

# itamar


## CloudPAT™

### Web Software Operation Manual

Itamar Medical REF: OM2200000



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Revision Table

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0	August 2011	Preliminary	All	All
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## **1. Introduction to CloudPAT**

### **1.1. Intended Use of WatchPAT**

WatchPAT is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT device is used as a diagnostic aid for the detection of sleep-related breathing disorders, and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep and Deep Sleep). The device generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification ("PSTAGES"). The device's "PSTAGES" provides supplemental information to its PRDI/PAHI. The device's "PSTAGES" is 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.

WatchPAT is not indicated for children less than 17 years old.

### **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 application supporting the sleep apnea lifecycle from diagnosis through interpretation. 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. CloudPAT uses zzzPAT's analyzing software modules that are responsible for the identification of the breathing disordered events and REM, Light Sleep and Deep Sleep stages.

CloudPAT offers simple preparation and uploading of WatchPAT sleep studies that can be sent transparently for interpretation by a local Board-certified specialist or from a national network of telemedicine Board-certified specialists. 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 data is securely stored and backed up on the Web.

## **1.4. Overview**

Obstructive sleep apnea syndrome (OSAS) is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. It is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep, often leading to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is based on the Respiratory Disturbance Index (RDI), the number of Apneas, Hypopneas and Respiratory Effort Related Arousals (RERA) per hour of sleep and/or apnea-hypopnea index (AHI), 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 OSAS 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 micro-SD card along with pulse rate (derived from the PAT signal), data from a built in pulse-oximeter (the sensor is mounted on an adjacent finger) and an actigraph (embedded in the device). 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 same algorithms as zzzPAT. 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 software.

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

## 1.5. Terminology

CloudPAT supports various types of users and entities.

- **Office** – a practice including one or more referring physicians, as well as technicians and administrative staff.
- **Doctor** – the primary physician administering 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 and Viewing reports (see Section 3).
- **Specialist** – a Board-certified physician performing the sleep study analysis, interpretation and diagnosis. This is another type of user using CloudPAT functions: Reviewing studies and Managing templates for diagnosis and recommendations (see Section 4).
- **Patient** – the person who undergoes the sleep study.

## 1.6. Minimum requirements

An internet connection using a PC workstation with Microsoft XP SP2 and above, running at a minimum upload speed of 1 Mbps and **Internet Explorer version 7.0 or higher** is required.

## 2. Setting CloudPAT Access

### 2.1 Obtaining an account

Usage of CloudPAT is intended for WatchPAT customers' only (using WatchPAT200 devices). A secure and individual login account must be assigned by the trusted Itamar administrator.

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



#### Note

Be sure to change the initial password upon sign in.



## 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](http://www.Itamar-Medical.com) or directly at <https://cloudpat.precisemd.com>. Access to CloudPAT starts with the Sign In screen where Username and Password are entered (see Figure 1).

