



Medicines & Healthcare products
Regulatory Agency

Contract Direct Award Recommendation

Project Title: Lease with the view to purchase a Fragment Analyser

Project Ref: P_5872

Procurement Number	Ref	P_5872
Submitted By:		██████████
Value:		£62,843.76
Date:		21.10.2020
Status:		Final
Version:		1.0
Supplier:		Agilent Technologies/ Bios Analytique Ltd

Template Version: 2.0

Author: ██████████. Category Lead – Science and FM, Finance and Procurement

Effective Date: 24th April 2020

Review Date: 24th April 2022

1 Introduction

1.1 Brief Description.

NIBSC is the UK OMCL (Official Medicines Control Laboratories) for biological medicines and is [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] associated equipment and software for 24 months with the option to return, purchase outright or extend the lease agreement after 2 years.

[REDACTED]

This project aligns with the Agency Corporate Plan and strategy, specifically supporting the first two objectives:

Objective 1: *We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and health care products in the UK and internationally, including:*

- *with Government and strategic partners, we will deliver our statutory functions to protect public health and ensure the safety and quality of medicines and health care products in the UK*
- *we will enhance our public health impact through building stronger partnerships, collaboration and engagement across the UK healthcare sector to improve clinical practice and protect public health*

Objective 2: *We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences.*

1.2 Introduction is to provide a concise summary of why we are intending to direct award a contract and to request approval of the recommended option.

[REDACTED]
[REDACTED]
[REDACTED]

There are other fragment analysers on the market, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

regulation 32(2)(c) under the Public Contract Regulations 2015 applies.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] In addition, the option of contracting the work out to another laboratory is not feasible due to the quality management system requirement and the time taken to set up the relevant contracts and carry out the required audits.

The Agilent fragment analyser system is only available via Agilent. Please see below a sole source letter from Agilent.



Agilent Technologies, Inc.
5301 Stevens Creek Blvd
Santa Clara, CA 95051
United States

November 1, 2018

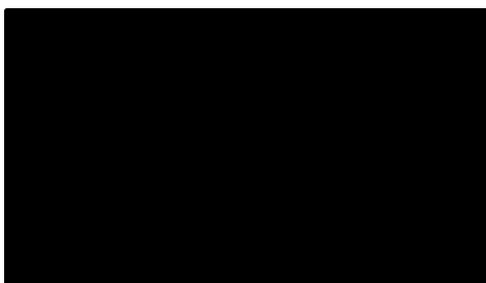
**The Agilent Fragment Analyzer Systems
- Unique Specifications and Facts -**

We are pleased to hereby confirm that the Agilent Fragment Analyzer Systems are unique for the standard and high sensitivity analysis of nucleic acids (RNA and DNA) using proprietary parallel capillary electrophoresis. This fully and easy-to-use integrated system of reagents, capillary arrays, automated pre-set methods and analytical software enable users to increase accuracy and reproducibility of analyses.

The Fragment Analyzer Systems, software, and all reagent kits are exclusively manufactured and controlled by Agilent Technologies. All of its components are exclusively available through Agilent Technologies or authorized resellers.

The current Fragment Analyzer Systems are sold under part number M5310AA, M5311AA, and M5312AA and are compliant with European RoHS directives.

Enclosed please find a complete list of unique features of the Agilent Fragment Analyzer systems.



PHARMACEUTICAL SCIENCES		ANALYTICAL METHOD	
	TITLE: RNA integrity of mRNA drug substance and LNP-mRNA drug product samples by fragment analyzer	NUMBER: TMI00010392	
		GDMS VER: 3.0	PAGE: 1 OF 20

1. PURPOSE

This laboratory method describes the procedure used to determine the percent integrity of messenger RNA (mRNA), specifically nucleoside-modified RNA (modRNA) for BNT162. This procedure also applies to RNAs that are isolated from BNT162 lipid nanoparticle (LNP) DPs by disruption of the nanoparticles.

2. SCOPE

This qualified procedure is applicable to drug substance and drug product release and stability samples.

3. RESPONSIBILITIES

- 3.1 It is the responsibility of the analyst to follow this procedure as written. All deviations from the methods must be documented and properly reported.
- 3.2 Training on this method, on sample handling, and on all applicable equipment should be carried out per laboratory guidelines and should be properly documented prior to analysis.

4. PRINCIPLE

The Fragment Analyzer system is a multiplexed capillary electrophoresis (CE) instrument for performing automated, high throughput separation and quantification of mRNA. Separation is achieved by applying an electric field through a narrow bore (50 µm i.d.) fused silica capillary array filled with a conductive gel matrix designed to sieve RNA molecules of a specific size range. When a high voltage is applied to the capillary array, injected RNA migrates through the gel matrix as a function of length or size, with smaller sized fragments eluting faster than larger sized fragments. At a point toward the far end of the capillary array, detection of the separated RNA is achieved by fluorescence of a sensitive intercalating dye present in the separation gel matrix, which fluoresces when bound to RNA molecules. The Fragment Analyzer system utilizes a high intensity light emitting diode (LED) excitation light source that is focused across the capillary array detection window and imaged onto a sensitive, two-dimensional chargecoupled device (CCD) detector. By monitoring the relative fluorescence unit (RFU) intensity as a function of time during the CE separation, digital electropherograms representative of the RNA content of 48 samples are collected in a single experimental run.

