NUVOAIR

NuvoAir Home for Asthma

Terms of engagement

Salisbury NHS Foundation Trust

NUVOAIR

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Contents

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Terms of Use for the NuvoAir Home Platform

These Terms of Use for the NuvoAir Home Platform shall apply to all sales, deliverables, and services from NuvoAir AB, Riddargatan 17D, 11457 Stockholm, Sweden (“NuvoAir” and/or "Supplier") to the organisation that wishes to use the NuvoAir Home Platform (“Customer”), jointly the “Parties”. The Terms of Use apply to and are incorporated into the offer, quote, confirmation or other agreement to which they are attached or in which they are referred to (jointly referred to as the “Agreement”). In case of discrepancy between such documents and these Terms of Use, these Terms of Use shall prevail unless explicitly stated otherwise. Any terms or conditions submitted by the Customer to NuvoAir which are inconsistent with, different than, or additional to these Terms of Use, are hereby rejected.

1. Background and Effectiveness of the Agreement

1.1. **Background.** The Supplier has developed a Platform for managing health data and the Customer wishes to purchase a license to use the Platform and associated services on the basis of this Agreement.

1.2. **Effectiveness:** This Agreement becomes effective at the date on which the Customer sends a request for purchase (“Purchase Order”) to the Supplier and remains effective during the entire license period (“License”) which is detailed on the related quote. No signatures are required.

1.3. **Exception**: In case the Parties decide to enter into individual signed agreements (such as Service Level Agreement, Data Processing Agreement or similar), the terms set out in this Agreement is superseded by the individual agreements as regards the individual terms and subject matter of such individual agreement. Remaining parts and terms set out in this Agreement not covered by an individual agreement shall remain unaffected.

2. Description of the Platform

2.1. **Components:** The NuvoAir Home Platform (“Platform”) is a CE class Im medical device and consists of four components, (i) the smartphone application called NuvoAir Home (“Application”) that is used by patients at home to measure their lung functions, track symptoms and other parameters, (ii) Bluetooth-connected devices such as the NuvoAir Air Next spirometer (“Hardware”) that connect to the Application, (iii) Disposable Turbines (single Patient, single use) that are a component to the Air Next Spirometer, and a (iv) web-based interface (“Portal”) that allows healthcare providers to remotely see the Personal Data (as defined in section 5.6.1 below) that was collected with the Application and (v) the optional use of the NuvoAir digital coaches to support patients to onboard and engage with the platform..

2.2. **License:** By paying an agreed fee, the Customer obtains the License to use all components of the Platform during an agreed license period for an agreed number of patients as set out in the Purchase Order. The License does not transfer ownership of the components from Supplier to the Customer.

2.3. **Requirements Application:** The Supplier continuously maintains the Application and optimises its usage for the two latest released versions of the Android Mobile Operating System and Apple iOS. The Supplier works with best effort to also ensure Application usage with older versions but cannot guarantee compatibility. The Customer shall hence ensure that operating systems are kept up to date. To access all features in the Application, it is required to have internet access, Bluetooth access, location services (mandatory for Android, optional for iOS) and push notifications enabled.

2.4. **Requirements Portal:** Minimum system requirements for access to the Portal is internet access and one of the following supported web browsers: Chrome, Safari, Firefox. To access the PDF generation feature, Pop-ups need to be enabled. If the Customer wishes to enable two-factor authentication for Portal they are required to inform their NuvoAir account manager.

2.5. **Service:** If requested and paid for by the Customer (explicitly stated in Quote and Purchase Order), the Supplier can provide the Customer and their patients additional support from a digital coach employed to act on behalf of the Supplier. The NuvoAir digital coach provides support to patients onboarding to the Platform and assists them with collecting the data agreed by the Supplier and the Customer in the protocol. The Supplier and Customer agree on the protocol (documented outside of this agreement) and communication route/frequency between

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Customer and NuvoAir digital coaches prior to commencing the engagement, only for the duration that is necessary.