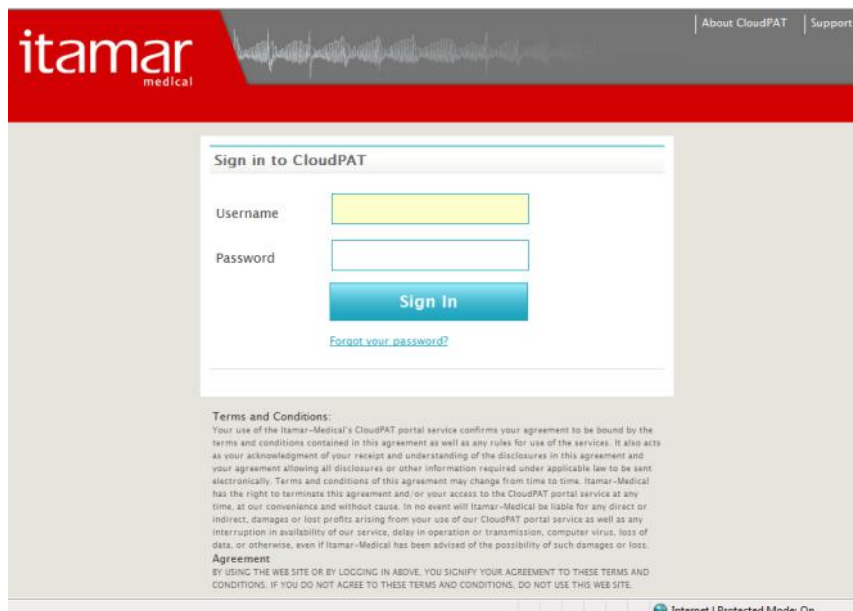


Figure 1: Sign In screen

## 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 2).

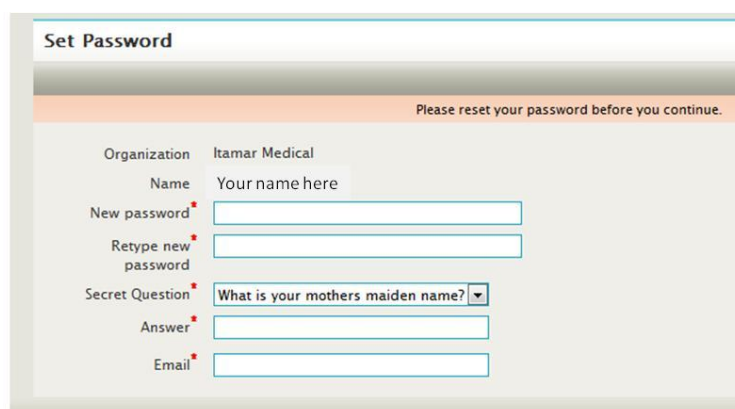


Figure 2: Set Password screen

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

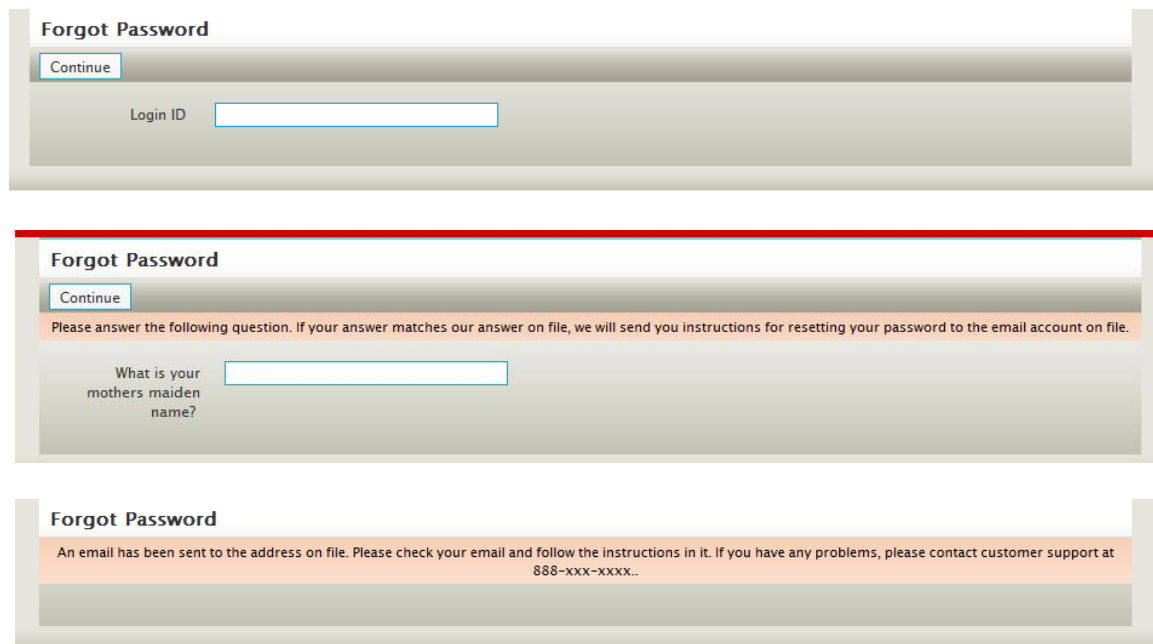


### Note

All asterisk (\*) tagged fields are mandatory and should be filled (see Figure 2).

## 2.4 Resetting Password

In the event you forgot 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 3).



**Forgot Password**

Continue

Login ID

**Forgot Password**

Continue

Please answer the following question. If your answer matches our answer on file, we will send you instructions for resetting your password to the email account on file.

