


CloudPAT™

Web Software Operation Manual
Itamar Medical REF OM2200000




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Software Version: 2.8

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EN ISO 13485:2016

See appendix E for contact information of the regulatory authorized representative

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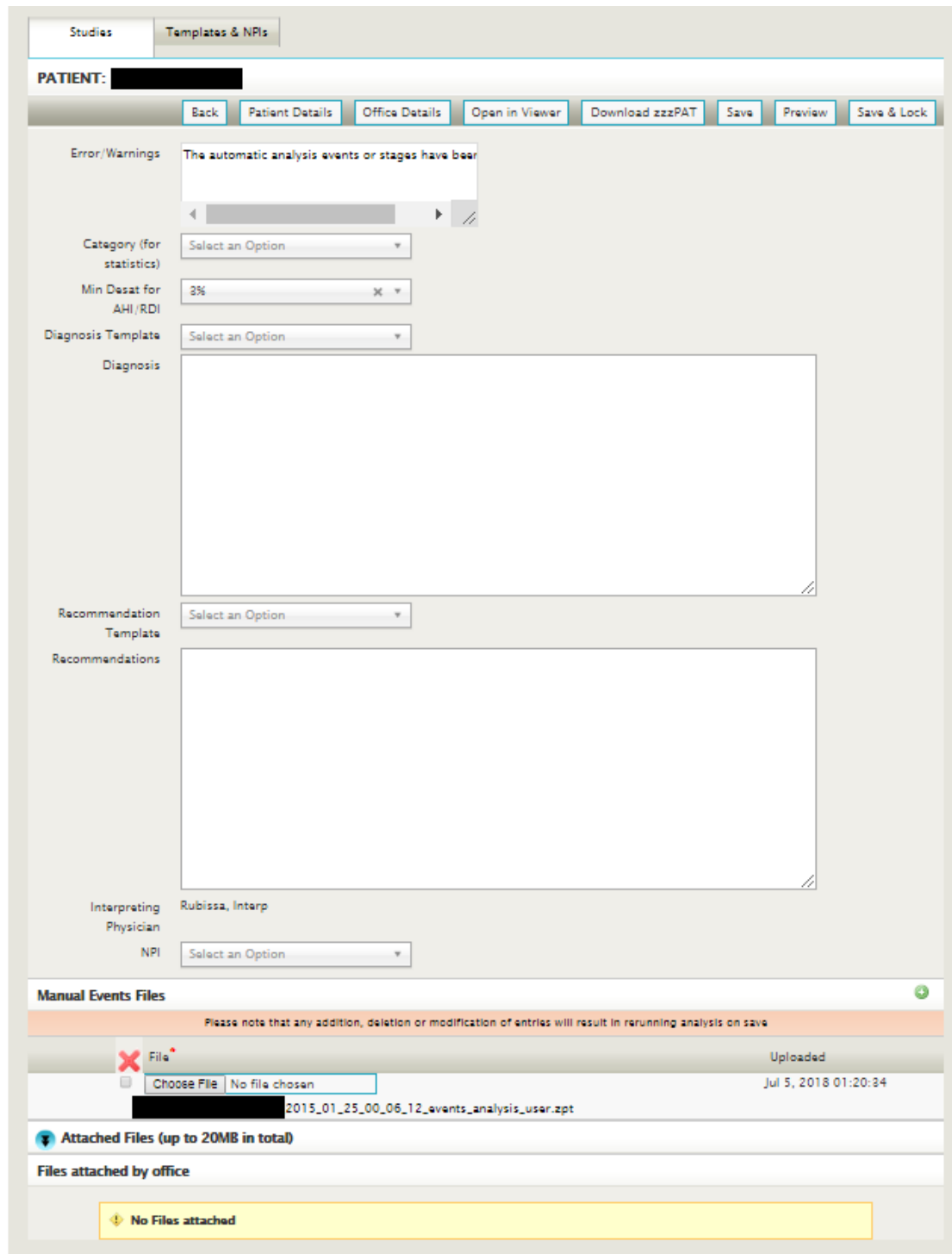
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1	November 2012	1 st Release	All	All
2	March 2014	Update software version Updating Itamar Medical address Updating ISO symbols Updating authorized regulatory representative address	All	All
3	April 2015	Update software version	All	All
4	July 2015	Update CloudPAT S/W – Definition	1.3	7
5	July 2017	Version 2.0: Update company logo, Rx caution Update company standards Update screen to fit the new design New installation process Updated intended use (Central+)	- - All 3.2.2 1.1	1 2 All 25 7
6	July 2018	Updating Cloud ver, updating trademarks Updating CE marking with the accompanying BSI notified body number 0086; Updating Intertek certification marks Adding OM information Updating Intended use for EU Version 2.5: New functionality – Open in Viewer, SleepPATH dashboard	- - - 1.1.1 3.2, 4.2.1	1 2 6 7 18, 52
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- Latest version of CloudPAT™ Operation Manual is available at:



<http://www.itamar-medical.com/Support/Downloads.html>

- Printed copy will be provided within 7 calendar days if requested at no additional cost.

1. Introduction to CloudPAT

1.1. Intended Use of WatchPAT™ device

1.1.1. WP200U and WP300 in US and EU

The WatchPAT™200U (WP200U) and WatchPAT™300 (WP300) devices are non-invasive home care devices for use with patients suspected to have sleep related breathing disorders. The WP200U and WP300 are a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP200U and WP300 generate a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. PSTAGES and snoring level and body position provide supplemental information to the PRDI/PAHI/PAHIc provided by WP200U and WP300. PSTAGES and snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.

1.1.2. WP200 / WP200U and WP300 in ROW

WatchPAT™200 (WP200), WatchPAT™200U (WP200U) and WatchPAT™300 (WP300) (collectively known as WatchPAT™ device) are a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT™ device is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The device generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), PAT sleep staging identification ("PSTAGES") and optional snoring level and body position discrete states from an external integrated snoring and body position (SBP) sensor. The device's "PSTAGES" and SBP provide supplemental information to its PRDI/PAHI. The device's "PSTAGES" and SBP are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

1.1.3. WatchPAT™ ONE in US

The WatchPAT™ ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT™ ONE is a diagnostic aid for the detection of sleep related

breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WatchPAT generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and snoring level and body position discrete states from an external integrated snoring and body position sensor. The WatchPAT's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WatchPAT's PSTAGES and snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.

1.2. zzzPAT S/W – Definition

zzzPAT is an analysis software package used with the WatchPAT™ device to aid in diagnosis of sleep related breathing disorders and detects REM, Light Sleep, Deep Sleep and Wake stages. The zzzPAT S/W displays the signals recorded by the WatchPAT™ device, automatically identifies breathing disordered events and REM, Light Sleep, Deep Sleep stages, and generates a comprehensive report for the physician.

1.3. CloudPAT S/W – Definition

CloudPAT is a HIPAA-compliant (PL104-191) web-based cloud application used for providing management system for sleep studies. It offers individual physicians or large organizations the ability to control the process of sleep disorder management seamlessly and electronically in a turnkey fashion.

In its basic implementation, CloudPAT is a parallel adjunct to the local zzzPAT sleep analysis software sold separately with WatchPAT™ device. CloudPAT uses zzzPAT's analyzing software modules (part of WP Interface package) that are responsible for the identification of the breathing disordered events and Sleep stages.

CloudPAT offers simple preparation and uploading of WatchPAT™ sleep studies that can be sent transparently for interpretation by a local Interpreting Physician or from a national network of telemedicine to a Board-certified Interpreting Physicians. After interpretation the sleep study results will be attached to the patient's record. The regular, comprehensive WatchPAT™ sleep study report is available for printing, export, and analysis. All actions performed in the CloudPAT described above are performed from a secure website. Each user will have his own permissions and restrictions that enable to see only her/his sleep patients. All data is securely stored and backed up on the Web.

1.4. Overview

Sleep apnea is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. Obstructive Sleep apnea is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep with the presence of breathing effort, while Central Sleep apnea is characterized by no respiratory effort. Both conditions often lead to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is usually based on apnea-hypopnea index (AHI – the number of Apneas, and Hypopneas per hour of sleep) and / or the Respiratory Disturbance Index (RDI) which is AHI plus Respiratory Effort Related Arousals (RERA), along with sleep architecture. The common consequences of this sleep disruption are daytime sleepiness, poor daytime performance and increased vulnerability to accidents. Cardiovascular complications such as systemic/pulmonary hypertension, ischemic heart disease and arrhythmias are the major sequel of sleep apnea in the adult population.

The WatchPAT™ device is worn on the wrist and utilizes a plethysmographic based finger-mounted probe, to measure the PAT (Peripheral Arterial Tone) signal. The PAT signal is a measurement of the pulsatile volume changes in the fingertip arteries which reflects the relative state of the arterial vasomotor activity, and thus indirectly the level of sympathetic activation. Peripheral arterial vasoconstriction, which mirrors sympathetic activation, is shown as attenuation in the PAT signal amplitude. The PAT signal is recorded continuously and stored on a device's memory along with pulse rate (derived from the PAT signal), together with either data from oximetry channels integrated into the uPAT probe (WP200U/WP300/WP1), or from a built-in pulse-oximetry sensor (WP200) and an actigraph (embedded in the device). Snoring and Body Position signals are generated from the SBP/RESBP integrated sensor (optional). The RESBP (Respiratory Effort Snoring and Body Position) sensor records the subject's chest movement signal in addition to the snoring and body position signals that are included with the SBP sensor. Following the sleep study, in an offline procedure, the recordings are uploaded to a web server and analyzed using the proprietary CloudPAT software.

CloudPAT uses the zzzPAT's analysis. The study data can be downloaded to a local PC in case the whole night data needs to be viewed and the automatically detected events need to be revised manually using the zzzPAT.

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

1.5. CloudPAT Version 2.8 Overview

CloudPAT Version 2.8 introduces the following main capabilities:

1. WatchPAT™ ONE Support.
2. Option to exclude Patient Health Information from data on WatchPAT device.
3. Create patient record from details provided in file.

4. Enhanced access restrictions to patient's health information and user login.

Additional changes introduced with V2.8:

5. Notify interpreting physician when study is reassigned
6. Allow interpreting physician to change Desaturation Threshold
7. Office Request Script
8. Automatically set Medicare insured patients to 4% Desaturation Threshold
9. Allow re-run failed analysis
10. Final report preview (prior to locking the study).
11. Shortcut icons in Enhanced Patient Care Pathway Chart.

1.6. Terminology

CloudPAT supports various types of users and entities.

- **Office** – a practice responsible to dispensing 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 (see Section 3).
- **Interpreting Physician** – a physician (typically Board-certified) performing the sleep study analysis, interpretation, diagnosis and recommendations. This is another type of user using CloudPAT functions: Reviewing and interpreting studies and Managing templates for diagnosis and recommendations (see Section 3.6).
- **Patient** – the person who undergoes the sleep study.

1.7. Minimum requirements

An internet connection using a PC workstation with Microsoft Win7 and above, running at a minimum upload speed of 1 Mbps and supported browser (Internet Explorer version 11 or higher, Edge, Chrome or Firefox) is required.



Note


Figures included in this Operation Manual are for reference only and 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 WatchPAT200/200U/300 devices). A secure and individual login account must be assigned by Itamar administrator.

To obtain a Username and Password, contact Itamar Medical or send an email to info@itamar-medical.com. After a vetting process, you will get an email invitation containing your assigned Username followed by a 2nd email with the initial password.

	<p style="text-align: center;">Note</p> <p>Be sure to change the initial password upon sign in.</p> <p>Be sure to select Secret Question and provide an answer, so you will be able to generate a new password in case you will forget your password.</p>
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2.2 Accessing CloudPAT

All subsequent access to CloudPAT will be via the Sign-in icon located on the home screen of www.Itamar-Medical.com or directly, according to the server location at:

Server location	Direct link
United state	https://cloudpat.precisemd.com
European union	https://cloudpateu.precisemd.com
United Kingdom	https://cloudpatuk.precisemd.com

Access to CloudPAT starts with the Sign In screen where Username and Password are entered (see Figure 1).

Support

itamar
medical

Sign in to CloudPAT

Username

Password

Sign In

[Forgot your password?](#)

[STOP-BANG Questionnaire](#)

Terms and Conditions:
Your use of the Itamar-Medical's CloudPAT portal service confirms your agreement to be bound by the terms and conditions contained in this agreement as well as any rules for use of the services. It also acts as your acknowledgment of your receipt and understanding of the disclosures in this agreement and your agreement allowing all disclosures or other information required under applicable law to be sent electronically. Terms and conditions of this agreement may change from time to time. Itamar-Medical has the right to terminate this agreement and/or your access to the CloudPAT portal service at any time, at our convenience and without cause. In no event will Itamar-Medical be liable for any direct or indirect, damages or lost profits arising from your use of our CloudPAT portal service as well as any interruption in availability of our service, delay in operation or transmission, computer virus, loss of data, or otherwise, even if Itamar-Medical has been advised of the possibility of such damages or loss.

Agreement
BY USING THE WEB SITE OR BY LOGGING IN ABOVE, YOU SIGNIFY YOUR AGREEMENT TO THESE TERMS AND CONDITIONS. IF YOU DO NOT AGREE TO THESE TERMS AND CONDITIONS, DO NOT USE THIS WEB SITE.

Figure 1: Sign In screen

If wrong password is entered twice, reCAPTCHA security service is added to the sign-in sequence.


After several failures to sign in to CloudPAT, your account might be temporarily locked. In such event, CloudPAT sends notification message to your email account.

Sign in to CloudPAT

We do not recognize your ID and/or password. Remember, passwords are case-sensitive. Please try again.

Username

Password

I'm not a robot  reCAPTCHA
Privacy - Terms

Sign In

[Forgot your password?](#)

[STOP-BANG Questionnaire](#)

Figure 2 - Sign-in screen with reCAPTCHA security service

An office you belong to may restrict CloudPAT access to specific IP address range. In such case, if you reside out of this IP address range, your login will be blocked and the following error message will be displayed:

Access denied. Your IP address () is not permitted for your office(s). Please login from a permitted IP.

To setup login restrictions, please contact CloudPAT Support at CloudSupport@itamar-medical.com.

2.3 Setting [Initial] Password

Upon initial account setup, you will be prompted to enter an initial temporary password. Upon first time signing in CloudPAT you will be prompted to pick a new password (see Figure 3). The minimum password length is eight characters, that 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 !, \$, #, %).

Figure 3: Set Password screen

For identification purposes you will be prompted to fill in an answer to a secret question.

You must select a secret question and provide an answer to it. This answer will be used for authentication in case you forget your password and need to reset it (in such case a new temporary password will be sent to your email address).

	<p style="text-align: center;">Note</p> <p>All asterisk (*) tagged fields are mandatory and should be filled (see Figure 3).</p>
--	---

2.4 Changing password

When an office is defined, there's an option to determine the period of time (in days) that the password is valid before it expires. After that the system will require the user to change his password by the same rules mentioned in section 2.3 (see Figure 4).

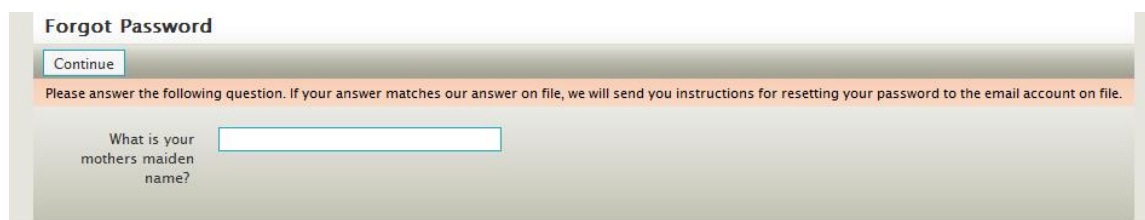
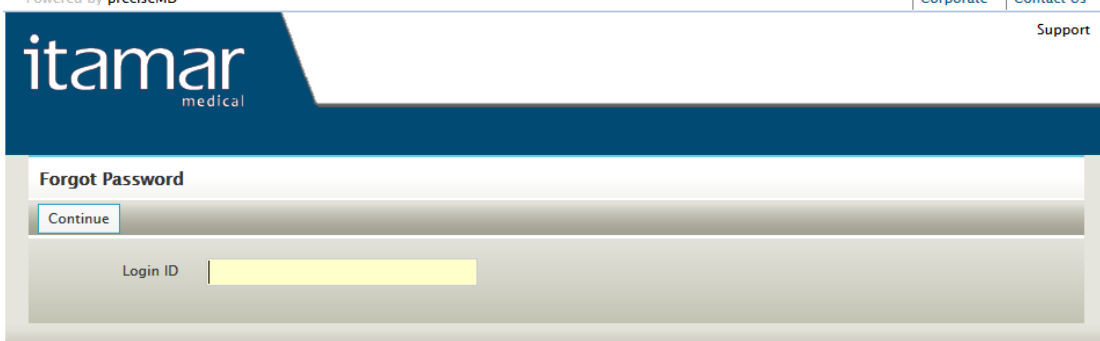
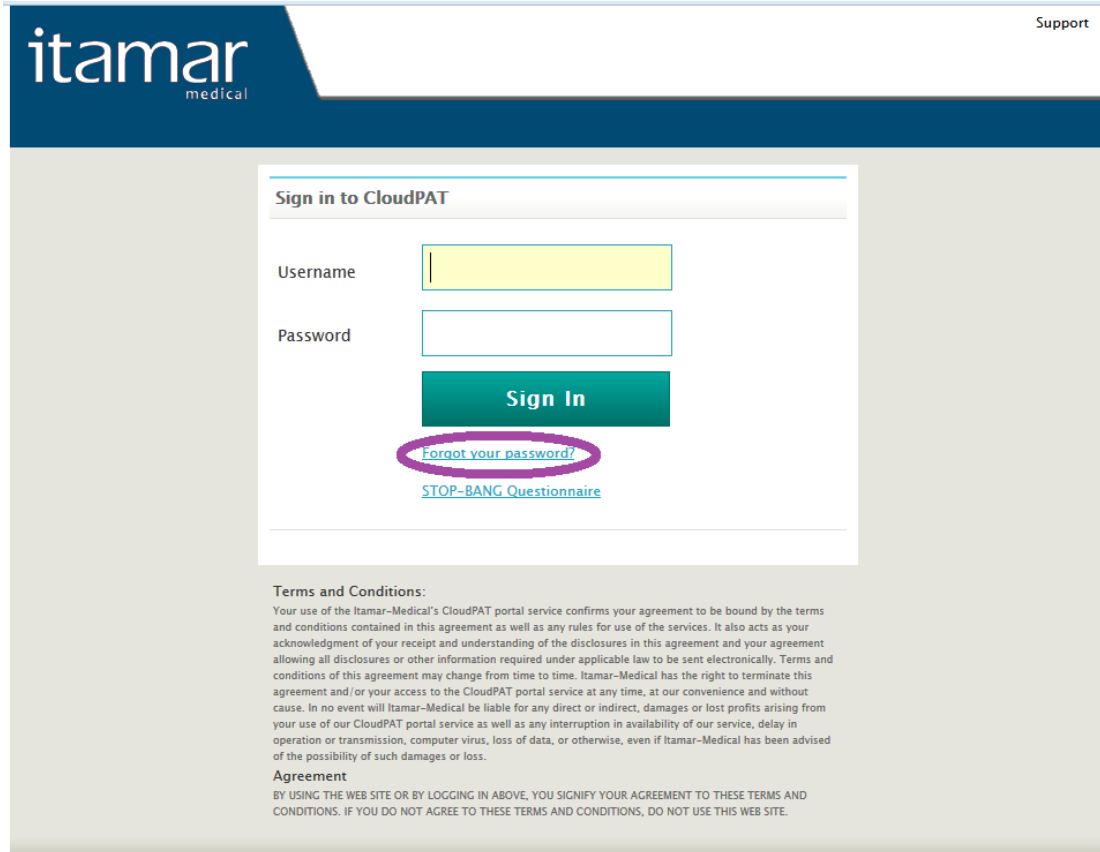
The screenshot displays the 'Change Password' interface. At the top, the 'itamar medical' logo is on the left, and navigation links 'Home', 'Settings', 'Support', and 'Logout' are on the right. Below this is a secondary navigation bar with tabs for 'Home', 'View Reports', 'Patients', and 'Manage Lists', and buttons for 'Create New Study' and 'Upload Study'. The main section is titled 'User Details' and contains a form with the following fields: 'Organization' (Itamar Medical), 'Name' (redacted), 'New Password' (with a red asterisk), and 'Retype New Password' (with a red asterisk). 'Cancel Change' and 'Save' buttons are located at the bottom right of the form. The footer shows 'Powered by preciseMD' and links for 'Corporate' and 'Contact Us'.

Figure 4: Change Password Screen

2.5 Resetting Password

In the event you forget your password, simply click on “Forgot your password?” link on Sign In screen (see Figure 1) and you will get the following sequence where you press “Continue” after each stage. Follow the instructions on each screen (see Figure 5).

In the event you forget your username, first try this: “first-name.last-name” and if it doesn’t work contact customer support (i.e. john.smith).



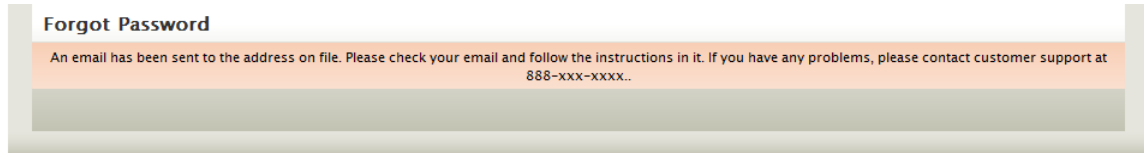


Figure 5: Reset Password screens

2.6 Profile Settings & Support

Users may set their preferences by selecting the “Settings” option from the top of any screen at any time (see Figure 6). Last name and Email address are mandatory fields (see Figure 7). The secret question you have chosen and your answer will be displayed here as well. You may change the secret question at any time if you want. The “Notifications” check-box is for receiving emails notification:

- User will get notification when a report for a study that has been uploaded is ready.
- Interpreting Physician will get notification when there is a new study awaiting interpretation.

For administration support and help with any problems you experience with CloudPAT, please contact us by clicking the “Contact Us” link from any window. This link creates an e-mail sent to Itamar-Medical CloudPAT Support. Use the form shown in Figure 10 to send us a message with your problem description.

Please contact customer support by pressing “Support” from any screen if any difficulties arise. The Support screen contains the up to date phone numbers (see Figure 8).



Figure 6: Functions available from all screens

Profile Settings

Login ID US1 b

Prefix

First Name

Middle Initial

Last Name

Suffix

Secret Question

Answer

Job Title

Address

City

State

Zip Code

Country

Work Phone

Extension

Mobile Phone

Email

Notifications

Figure 7: Profile Settings

Support

For assistance please call one of the numbers listed below.

When instructed by the support agent please click this link : [Click Here](#)

US and Canada:
Tel : 1 888 748 2627

International:
Tel : +972 4 6177000


Toll free numbers:

Australia - 1800256948	Italy - 800782332
Austria - 800295881	Netherlands - 8000229588
Belgium - 80073034	Norway - 80010023
Canada - 18662562506	Sweden - 20795399
Denmark - 80887119	Spain - 900949784
France - 800902142	UK - 8009175110
Germany - 8001825392	USA - 18002066952

Figure 8: Support screen

Note that the contact numbers shown above are subject to change. Always use the updated numbers.

3. Using CloudPAT as a User


	<p style="text-align: center;">Note</p> <p>Access to certain screens or viewing information within a screen might be restricted when user accesses CloudPAT from a non-permitted IP and an office has enable restrictions for viewing Patient Health Information.</p> <p>To setup restrictions for viewing Patient Health Information, contact CloudPAT Support at CloudSupport@itamar-medical.com.</p>
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3.1. Main Access Screen

Here are the main actions that can be selected from this screen (see Figure 9):

1. **SleePAtH** – a dashboard providing patient care pathway management tool which monitors patient care progress: patients’ check-in, diagnosis status and results, allowing the physicians and their staff to better control over the process.
2. **Create New Study** – prepares a new patient & initializes WatchPAT™ device for a new sleep study.
3. **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.
4. **View Reports** – enables the User to see which sleep studies have been analyzed and for which diagnosed sleep reports exist. The User may optionally elect to receive an email notification that a sleep study has been interpreted and diagnosed.
5. **Patients** – enables the User to see which sleep studies have been performed on patients, alter the patient’s information or generate a follow-up sleep study for an existing patient.
6. **Manage Lists** – allows the user to manage the following lists:
 - Medications – enables the User to search for existing medications from global and office level lists and add new ones.
 - Diseases – enables the User to search for existing diseases from global and office level lists and add new ones.
 - Statuses - enables the User to search for existing status from global and office level lists and add new ones.
 - Insurances - enables the User to search for existing Insurer from global and office level lists and add new ones.
7. **Contact** – for help with any problems you experience with CloudPAT, please contact us by clicking the “Contact Us” link from any window. This link creates an e-mail sent to Itamar-Medical CloudPAT Support. Use the form shown in Figure 10 to send us a message with your problem description. The e-mail sent to us will include information about the web page the user viewed when he pressed “contact us”. This will help us

locate and understand the problem.

	<p style="text-align: center;">Note</p> <p>Make sure to specify the correct name and e-mail address so Itamar support will be able to return to you if needed. If you already logged-in your name and e-mail will be taken from the system</p>
---	---

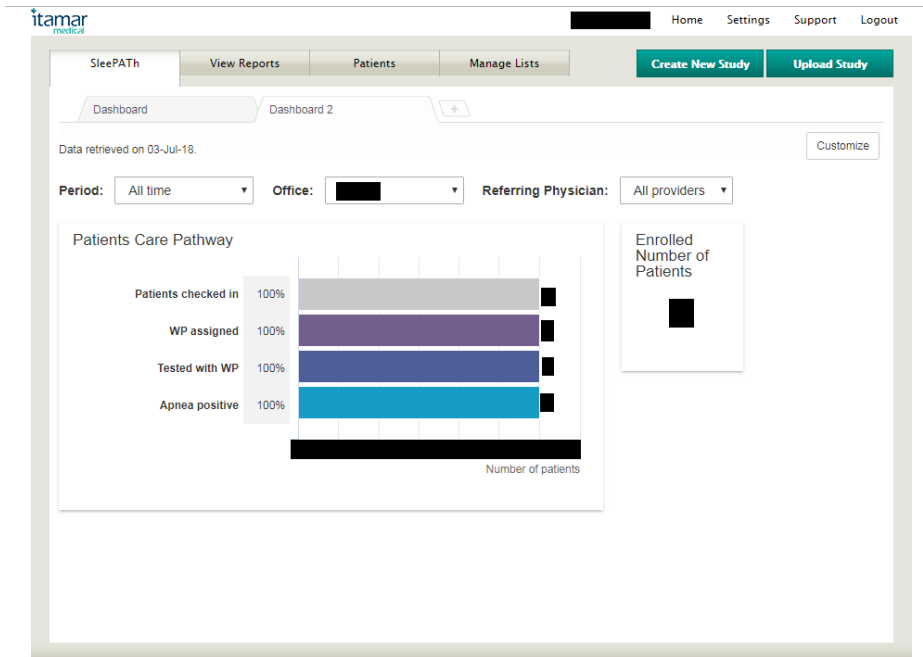


Figure 9: Home Page - SleepPATH

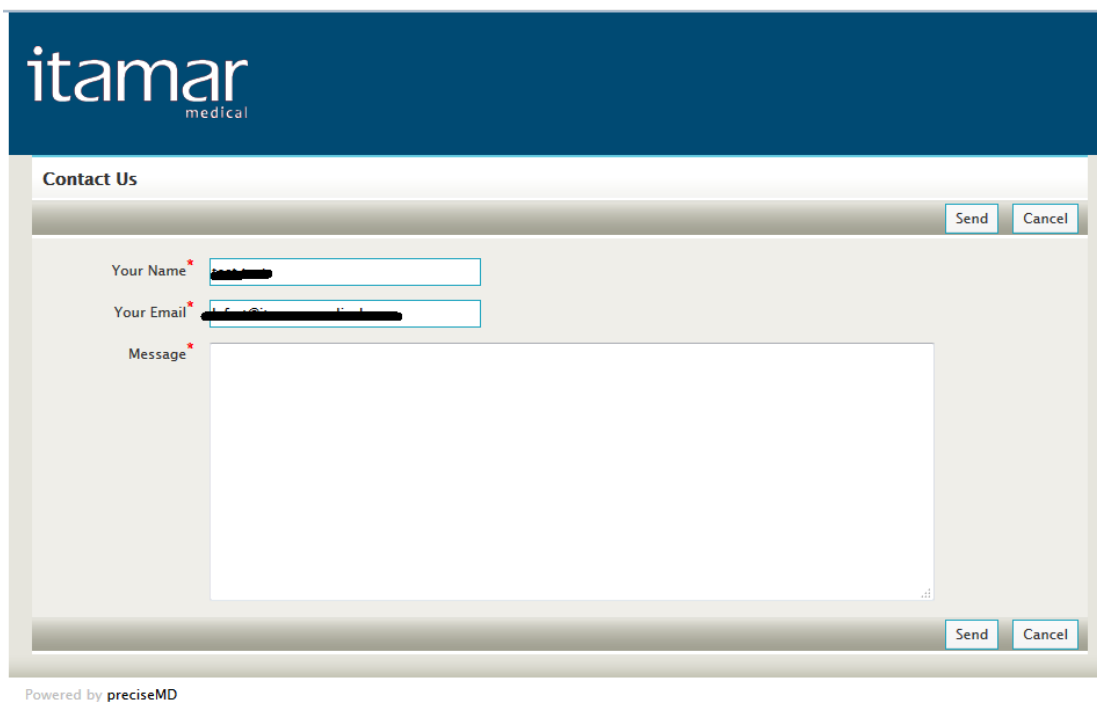


Figure 10: Contact Us screen

3.2. SleepPATH™ Module

SleepPATH Module is a Patient Care Pathway dashboard enabling physicians and provide office admins to track their patients' sleep apnea. Physician can easily focus on the patients group of interest based on their care pathway status. Refer to Figure 9 for typical SleepPATH dashboard layout.

