# LungHealth: Sleep Clinical and Technical Risk Analysis

## Document review

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## Background

LungHealth guided consultation products, including Sleep have been developed in an iterative manner from its conception of the idea, through to delivery of our current products. The final product has been developed by incorporating feedback from Clinical Leads for Sleep Medicine, Respiratory Consultants, Sleep Physiologists, Respiratory Nurses and Commissioners of NHS Services.

The framework for review, is already in existence in the form of AASM / NICE guidelines for sleep, the challenge was translating these evidence-based guidelines into a product that would ensure that every patient requiring investigation of their sleep condition received a review, which was bespoke to them and bespoke to their disease severity i.e. to ensure that all patients with a sleep condition received a guideline level review and personalised care.

## Risk analysis

LungHealth recognised that as part of the process outlined above, both a comprehensive clinical and technical risk analysis were required to be completed prior to our products being used in a live environment with patients. The risk analysis was conducted by the LungHealth (LH) clinical team, which consisted of four Consultant Chest Physicians including a Consultant with a specialist interest in sleep, supported by a team of Respiratory Nurse Advisors from National Services for Health Improvement Ltd. (NSHI) and associated clinical team.

## Clinical risk analysis

The risk analysis was conducted based one the following assumptions:

1. ***Patients entering the LH Sleep app. have been referred for investigation, diagnosis and managment of a sleep condition***
2. ***Healthcare professionals using the app. where deemed competent by their Hospital/Trust to review patients, in line with a service level agreement and in the absence of the LungHealth app***.
3. ***The Sleep product was to be used in secondary care/ specialist sleep centres***

## Purpose

The risk assessment was performed on the software to identify areas of the programme that represented any clinical risk to the patient, which included, but was not limited to:

- Diagnostic algorithms
- Algorithmic pathways
- Automated calculations
- Disease severity classification
- Referral pathways
- Data written to the clinical dashboard

## Approach

- All identified clinical risks were identified and subject to both logic and algorithmic review by a minimum of two respiratory consultants for each assessment. This included testing. In addition, user acceptance testing was conducted by Respiratory Nurse Specialists and sleep physiologists.
- All identified clinical risks underwent consultant testing and user acceptance testing (UAT) following programming and prior to any new deployment to ensure the integrity of the whole Sleep package utilising a unit testing methodology

As part of LungHealth's 'Change Request process' the same Data Protection Impact Assessment is carried out to determine the impact of the change on GDPR.

## Scope

The Risk Assessment is intended to review a number of areas of distinct risk.

These include:

- Clinical risks to the patient when undergoing a Sleep consultation
- Identified levels of risks to the integrity of the LungHealth Guided Consultation package and its data

With each risk assessment describing:

- The risk location within the package
- The identification of the risk
- The level of risk posed to the patient or program integrity if the risk is not mitigated / addressed
- Detail of possible Risk Avoidance measures that have been put in place
- The detail of any risk mitigation
- The testing of avoidance / mitigation solutions

## 1. Sleep Risk Analysis

A summary of the LungHealth Sleep risk analysis is shown below, with our testing documents available for review by registered users if requested.

In addition to the risk levels indicated below LungHealth have also conducted likelihood and residual risk rating (i.e., the rating post mitigation to show that the risk is controlled), which is available to LungHealth users upon request.

Please contact info@lunghealth.co.uk if you are a registered user and would like to review any of the testing documents in relation to specific 'Risk Descriptions'.