3. Description of Responsibilities

3.1. **Purchase confirmation**: The Customer accepts a quote by sending a Purchase Order to orders@nuvoair.com.

3.2. **Setup of platform:** The Platform is set up remotely. Supplier ships all hardware (incl. disposables) to the address indicated on the Customers Purchase Order, provides the access details for Portal and Application to the Customer and schedules a virtual training. Under normal circumstances this happens within 14 days from receiving the Purchase Order.

3.3. **Service:** The NuvoAir digital coaches will not take medical responsibility for the patient nor provide medical advice or intervention to the patient, this remains the responsibility of the Customer. The NuvoAir digital coach reviews and handles data required to meet the specification determined by the Supplier and Customer in the agreed protocol only. The Supplier and Customer agree the clinical protocol and communication route and frequency between Customer and NuvoAir Clinical Service.

3.4. **Support service:** Supplier offers technical support to the Customer during regular business hours (weekdays local Swedish time 9am – 5pm). In case of requests, the Customer shall contact support@nuvoair.com.

3.5. **Replacement of Hardware:** Supplier replaces any hardware of the Platform without additional costs beyond the license for the Customer in case problems occur that cannot be resolved otherwise.

3.6. **Medical Records:** The Customer maintains adequate medical records, comply with applicable national legislation relating thereto and agree not use the Platform to store patient data. The Platform is not designed to keep medical records like an Electronic Health Record (EHR) and may not in any way be used for these purposes. Accordingly, the Customer undertakes to indemnify the Supplier for any and all damages as the Supplier may suffer as a consequence of the Customer keeping medical records in the Platform and/or otherwise use the Platform for medical record purposes in violation with this Agreement. If the NuvoAir digital coach is included, the Supplier will record encounters in a GDPR compliant EHR for the purposes of record keeping. Supplier and Customer will agree on a compliant data transfer process (documented outside of this agreement) where applicable to share information.

3.7. **Access Rights:** The Customer shall send a list of authorised personnel that shall be given access rights to the Portal to the Suppliers Account manager. The list must include names and email addresses of the personnel. It is the Customers responsibility to ensure that the authorised personnel are trained to treat sensitive Personal Data under GDPR.

3.8. **Train-the-Trainer:** Supplier provides one virtual training of the Platform to the Customer. The Customer is then responsible for training patients in using the Application and the Hardware.

3.9. **Platform Quality:** Supplier has implemented a Quality Management System that is ISO:13485 certified and follows strict guidelines on information security including regular system tests and backups. In the unlikely event of security incidents, Supplier will inform the Customer about mitigating actions and work with local medical authorities if needed.

3.10. **Collaboration:** When required, Customer and Supplier will collaborate to resolve issues in line with applicable legislation including but not limited to the medical device regulation.

4. Intellectual Property Rights

4.1. **No transfer of rights.** The Customer understands that the Platform contains intellectual property rights that the Supplier or third parties own. Nothing in this Agreement shall mean that such intellectual property rights are transferred to the Customer or that the Customer otherwise acquires the right to use such intellectual property rights in any way beyond what is expressly stated in this Agreement.

4.2. **Conditional rights.** The license to use the Platform which is stated in section 2 is conditional on the Customer not copying, making available (by subletting, transfer or otherwise), carrying out so-called reverse engineering or perform any other action that would allow copying of all or part of the Platform or its concept.

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5. Processing of Personal Data

5.1. **Applicable Regulation:** The Parties undertake to always protect the privacy of individuals and personal data processed within the Platform ("Personal Data") and to comply with applicable Personal Data legislation in the country of the controller when using the Platform, including but not limited to the General Data Protection Regulation ("GDPR").

5.2. **Responsibilities:** The Customer is considered the controller and Supplier the processor as defined in the GDPR of the Personal Data.