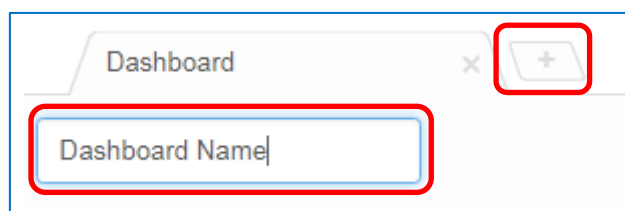
The SleepPATH dashboard is customizable, and can include the following widgets:

- 1) Patient Care Pathway Funnel
- 2) Number of Enrolled Patients
- 3) Sleep Apnea Severity Prevalence
- 4) Customized SA Criteria

Users can create their own dashboards.

3.2.1. Creating and modifying dashboard

To create a new dashboard, click on the “+” tab, and assign a name to the dashboard.



Clicking on *Add widget* button, a popup window is displayed, allowing the selection of a widget. Clicking on a widget will place it on the dashboard, and user can arrange the layout of the dashboard screen by dragging it to desired location.

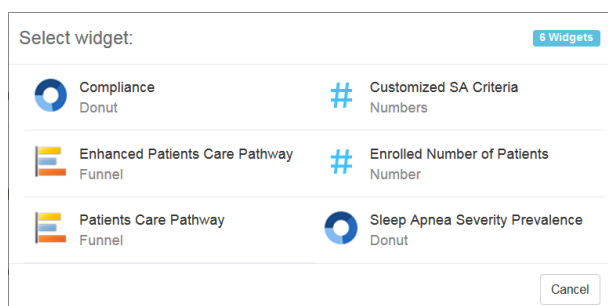



Figure 11: Dashboard widgets selection popup

Widgets can be removed by clicking on the X on its upper right corner. When all widgets are added and placed on their location, click *Save*.

	<p style="text-align: center;">Note</p> <p><i>The Compliance Chart is relevant only for specific DME providers. If these DMEs are not among the offices assigned to the user, the Compliance Chart will be empty. Consult with your office administrator prior to adding this widget to dashboard.</i></p>
--	--

To switch between dashboard, click on the desired tab.

3.2.2. Define patient group

User can focus on specific patient population group that will be presented on the dashboard defining combination of 3 filters:

- A. **Period** - Filtering by specific period based on:
 - a. Admittance date: Patient admitted over the last N weeks/months where N=All time, 1 week, 2 weeks, 1 month, 3 months, 6 months, 12 months, 24 months and 36 months.
 - b. Ablation date: Patient had ablation over the last N days where N=30 days, 90 days and 180 days.
- B. **Office** – either all offices the user belongs to or specific office.
- C. **Referring Physician** – either all physicians or specific one.



Figure 12: Dashboard patient population group filter

3.2.3. Filtered Patient Group Window

SleePATH dashboard provides shortcuts for displaying the list of patients included in the chosen group, based on the selected criteria (see 3.2.2 Define patient group). The title of the list describes the filters used for creating the list including the period, office, referring physician and dashboard shortcut object. Refined search is available by opening the “Refined Search in Filtered Patient Group” subsection (see Figure 13).

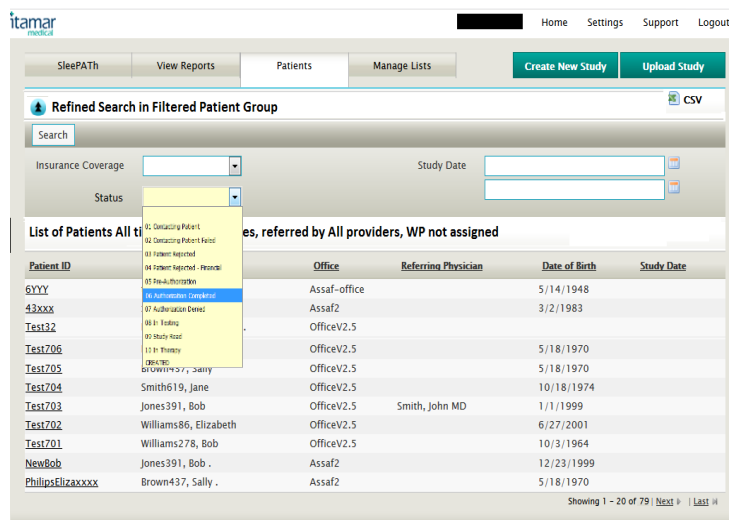


Figure 13: Refined Search in Filtered Patient Group

3.2.4. Patient Care Pathway Funnel Chart

Patient Care Pathway Funnel (see Figure 14) is a bar chart that provides statistics on the selected patient group, along four stages starting from their check-in towards assessment of their Sleep Apnea. For each stage along the pathway, the total number of patients in this stage is provided as well as the percentage of them from the previous stage.

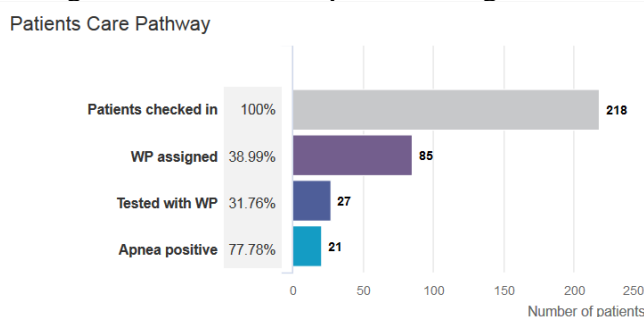


Figure 14 - Patient Care Pathway Chart

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:** Patients assigned with initialized WatchPAT device, including patients returned the device and WP study was uploaded to CloudPAT but yet not analyzed. The number of patients is displayed and their percentage of the checked-in patients.

- 3) **Tested with WP:** Number of patient successfully completed the WatchPAT Study and successfully analyzed, and their percentage out of the patients assigned with WatchPAT.
- 4) **Apnea positive:** Number of patient that were positively diagnosed with sleep apnea, i.e. AHI above threshold¹, and their percentage of all WP tested patients.

Clicking on any of the bars in the Patient Care Pathway bar chart will display a list of patients included in the chosen group, based on the selected criteria (see 3.2.3 Filtered Patient Group Window). Clicking on a patient within the list displays the Patient Details window.

3.2.5. Enhanced Patient Care Pathway Funnel Chart

The Enhanced Patient Care Pathway Funnel is a stacked bar chart that provides statistics on the selected patient group, along four stages starting from their check-in towards assessment of their Sleep Apnea (see Figure 15). For each stage along the pathway, the total number of patients in this stage is provided as well as the percentage of them from the previous stage. Each stage is built from 1-3 subsections, main/first section and additional 1-3 complementary sections, that all together sum to the number of patients in the main/first section of the previous stage. The first (main) section is assigned with unique color, while the complementary sections are in gray levels.

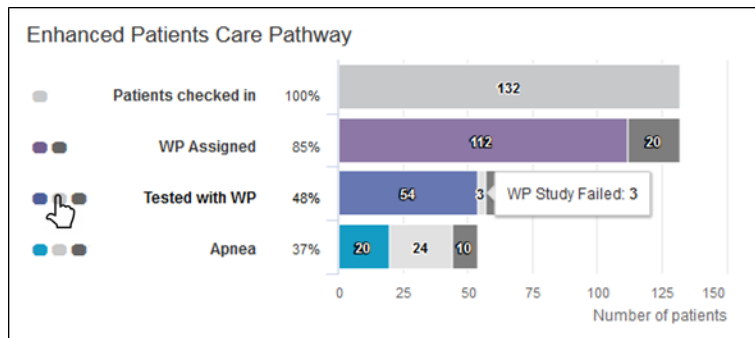


Figure 15 - Enhanced Patient Care Pathway Chart

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 patients returned the device and WP study was uploaded to CloudPAT but yet not analyzed.
 - b. WP not assigned: Patients yet not assigned with WatchPAT device.
- 3) **Tested with WP:**
 - a. Tested with WP (main): Patients successfully completed the WatchPAT Study and successfully analyzed.
 - b. WP Study Failed: Patients that their WP study was uploaded to CloudPAT but no AHI was calculated.
 - c. Not tested yet: Patients that their WP study yet not uploaded to CloudPAT.
- 4) **Apnea:**

¹ AHI Threshold is configurable per office. Refer to your office admin to determine the AHI threshold defined for your office(s).

- a. Apnea Positive (main): Patients that were positively diagnosed with sleep apnea, i.e. AHI above the office-defined threshold.
- b. Apnea Negative: Patients that their AHI is below the threshold.
- c. Report not ready²: Patients that their study was successfully uploaded to CloudPAT but their report is yet not ready.

Clicking on any of the sections of the bars in the Patient Care Pathway bar chart will display a list of patients included in the chosen group, based on the selected criteria (see 3.2.3 Filtered Patient Group Window). Clicking on a patient within the list displays the Patient Details window.

For simplifying the selection of small / hidden section, shortcut icons are located left to the bar title. Tooltip is displayed next to the segment when mouse hovers over the icon. Clicking on the shortcut icons opens the relevant Filtered Patient Group window.

3.2.6. Sleep Apnea Severity Prevalence Widget

The SA Severity Prevalence Widget is a half-donut chart displaying 4 levels of sleep apnea severities, as configure per office:

- No Apnea (Green section)
- Mild Apnea (Yellow Section)
- Moderate Apnea (Orange)
- Sever Apnea (Red)

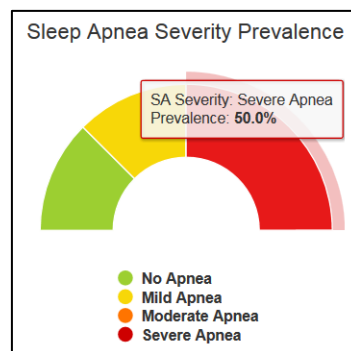


Figure 16: Sleep Apnea Severity Prevalence Widget

Each section represents the number of patients diagnosed with correlated SA severity.

Clicking on any of the sections in the SA Severity Prevalence chart will display a list of patients included in the chosen group, based on the selected criteria (see 3.2.3 Filtered Patient Group Window). Clicking on a patient within the list displays the Patient Details window.

3.2.7. Customized SA Criteria Widget

The Customized SA Criteria Widget allows the users to define their own SA threshold. Bar graph is presented with same color of funnel bar #4, and has the same three values, including Positive, Negative, and Report Not Ready.

² Applicable only for offices configured not to show analysis file, and therefore, the AHI is only taken from locked report. For all other offices, this section will always be zero.

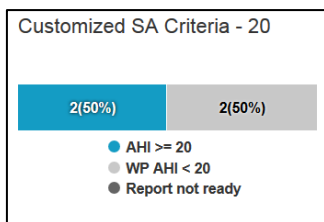


Figure 17: Customized SA Criteria Widget

Multiple instances of this widget can be included in the dashboard. Defining or changing this threshold is available only during dashboard customization.

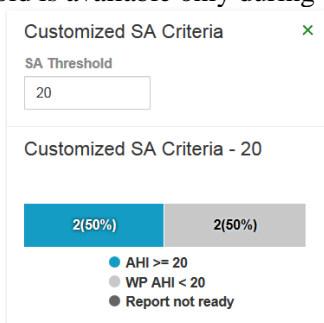


Figure 18 - Defining SA Threshold

Clicking on any of the sections of the bars in the bar will display a list of patients included in the chosen group, based on the selected criteria (see 3.2.3 Filtered Patient Group Window). Clicking on a patient within the list displays the Patient Details window.

3.3. Create New Study and manage patients

In order to prepare WatchPAT™ device for a new study select “Create New Study” from the Home screen (see Figure 19). This will create a new patient record and open the patient screen (see Figure 22).

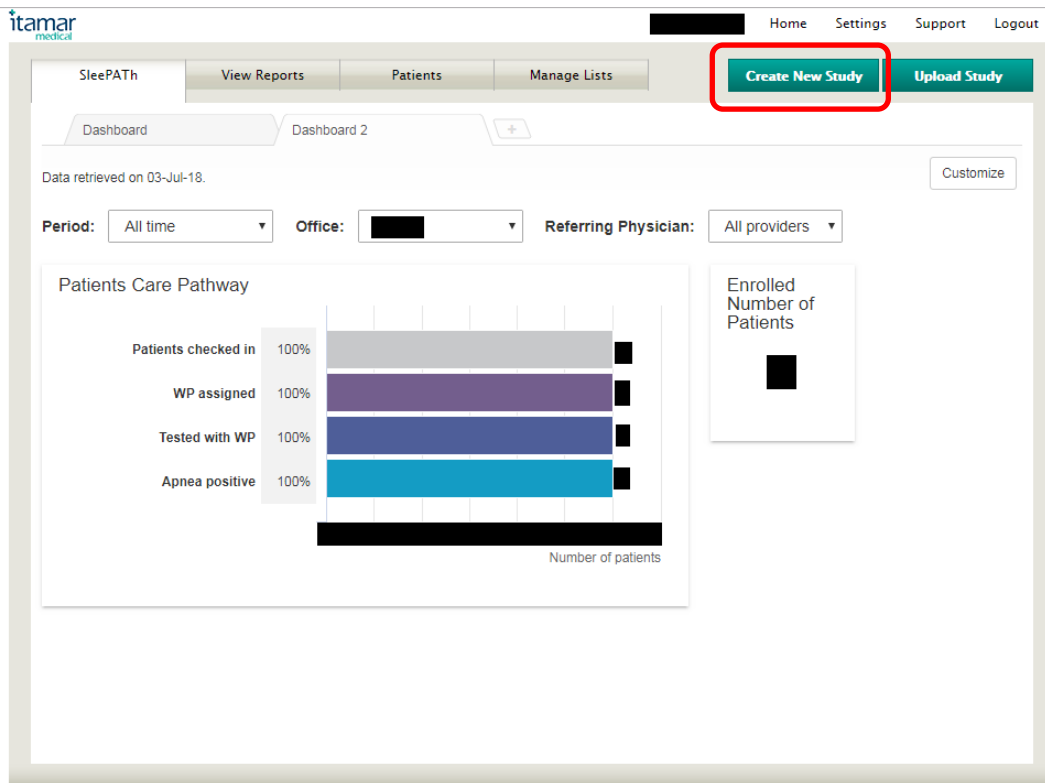


Figure 19: Create New Study selection

You may browse or edit existing patient details by pressing “Patients” from the main screen which will display the Search for Patients screen (see Figure 20). Click “Search” to see a list of all patients (see Figure 21). You can enter filters (patient ID, name, office, etc.) to limit the search results.

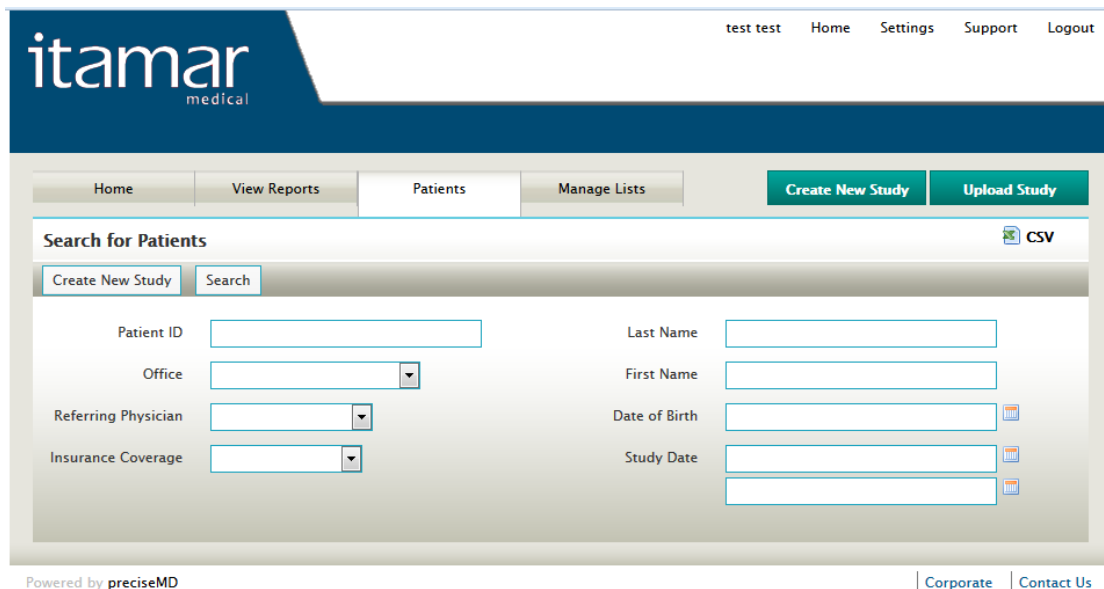


Figure 20: Search for Patients screen

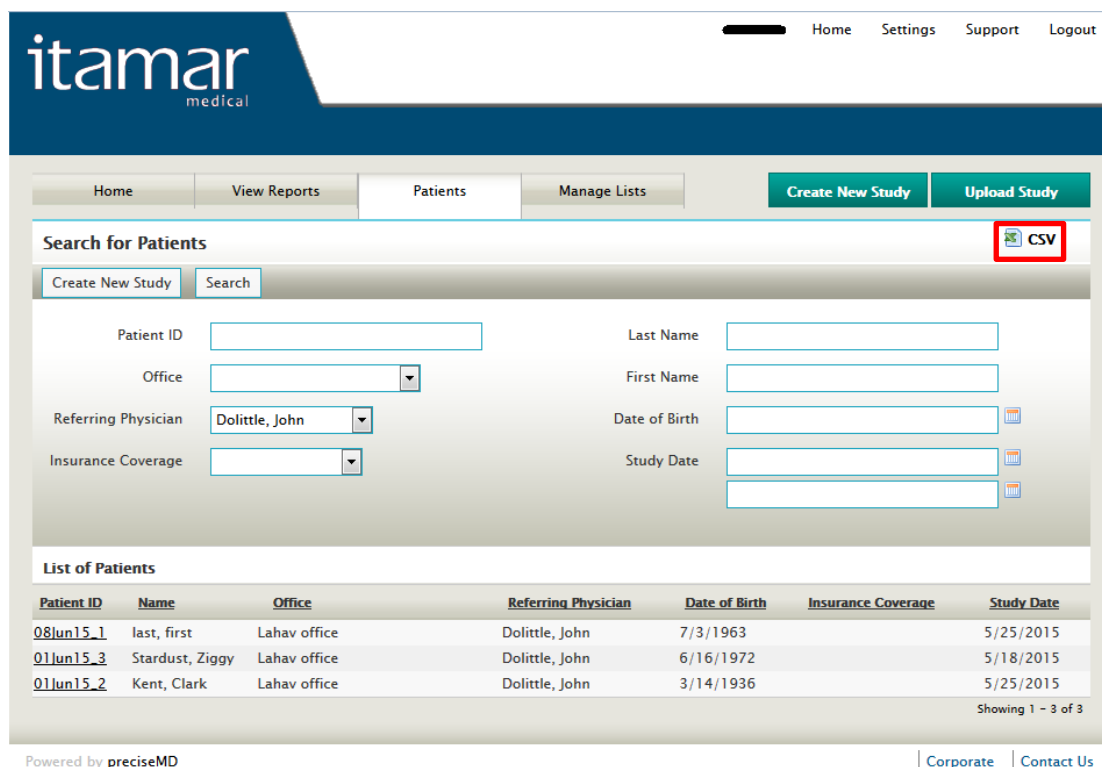


Figure 21: Search for Patients screen

Selecting a Patient ID, will display the patient’s details screen (see Figure 22).

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


3.3.1. Preparing for a New Study

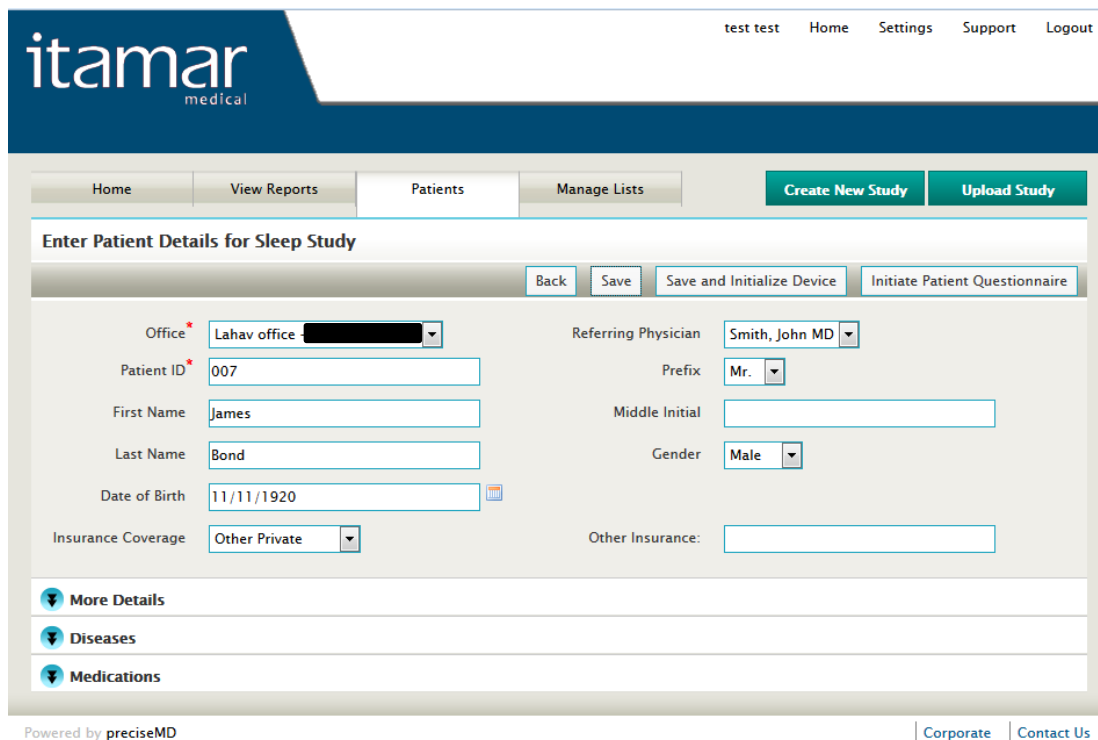
	Note
	CloudPAT can be configured to avoid uploading patient information onto the WatchPAT device. Please refer to Customer Service for activating this mode.

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

1. Fill the **mandatory Patient ID** in the Patient fields as in Figure 22.

	Note
	Patient ID cannot be changed once a device was initiated.


	<p style="text-align: center;">Note</p> <p>Users that are associated with more than one office will have to choose an office as well.</p>
---	--




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Figure 22: Patient data entry screen

- It is recommended you save the patient record at this stage, by pressing the ‘save’ button on the top (see Figure 22). You can save the patient record at any stage and return to it later from the “Patients” screen.


	<p style="text-align: center;">Note</p> <p>Once the system saves the patient details the system checks the values of the entered fields.</p> <p>Erroneous fields and empty mandatory fields will be highlighted in red. Correct the errors and proceed.</p>
---	--

- Insert additional information as needed, the rest of the fields are optional, but filling the patient name is recommended for easier patient management.
You may update the patient status field and additional details in other fields as required by office procedures.


	<p style="text-align: center;">Note</p> <p>Office may be configured to allow attaching files to Patient form at this stage. These files will be associated to the next WP study once successfully uploaded to CloudPAT.</p>
---	--


You may insert additional information after the study is saved to the device if necessary, this information will be updated in the report as long as the report has not been signed yet.

4. More Details (optional): Figure 23 shows the ability to add More Details as the following:
- Patient demographics.
 - Contact details.
 - Sync Clock – select this option if the WatchPAT device clock needs to be set.
 - 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).
 - Pacemaker (available only if office setting permits) – select this option if the patient has an implantable pacemaker. The CloudPAT will automatically detect segments where the PAT pulses seem to be paced i.e. very low pulse rate variations (near to stable) and exclude these segments from the analysis.

	<p style="text-align: center;">Note</p> <p>Some types of pacemakers are excluding the use of the WatchPAT device. See the exclusion criteria section of the device operating manual for more details.</p>
---	---


- If the office setting permits Multiple Nights Study: in order to run up to 3 nights recording with the same WatchPAT device, select the number of nights needed. There are two options for Multi 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)

	<p style="text-align: center;">Note</p> <p>Changing the number of night in a multiple night study might require longer initiation of the device.</p>
---	---

	<p style="text-align: center;">Note</p> <p>The "Enable Tamper-Proof Testing" and "Enable Multiple Nights" options are available only when the WP200</p>
---	--


	internal S/W is version 2.2182 and higher.
--	--

5. Diseases, and/or Medications can be added in the respective drop down lists or as free text.


	<p style="text-align: center;">Note</p> <p>Free text entered to lists will automatically be added to the office's list. You can add/update and remove items from the office lists – see section 3.6 for more details</p>
---	---

6. You will be able to let the patient fill a **STOP BANG** questionnaire: click on “Initiate Patient Questionnaire” in Patient Details page, to receive an individual code, which will be valid for 20 minutes only. Alternatively, office can be configured to allow filling-in STOP-BANG questionnaire within CloudPAT, while entering patient details. Alternatively, if STOP BANG questionnaire was completed out of CloudPAT, you can enter the resulted STOP BAND score.


If more than one questionnaire is filled for the patient, the score of the most recent one is displayed in Patient's More Details section, overwriting the previous score.

	<p style="text-align: center;">Note</p> <p>Once the patient starts the questionnaire, he/she has 20 minutes to complete it. If they don't complete it in that time, a new code will need to be generated from within the Patient Details screen.</p>
---	---

Click the STOP-BANG link shown on the CloudPAT Sign In screen (see Figure 1), and after inserting the code, the patient will be able to start the questionnaire.

	<p style="text-align: center;">Note</p> <p>If the patient will use the same computer as you, make sure to logout from the system, close the browser and reopen a browser before handing the computer to the patient, to ensure data safety.</p>
---	--

The questionnaire will be viewable in the patient screen form after patient submitted the questionnaire. The last questionnaire of the patient will also be viewable by the Interpreting Physicians the study will be sent to.

	<p style="text-align: center;">Note</p> <p>Patient filled information will update any empty fields in the patient record, but will not update fields that already</p>
---	--

had data in them.
If you want to update the patient record based on the newly entered information you will need to do it manually.

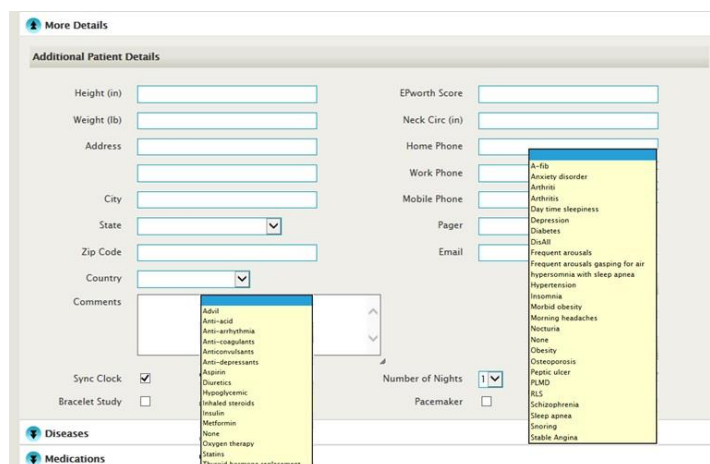



Figure 23: More Detail screen for patient data (optional)


- Once the study definition is completed, press “Save and Initialize Device” (see Figure 22).



Note

Refer to section 3.3.5 for instructions for initiating WatchPAT™ ONE device.


- 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” (see Figure 24).



Note

The first time you run the initialization process, a one-time PC-App will be downloaded (see Section 3.3.2).

- A pop-up application will open and manage the initialization of the device. See section 0 for error handling in different cases.





Note


Make sure to connect the device, perform a device test and guide the patient before handing out the WatchPAT™ device. Refer to the WatchPAT™ operation manual for more details.

10. The system will prompt you once the initialization process is completed. Then you will be asked to select an Interpreting Physician for this study. You will be able to change the Interpreting Physician during the upload process and later on, once the study is uploaded from the study page. As long as there is no Interpreting Physician (leaving this field empty) the report is not sent for interpretation and final report cannot be generated.

It is recommended to review the study and correct the entire patient and study information that needs update before sending it to Interpreting Physician.

