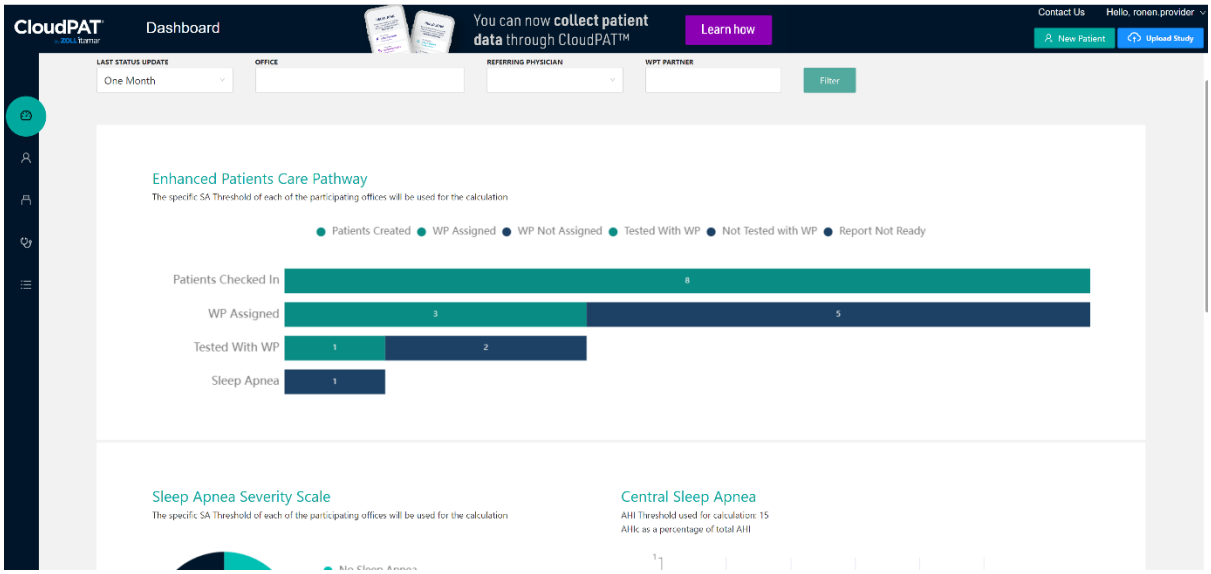
# CloudPAT

## Itamar Medical OM2200005

## Web Software Operation Manual




**March 2023**

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# 1 Introduction to CloudPAT

## 1.1 Intended Use of the CloudPAT (CP) ®

The CloudPAT (CP) is a web-based, cloud system for patient care pathway management specifically for patients suspected to have sleep-related breathing disorders. The CloudPAT is intended to display and store the medical device data from WatchPAT by interfacing with zzzPAT modules. The system allows physicians to enter patient data.

## 1.2 zzzPAT & WatchPAT Interface S/W – Definition

zzzPAT and WatchPAT Interface are software packages used with the WatchPAT™ device to aid in the diagnosis of sleep related breathing disorders, detecting REM, Light Sleep, Deep Sleep and Wake stages and measuring snoring intensity and body position states. The S/W displays the signals recorded by the WatchPAT™ device, automatically identifies breathing disorder events, records sleep stages; tracks snoring and body position data; and then generates a comprehensive report for the physician.

## 1.3 CloudPAT S/W – Definition

1. The CloudPAT (CP) is a HIPAA-compliant, web-based cloud application providing a management system for sleep/breathing disordered patients from diagnostic to treatment compliance.
2. CP uses data that has been taken from the WP device. CloudPAT uses the WatchPAT Interface package for the WatchPAT device.
3. CP is intended to display and store the medical device data without controlling or altering its functions or parameters. CloudPAT does not modify, interpret, or add value to the data or the display of the data.
4. CP allows management of the study by different practitioners, including the preparation and uploading of the study by one group of sleep technicians /physicians and the review and interpretation of the sleep study by other sleep specialists.
5. CP can be connected with different CPAP compliance databases and can present CPAP usage data.
6. CP is compatible with the SleePath application - assigning digital questionnaires, sending notifications, and presenting data collected via SleePath.

## 1.4 Overview

CloudPAT uses the zzzPAT's analysis. In cases where the entire night's data needs to be viewed and automatically detected events need to be revised manually, the study data can be downloaded to a local PC using the zzzPAT.

This manual provides the information necessary for routine use of the CloudPAT software.

## 1.5 Terminology

CloudPAT supports various types of users and entities.

- Office – a practice responsible for administering the tests. Office can include one or more referring physicians, as well as technicians and administrative staff.
- Referring Physician – the primary physician or dentist prescribing the sleep test.
- User – typically a Provider such as a technician or a nurse, but might also be a physician. This is the most common type of user using CloudPAT functions such as Creating a new study, Uploading a study, Viewing reports and Managing Patient Information.
- Interpreting Physician– a physician (typically Board-certified) performing the sleep study analysis, interpretation, diagnosis and recommendations. CloudPat functions such as reviewing and

interpreting studies and managing templates for diagnosis and recommendation may also be performed.

- Sleep Physician – a combination of Provider and Interpreter.
- Patient – the person undergoing the sleep study.

## 1.6 Minimum Requirements

An internet connection using a PC workstation with Microsoft Win8 and above, running at a minimum upload speed of 1 Mbps and supported browser (Edge, Chrome or Firefox) is required.

**Note**

Figures included in this Operation Manual are for reference only and the actual design and appearance might be different in the final product.

# 2 Setting CloudPAT Access

## 2.1 Obtaining an Account

Usage of CloudPAT is intended for WatchPAT customers only (using all supported devices). A secure and individual login account must be assigned by an Itamar administrator.

To obtain a Username and Password, contact your Sales Representative or send an email to CloudSupport@itamar-medical.com. After a vetting process, you will get an email invitation containing your login information.

CloudPAT supports SSO connectivity. If enabled for your organization, the login shall be done through your SSO portal. Please contact your system administrator for further details.

CloudPAT supports the following languages based on user settings (including emails, zzzPAT viewer, Sleep Report and Exports to CSV): English, French.

## 2.2 Accessing CloudPAT

All subsequent access to CloudPAT will be according to the server location:

| Server location | Direct link |
|---|---|
| United states | https://cloudpat.itamar-medical.com/ |
| European Union | https://cloudpat-eu.itamar-medical.com/ |
| United Kingdom | https://cloudpat-uk.itamar-medical.com/ |
| Australia | https://cloudpat-au.itamar-medical.com/ |

Access to CloudPAT begins with the Sign In screen and includes a link to Itamar's Terms and Conditions Screen where Username and Password are entered.

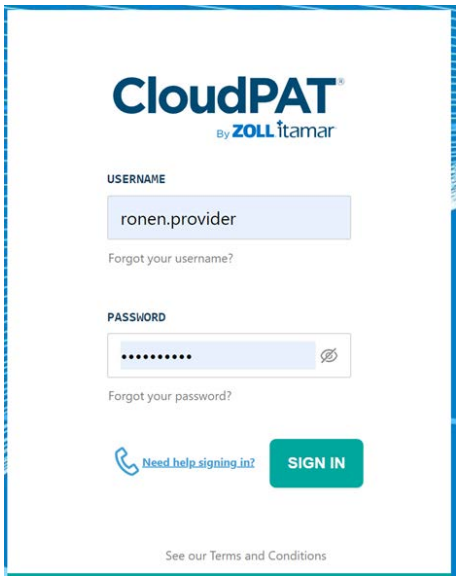


**Figure 1: Sign In Screen**

After several failures to sign into CloudPAT, your account may be temporarily locked. If such an event occurs, CloudPAT will send a notification message to your email account.

An office you belong to may restrict CloudPAT access to a specific IP address range, or to a particular country group within their region.

If you do not meet the access settings, your login will be blocked, and the proper error message will be displayed.

To set up login restrictions, please contact CloudPAT Support.

After a successful login, a what's new message may be displayed, listing the new features of the latest version and a banner may be displayed at the top of the screen.

## 2.3 Setting [Initial] Password

Upon initial account setup, you will be prompted to enter a temporary password.

CloudPAT will prompt you to pick a new password upon first-time sign in.

The minimum password length is eight characters, and the password must contain characters from three of the following four categories: English uppercase characters (A through Z), English lowercase characters (a through z), digits (0 through 9), Non-alphabetic characters (for example: ! , $, #, %).

The new password shall be different from any of the user's previous passwords.

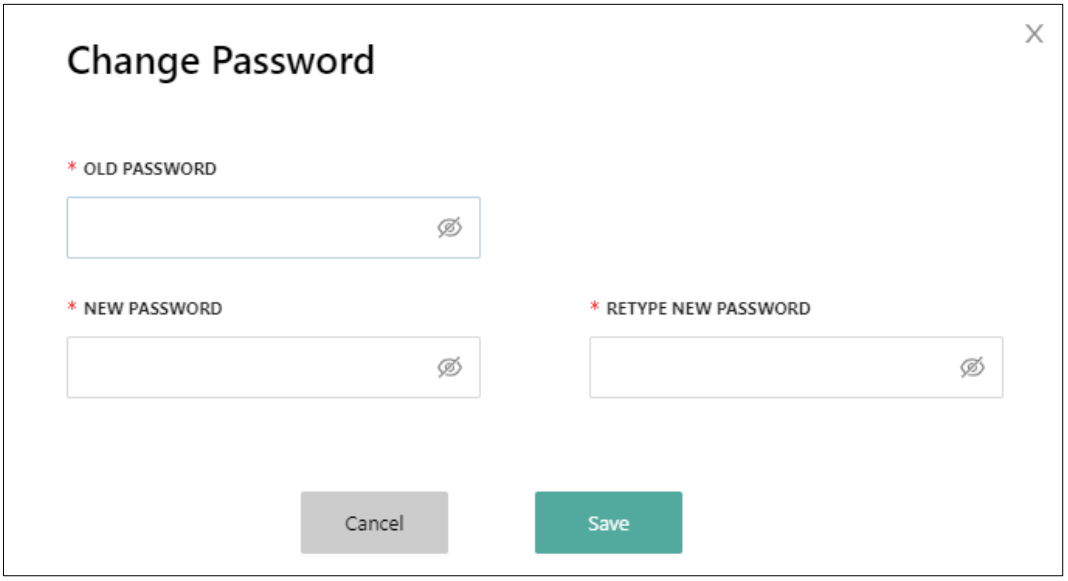


**Figure 2: Change Password Screen**

**Note**

All asterisk (*) tagged fields are mandatory and should be filled.

### 2.3.1 Forgot Password / User Name

In the event you forget your password, simply click on the “Forgot your password?” link on the Sign In screen, enter your User Name and an email will be sent to you with a link to reset password.

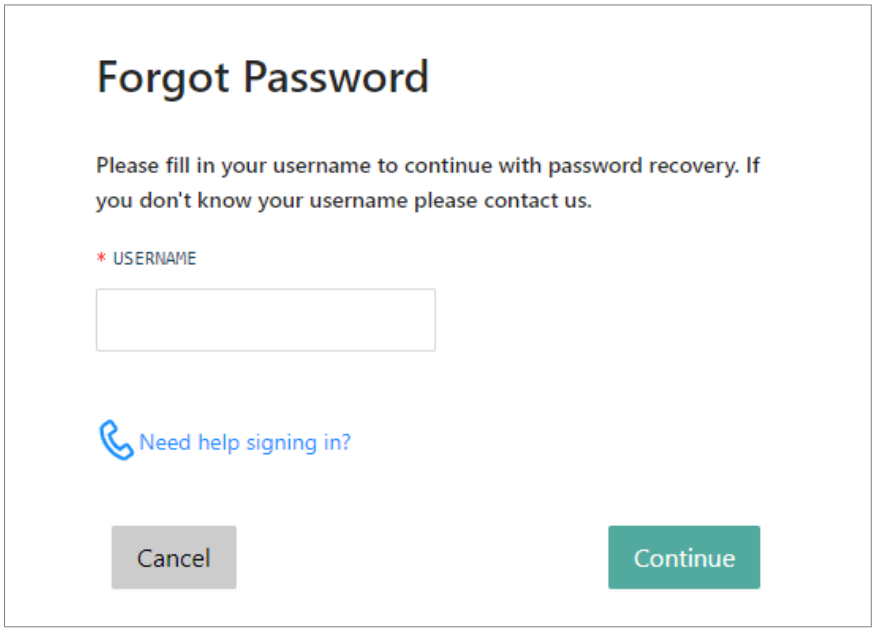


**Figure 3: Forget Password Screen**

In the event you forgot your User Name, simply click on the “Forgot your username?” link on the Sign In screen, enter your Email and an email will be sent to you with the associated User Name.

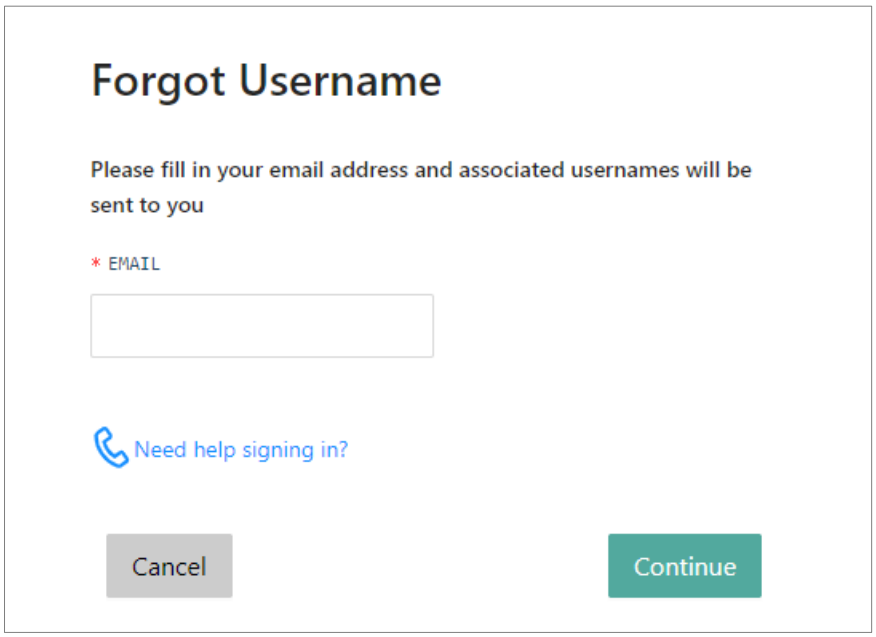


**Figure 4: Forget User Name Screen**

### 2.3.2 Contact Us

The Contact Us screen includes two communication channels as well as links for downloading the latest CloudPATio client and WatchPAT 300 Device Drivers.