5.3. **Processor's commitment:** The Supplier commits to:

a) process the Personal Data only on Customer's documented instructions as set out in this Agreement and this section 5, which may, subject to section 5.4, be supplemented at a later date;

b) having adequate technical and organizational security and taking the security measures as set out in Article 32 of the GDPR to protect the Personal Data processed under this Agreement, including an appropriate duty of confidentiality imposed the persons at the Supplier with the authority to process this Personal Data;

c) assisting the Customer to comply with (I) the security requirements set out in articles 32-36 of the GDPR (such as technical and organizational measures, notification and information to the Customer without undue delay in personal data breach, impact assessment and prior consultation), and (II) the Customer's obligations regarding individual rights in Chapter III of GDPR (such as the right to information, access, correction, deletion, restriction of processing, data portability, objection to automated decision-making);

d) depending on what the Customer chooses; deleting, anonymising or returning all Personal Data to the Customer when the Agreement terminates, regardless of the reason for this, including deleting all copies which according to applicable legislation must not be saved;

e) make available to the Customer all information necessary to demonstrate compliance with the obligations in section 5 of this Agreement and allow for and contribute to audits, including inspections, conducted by the Customer or another auditor mandated by the Customer. The Supplier shall without delay inform the Customer of any contacts from the supervisory authority that concern or may be of significance for the processing of Personal Data and the Supplier shall also immediately inform the Customer if, in its opinion, an instruction infringes the GDPR;

f) otherwise providing the Customer with access to such information as is necessary for the Customer to be able to fulfil its obligations as a controller vis-à-vis the supervisory authority and/or individuals,

5.4. **CE-Marking:** The Customer acknowledges and accepts that the Platform is CE-marked and distributed to a large number of customers. For this reason, the Supplier is not necessarily able to follow such instructions from the Customer that are not a direct consequence of the Customer's need to follow the GDPR. If the Customer gives the Supplier instructions that the Supplier do not have the possibility to follow, the Customer undertakes to stop entering and exporting all such Personal Data that is affected by the current instructions. The foregoing shall not constitute a breach of the Agreement or the availability of the Platform.

5.5. **Sub-Processors and transfer to third countries**: The Supplier has the right to hire sub-processors for the processing of Personal Data on behalf of the Customer, for which the Supplier shall be fully responsible to the Customer. The Supplier undertakes to inform the Customer regarding Supplier's possible plans to hire and/or replace a sub-processor, so that the Customer has the opportunity to object to such changes. As of the conclusion of this Agreement, the Supplier has the following sub-processors, which may, however, be amended: Microsoft Azure and AWS (Backups) to store Personal Data. The respective servers are located in EU. Both sub-processors are ISO:27001 certified. Stored Personal Data is encrypted according to AES-156. Personal Data in transit is encrypted using TLS 1.3. Within the Portal, the Customer may choose to initiate video calls with their patients. To enable this service, Supplier is using Twilio as a SMS and Video Call Service Provider. Twilio is certified under ISO:27001. Provided that the Supplier applies adequate and, in accordance with the GDPR, approved security mechanisms, the Supplier has the right to transfer Personal Data to the United Kingdom (UK). If the controller is located in the UK, the Supplier has the right to transfer Personal Data to the EU/EEA provided that the Supplier applies adequate and, in accordance with the local UK legislation, approved security mechanisms.

5.6. **Purpose, nature and object of processing, and Categories of Personal Data:** Taking into account the Supplier's main function and purpose of providing the Platform, i.e. to provide the possibility for the Customer to remotely monitor Personal Data, the overall purpose for the Supplier's processing is thereby providing storage of Personal

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Data which includes all categories of personal data that may occur in the Platform, including but not limited to sensitive data from patients such as Lung Function, Symptoms, Age, Weight and Height.

5.7. **Categories of Data Subjects:** Everyone who is given access to the Platform and those who are mentioned in the Platform. The Parties acknowledge that the Data Subjects are identifiable natural persons, that have numerous rights under GDPR, including the right to captured consent, to access data, to erasure, to data portability, etc.