	<p style="text-align: center;">Note</p> <p>There are few patient details that might change the analysis. See section 3.5.2.6 for more details.</p>
---	---

	<p style="text-align: center;">Note</p> <p>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.</p> <p>To prevent double work for the Interpreting Physician and the need to open signed report, it is recommended to not assign the study until all patient and study fields are updated correctly.</p>
--	--

	<p style="text-align: center;">Note</p> <p>If the office defined Interpreting Physician as Medicare Physician Interpreting, it will be indicated next to his name while selecting Interpreting Physician from the list.</p>
---	--

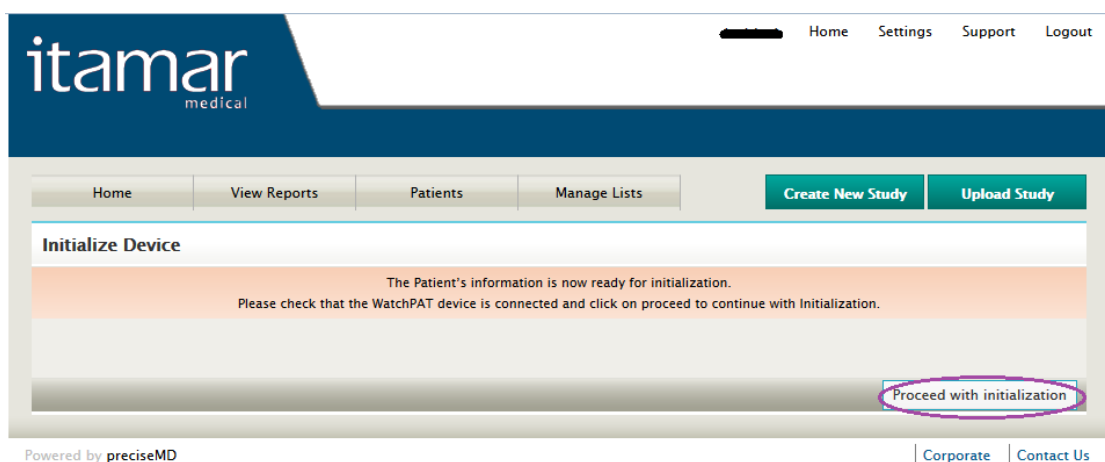
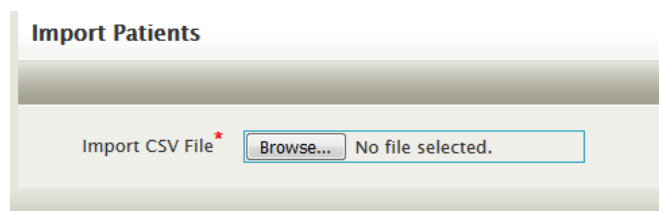


Figure 24: Initialize Device screen

3.3.2. Create patient entries from file

An alternative way for creating patient entry is provided by uploading a CSV file containing patients' information and automatically create these patients in an office the user belongs to.

A new "Import Patients" button is added to the Search for Patients screen that open a window for selection of the CSV file.



The file should have the same format as the export CSV file (see 3.3 and Figure 21). Patient ID and Office columns are mandatory. All other columns are optional and can be omitted.


First two rows shall not be empty rows. It is recommended it would contain the following text:

**List of Patients (SENSITIVE MEDICAL INFORMATION) <<date>>
Created from <<EMR>>>**

Any field that has dropdown in patient details form (e.g. State, Insurance, Gender etc) shall match the text in dropdown – otherwise left blank.

Upload Results:

An output CSV file will be downloaded to the user's desktop automatically with the results per patient. Errors will be highlighted.

Notes	
	<ul style="list-style-type: none">• The User that uploads the file must belong to all offices indicated for the patients.• Any record with an error will cause rejection of the entire file without creating any patient records.

3.3.3. First Time Installation

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

Your browser might only prompt you for the installation after a failed attempt to initialize device / upload (see Figure 25), or might prompt you before, but still fail and prompt you again one time afterwards (see Figure 26) - both are normal, depending on the browser and its setting. You should download the PC-App and run its installation - follow your browser instructions (see Figure 27). Figure 28 and Figure 29 depict the download and run processes in Firefox and Chrome respectively. Once it is installed – approve the use of the application as default (see Figure 30).

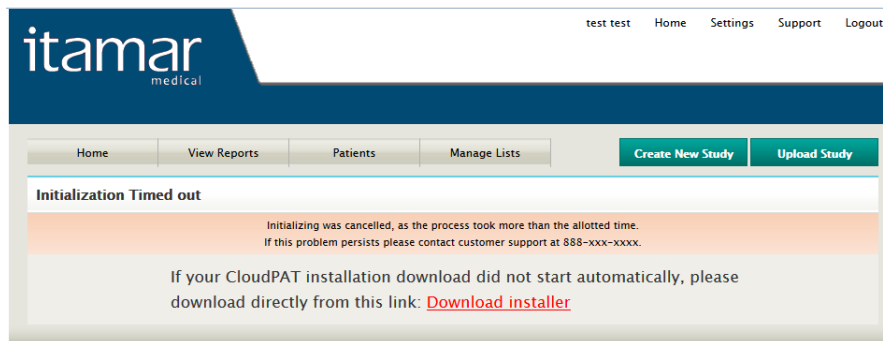


Figure 25: the browser will prompt you to download the installer

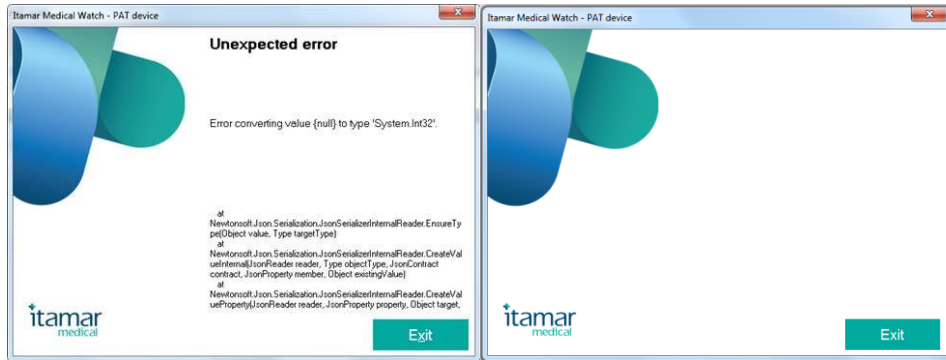


Figure 26: Failing to work with PC App

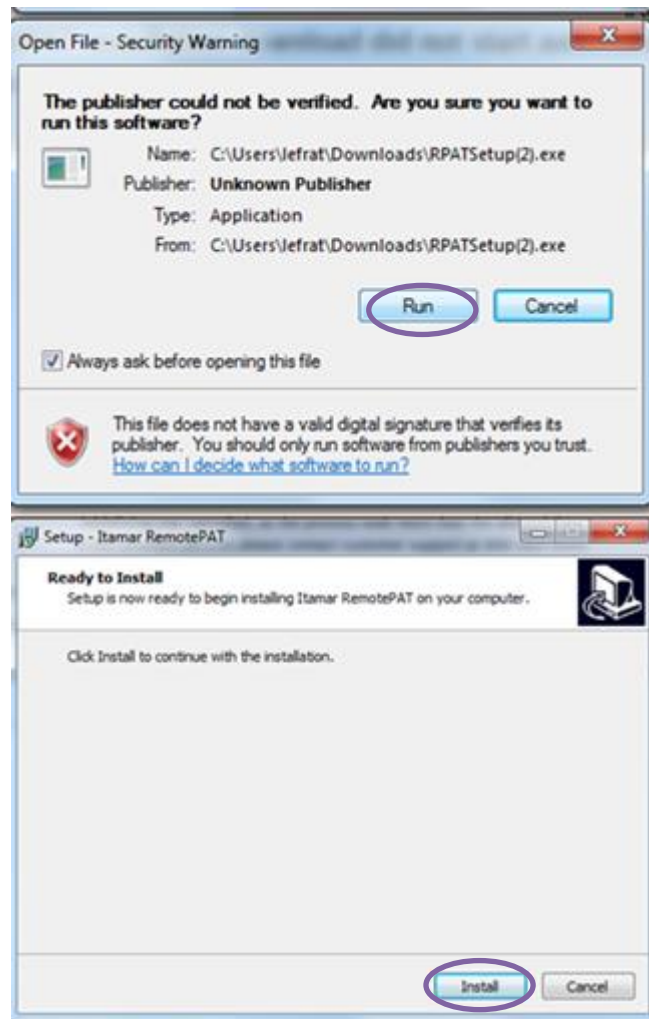


Figure 27: Installation process

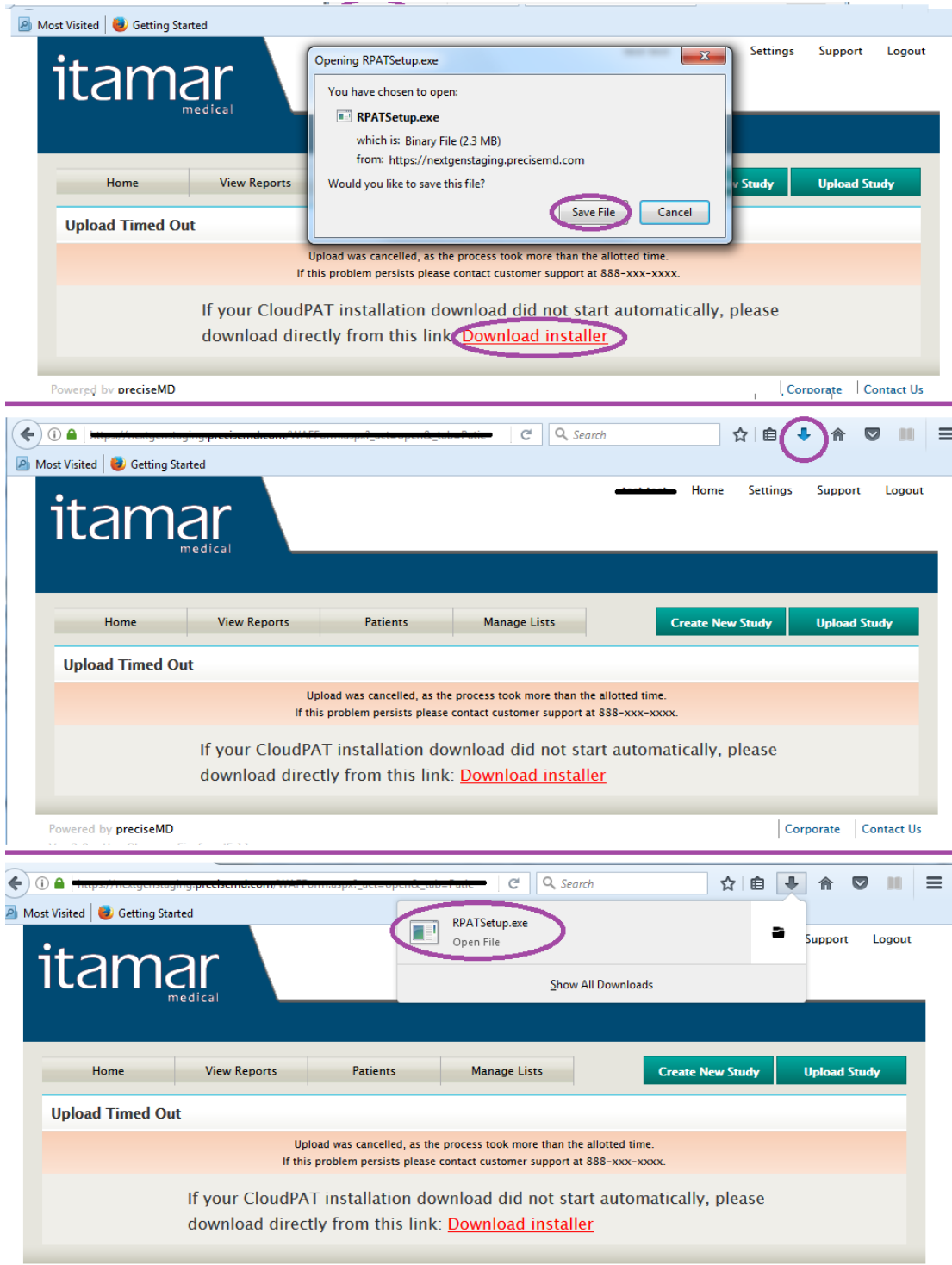


Figure 28: Download and run on Firefox

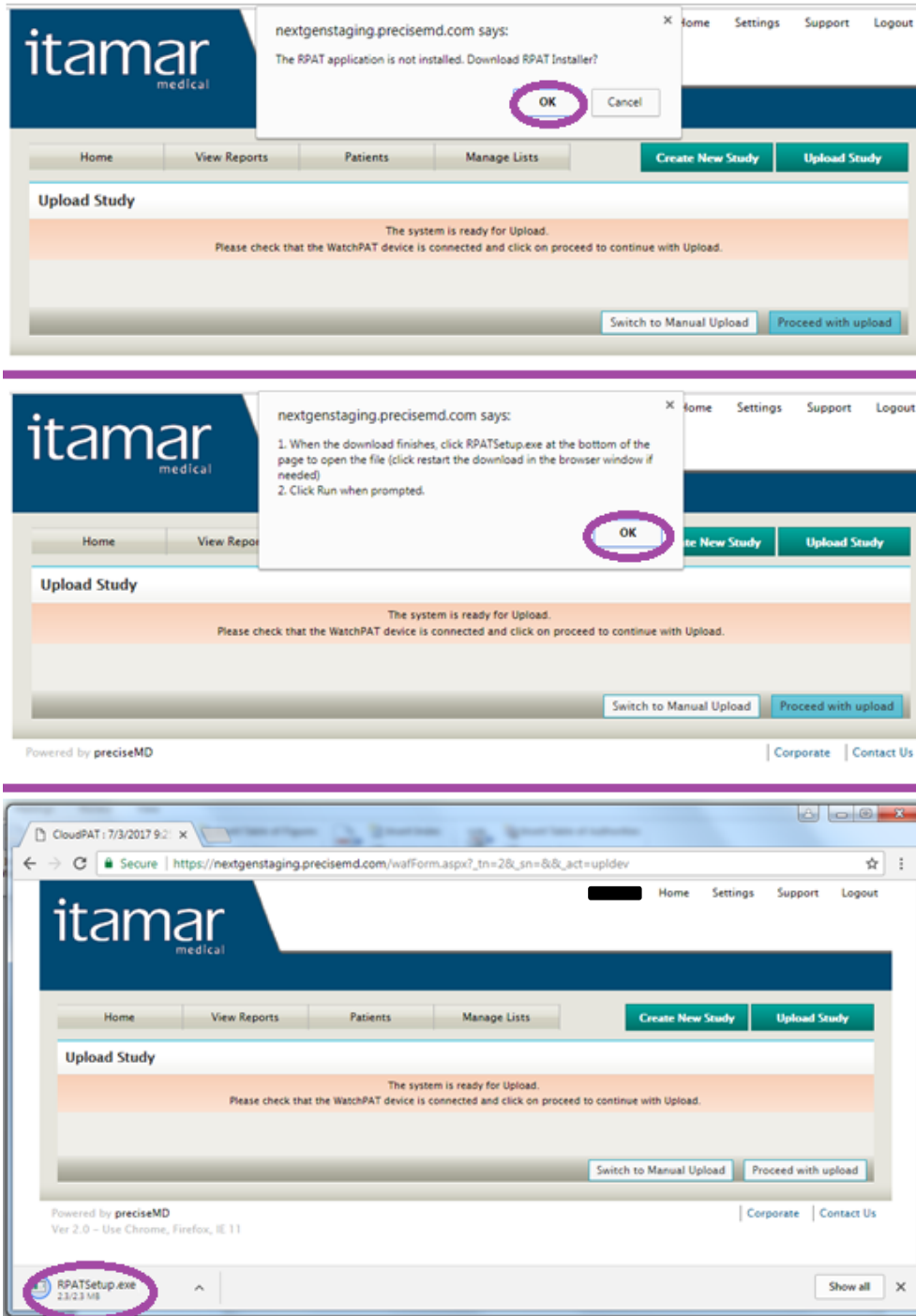


Figure 29: Download and run on Chrome

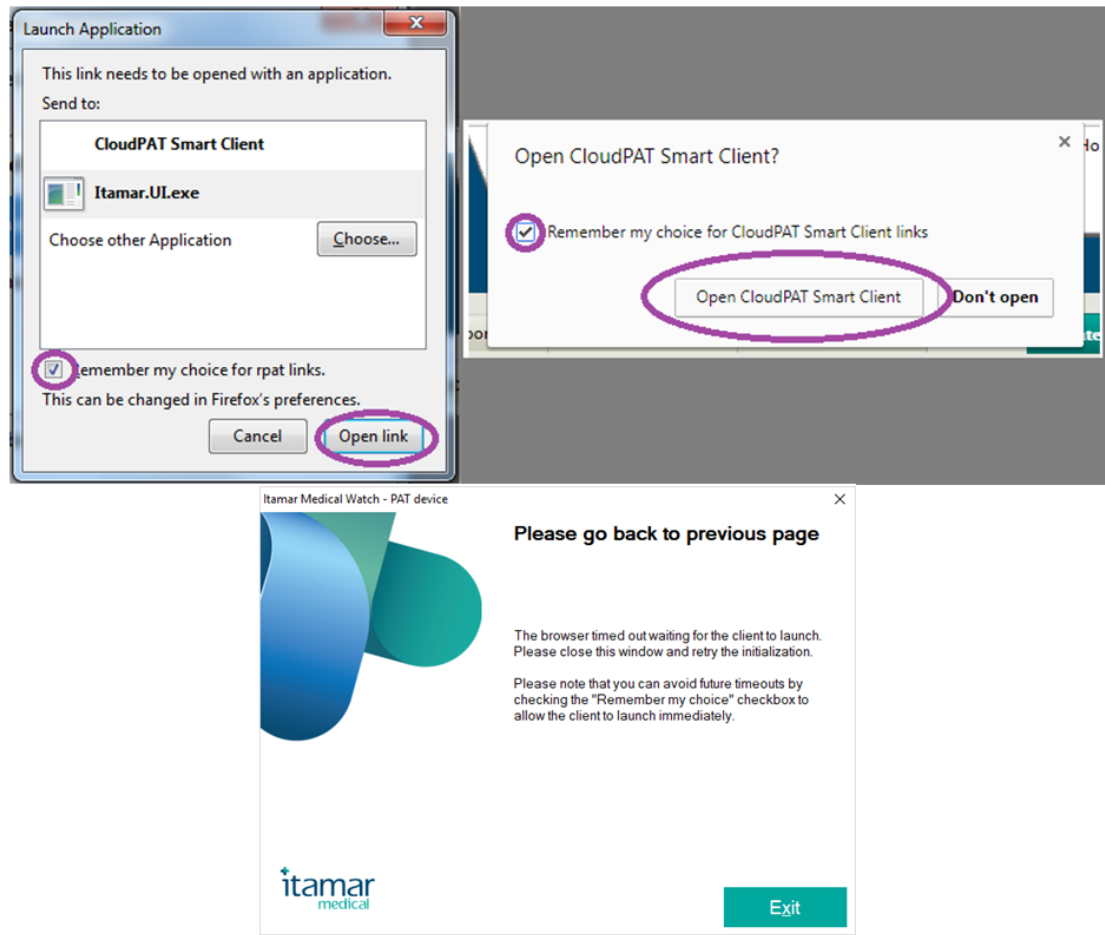


Figure 30: Select the Itamar application
(right – FireFox, left: Chrome)

3.3.4. Initialization Process Protection

Overwrite protection: If a previous study was found on the WatchPAT™ device that was not uploaded to CloudPAT, it will not permit you to overwrite that data but will prompt by saying “Previous study found” (see Figure 31) and that you should upload the study before proceeding. This behavior prevents you from accidental overwriting a study that was not uploaded.

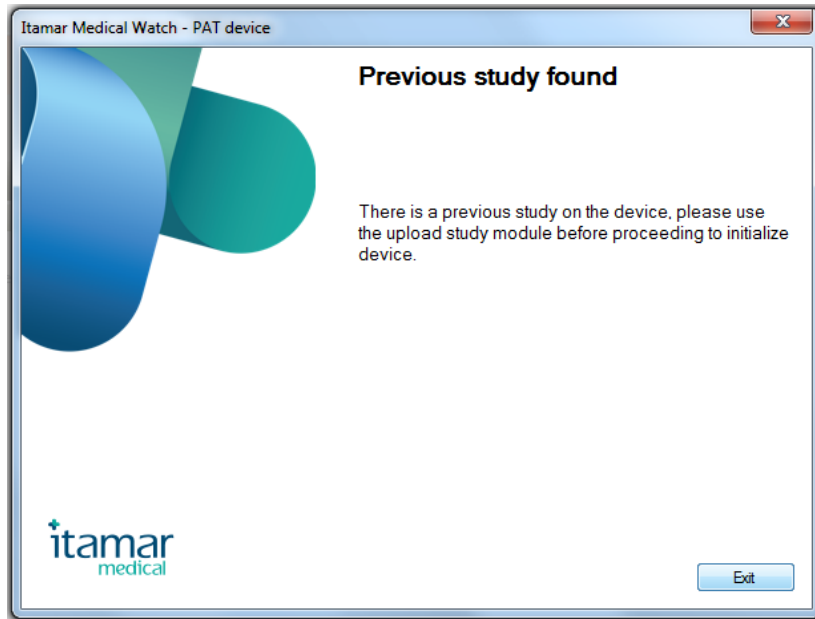


Figure 31: Protection from accidentally overwriting previous sleep study

3.3.5. Initiating study on WatchPAT™ ONE Device

Within Patient Details screen (see Figure 32), click on “Register WP1” button to open the Register WP1 screen (see Figure 33).

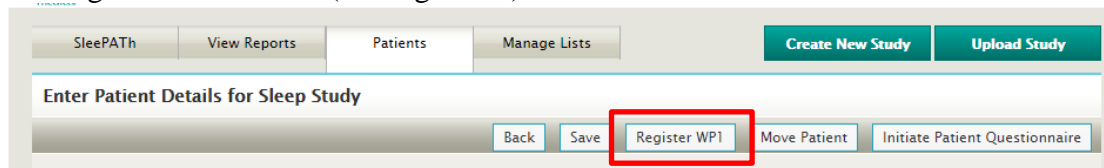


Figure 32 - Register WP1 button in Patient Details Screen

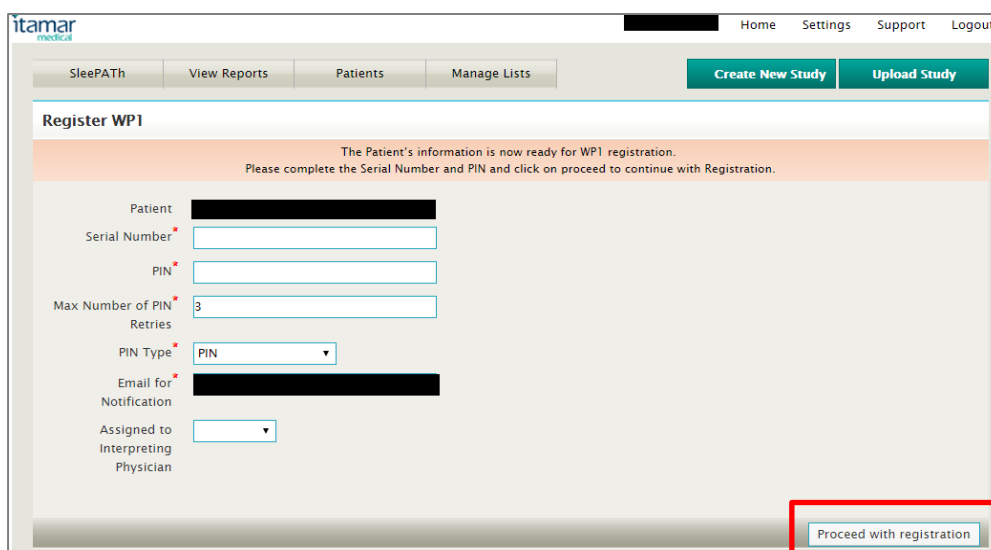


Figure 33 - WP1 Registration Screen

Enter the WatchPAT™ ONE's Device serial number, the PIN and PIN Type (hint) provided to the patient.

- Enter the max number of PIN Retries (default:3).
- The Email for Notification is required, indicating the email for notification on study completion and upload to CloudPAT. The field is automatically filled with office default address, and can be modified yet must include valid email address.
- The Interpreting Physician that the study will be sent to can be assigned at this stage. If Interpreting Physician is not assigned, they can be selected after study is successfully uploaded to CloudPAT.
-

Click on “Proceed with Registration” to complete the initialization process.

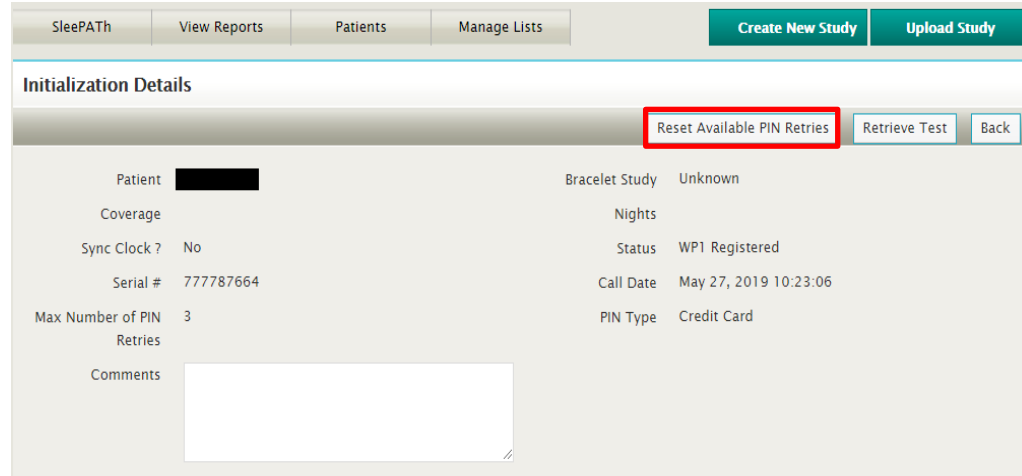
After the registration is completed, a new entry is added to the Initialization section (see Figure 34).



Call Date	Serial #	Status
May 27, 2019 10:23:06	77787664	WP1 Registered

Figure 34 - Registered WPI entry in Initialization section

If patient exceeded max PIN retries, you may reset the counter entering the registered entry in Initialization section and click on “Reset Available PIN Retries” button (see Figure 35).



SleepPATH View Reports Patients Manage Lists Create New Study Upload Study

Initialization Details


Reset Available PIN Retries Retrieve Test Back

Patient [Redacted] Bracelet Study Unknown
Coverage Nights
Sync Clock? No Status WP1 Registered
Serial # 77787664 Call Date May 27, 2019 10:23:06
Max Number of PIN Retries 3 PIN Type Credit Card
Comments [Text Area]

Figure 35 - Reset Available PIN Retries

3.4. Uploading a Study

This section covers uploading a study from the device and manual upload of study (for zzzPAT users).

	<p style="text-align: center;">Note</p> <p>WatchPAT ONE studies are automatically uploaded to CloudPAT once sleep study is completed.</p>
---	--

3.4.1. Normal upload Mode (WP200U/WP300)

When a patient returns 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 select “Upload Study” from the Home Screen (see Figure 36).

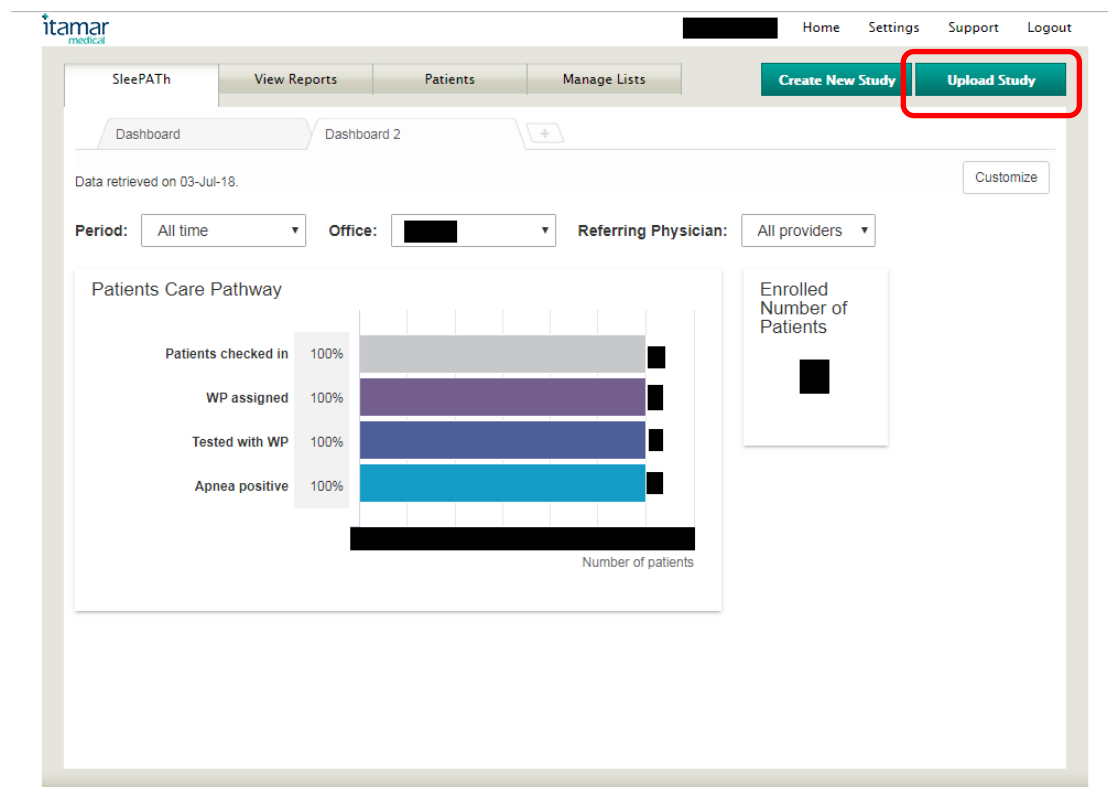


Figure 36: Upload Study Selection

Proceed by selecting the “Proceed with upload” button (see Figure 37).