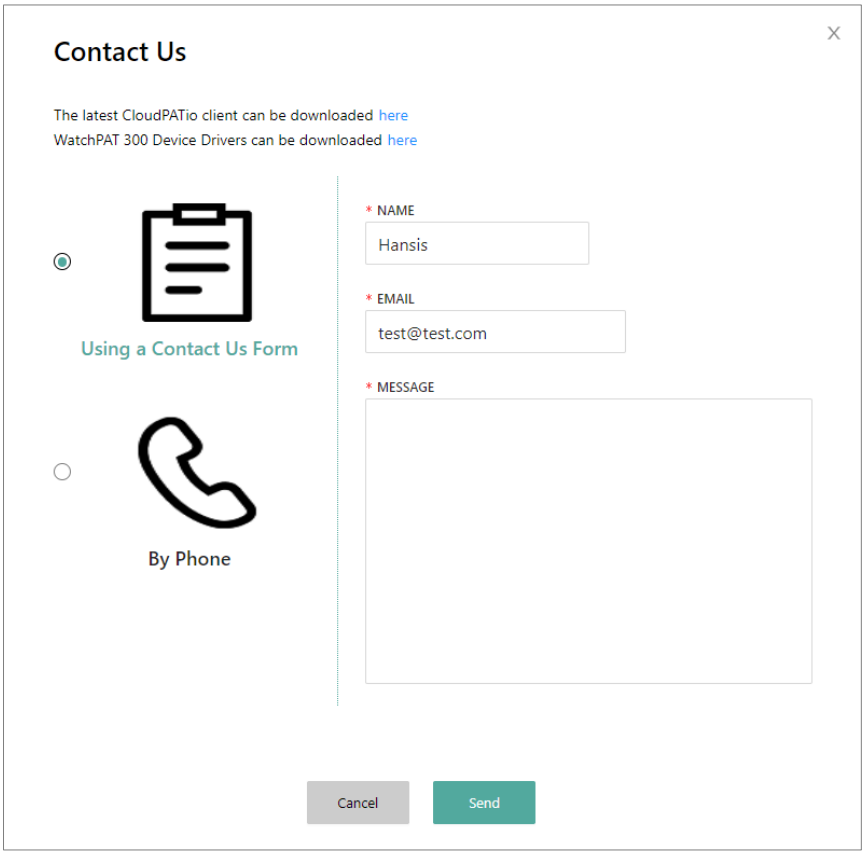


**Figure 5: Contact Us Screen – by form**

For administrative support and help with any problems you experience with CloudPAT, please contact us by clicking the “Contact Us” link from any window.

The Contact Us Using a Form creates a ticket for Itamar-Medical personnel to address.

Please contact customer support by selecting the “By Phone” option if any difficulties arise. This screen contains the up-to-date phone numbers.

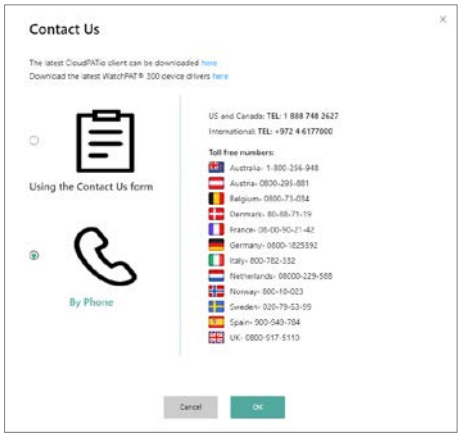


**Figure 6: Contact Us Screen – by phone**

### 2.3.3 Email Preferences

There is a link called “Manage User Preferences” under the User menu which opens a designated screen listing the email options for the user. The user may customize the options. Email options are role based and not identical to all system users.

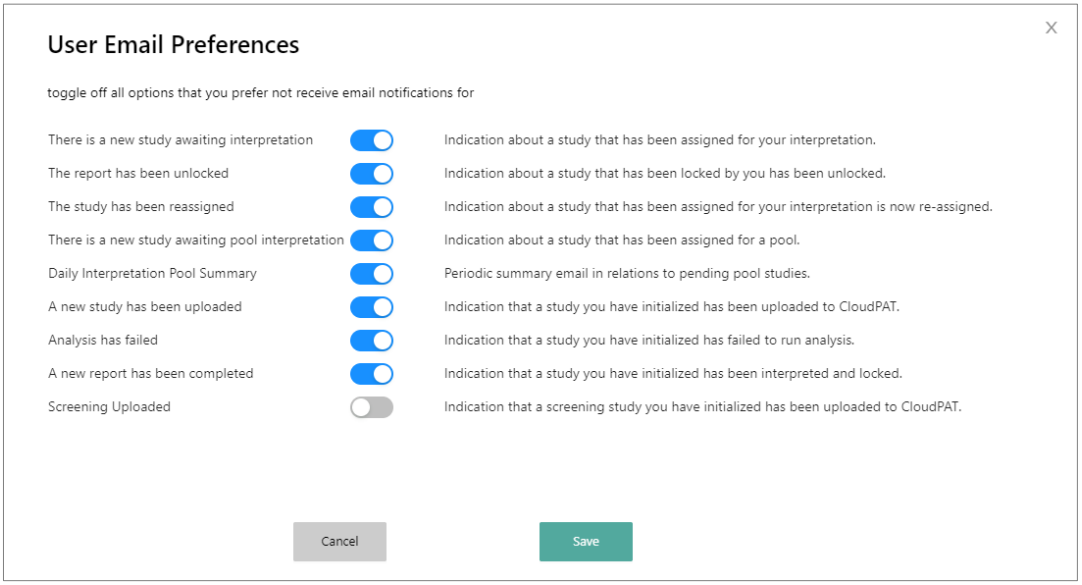


**Figure 7: Email Preferences**

# 3 Using CloudPAT as a User

## 3.1 Main Access Screen

Here are the main actions that can be selected from this screen:

- Dashboard - monitors patient progress and gives physicians and staff better control over patient care.
- New Study – prepares a new patient & initializes WatchPAT™ device for a new sleep study.
- Upload Study – uploads sleep study files from WatchPAT™ device to the CloudPAT web server and subsequent redirection (e.g., interpretation by an Interpreting Physician) according to pre-determined instructions.
- Patients – enables the user to see which sleep studies have been performed on patients, alter the patient's information and/or generate a follow-up sleep study for an existing patient.
- Devices – Displays a table of the associated devices; also allowing access for more details for particular device.
- Managing Referring Physicians – allows the user to directly manage the referring physicians associated with the office.
- Configuring Managed Lists - allows the user to manage the following lists: Medications, Diseases, Statuses, and Insurers; the user may also search for existing entries from global and local office level lists or add new ones.

## 3.2 Dashboard

The Dashboard includes the following items:

### 3.2.1 Enhanced Patient Care Pathway

The Enhanced Patient Care Pathway is a stacked bar chart displaying statistics from the selected patient group. It follows the patient through four stages, beginning at check-in until assessment of their Sleep Apnea.

At each stage along the pathway, the total number of patients is listed, along with the percentage from the previous stage.

Each stage is compromised from 1-3 subsections that when combined total the number of patients in the first section of the previous stage.

Selecting any of the sections will display a list of patients based on the selected criteria, and selecting a patient will display the Patient Details Screen.

Tooltip is displayed next to the segment when the mouse hovers over the icon.

The results can be filtered by Office, Referring Physician and Cycle Period.

The following stages are displayed in the funnel:

1. Patients checked in: Number of patients in selected group (percentage is always 100%).
2. WP assigned:
    a) WP assigned (main): Patients assigned with initialized WatchPAT device, including those patients who have returned the device and the WP study was uploaded to CloudPAT but not yet analyzed.
    b) WP not assigned: Patients not yet assigned a WatchPAT device.
3. Tested with WP:
    a) Tested with WP (main): Patients successfully completed the WatchPAT Study and the data successfully analyzed.
    b) WP Study Failed: Patients' WP study was uploaded to CloudPAT but no AHI was calculated.
    c) Not tested yet: Patients' WP study not yet uploaded to CloudPAT.
4. Sleep Apnea:
    a) Apnea Positive (main): Patients positively diagnosed with sleep apnea, i.e., AHI above the office-defined threshold.
    b) Apnea Negative: Patients with AHI below the threshold.
    c) Report Not Ready: Patients with successfully uploaded studies to CloudPAT but the report is not ready.
5. Treatment Setup: Patients belonging to an office with CPAP compliance enabled.
6. CPAP Compliance:
    a) Complying: Patients complying with CPAP therapy.
    b) Under 30 days: Patients having CPAP data for fewer than 30 days.
    c) Inactive: Patients having no CPAP data for more than a predetermined period (system parameter).
    d) Not Complying: Remaining patients in "Treatment Setup" segment.
7. Residual AHI > 10: Counting patients in treatment whose average AHI exceeds 10 during the last 30 days.

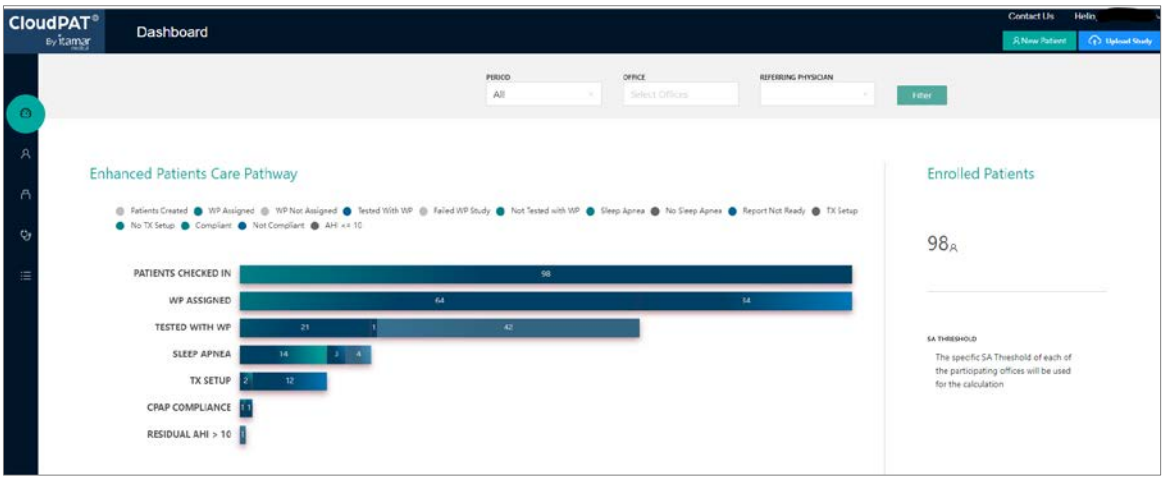


**Figure 8: Enhanced Patient Care Pathway**

### 3.2.2 Screening Patient Care Pathway

If your office is configured for screening questionnaires, you can create a new screening patient by compiling the answers to a series of questions from the SleePath app.

CP provides a screening funnel widget based on stacked rows displaying the patients' progression in the screening process. Each bar represents the status in respect to the relevant stage.

1. Screening Created
2. Screening Assigned
3. Screening Loaded
4. WatchPAT Decision
    a) Assign WP
    b) No Sleep Study
    c) Pending Decision.

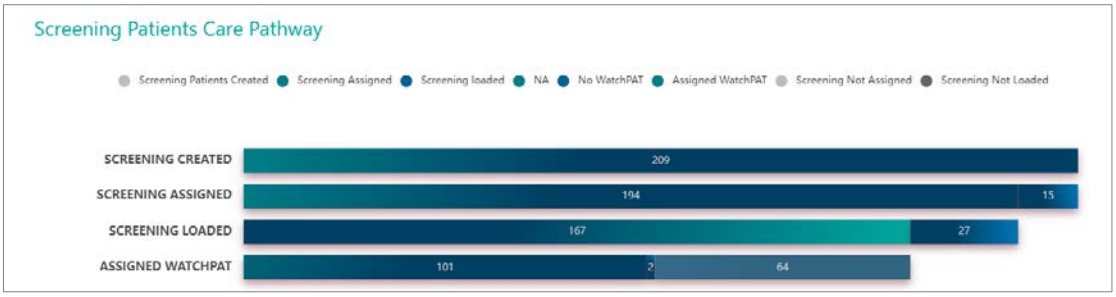


**Figure 9: Screening Patient Care Pathway**

### 3.2.3 Sleep Apnea Severity Scale

The Sleep Apnea Severity Scale is a pie chart indicating the Sleep Apnea Severity Scale for Tested with WP patients containing four levels (according to the office settings):

1. No Apnea (Green)
2. Mild Apnea (Yellow)
3. Moderate Apnea (Orange)
4. Severe Apnea (Red)

When a section is selected, the respective query in the patients' table and the Sleep Apnea filter will display the four levels.

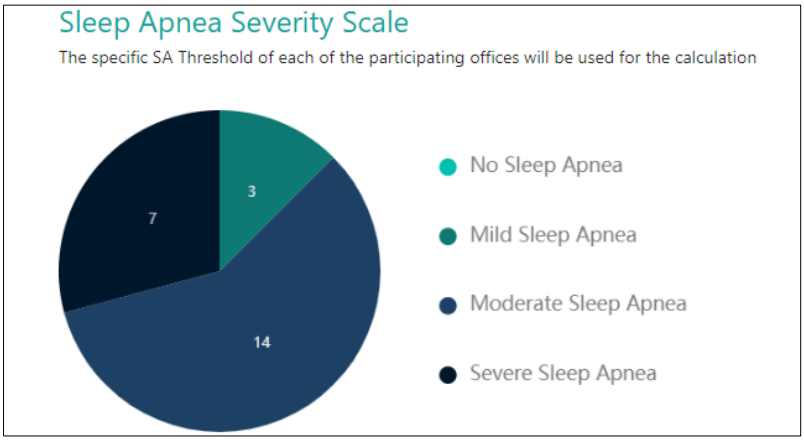


**Figure 10: Sleep Apnea Severity Scale**

### 3.2.4 Central Sleep Apnea bar chart

The Central Sleep Apnea bar chart shown to the right of the Sleep Apnea Severity Scale including these ranges of % AHIc / AHI. The calculations is based on the Central office settings. The thresholds are displayed if they are identical for the requested offices.