## 1.1. Clinical Risk Analysis: Guided Consultation

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation | Testing / Verification | Notes |
|---|---|---|---|---|---|---|
| Diagnosis | The patient being staged at an incorrect level of OSA severity | High | The Sleep module calculates the severity of OSA according to algorithms based on AHI | The result is displayed on screen and is subsequently used to guide the patient's level of treatment in conjunction with the level of daytime Sleepiness. If the diagnosis of OSA is not confirmed the program exits and refers the patient for specialist review if there are symptoms that remain unexplained | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | The patient being misdiagnosed, with their AHI being within the normal range | High | The Sleep module calculates the severity of OSA according to algorithms based on AHI | Patients with a normal AHI and / or with unexplained symptoms are recommended for specialist review | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | The patient being misdiagnosed as having OSA when they have underlying hypoventilation or | High | The Sleep module specifically asks for overnight oxygen saturation to be entered, daytime oxygen saturation to be entered and asks regarding a background of neuromuscular disease during the consultation | 1) Resting daytime hypoxia with triggers marked for specialist referral<br><br>2) Overnight oxygen level and time below a certain threshold triggers an alert prompting specialist referral<br><br>3) If there is a background of neurological disease indicated during specific questioning during the consultation, the operator is alerted to consider the possibility of | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |

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| | | | | hypoventilation thus triggering specialist referral | | |
| Diagnosis | The patient being misdiagnosed with OSA when in reality they have hypersomnia / narcolepsy | High | The Sleep module has specific algorithms that detect the presence of Sleepiness coupled with the absence of Sleepiness | The presence of unexplained Sleepiness is handled by the following:<br><br>1)Recommendation of specialist referral<br><br>2) A cohort of questions highlighting the possibility of Narcolepsy | Clinical Lead Testing following Risk Analysis: [T-003]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-003] | Tested 19/11/2020 Passed |
| Diagnosis | The presence of excessive daytime Sleepiness resulting in motor vehicle accidents | High | The Sleep module specifically asks regarding the possibility of driving related Sleepiness | The presence of driving related Sleepiness is highlighted, alerted, and reported | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | The presence of Central Sleep Apnoea misdiagnosed as Obstructive Sleep Apnoea | High | The Sleep Module asks the user to record the central apnoea index and incorporates this in its algorithms | 1)The number of central events are set at an abnormal threshold where an alert is triggered<br><br>2)Should the number of central events not been specified, the fact that they are missing is alerted to the operator | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Patient is misdiagnosed when a Sleep study is technically unsatisfactory | High | The Sleep module does not interpret the results of any technically unsatisfactory study | The software asks the operator whether the study is technically satisfactory and then whether the operator wishes to repeat the Sleep study or not. This is pulled over to the report. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | BMI<br><br>The patient's weight may be a contributing | Low | The patient's BMI is calculated | The presence of a high BMI contributing to OSA is alerted on the software. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002] | Tested 19/11/2020 Passed |

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| | factor to their presentation | | | | Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | |
| Diagnosis | Resting Oxygen saturation<br><br>The patient might be suffering from Hypoxia (where the body or a region of the body is deprived of adequate oxygen supply at the tissue level) | High | The Sleep module review's the patient's oxygen saturation level, and will display an alert should the patient be deemed to be hypoxic | Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient is hypoxic. All data is pulled through to the patient reports. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Blood Pressure<br><br>The patient might be suffering from high blood pressure | High | The Sleep module reviews the patient's Blood Pressure level, and will display an alert should the patient be deemed to have high blood pressure | Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient has high blood pressure. All data is pulled through to the patient reports | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Restless Legs/PLM index<br><br>The presence of restless legs complicating OSA will change the management for the patient and misinterpretation of the PLM index in isolation may lead to misdiagnosis of Restless Legs | Moder ate | The Sleep module detects the presence of restless legs syndrome and integrates this with the PLM index | The Sleep module specifically detects the following:<br><br>1)The symptoms consistent with Restless Legs<br><br>2) PLM index and algorithms specifically prompt advice regarding the presence of PLM index in isolation | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Smoking is considered a primary cause of cardiovascular disease within the patient population; therefore smoking cessation referrals are considered to be vital | Low | The Sleep module reviews the patient's smoking status – with the pack years calculated. The package prompts the clinician with further questions and a request to refer the patient to a smoking cessation course if | Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient is a current smoker. He patient's wishes and | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of | Tested 19/11/2020 Passed |