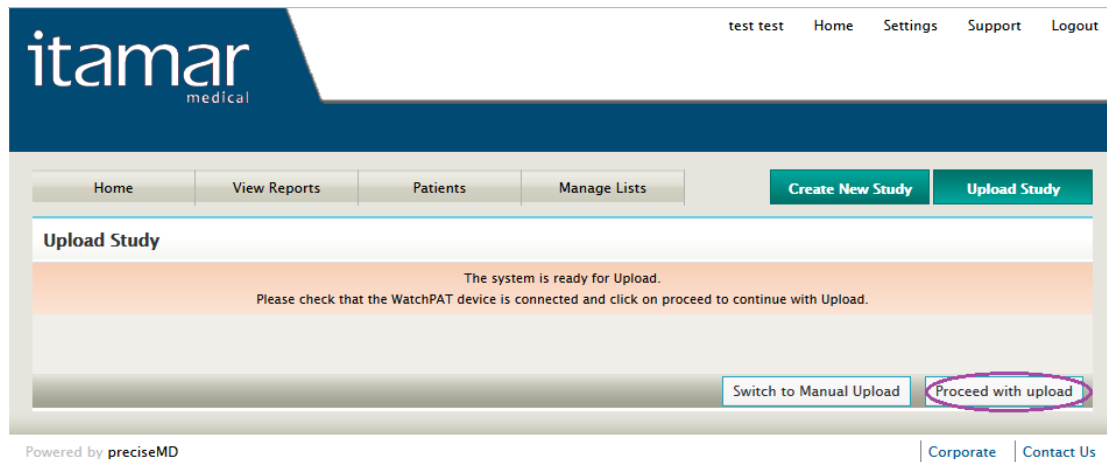


Figure 37: Upload Study Dialog box

A small PC-App will be downloaded the first time remote access is requested from CloudPAT and select “Run”. During the upload process you will see a screen informing that upload is in progress.

	<p style="text-align: center;">Note</p> <p>When a multi-night study is loaded all the night recordings are loaded automatically.</p>
--	---

While uploading, the following dialog (see Figure 38) will be displayed.

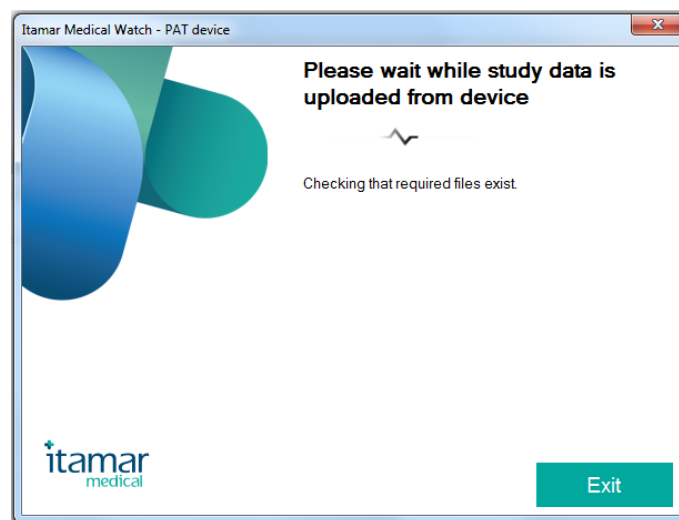


Figure 38: Patient sleep study upload in progress

	<p style="text-align: center;">Note</p> <p>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.</p> <p>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</p>
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initiation of new WatchPAT study.

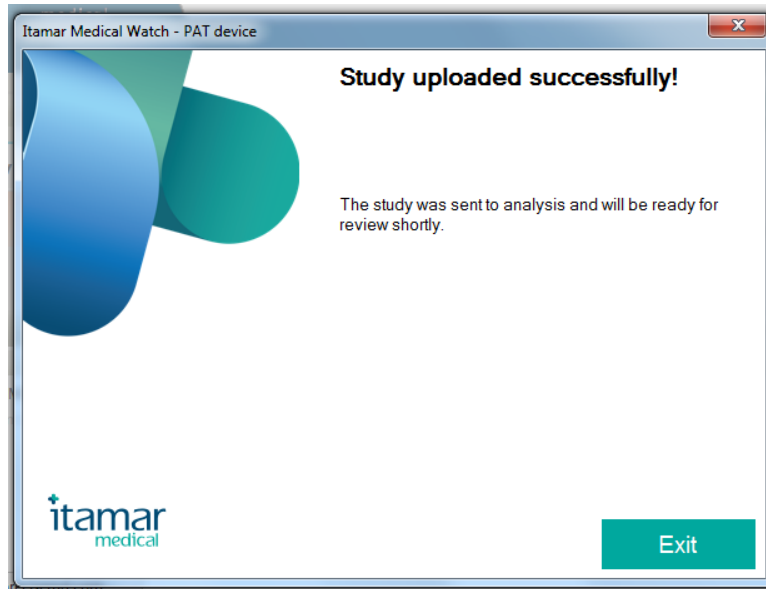


Figure 39: Successful upload screen

If upload is successful you will be asked to approve or change the Interpreting Physician selection (see Figure 40) from a list of Interpreting Physicians which were defined for your office and checkbox requesting for Script.

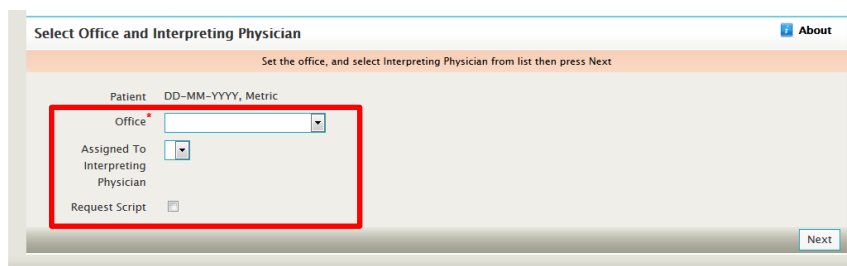
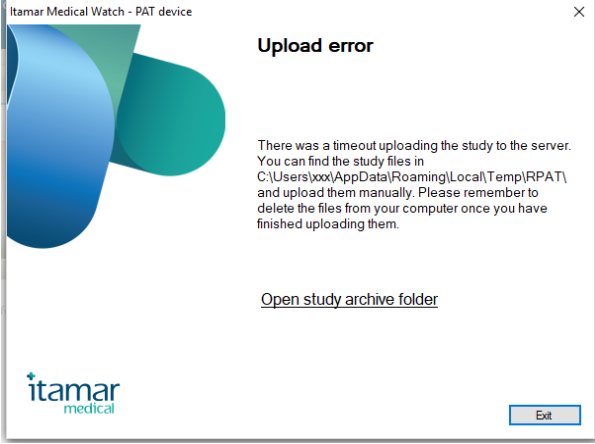


Figure 40: Select Interpreting Physician Dialog box

	<p style="text-align: center;">Note</p> <p>Users connected to two or more offices might be asked to select an office for the upload.</p>
--	---

At the end of the upload process you will receive the message: “Upload Complete: Study uploaded successfully. The analyzed data file will be ready shortly under View Reports”. If the data was assigned to be sent to an Interpreting Physician the message will also include “Data has been sent to be reviewed by [*Interpreting Physician’s name*]” (see Figure 41).

	<p style="text-align: center;">Note</p> <p>If at the end of the upload process you get an ‘Upload Error’ message,</p>
--	--



Make sure you either store the saved file until your internet connection is restore and upload again, or upload again form the device before you re-initiate it.

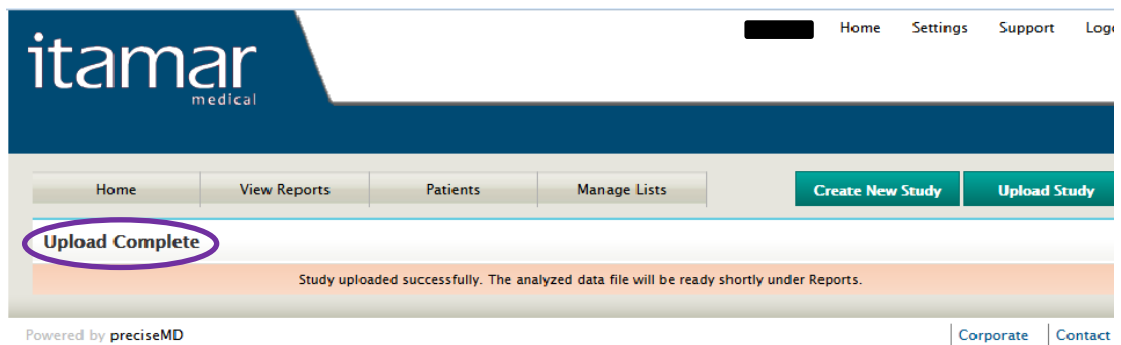


Figure 41: Upload complete screen

If an error is reported, you will need to try again (see Figure 42).

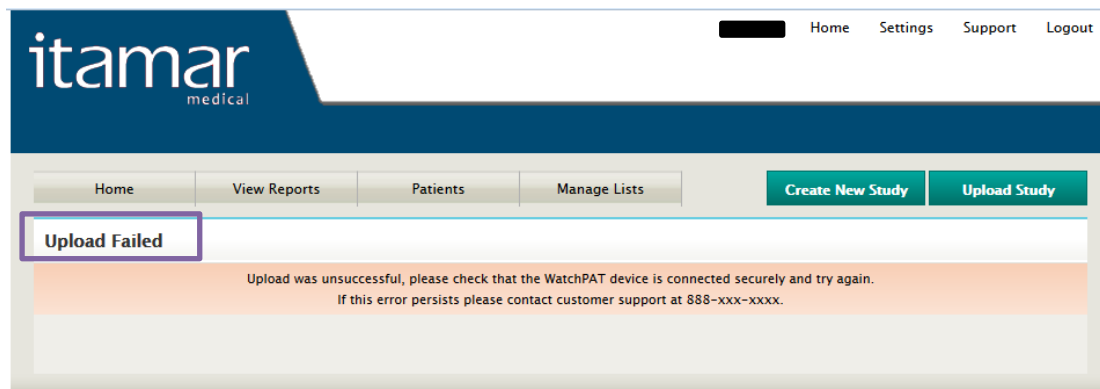


Figure 42: Upload failed screen

Once you upload a study you can choose to add documents to it, see section 3.5.2.2 for more details. These documents will be available for the Interpreting Physician to review when preparing the report. Once the Interpreting Physician locks the report, the Office is no longer able to attach further documents to the patient record.

3.4.2. Manual Mode (WP200U/WP300)

In the rare event that a “manual” upload is needed (such as when an internet outage occurred and sleep study was uploaded locally using zzzPAT), select “Switch to Manual Upload” in which case the following files: patient.dat, sleep.dat and if existing also log.dat, sleep1.dat and sleep2.dat (for multi night studies) should be concatenated into a single .ZIP file and uploaded this way. You may press “Browse” for the “Combined zzp file” (ZIP) file location and press “Next” (see Figure 43). See Appendix A: Exporting a study from **zzzPAT** to CloudPAT Guide for more information about how to export a study from zzzPAT,

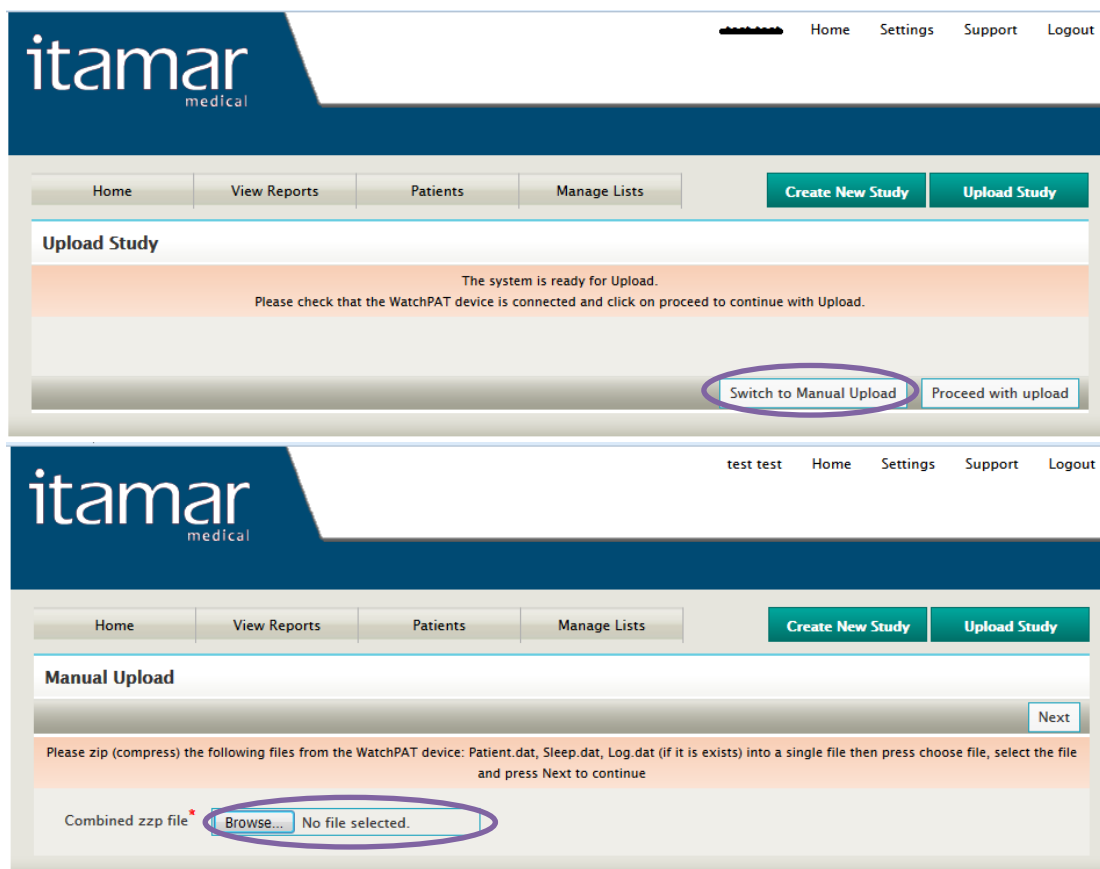


Figure 43: Manual Upload

The rest of the upload process is the same as for the regular upload (selecting Interpreting Physician and onward).

3.4.3. Manual upload of WatchPAT ONE study

In the rare occasions that WP1 study was not automatically uploaded to CloudPAT after sleep study recording was completed, you may upload the study manually via the Initialization section in Patient window.

Select the relevant WP1 registration entry (see Figure 34) and click on “Retrieve Test” button (see Figure 44). You may continue working with CloudPAT and the study will be uploaded in the background. Email will be sent when study is successfully uploaded to CloudPAT to the email address provided during the WP1 registration.

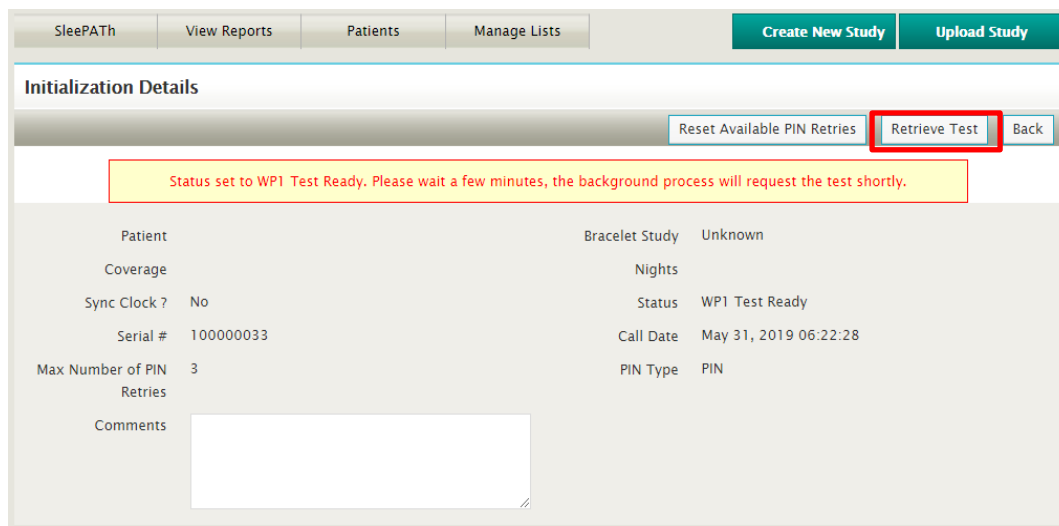


Figure 44 - Manual Retrieval of WP1 Study

3.5. Managing studies and Viewing Reports

3.5.1. Searching studies and reports

Clicking the “View Reports” gets the user to a search screen that enables viewing all or a subset of the studies and reports available to the current user (see Figure 45).

Filtering by patient name and ID, Office, Referring Physician, study and load dates and the study / report status (study sent to Interpreting Physician, report ready, report viewed) are available.

The patient ID in the search result is a link to the study record.

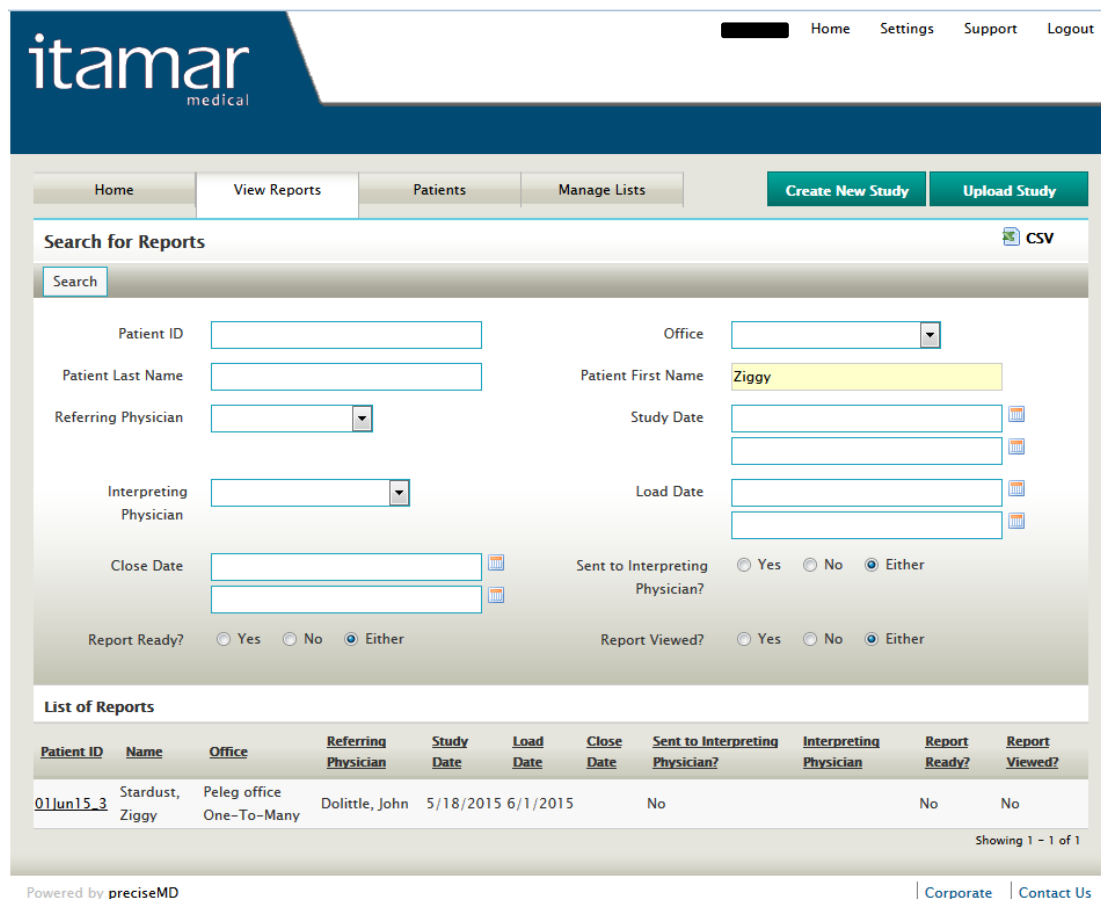


Figure 45: Viewing Sleep Study Reports

Search results can be exported to a CSV format.

3.5.2. Study management

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

3.5.2.1. Understanding the Study screen


Figure 46 shows the study screen on unlocked study (no report yet).

This screen presents information about the study – patient information (the patient name is a link to the patient record and any information modified in the patient record will be reflected in the report until the report is locked), study date, assigned Interpreting Physician, Minimum % of Desaturation for AHI/RDI calculation, analysis status, report status and errors or warnings returned from the analysis. You can indicate to the Interpreting Physician that a script is required for this study and attach files for the Interpreting Physicians review.

Information can be also found about the assignment history.

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

Most of the fields are not editable. The next few sections present what can be done in this screen.

	<p style="text-align: center;">Note</p> <p>To prevent double work for the Interpreting Physician and the need to open signed reports, it is recommended to not assign the study until all patient and study fields are updated correctly and all the relevant files are attached.</p>
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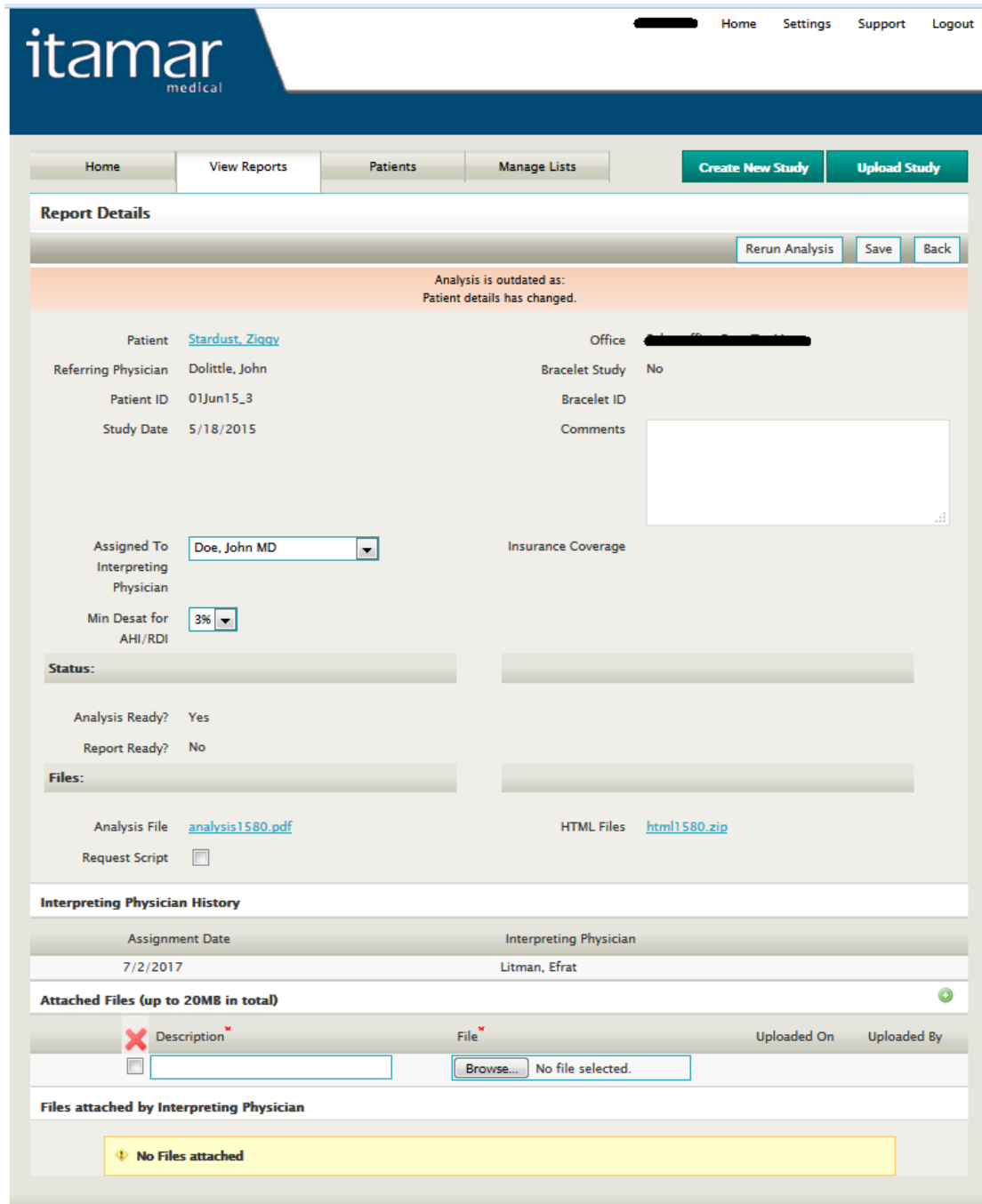



Figure 46: Study screen

3.5.2.2. Attaching files to a study

Once a study is uploaded, and as long as the report is not locked, the user can choose to add documents to it. These documents will be available for the Interpreting Physician review when preparing the report.

To attach a file – enter a description and select the file to be uploaded using the Browse button. To add additional files click the ⊕ icon at the top of the list and a new line will be added to the table.

	<p>Note</p> <p>The maximal size of all attached files is limited to 20MB.</p>
---	--

The user can also remove attached files by marking them for deletion (see Figure 47).

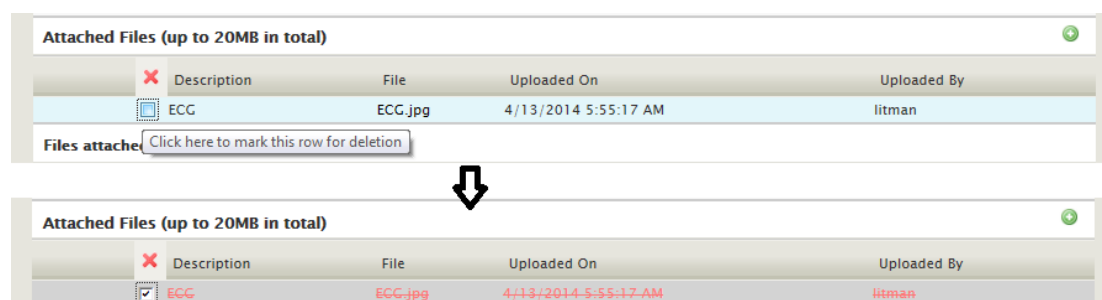


Figure 47: Deleting attached files.


Save the study by pressing the “Save” button on the top of the screen to complete uploading the attached file and to remove deleted files.

3.5.2.3. Changing Interpreting Physician and viewing assignment history

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

The user can view Assignment History to see how long a study is waiting for an Interpreting Physician in an Interpreting Physician queue. Based on that information the user can also change the assignment between the different Interpreting Physicians connected to the office.

Notification of a new study will be sent to the Interpreting Physician only in the first assignment of the study, in all later assignments the study will simply appear in the new Interpreting Physician queue and disappear from the old Interpreting Physician queue. Notification is also sent to the previous Interpreting Physician indicating that the study has been reassigned.

	<p>Note</p> <p>It is up to the user to verify the old and new Interpreting Physician are notified about the change, and to check there will be no surplus charges for the interpretation of this study as 2 Interpreting Physicians have seen it.</p>
---	--


3.5.2.4. View analysis file

Some offices have settings that allow their users view the analysis file (pages 2 and 3 of the report) 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 sets.

Users of such offices can click the analysis file link to open pages 2 and 3 of the report immediately after uploading the study.

When a multi-night study is uploaded, all the reports of the night studies results will appear in one analysis file one after another, with a summery page in the end.

	<p style="text-align: center;">Note</p> <p>Analysis file is created during the analysis and may include patient details that were entered to the system at the time of the analysis. Patient details will not change in the report until report is locked or analysis is re-run.</p>
---	---

3.5.2.5. Request for a script

In case Interpreting Physician should add a script to the report, check the “Request Script” box. Save the study by pressing the “Save” button on top of the screen to complete sending the request to the Interpreting Physician.


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

3.5.2.6. Changes of Study Parameters

The user can change patient information and some study parameters as long as the report is not close. Some of the parameters will require running the analysis again:

- AHI index – according to 3% or 4% desaturations.
- Pacemaker – this option is shown only if the feature is enabled.
- Gender
- Date of Birth

After making changes to these parameters (whether in the patient screen or in the study screen), the user should rerun the analysis to get the new correct results (see Figure 48). A reminder about the need to rerun the analysis will appear on the top of the page together with an option to rerun the analysis. Once reanalyze a notification will be sent to the Interpreting Physician.