5. SAFETY

It is the responsibility of the analyst to ensure that adequate safety assessments are performed on the materials required for this procedure prior to use. All sample handling steps should be performed in a Biological Safety Cabinet (BSC) or PCR Workstation. Workspace and equipment should be cleaned with RNaseZap, germicidal wipes, and alcohol wipes or equivalent cleaning supplies prior to and after use to ensure an RNase free environment. Materials should be sterile and RNase free from the manufacturer. Analysts must wear gloves and disposable sleeves in addition to all standard lab PPE. Sample vials and tubes should only be wiped with alcohol wipes or spray

6. DEFINITIONS

PHARMACEUTICAL SCIENCES		ANALYTICAL METHOD	
	TITLE: RNA integrity of mRNA drug substance and LNP-mRNA drug product samples by fragment analyzer	NUMBER:	TMI00010392
		GDMS VER:	3.0

TERM	DEFINITION
BSC	Biosafety cabinet
%CV	Percent coefficient of variation
DP	Drug product
DEPC	Diethylpyrocarbonate
DS	Drug substance
LNP	Lipid nanoparticle
mRNA	Messenger RNA
modRNA	Nucleoside-modified RNA (aka nmRNA)
N/A, NA	Not applicable
RNA	Ribonucleic acid

7. EQUIPMENT AND REAGENTS

Substitute materials, equipment or reagents can be used unless specified.

7.1 Equipment

Item	Manufacturer
Fragment Analyzer Automated CE System	Agilent
Software: PROSize v3.0 or later	Agilent
48-Capillary Array, Short 33 cm	Agilent (A2300-4850-3355)
p10 µL pipette	Ranin
p20 µL pipette	Ranin
p200 µL pipette	Ranin
2-20 µL 12 channel pipette	Ranin
10-100 µL 12 channel pipette	Ranin
100-1000 µL 12 channel pipette	Ranin
ThermoMixer C	Eppendorf
SimpliAmp Thermal Cycler	Applied Biosystems (Thermo Fisher)
BioShake XP Thermoshaker	Q Instruments
Plate Centrifuge (mini benchtop single speed, or tabletop capable of 200 x g)	Axygen or Thermo
Biosafety cabinet (BSC) or PCR hood	LabConco. or AirClean Systems
Analytical Balance	Mettler Toledo
Vortex	VWR

7.2 Materials

Item	Source	Catalog Number
Pipette tips, sterile + filtered	Biotix or substitute	
0.1-20 µL		12-111-400
200 µL		12-111-362
300 µL		12-111-363
1000 µL		12-111-364
PCR-tubes, 1.5 mL, sterile	Eppendorf	022431081

PFIZER CONFIDENTIAL

PHARMACEUTICAL SCIENCES		ANALYTICAL METHOD	
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Item	Source	Catalog Number
96-well PCR plates, sterile	Eppendorf	951020303
96 DeepWell Plates, 1 mL	Fisher Scientific	12566120
Adhesive PCR plate seal	Thermo	236366
Conical tube, 15 mL	Corning	430052
Conical tube, 50 mL	Corning	4320290
Conical tube, 250 mL	Corning	430776
RNase Zap spray or wipes	Invitrogen	AM9782, or AM9786
70% alcohol wipes or spray(below)	Fisher Scientific	06-665-24
70% alcohol spray	Decon	8616
Germicidal Disposable Wipes	PDI	Q55172
PF-07305885 DS reference material (or other suitable material) is used as a control and subsequently referred to as a DS reference material in this test method.		
PF-07302048 DP reference material (or other suitable material) is used as a control and subsequently referred to as a DP reference material in this test method.		

7.3 Reagents

Item	Source	Catalog Number
DEPC-treated water	Ambion	AM9916
Standard Sensitivity (SS) RNA kit:	Agilent	DNF-471-1000 (or DNF-471-500)
RNA separating gel		DNF-265-0500
Intercalating dye		DNF-600-U030
5X 930 dsDNA inlet buffer		DNF-355-0300
RNA diluent marker		DNF-369-0004
RNA ladder		DNF-382-U020
0.25x TE Rinse buffer		DNF-497-0125
BF-25 Blank solution		DNF-300-0008
5X Capillary Conditioning Solution	Agilent	DNF-475-0100
Capillary storage solution	Agilent	GP-400-0100
Triton X-100 X-100	Sigma	T8787-100ML
Ethanol	Fisher	BP2818
Purified Water	MilliQ, etc	N/A

Note: Kit options have identical components and differ in amount of kit reagents supplied. DNF-471-0500 is suitable for analysis of 500 plate wells, and DNF-471-1000 is suitable for analysis of 1000 plate wells.

8. PROCEDURE

Notes:

- Work should be done in a biosafety cabinet (BSC) or PCR hood workstation, ensuring workspace and equipment are RNase free. Clean surfaces and equipment with RNaseZap followed by germicidal wipes, followed by alcohol wipes or spray. Sample containing tubes should only be cleaned with alcohol wipes or alcohol spray.
- Use materials that are sterile and RNase free from the manufacturer (e.g. pipette tips, Eppendorf tubes).

PFIZER CONFIDENTIAL

PHARMACEUTICAL SCIENCES		ANALYTICAL METHOD	
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- Allow RNA separating gel, intercalating dye, 5X 930 dsRNA inlet buffer, 0.25x TE rinse buffer, and blank solution to come to room temperature before use.
- Keep all samples, RNA ladder, and RNA diluent marker on ice until ready for use.
- Always use clean disposable gloves while handling all materials and solutions.
- All volumes can be proportionally scaled up or down.