5.8. **Duration of Processing:** Personal Data will only be processed for as long as necessary to perform the obligations under this Agreement, i.e. minimum as long as the Customer is paying the License fee and maximum until the Customer explicitly asks for the termination of the processing to support@nuvoair.com.

6. Prices

6.1. **Licence:** For each patient on the Platform, the Customer is paying a License fee according to the License duration and payment frequency stated in the quote. Invoice is sent when sending the hardware against a Purchase Order. Paid fee is non-refundable.

6.2. **Payment:** The License fees and other amounts stipulated under this Agreement will be invoiced by NuvoAir up-front for the entire license period. Payment should be done as a bank transfer and must be made within thirty (30) days from the invoice date. In case of late payments and after one reminder, the Supplier reserves the right to (I) charge a delay fee of 45 EUR and (II) receive statutory default interest in accordance with the Swedish Interest Act.

7. Termination

7.1. **Licence Termination:** The Customer shall inform the Supplier if they wish to discontinue the Platform License at least thirty (30) days prior the end of the License period. This communication shall be made in written in form of a mail. In case the Supplier does not receive such a communication, the Supplier may send a new invoice for the same scope as initially quoted.

7.2. **Return of Devices:** In case the Platform License is discontinued, the Customer may choose to return all hardware to the Supplier or alternatively dispose or store hardware on behalf of the Supplier. Turbines shall be disposed of by patientsdisposed by patients.

7.3. **Platform Access:** In case the Platform License is discontinued, access of the Customer to the Portal and access of the Data Subject to the Application is both revoked thirty (30) days after license end date. From this point, Personal Data will not be accessible via the Platform. It is the responsibility of the Customer to instruct the Data Subject about the discontinuation of the service and to transfer and store Personal Data adequately in separate systems if required by local national legislation.

7.4. **Anonymisation**: The Supplier reserves the right to keep anonymised data in its system beyond termination for product development purposes. Anonymisation is performed in line with Recital 26 of the GDPR.

8. Liability

8.1. **GDPR Article 82:** The Parties shall each be responsible and liable for their own acts. For the avoidance of doubt, each Party shall be liable in accordance with Article 82 of the GDPR.

8.2. **Limitations:** Neither Party shall be liable to the other Party in any event for indirect damages such as loss of profits, reduced turnover, loss and corruption of data, failure to comply with third party obligations or loss of benefit of the processing or this Agreement, unless they are caused intentionally or by gross negligence. The Suppliers liability under this Agreement shall under no circumstances exceed the invoiced amount as stated on Purchase Order.

8.3. **Insurance:** The Parties shall ensure that their liability is sufficiently covered by appropriate liability insurances.

8.4. **Disputes:** The Parties must promptly use their best endeavors and reasonable efforts to resolve any dispute, disagreement or material difference of opinion arising out of, in connection with, or relating to this Agreement. If the Parties are unable to resolve the dispute by negotiation amongst themselves, the dispute shall be finally resolved through arbitration proceedings administered by the Stockholm Chamber of Commerce Arbitration Institute (”SCC”). Rules for Expediated Arbitration Procedure shall be applied unless SCC, taking into account the severity of the case, the value of the dispute and other circumstances, determines that Arbitration Rules shall be applied. The seat of the arbitration procedure shall be Stockholm. The Parties agree that both the proceedings and the award shall be covered by confidentiality.

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8.5. **Applicable Law:** This Contract shall be governed by and construed in accordance with the laws of England and Wales.

8.6. **Collaboration:** Both Parties remain reasonably available to assist each other at all times and to each Party's benefit.