	<p style="text-align: center;">Note</p> <p>Per office setup, desaturation threshold may automatically be set to 4% for patients insured by Medicare.</p> <p>Warning message will appear in desaturation threshold is not 4% for Medicare insured patient.</p>
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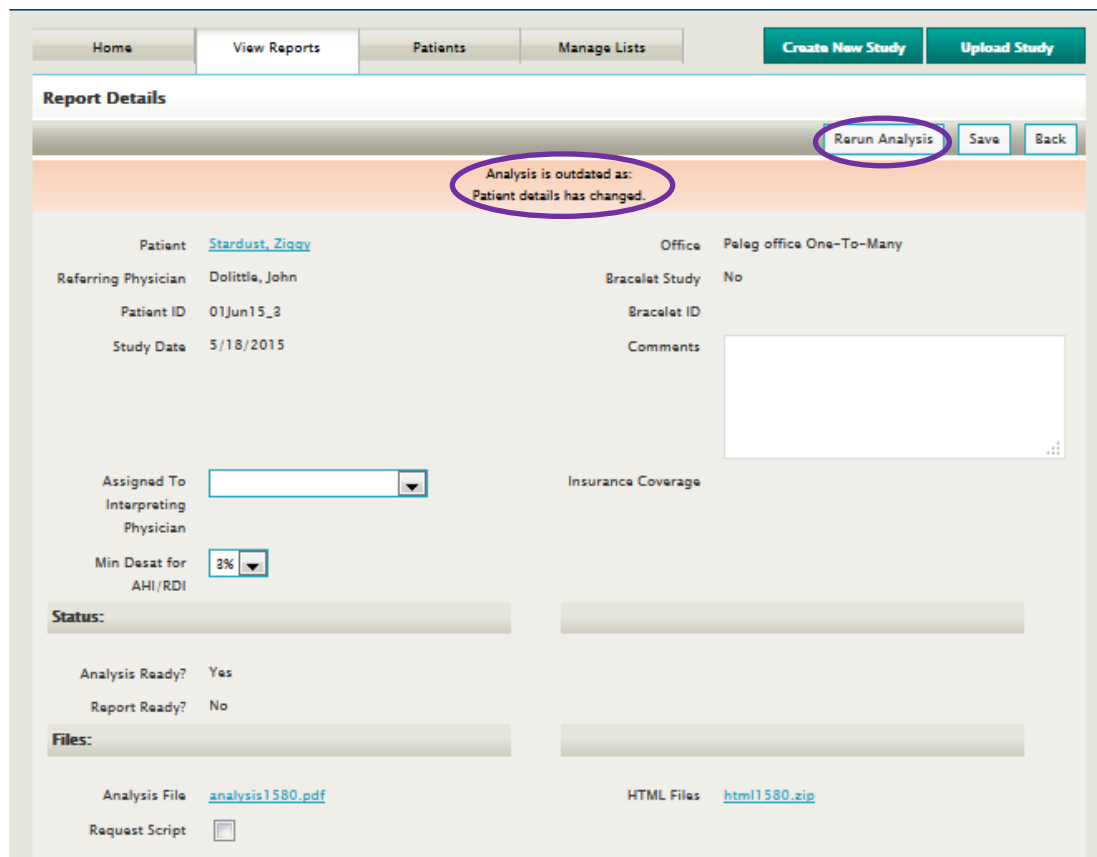


Figure 48: Rerun Analysis Message

3.5.3. 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 “View Reports” from the main screen which will display the newest studies (as well as a list of previously viewed sleep study reports).

After selecting a Patient ID from the list of reports, you will be brought to the report screen (see Figure 49) from which you can review the signed sleep study report and the attached files.

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medical

Home Settings Support Logout

Home View Reports Patients Manage Lists Create New Study Upload Study

Report Details Back

Report is locked. Modifications are not allowed at this time.

Patient: [Kent, Clark](#) Office: [Redacted]

Referring Physician: Dolittle, John Bracelet Study: No

Patient ID: 01Jun15_2 Bracelet ID: [Redacted]

Study Date: 5/25/2015 Comments: [Redacted]

Assigned To: [Redacted] Insurance Coverage: [Redacted]

Interpreting Physician: [Redacted]

Min Desat for AHI/RDI: 3%

Status:

Analysis Ready? Yes

Report Ready? Yes

Error/Warnings: Inconclusive REM. Incomplete analysis due to a Nc

Files:

Result File: [Result1120.pdf](#) HTML Files: [html1579.zip](#)

Request Script: No

Interpreting Physician History

Assignment Date	Interpreting Physician
7/2/2017	Litman, Efrat

Attached Files (up to 20MB in total)

Description	File	Uploaded On	Uploaded By
No Files attached			

Files attached by Interpreting Physician


No Files attached			
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Figure 49: Report Details for reviewing sleep study reports

Simply click on the “Result File” link for a details report complete with 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 multi-night study, the analysis of each night will appear one after another in the report, followed by a summary page at the end.

	<p style="text-align: center;">Note</p> <p>Contact Itamar Medical support for other file type options of report availability.</p>
---	--

3.6. Manage lists

This section explains how to manage the office's lists of medications, diseases, statuses and insurances. The user can add items to the list and edit or delete them. Selecting the "Manage Lists" tab will open up a search screen in which the user can choose between medications and diseases (see Figure 50).

Notice that each list contains both the office list and a global list for the whole system. Items in the global list cannot be changed.

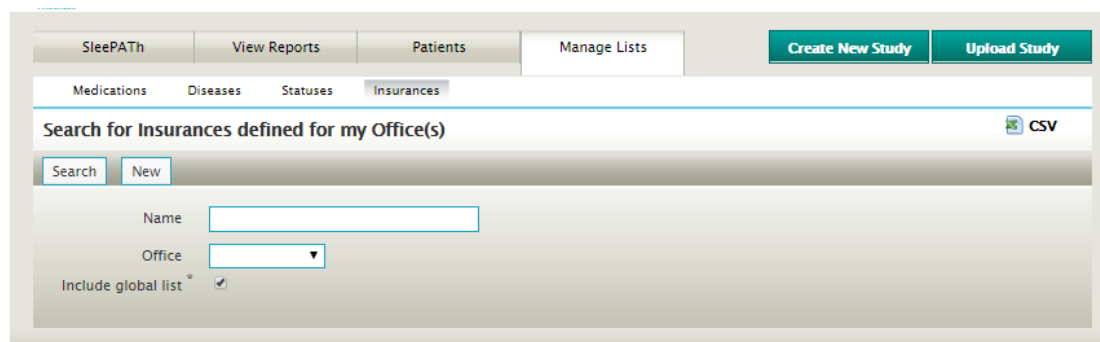



Figure 50: Manage Lists screen

3.6.1. Medications

Under "Manage Lists" choose "Medications". Click on the "Search" button to see the list of all medications (see Figure 51). You can enter filters (medication name, office, include items from the global list) to limit the search results. Clicking on an existing medication name will display the medication's details screen, in which you can delete or edit details and save the changes (see Figure 52).

	<p style="text-align: center;">Note</p> <p>Click on the CSV icon if you want to obtain an Excel file containing a tabular presentation of the search results.</p>
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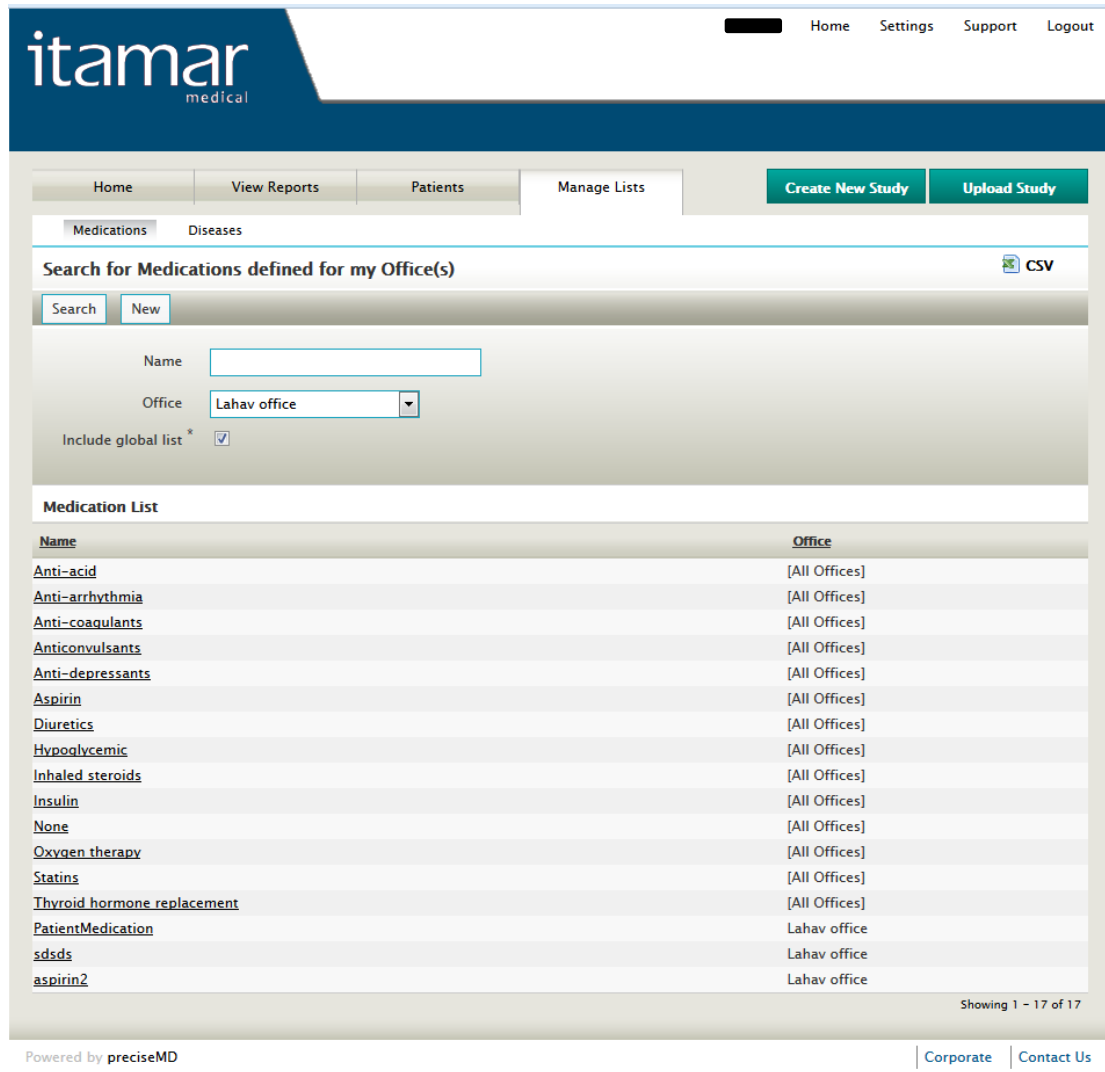


Figure 51: Search for medication screen

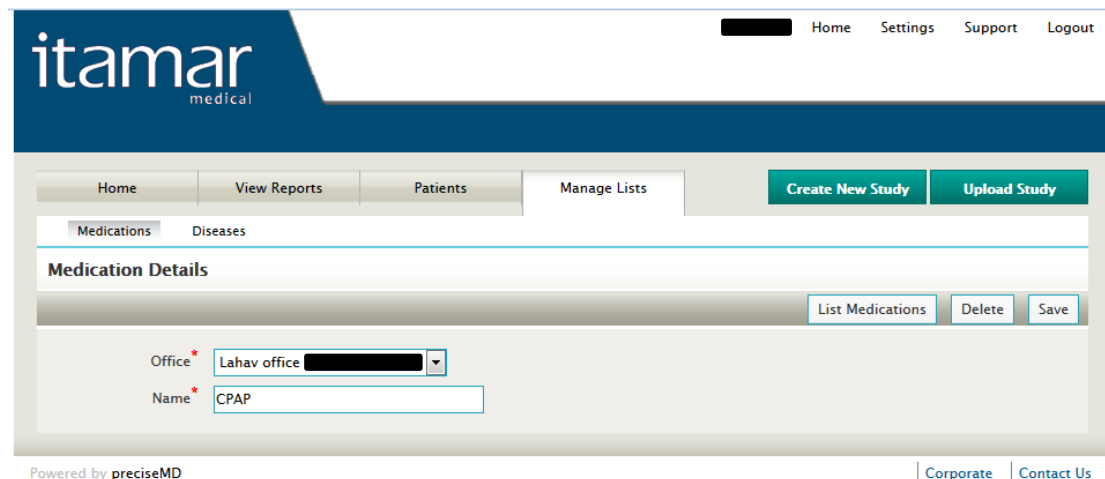


Figure 52: Medication Details screen

On “New” tab you can add a new medication to the list. If you are connected as user to more than one office, you will be asked to select the office for which the medication will be added. Do not forget to click save after you add or change an item (see Figure 53).

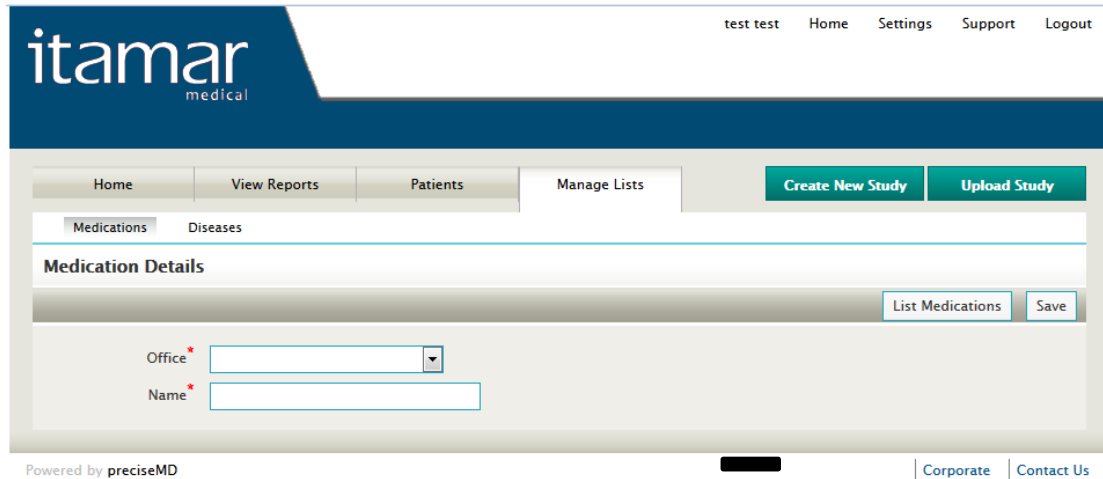



Figure 53: New Medication screen

3.6.2. Diseases

Under “Manage Lists” choose “Diseases”. Click on the “Search” button to see the list of all diseases (see Figure 54). You can enter filters (disease name, office, include items from the global list) to limit the search results. Clicking on an existing disease name will display the disease details screen, in which you can delete or edit details and save the changes (see Figure 55).

	<p style="text-align: center;">Note</p> <p>Click on the CSV icon if you want to obtain an Excel file containing a tabular presentation of the search results.</p>
---	--

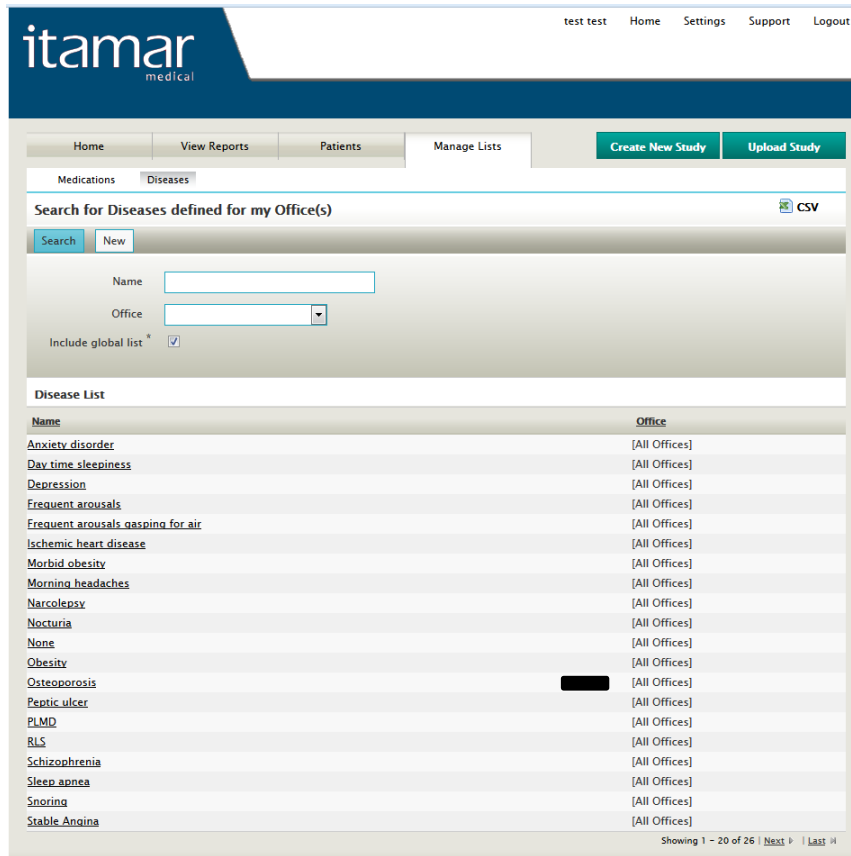


Figure 54: Search for diseases screen

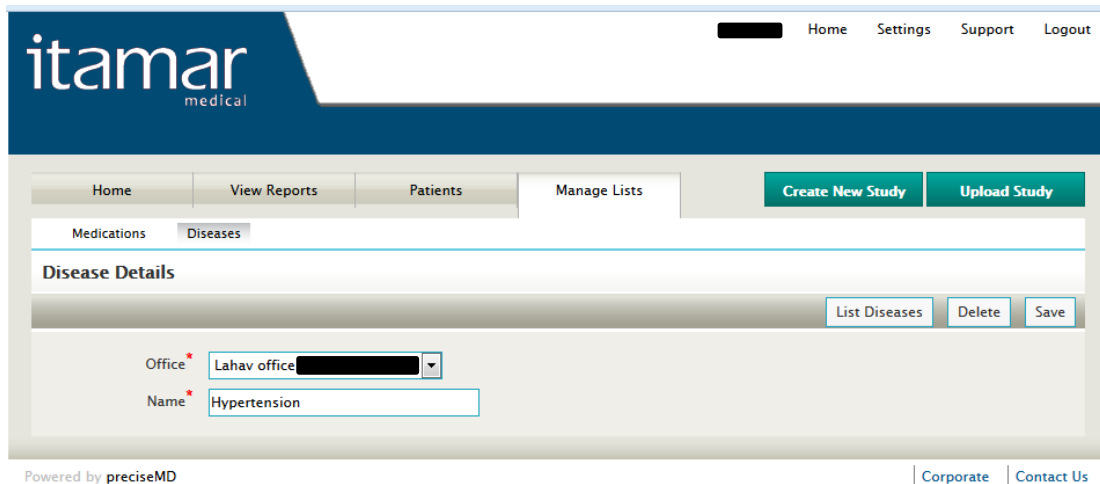


Figure 55: Disease Details screen

On “New” tab you can add a new disease to the list. If you are connected as user to more than one office, you will be asked to select the office for which the disease will be added. Do not forget to click save after you add or change an item (see Figure 56).

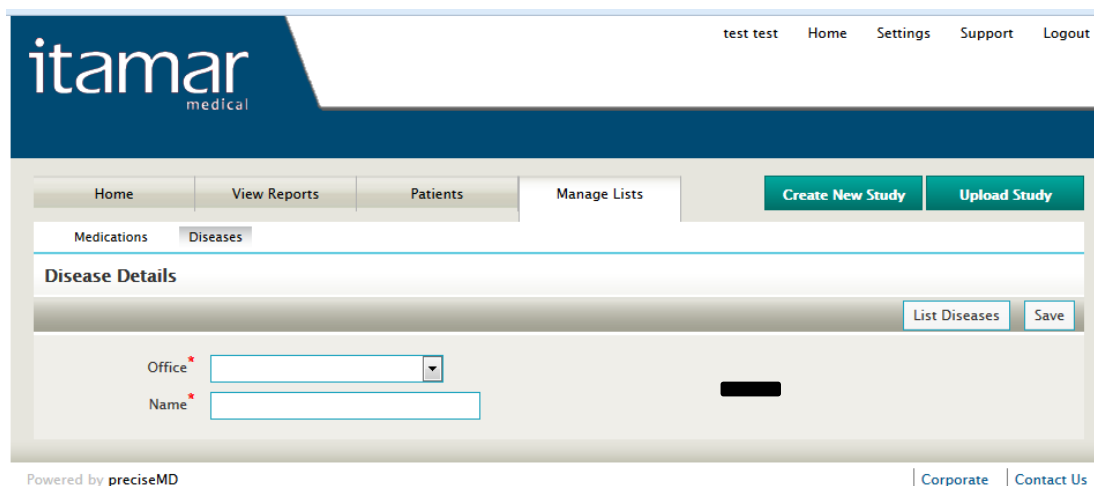


Figure 56: New Disease screen

3.6.3. Statuses

Under “Manage Lists” choose “Statuses”. Click on the “Search” button to see and modify the list of statuses applicable for the selected office. To create new status, click on “New”, select the specific office the status will be applied to and the name of the status and click “Save”.

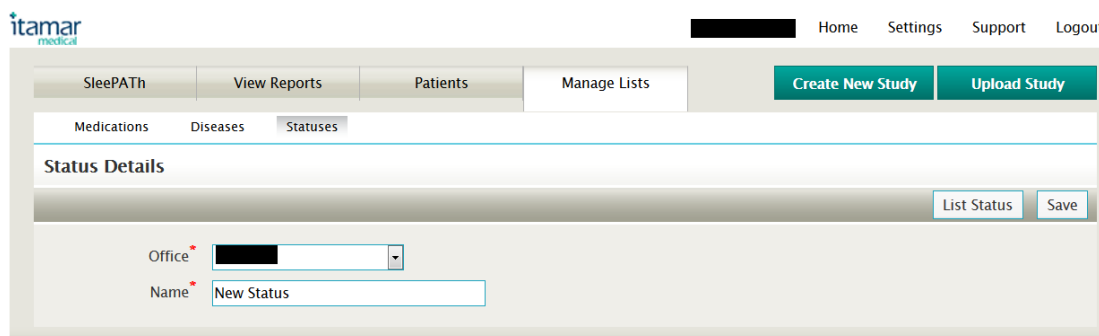


Figure 57 - Creating new status

3.6.4. Insurances

Under “Manage Lists” choose “Insurances”. Click on the “Search” button to see and modify the list of statuses insurances for the selected office. There are Global Insurances, applicable for all the offices, and Insurances applicable to a specific office. To create new insurance, click on “New”, select the specific office the insurance will be applied to and the name of the insurance and click “Save”.

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 (see Figure 58).

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

1. **Review studies** – reviews new or displays completed studies.
2. **Manage templates and NPIs** – defines new or edits existing NPIs and templates used for Clinical diagnosis and recommendations while reviewing studies.
3. **Contact** – for help with any problems you experience with CloudPAT, please contact us by clicking the “contact” link from any window. This link leads to Itamar-Medical CloudPAT Support. Use the form shown in Figure 59 to send us a message with your problem description.

The screenshot shows the 'itamar medical' logo in the top left corner. In the top right corner, there is a user profile section with 'Dr.' followed by a redacted name, and links for 'Settings', 'Support', and 'Logout'. The main interface has two tabs: 'Studies' (which is selected) and 'Templates & NPIs'. Under the 'Studies' tab, there are two sub-tabs: 'New' (highlighted in green) and 'Completed'. Below these is a 'Results search' section with a search button and a 'CSV' export icon. The search form contains several input fields: 'Patient ID', 'Office' (a dropdown menu), 'Patient Last Name', 'Patient First Name', 'Study Date', and 'Study Load Date'. The 'Study Date' and 'Study Load Date' fields have calendar icons next to them.

Figure 58: Interpreting Physician's Home screen

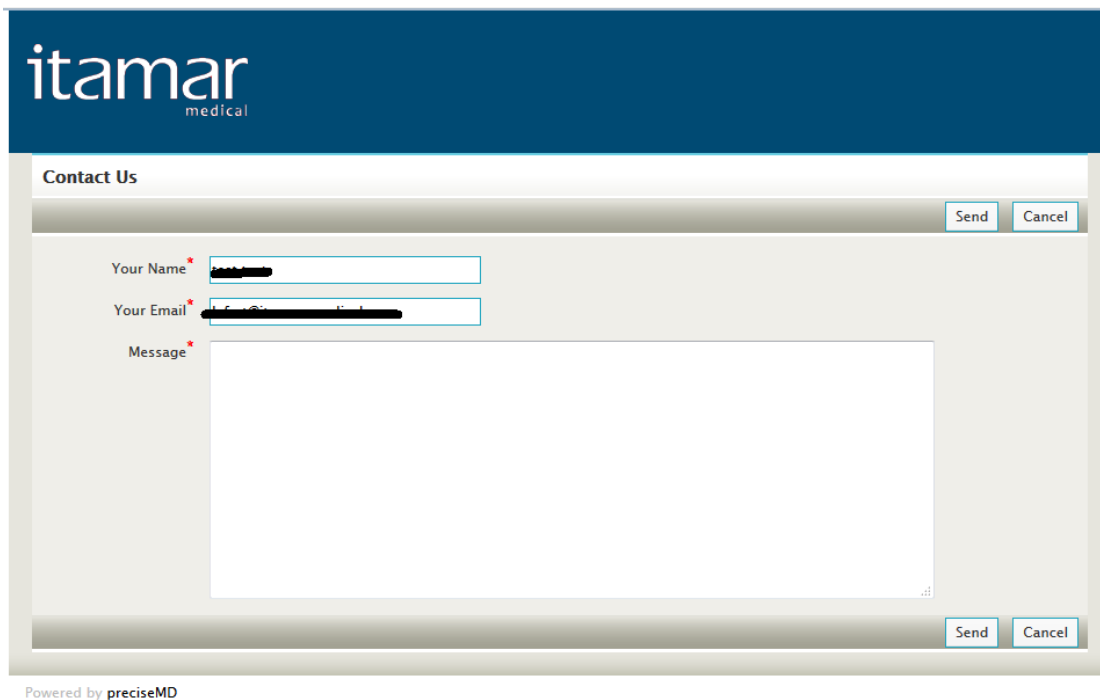



Figure 59: Contact Us screen

4.2. Studies

After a patient 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 pressing on the “New” tab from the main screen which will display the new studies screen (see Figure 60) which includes all unlocked studies waiting for you. You may also select the “Completed” tab 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. (see Figure 60).

	<p style="text-align: center;">Note</p> <p>Click on the CSV icon if you want to obtain an Excel file containing a tabular presentation of the search results.</p>
---	--

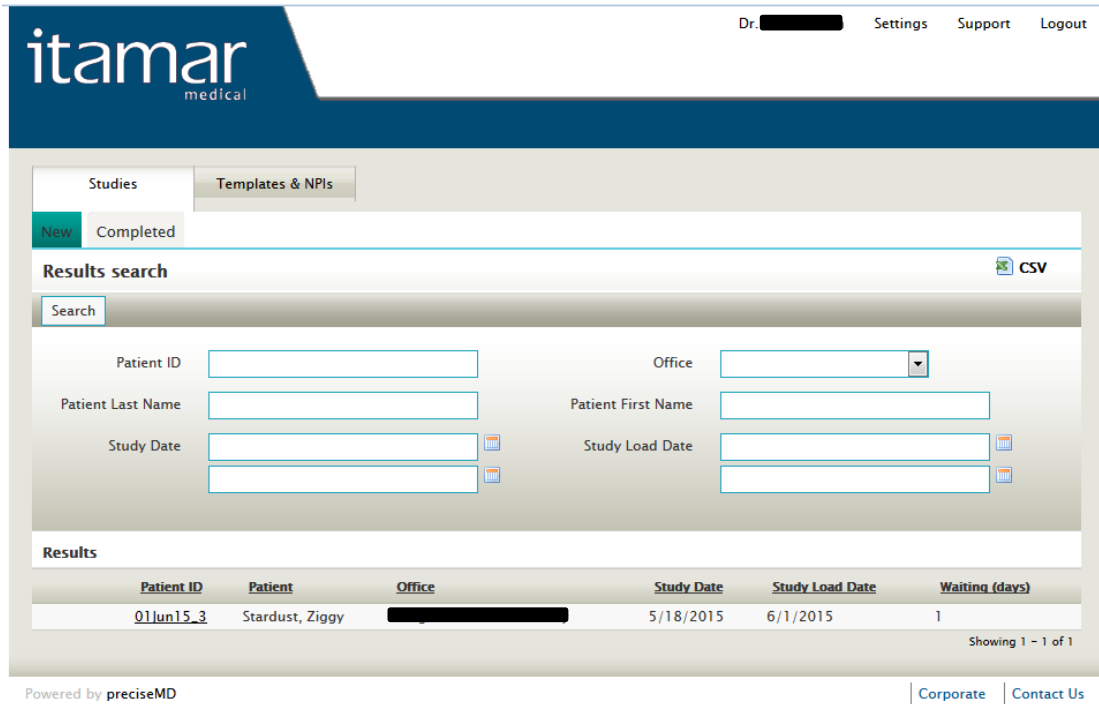


Figure 60: Study selection screen

4.2.1. Reviewing a Study

When you are in “New” studies tab, selecting a study you want to review (clicking on the Patient ID link), will display the following screen (Figure 61) from which you can review the new sleep study.

The screenshot shows the 'Review a new study' interface in CloudPAT. At the top, there are two tabs: 'Studies' and 'Templates & NPIs'. Below the tabs, the patient ID is displayed as 'PATIENT: [REDACTED]'. A row of navigation buttons includes 'Back', 'Patient Details', 'Office Details', 'Open in Viewer', 'Download zzzPAT', 'Save', 'Preview', and 'Save & Lock'. The main content area is divided into several sections:

- Error/Warnings:** A message box stating 'The automatic analysis events or stages have been...'. Below it is a scrollable area.
- Category (for statistics):** A dropdown menu with 'Select an Option'.
- Min Desat for AHI/RDI:** A dropdown menu with '3%'.
- Diagnosis Template:** A dropdown menu with 'Select an Option'.
- Diagnosis:** A large empty text area for entering the diagnosis.
- Recommendation Template:** A dropdown menu with 'Select an Option'.
- Recommendations:** A large empty text area for entering recommendations.
- Interpreting Physician:** The name 'Rubissa, Interp' is displayed.
- NPI:** A dropdown menu with 'Select an Option'.