[REDACTED]

[REDACTED]

Running costs are estimated to be £6,660 per annum, £555 per month [REDACTED]. All figures are inclusive of VAT (45% VAT recovery rate).

The equipment will fit within an existing laboratory and does not need any alterations or additional services added.

Business has acknowledged the above risks and decided to proceed.

2 Justification for use of the negotiated procedure without prior publication

It is proposed to direct award this contract under the following section of the PCR2015, Regulation 32

- 32(2)(c) For reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with.

3 Costings

The lease cost will be £2,063.49 per month (including maintenance) for 24 months with the option to return, purchase outright or extend the lease agreement after 2 years. All figures are inclusive of VAT (45% VAT recovery rate). Currently there is an option to purchase the equipment at the end of 2 years for £14,626.47 plus maintenance, £8,650.01 for maintenance contract for 2 years. All figures are inclusive of VAT (45% VAT recovery rate) as stated under Business Case.

Item	Cost	Years Required	Total	Notes
Cost of Purchase (Capital Cost)	£2,063.49 per month, including maintenance		£49,523.76	
Maintenance Servicing /	Included for the 24 month rental	24 month rental	Included	
Operate Costs / Consumables	£6,660 per annum	24 month rental	£13,320	

4. Approvals

4.1. Agency approvals

What approvals have already been made through Agency business processes.	Full Business Case (FBC) pending approval
Business Case Ref number	
Financial limits and restrictions	

4.2. Cabinet Office Controls

Do CO Controls apply? (See SOP on INsite)	
If yes which control applies?	
Control Ref number	
Financial limits and restrictions	

4.3. Proposed Length of Contract

Initial Contract: 24-month rental to include maintenance

Potential Extensions: Potential purchase following end of rental period. This will depend on current requirement and guidelines.

4.4. Terms and Conditions of Contract supplier quoted down payment as 1st quarterly rent paid in advance. At the end of the rental period, equipment can be purchased for its residual value £13,177.00 + VAT

5. Savings

No capital outlay for 2 years or maintenance costs. Have the option to return the machine at the end of 2 years if no further batches received. Have the option to extend the rental for longer period. Have the option to purchase with a reduced Capital outlay, reduced from £55,500.44 to £14,626.47 + maintenance costs following end of rental period. All figures are inclusive of VAT (45% VAT recovery rate) as stated under business case.



Specialists in the **Rental & Leasing** of scientific equipment & related IT hardware

Quote No: **6855**
Date: 26/10/2020



Quote Validity: 29th October 2020



Currency: GBP excluding VAT

NIBSC
National Inst. for Biological Standards & Control
Blanche Lane
South Mimms
EN6 3QG Potters Bar
United Kingdom

Rental Period: 24 months

Equipment: Agilent 5300 Fragment Analyser
Manufacturer: Agilent Technologies
Delivery time: 4-6 weeks
Warranty: 2 year Agilent warranty
Comment: Installation & familiarisation

Configuration					
Reference	Description	Qty	Unit Price	%	Total (GBP)
M5311AA	Includes the 5300 Fragment analyzer instrument, computer and monitor, controller and analysis software, capillary array (price added)	1	54,191.00	10.00	48,771.90
M5311AA-001	FA 48-Capillary Array Short, 33cm	1	1,365.00	10.00	1,228.50
SYS-UF-FA2-8R2	CrossLab Silver - 2yrs total	1	9,168.00	15.00	7,792.80
Total					57,793.20

Rental					
Reference	Description	Qty	Unit Price	%	Total (GBP)
M24	24 months Evolving rental offer of the detailed configuration At the end of the rental period, you could : * Return the equipment without penalty * Purchase the equipment for the Residual Value * Extend the rental for one or two additional years	24	1,859.00		44,616.00
Total					44,616.00

Down payment: 1st Quarterly rent
Terms of payment: Quarterly rent in advance
Purchase option: At the end of the rental period, the equipment can be purchased for its residual value.



Specialists in the **Rental & Leasing** of scientific equipment & related IT hardware

Quote No: **6855**
Date: 26/10/2020

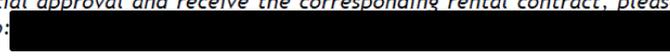


Rental Contract Request

Equipment: Agilent 5300 Fragment Analyser

Reference	Description	Qty	Monthly Rent	Total Rent	Residual Value
M24	24 months Evolving Rental Offer	24	1,859.00	44,616.00	13 177,00

To accept this offer subject to financial approval and receive the corresponding rental contract, please complete and return this document to:



Date: _____

Name: _____

Position: _____

Savings Type

Operational Transformation Benefits Definition				Equivalent Definition(s) in Bravo
Benefit Type	Benefit Category	Ref	Investment in the project or programme will ...	
Non-cashable	Service Enhancement	NC2	... result in measurable improvements to the quality of services provided to customers (whether internal or external) and/or to our efficiency in delivering them	<ul style="list-style-type: none"> • Quality increases
Non-cashable	Risk Mitigation	NC4	... measurably reduce the likelihood or impact of documented risks	<ul style="list-style-type: none"> • Quality increases • Rationalisation Savings

6. Approvals

Name	Position	Signature	Date
██████████	SRO/Budget Approval	██████████	21 st Oct 2020
██████████	End User/Contract Owner	██████████	21 st October 2020
██████████	Commercial Representative	██████████	21 st of October 2020
██████████	Commercial Representative	██████████	22 nd October 2020
██████████	Commercial Representative	██████████	27 th October 2020



A089014075



Agreement Number: A089014075

LEASE AGREEMENT

A - THE OWNER ("we", "us", "our")

Societe Generale Equipment Finance Limited, Parkshot House, 5 Kew Road, Richmond, Surrey TW9 2PR (company no. 0359 6854). The Owner is entirely separate from the Supplier and any third party who introduced this Agreement to the Owner. Our details will be inserted above and notified to you when this Agreement is accepted. You agree to be bound by the terms and conditions stated in this Agreement upon acceptance of this Agreement by us.