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| | | | they are considered to be smokers | referrals are pulled through to the patient reports. An information box containing the key principles of smoking cessation. | Development cycle: [T-001], [T-002] | |
| Diagnosis | Occupation:<br><br>The subject's occupation may be a contributory factor to the Sleepiness | Mod | The Sleep module algorithms contain questions specifically regarding the presence of Shift Work Syndrome | Tested BC Don McClean9<br><br>Pass 19/11/20 | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Insomnia:<br><br>The patient could be misdiagnosed if the presence of insomnia is not investigated | Mod | The Sleep module algorithms contain questions specifically regarding the presence of Insomnia | Appropriate prompts are included in the module for an expected action to be taken by the clinician in the event that the patient has suspected insomnia and causes of insomnia listed in an information box | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Caffeine:<br><br>Missing the contribution of caffeine to the patient's symptoms | Low | An alert appears on screen should caffeine intake be close to Sleeping time | Appropriate prompts are included in the module for an expected advice to be taken by the clinician and this is featured in the reports | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Missing the contribution of alcohol to the patient's symptoms | Low | Alerts for consideration if the subject indicates alcohol consumption telling the operator re alcohol consumption prior to bedtime | Appropriate prompts are included in the module for an expected advice to be taken by the clinician and this is featured in the reports | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |

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| Diagnosis | Missing the contribution of insufficient Sleep to the patient's symptoms or a Sleep circadian issue | Low | The Sleep module records the Sleep onset times and duration of Sleep | Appropriate alert should short Sleep duration be present | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Tested Passed 19/11/20 |
| Diagnosis | Medications as a contributory factor to a symptoms/subject's presentation | Mod | Alert for medications contained in the software | Medications are linked in the report and there is a specific question regarding this. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |
| Diagnosis | Recognising the contribution of insomnia to the subject's presentation | Low | Alert for the presence of Insomnia according to ICSD criteria | Appropriate prompts are included in the module, with alerts are pulled through to the reports<br><br>Information regarding causes of insomnia provided | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Misdiagnosis of OSA as a cause of nocturia: May be a sign of other underlying health conditions e.g., prostatic cancer | High | Threshold for nocturia present | Appropriate prompt are present should the threshold be exceeded recommending further evaluation | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| Diagnosis | Documentation of Past Medical History and cardiac pathology<br><br>Useful for management particularly regarding | Mod | Alert at time of management decisions.<br>Atrial Fib<br>Stroke<br>Hypertension<br>Cardiac Issues | Past medical history is carried through to the patient reports. This highlights any previous cardiac issues and links it to screening for OSAS hence improving | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing | Tested 19/11/2020 Passed |