At the bottom of the interface, there are two sections:

- Manual Events Files:** A section with a green plus icon and a warning message: 'Please note that any addition, deletion or modification of entries will result in rerunning analysis on save'. Below this is a table with columns for 'File' and 'Uploaded'. A row shows a file named '2015_01_25_00_06_12_events_analysis_user.zpt' uploaded on 'Jul 5, 2018 01:20:34'.
- Attached Files (up to 20MB in total):** A section with a blue plus icon and a yellow box stating 'No Files attached'.

Figure 61: Review a new study


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

Analysis File link - you can Click on the Analysis File link in order to see the two page report (or more in case of a multi night study) that was produced automatically by CloudPAT. According to the Respiratory indices, various statistics and sleep stages you will be able to make your interpretation and fill in the Diagnosis and Recommendations sections (see Figure 61).


1. **Patient Details** – patient details are displayed and if the patient filled a STOP BANG questionnaire, you will be able to view the results
2. **Office Details** – by clicking the “Office Details” button, you can see the following details of the office that sent the sleep study: Name, Address, City, State, Zip Code, Country, Phone and Minimum % Desaturation for AHI/RDI calculation.
3. **Preview report** - You can click the “Preview report” button in order to see the first page of the final report. This page will present to you patient information as well as your interpretation as it was last saved (see Figure 63).

The Study window provides two **equivalent** methods for seeing more details on the study’s signals and to review and edit the events:

- **Open in Viewer (RECOMMENDED)** - This utility avoids the need to install zzzPAT on the PC, to download the study to the PC and upload the results.
 - **Download to zzzPAT** – The Interpreting Physician is required to keep zzzPAT Software updated, 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.
4. **Open in Viewer** - 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 in order invoke the zzzPAT utility viewer on your local computer with study data. This utility avoids the need to install zzzPAT on the PC, to download the study to the PC and upload the results. Refer to **zzzPAT Operation Manual** for description of the operation can capabilities of the Viewer.


	<p style="text-align: center;">Note</p> <p>On your first use of Open in viewer on your PC, installation of a small PC-app, RPA Agent. Refer to section 3.3.2 for the description of installation process.</p>
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5. **Download to zzzPAT** - if you wish to see more details on the study’s signals or to review and edit the events, you can use the “Download to zzzPAT” function in order to download a copy of this study to your local computer.

	<p style="text-align: center;">Note</p> <p>On first use configure the zzzPAT to allow interpretation for CloudPAT studies:</p> <p>go to: “Setup”→ “General Settings”→ ”General Options”, then check the “Enable Packed Studies Import” checkbox and go to “Setup”→ ”User Settings”→ ”Options”, then check the “Enable Manual Scoring” and the “Enable Export Manual Events” checkboxes.</p>
---	--

Once the study files are downloaded, you can use the “Import Packed


study” zzzPAT’s function in order to open the study, view the signals and edit the Respiratory events or sleep stages if needed (see zzzPAT’s OM).

	<p style="text-align: center;">Note</p> <p>You should make sure that the zzzPAT has the same AHI calculation method (3% or 4%) setting as the study:</p> <ul style="list-style-type: none"> • In the Analysis File look for the “<i>pRDI/pAHI are calculated using oxi desaturations</i> ≥ “ number • In the zzzPAT look at “Setup”→”General Settings”→”Analysis/ Statistics Parameters”.
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6. **Errors/Warnings** – in case of errors or warnings returned from the analysis, a message will appear in the Errors/Warnings box.
7. **Change Min Desat for AHI/RDI** – change the value used for analysis. Change becomes effective only after saving. At this event, the following message will be displayed:

Rerun is required. Analysis is outdated. [Reason(s): AHI has changed.]

Click on “Rerun Analysis” button to see the results based on the new threshold.

	<p style="text-align: center;">Note</p> <p>Make sure to upload the correct manual event file. The filename will be comprised of</p> <p style="padding-left: 40px;">ID_[<i>patient ID</i>] SD_[<i>study Date & time</i>] events_analysis_user.zpt</p> <p>other file will generate an error during the post upload analysis and will not change the analysis file</p>
---	--

8. **Load Manual Events and Reanalyze** - in case you used the “Download to zzzPAT” function and manually edited the Respiratory events or sleep stages you will be required to save the new manual events file (in zzzPAT press “File” → “Export Manual Events...”) and add the manual event file to CloudPAT by selecting it on the “Manual Events Files” table (see Figure 61). This action will re-analyze the study using your input and will generate an updated sleep report. You may review the new report by clicking on the Analysis File link.


	<p style="text-align: center;">Note</p> <p>In case of a multi night study – you can upload a manual event file for each of the nights. The system will know to link the files correctly.</p>
---	---

9. **View files attached by the office** – if the office attached file to the study, you can view them by clicking on the file name in the attached file by office section.
10. **Enter interpretation** - Diagnosis and Recommendations by typing in the information in the relevant sections.
You may use the Diagnosis and Recommendations templates if you wish to insert an already predefined paragraph in the corresponding section (See section 4.3).
11. **NPI** – you can add the NPI to the report. If you have more than one NPI, select the right NPI number that matches the office details.
12. **Add attachments** like prescription 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 files enter a description and select the file to be uploaded using the Browse button. To add additional files click the ⊕ icon at the top of the list a new line will be added to the table.
The user can also remove attached files by marking them for deletion (see Figure 62).


Attached Files (up to 20MB in total)				
	Description *	File *	Uploaded On	Uploaded By
<input type="checkbox"/>	Prescription	prescription.pdf	4/16/2014 12:36:42 AM	Efrat, test
<input type="checkbox"/>	letter to patient	letter to patient.pdf	4/16/2014 12:38:51 AM	Efrat, test
<input checked="" type="checkbox"/>	images	CPAP-image.jpg	4/16/2014 12:38:51 AM	Efrat, test
<input type="checkbox"/>				


Figure 62: Attach files to a report

Save the study by pressing the “save” button on the top of the screen to complete uploading the file and to remove deleted files.

	<p>Note</p> <p>The maximal size of all attached file is limited to 20MB</p>
---	--

13. **Save** – saves your input without locking the report.
14. **Save and Lock Report** - finally 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.

	<p>Note</p> <p>Once a report is Locked no more changes can be added. Use the “Save” button if you are not sure if you are done with this study. If a report is accidently locked contact Itamar Medical in order to unlock it.</p>
---	---

	<h3>Note</h3> <p>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 button is replaced by Rerun Analysis button. After rerunning the analysis the Save and Lock Report button will be available. Opening the study on Viewer also re-run the analysis.</p>
---	--

Test Header Row1
Test Header Row2



Patient Information

First Name: Ziggy	Last Name: Stardust	ID: 01Jun15_3
Birth Date: 06/16/1972	Age: 45	Gender:
Insurer:	BMI:	
Neck Cir.:	EPworth:	
Address:		

Sleep Study Information

Study Date: 05/18/2015	H/A Version: 2.2214/4.4.64.5
-------------------------------	------------------------------

Referring Physician Information

First Name: John	Last Name: Dolittle	E-mail:
Work Phone:	Mobile Phone:	Fax:

Medical Information

Medical History

Medications

Comments

Summary & Diagnosis

the patient appears to have moderate sleep apnea.

Recommendations

consider CPAP therapy


Report prepared by : XXXXXXXXXX Electronically Signed: 7/2/2017 9:43:28AM PST
NPI

Figure 63: First page of sleep report (example)

15. **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, 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 “Rerun Analysis” button will appear. You won’t be able to lock the report before rerun the analysis.

	<p style="text-align: center;">Note</p> <p>Manual events file are based on a specific analysis. Verify the manual events you are loading are based on the same parameters as the current study parameters.</p>
---	---

4.2.2. Viewing a Completed Study

After selecting a Patient ID while on the “Completed” studies tab, you will be brought to the following screen (see Figure 64) from which you can view the old sleep study.

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

1. **Analysis File link** - you can Click on the Analysis File link in order to see the two page report that was produced automatically by CloudPAT (without your interpretation).
2. **View report** - you can click on the “View report” button in order to see the full final report (with your interpretation included).

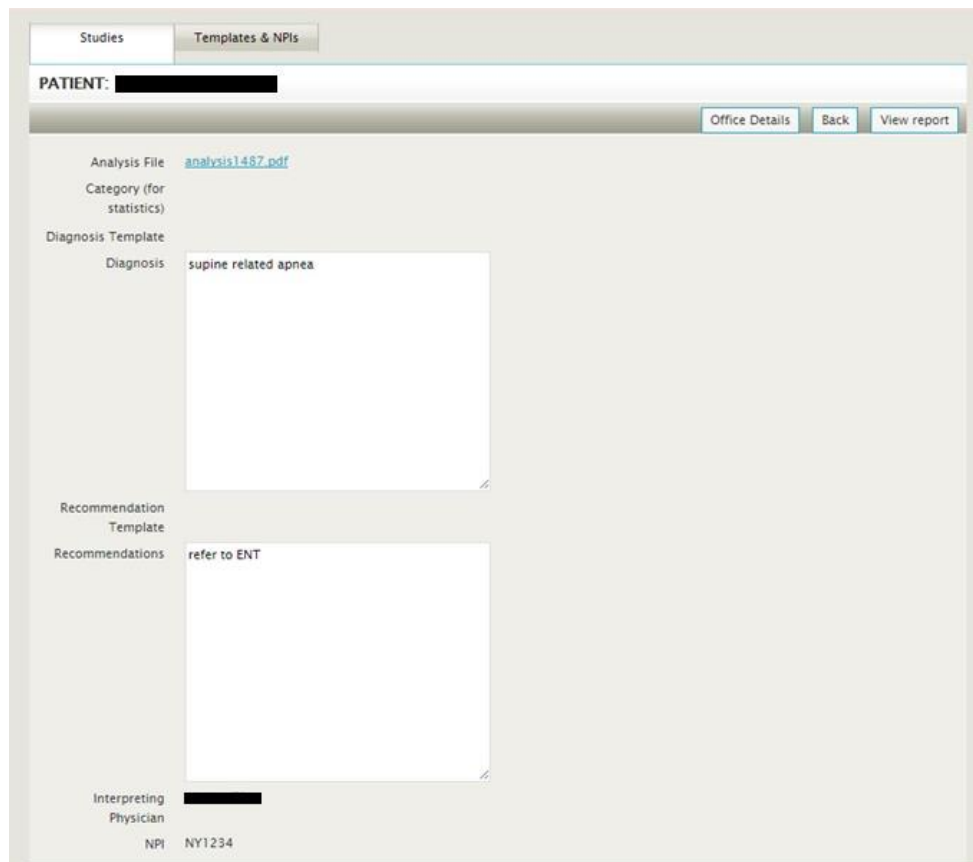


Figure 64: View a completed study

4.3. Manage Templates & NPIs

This section explains how to manage the lists of templates and NPIs each Interpreting Physician has. Selecting the “Templates & NPIs” tab will open up a search screen in which you can choose between templates and NPIs (see Figure 65).

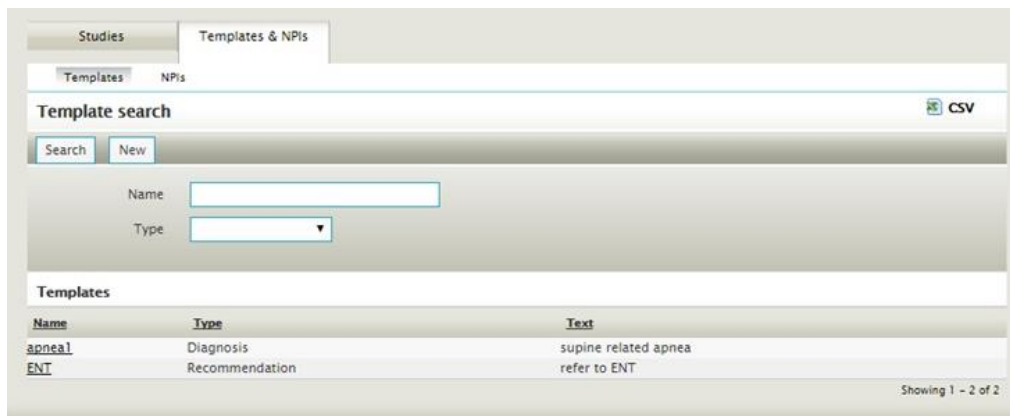


Figure 65: Templates & NPIs screen

4.3.1. 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.

Selecting the Templates tab will open up the Template Search screen (see Figure 66).

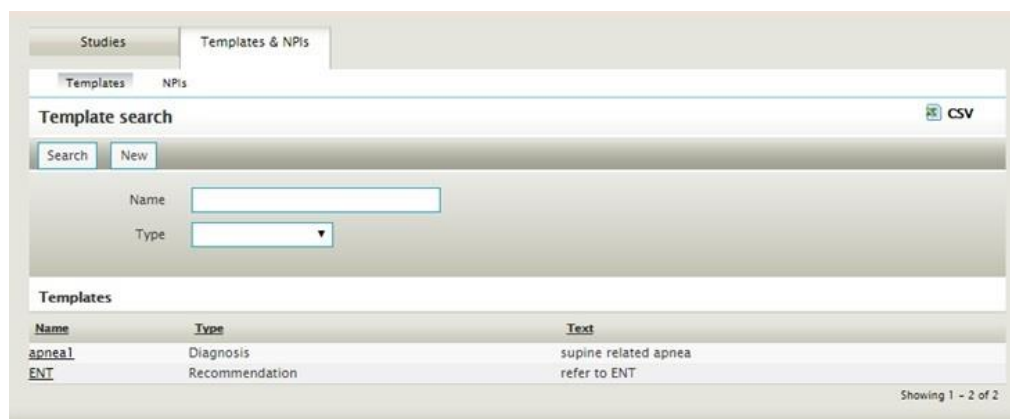



Figure 66: Search a template screen

	<p style="text-align: center;">Note</p> <p style="text-align: center;">Click on the CSV icon if you want to obtain an Excel file containing a tabular presentation of the search results.</p>
---	--

Clicking on the “New” button will open up a new template for editing (see Figure 67).

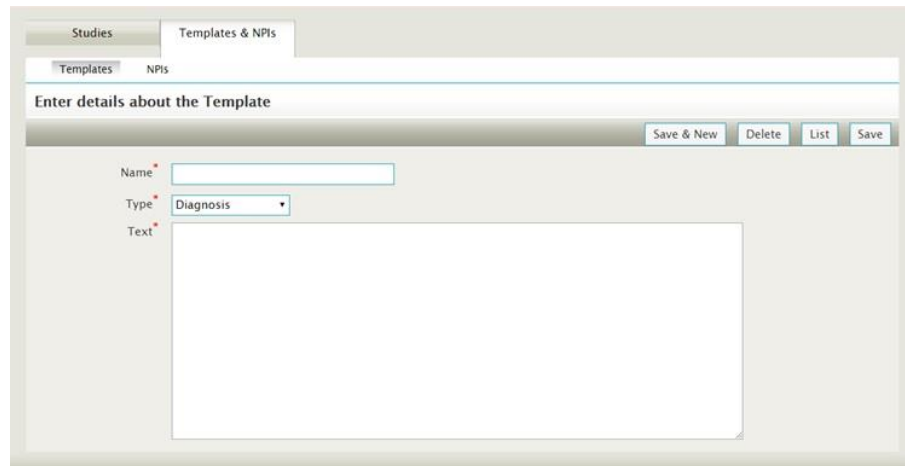


Figure 67: New Template screen

You need to fill all three fields (Name, Type and Text) in order to define the new template.

Clicking on an existing template name (see Figure 66) will open up the Template screen for editing (see Figure 68).

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

1. **Save & New** – Saves the template and creates a duplicate template.
2. **Delete** – Deletes the template.
3. **List** – Returns to the list of templates.
4. **Save** - Saves the template.

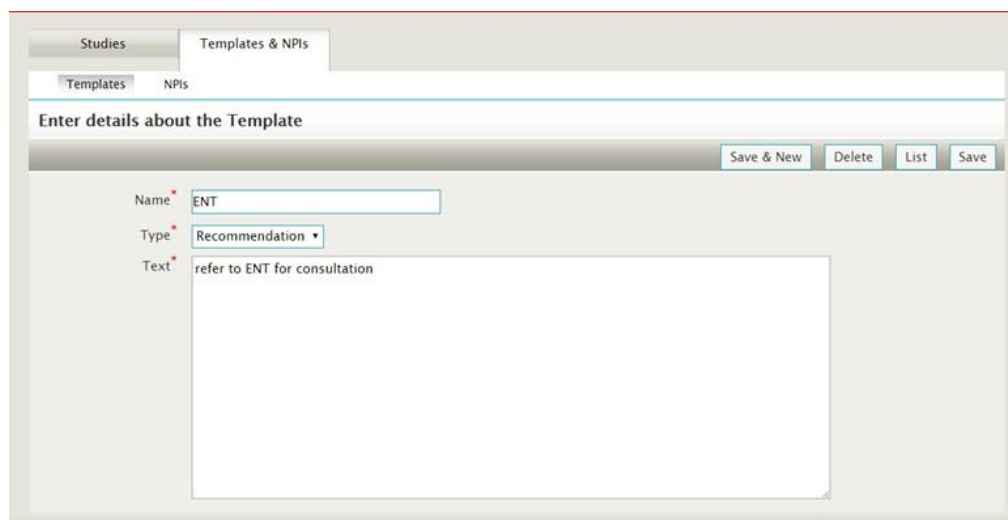



Figure 68: Existing Template screen

4.3.2. NPIs

You can manage a list of NPI to later be used in the report. Under “Templates & NPIs” choose “NPIs”.

Click on “Search” to see the list of all NPIs currently in the system (see Figure 69). 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, in which you can edit the NPI number and save the changes (see Figure 70).

Clicking on the “New” button can be used to add a new NPI to the list. Make sure you save your changes (see Figure 71).

	<p style="text-align: center;">Note</p> <p>Click on the CSV icon if you want to obtain an Excel file containing a tabular presentation of the search results.</p>
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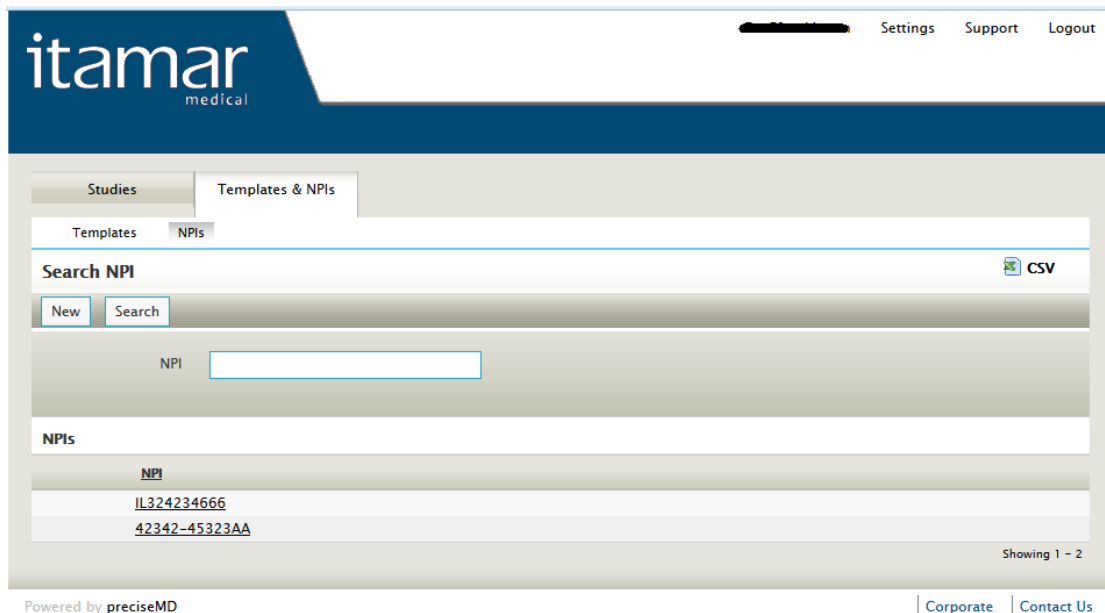


Figure 69: Search NPI screen

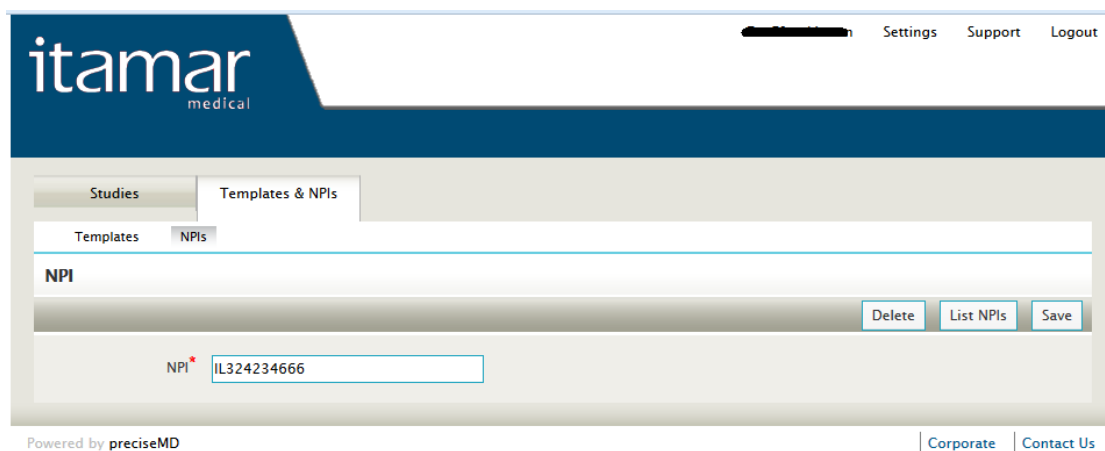


Figure 70: Existing NPI screen

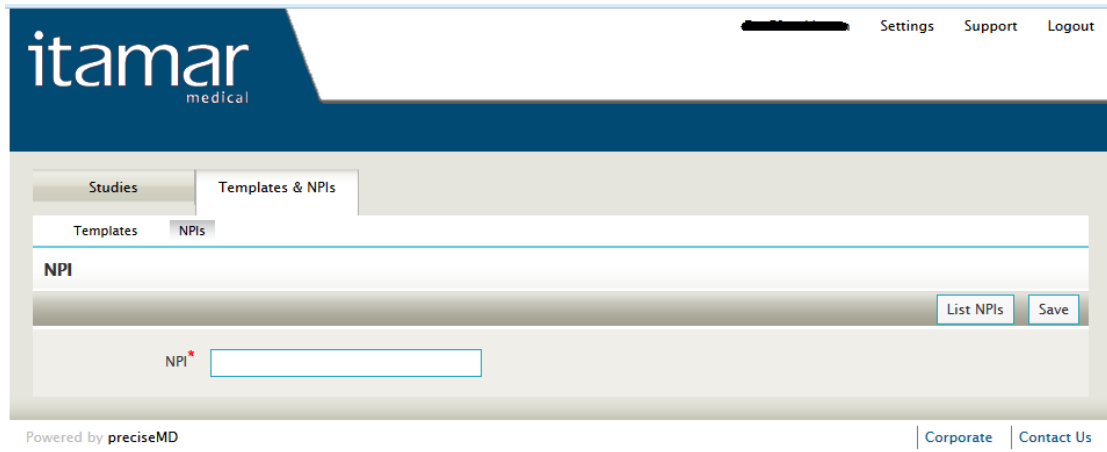


Figure 71: New NPI screen

4.4. Signature

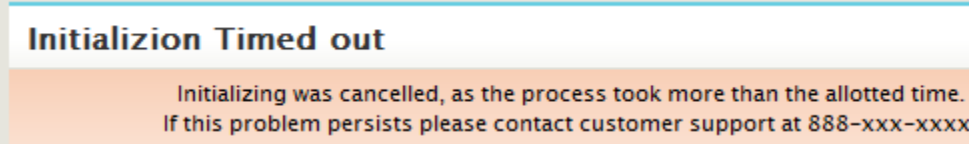
Interpreting Physicians can send Itamar Medical their signature sample as a graphical file. In this way, the Interpreting Physician's signature will be added to the report automatically. The file of the signature should be bmp or jpg file, size 384 pixels in width and 186 pixels in height. Contact Itamar-Medical support for more details.


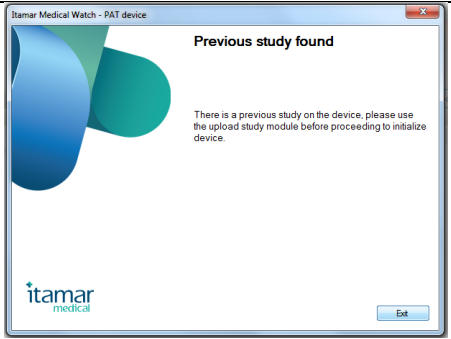
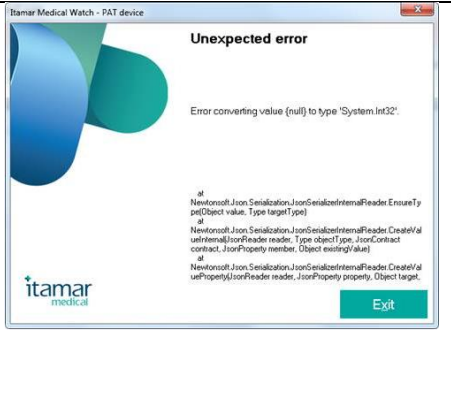
5. Troubleshooting

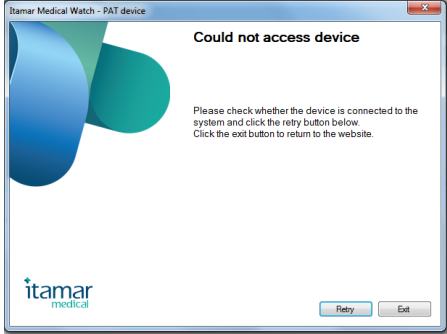



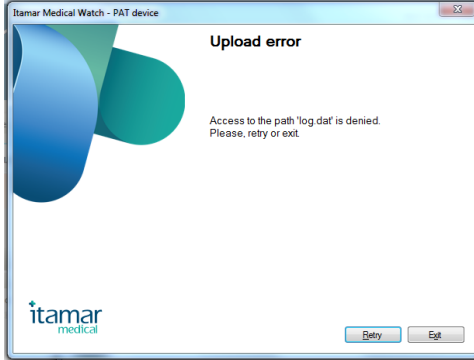
Note

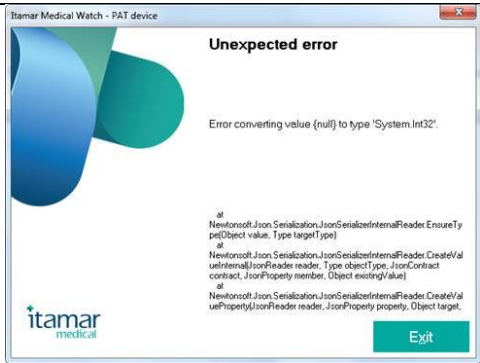
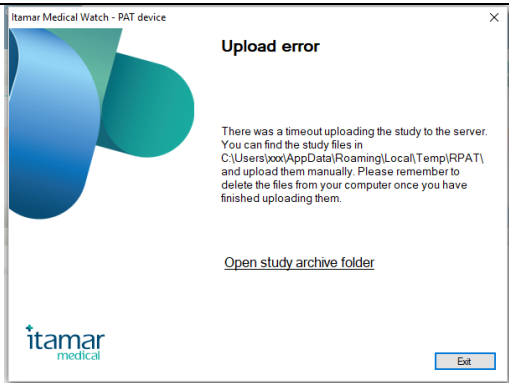
Make sure you are using Chrome, Firefox, Edge or Internet Explorer 11 or above as your browser.

Trouble	Possible Cause	Solution	Error Message
New Study screen			
Creating a new study timed out	You took too long in replying to a message that there is another study resident on WatchPAT™ device.	Re-run the initialization process a little quicker. If the problem persists it could be an internet connectivity problem so contact Support.	