B - THE CUSTOMER ("you", "your")

Name: The National Institute for Biologic
Address: National Institute for Biological Standards and Co, Blanche Lane, Hertfordshire, South Mimms EN6 3QG
Tel. No: 01707 641000
Company No:
Business Email:

C - THE SUPPLIER

Name: AGILENT TECHNOLOGIES LDA UK LIMITED
Address: 5500 Lakeside CHEADLE SK8 3GR
Tel. No:
Fax No:

D - EQUIPMENT

Location of Equipment: At the Customer address as detailed above (unless advised differently in the Acceptance Certificate or Equipment Schedule, and agreed by the Owner)

Description/Details

Agilent 5300 Fragment Analyzer

Serial Number

M42021A631

E - PERIOD OF HIRE

Fixed Period:	24 months	Commencement Date:	30.11.2020.
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The hiring will start on the Commencement Date stated above and will continue unless terminated or cancelled in accordance with the terms of this Agreement, until expiry of the Fixed Period. You may terminate this Agreement during the Fixed Period by giving us three months' written notice and paying the Termination Payment (see clause 2.3 overleaf)

F - PAYMENTS

Payment Frequency:	Monthly	First Payment amount:	£1,859.00 Plus VAT
First Payment due date:	30.11.2020	Documentation Fee:	£0.00 Plus VAT
Followed by a minimum of:	23	Payments of:	£1,859.00 Plus VAT

You will pay the Payments to us on the same date in the month as the date of the First Payment at the Payment Frequency. Each sum due under this Section F is a "Payment" and collectively the "Payments". The Payments may be increased should the rate of VAT or Corporation Tax be increased (see clauses 3.2 and 12 overleaf). You are required to insure the Equipment. If you do not, we may arrange insurance cover at your expense in accordance with clause 7.2. Societe Generale Equipment Finance Limited is a member of the Finance and Leasing Association and uses the FLA's Business Code of Practice.

Extra Conditions (if any)

USE OF YOUR PERSONAL INFORMATION - IMPORTANT - READ THIS CAREFULLY

- c) accurately describes the equipment you are expecting to receive (e.g. whether it is new or used) and that its working life is appropriate to the length of the finance agreement.
- 3. Make it clear who has the authority within your own organisation to sign the agreement.
- 4. Make sure you understand and agree with all terms and conditions of the business finance agreement and, if you are unsure, ask for these to be explained or seek advice.
- 5. Make sure you understand all the costs involved and whether these will change during the course of the business finance agreement.
- 6. Check that the supplier of the equipment is reputable.
- 7. Understand whether there are any notice period or settlement terms required to terminate the agreement.
- 8. If the name of the leasing company contracting with you is not shown on the agreement ensure that you are informed at the earliest possible time.
- 9. Check whether the funder is a member of the FLA, as all asset finance members adhere to the FLA Business Finance Code.
- 10. If any amendments are made to the business finance agreement or a further agreement is required to replace an existing agreement, do not sign it until you have made the same checks as you did for the original agreement.
- 11. If a new business finance agreement includes an element of refinancing from a previous agreement with a different provider, check that the settlement figure provided the refinancing figure used by the new provider.

Societe Generale Equipment Finance Limited is authorised and regulated by the Financial Conduct Authority.

General Terms 1

This Agreement

- 1.1 These terms and those over the page make up the whole Agreement between you and us. No other terms will apply to this Agreement unless we have agreed to them in writing. This Agreement is for the hire of the Equipment for use in your business. Maintenance or service of the Equipment is not provided under the terms of this Agreement.
- 1.2 If you, the Customer, are two or more people then you are each jointly and separately liable under the terms of this Agreement.
- 1.3 This Agreement shall be governed by and construed in accordance with English law. You hereby irrevocably submit to the non-exclusive jurisdiction of the English Courts.
- 1.4 For the purposes of this Agreement the Equipment shall mean all of the hardware and software specified in Section D overleaf or a separate schedule to this Agreement.
- 1.5 For the purpose of this Agreement and in particular clause 8 below, the following definitions shall apply:
"Ultimate Beneficial Owner" means any individual who is a "beneficial owner" (as defined in section 5 and 6 of the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 as re-enacted, amended or updated from time to time) (2017 Regulations) in respect of the Customer (provided that all the references to 25% in the relevant sections of the 2017 Regulations shall be deemed to be replaced by 10% where the relevant individual is a national of a jurisdiction which is regarded as high risk determined by The Financial Action Task Force from time to time).
- 1.6 You must notify Us promptly in writing if any individual becomes, or ceases to be, a UBO in respect of You. You must provide Us with such information about Your UBOs as We request from time to time, to enable Us to comply with Our or Our Group's anti-money-laundering, customer due diligence and know your customer policies or criteria. You must ensure that any information which You provide to Us about Your UBOs is accurate and up to date.
- 1.7 For the purpose of this Agreement and in particular clause 7 below, the following definition shall apply:
"Insurance Fees" means the amounts payable in accordance with clause 7.2 and notified to the Customer in advance.
- 2 Period of Hire**
- 2.1 The hiring will start on the Commencement Date specified in Section E overleaf and will continue unless terminated or cancelled in accordance with the terms of this Agreement, until expiry of the Fixed Period.
- 2.2 The connection of the Equipment to a network or any other facility is your responsibility and this will in no way affect the start of this Agreement.
- 2.3 You may terminate the hiring under this Agreement before the end of the Fixed Period by giving us three months' written notice of termination AND paying to us the Termination Payment as set out in clause 10 on expiry of such notice period. Your liabilities under this Agreement shall continue notwithstanding you serving notice under this clause unless you comply with this clause 2.3 in respect of payment of the Termination Payment and clause 9 in respect of return of the Equipment.
- 2.4 All requests for a quotation of the Termination Payment must be made to us by you in writing.