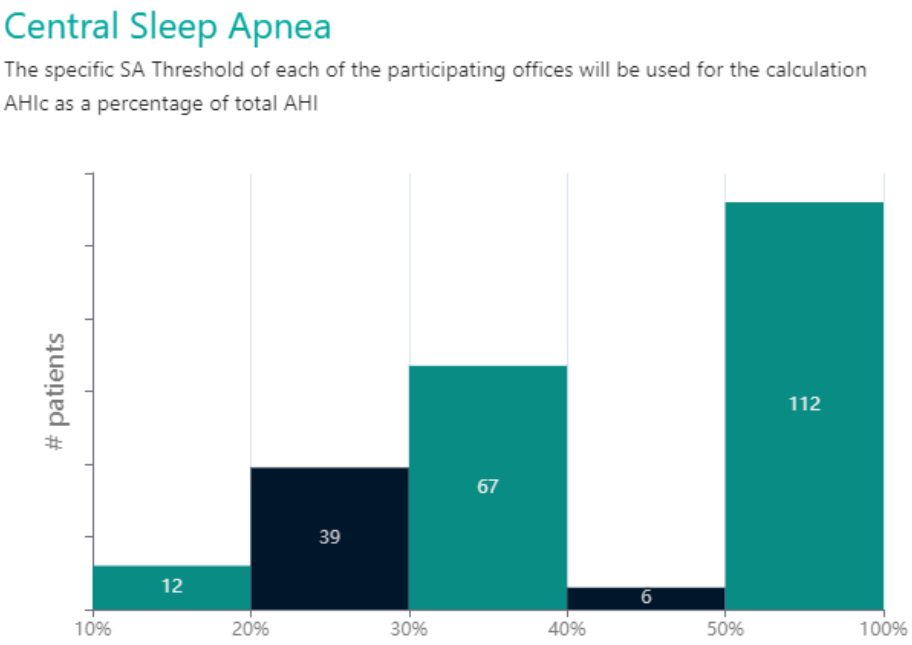


**Figure 11: Central Sleep Apnea bar chart**

## 3.3 Managing Patients

You may browse or edit existing patient details by pressing “Patients” from the main screen which will display the Search for Patients Screen. Click “Search” to see a list of all patients.

You can enter filters to limit the search results.

The search fields are dynamic and so are the table columns.

You may click on the CSV icon to export the list of patients to your PC.

There is an option to toggle between single (latest) study per patient to multiple (show all studies).

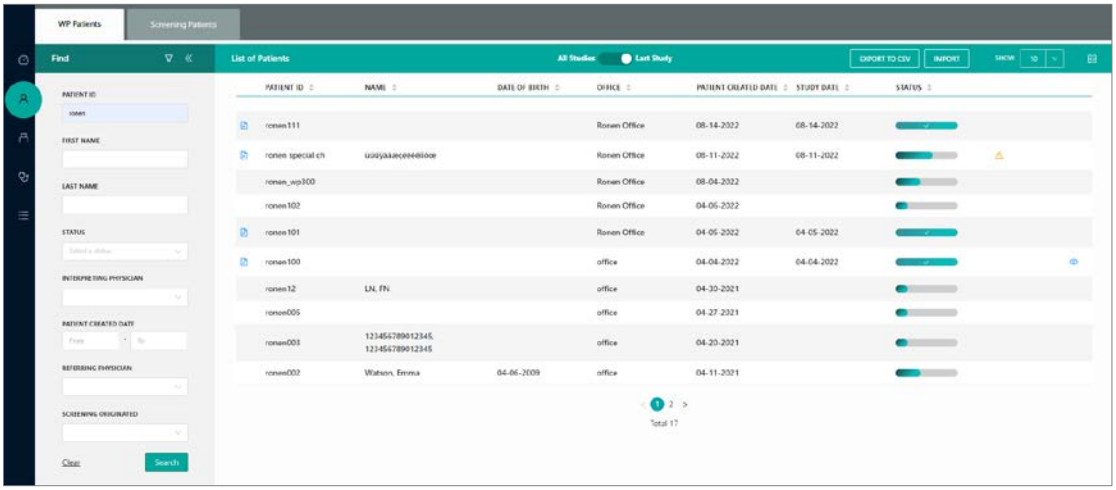


**Figure 12: Patient Table Screen**

Clicking on a row opens the patient's details screen.

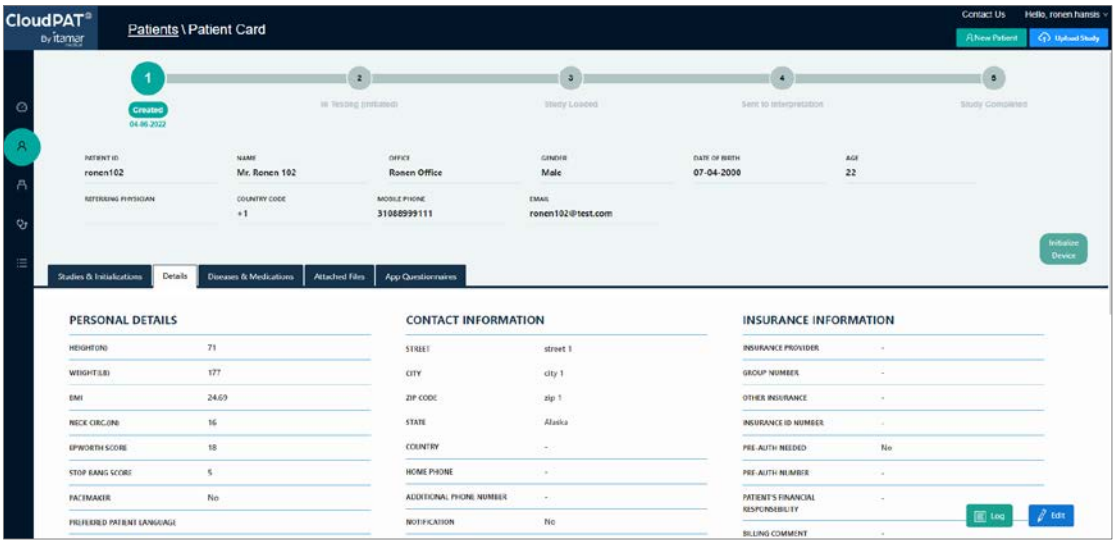


**Figure 13: Patient Details Screen**

## 3.4 Creating a New Patient

When creating a new patient, erroneous fields and empty mandatory fields will be highlighted in red.

It is possible so configure specific fields as additional mandatory fields by contacting the system administrator.

The user may attach files which will be associated to the patient's record.

You can save the patient record at any stage and return to it later from the "Patients" screen.

Filling in the patient name is recommended for easier patient management.

There is an office setting to configure key patient details fields as mandatory or not.

When a new patient is created or edited for an office, saving would not be possible if fields defined as mandatory are left blank.

Patient Details screen includes the following tabs: Details, Diseases & Medications, Attached Files and options for Studies & Initializations, App Questionnaires and Compliance Data

Patient Details tab includes the following sections: Header Section, Personal Details, Logistic Comments, Contact Information, Study Details, Insurance Information, Additional Information, Status Information.

Changes to Patient Details are captured in the Audit Trail Screen by clicking on the Log button.

### 3.4.1 Creating a New WatchPAT Patient

In order to prepare the WatchPAT™ device for a new patient please select “New WP Patient”.

This will create a new patient record and open the patient screen.

The following steps are involved in preparing for a new study:

- The mandatory fields are Patient ID and the selection of an office, if the user is associated with more than one office. Other mandatory field may be defined at the office level.
- The Patient ID cannot be changed once a device was initiated.
- Pacemaker – select this option if the patient has an implantable pacemaker. The CloudPAT will automatically detect segments where the PAT pulses seem to be paced and exclude these segments from the analysis.

**Note**

Some types of Pacemakers are excluded from the use of the WatchPAT device. See the device’s Operating Manual for more details.

Once the patient definition is completed, press “Save and Initialize Device”.

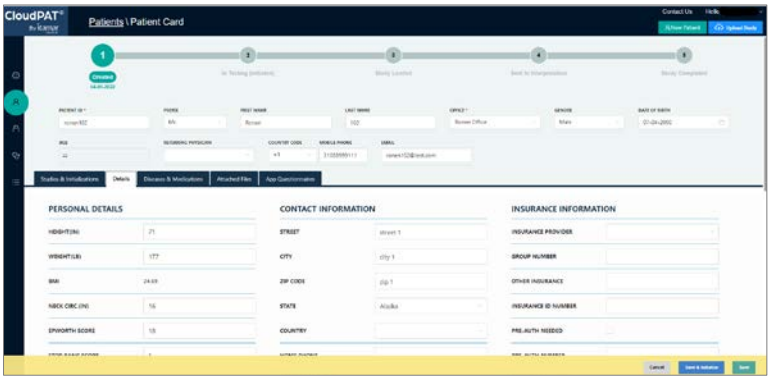


**Figure 14: WP Patient Card**

### 3.4.2 Creating a New Screening Patient

- Similarly to WP Patients, if your office is configured for screening questionnaires, it is possible to create a new screening patient by using the New Screening Patient button.
- This would allow getting the patient's answers to a series of questions through the SleePath app to be added as a PDF report in the App Questionnaires tab.
- A screening patient has additional mandatory fields to be used to identify in the SleePath app such as email and mobile phone number.
- Most of the patient tabs are similar to a WP patient card except Compliance Data and Study & Initializations tabs.
- Clicking on the Initialize Screening button triggers the SleePath experience, sending a text message with a link to download the Sleepath App.
- The progress bar updates according to each stage in the journey and to the office setting.
- You may expedite a screening patient into a WP patient by either initializing a WP device or by changing the progress bar to Assign WatchPAT.

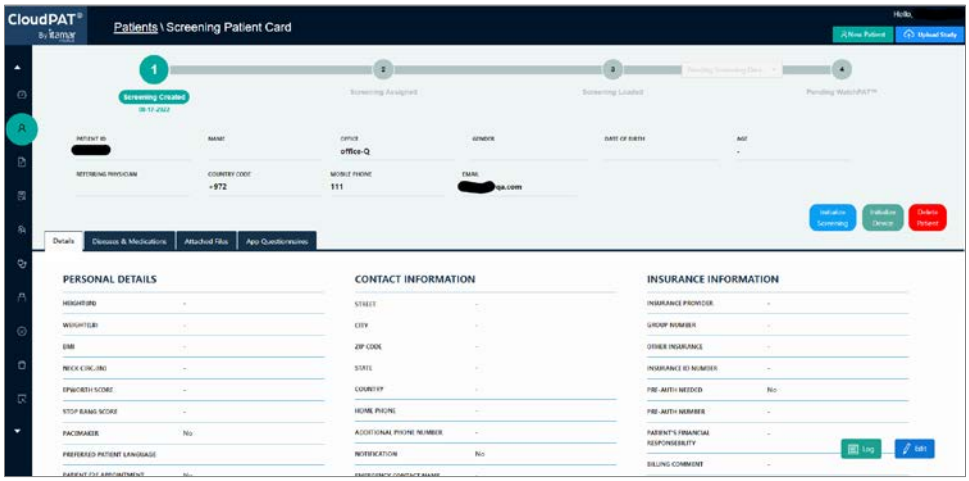


**Figure 15: Screening Patient Card**

## 3.5 Importing Patients

New patients can be added using the Import button which also allows creating multiple patients from a CSV file.

The Patient ID will be unique per Office. The following fields are supported:

- Patient ID (Mandatory)
- Office (Mandatory)
- Last Name
- First Name
- Referring Physician
- Gender
- Insurance Provider
- Other
- Status
- Custom Fields
- City
- ZIP

- Country
- Home Phone
- Mobile Phone
- Email
- Number of Nights
- Bracelet Study
- Address
- State
- Work Phone
- Pacemaker
- Prefix
- DOB

## 3.6 First Time Installation

The first time you run the Initialization process or upload from the WP device, a one-time PC-App will be downloaded from CloudPAT.

CloudPATio (CloudPAT Input/Output) is a Windows application developed in Java and installed on the desktop computer for managing patient sleep data for Itamar Medical WatchPAT (WP) devices.

This includes the initialization and upload of studies, and launch of the Study Viewer application.

Please note that the installation package size may reach a few hundred MBs since it includes some prerequisites such as Java JDK and AWS SDK (without installing them).

CloudPATio can be initially downloaded and installed as part of a required operation or deliberately though the Contact Us screen.

You should download the PC-App and run its installation - following the installation instructions.

Once it is installed – approve the use of the application as default.

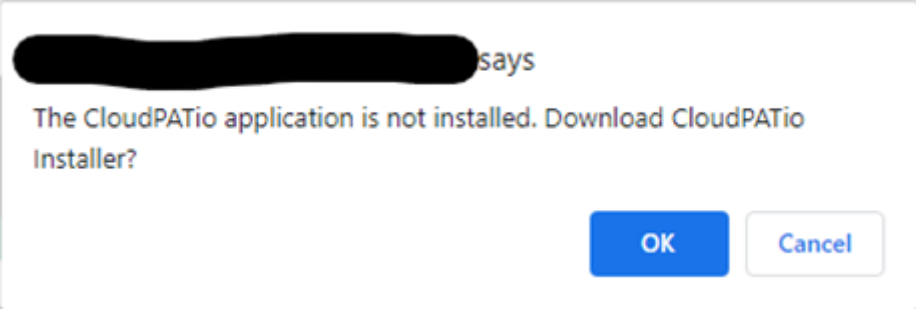


**Figure 16: Download CloudPATio Screen.**

Double click the downloaded installation file.

