

CONTRACT FOR THE PROVISION OF RAPID MANUFACTURE VENTILATOR SYSTEM (RMVS)

This Contract is dated 27/03/20 and is made between:-

1. **The Minister for the Cabinet Office** (the "**Customer**") of 1 Horse Guards Road, London SW1A 2HQ, acting as part of and on behalf of the Crown;

and
2. **TTP plc** (the "**Supplier**") whose registered office is at Melbourn Science Park, Melbourn, Hertfordshire SG8 6EE.

INTRODUCTION

- (A) The present Covid-19 situation is an urgent national matter and the Cabinet Office is taking the necessary precautions to commission the design of mechanical ventilators in response to the crisis.
- (B) On 13/03/2020 the Customer issued its requirement for certain services for the project to design mechanical ventilators in response to the Covid-19 crisis (the "**Project**"). The aim of the Project is to develop a design for mechanical ventilators that conforms to the specification, a copy of which is set out in Schedule 1 (the "**Specification**"). The Supplier has indicated its willingness to provide certain services in relation to the development of such a design (the "**Services**"). The Specification and the scope of the Services may be amended over time by the Customer on notice in writing to the Supplier to reflect changing requirements as the crisis develops.
- (C) The Specification and scope of the Services has been supplemented and clarified by any correspondence copies of which are set out in Schedule 5 (the "**Correspondence**").

The parties agree as follows:-

1. SUPPLY OF SERVICES AND PRICE

In consideration of the payments to be made by the Customer to the Supplier for the Services in accordance with paragraph 6 (such payments being together termed the "**Contract Price**"), the Supplier shall provide the Services to the Customer in accordance with: (a) the Specification as amended by any Correspondence; and (b) the Cabinet Office Short-Form Terms and Conditions of Contract for Supplies/Services (a copy of which are attached at Schedule 3) (the "**Terms and Conditions**") as amended by this Contract; and (c) the other terms and conditions of this Contract.

Neither Party limits its liability (if any) to the other for: personal injury or death resulting from negligence; fraud; or any matter for which its liability may not be excluded as a matter of law. Subject to this, the total liability of the Supplier under or in connection with this Contract, whether for breach of contract, negligence or otherwise, shall be limited to the higher of: (i) £500,000; and (ii) one and a half times the aggregate of the Contract Price. Neither the Customer nor the Supplier shall have any liability to the other under or in connection with this Contract for any of the following types of losses: loss of profits; loss of business; loss of contracts; loss or depletion of goodwill; loss of anticipated savings; or any indirect or consequential loss.

The Customer shall indemnify the Supplier, its group companies, and its and their directors and officers, agents and employees in respect of any claim made by a third party which results from the use made by the Customer or any person directly or indirectly authorised by or through the Customer of any product developed or manufactured using the Results and which is not a claim covered by clause 12.6 of the Terms and Conditions (as set out in paragraph 3.2 below).

The Customer is acting as part of the Crown and the Services and Results provided are for the benefit of the Crown. Subject to paragraph 3.2 of this Contract (replacing Clause 12 of the Terms and Conditions), nothing in this Contract shall prevent the Customer from disclosing any of the Results or other information obtained by the Customer pursuant or relating to this Contract to any other central Government body or any third party involved in making use of the Results.

2. COMMENCEMENT AND CONTINUATION

This Contract shall be deemed to have commenced on 13/03/2020 (the "**Effective Date**") and shall continue subject to any provisions for termination contained in the Terms and Conditions or this Contract. Notwithstanding the previous sentence, the Customer shall be entitled to terminate this Contract upon two days' notice in writing at any time subject to paying the Supplier in respect of any Services performed up to the date of termination.

For the avoidance of doubt, in the event of termination of this Contract, the provisions of paragraph 3.2 (replacing Clause 12 of the Terms and Conditions) shall persist.