What is your mothers maiden name?

**Forgot Password**

An email has been sent to the address on file. Please check your email and follow the instructions in it. If you have any problems, please contact customer support at 888-xxx-xxxx..

Figure 3: Reset Password screens

## 2.5 Profile Settings & Support

Users may set their preferences by selecting the “Settings” option from the top of any screen at any time (see Figure 4). The only mandatory fields are the Last name and Email address (see Figure 5). In addition, you must select a secret question and provide an answer to that question for the purpose of resetting your password. A new temporary password will be sent to your email address.

Please contact administration support by pressing Support from any screen if any difficulties arise. The Support screen contains the up to date phone numbers (see Figure 6).



Figure 4: Functions available from all screens

**Profile Settings**

Login ID US1b

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 5: 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: +372 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 6: Support screen

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

### 3. Using CloudPAT as a User

#### 3.1. Main Access Screen (Home “Lobby”)

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

1. **Create New Study** – prepares & initializes WatchPAT for a new sleep study.
2. **Upload Study** – uploads sleep study files from WatchPAT to the CloudPAT web server and subsequent redirection (e.g., Board-certified interpretation by a Specialist) according to pre-determined instructions.
3. **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.
4. **Manage 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.



Figure 7: Home (Lobby) screen

#### 3.2. Creating a New Study

In order to prepare WatchPAT for a new study select “Create New Study” from the Home screen (see Figure 8).

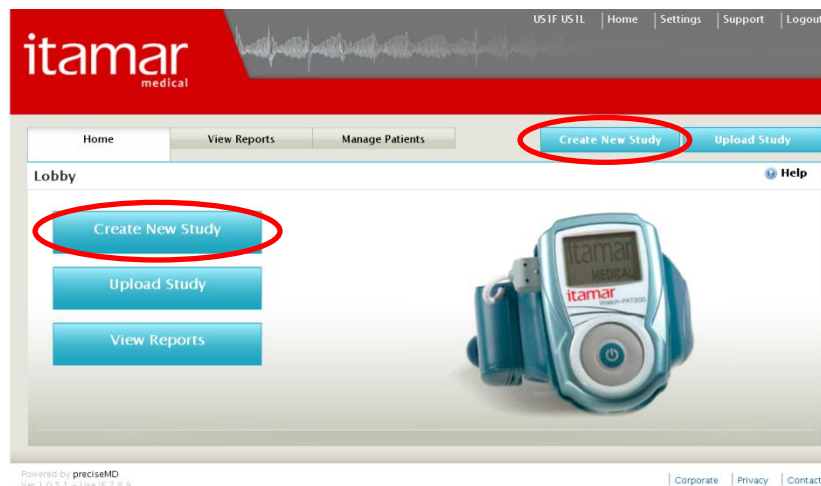


Figure 8: Create New Study selection

### 3.2.1. Preparing WatchPAT for a New Study

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

1. Fill the **mandatory Patient ID** in the Patient fields as in Figure 9.



#### Note

If the User is associated with only one Office then this Office will be automatically filled.

2. Insert any additional information if needed, the rest of the fields are optional. You may insert additional information after the study is saved to WatchPAT if necessary (see Section 3.5).

Note that you will be prompted to select a **Specialist** while uploading the study (see Section 3.3.13.2.1) if the "Sent to Specialist" field is left empty and you have more than one Specialists to choose from.

3. More Details (optional): Figure 10 shows the ability to add More Details, Diseases, and/or Medications in the respective drop down lists. From this screen you may require a **bracelet** to be used as **Positive Chain of Custody** in Occupational Testing (e.g., truck drivers. See WatchPAT user manual for further details).
4. Once the study definition is completed, press "Save and Initialize Device" (see Figure 9).
5. 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 11).
- 6.



#### Note

The first time you run the initialization process, a one-time PC-resident program will be downloaded (see Section 3.2.1.2).

7. A pop-up application will open and manage the initialization of the device.  
See section 3.2.1.3 for error handling in different cases.
8. The system will prompt you once the initialization process is completed.