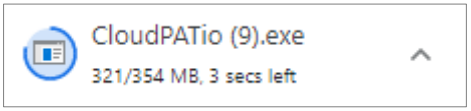


**Figure 17: Start the CloudPATio Installation.**

Follow the installation instructions:

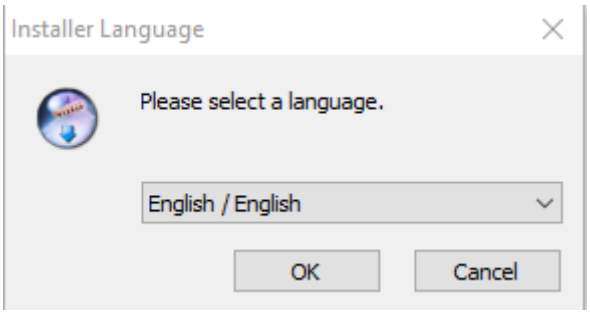


**Figure 18: Language Selection**

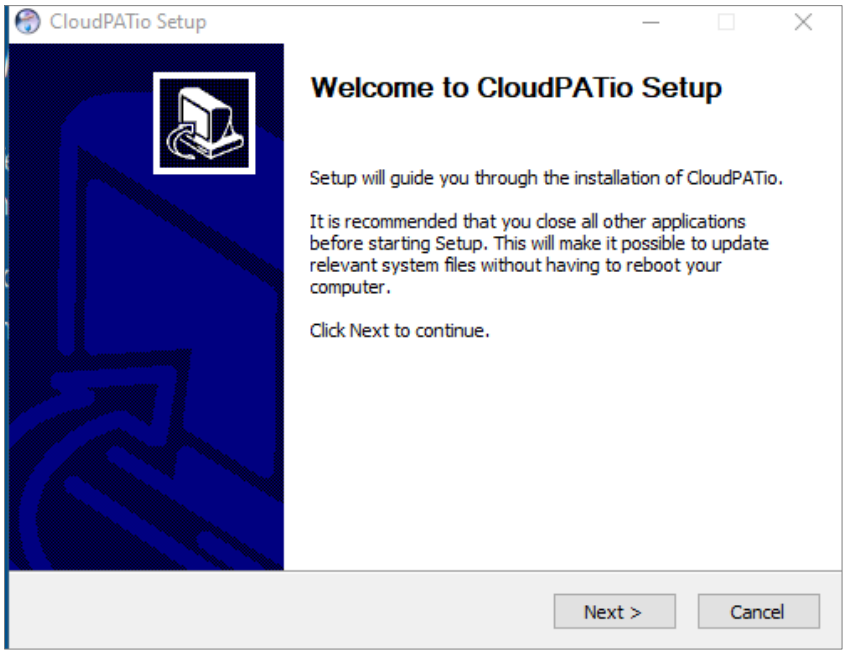


**Figure 19: Running the Installation Wizard**

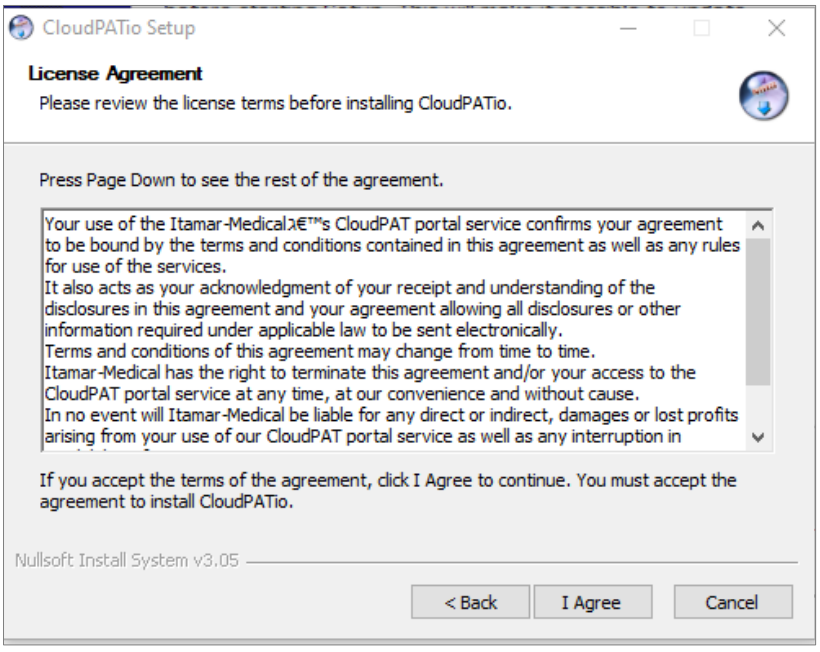


**Figure 20: License Agreement Screen**

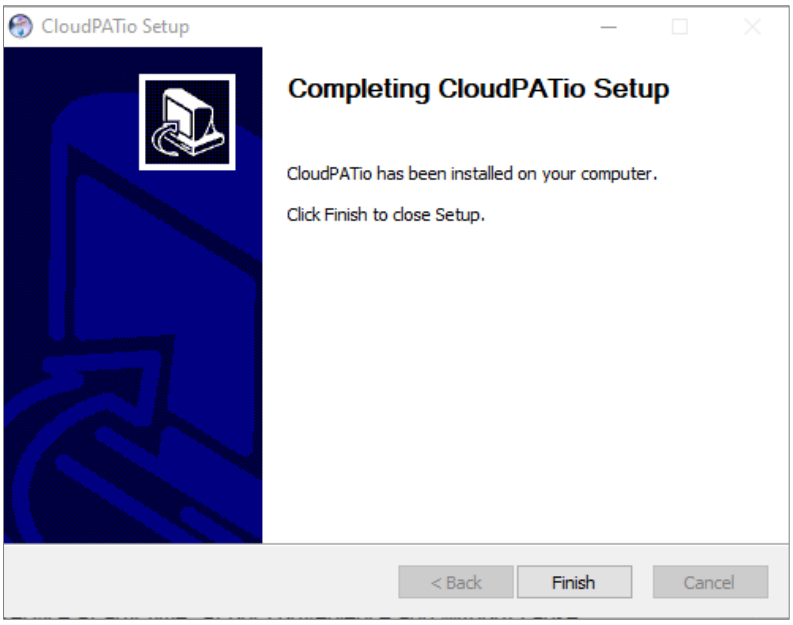


**Figure 21: Installation Completion Screen**

## 3.7 Initialize WP200U/WP300 Device

Click on the Initialize Device button, select WatchPAT200U/300 option and input the desired settings on the screen:

- Bracelet Study (available only if office setting permits) - from this screen you may require a Tamper Proof Bracelet to be used as Positive Chain of Custody in Occupational Testing (e.g., truck drivers. See WatchPAT™ Operation Manual for further details).
- If the office setting permits a Multiple Nights Study: in order to record up to 3 nights with same WatchPAT device, select the number of nights needed. There are two options for Multiple Nights Study:
    - Two nights when no charging is needed between the nights (maximum length of study is approximately 8 hours)
    - Three nights when charging is necessary between the nights (maximum length of study is approximately 10 hours)
- The Request Script option informs the Interpreting Physician that a script is requested.
- An associated interpreting physician may be selected for the study, and the option to change this selection will be allowed later on.

Click on the Initialize Button once all inputs are set.

The system will prompt you to verify that the WatchPAT device is connected to the computer and then you should continue by selecting ”Proceed with initialization”.

A pop-up application will open and manage the initialization of the device.

**Note**

Make sure to connect the device, test the device and instruct the patient before giving out the WatchPAT™ device. Refer to the WatchPAT Operation Manual for more details.

The system will prompt you once the initialization process is completed.

If no Interpretation choice is listed (no physician selected) the report will not be sent for interpretation and a final report cannot be generated.

An office can configure a mandated interpretation selection as part of the device initialization process.

After the initialization is completed, a new entry is added to the Initializations section under the Studies & Initializations tab.

Overwrite protection: If a previous study was found on the WatchPAT™ device that was not uploaded to CloudPAT, you will not be permitted to overwrite that data. A prompt will appear: “Previous study found”. At this time, you should upload the study before proceeding. This prevents you from inadvertently overwriting a study that was not uploaded.

**Note**

The office can update the patient’s details as long as the report wasn’t electronically signed. Once the report is electronically signed, the modified patient data will not be included in the report.

To prevent redundant work for the Interpreting Physician and the need to open a signed report, it is recommended not to assign the study until all patient and study fields are updated correctly.

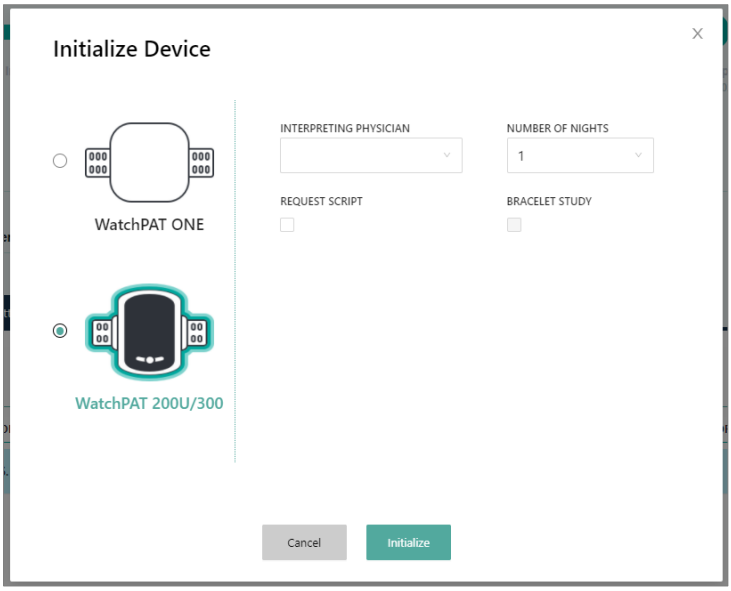


**Figure 22: Initialize WatchPAT 200U/300 Device Screen**

## 3.8 Initialize WatchPAT™ ONE Device

Click on the Initialize Device button, select WatchPAT ONE option and input the desired settings on the screen:

- Enter the WatchPAT™ ONE’s Device serial number.
- Enter the PIN and PIN Type (hint) provided to the patient. Pin Type can be pre-set as an office setting.
- Enter the max number of PIN Retries (default:3, can be pre-set as an office setting).
- Accept default or change the Email for Notification, indicating the email for notification on study completion and upload to CloudPAT.

- Optional: Select the desired Interpreting Physician that the study will be sent to. If Interpreting Physician is not assigned, they can be selected after study is successfully uploaded to CloudPAT.
- An office can configure a mandated interpretation selection as part of the device's initialization process.
- Click on the "Initialize" button to complete the initialization process.

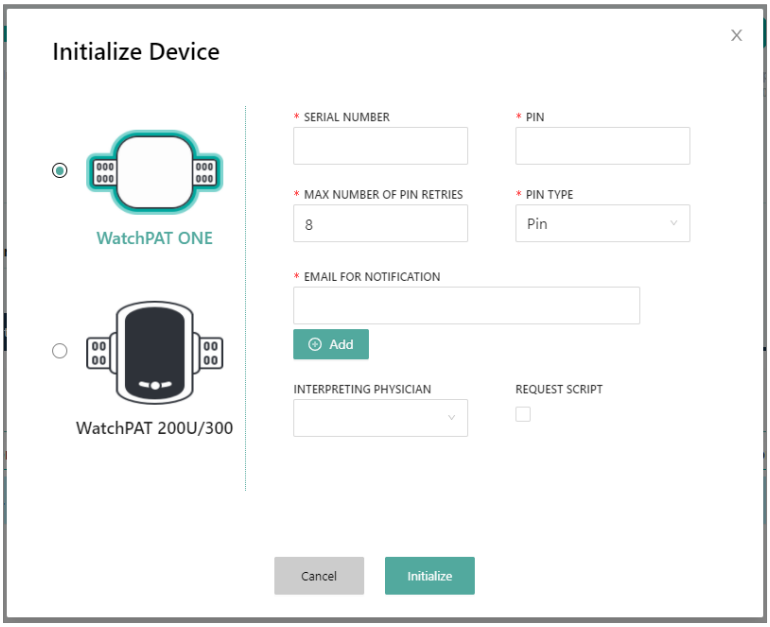


**Figure 23: Initialize WatchPAT ONE Screen**

After the initialization is completed, a new entry is added to the Initializations section under the Studies & Initializations tab.

If patient has exceeded the maximum PIN retries, The counter may be reset by entering the Intialization section and selecting the "Reset Available PIN Retries" button.

If there is an error with the registration, you may select the Unregister button to cancel.

**Figure 24: Reset Available PIN Retries**

## 3.9 Initialize WatchPAT™ ONE Multi-Night Device

CP supports initializing multi-night WP1 devices (WP1-M) where the max Number of nights is 3 using a designated option in the Initialize Device screen.

The first Serial # will be the WP1-M, and the others will be of the additional probes.

Once the Initialize button is clicked, the corresponding initializations shall take place and the PIN code shall remain the same for all initializations.

**Figure 25: Initialize WatchPAT ONE Multi-Night Screen**

## 3.10 Uploading a Study

This section covers uploading studies from the device or manually.

**Note**

WatchPAT ONE studies are automatically uploaded to CloudPAT once the sleep study is completed.

## 3.11 Normal Upload Mode (WP200U/WP300)

When a patient returns the WatchPAT™ device after a night study, simply connect WatchPAT™'s mini USB port to any USB port on the PC by using WatchPAT™'s communication cable and click on the "Upload Study" button from any Screen.

Proceed by selecting the "Proceed with upload" button.

In case your browser asks for permission to run a command line for performing the upload, click on the button to allow – you may also select a checkbox to not recieve this message again.

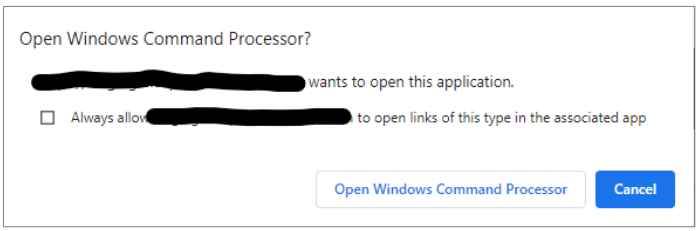


**Figure 26: Allowing Windows Command Processor**

During upload, a screen appears which details the various steps of the upload.

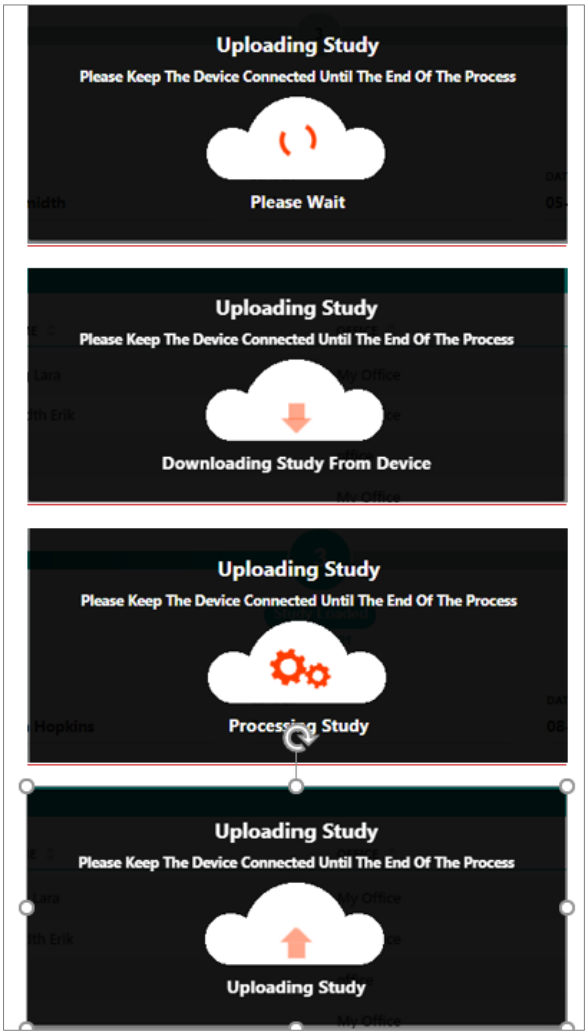


**Figure 27: Patient Sleep Study Upload in Progress**

**Note**

When a multi-night study is loaded all the night recordings are loaded automatically.

**Note**

Depending on your connection speed to upload, the number of nights included in the study and the type of device, the upload time will vary between 2 and 15 minutes.

Do not disconnect the WatchPAT device from the PC workstation until CloudPAT displays a message indicating that the study was successfully uploaded, otherwise the WatchPAT device might not be ready for initiation of a new WatchPAT study.

A notification message will be presented to the user as soon as the process completes.