End of Agreement

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NuvoAir Home Monitoring Clinical Protocol

Here follows a step-by-step explanation of the patient pathway:

1. **Referral to the NuvoAir Asthma Service via Jotform survey (or alternative if preferred) to be completed with the following information:**

- Hospital patient is being referred from
- Agreement that patient has the technology compatible to be part of NuvoAir Asthma Assessment
- Patient details (name, sex at birth, DOB, height, address, email and contact telephone number)
- Brief explanation for need for assessment
- Brief medical history
- Confirmation that contraindications for spirometry have been checked
- List of current medications
- List of inhalers that wish to be tracked (if relevant)
- Acknowledgement the patient has or will be provided with a spacer from the clinician (if relevant)
- Consent for performing asthma protocol either by patient or guardian

2. **NuvoAir Digital Coach (DC) will triage Jotform survey:**

- Check patient is suitable for NuvoAir Home monitoring - not contraindicated
- Form has been completed fully and consents obtained
- Contact made with patient to confirm they're happy to participate
- DC to check current inhaled medications are Aos compatible and how many Aos devices the patient requires e.g. one for preventer one for reliever (if relevant)
- DC to pass on patient details to shipping department

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3. Direct shipping to the patient inclusive of:

- AirNext spirometer with instructions
- Turbine x10 (1 included in the spirometer box)
- Aos with instructions (if relevant)
- Contact details for DC

4. Digital Coach onboarding process:

- DC receives notification of date patients will receive their package
- DC checks package has been received by patient and sends text message to set up AirNext spirometer and Aos (if relevant)
- DC to reach out within the first week of receiving AirNext to onboard the patient officially via video or phone call (lasting 30-45 minutes) This includes:
    - Introduction to programme, how to set up their connected devices

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  - DC to explain frequency of spirometry
  - Establish good baseline spirometry technique (grade A-C)
- Complete ACQ (once monthly where relevant)

5. Patient contact:

- Patient is to be contacted with video calls through the portal or via zoom
- Patient to schedule onboarding appointment through Calendly link to DC calendar
- Following appointments can be done in the same format, alternatively via phone call or sometimes text message where appropriate
- DC to document all contacts with patient

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6. **Clinician contact via weekly (15-30 min) huddles to feedback:**

- Inform clinicians of patient's progress
- Are the patients engaging?
- Are they producing quality spirometry?
- Are they declining/variable/stable?
- Update on AOS usage?
- Exacerbations?
- New onboards?
- Any reports for patients completing 3 months assessment

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Clinician (1+2) contact information for huddles/patient queries:

Clinician 1

Name	Dr Seb Gray
Role	
Telephone contact	07941 244877
Email address	Sebastian.gray@nhs.net

Clinician 2

Name	
Role	
Telephone contact	
Email address	

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Assessment timings (approximate):

Week 1-2
- Onboarding AirNext and Aos (30-45mins)
- QA spirometry grade (A-C)
- ACQ (if relevant)

Week 4
- ACQ (if relevant)
- DC check in 30 mins
- Assess confidence in managing health

Week 8
- ACQ (if relevant)
  DC check in 30 mins
- Assess confidence in managing health

Week 12
- ACQ (if relevant)
- DC check in 30mins debrief patient
- Assess confidence in managing health
- Provide clinician with a full data report at week 12 for final weekly huddle

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Engagement

- DC point of contact for patients if they are struggling,
- DC to review patient's spirometry each week and report back at weekly huddle if there are issues with engagement to service but DC not to drive engagement* agreement for engagement levels to be discussed with the clinician of each service
- If DC reviews spirometry and technique is poor, then DC to arrange additional appointments call/video to review quality spirometry technique

Report of 12 week assessment:

- Patient details
- FEV1 trend graph
- PEF trend graph (either L/s or L/min)
- AOS usage trend (if relevant)
- ACQ scores (if relevant)
- Confidence of self management information (if applicable)
- Digital coach feedback including interpretation of results, comment on the quality of spirometry, engagement and anything else relevant to the patients experience.