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| | threshold for therapy decisions | | | diagnostic accuracy | Phase of Development cycle: [T-001], [T-002] | |
| Diagnosis | A Clinical Examination should be performed on all patients at the time of the diagnosis, or where the patient's presentation warrants further examination. Not performing the Clinical Examination where appropriate could result in misdiagnosis. | High | The Sleep module reviews the patient's Clinical Examination status at the time of diagnosis. All patients are recommended to undergo an appropriate clinical examination | Appropriate prompts are included in the module, with alerts are pulled through to the reports. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| CPAP compliance : Residual Sleepiness | Residual Sleepiness on CPAP suggestive of alternative pathology and warrants further investigation.<br><br>Increased risk of motor vehicle accidents | High | The CPAP compliance module specifically measures the degree of Sleepiness on CPAP and asks regarding the presence of driving related Sleepiness | Appropriate alerting of residual Sleepiness recommending specialist referral | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |
| CPAP compliance : Ineffective therapy | The presence of an elevated AHI on CPAP could result in misdiagnosis | High | The CPAP compliance module contains a section regarding AHI on CPAP | Appropriate alerting of an elevated AHI on CPAP which is pulled through to the reports along with management plan<br><br>If an AHI is absent, this is mentioned in the report and prompts the clinician | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation | Testing / Verification | Notes |
|---|---|---|---|---|---|---|
| **Identification and management of abnormal blood results in the "Sleep Bloods section"**<br><br>**These include the following measurements:**<br>➢ **Glycated Haemoglobin (HbA1c)**<br>➢ **Sodium**<br>➢ **Potassium**<br>➢ **Urea**<br>➢ **Creatinine**<br>➢ **Hgb**<br>➢ **WBC**<br>➢ **Platelets**<br>➢ **Bicarbonate**<br>➢ **NT-ProBNP**<br>➢ **TSH**<br>➢ **Ferritin** | Blood results being entered incorrectly by the operator in the Guided Consultation in the "Sleep Bloods" section | High | The Sleep module does have the normal ranges on the "Sleep bloods" section". Any blood results that are outside the normal range are alerted and highlighted to the operator in the "Additional Considerations" section of the Patient report.<br><br>Any abnormalities in serum BNP and Bicarbonate are also highlighted on the "Management dashboard" | The result is displayed on the screen with a red warning sign should the value fall outside the specified normal range and these are pulled over to the patient report alerting the operator<br><br>The software has a "prescriber verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any high-risk issues identified will be looked at by a 2nd operator. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| **Identification and management of abnormal blood results in the "Sleep Bloods section"**<br><br>**These include the following measurements:**<br>➢ **Glycated Haemoglobin (HbA1c)**<br>➢ **Sodium**<br>➢ **Potassium**<br>➢ **Urea**<br>➢ **Creatinine**<br>➢ **Hgb**<br>➢ **WBC**<br>➢ **Platelets**<br>➢ **Bicarbonate**<br>➢ **NT-ProBNP**<br>➢ **TSH**<br>➢ **Ferritin** | Abnormal Blood results not being acted on despite being entered correctly by the operator | High | Any blood results that are outside the normal range are alerted and highlighted to the operator in the "Additional Considerations" section of the Patient report.<br><br>Any abnormalities in serum BNP and Bicarbonate are also highlighted on the "Management dashboard". These are key bloods which count as higher clinical risk than the others if overlooked<br><br>The software has a "prescriber verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any high-risk issues identified will be looked at by a 2nd operator. | This process has undergone rigorous testing which will continue periodically.<br><br>We also remind and alert the operator at the conclusion of the consultation to act on any abnormal findings including investigations | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 19/11/2020 Passed |
| **Identification and management of abnormal blood results in the "Sleep Bloods section"**<br><br>**These include the following measurements:** | Blood results not being appropriately alerted by the software despite being entered correctly by the | High | This has been tested and documented individually for each blood result displayed<br><br>The software has a "prescriber | This process has undergone rigorous testing which will continue periodically. | Clinical Lead Testing following Risk Analysis: [T-001], [T-002] | Tested 19/11/2020 Passed |

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| ➢ **Glycated Haemoglobin (HbA1c)**<br>➢ **Sodium**<br>➢ **Potassium**<br>➢ **Urea**<br>➢ **Creatinine**<br>➢ **Hgb**<br>➢ **WBC**<br>➢ **Platelets**<br>➢ **Bicarbonate**<br>➢ **NT-ProBNP**<br>➢ **TSH**<br>➢ **Ferritin** | operator and being outside the normal range clinically | | verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any high-risk issues identified will be looked at by a 2nd operator. | | Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | |
| **Identification and management of abnormal blood results in the "Sleep Bloods section" due to the abnormalities not being pulled over to the Management Dashboard**<br><br>**These include the following measurements:**<br>➢ **Bicarbonate**<br>➢ **NT-ProBNP** | Abnormal Blood results not being pulled over by the software to the Clinical Dashboard following completion of consultation | High | The software has a "prescriber verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any high-risk issues identified will be looked at by a 2nd operator. | There is a second screen on the clinical dashboard where there is another list of those patients triggering the "high risk" alerts appear. | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |

## 1.2. Clinical Risk Analysis: Management Dashboard

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation | Testing / Verification | Notes |
|---|---|---|---|---|---|---|
| **Clinical Dashboard** | The patient being incorrectly listed as having had or not having had an Initial Review/Return Consultation/CPAP set up consultation on the clinical dashboard graphs | High | Patients must be marked on a specific pathway when they are registered on the Lunghealth software. This forms part of the Lunghealth training. | There is a second screen on the clinical dashboard where there is another list of those patients who have been marked for a particular review e.g., Initial Review.<br><br>There is also a "Completed Review" list where | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |

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| | | | | patients who have already completed a designated review are marked, and this again is separate from the dashboard graphs | | |
| **Clinical Dashboard** | The patient not being assigned an RTT pathway and therefore the "RTT clock" would not accurately capture when the RTT date for the patient has been breached | Moderate | The RTT clock starting date must be marked at the time of registration on the software. This forms part of the Lunghealth training | We have built in the backup measure of the RTT clock starting at the point of registration into the software platform in the event of the patient not being assigned an RTT date by the operator. Whilst this does may not give an exact date i.e. point at which the referral was reviewed, it still gives the operator a date which can be used to map RTT with a degree of accuracy. | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |
| **Clinical Dashboard** | The presence of "high risk" clinical features related to driving not being pulled over to the dashboard related to the Initial Review and the CPAP compliance consultation | High | The software has a "prescriber verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any driving related issues identified will be looked at by a 2nd operator. | There is a second screen on the clinical dashboard where there is another list of those patients triggering the "high risk" driving alerts appear. | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |
| **Clinical Dashboard** | The presence of "high risk" clinical features not related to driving e.g., presence of neurological conditions not being pulled over to the dashboard | High | The software has a "prescriber verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any high-risk issues identified will be looked at by a 2nd operator. | There is a second screen on the clinical dashboard where there is another list of those patients triggering the "high risk" alerts appear. | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |

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| **Clinical Dashboard** | The presence of hypoventilation alerts e.g., low oxygen saturation not being pulled through to the dashboard | High | The software has a "prescriber verification" system where a designated prescriber has to approve each consultation performed by a non-prescriber. Hence any high-risk issues identified will be looked at by a 2nd operator. | There is a second screen on the clinical dashboard where there is another list of those patients triggering the "high risk" alerts appear. | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |
| **Clinical Dashboard** | Patients being incorrectly assigned a therapy option on the dashboard graphs which was different from the actual therapy option chosen by the operator | High | This has been tested and cleared testing. Regular auditing is performed by the Lunghealth team to ensure data accuracy. | Once a subject has been assigned CPAP therapy as a treatment option, they automatically enter the category box "Awaiting CPAP therapy". This allows the operator to identify those who need CPAP. This is a separate mechanism from that of the dashboard graphs. It applies to CPAP only but the majority (i.e., 80% and above) of patients entering the service need CPAP so it covers most of the patient population | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |
| **Clinical dashboard** | Patients incorrectly assigned an erroneous CPAP compliance status on the clinical dashboard graphs | High | This has been tested and cleared testing. Regular auditing is performed by the Lunghealth team to ensure data accuracy. | There is a backup mechanism where those who are still Sleepy despite being on CPAP can also be identified irrespective of CPAP compliance. Whilst this doesn't deal with the compliance | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |

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| | | | | issue directly, it enables the operator to deal with those patients who are still symptomatic on CPAP irrespective of compliance status | | |
| **Clinical Dashboard** | Patients having their consultation performed and this activity hasn't been pulled over to the dashboard | High | This has been tested thoroughly and has cleared testing | Regular auditing is performed by the Lunghealth team to ensure data accuracy. | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |
| **Clinical Dashboard** | Patients being incorrectly assigned a therapy option on the dashboard graphs which was different from the actual therapy option chosen by the operator | High | This has been tested and cleared testing. Regular auditing is performed by the Lunghealth team to ensure data accuracy. | Once a subject has been assigned CPAP therapy as a treatment option, they automatically enter the category box "Awaiting CPAP therapy". This allows the operator to identify those who need CPAP. This is a separate mechanism from that of the dashboard graphs. It applies to CPAP only but the majority (i.e. 80% and above) of patients entering the service need CPAP so it covers most of the patient population | Clinical Lead Testing following Risk Analysis: [T-006][T-007]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-006][T-007] | Tested 06/04/2021 Passed |

## 1.3. IT Integrity Data Risk Analysis

This section outlines the identified levels of risks to the integrity of the LungHealth Guided Consultation package and its data - and the measures that have been put in place to avoid and/or mitigate such risks

### 1.3.1. Data Processing or Handling

The identified levels of risk as a result of system, communication and application errors or failures that may result in data being corrupted or lost - and the measures that have been put in place to avoid and/or mitigate such risks

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation |
|---|---|---|---|---|
| System | System Crash or local failure resulting in an unhandled error within the software | High | If an unhandled error occurs during a Guided Consultation the User is presented with an error screen with an option to attempt to reload the page | The error screen contains information explaining that the error has been logged, with information on how they may contact technical support and expected response times if the error persists.<br><br>In addition, the Contact screen contains the same information<br><br>The Patient record is maintained with the review left open for 24 hours. Following this, a new review must be started. |
| System | Complete System Crash or local failure resulting in an inability to complete the current review | High | | If the error screen is displayed, this contains information explaining that the error has been logged, with information on how a User can contact LungHealth technical support and expected response times.<br><br>In addition, the Contact screen contains the same information<br><br>If a complete failure results in the User losing complete access to the LungHealth Consultation software; the Patient record is also maintained with the review left open for 24 hours. Following this, a new review must be started. |
| Hardware Failure | A hardware error at the data centre resulting in a loss of patient data | High | The LungHealth Guided Consultation is a web-based application hosted within the HSCN network, via our ISO 27001 certified hosting partner, AIMES Ltd. (https://aimes.uk/p-accreditation/)<br><br>AIMES Organisation Code: 8J121<br><br>Onsite and offsite web server backups are performed nightly | All server data (including patient data) is backed up by AIMES, the LungHealth hosting supplier every 24 hours<br><br>A continuity plan is in place with actions detailed in a Disaster Recovery plan in the result of any software downtime or data loss. The Disaster Recovery plan is tested annually. |
| **Patient Mismatch** | The wrong patient might be matched at LungHealth | High | All patient matches must match by NHS Number, which acts as a unique identifier across all NHS systems | |
| **Patient Medications** | Miss-entry of patient's current prescription | High | The LungHealth software communicates with the local clinical system to pull down the | Alerts exist to check for inconsistencies and unusual / not recommended drug combinations. |

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| | | | patient's most recent demographics. An alert appears on the current medication screen advising the clinician to check the patient's prescription with the patient's clinical record and the patient themselves | Such alerts are carried through to the reports if not addressed. |
| **Patient Data Processing Error** | Previous historic patient data may be over-written when performing new reviews or viewing patient's | High | - Patient data is timestamped<br><br>- Historic data (such as patient reviews) cannot be overwritten or re-opened for edit | |

### 1.3.2. Data Validation Control Risks

The identified levels of risk that may result in the input of poor or incomplete data - and the measures that have been put in place to avoid and/or mitigate such risks

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation | Testing / Verification | Notes |
|---|---|---|---|---|---|---|
| Diagnosis | The patient being staged at an incorrect level of OSA severity of poor or incomplete Test Result Data | High | Input validation for Spirometry is in place for:<br>• Total Recording Time<br>• Total Sleep Time<br>• Ensuring Either an OHI or AHI is input | A regular data analysis is performed on historic data to check the validity of Spirometry data | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |
| | Incorrect BMI through incorrect data entry | Low | Input validation is in place for:<br>• Height<br>• Weight | A regular data analysis is performed on historic data to check the validity of data | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |
| Smoking | Incorrect pack years calculated | Low | Input validation is in place for:<br>• Smoking years<br>• Cigarettes per day | A regular data analysis is performed on historic data to check the validity of data | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing | Tested 20/11/2020 Passed |