HLTech EFD 01/2020

3 Payments

- 3.1 It is an essential condition of this Agreement that you make all Payments and any applicable Insurance Fees under the Agreement on the dates they are due. If you do not make payment on time, this will represent your intention not to continue to abide by this Agreement ("Repudiation") and we will be entitled to accept such Repudiation.
You must pay VAT on all payments and Insurance Fees under this Agreement at the appropriate rate and we will provide you with VAT invoices or schedules. If the rate of VAT changes this will change the amount of the Payments.
- 3.2 You will make all the Payments and any applicable Insurance Fees by Direct Debit unless we have agreed otherwise with you. If you stop paying the Payment and any Insurance Fees by Direct Debit we may collect all future Payments by invoice and increase the Payments by up to 3% or £35 plus VAT per Payment, whichever is greater.
- 3.3 If you do not pay any Payment and any applicable Insurance Fees under this Agreement on time you will pay interest at the rate of one and a half per cent (1.5%) per month from the date you should have paid until it is paid. On each occasion that a Direct Debit is returned unpaid you will pay an administration charge of £30 + VAT.
- 3.4 All Payments, Insurance Fees and other sums payable by you under this Agreement shall be made without set-off, deduction or withholding. If you are required by law to deduct any sum from a payment then the amount of such payment shall be increased by the amount of such deduction so that the amount received by us is equal to the original amount due.
- 3.5 You acknowledge that the inclusion and detailing of any software in Section D of the Agreement is intended only to evidence the fact that the Payments being made by you to us are calculated taking into account the cost of the software but are in no way intended to and are not relied upon by you to imply that we have title to it or licensed the software nor had any rights to do so and you confirm that you have obtained all necessary licences and permissions to use the software from all relevant persons including appropriate licensors.
- 3.6 You acknowledge that your obligation to make the Payments shall not be affected by your inability to use any software the subject of the Equipment for any reason, including if your software licence is ended, or you are unable to use it by virtue of any defect in the software or any licences or rights in respect of it and your sole claim in this respect will be against the licensor or supplier who granted you rights in respect of the software.
- 3.7 It is not a condition of this Agreement that software maintenance and support is provided, and therefore you will continue to be obliged to make all Payments in full and on the due date regardless of whether any supplier or licensor of software does not provide such maintenance and support in respect of software.

4 Exclusion of Liability

- 4.1 The Equipment comprises the items listed in Section D overleaf or on a separate schedule to this Agreement. All replacement or additional parts which are fitted to or on the Equipment become part of the Equipment and our property.
- 4.2 You are responsible for choosing the Equipment and for making sure that it is fit and suitable for your purposes. You acknowledge that you have obtained all warranties and guarantees that you require in relation to the quality and fitness for purpose of the Equipment from the Supplier or manufacturer and that you will have no claim against us should the Equipment be unsatisfactory or unfit for its purpose.

- 4.3 The Equipment is selected by you and acquired by us at your request solely for the purpose of hiring the Equipment to you (or financing the software licence payments). We do not hire or provide any funding in respect of the Equipment with any representation concerning its description, capacity, age, suitability, fitness for purpose, condition, performance or quality and all such representations, conditions and warranties (express or implied) whether relating to the capacity, age, quality, description condition or use of the Equipment or to the suitability or fitness of the Equipment for a particular or any purpose are excluded to the full extent permitted by law.
- 4.4 We shall not be liable to you:
- (a) in contract or in tort for any loss (whether loss of revenue, business, anticipated savings or profits and whether direct or indirect), injury, loss of value, or damage howsoever arising (other than liability for death or personal injury arising from our negligence);
 - (b) for any statement, term, condition, warranty or representation made by any supplier, dealer, agent or broker or other person through whom this transaction may have been introduced, negotiated or conducted and persons other than those employed by us have no authority express or implied, to act as our agent;
 - (c) either for any loss whatsoever suffered by you as a result of the Equipment or any part of it being unusable or defective (whether such defect be latent or apparent on examination) or to supply any replacement Equipment during any period when the Equipment or any part of it is unusable;
 - (d) for any loss or damage incurred or sustained by you in consequence of us terminating the hiring and/or the financing of the Equipment or repossessing the Equipment.
- 4.5 In no event will our liability to you under this Agreement exceed the aggregate of the Payments to be made by you under this Agreement.
- 4.6 You will inspect the Equipment when it is delivered to you and notify us immediately in writing of any defect. If you do not notify us of any defect within 48 hours from the time of delivery, then you shall be deemed to have accepted the Equipment and the Equipment shall be deemed to be complete, in good working order and condition, of satisfactory quality and suitable for all your intended purposes.
- 4.7 We are not liable for the late delivery of the Equipment nor do we have any obligation to replace the Equipment if it is lost or damaged. You must continue to make all Payments and you are not entitled to any rebate if the Equipment is unusable for any reason.