**Figure 28: Successful Upload Notification**

Upon a successful upload, the system will present the study information under the patient's Studies & Initializations tab for observation of the study details.

Here you can set or change the desired interpreting decision or update the MIN DESAT FOR AHI/RDI if needed – both by clicking on the pencil icon for editing and on the checkmark for saving.

By the end of the WP300 initialization process, CP will notify the user in case there is an updated firmware version for this device.

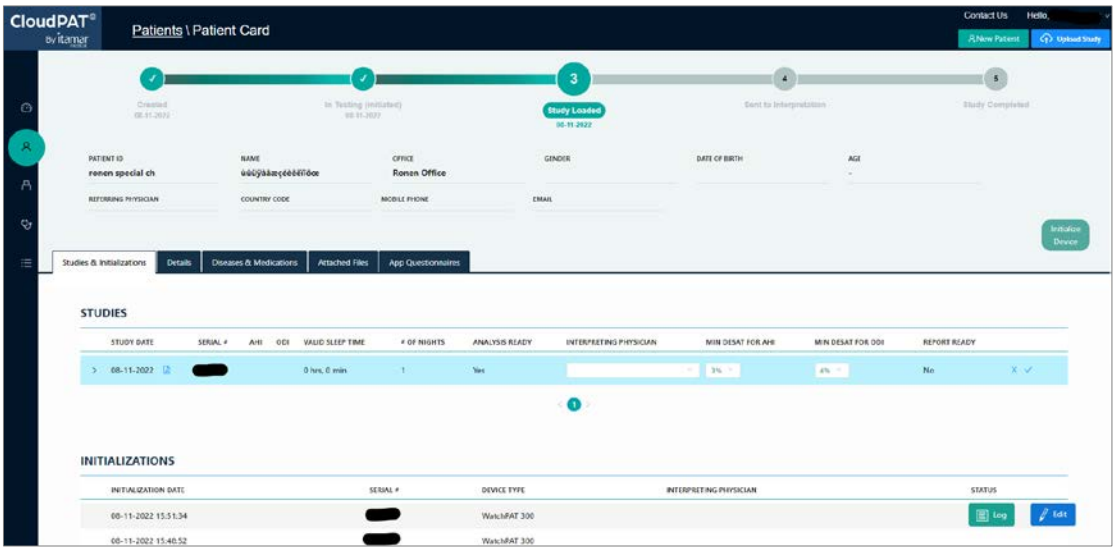


**Figure 29: In-Row Editing in Study Details Screen**

## 3.12 Manual Mode (WP200U/WP300)

In the rare event that a "manual" upload is needed (such as an internet outage and the sleep study was uploaded locally using zzzPAT), select "Switch to Manual Upload".

The study files have to be zipped together into one zip file to be selected through a file browser.

These files are patient.dat, sleep.dat and if existing, also log.dat, sleep1.dat and sleep2.dat (for multi night studies).

Click on the Upload Area for opening a file browser to locate the desired zip file.

Once added, click on the Upload ZIP File button to continue.

From this point on, the process is similar to the Normal Upload Mode described above.

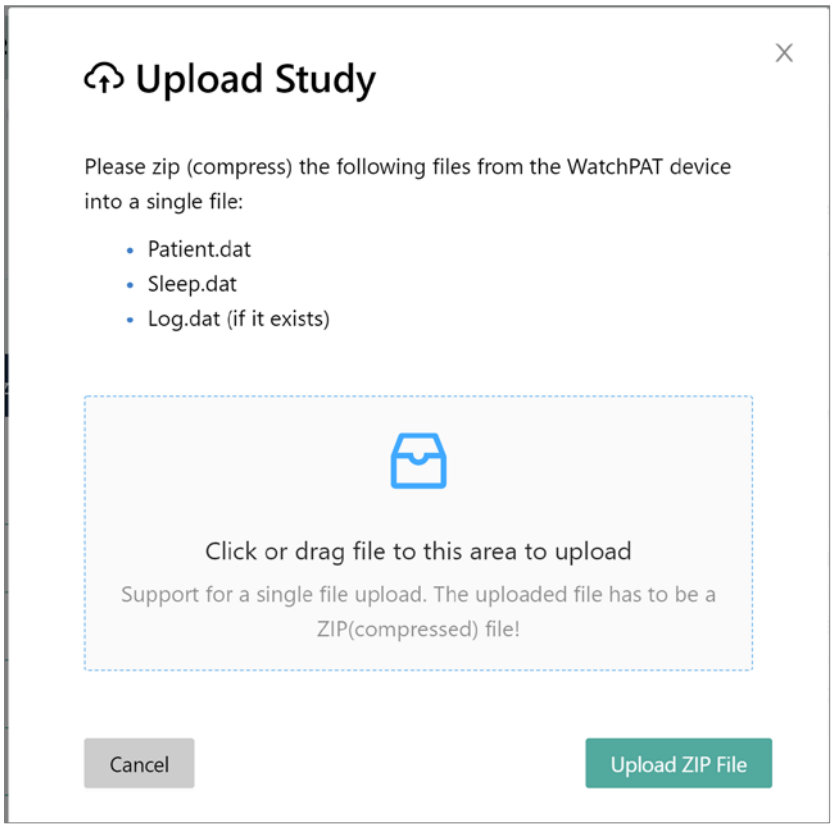


**Figure 30: Upload Study Screen**

## 3.13 Manual Upload of WatchPAT ONE Study

In the rare occasion, the WatchPAT ONE (WP1)study was not automatically uploaded to CloudPAT after the sleep study recording was completed, you may upload the study manually via the Initializations section.

Select the relevant WP1 registration entry and click on “Retrieve Test” button.

You may continue working with CloudPAT and the study will be uploaded in the background.

An email will be sent to the email address provided during the WP1 registration when the study is successfully uploaded to CloudPAT.

**Figure 31: Manual Retrieval of WP1 Study**

## 3.14 Searching Studies and Reports

Selecting the “Patients” icon opens a search screen where you can view all or a subset of the studies and reports available to the current user. Clicking on the table’s icon will perform a table refresh.

The following filters are available: Patient ID, First Name, Last Name, Email, Office, Status, Custom Status, Period, Sleep Apnea, Serial #, Study Date, Study Load Date, Study Close Date, Waiting for

Interpretation, Interpreting Physician, Patient Created Date, Referring Physician, Insurance Provider, and Report Viewed (indicates if the report file has been opened by a provider from the office).

When the filter fields include study information, the result is a list of patients having at least one study matching the search filter.

The table including the search results is customizable and includes the majority of the search fields.

Search results can be exported to CSV files.

- Export to CSV: Including patients' details.
- Export Summary Report: Including some analysis information.
- Export History: Including progress bar changes.

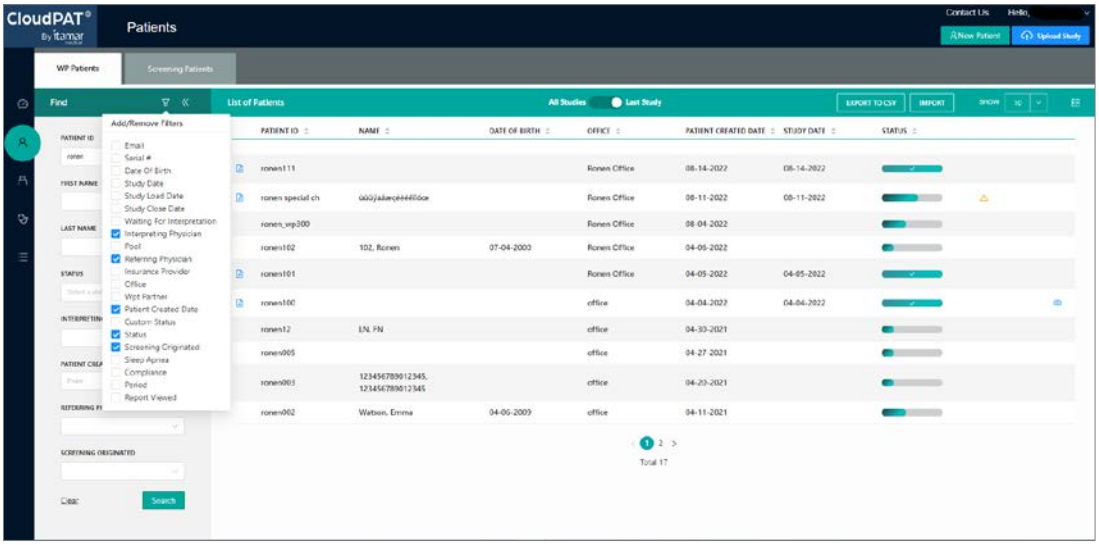


**Figure 32: Viewing Sleep Study Reports**

## 3.15 Study Management

Once a study is uploaded and until the Interpreting Physician locks the report, there are several tasks that a user can do.

### 3.15.1 Understanding the Study Screen

This screen presents information about the study.

The more frequently used fields are displayed on the collapsed row.

Changing the Minimum % of Desaturation for AHI/RDI Calculation and Assigning Interpreting Physician can be done here, using the pencil icon for editing, and the check mark icon for saving.

Selecting the caret expands the view to include all additional information from the study: errors or warnings from the analysis, Bracelet information, and if the Request Script box is checked or not.

If the office settings allow you can see the Analysis File under “Files”.

The office settings control what information in the study is shown in the row.

**Note**

To prevent redundant work for the Interpreting Physician and the need to open signed reports, it is recommended not to assign the study until all patient and study fields are updated correctly and all the relevant files are attached.

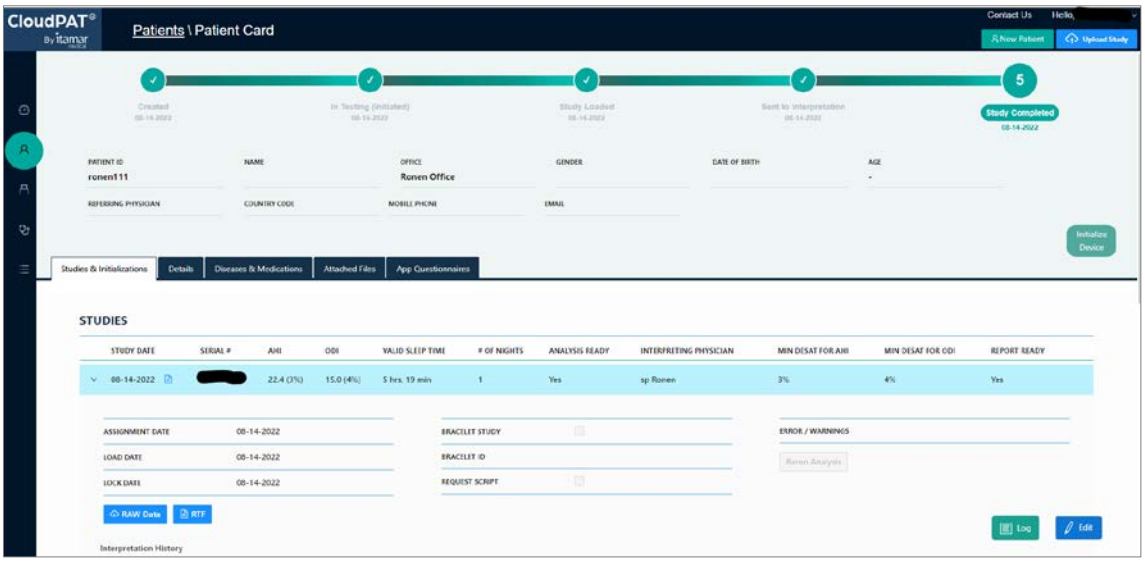


**Figure 33: Study Details Screen**

### 3.15.2 Attaching Files to a Patient

Once a patient is created, the user can choose to add documents to the patient record. These documents will be available for the Interpreting Physician to review when preparing the report.

To attach a file – enter a description and select the file to be uploaded using the upload area.

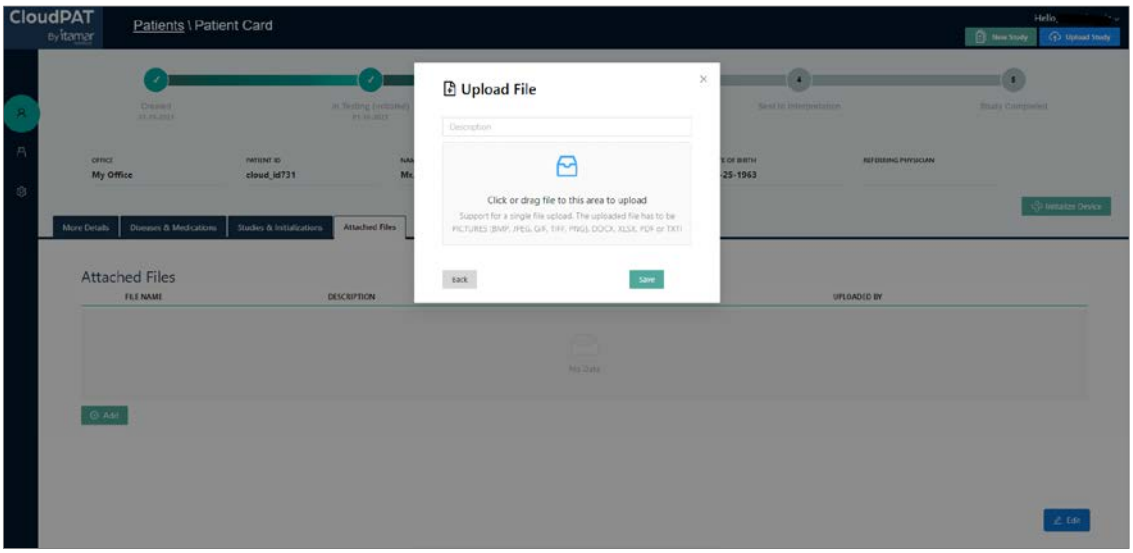


**Figure 34: Attach File Screen**

The user can also remove or download the attached files by clicking on the respective buttons.

Offices can mandate to configure at least one attached file before the initialization process.

Additions, updates or deletions of attached files are tracked in the Audit Trail Screen which may be viewed by clicking on the Log button.