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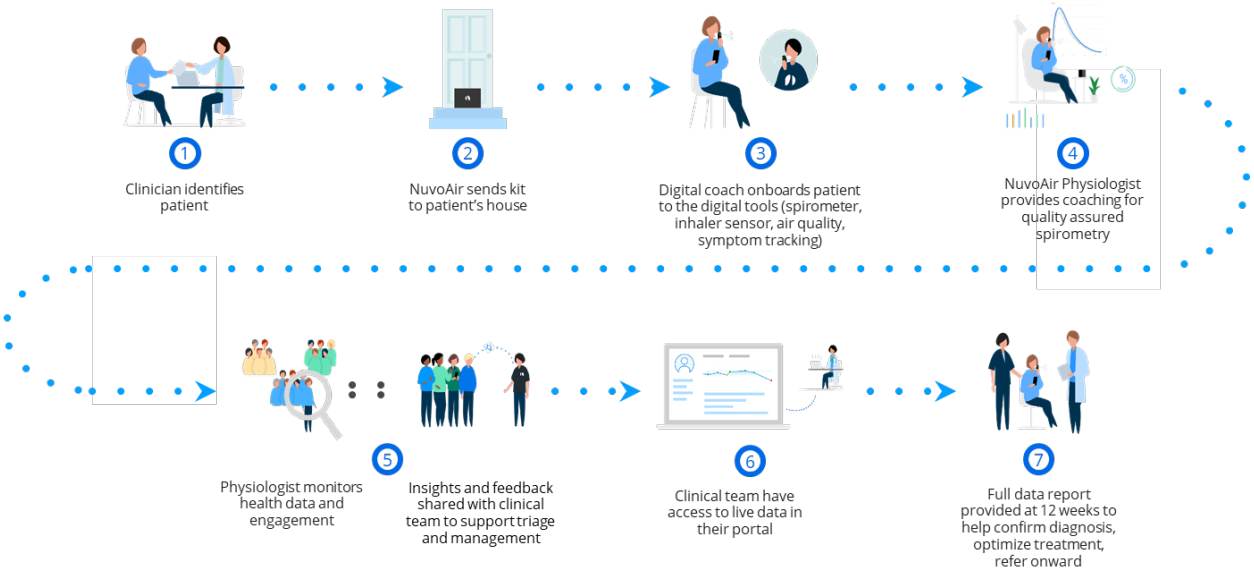
Week 12

- At week 12, the patient will have a final phone or video call with the DC. The DC will explain all the information from the 12 weeks will be sent to the clinician *and it will be the clinicians responsibility to share the report and the information with the patient directly*.
- For the clinicians at week 12 the formal report will be produced and sent directly to the clinicians and discussed in the weekly huddle.
- At this stage, the DC will no longer review or engage with the patients' data.
- The clinician then has two options with the patient;
    1. The patient can stay on the platform for the remainder of the year if the clinical team prefer the patient to continue to monitor and the clinical team can review the data on the portal
    2. The patient does not require to be monitored any further as a diagnosis of asthma has not been made. The patient should be informed by their clinical team what they would like them to do from a self monitoring perspective

Pathway at a glance



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NuvoAir Digital coaches:

Hello,

My name is Meg and I am a Digital Coach at NuvoAir. I am a registered Respiratory Physiologist with the Association for Respiratory Technology and Physiology (ARTP) and the Registration Council for Clinical Physiologists (RCCP). I have 7 years experience working within the NHS across the three disciplines of respiratory, cardiac and sleep physiology.

My background is in exercise and sport physiology in which I have obtained a BSc and MSc. I have taken then non-traditional route to becoming a qualified Physiologist and I have obtained equivalence through the RCCP. I have completed the ARTP practitioner's qualification, ARTP spirometry certificate, SCST ECG practical and interpretation qualification, I am trained in cardiopulmonary exercise testing, respiratory polysomnography scoring and CPAP therapy which lead to my position as a Senior Clinical Physiologist.