3. TERMS AND CONDITIONS

- 3.1 Save as expressly provided in this Contract, the Terms and Conditions shall form part of this Contract. The following provisions of the Terms and Conditions shall not apply to this Contract and shall be deemed for the purposes of this Contract to be deleted from the Terms and Conditions:

- Clause 10 (Inspection of premises);
- Clause 11 (Insurance);
- Clause 23 (Environmental Requirements);
- Clause 26 (Official Secrets Acts); and
- Clauses 30.7 and 30.8 (Staff Vetting Procedures).

This Contract shall be deemed to constitute a "**Purchase Order**" for the purposes of the Terms and Conditions.

The "**Expiry Date**" shall be any future date notified in writing by the Customer to the Supplier as the Expiry Date (which shall be no less than two days from the date of such notice).

Where used in the Terms and Conditions the term "**this Agreement**" shall be deemed to refer to "this Contract".

Clause 33.1(c) of the Terms and Conditions shall also exclude from being confidential "*any information that is independently developed without reference to the other party's confidential information*".

- 3.2 Clause 12 of the Terms and Conditions shall be amended as follows by replacing the same with the following new Clause 12: -

Clause 12 Intellectual Property rights

12.1 *All intellectual property rights of any nature in any designs, inventions, materials or other results:*

(i) provided by or on behalf of the Customer to the Supplier for the purposes of this Agreement shall remain the property of the Customer (or the original third party owner); or

*(ii) generated by or for the Supplier for or in connection with the performance of the Services ("**Results**"), shall vest in the Customer.*

If, and to the extent, that such intellectual property rights in the Results do not vest automatically in the Customer, the Supplier hereby assigns (with full title guarantee and free from all third-party rights) all intellectual property rights in the Results to the Customer and shall take all necessary measures to secure that vesting. On request, the Supplier shall demonstrate to the Customer's reasonable satisfaction that, where it has sub-contracted work under this Agreement, it has secured that vesting in the work performed by its sub-contractors.

Apart from intellectual property rights vested in the Customer by virtue of this Clause 12.1, ownership of all other intellectual property (including without limitation any intellectual property rights owned by a third party which have been developed prior to

the Effective Date or otherwise than in performing the Services) are not transferred to the Customer by this Clause 12.

- 12.2 *The Customer may use, have used, copy and disclose the Results by itself or through other central Government bodies or third parties for any purpose whatsoever subject to the rights of third parties not employed in the performance of work under this Agreement.*

Where the Results are subject to the Supplier's or any relevant third party's pre-existing patents and/or registered or unregistered design rights then without prejudice to the Customer's rights under this Clause 12, the Supplier or relevant third party shall, where applicable, be entitled to claim compensation as provided for under the provisions of the Patents Act 1977, the Registered Designs Act 1949, and/or the Copyright, Designs and Patents Act 1988 in the event that such patents and/or designs are used for the services of the Crown.

- 12.3 *The Supplier shall mark any copyright work comprising Results with the legend '© Crown-owned copyright 2020'.*
- 12.4 *The Supplier hereby grants to the Customer a royalty-free, perpetual, irrevocable and non-exclusive licence (with a right to sub-license) to use copy and disclose any intellectual property rights contained in a Contract deliverable, that the Supplier owns, or has developed, prior to the Effective Date, or otherwise than in connection with the performance of the Services, and which the Customer reasonably requires in order to exercise its rights to use the Results and take the benefit of this Contract including the Services and the Results provided. For the avoidance of doubt, the Customer shall be responsible for obtaining, at its cost, any licence or authority from any third party owning relevant intellectual property rights that the Customer requires in order to exercise its rights to use the Results.*
- 12.5 *The Supplier shall deliver up to the Customer all Results and other deliverables to be provided under this Contract, including without limitation specific outputs and deliverables required by the Specification, as and when required by the Customer, and such other information as is reasonably requested by the Customer for the purposes of: (i) understanding the Results and the Supplier's outputs from the Services; and (ii) further developing, manufacturing and putting to use any product developed using the Results, including without limitation for assessing the safety or dealing with any safety concern with regard to such product. The Supplier shall promptly provide all such reasonable assistance and cooperation to the Customer as is required further in that regard.*