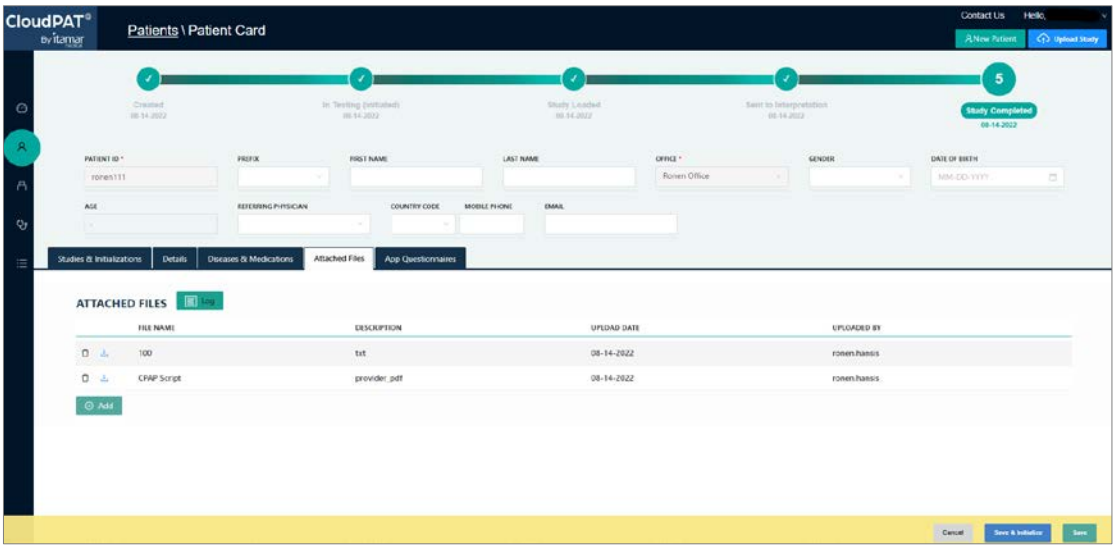


**Figure 35: Deleting Attached Files.**

### 3.15.3 Changing Interpreting Physician

The user can assign a non-assigned study to any of the Interpreting Physicians connected to the office.

The user can also change the assignment between the different Interpreting Physicians connected to the office.

Assigning interpreting physicians can be done through the study's row using the pencil icon for edit and check mark icon for saving.

Notification of a new study will be sent to the assigned Interpreting Physician while another notification will be sent to the previous Interpreting Physician indicating that the study has been reassigned.

### 3.15.4 Interpretation Pools

Interpretation Pool is a group of interpreting physicians that can be assigned to an office; studies may then be assigned to a pool instead of a designated interpreting physician.

Each pool member could then pull a study from the pool and become the designated interpreting physician for this study.

Assignment to an interpretation pool is done similarly as with interpreting physicians.

An interpreting pool member may return a study to the pool for someone else to proceed with, as long as the study isn't locked by clicking on the release button.

A pool member may be configured as a pool manager and as such they would be able to re-assign studies and get daily emails about studies that have not been assigned.

A pool member may be configured as not authorized to lock a study, only to save changes to it.

### 3.15.5 View Analysis File

Some offices have settings that allow their users to view the analysis before the report is ready.

This setting is usually given to sleep labs using the CloudPAT where the expertise needed to understand the results are part of the office skill set.

Users of such offices can click the analysis file link immediately after uploading the study.

When a multi-night study is uploaded, all the results from the reports will appear in an analysis file, one after another, followed by a summary page.

**Note**

An analysis file is created during the analysis and may include patient details entered at the time of the analysis. Patient details will not change in the report until the report is locked or re-run.

### 3.15.6 Request for a Script

In case the Interpreting Physician is required to add a script to the report, the “Request Script” box should be checked. Save the study by selecting the “Save” button, and complete the request by sending it to the Interpreting Physician.

The Interpreting Physician will get a reminder to add a script upon locking the report.

### 3.15.7 Changes of Study Parameters

The user can change patient information and some study parameters as long as the report is not closed.

Some of the parameters will require running the analysis again:

- •AHI index – according to 3% or 4% desaturations.
- •Pacemaker.
- •Gender
- •Date of Birth

After making changes to these parameters, the user should rerun the analysis to get the new results. A reminder about the need to rerun the analysis will appear on the page together with an option to rerun the analysis. A re-analyze notification will be sent to the Interpreting Physician.

**Note**

Per office setup, Desaturation Threshold may automatically be set to 4% for patients insured by Medicare.

A warning message may appear if the Desaturation Threshold is not 4% for Medicare insured patients.

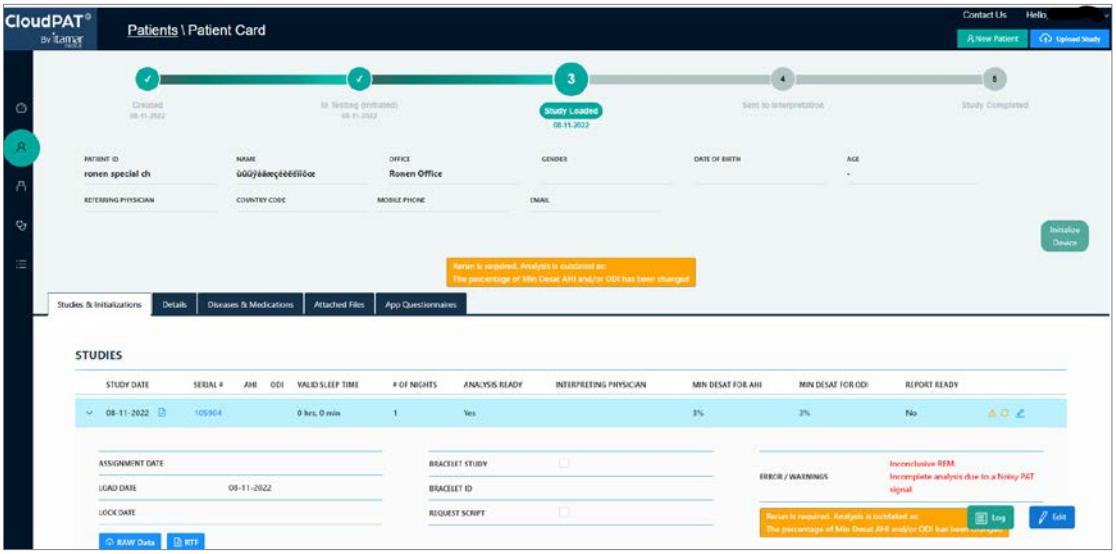


**Figure 36: Rerun Analysis Indication**

## 3.16 App Questionnaires

App Questionnaires are introduced to upgrade the HSAT experience. On a digital version, these questionnaires are customizable by provider and patient, and help sleep physicians quickly and efficiently centralize data management and enhance the diagnosis process.

The provider can turn questionnaires On / Off from the App Questionnaire tab and select / de-select groups of items from the Assessment Module although the Bedtime and Morning sections are mandatory.

Once questionaries are turned on, the questionnaire menu is displayed.

When using questionnaires, Email and Mobile fields become mandatory and CP issues an error message on attempt to Initialize a Device if empty.

The Patients Table includes an icon to indicate the App Questionnaires status (Pending /Ready).

When Selecting the "Resend Entry Code" button it sends an SMS message to the patient's mobile phone with a new entry code to be used in the APP.

The answers are added to the PDF report file.

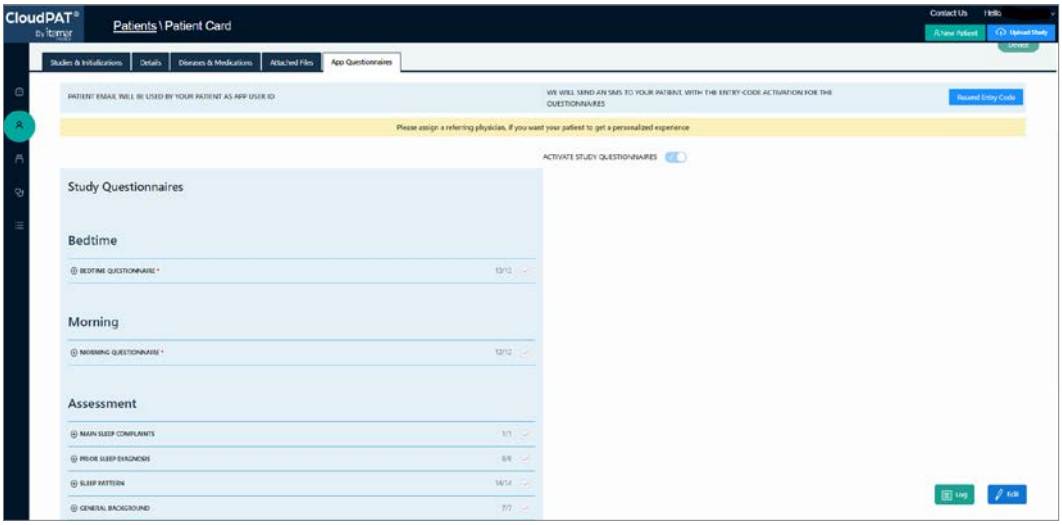


**Figure 37: App Questionnaires**

## 3.17 Compliance Data Optional Tab:

If an office is configured for getting CPAP compliance data and information has been received for a patient, it will be presented in an optional tab called "Compliance Data" including compliance graph, fields and table.

The Daily Compliance Graph shall show both the usage (h) and AHI (#) graphs, a treatment Date vertical line.

The compliance fields include additional information about the compliance of the patient.

The compliance table displays calculations of the CPAP usage and PAP Reported AHI.

## 3.18 Viewing Reports

After a patient sleep study has been sent to your Interpreting Physician for review and interpretation, and the Interpreting Physician has reviewed and finalized the report, the user who uploaded the study will receive an email notification that your patient sleep study report is available.

Alternatively, you may poll the system by pressing on the caret of the study and checking the "Report Ready" field.

If yes is shown, you can review the signed sleep study report and the attached files by clicking on the PDF File button

The report will include comments and diagnosis from the Interpreting Physician. PDF file attachments added by the Interpreting Physician will be appended at the end of the report. Other attachments (non-PDF) will only be viewable by downloading them (clicking on the link to the file).

In case of a multi-night study, the analysis of each night will appear one after another in the report, followed by a summary page at the end.

Subject to office configuration, the report may show the other AHI / ODI values in the report based on the alternative MIN DESAT values.

Based on the office setting, it is possible to get the report in a secondary format which is either HTML or RTF.

If configured for the office, the report will include a page with OXI and Pulse Rate Histograms.

If configured for the office, the report will include Arrhythmia events.

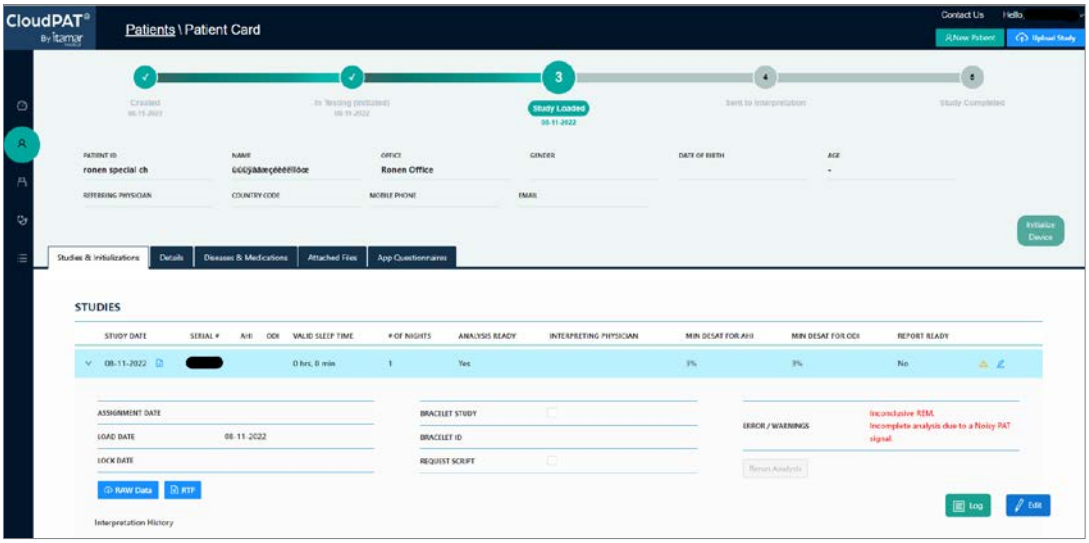


**Figure 38: Download Buttons for the Reports**

**Note**

Contact Itamar Medical Support for the availability of other file type options for reports.

## 3.19 Managing Devices

This is an inventory management feature allowing the users to keep track on the multi-usage devices of the office.

A device can be added through the new button, or once it is initialized through the Initialize Device button.

### 3.19.1 Devices Table

You can search devices from the table using designated filter fields:

Serial #, Device Type, Status, Office, Status Change Date, Device Assignee, Firmware Version.

Once a study is being uploaded from the device, its status changes to Available.

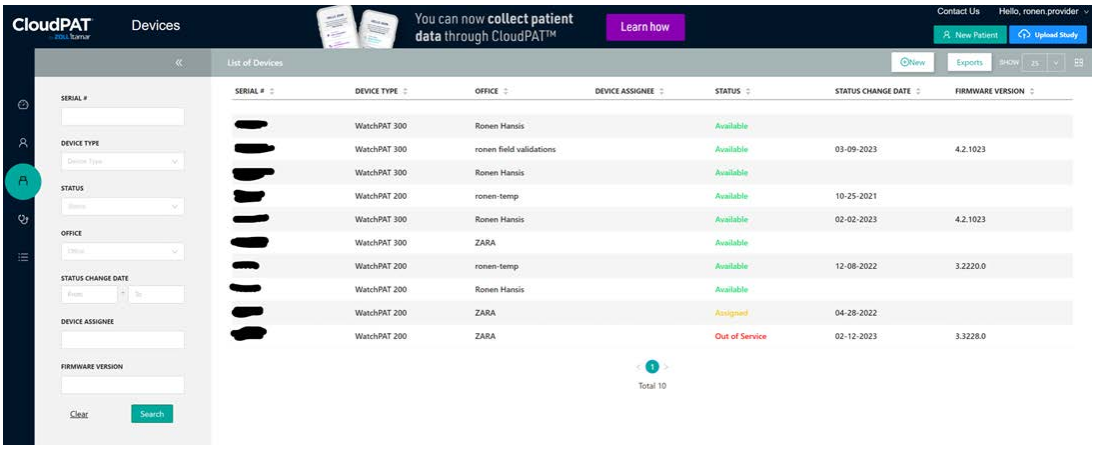


**Figure 39: Devices Table Screen**

### 3.19.2 Device Details

Selecting the Device row, opens the Device Details Screen showing additional information.

The screen includes the following fields: Device Type, Status, Comment, Bracelet Study, Serial #, Assigned Patient ID, Office, Firmware Version, History.

A device may be labeled as “Out of Order” by selecting the “Out of Order” button.

Initialization of a device that is marked as “Out of Order” is prohibited.

A device can be transferred between offices by using the Office dropdown.