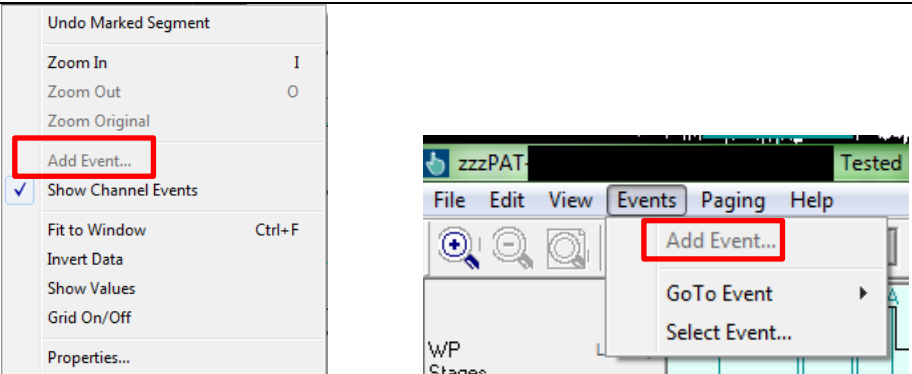
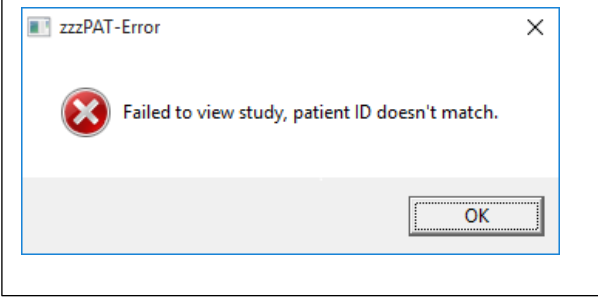
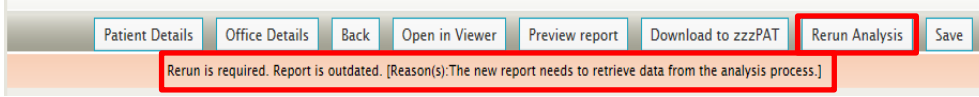
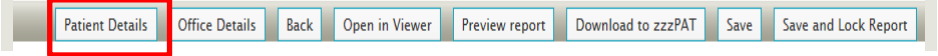
<p>WatchPAT Device Serial Number not shown in initialization message</p>	<p>RPAT Smart Client does not support this feature</p>	<p>Contact customer service for instructions for RPat Smart Client upgrade</p>	 <p>A screenshot of a dialog box titled "Itamar Medical Watch - PAT device". The main text reads "Device Initialized successfully!". Below this, it says "The device is ready for study." There is an empty text input field and an "Exit" button at the bottom right.</p>
<p>Previous Study found</p>	<p>There is a sleep study still on WatchPAT™ device that has not been uploaded from the device.</p>	<p>Press Exit and upload this old study.</p>	 <p>A screenshot of a dialog box titled "Itamar Medical Watch - PAT device". The main text reads "Previous study found". Below this, it says "There is a previous study on the device, please use the upload study module before proceeding to initialize device." There is an "Exit" button at the bottom right.</p>
<p>Error - unexpected</p>	<p>The PC App didn't start on time. The problem might be that it is not installed or that the browser is waiting for your approval to use it.</p>	<p>Select the application as default. See Figure 30</p>	 <p>A screenshot of a dialog box titled "Itamar Medical Watch - PAT device". The main text reads "Unexpected error". Below this, it says "Error converting value {null} to type 'System.Int32'". There is a stack trace of .NET exceptions and an "Exit" button at the bottom right.</p>

<p>Could not access device.</p>	<p>The PC does not recognize WatchPAT™ device.</p>	<p>Make sure WatchPAT™ device is connected to the PC via the USB. Select Retry.</p>	
<p>Upload Study screen</p>			
<p>Failed to Send.</p>	<p>The station may not have Internet access.</p>	<ul style="list-style-type: none"> • Check your internet connection • Repeat the upload process 	
<p>Failed to Send.</p>	<p>The Itamar Upload service is temporarily unavailable.</p>	<ul style="list-style-type: none"> • Save the study using zzzPAT • Collect the data from the device manually by copying all the files on the device and zipping them. Use manual upload at a later stage to upload the data in to the CloudPAT. <p>If you use this option contact Itamar-Medical support to reset the device.</p>	
<p>Failed to analyze a CloudPAT study. The error appears in</p>	<p>Mismatch between Patient.dat and Sleep.dat files.</p>	<p>Contact Itamar-Medical support for help.</p>	

<p>the Report Details screen, and an email notification is sent to the user.</p>			
<p>Could not access device.</p>	<p>The PC does not recognize WatchPAT™ device.</p>	<p>Make sure WatchPAT™ device is connected to the PC via the USB. Select Retry.</p> <p>If device is WatchPAT™300, follow the instructions posted on Itamar Medical Ltd. website or call Customer Service</p>	
<p>Error – access denied</p>	<p>There are remaining files from previous upload or initializations</p>	<p>Remove all files form C:\Users\username\AppData\Local\RPAT\OUT</p> <p>And form C:\Users\username\AppData\Local\RPAT\IN</p> <p>And try again</p>	


<p>Error - unexpected</p>	<p>The PC App didn't start on time. The problem might be that it is not installed or that the browser is waiting for your approval to use it.</p>	<p>Select the application as default. See Figure 30</p>	
<p>Upload error</p>	<p>Internet connection was lost during upload of the study, site is done</p>	<p>The files from the device are temporary stored on your computer. Follow the link in the message to their location. Copy the files to a secure location and once communication with the site is restore – manually upload them to the CloudPAT.</p> <p>Make sure to permanently delete the files after uploading them, as they might contain patient information.</p>	
<p>Attach files to a study or a report</p>			


	Trying to attach a very large file(s)	File attachment is limited to 20MB per study or report. Reduce file size	<p>Maximum request size has been exceeded. This would occur if you attempted to upload a file that is greater than 20MB. If the file you were attaching was well within the limits, or you weren't attempting to attach a file, please contact the system administrator.</p> <p>Technical Information:</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>
STOP BANG			
Session has been completed. Cannot restart.	The questionnaire has been submitted	Find the completed questionnaire in the patient record. If needed – generate a new questionnaire from the patient record.	<p>Begin Patient STOP-BANG Session</p> <p>Enter the STOP BANG Code and click on Start Session. Please bear in mind that a STOP BANG Code is only valid for 20 minutes.</p> <div style="border: 1px solid red; background-color: yellow; padding: 5px; text-align: center;"> <p>Session has been completed. Cannot restart.</p> </div>
Expired code.	STOP BANG Code is valid for 20 minutes.	Generate a new STOP BANG Code from the patient record.	<p>Begin Patient STOP-BANG Session</p> <p>Enter the STOP BANG Code and click on Start Session. Please bear in mind that a STOP BANG Code is only valid for 20 minutes.</p> <div style="border: 1px solid red; background-color: yellow; padding: 5px; text-align: center;"> <p>Expired code. STOP BANG Codes must be used within 20 minutes of generation. Please generate a new STOP BANG Code</p> </div>
Open in Viewer			
Unable to install or update RPAT Agent	User has no privileges to perform installation on the PC	Contact your IT administrator.	
Unable to open study in Viewer	Study that has non-current analysis with User events cannot be viewed	User may choose to delete the user events, allowing running current analysis.	

<p>Unable to edit signals in Viewer</p>	<p>Study was locked.</p>	<p>If you want to change the edits and generate a new report contact your Office administrator to unlock the study.</p>	
<p>Unable to open study in Viewer</p>	<p>Mismatch between study and patient</p>	<p>Contact your Office administrator.</p>	
<p>Missing the Save and Lock Report Button</p>	<p>Report/ analysis is outdated</p>	<p>Rerun analysis</p>	
<p>Report is not showing the updated patient details</p>	<p>Patient details are embedded / updated in the report only on analysis run or report locking.</p>	<p>Click Patient Details button.</p>	
<p>Unable to change</p>	<p>Computer configuration</p>	<p>Contact Customer Service</p>	

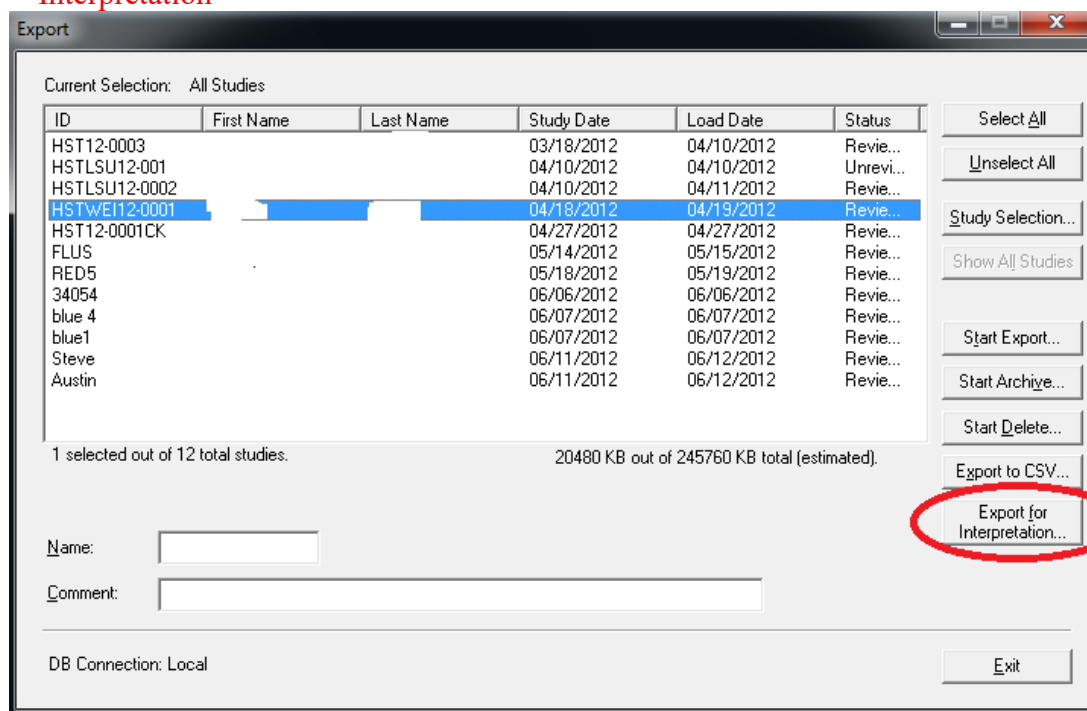
signal colors on viewer	missing library		
Unable to initiate new study after previous study uploaded to CloudPAT	Upload to CloudPAT was not successfully completed	Re-load study, ensuring that the WatchPAT device is kept connected to the Personal Computer until CloudPAT displays the message the upload is completed.	

6. Appendix A: Exporting a study from zzzPAT into CloudPAT

	<h3>Note</h3> <p>This guide gives instructions on how to upload a study from zzzPAT to CloudPAT. This process will be utilized when you do not have an internet connection and you loaded the study to zzzPAT from the WatchPAT™ device.</p> <p>If you do have internet connection it is recommended not to switch between the CloudPAT and the zzzPAT</p>
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	<h3>Note</h3> <p>Multi night studies uploaded to zzzPAT will be exported night by night, if you wish to join them into one study please contact Itamar Medical support for more information.</p>
---	--

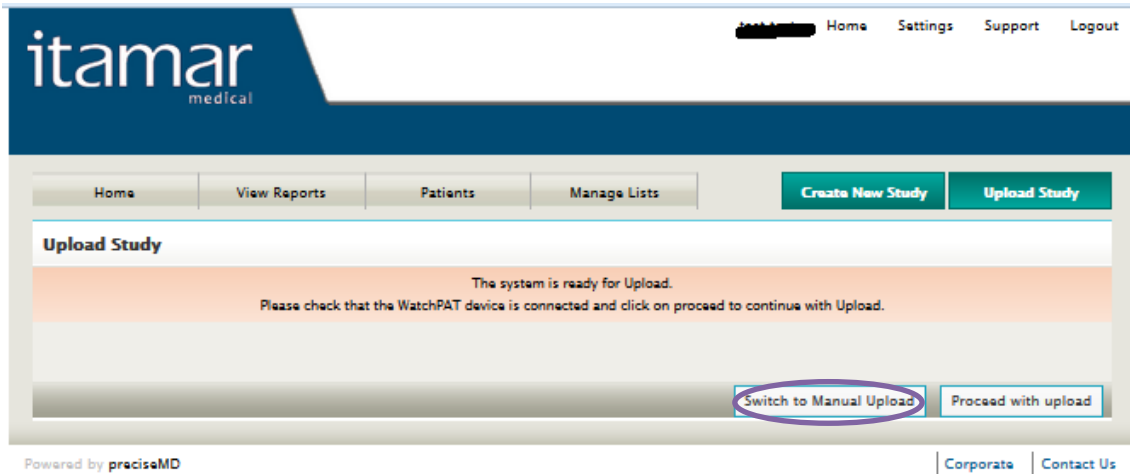
1. Open zzzPAT (default Login and Password: “111” for both entries)
2. Select “**Export/Delete**” under “**Tools**”
3. Highlight the study that you want to export to CloudPAT and select “**Export for Interpretation**”



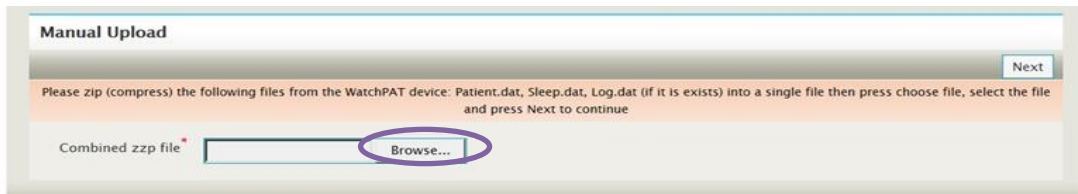
4. You will now be asked to save this file to your hard drive. It is recommended to choose a folder called “CloudPAT” that I create prior to this step. After selecting the folder to save the exported file, click “**OK**”.

Now go to the CloudPAT site (for US <https://cloudpat.precisemd.com>, for EU <https://cloudpateu.precisemd.com> and for UK <https://cloudpatuk.precisemd.com>) and login using your username and password.

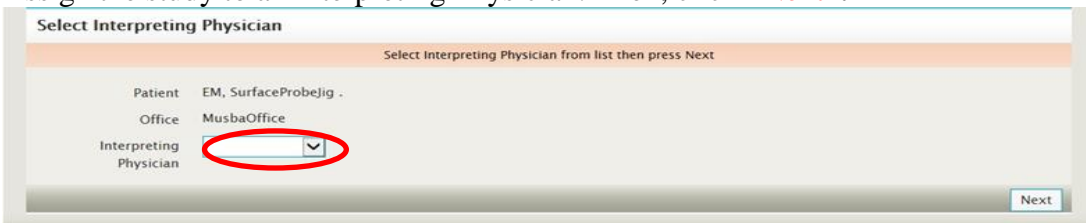
5. Select “**Upload Study**” from Home screen.
6. Thereafter, the following screen will open up. Select “**Switch to Manual Upload**”.



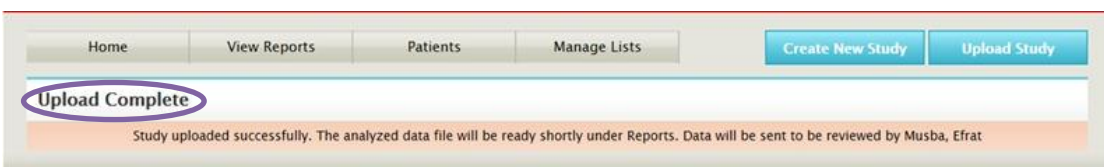
7. Now you need to find the file that was exported out of zzzPAT by selecting “Browse”.




8. The exported file from the zzzPAT will end in .zzp. Select the file that you want to upload and select “Open”. Then click the next button.
9. Depending on your connection speed to upload and the size of the study data file, the upload time will vary between 2 and 5 minutes. If an error is reported, you will need to try again.
10. Assign the study to an Interpreting Physician. Then, click “Next”.



11. The following screen will appear and the process is complete.

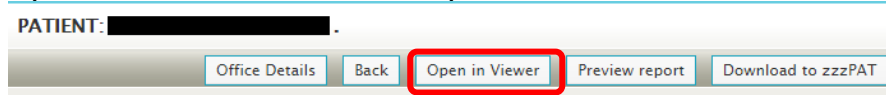


7. Appendix B: Interpretation and editing of events by the Interpreting Physician Guide

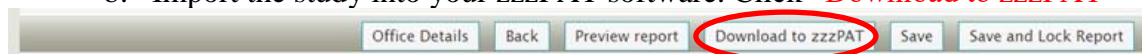
Note	
	<p>Open in Viewer is the RECOMMENDED method for interpretation and editing of events. It is equivalent to Download to zzzPAT method, but without the burden of keeping zzzPAT Software updated, manually downloading the study to zzzPAT, and manually uploading editing results to CloudPAT.</p> <p>To support the Download to zzzPAT method, this guide gives instructions on how to download a study from the CloudPAT to zzzPAT for review and manual editing, and how to upload the changes back to the CloudPAT. These manual operations are not required when Open in Viewer is used.</p> <p>This Guide is directed to Interpreting Physicians, already familiar with the zzzPAT and it is replacing the zzzPAT operation manual.</p>

Go to [CloudPAT site](https://cloudpat.precisemd.com) (for US <https://cloudpat.precisemd.com>, for EU <https://cloudpateu.precisemd.com> and for UK <https://cloudpatuk.precisemd.com>) and login using your user name and password.

1. From the new study screen select the study you want to view in zzzPAT. Click on the patient ID to move to the report screen.
2. Once you have reviewed the study (see section 3.6 above) using “**Preview Report**”, the analysis file and the attachments added by the office, you can decide which method to use for study interpretation by zzzPAT software:
 - a. **Open in zzzPAT viewer**: Click “Open in Viewer”.



- b. Import the study into your zzzPAT software. Click “**Download to zzzPAT**”

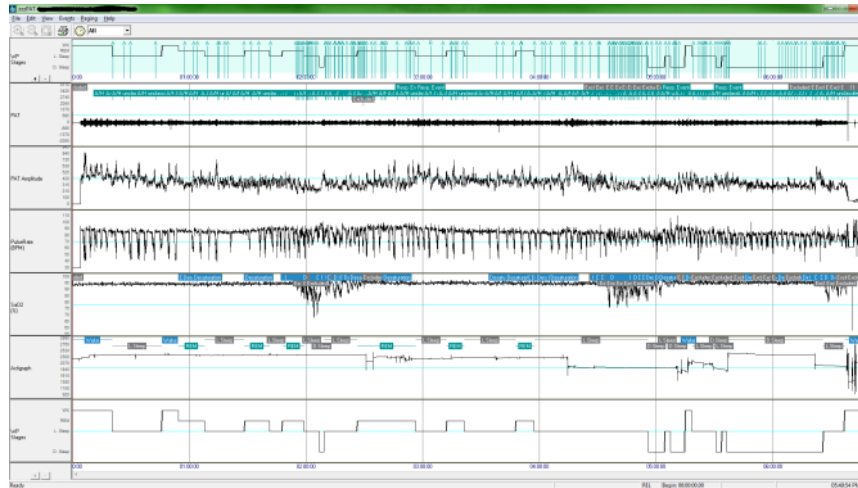


Subsections 3-6 below describe the workflow when selecting “Open in Viewer”:

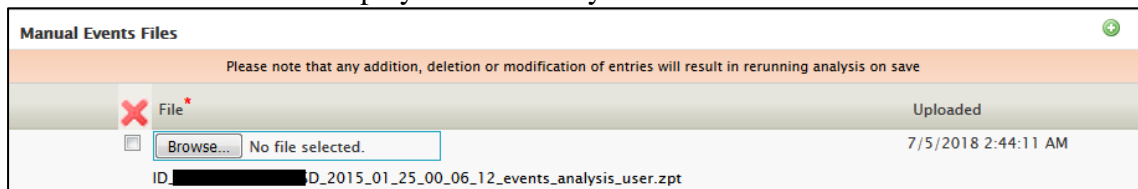
3. zzzPAT Viewer Launcher automatically downloads study data to your PC.



4. zzzPAT Viewer is automatically launched.

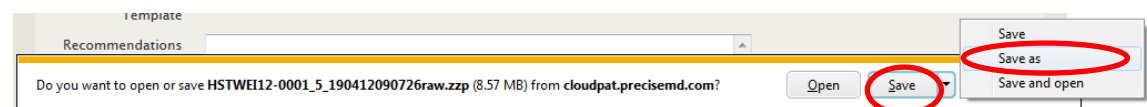


5. Once the interpretation process is done, select File → Exit to store Manual Events on CloudPAT and return to CloudPAT.
6. Manual Events Files are displayed in the study window.

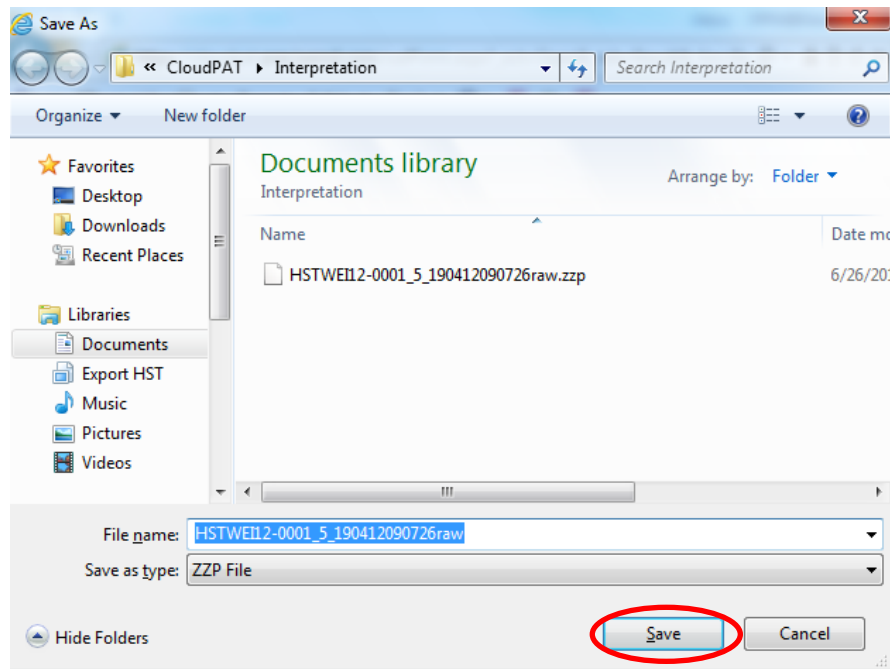


Subsections 7-22 below describe the workflow when selecting “Download to zzzPAT”:

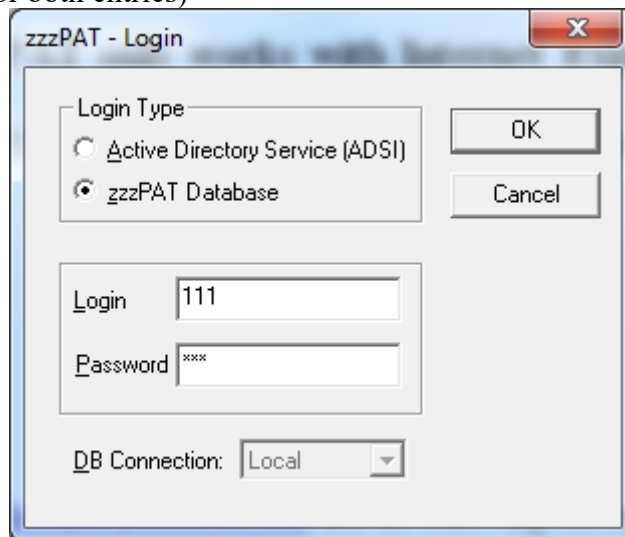
7. At the bottom of the webpage, you will see a new box open. Click on “Save” and a new box will open then click on “Save as”:



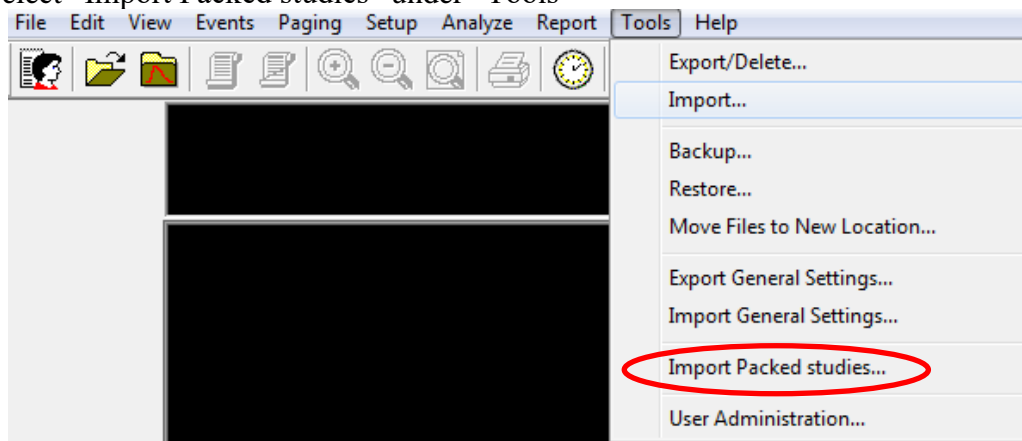
8. Save the file to a predefined location on your hard drive. We recommend creating a folder called CloudPAT for such file exchange.



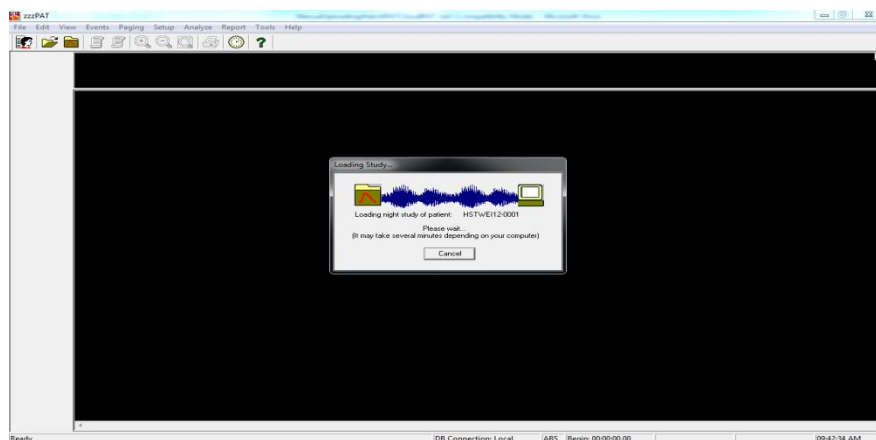
9. To review the raw data open zzzPAT software and login (default Login and Password: “111” for both entries)




10. Select “Import Packed studies” under “Tools”



11. In the dialog box that opens, select the file you have just saved in the CloudPAT and click “Open”.
12. A new box will now open and the imported study will now be loaded and analyzed.



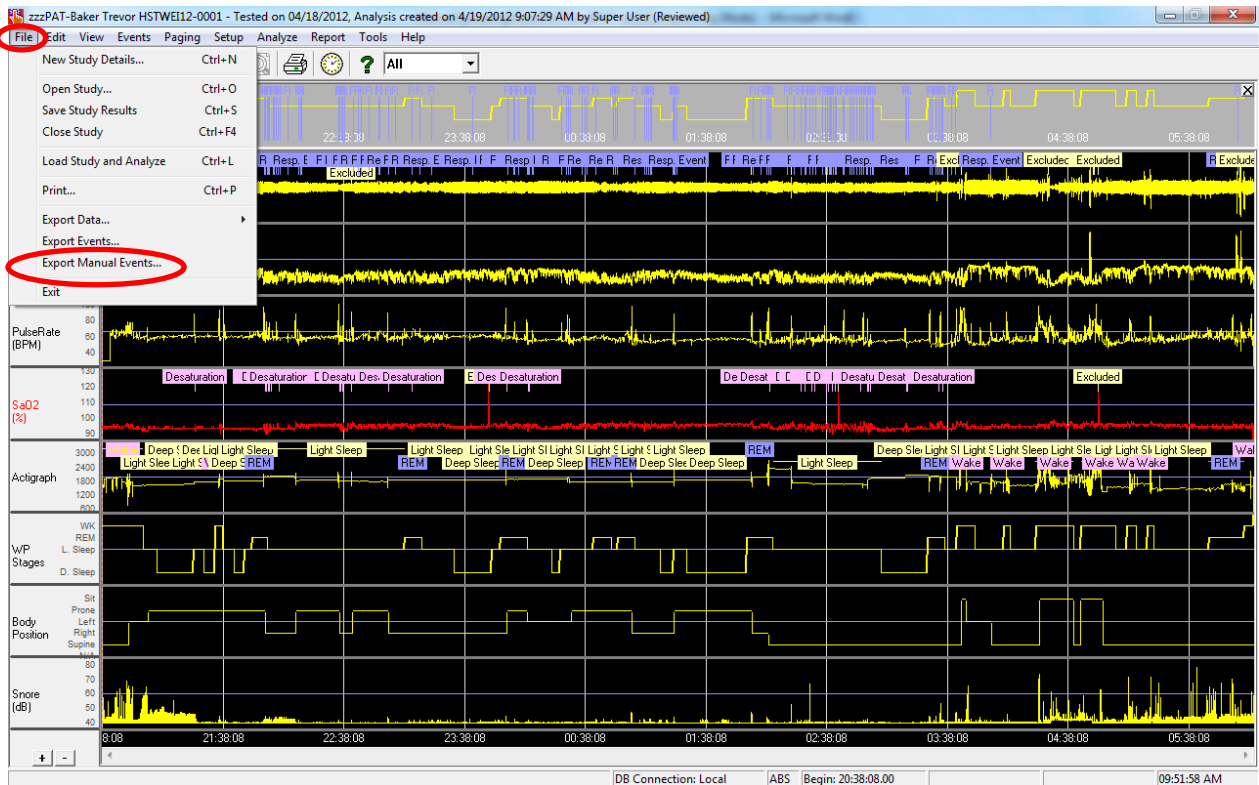
13. The study is now available to be reviewed and manually edited by the interpreting physician.

	<p style="text-align: center;">Note</p> <p>When importing multi night study into zzzPAT, each night will create a different zzzPAT study. Each of the night should be reviewed and edited separately.</p>
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Once the interpretation process is done

If changes were made in the study, the study will need to be uploaded to CloudPAT by following the steps below.