- 12.6 The Customer shall assume all liability for, and shall indemnify the Supplier, its group companies, and its and their directors and officers, agents and employees against liability, including the Supplier's costs, as a result of, any claim made by a third party for infringement by the Supplier or its sub-contractors of any patent or other intellectual property right in the performance of the Services and this Contract when such infringement arises from or is incurred by reason of the Supplier or its sub-contractors: (a) following any specification, statement of work or instruction required by the Customer under this Contract; or (b) using, keeping, modifying or disposing of any item given by the Customer for the purpose of this Contract (an "IP Claim"). This indemnity is given subject to the Customer promptly being given control of the defence of any IP Claim and the Supplier and its group companies providing such reasonable cooperation as may be required by the Customer, at the Customer's cost, with regard to such defence.
- 12.7 As soon as the Supplier becomes aware, it shall notify the Customer (and provide reasonable details) of:
- a. any invention or design which may be the subject of a patent or registered design (or application therefor) owned by a third party which appears to be relevant to the performance of the Supplier or the use by the Customer of anything required to be done or delivered under this Contract;
 - b. any restriction as to disclosure or use, or obligation to make payments in respect of any other intellectual property (including technical information) required for the purposes of this Contract or subsequent use by the Customer of anything delivered under this Contract; and
 - c. any allegation of infringement of intellectual property rights made against the Supplier or its sub-contractors and which pertains to the performance of this Contract or subsequent use by the Customer of anything required to be done or delivered under this Contract.
- 12.8 Notwithstanding anything to the contrary in this Contract: (a) it shall not form part of the Services for the Supplier to carry out searches or make enquiries with third parties as to the existence of intellectual property rights of third parties (other than providing reasonable details of relevant intellectual property rights of which it is aware pursuant to Clause 12.7) that shall or may be infringed by the performance of the Services or use of the Results by the Customer; and (b) the Supplier makes no representation and gives no warranty under or in connection with this Contract concerning non-infringement of such intellectual property rights.

12.9 *If, under Clause 12.7, a relevant invention or design is notified to the Customer by the Supplier after the Effective Date, then:*

- a. if the owner (or his exclusive licensee) takes or threatens in writing to take any relevant action against the Supplier or its sub-contractors, the Customer shall issue to the Supplier a written authorisation in accordance with the provisions of Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Section 240 of the Copyright, Designs and Patents Act 1988, and*
- b. in any event, unless the Supplier and the Customer can agree an alternative course of action, the Customer shall not unreasonably delay the issue of a written authorisation in accordance with the provisions of Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Section 240 Copyright, Designs and Patents Act 1988.*

12.10 *The Customer shall give reasonable consideration to and enter into good faith discussions with the Supplier pursuant to any request made by the Supplier to further commercialise the Results subject to terms being agreed in writing with the Customer.*

3.3 The amendments set out in paragraphs 3.1 and 3.2 of this Contract are for the purposes of this Contract only and do not set a precedent for future contracts between the Supplier and the Customer.

3.4 The Supplier's terms and conditions of business shall not apply to this Contract.

3.5 This Contract is formed of these paragraphs 1 - 9 and the Schedules hereto. Any other attachments are provided for information purposes only and are not intended to be legally binding. In the event of any conflict or inconsistency, the documents prevail in the following order:

- a) these paragraphs 1 to 9;
- b) the Terms and Conditions, as amended by this Contract; and
- c) the Specification, as supplemented by the Correspondence (if any).

4. SUPPLIER'S OBLIGATIONS

4.1 The Services and the Results shall be delivered by the Supplier to the Customer in full compliance with this Contract and the Customer's lawful and reasonable instructions..

5. MANAGEMENT AND COMMUNICATIONS

- 5.1 The Supplier shall perform the Services under the direction of the Customer.
- 5.2 Any direction by the Customer may be given by [redacted] (the "**Contract Manager**") who is an officer in Cabinet Office or such other person as is notified by the Customer to the Supplier in writing.
- 5.3 The Supplier appoints [redacted] to be the Supplier's first point of contact for this Contract. All queries to the Supplier from the Customer's Contract Manager shall initially be addressed to the Supplier's first point of contact.
- 5.4 The Supplier's first point of contact and the Contract Manager shall meet as often as either the Supplier or the Customer may require, where appropriate by telephone or other remote communication means, to review the Supplier's performance of this Contract.
- 5.5 Clause 41.1 of the Terms and Conditions shall be deemed to be amended such that a notice sent by e-mail shall be a valid notice under this Contract whether or not such notice is confirmed by first class mail or air mail.