My job at NuvoAir is to assist patients to become familiar with our technology, to teach the patients how to perform quality assured spirometry and to empower the patients to take control of their own respiratory health.

Technology doesn't always come easy to some and I facilitate the onboarding process. Once the patient is successfully onboarded with their spirometer and/or Aos inhaler sensor, I am a point of contact for the patients if they're struggling. I also review their spirometry weekly to ensure they are obtaining high quality spirometry and if they're struggling I would book a coaching session to aid their spirometry technique. It is vital we ask our patients to achieve grade A-C spirometry to facilitate correct diagnoses.

I am a point of contact for the clinicians as well as patients. I can assist with the portal or teaching the onboarding process and I can feed back information to the clinicians in a weekly huddle about their patients.

Hello,

My name is Emma and I am a Digital Coach at NuvoAir. I am a registered respiratory physiologist with the Association for Respiratory Technology and Physiology (ARTP). I have a physiology MSc and I am currently awaiting my PhD viva. My PhD used home based remote monitoring to assess daily treatment quality and gamification for children with cystic fibrosis.

I am very experienced in the performance and interpretation of standard and advanced pulmonary function tests in children and adults of all ages. I have over 10 years experience working in the NHS and academia as a respiratory physiologist, including as a senior clinical physiologist at a leading London paediatric hospital. I have specialist experience in both preschool lung function testing (with children from 3 years of age) and with the Global Lung Function Initiative reference values. I have taught on the ARTP paediatric spirometry course, UCL MSc programmes and presented at many UK and international conferences.

My role at NuvoAir is to assist patients to become familiar with our technology, to teach them how to perform quality assured spirometry and to empower people to take control of their own respiratory health. As I saw during my PhD, technology doesn't always come easy to some and I facilitate the NuvoAir onboarding process. Once the patient is successfully onboarded with their spirometer and/or Aos inhaler sensor, I am a point of contact for the patients if they're struggling. I also review their spirometry weekly to ensure they are obtaining high quality spirometry and if they're struggling I would book a coaching session to aid their spirometry technique. It is vital we ask our patients to achieve grade A-C spirometry to facilitate correct diagnoses.

I am a point of contact for clinicians as well as patients. I can assist with using the portal or teaching the onboarding process and I can feedback information to clinical teams in a weekly huddle about their patients.

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Notes of any amendments requested by the clinical team at kick off meeting *(NuvoAir representative to complete)*:

Notes made by:
Signed:
Date:

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Measuring Success

Additional measures can be agreed and added here by the NuvoAir representative

Criteria for agreement to purchase	
	NuvoAir have fulfilled the following:
☐	All patients shipped relevant hardware following referral from clinical team
☐	Customised clinical portal set up for clinical team
☐	All patients onboarded to the technology by digital coach
☐	Spirometry coaching offered to all patients
☐	4, 8 and 12 week check-in offered to all patients (if relevant)
☐	Provision of 12 week asthma report for all patients (if relevant)
☐	Regular huddles attended by NuvoAir team as agreed

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The Debrief:

Stake Holders Required:
Sales
Digital Coach
Director of Operations
Clinician
Customer with Spend Authority
NuvoAir presents success metrics
Pain-points/success discussed.
Agree next steps with current patients
Agree next steps with respect to procurement and ongoing plan

Please attach/record notes from the debrief meeting here:

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Agreement with NuvoAir to provide Asthma Assessment Service for fixed term evaluation as detailed in this document:

NuvoAir representative - please complete:

Name of service provider	**Salisbury Hospital**
No. of patients included in evaluation	**Up to 20 patients**
Length of assessment (weeks)	**12 weeks**
Onboarding window (dates)	**TBC**
Referral method agreed (e.g. Jotform/word doc via email etc)	**Jotform**
Preferred date/time of huddles	**TBC**
Preferred date of debrief	**TBC**

Clinical service signing authority **Date**

_____

Name
Role

NuvoAir signing authority **Date**

_____

Name
Role

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