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|---|---|---|---|---|---|---|
| | | | | | Phase of Development cycle: [T-001], [T-002] | |
| Oxygen Saturation | Patient inputs incorrect oxygen saturation. Inputs words or puts in a value greater than 100% | High | Input validation is in place for:<br>• Oxygen saturation | A regular data analysis is performed on historic data to check the validity of data | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |
| Blood Pressure | The patient inputs the wrong blood pressure. Inputs words or mixes the diastolic and systolic values around | High | Input validation is in place for:<br>• Diastolic Blood Pressure<br>• Systolic Blood Pressure<br>• The Health professional is asked to repeat an abnormal measurement | A regular data analysis is performed on historic data to check the validity of data | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |
| Pulse | The clinician may input a value that one would consider too high for any pulse value. Or input words. | **High** | Input validation is in place for:<br>• Pulse | A regular data analysis is performed on historic data to check the validity of data | Clinical Lead Testing following Risk Analysis: [T-001], [T-002]<br><br>Standard UAT Performed during Testing Phase of Development cycle: [T-001], [T-002] | Tested 20/11/2020 Passed |

## 1.3.3. System Updates / Data Changes

The identified levels of risk as a result of system changes or system updates

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation |
|---|---|---|---|---|
| **Process** | System errors introduced due to unplanned system or data updates performed by the developer | High | Change request process is in place with a 2-step sign-off process is in place for all system changes | System data backups are performed nightly to roll back any erroneous changes<br><br>Onsite and offsite web server backups are performed nightly, performed by AIMES UK<br><br>When hosted privately, the LungHealth development team will work with local IT providers to ensure a suitable rollback plan is in place. |
| **Process** | System errors introduced due to planned system or data updates performed by the developer | High | Multi-phased Test process is in place, which requires a clinical lead, and a separate clinical tester to test each change within a planned change | System data backup is performed nightly to roll-back any erroneous changes<br><br>Onsite and offsite web server backups are performed nightly, performed by AIMES UK<br><br>When hosted privately, the LungHealth development team will work with local IT providers to ensure a suitable rollback plan is in place. |
| **Process** | Clinical errors introduced following a planned system or data update | High | A specification is developed and signed off by the clinical lead before any planned development. | Following development changes, the testing documentation and process flows are updated and signed off by the clinical lead following clinical updates |

## 1.3.4. System Data & Security Risks

The identified levels of risk as a result of malicious actions

In addition to the specific avoidance and mitigation measures listed below, LungHealth also routinely maintains the following commitments:

- LungHealth Ltd maintains a commitment to the NHS Data Security and Protection Toolkit and the standards maintained within it
  - Organisation Code: 8K653
- LungHealth Ltd has Cyber Essentials accreditation
  - ASME-CE-019796
- LungHealth undertakes a regular PEN test, performed by BSI Group [R10]
- LungHealth maintains a commitment to training all people within the organisation with access to personal data with appropriate data security and protection, and cyber security, training every year
  - LungHealth employees are granted continuous access to the e-LfH training database for all its training requirements.