6. INVOICES AND PAYMENT

- 6.1 Subject to the Supplier providing the Services to the Customer in accordance with this Contract and submitting invoices to the Contract Manager in the manner reasonably required by the Contract Manager, payment shall be made by the Customer to the Supplier in accordance with Clause 6 of the Terms and Conditions.
- 6.2 All Services shall be rendered on a time and materials basis according to the rates set out in Schedule 4 – The Pricing Schedule. Each week the Supplier shall provide to the Customer a summary of the incurred time and materials costs for the preceding week and a projection for the forthcoming week. The total Contract Price shall not exceed £1,500,000 plus VAT without prior written approval from the Customer. For clarity, any number of days specified in Schedule 4 is an estimate only and nothing in this Contract shall require the Supplier to produce a design fully meeting the Specification within any estimated number of days in Schedule 4 or within the amount specified in this paragraph 6.2.
- 6.3 The Supplier shall submit invoices for actual hours worked at the time and materials rates as outlined in the Schedule 4 – The Pricing Schedule. Travel and living expenses are not included in the rate. Any travel and living expenses incurred shall be submitted to the Customer as actuals and copies of receipts (where available), and any other information required by the Customer for the purposes of determining payments to be made to the Supplier, shall be required for invoicing and payment purposes.

- 6.4 Invoices provided by the Supplier shall include the following information: Supplier name, address, VAT number, bank name, bank account number, sort code, VAT number and detailed description of goods and services provided. Invoices shall include an electronic signature, if possible, and shall be sent to the following email address: [REDACTED] with a copy to

7. TRANSPARENCY

- 7.1 The Customer may be required to submit a Voluntary Ex-ante Transparency Notice (VEAT) about this Contract within the Official Journal of the European Union.

The Customer's decision not to publish full details of this Contract does not however preclude it publishing such information in the future (subject to applicable redactions) and the Customer may be required to disclose such information under the Freedom of Information Act 2000, the Environmental Information Regulations 2004 (EIR) or other legal requirement. In such cases, the Customer would need to consider disclosure in the context of the circumstances of the request or requirement concerned.

8. ENTIRE AGREEMENT


This Contract constitutes the entire agreement between the Customer and the Supplier regarding its subject matter, and supersedes all prior or contemporaneous understandings or agreements regarding that subject matter, whether oral or written, including any non-disclosure agreement entered into between the Customer and the Supplier in connection with the Project.

9. SUB-CONTRACTING

Notwithstanding anything to the contrary in this Contract (but without prejudice to the obligations of the Supplier in this Contract relating to any sub-contractor appointed by it), the Supplier may, subject to written notification to the Customer, appoint sub-contractors to perform the Services.

Signed by the parties' duly authorised representatives:-

For The Minister for the Cabinet Office

Signature: 

Print Name

Job Title: Government Chief Commercial Officer

Date: 27/03/20

For the Supplier

Signature: 

Print Name:

Job Title: **Managing Director**

Date: **27 March 2020**

The following Schedules form part of this Contract:

Schedule 1	The Specification
Schedule 2	Not used
Schedule 3	The Customer's Short-Form Terms & Conditions of Contract for Services
Schedule 4	The Pricing Schedule
Schedule 5	The Correspondence (if any)

Schedule 1

The Specification



MHRA RMVS
specification v2.1.pc

Schedule 2

Not used

Schedule 3

Short-Form Terms & Conditions of Contract for Services



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rt_Form_Terms_and

Schedule 4 Pricing Schedule

Professional fee rates:

TTP hourly fee rates are set individually. All individuals and hours booked to the assignment will be listed.

Charges shall be made on a per day basis and will be made on the basis of a "day" consisting of 8 hours per resource.

