with those seizing the limelight with ambitions to innovate, of questionable designs, and the desperation of a government setting targets and then deciding it didn't need to meet them after all.*"

94. Rolls-Royce has been asked to comment on this characterisation of the Ventilator Challenge. Rolls-Royce was committed to assisting the Ventilator Challenge and identified that the quickest way to manufacture the number of ventilators required would be to use an existing approved design. The Consortium was formed in unique circumstances and Rolls-Royce's experience was that members worked well together and supported one another.

95. At the outset of the Ventilator Challenge, HM Government expressed a requirement for 5,000 to 10,000 ventilators. Given the desire to mitigate life-threatening risk

coupled with the great sense of urgency and assurances of support from the Prime Minister and HM Government, the Consortium made the decision to order components for 8,000 units to secure scarce components (which accorded with the indication given by the Prime Minister on the call on 26 March 2020).

96. The Consortium was mindful of the need for safety and quality. Despite the unique and pressurised circumstances, Rolls-Royce, and to its knowledge all members of the Consortium, always prioritised safety over speed. Issues in the assembly line had been identified and resolved, and the assembly lines were at peak production, with the three lines hitting 60% to 90% of the planned full rate in the last two weeks of production.

97. In the Inquiry's formal request under Rule 9 of the Inquiry Rules 2006, reference is made to an email from Ben Boagey of the Office for Product Safety and Standards dated 17 April 2020, stating that Rolls-Royce gave feedback around the "*messy NHS trust landscape asking for different standards and attempting to compete with each other for PPE*." I have reviewed a copy of document INQ000478740. That document appears to suggest that these comments were made by a representative of Rolls-Royce Motor Cars Limited in relation to PPE procurement. I am not in a position to confirm this. Rolls-Royce Motor Cars Limited is a subsidiary of the BMW Group and is entirely separate from and independent of Rolls-Royce plc. Rolls-Royce is unable to comment further.

Equality and diversity

98. The Consortium quickly responded to an urgent request for the manufacture and supply of ventilators. While the Consortium was not working to an agreed equality and diversity policy, all Rolls-Royce's employees are trained on and are expected to comply with the provisions of the Group's People Policies (which include the Rolls-Royce Global Diversity and Inclusion policy and the Rolls-Royce Anti-Discrimination policy). Rolls-Royce is committed to creating an environment where every employee can reach their full potential, by encouraging diversity, wellbeing and development. It seeks to embed diversity and inclusion in employee training, communications and its cultural change programme.

Lessons learnt

99. Rolls-Royce is proud to have been a member of the Consortium. The scale up of the Smiths Ventilator was achieved from a standing start and the supply chain was set up in approximately two weeks, which required a monumental effort from those involved.

100. It has been reported in publicly accessible sources that no patient was unable to access a ventilator when they needed it. Parliamentary Privilege

Parliamentary Privilege

101. All members of the Consortium demonstrated a huge willingness to step up to the challenge. There was a strong focus on a common goal, to ensure ventilators were available for those who needed one, which helped provide focus and pace.

102. Good practice included strong communication and co-ordination between Consortium members. Communication amongst members was frequent and different methods were used for communication, such as e-mail, digital sharing platforms, virtual calls and (where appropriate in light of the risk of transmission of the virus) site visits. There was a circulation of daily update reports amongst members, sharing of information as to quality issues that had arisen and an 'embargo log' was generally circulated twice a day, updating members on any quality concerns on incoming parts.

103. Another example of how the Consortium worked in practice and the level of communication is the daily updates (later reducing in frequency as the challenge progressed) from Nigel Pearce, as seen in Exhibit RC/51 - INQ000536475.

104. The Consortium was reactive and agile, and put in place short interval control rather than a full failure mode effect analysis. This meant that the whole Consortium could react to problems if they arose. Across the Consortium, agility was demonstrated not only in the pace needed to deliver parts but also in responding to issues and applying the relevant knowledge and skills when required.

105. Inevitably on a project of this scale, which was set up at speed and operating within the context of a national emergency and a highly regulated market, there were

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1 Investigation into how government increased the number of ventilators available to the NHS in response to COVID-19

challenges faced along the way. Rolls-Royce's learnings from an operational perspective were:

105.1 The implementation from the outset of a 'single source of truth', to prevent multiple data sources being created.

105.2 The need for a greater recognition and understanding of Smiths' tacit knowledge, particularly for key parts or those with historical issues. Rolls-Royce had reviewed all Smiths engineering drawings at the outset of the project and if there was any ambiguity, clarification was sought from PA Consulting. If in the same situation again, Rolls-Royce would put in place increased quality checks from the beginning on made-to-drawing parts;

105.3 The need to map out the complete programme up front, to better understand the complete build process. An exercise was undertaken at the start of the project to map the building of the ventilators on the assembly line, but this excluded the sourcing of materials.

106. From a commercial perspective, Rolls-Royce's key learnings were:

106.1 The need for a clear signal on demand – HM Government had committed to purchasing 5,000 ventilators and signalled a potential need for a further 5,000 ventilators. The Consortium therefore took the decision to order parts to produce 8,000 ventilators, but the demand for ventilators changed as time passed. Rolls-Royce is of course, pleased that the demand for ventilators ended up being less than anticipated.

106.2 The need for certainty on operating risks – In an environment where the Consortium was progressing with the procurement of parts without having agreed full contracts with HM Government, an assumption was made by the Consortium that costs for participation in the Ventilator Challenge would be reimbursed by HM Government and Rolls-Royce acted on this in good faith.

PPE supplies

107. Like many other companies during the pandemic, Rolls-Royce donated personal protective equipment ("PPE") from its supplies, including face masks, to healthcare workers. Employees also used 3D printers to produce face visors for healthcare workers. Over 16,000 face visors were delivered, mainly to hospitals, from local

cluster teams. This was done on a local basis, and Rolls-Royce did not have a formal contract with the NHS or any government department to provide PPE. Rather, this came about by way of employee initiative and a desire to help at a time when there were media reports of a shortage of PPE.

108. Rolls-Royce also participated in the design of an 'Aerosol Generating Procedures' shield. An article on this shield is exhibited at Exhibit RC/52 - INQ000536476 and Exhibit RC/53 - INQ000536477 details the initial project briefing notes.

109. Rolls-Royce collaborated with medical specialists from the Royal London Hospital and engineers at The Manufacturing Technology Centre ("MTC") to develop, test and put a shield into clinical trial in just under a week. This came about following a call with Dr Ian Renfrew, a consultant interventional radiologist, and Andy York and Neil Mantle from Rolls-Royce. Dr Renfrew requested help to get a protective cover to shield healthcare workers when administering ventilators.

110. The initial conception was to minimise the exposure of healthcare workers to the dispersal of the SARS-CoV-2 virus during the insertion and removal of patient ventilator tubes. Neil Mantle spoke with Clive Hickman, the Chief Executive Officer of the MTC, and investigations started as to what a rapid prototype cover may look like. Rolls-Royce continued to support the initiative as demand for the shields increased, facilitating discussions with Innovate UK and the Cabinet Office to support the MTC and partners for a series run of 800 units.

111. Rolls-Royce did not receive any payment in relation to PPE or the 'Aerosol Generating Procedures' shield. Rolls-Royce invested its own time at its own cost.

112. Overall, Rolls-Royce is proud of its contribution to provide support to HM Government and healthcare workers during the pandemic through the provision of PPE and its role in the Ventilator Challenge. Despite the enormity of the programme and challenges along the way, its employees pulled together and faced these challenges head on, with unwavering support to the programme.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed:

Personal Data

Dated:

14th February 2025