| Risk Location | Risk Description | Risk Level | Avoidance Measures | Mitigation |
|---|---|---|---|---|
| **Access** | Loss or editing of data due to unauthorised access | High | User access is controlled by access roles within the application. User Role access is tested as part of LungHealth's annual PEN Test, performed by BSI Group<br>Healthcare professionals using the app. are deemed competent by the practice to review Sleep patients, and understand that in the event of failure that they can revert to a paper / manual process in the absence of LungHealth<br><br>All LungHealth staff complete mandatory data security training as part of their GDPR training suite. | Onsite and offsite web server backups are performed nightly. Server Backups are performed by AIMES UK.<br><br>A continuity plan is in place with actions detailed in a Disaster Recovery plan in the result of any software downtime or data loss. The Disaster Recovery plan is tested annually. |
| **Availability** | Loss of access due malicious actions | High | LungHealth undertakes an annual PEN test of its Guided Consultation software to ensure it is protected and not susceptible to common security vulnerabilities, such as described in the top ten Open Web Application Security Project (OWASP) vulnerabilities. LungHealth's annual PEN Test is performed by BSI Group<br><br>Healthcare professionals using the app. are deemed competent by the practice to review Sleep patients, and understand that in the event of failure that they can revert to a paper / manual process in the absence of LungHealth<br><br>Within LungHealth's server: All traffic passing through LungHealth Ltd. firewalls – whether internally from one network to another or externally to and from the Internet – is monitored. However only critical, error and warnings are logged (i.e., all traffic that is denied access).<br><br>A Network monitoring tool is used to analyse traffic on LungHealth Ltd. systems. This provides LungHealth Ltd. system administrators with data about current levels of network utilisation, which can assist with diagnosing network problems and may provide information about potential security problems. | A continuity plan is in place to respond to threats to data security, including significant data breaches or near misses, and it is tested once a year as a minimum.<br><br>LungHealth's business continuity plan covers both data and cyber security.<br><br>Onsite and offsite web server backups are performed nightly. Server Backups are performed by AIMES UK.<br><br>A continuity plan is in place with actions detailed in a Disaster Recovery plan in the result of any software downtime or data loss. The Disaster Recovery plan is tested annually. |

LungHealth maintain the following documents, and SOPs which relate to our overall risk assessment and these documents are available to LungHealth users upon request.

Please contact info@lunghealth.co.uk if you are a registered user and would like to review any of the documents highlighted below.

| # | Document Descriptor | Document Title |
|---|---|---|
| R1 | Data Protection Impact Assessment - LungHealth | 2020-08-19 Data Protection Impact Assessment - LungHealth v1.docx |

| # | Document Descriptor | Document Title |
|---|---|---|
| R2 | Change Request SOP | 2020-08-14 - Change Request SOP process - v1.1.docx |
| R3 | Bug Reporting SOP | 2020-08-12 - Bug Reporting SOP process - v1.docx |
| R4 | Testing Specification LungHealth Template Document | 2020-08 - Testing Specification LungHealth Template 08-20.docx |
| R5 | Technical Specification LungHealth Template Document | 2020-08 - Technical Specification LungHealth Template 08-20 |
| R6 | LungHealth Disaster Recovery & IT Continuity SOP Document | LungHealth Disaster Recovery & IT Continuity SOP v1.docx |
| R7 | LungHealth Data Quality Management Policy - v2.0 November 2020 Document | LungHealth Data Quality Management Policy - v2.0 November 2020.docx |
| R8 | Technical support SOP process Document | 2019-09-04 - Technical support SOP process - v3.docx |
| R9 | LungHealth Guided Consultation Server Overview Document | LungHealth Guided Consultation Server Overview v1.docx |
| R10 | PEN Testing Report, BSI | CSIRUKPRJ-1181-RPT-01 LungHealth Limited Summary of Findings v1.0.xlsx<br><br>CSIRUKPRJ-1181-RPT-01 LungHealth Limited Web Application Test Report v1.0.pdf |
| R11 | LungHealth Software Architecture Document | LungHealth Software Architecture Overview v1.docx |

## Summary

LungHealth are committed to ensuring that our product development is clinically led. Our products are robustly tested through both a formal risk assessment process and robust testing process by experts in the respiratory field prior to deployment.

LungHealth continuously refine our products based on user feedback and changes to NHS requirements in relation to the management of patients with Obstructive Sleep Apnoea and or sleep related conditions.