14. Save the study in the zzzPAT.
15. Go to **File** and select **“Export Manual Events...”**



16. Select a file location – again we recommend using a predefined location. Press ok.

The manually edited changes now need to be uploaded to CloudPAT. Go to CloudPAT site (for US <https://cloudpat.precisemd.com>, for EU <https://cloudpateu.precisemd.com> and for UK <https://cloudpatuk.precisemd.com>) and login using your user name and password. Locate the study you were working on and enter the report screen like before.

17. Click the “**Choose File**” button near the manual events files box.



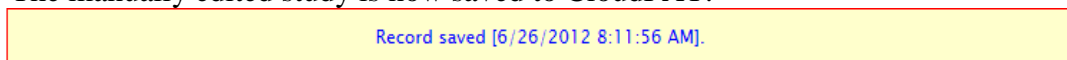
18. Find the saved file. The file name will consist from the patient id and the study date & time in the following structure:

ID_[patient ID]_SD_[study Date & time]_events_analysis_user.zpt
 Select the file and click “Open”.

19. Save the report.




The manually edited study is now saved to CloudPAT:



20. You can check that the analysis file was updated with your manual events.

21. Fill the Diagnosis and Recommendation fields and add attachments as needed.

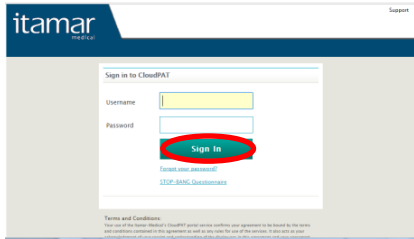

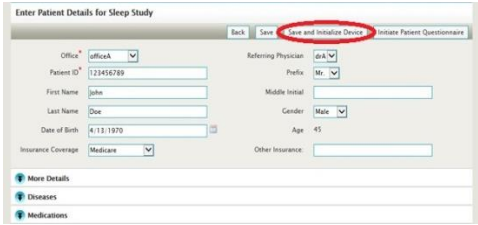
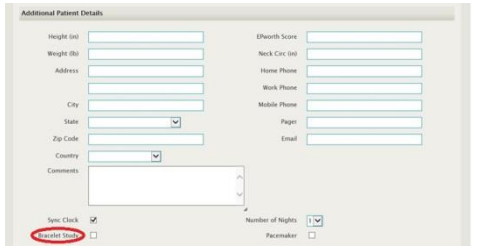

22. “Save and Lock Report” to complete the process and alert the provider that the study is complete.

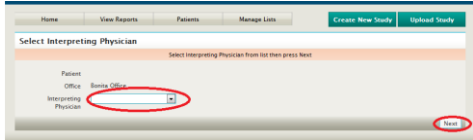
	<p style="text-align: center;">Note</p> <p>In a multi night study, a manual events file might be created for each of the nights. Upload all of them into the cloudPAT. Add files by pressing the ⊕ icon.</p>
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8. Appendix C: CloudPAT Assistant “cheat sheets”

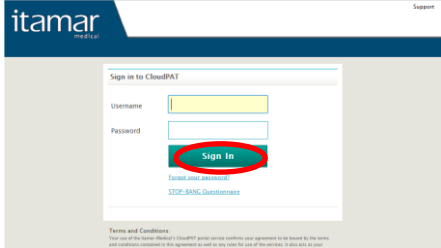

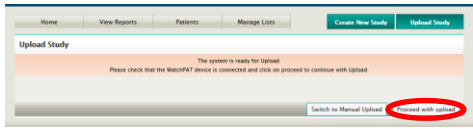
You may print the following pages for a quick reference to frequent tasks.

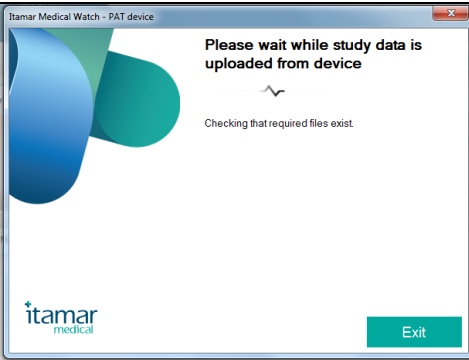
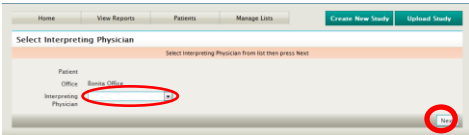
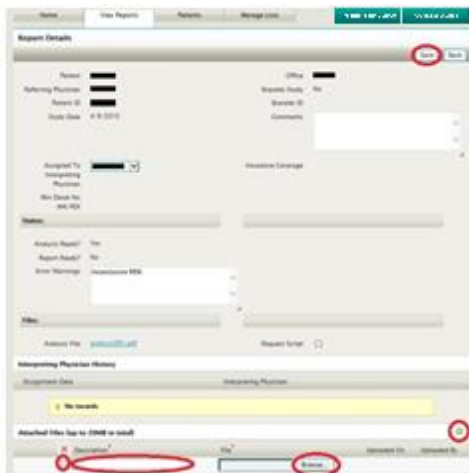
Create a New Study (Initialization) via CloudPAT

	Step	Action(s)	Comment
Minimum	0.	Before you start... Do you have...? 1. PC workstation w/internet access? 2. Username & Password? 3. Minimum upload speed of 1 Mbps	Problems or Questions? Select Support or Call: +1-888-748-2627
Logging in	1.	Enter CloudPAT via the Web Log in to CloudPAT : US - https://cloudpat.precisemd.com EU - https://cloudpateu.precisemd.com UK - https://cloudpatuk.precisemd.com • Enter your Username & Password • Select “Sign In”	
Connecting	2.	Create (initialize) new Sleep Study using CloudPAT • Select “Create New Study” • Slide WatchPAT™ device out of its “cradle” to reveal the USB connection. • Connect WatchPAT™ device to any USB port.	
Patient Detail Entry	3.	Patient Detail Entry • Only the “Patient ID” and office are mandatory. • We recommend you fill the patient name to ease searching for the study. • Select “Save & Initialize Device”	
	4.	OPTIONAL Chain of Custody Bracelet • For more patient detail entry, select “More Details” section • Select the box “Bracelet Study” for occupational testing using a Chain of Custody bracelet. • For multi night study select the number of nights • Select “Save & Initialize Device”	
Success?	5.	Initialization complete • Select: “Proceed with initialization” • 1st time usage: a small PC-App will be downloaded. Select: “Run”	

		Step	Action(s)	Comment
Interpreting Physician	6.	Select Interpreting Physician	<ul style="list-style-type: none"> Select the Interpreting Physician (or leave empty at this point) Select "Save" 	
Finalize	7.	Prepare the device	<ul style="list-style-type: none"> Reinsert the WatchPAT™ device into its "cradle" Complete a device test Instruct the patient about the use of the device. 	

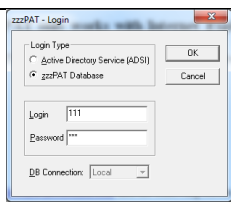
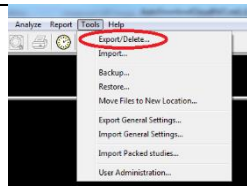
Upload Sleep Study from WatchPAT™ to CloudPAT

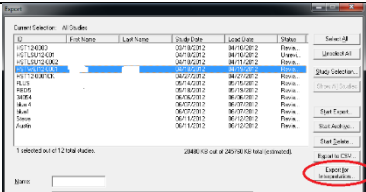
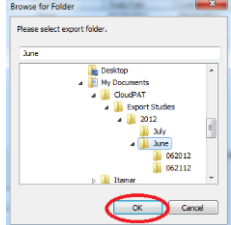
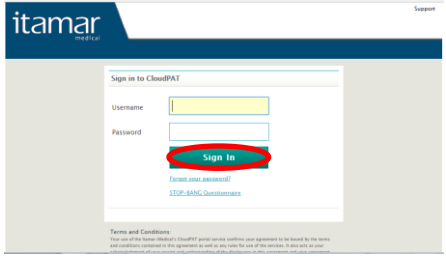
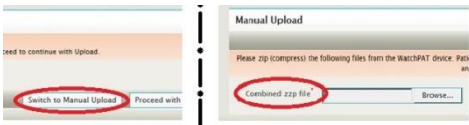
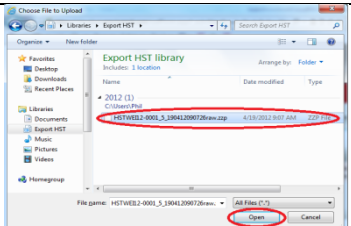
		Step	Action(s)	Comment
Minimum	0.	Before you start...	<p>Do you have...?</p> <ol style="list-style-type: none"> Computer running Win7 or higher with internet access? Username & Password? Minimum upload speed of 1 Mbps 	<p>Problems or Questions? Select Support or Call: +1-888-748-2627</p>
Logging in	1.	Enter CloudPAT via the Web	<p>Log in to CloudPAT :</p> <p>US - https://cloudpat.precisemd.com EU - https://cloudpateu.precisemd.com UK - https://cloudpatuk.precisemd.com</p> <ul style="list-style-type: none"> Enter your Username & Password Select Sign In 	
Upload Study	2.	Upload a Sleep Study-WatchPAT™ device to CloudPAT	<ul style="list-style-type: none"> Select "Upload Study" Slide WatchPAT™ device out of its "cradle" to reveal the USB connection. Connect WatchPAT™ device to a USB port. 	
Internet Connection required	3.	Connect WatchPAT™ device to USB port	<p>Select: "Proceed with upload"</p> <ul style="list-style-type: none"> 1st time usage: a small PC-App will be downloaded. Select: Run You will be prompted to select an Interpreting Physician <u>after</u> the study has uploaded. 	

	Step	Action(s)	Comment
	4. Upload progress	Depending on your connection speed, the device type and the number of night (in a multi night study) upload time will vary between two (2) and fifteen (15) minutes. If an error is reported, you will need to try again. Keep the WatchPAT device connected until CloudPAT displays the message the upload is completed.	
Success?	5. Select Interpreting Physician	“Upload Complete” : Study uploaded successfully. Now you can select the Interpreting Physician that will interpret the study (can be done later on form the study page). Select: Next “Upload Failed” : try again or call Support	
Attach files	6. OPTIONAL Attach Files (up to 20MB) and update study details	<ul style="list-style-type: none"> • Select “View Reports” • Select the Study for which you want to attach files by clicking on the “Patient ID” link. • Go to the “Attached Files” section at the bottom of the “Report Details” screen and “Browse” to the file and add “Description”. • Add additional files by clicking on the + sign on the right. • Select the box under the x to delete a file. • Update study parameters if needed and Assign to Interpreting Physician if needed. • Select “Save” to save your changes. 	

Manual Upload from zzzPAT to CloudPAT

(Rarely needed. e.g. if an internet outage occurred and sleep study was saved locally on zzzPAT)

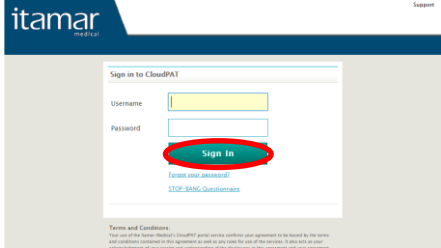
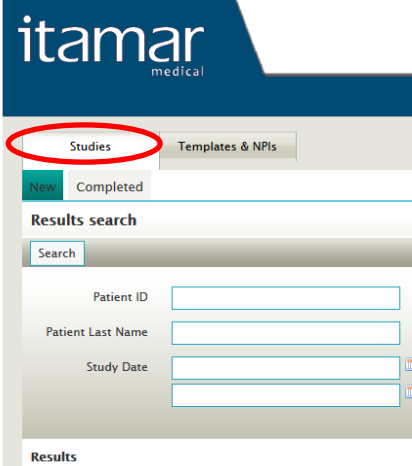

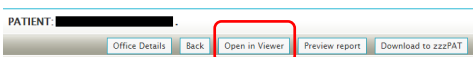
	Step	Action(s)	Comment
Preparation	1. Start zzzPAT	<i>Open zzzPAT (default Login and Password: “111” for both entries)</i>	
Create Export	2. Start Export process	Select “Export/Delete” under “Tools”	

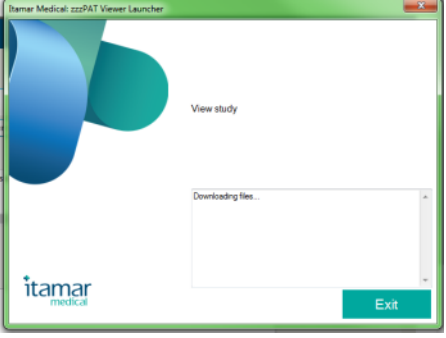
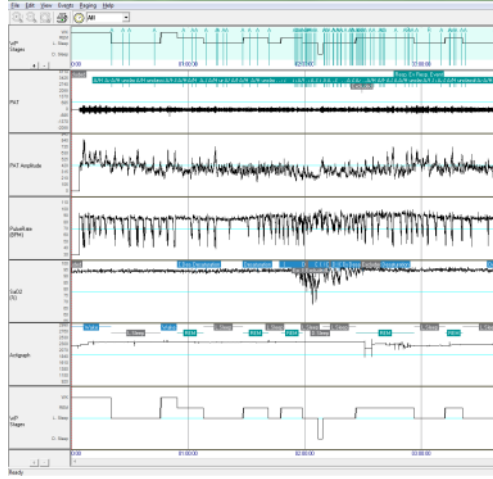
	Step	Action(s)	Comment
Locate Study	3.	Find a patient via ID number Highlight the patient that you want to export to CloudPAT and select “Export for Interpretation”	
Save Export	4.	Save Exported file <ul style="list-style-type: none"> Browse for a Folder you created prior to this step (suggestion: name it “CloudPAT”). After selecting that Folder, Save the exported file by selecting “OK” The file will end in .zzp. 	
CloudPAT login	5.	Log into CloudPAT : US - https://cloudpat.precisemd.com EU - https://cloudpateu.precisemd.com UK - https://cloudpatuk.precisemd.com a regular study <ul style="list-style-type: none"> Enter your Username and Password Select Sign In 	
Select Manual	6.	Manual Study Upload Select “Upload Study” Select “Switch to Manual Upload” Find the file: select “Browse”	
Open	7.	The file extension is .zzp . Select “Open” for the file you want to upload. Proceed as in Step 3 for a regular <i>Upload Sleep Study</i>	

**Interpreting Physician: Physician review of raw sleep study data using
zzzPAT Study Viewer**

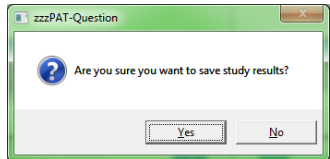
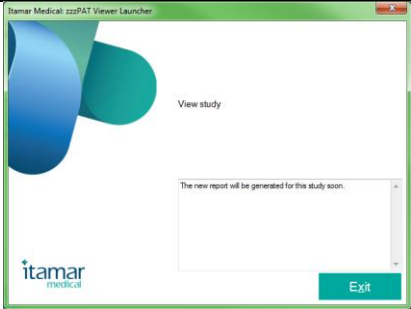

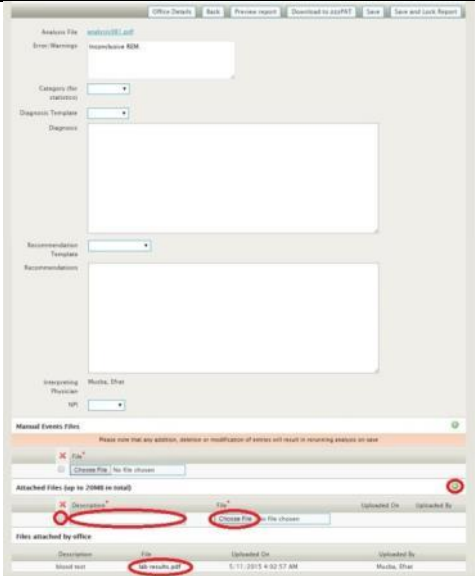
Open in Viewer is superior on Download to zzzPAT as it allows view and edit the signals of WatchPAT study using the most updated WatchPAT analysis and Viewer software, avoiding the process of installing zzzPAT™, downloading the study to zzzPAT and uploading editing results to CloudPAT, and maintain zzzPAT software upgrades.


part -1

	Step	Action(s)	Comment
Preparation	1.	Before you start... Do you have...? 1. Computer running Win7 or higher with internet access? 2. Username & Password? 3. zzzPAT Viewer familiarity	Problems or Questions? Select Support or Call: +1-888-748-2627
Login	2.	Enter CloudPAT via the Web Log in to CloudPAT : US - https://cloudpat.precisemd.com EU - https://cloudpateu.precisemd.com UK - https://cloudpatuk.precisemd.com • Enter your Username & Password • Select "Sign In"	
Find study	3.	Select patient study Select "Studies". Select the patient you want to analyze. Various Sort options are available at the bottom	
View	4.	View auto-analyzed suggestions • To view the auto analyzed, 2-page report select "Analysis File" • To view patient information, select "Preview Report" • Open attachments if exist If analysis is satisfactory, skip to step 12	
Analyze	5.	Analyze & save Sleep Study raw data To view the signals and edit the analysis: • Select "Open in Viewer"	

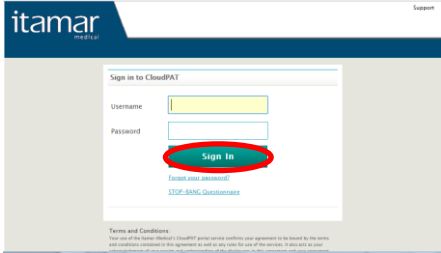
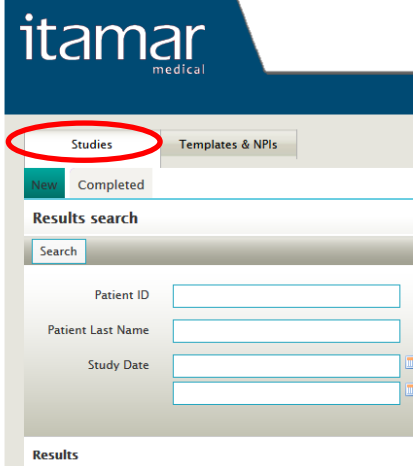


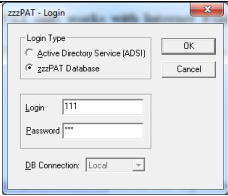
Download study data	6.	zzzPAT Viewer Launcher	zzzPAT Viewer Launcher automatically downloads study data to your PC	
Work zzzPAT	7.	zzzPAT Viewer	zzzPAT Viewer is automatically launched	

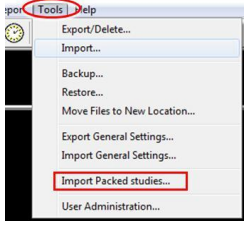
**Interpreting Physician: Physician review of raw sleep study data using
zzzPAT Study Viewer
part 2**

		Step	Action(s)	Comment
Score raw data	8.	Manually edit and score the sleep study	<ul style="list-style-type: none"> • Add and/or Delete Events per your training 	Refer to zzzPAT Operations Manual
Save locally	9.	Save Event changes on local disk	<ul style="list-style-type: none"> • Select "File" • Select "Save Study Results" 	
Upload	10.	Upload Event changes to CloudPAT	<ul style="list-style-type: none"> • Select "File" • Select "Exit" 	 <p>User Events file is automatically added to study files.</p>  <p>The analysis will automatically run with the manual event file, creating a new analysis file.</p>
Prepare	11.	Prepare report	<ul style="list-style-type: none"> • Preview the new report. • Enter Diagnosis and Recommendations. • Open files attached by the office (if any) by clicking on the file link. • Add prescriptions or additional information as PDF attachments <ul style="list-style-type: none"> ○ Go to the "Attached Files" section at the bottom of the screen and "Browse" to the file and add "Description". ○ Add additional files by clicking on the + sign on the right. ○ Select the box under the x to delete a file. • Select "Save" to save your changes. 	

Lock & Notify	12.	Lock report; notify Provider	<ul style="list-style-type: none">• Select “<i>Save and Lock Report</i>” to complete the process• Provider will be alerted automatically that the study is complete. <p style="text-align: center;"><i>DONE</i></p>	 <p>PATIENT: 1 Download to zzzPAT Save Save and Lock Report</p>
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Interpreting Physician: Physician review of raw sleep study data
part -1

		Step	Action(s)	Comment
Preparation	13.	Before you start...	Do you have...? 4. Computer running Win7 or higher with internet access? 5. Username & Password? 6. zzzPAT familiarity & installed	Problems or Questions? Select Support or Call: +1-888-748-2627
Login	14.	Enter CloudPAT via the Web	Log in to CloudPAT : US - https://cloudpat.precisemd.com EU - https://cloudpateu.precisemd.com UK - https://cloudpatuk.precisemd.com <ul style="list-style-type: none"> Enter your Username & Password Select "Sign In" 	
Find study	15.	Select patient study	You may <ul style="list-style-type: none"> Analyze a study ("Studies") or Create custom forms ("Templates") or NPI number ("NPIs") Select the patient you want to analyze. Various Sort options are available at the bottom	
View	16.	View auto-analyzed suggestions	<ul style="list-style-type: none"> To view the auto analyzed, 2-page report that the Provider uploaded, select "Analysis File" To view patient information, select "Preview Report" Open attachments if exist If analysis is satisfactory, skip to step 12	
Analyze	17.	Analyze & save Sleep Study raw data	To download the raw data for review: <ul style="list-style-type: none"> Select "Download to zzzPAT" Browse for a Folder you created prior to this step (suggestion: name it "CloudPAT") 	
Work zzzPAT	18.	Start zzzPAT	Open zzzPAT (default Login and Password: "111" for both entries)	

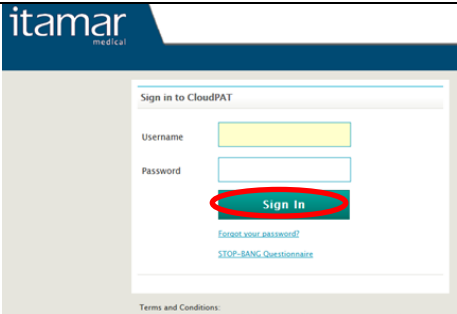
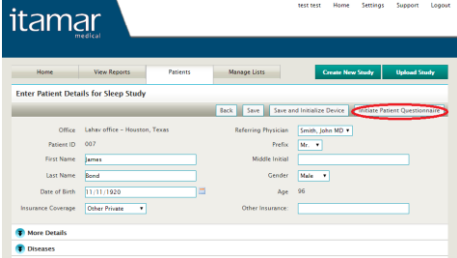
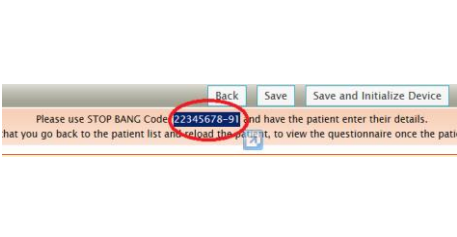
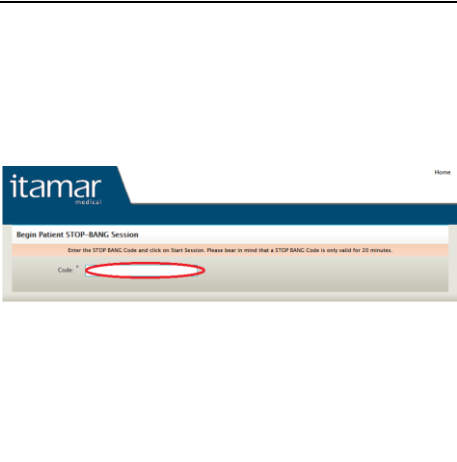
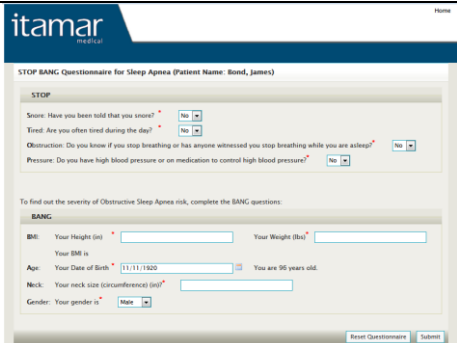
Import Study	19.	Manual Study Upload	<ul style="list-style-type: none">• Select “<i>Import Packed studies</i>” under “<i>Tools</i>”• Get to “<i>Select Packed Studies to Import</i>”• Go to your previous CloudPAT Folder• Highlight the .zpz file to Import• Select “<i>Open</i>”• Edit/Score as usual with zzzPAT	
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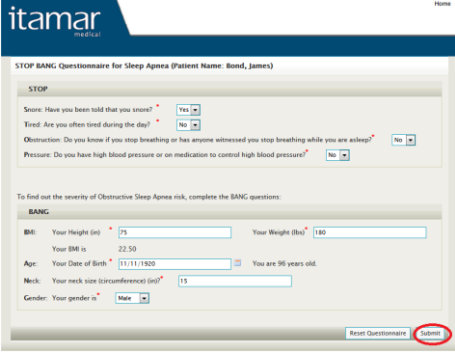
Interpreting Physician: Physician review of raw sleep study data
part 2

		Step	Action(s)	Comment
Score raw data	20.	Manually edit and score the sleep study	<ul style="list-style-type: none"> • Add and/or Delete Events per your training • The changes now need to be saved on your local disk. 	
Save locally	21.	Save Event changes on local disk	<ul style="list-style-type: none"> • Select "File" • Select "Export Manual Events..." • A new box will open; • Save the changes to your <u>local</u> CloudPAT Folder • Select "OK" 	
Upload	22.	Upload Event changes to CloudPAT	<ul style="list-style-type: none"> • The manually edited changes now need to be uploaded back to CloudPAT. • Select "Browse" • Find the saved file, highlight it, select "Open" 	
Save Cloud	23.	Save Event changes on CloudPAT	<ul style="list-style-type: none"> • Select "Save" from the CloudPAT toolbar. • Your manually edited study is now saved on CloudPAT, ready for diagnosis using your customizable template system 	
Prepare	24.	Prepare report	<ul style="list-style-type: none"> • Preview the new report. • Enter Diagnosis and Recommendations. • Open files attached by the office (if any) by clicking on the file link. • Add prescriptions or additional information as PDF attachments <ul style="list-style-type: none"> ○ Go to the "Attached Files" section at the bottom of the screen and "Browse" to the file and add "Description". ○ Add additional files by clicking on the + sign on the right. ○ Select the box under the x to delete a file. • Select "Save" to save your changes. 	

Lock & Notify	25.	Lock report; notify Provider	<ul style="list-style-type: none">• Select “<i>Save and Lock Report</i>” to complete the process• Provider will be alerted automatically that the study is complete. <p style="text-align: center;"><i>DONE</i></p>	 <p>PATIENT: 1 Download to zzzPAT Save Save and Lock Report</p>
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Fill a STOP BANG questionnaire

		Step	Action(s)	Comment
Login	1.	Enter CloudPAT via the Web	<p>Log in to CloudPAT :</p> <p>US - https://cloudpat.precisemd.com</p> <p>EU - https://cloudpateu.precisemd.com</p> <p>UK - https://cloudpatuk.precisemd.com</p> <ul style="list-style-type: none"> • Enter your Username & Password • Select <i>Sign In</i> 	
Find Patient	2.	Select patient	<ul style="list-style-type: none"> • Select Patient either through “<i>Manage Patients</i>” or through “<i>Create New Study</i>” • Select “<i>Initiate Patient Questionnaire</i>” 	
Get code	3.	Get code	<ul style="list-style-type: none"> • You will receive an individual code, which will be valid for 20 minutes only • The code starts with the Patient’s ID and is part of the 2 line message displayed on the screen • Copy the code. You will need it to start the questionnaire 	
Use code	4.	Use code	<ul style="list-style-type: none"> • On the laptop or tablet given to the patient, Go to: US - https://cloudpat.precisemd.com/sb.aspx EU - https://cloudpateu.precisemd.com/sb.aspx UK - https://cloudpatuk.precisemd.com/sb.aspx <ul style="list-style-type: none"> • Enter code in “Code” field • Select “<i>Start Session</i>” 	
Fill questionnaire	5.	Fill STOP BANG	<p>Let the patient fill in the questionnaire.</p> <p>Note: Once the patient starts filling in the questionnaire, they have 20 minutes to complete it. If they don’t complete it during that time, a new code must be generated from within the Patient Details screen.</p>	

Submit questionnaire	6.	Submit	<ul style="list-style-type: none"> • Select the “<i>Submit</i>” button once the patient has filled in the questionnaire • The Patient details will be automatically updated with the new information (except if the fields were already filled previously) • Filled questionnaires can be viewed from the “<i>Questionnaires</i>” section of the Patient details screen. 	 <p>The screenshot shows the 'STOP BANG Questionnaire for Sleep Apnea' interface. The patient's name is 'Bond, James'. The 'STOP' section contains three questions with dropdown menus for 'Yes' and 'No'. The 'BANG' section includes fields for BMI (Height: 175, Weight: 180), Age (Date of Birth: 11/11/1920, Age: 95), Neck size (15), and Gender (Male). A 'Submit' button is circled in red at the bottom right of the form.</p>
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9. Appendix D: License Agreement

License to User from Itamar Medical Ltd can be found on Itamar Medical website:
<https://www.itamar-medical.com/wp-content/uploads/2019/03/Itamar-License-2019.pdf>

10. Appendix E: Regulatory Representative

Itamar Medical's authorized regulatory representative is:

EC REP	Arazy Group GmbH
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The Squire 12, Am Flughafen,
60549 Frankfurt am Main, Germany