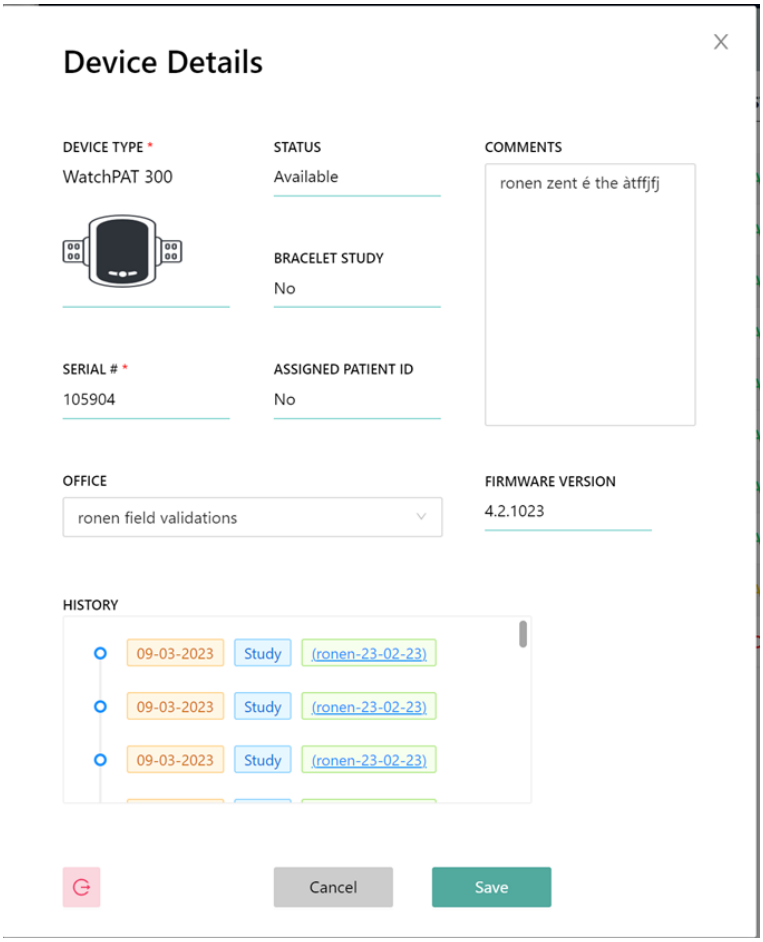


**Figure 40: Devices Table Screen**

## 3.20 Managing Referring Physician

It is possible to manage referring physicians at the office level without waiting for system administrators.

A referring physician may be added, edited, or named as inactive by the provider.

### 3.20.1 Referring Physicians Table

You can search, add or remove a referring physician using designated filter fields.

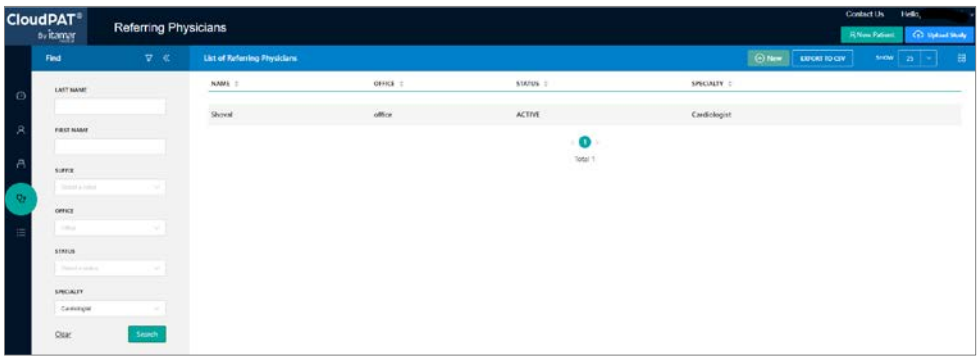


**Figure 41: Referring Physician Table Screen**

### 3.20.2 Referring Physician Details

Selecting the Referring Physician row opens the Referring Physician Details Screen displayed with additional information.

A Referring Physician can be designated as Inactive by using the designated checkbox.

If the user is associated with multiple offices, they may move a referring physician to one of the other offices.

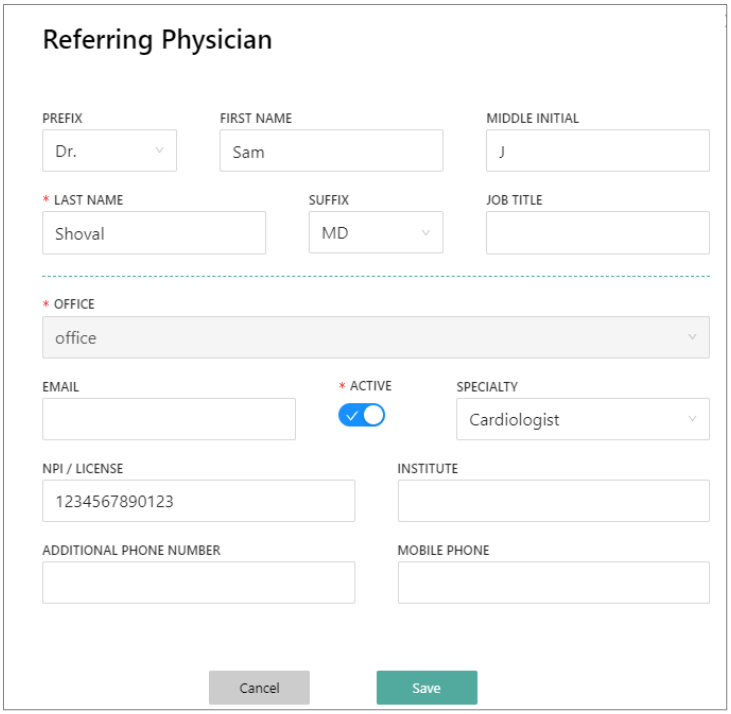


**Figure 42: Referring Physician Details Screen**

## 3.21 Managing Lists

Managed Lists include medications, diseases, statuses, and insurances.

The user can add items to the list and edit or delete them.

Selecting the “Managed Lists” icon opens a search screen where you may search for items both globally or locally. The Global list cannot be changed.

It is possible to create multiple items using the semicolon separator.

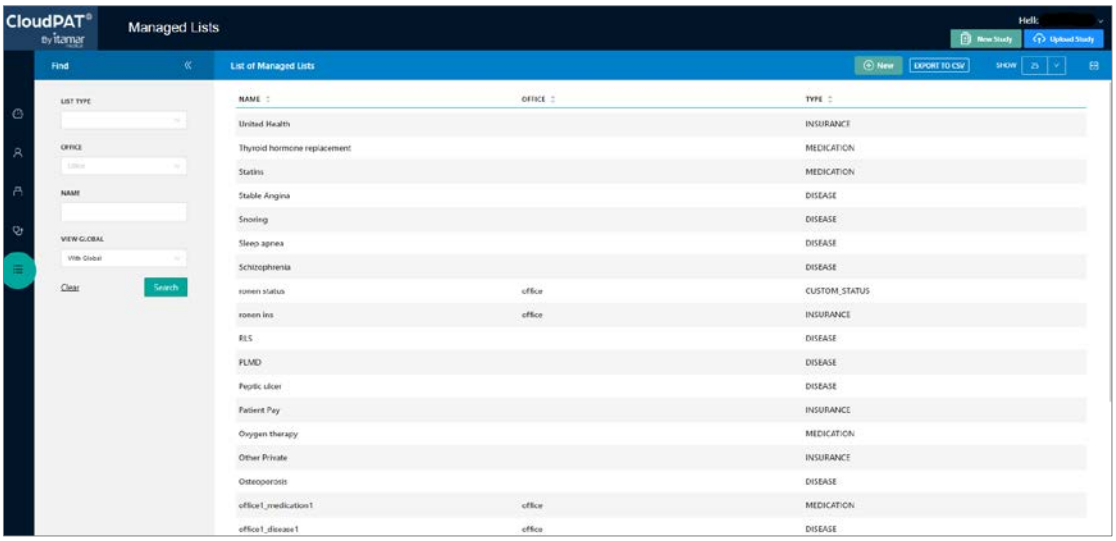


**Figure 43: Managed Lists**

# 4 Using CloudPAT as an Interpreting Physician

## 4.1 Main Access Screen

When you sign in CloudPAT as an Interpreting Physician you will be presented with the Interpreting Physician's Home screen.

Here are the main actions that can be selected from this screen:

1. Review studies – reviews new or display completed studies.
2. Manage templates and NPIs – defines new or edits existing NPIs and templates used for Clinical diagnosis and recommendations.
3. Update settings including Interpreter Signature.

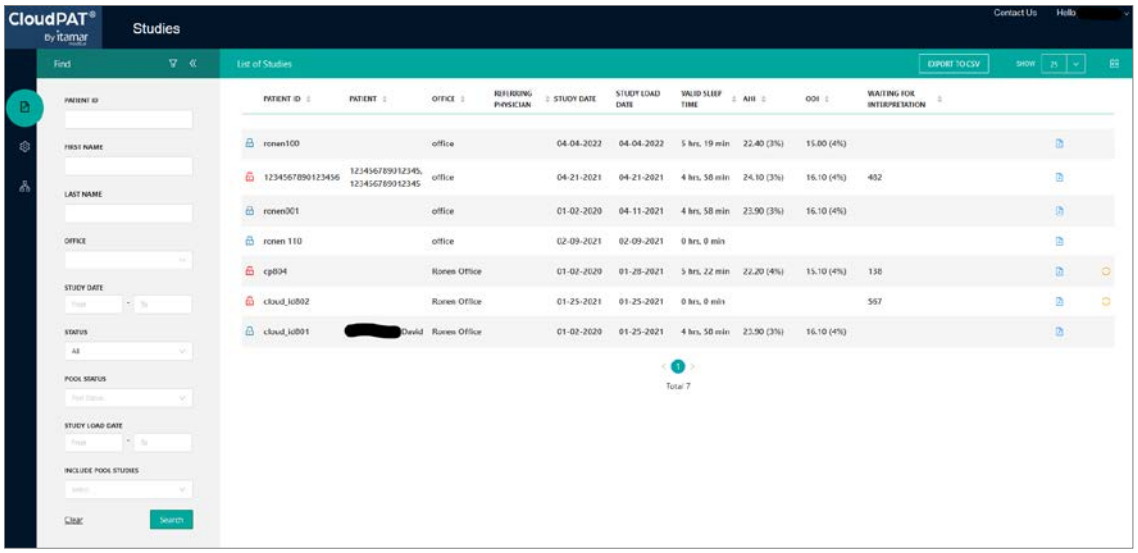


**Figure 44: Interpreting Physician's Home Screen**

### 4.1.1 Studies Assigned to the Interpreter

After a patient's sleep study has been sent for interpretation, you will receive an email notification that a sleep study is awaiting interpretation. Alternatively, you may poll this by selecting "Unlocked" Status in the filter of the main screen which will display all unlocked studies waiting for you. You may also select the "Locked" status for viewing completed (signed) sleep study reports. You have the option to review subsets of your studies by selecting a particular Office, Patient name, etc.

**Note**

Click on the CSV icon if you want to obtain an Excel file containing a tabular presentation of the search results.

### 4.1.2 Reviewing a Study

When you filter for “Unlocked” status, select the study you want, and the screen will display the study details for you to review.

Here are the main actions that can be selected from this screen:

1. Interpretation Details tab including:

- Input fields for the interpreter to fill in the Diagnosis and Recommendations. You may use the Diagnosis and Recommendations templates if you wish to insert an already pre-defined paragraph in the corresponding section.
- Errors/Warnings – in case of errors or warnings returned from the analysis, a message will appear in the Errors/Warnings box.
- Change Min Desat for AHI/RDI – change the value used for analysis. Change becomes effective only after saving. If this occurs, a message will display indicating that rerun analysis is required for the new setting. Click on “Rerun Analysis” to see the results from the new threshold.
- NPI – you can add the NPI to the report if have one. If you have more than one NPI, select the right NPI number that matches the office details.
- Add attachments like prescriptions or any other files to the report. If you add PDF files they will be added to the report itself. Any other files will be available to download in the office. To attach a file – enter a description and select the file to be uploaded using the upload area. The user can also remove or download the attached files by clicking on the respective buttons.
- Interpretation History section listing interpretation related operations done on the study
- Interpretation Comments section facilitates communication between interpreting physicians and pool members about the study.

2. Therapy tab:

- Allows the interpreter to produce a Therapy Prescription which when enabled retrieves patient information which can be edited and prescription items selected from the list.
- Once the Generate Script button is clicked, an auto-generated PDF file shall be created and displayed, including the submitted information to be attached to the report during the Save and Lock operation.
- The supported therapies are CPAP and Oral Appliance.

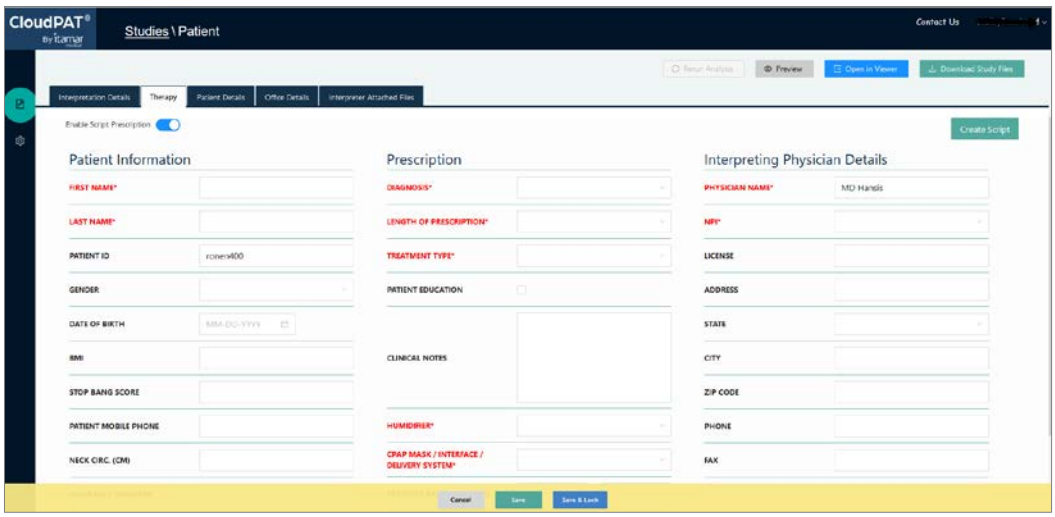


**Figure 45: Therapy Tab**

3. Patient Details Tab– Patient details are displayed.
4. Office Details Tab – by clicking the “Office Details” button, you can see the details of the office that sent the sleep study: address, phone and minimum % Desaturation for AHI/RDI Calculation.
5. Interpreter Attached Files Tab: Showing files that were attached by the interpreter.
6. Diseases & Medications tab: Showing Diseases, Medications and Clinical Comments entered by the provider.
7. Preview Report Button- You can click the “Preview Report” button to see the report that was produced automatically by CloudPAT. According to the Respiratory Indices, Various Statistics, and Sleep Stages, you will make your interpretation and fill in the Diagnosis and Recommendations sections. This also includes the patient information and your last saved interpretation.
8. Open in Viewer button (RECOMMENDED) – This utility avoids the need to install zzzPAT on the PC, to download the study to the PC and upload the results. If you wish to see more details on the study’s signals or to review and edit the events, you can use the “Open in Viewer” function to start the zzzPAT utility viewer on your local computer. Refer to the zzzPAT Operation Manual for a description of the operational capabilities of the Viewer.