5 Software

- 5.1 You are responsible for choosing any software included in the Equipment (the "Software") and for making sure that the Software is fit and suitable for your purposes and that it complies with your specification.
- 5.2 We are not involved in the preparation or specification of the Software and you will, upon request, provide us with a copy of any specifications.
- 5.3 You undertake to procure from the relevant licensor any software licence required in connection with the Software and to maintain the same throughout the term of this Agreement.
- 5.4 You will comply with the terms of any Software licence provided to you and you will indemnify us against any claim made against us for breach of any Software licence or your failure to obtain any relevant Software licence.

6 Conditions of using the Equipment

- 6.1 You will keep the Equipment at all times in your possession and control and, except in the case of portable Equipment, you will keep it at the location stated in this Agreement and you will not move it without our prior written permission. You will notify us of the whereabouts of any portable Equipment, and not remove nor permit it to be removed outside the UK. You must let us inspect the Equipment at all reasonable times and, if we wish, permit us to affix labels to the Equipment indicating our interest in it.
- 6.2 You will be responsible for maintaining the Equipment in good repair and condition, for ensuring that the Equipment is used properly and safely and that it complies with all legal requirements for its use. You will be responsible for any damage caused to the Equipment apart from that caused by fair wear and tear.
- 6.3 You will be responsible for paying any fines, duties, insurance premium and other payments due for the Equipment.
- 6.4 You must not alter, improve or add anything to the Equipment without our written permission.
- 6.5 You must not transfer the benefit of this Agreement or do anything which affects our rights in the Equipment including using it as a security for a debt or any other obligation or selling or disposing of it. You must not sub-hire the Equipment or permit any encumbrance to exist over it. You must ensure that the Equipment does not become affixed to any land or buildings and that if the Equipment is kept on rented property in Scotland, it will not form part of the landlord's hypothec.

7 Insurance

- 7.1 Risk in the Equipment shall remain with you from the Commencement Date until the date that the Equipment is returned to us by you pursuant to clause 9 below. You shall insure the Equipment for the greater of its full replacement value or the Termination Payment (as specified in clause 10.1 below), with full comprehensive cover against all insurable risks and effect third party liability insurance (and any such third-party liability insurance policy shall provide cover in such amount as is prudent in the circumstances), in each case with a reputable insurer approved by us. You must arrange for our interest in the Equipment to be endorsed on each insurance policy and we must be noted on the policy as sole loss payee.
- 7.2 If you fail to insure the Equipment in accordance with clause 7.1 or you fail to provide evidence of such insurance which is satisfactory to us, we shall have the right, but not an obligation, to take out our own insurance to protect the Equipment and charge you an Insurance Fee by increasing the amounts payable under this Agreement. We will give notice before charging you any Insurance Fees. You must notify us as soon as possible of any damage to or loss of the Equipment and provide our insurer with a true, complete and accurate statement of loss and any other information that our insurer reasonably requires in support of our claim. In the event that we make a

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claim, you must make every reasonable effort to protect the Equipment from further loss.

- 7.3 Where we choose to exercise our right under clause 7.2 to insure the Equipment, we will be the sole policyholder under such insurance and shall not enter into such insurance on behalf of or as agent of you.
- 7.4 You hereby irrevocable appoint us as your agent with full authority to deal with any insurance claims under your own insurance policy on your behalf.
- 7.5 You must tell us immediately of any insurance claim and you cannot settle any claims without our agreement. You appoint us as your agent for receiving insurance settlements and you must tell the insurance company that any settlements from a Total Loss claim should be paid to us. If you receive any insurance monies you shall immediately remit them to us and until such payment you shall hold them on trust for us.
- 7.6 If the Equipment or any part of it is, in our opinion, lost or stolen or damaged beyond economical repair (a "Total Loss") then you will, within twenty eight days at our option, either:-
- (a) replace the affected Equipment at your own expense (using the insurance monies) with Equipment that is acceptable to us (title to which shall pass to us), and continue with this Agreement; or
 - (b) settle this Agreement by paying to us the Termination Payment (calculated on the assumption that the hiring of the Equipment was terminated on the date of the Total Loss). Any insurance settlement we receive from the insurers will be credited to the amount payable.
- 7.7 Until we receive the Termination Payment following a Total Loss your liability to make all the Payments due under this Agreement will continue and any replacement Equipment will become our property.