Below are approximate fee rates (excluding VAT) grouped by role:

£ fees / hr

Team Lead - Mechanical Eng

Senior Consultant - Mechanical Eng

Consultant - Mechanical Eng

Engineer - Mechanical Eng

Junior Engineer - Mechanical Eng

Support/test Engineer - Mechanical Eng

Intern - Mechanical Engineer

Team Lead - Electronics

Senior Consultant - Electronics

Consultant - Electronics

Engineer - Electronics

Junior Engineer - Electronics

Support/test Engineer - Electronics

Intern - Electronics

Team Lead - Software/Firmware

Senior Consultant - Software/Firmware

Consultant - Software/Firmware

Engineer - Software/Firmware

Junior Engineer - Software/Firmware

Support/test Engineer - Software/Firmware

Intern - Software/Firmware

Senior CAD designer

Junior CAD designer

Team Lead - Human Factors/Ind Des

Senior Consultant - Human Factors/Ind Des/UI

Consultant - Human Factors/Ind Des/UI

Human Factors Designer

Junior Human Factors/Ind Des/UI

Intern - Human Factors/Ind Des/UI

Quality Lead

Regulatory Lead

Risk Management Lead

URS Development Lead

Test planning

FMEA, Manufacturing Process FMEA

Team Lead - Physics/Maths/Modelling

Senior Consultant - Physics/Maths/Modelling

Consultant - Physics/Maths/Modelling

Physicist - Physics/Maths/Modelling

Intern - Physics/Maths/Modelling

Team Lead - Bioengineering

Senior Consultant - Bioengineering

Consultant - Bioengineering

Programme Specific Roles

- Clinical Lead

Managing Director

Programme Director

Project Manager

Programme Lead

Materials and expenses:

Materials and expenses for the project will be bill as incurred with a handling charge of and evidenced by supporting documentation.

SCHEDULE 5 - CORRESPONDANCE

Outline Scope of Works

The objective is to design a ventilator to meet the Customers requirements. Supplier plans to undertake the following tasks to meet this objective. The tasks are subject to change.

Product

Key milestones for prod dev:

- Functional prototype tested:
 - Pre-clinical prototype verification test complete:
 - Design release for production
 - Complete pre-clinical system design
 - Manufacture and build 10 off pre-clinical systems
 - Incorporate final design for manufacture and assembly input from manufacturer
-

Specifications

- **URS and TRS**
 - Releases available under version control (tracking evolving MHRA specs – latest spec MHRA Document RMVS001 - Specification, sent out 20th March).
 - Currently awaiting MHRA response (due 22nd March at the earliest) before spec review with clinical / spec freeze
 - Compiling Use Cases for the system to be sent to MHRA for review (expected March 22nd)
 - **Architecture specification**
 - First formal document released for internal review (issued March 19th)
 - Updates (under version control) in response to evolving
 - o URS/TRS
 - o input from testing
 - o risk analysis
 - o human factors activities
 - sub system features and critical components are being specified and documented
-

Quality/risk management/test planning

Quality

- Define Quality / regulatory agreement, Documentation-pla
- Complete essential requirements document
 - o Takes the essential requirements from the Medical Device Regulations and demonstrates conformance with each item.
- Collate documentation package
 - o Pull together all the documentation required to demonstrate the above
 - o Ensure its up to a suitable standard
- Collate Clinical trial documentation pack
 - o Subset of above
 - o PCA 1 and 2 forms for MHRA submission
 - o Obtain QP approval

Clinical

- o Draft clinical protocol and brochure
- o Obtain MHRA approval
- o Obtain Ethics committee approval

- Secured transfer-to-manufacture team
- Build production line
- Test and validate production line
- Transfer product to production

Sourcing

- major milestone:
 - Commit orders for prototype build 23 Mar
 - Commit order for first run parts 27 Mar
 - Identify suppliers of critical components
 - Secure supply commitment for all components
 - Determine bill of materials for V1 product
- Place orders for prototype build
- Determine ramp up capacity of supply chain
- Place orders for volume build
- Place order for continuing production