**Note**

When you first use of Open in Viewer on your PC, installation of a small PC-app, CloudPATio will begin (if not installed already as part of the device initialization / study upload process).

9. Download Study Files Button (Legacy) – Manually download the study to zzzPAT, and manually upload editing results to CloudPAT. This legacy option is kept in CloudPAT during the Migration to Open in Viewer method.

**Note**

Make sure to upload the correct manual event file. The filename will be comprised of

ID_[patient ID]_

SD_[study Date & time]_

events_analysis_user.zpt

other file will generate an error during the post upload analysis and will not change the analysis file

10. Save – saves your input without locking the report.
11. Save and Lock Report – When you are satisfied with your interpretation select the “Save and Lock Report” button. At this point the study report will be automatically digitally signed with your name, tagged as completed and be available for the Physician’s review.

**Note**

Report can be locked only if created during updated analysis. If analysis is outdated, the system will display a message and the Save and Lock Report will be disabled. After rerunning the analysis the Save and Lock Report button will be available again.

12. Unlock a Report – interpreting physicians can unlock their own locked studies by clicking on the Lock icon on the List of Studies Screen. An Audit Trail Record will be added to the study indicating the user and when the previously locked report will be added.

13. Notifications – you may receive notifications which will be displayed on the screen in the following cases:

- If a script was requested by the office, a “Study requires a script” notification will be displayed on the screen. Also, a reminder will appear before locking the report.
- If the office changed one of the following analysis parameters: Minimum % Desaturation for AHI/RDI calculation, Pacemaker, Gender, Date of Birth, or a rerun of the analysis is required to update the analysis result. In case rerun was not initiated by the office, a notification that rerun is required will be displayed on the screen and the “Rerun Analysis” button will appear. You won’t be able to lock the report before re-running the analysis.

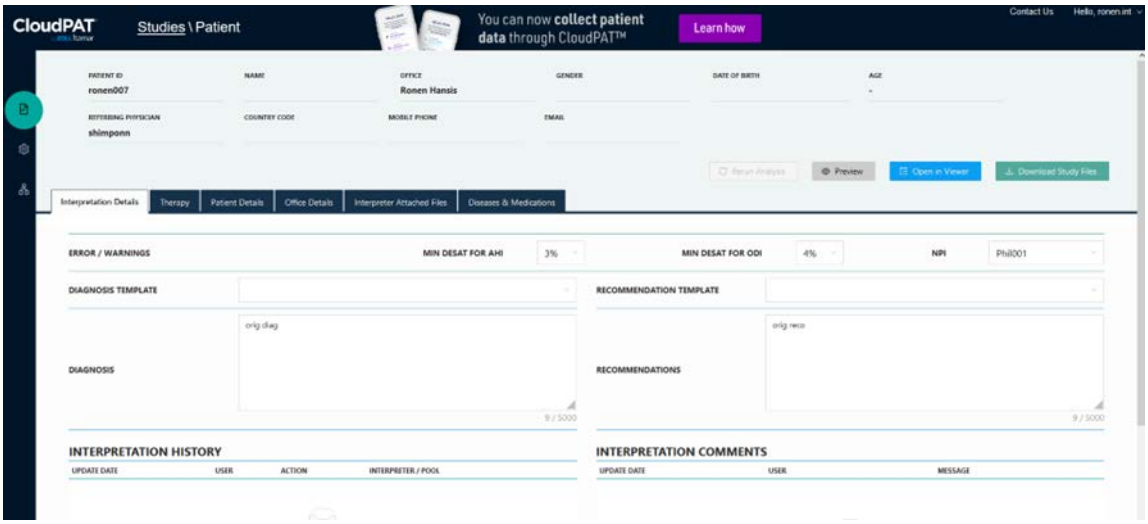


**Figure 46: Interpretation Details Screen**

### 4.1.3 Viewing a Completed Study

When you filter for “Locked” status, select the study you want, and the study details screen will appear.

Here are the main actions that can be selected from this screen:

1. View report - you can click on the “View report” button in order to see the full final report (with your interpretation included).
2. Open in Viewer (read only).
3. View data on all tabs.

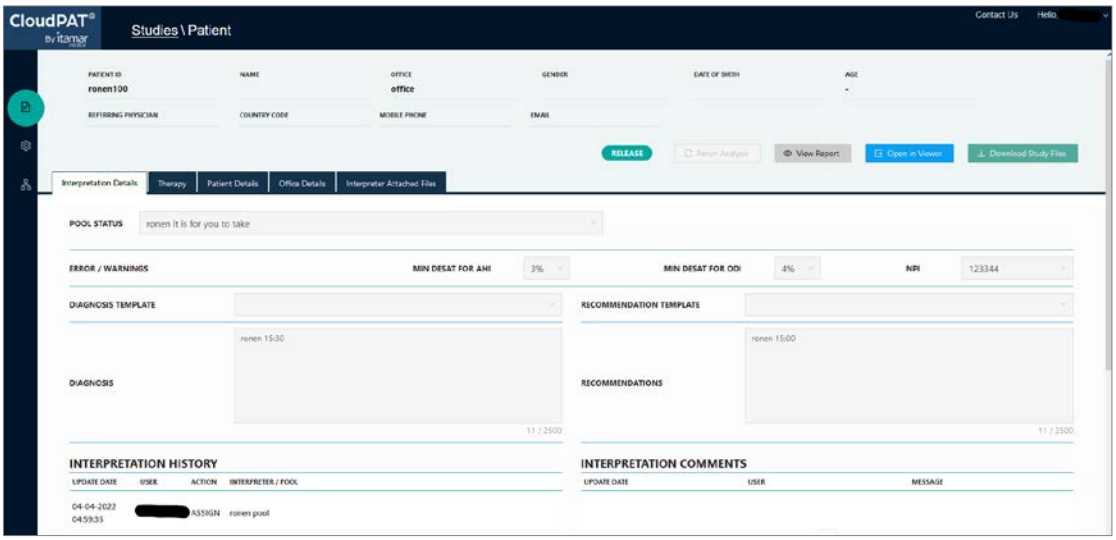


**Figure 47: A Completed Study Screen**

## 4.2 Manage Templates & NPIs

This section explains how to manage the lists of templates and NPIs available to each Interpreting Physician. Selecting the “Settings” icon will open a table used to browse for templates and NPIs. You can narrow the search by using the “Type” field.

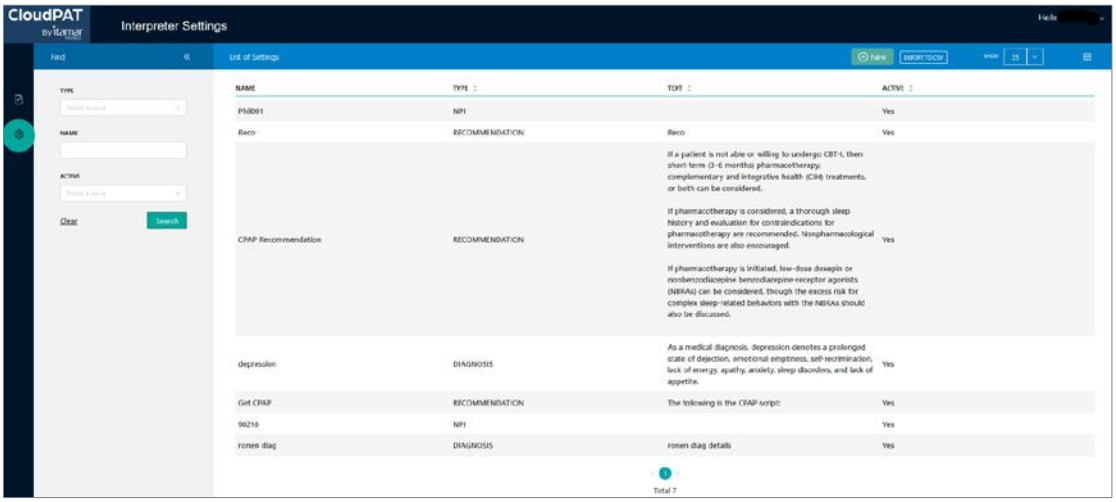


**Figure 48: Templates & NPIs Screen**

### 4.2.1 Templates

Templates are predefined paragraphs ready for use while reviewing a study and entering the Clinical Diagnosis or Recommendations sections. For example, you may define a diagnosis template for Severe Sleep Apnea and a different one for Mild Sleep Apnea.

You may have a number of predefined templates for Clinical diagnoses and for Recommendations which can be used with a click of a button in order to facilitate the Reviewing process.

Using a template will fill the relevant section (diagnosis or recommendation) in the report. After choosing a template you may edit the text.

Clicking on the “New” button will open up the New Setting Details screen.

Please select the Type, enter the Name, and decide if Active. Then add text to the Template.

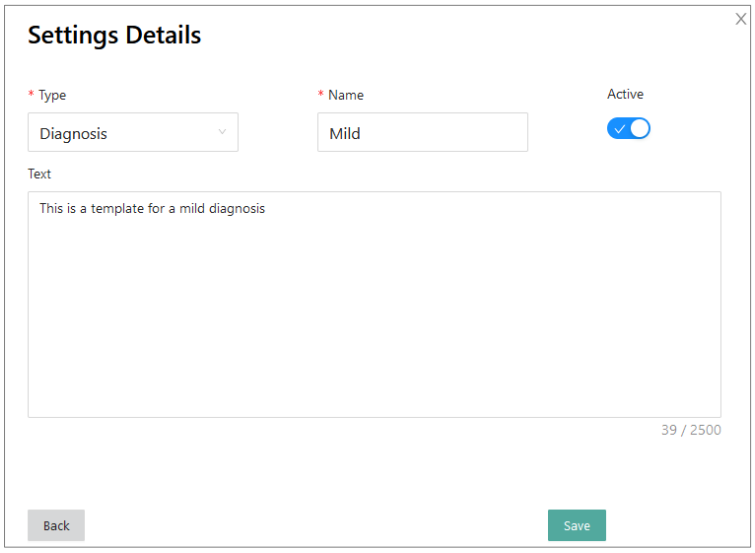


**Figure 49: New Setting Details Screen**

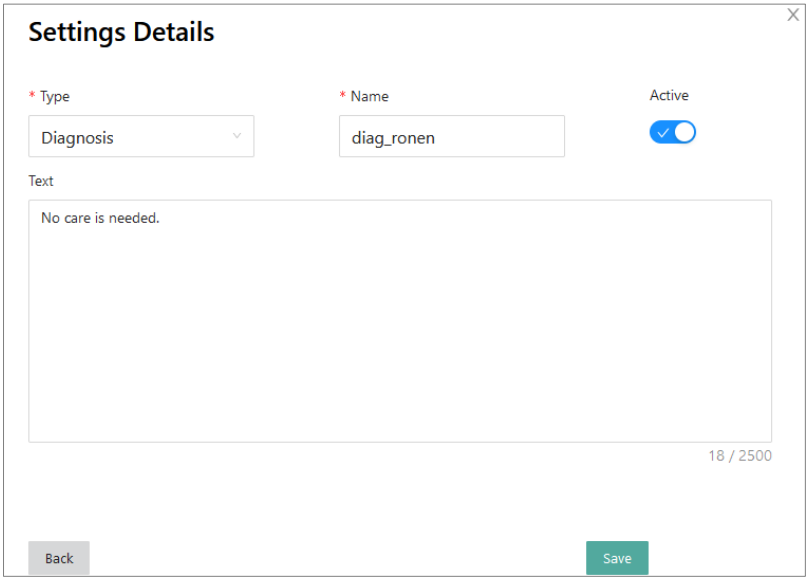


**Figure 50: Existing Template Screen**

### 4.2.2 NPIs

You can manage a list of NPI to be used later in the report by selecting Type = NPI in the search fields.

Click on “Search” to see the list of all NPIs currently in the system. You can also enter text in the NPI field to limit the search results. Clicking on an existing NPI will display the NPI’s details screen, where you can edit the NPI number and save the changes.

Clicking on the “New” button and selecting Type = NPI can be used to add a new NPI to the list.

### 4.2.3 Signature

Interpreting Physicians can add their signature sample as a graphic file. Thus, the Interpreting Physician’s signature will be added to the report automatically. Click on the caret next to the user name, select Set Signature and use the upload area in the screen to upload your signature file.

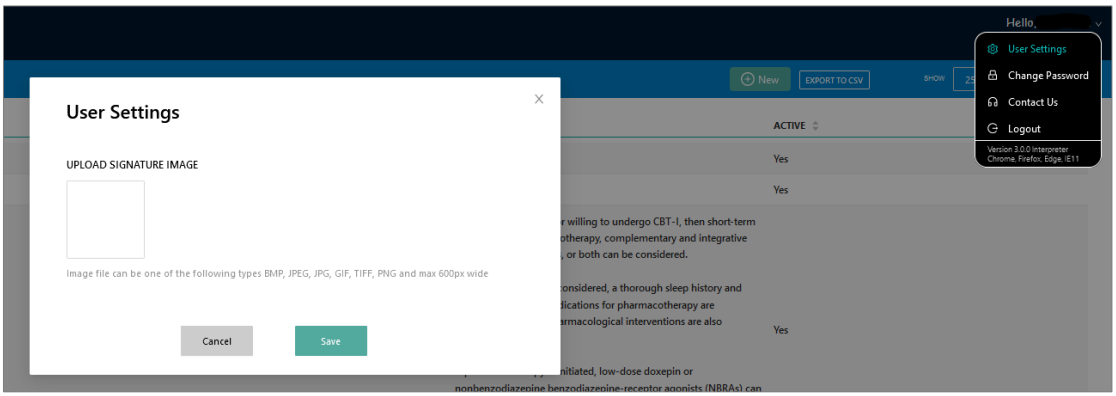


**Figure 51: Interpreter Signature Screen**

# 5 Appendices

This chapter includes the following appendices:

- Appendix A: License Agreement
- Appendix B: Regulatory Representative

## Appendix A. License Agreement

License to User from Itamar Medical Ltd can be found on the Itamar Medical website:

- https://www.itamar-medical.com/wp-content/uploads/2020/09/License-Agreement-09.2020.pdf

## Appendix B. Regulatory Representative

Itamar Medical's authorized regulatory representative is:

| | |
|---|---|
| EC REP | **Arazy Group GmbH** |

The Squaire 12, Am Flughafen,
60549 Frankfurt am Main, Germany