8 Default

- 8.1 We can terminate your hiring of the Equipment and/or this Agreement by giving you written notice if:-
- (a) you Repudiate this Agreement by failing to pay any Payment, Insurance Fees or any other sum due under this or any other agreement with us on time; or
 - (b) you fail to abide by any other terms of this or any other agreement with us (including clause 7), where such failure has been notified to you by us and you have not remedied such failure within 14 days; or
 - (c) you have made any untrue statement or given any false information to us in connection with this Agreement; or
 - (d) the Equipment is taken to settle a debt or judgment or any other event happens which might prejudice our interest in the Equipment; or
 - (e) you have a petition presented against you for bankruptcy or an administration order (or other similar petition) under bankruptcy or insolvency law or you propose any scheme of arrangement or composition with your creditors; or
 - (f) you breach the terms of any software licence provided in connection with the Equipment; or
 - (g) you are unable to pay your debts as they fall due or you have a receiver, administrative receiver, administrator, liquidator, custodian (or other similar official) appointed or a petition is presented (or resolution passed) for the appointment of such a party or for your winding up or any person who is entitled to do so applies to appoint or gives written notice of its intention to appoint an administrator over any of your assets or files such a notice with the courts or any steps are taken to appoint an administrator or (if you are a partnership) you are or become dissolved or any creditor seeks judgment from any of the partners for a partnership debt; or

- (h) you cease or threaten to cease trading or you sell or dispose of a substantial part of your business or assets without our consent; or
 - (i) at any time you (except in relation to a solvent reconstruction or amalgamation or intra-group reorganisation) are no longer a subsidiary of the ultimate holding company as defined in s1159 of the Companies Act 2006 being or the ultimate holding company itself is subject to a change in shareholding control as defined in s1124 of the Corporation Tax Act 2010 (each a "Change of Control"), or
 - (j) you undergo a Change of Control (whether direct or indirect) or your present holding company ceases to be the legal and beneficial owner (free from encumbrances) of the whole or any part of your issued share capital from time to time; or
 - (k) any individual who is or becomes a UBO in respect of you is not compliant with our or our group's credit, anti-moneylaundering, customer due diligence or know your customer policies or criteria from time to time; or
 - (l) you breach any of your obligations under clause 1.6; or
 - (m) the Equipment (or any part of it) becomes an actual or constructive Total Loss; or
 - (n) any event occurs which has or is likely to have in our opinion a material adverse effect on your business, properties or condition, financial or otherwise, or on your ability to duly perform and observe any of your obligations under this Agreement; or
 - (o) you are in material default under any other lease, or other agreement at any time executed with us; or
 - (p) you are a local authority within the meaning of the Local Government Act 1972, and are likely to be dissolved deconstituted or reconstituted or there shall be carried out an extraordinary audit by the Audit Commission pursuant to the Audit Commission Act 1998.
- 8.2 If any of the events in clause 8.1 (g) to (p) (inclusive) occurs in relation to any guarantor of any of your obligations under this Agreement we can terminate your hiring of the Equipment and/or this Agreement by giving you written notice.
- 8.3 If we give you notice under clause 8.1 or 8.2 you will pay to us the Termination Payment as set out in clause 10 as damages which you agree are a true reflection of the loss we will have suffered. You will in any event pay to us on demand any costs and expenses we may incur in enforcing the terms of this Agreement following breach by you.
- 8.4 Immediately on occurrence of any of the events of Default set out in clause
- 8.1, you hereby agree that the Supplier or licensor of any Software as

applicable will in accordance with an instruction from us be authorised to, a) immediately terminate your access to the relevant Software and you shall cease to use any software which, at the time of the Default, you are using pursuant to this Agreement, b) delete the Software from your computer systems and c) immediately cease to provide you with any maintenance or software support in respect of the Software.

- 8.5 If we give you notice that we intend to terminate this Agreement all Software will be de-activated and you must remove such Software from your computer systems and hardware and return to us all Software (and copies thereof) together with all manuals and media on which the Software is stored. You irrevocably grant us a licence to access any premises where the Software was utilised or will procure access on our behalf to any such premises not controlled by you so we can ensure you have complied with your obligations in this Clause 8.
- 8.6 By signing this Agreement you agree that the Supplier or Licensor's Software licence terms with you are deemed amended so that the Supplier or licensor may comply with the terms of clauses 8.4 to 8.5 above.

9 Returning the Equipment

9.1 When this Agreement and/or the hiring of Equipment detailed in it is cancelled or is terminated by us under clause 8 you must at your own expense return the Equipment in Fair Condition (as defined below) (including each and every part thereof) to us within 5 days of receiving cancellation or termination notice from us in accordance with clause 8.1. When this Agreement is terminated by you giving us prior written notice under clause 2.3, and paying us the Termination Payment in full in accordance with clause 2.3 you must at your own expense return the Equipment (including each and every part thereof) to us within 5 days of the expiry of such relevant notice period, to an address nominated by us within the United Kingdom in Fair Condition (as defined below), including operating manuals, all software (and any copies thereof) and any media on which the software is stored. We may arrange for any relevant software to be deactivated once this Agreement and/or the hiring under it is terminated.

The Equipment must be properly packed for shipment in accordance with the manufacturer's recommendations and specifications, kept upright and freight pre-paid and insured. If you fail to do so you will be liable for our costs in recovering the Equipment and/or restoring it to a Fair Condition.

"Fair Condition" means that all of the Equipment is immediately available for use by any third party other than you, in good working order and good condition, free from any defects and without the need for repair or refurbishment, fair wear and tear excepted. The Equipment must be free from markings, scratches, cracks or dents and the consumables left intact. You will pay us on demand for any damage, missing or defective parts or accessories. You are responsible for the costs of all data removal and wiping. If any storage drives or hard drives are removed or damaged, they must be replaced at your expense, with new replacements. If you do not return the Equipment (or any part of it) in accordance with this clause 9.1, then:

- (a) You must let us, or our representative, inspect the Equipment at any time, if we give You notice, and/or
- (b) We, or our representative, may immediately repossess the Equipment and may require you to remove the software from any computer system or hardware that it may utilised on. In the event we have to arrange for repossession of the Equipment, you agree that we or our representatives, may enter the location or any premises where the Equipment is believed to be located to recover the Equipment. You agree to pay on an indemnity basis, all costs and expenses incurred by us in connection with repossession or recovery of the Equipment and any part of it; and

10 Your Liability when the Agreement is terminated

10.1 On termination of this Agreement and/or the hiring of the Equipment for any reason, you shall pay us the Termination Payment which will be calculated as follows:-

- (a) all Payments, Insurance Fees, interest and other payments that have fallen due to be paid before the termination date but not yet paid; plus
- (b) an amount equal to the aggregate of all future Payments and any Insurance Fees which would have been payable by you during the unexpired part of the Fixed Period but for such termination, less a discount to reflect early receipt of 2% from the due date of payment until the date of termination; plus
- (c) such amount as may be necessary to indemnify us fully against costs or losses incurred or sustained by reason of the premature termination of any funding or financial arrangement entered into by us in order to fund our investment in the Equipment (together with any amount applicable to VAT); plus
- (d) all other costs and expenses incurred by us in connection with the repossession, insurance, refurbishment and disposal of the Equipment; plus
- (e) if we are unable to recover possession of the Equipment and/or the software for any reason or if they are a Total Loss) the amount which we anticipated the Equipment and/or software would be worth on expiry of the Fixed Period.

11 Sanctions

11.1 In this clause the following words and expressions shall have the following meanings:

"Sanctioned Person" means any person who is designated or targeted by Sanctions, or is otherwise a subject of Sanctions (including without limitation as a result of being (a) owned or controlled directly or indirectly by any person which is a designated target of Sanctions, or (b) located in, or organised under the laws of, any country that is subject to general or country-wide Sanctions).

"Sanctions" means any economic or financial sanctions, trade embargoes or similar measures enacted, administered or enforced by any of the following (or by any agency of any of the following):

- (a) the United Nations;
- (b) the United States of America;
- (c) the European Union or any present or future member state thereof; or
- (d) the United Kingdom.

11.2 You represent and warrant that neither you nor, to the best of your

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knowledge, any of your directors, officers, employees, agents or any person you have mandated for the purpose of executing this Agreement is a Sanctioned Person.

11.3 You agree that you shall not use, directly or indirectly, the facility made available to you pursuant to this Agreement, in any manner that would result in a violation of Sanctions by you or us. In particular, the facility provided by us to you shall not be used to finance any item the use of which would result in a violation of any Sanctions.

11.4 You represent and warrant that (i) no person (other than us or you) will have any legal or beneficial interest in the Equipment leased under this Agreement, and (ii) such Equipment shall not be used in violation of any Sanctions.

11.5 We may suspend and/or terminate this Agreement at any time, with immediate effect and notwithstanding any other provisions of this Agreement, if you become a Sanctioned Person or are in breach of any of

your representations, warranties and/or undertakings under this clause. In the event of termination by us, you shall return the Equipment without delay in accordance with clause 9.

12 General

12.1 You will indemnify us and keep us indemnified on demand from and against any loss, damage, proceedings, claims, costs or expenses arising directly or indirectly from your hire, possession, operation or use of the Equipment under this Agreement except for death or personal injury caused by our own negligence. The provisions of this clause 12.1 shall continue in full force and effect notwithstanding the termination of this Agreement for any reason.

12.2 You will pay and reimburse all legal costs and other costs and expenses which we may incur in connection with enforcing our rights under this Agreement, and/or in recovering possession of the Equipment including specifically (without prejudice to the generality of the foregoing) cost and expenses of repossessing, storing and disposing of the Equipment and of engaging an authorised debt collection agency and such charges as we shall deem reasonable to cover any costs and expenses of administration incurred by us.

12.3 You will pay us on demand our charges for changing the terms of this Agreement or for providing any information or additional services at your request or to compensate us for any additional costs of administration incurred by us such charges to be applied in accordance with our tariff of charges in force from time to time.

12.4 If any term or provision of this Agreement shall to any extent be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining terms or provisions (and any other application of the said terms or provisions) shall not in any way be affected or impaired thereby.

12.5 We may assign our rights and transfer our obligations but you may not.

12.6 Notices shall be deemed to be properly given if left or sent to you by post or facsimile to your last known address or registered office.

12.7 No forbearance or concession we allow you will affect our rights under this Agreement.

13 Tax

- 13.1 The Payments are based upon the assumptions that you will not claim any capital allowances in respect of the Equipment unless we agree in writing. The Payments have been calculated on the basis of the following assumptions (the "Assumptions"): (i) that there will be no change in the nature method or basis of taxation of companies and groups of companies in the United Kingdom including the rate of corporation tax, the rate or availability of capital allowances and the treatment of losses and expenses, and (ii) that the assumptions set out in any separate form of Tax Variation Appendix signed by you in conjunction with this Agreement will be fulfilled. If any of the Assumptions proves to be incorrect or is not fulfilled, we are entitled to adjust the Payments, or to demand payment of a lump sum, to ensure that our after tax return is not reduced.
- 13.2 We will give seven days notice of any variation of the Payments, Insurance Fees or any lump sum payable by you under clause 13.1.