Figure 9: Patient data entry screen

Figure 10: More Detail screen for patient data (optional)

Figure 11: Initialize Device screen

### 3.2.1.1. Initializing WatchPAT

Pressing the “Save and Initialize Device” button saves the patient information in the system and initializes the device. Alternatively, you can choose to prepare patient information without initializing the device by clicking the “Save” button shown in Figure 9. This action will save the patient information in the system for later use. You will be able to return later on to this patient from the “Manage Patients” screen and quickly initialize the device by clicking the “Save and Initialize Device”.

### 3.2.1.2. First Time Initialization

The first time you run the Initialization process, a small one-time PC-resident program will be downloaded from CloudPAT (see Figure 12). If your system asks you for permission to run this application, please enable to process, it is required for the successful connection to the WatchPAT device.

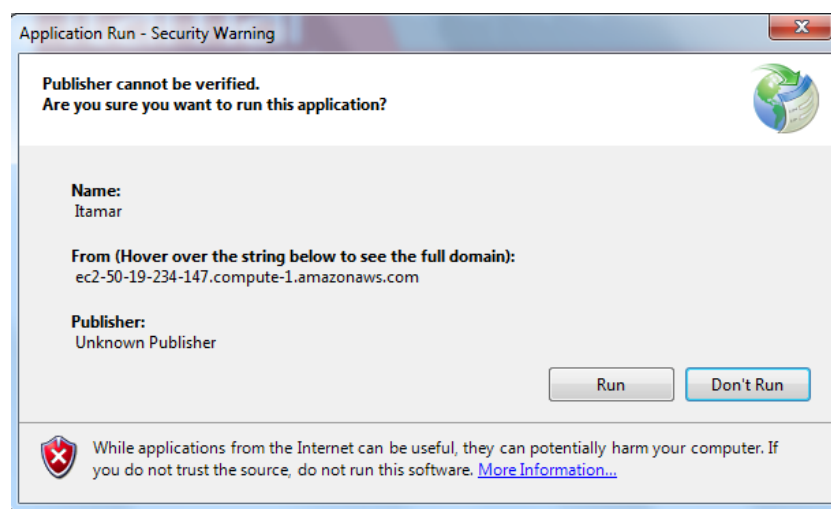


Figure 12: Message to download the PC-resident program

### 3.2.1.3. Initialization Process Protection

**Data entry protection:** Once the system saves the patient details (after pressing “Save” or “Save and Initialize”) the system checks the values of the entered fields. Relevant fields will be highlighted in red if not all mandatory fields have values, or if there are illegal/out of range values in any of the fields. Correct the errors and proceed.

**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 but will prompt by saying “Previous study found” (see Figure 13) and that you should upload the study before proceeding. This behavior prevents you from accidental overwriting a study that was not uploaded.

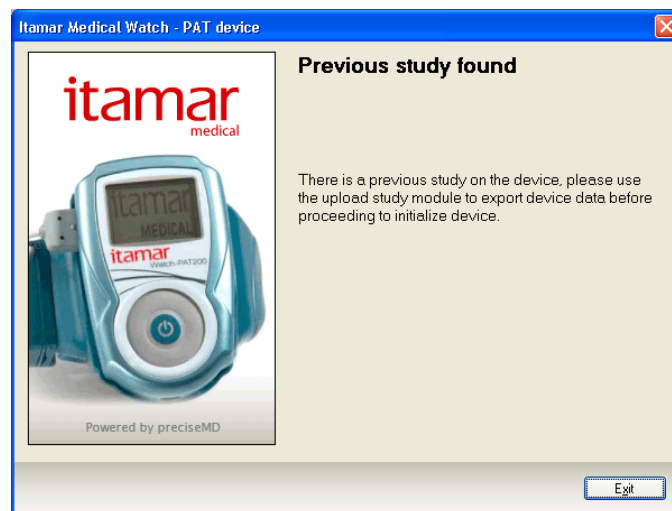


Figure 13: Protection from accidentally overwriting previous sleep study


### 3.3. Uploading a Study

#### 3.3.1. Normal Mode

When a patient returns WatchPAT after a night study, simply connect WatchPAT's Micro USB port (see Figure 14) to any USB port on the PC by using WatchPAT's communication cable and select "Upload Study" from the Home Screen (see Figure 15).



Figure 14: WatchPAT's Micro USB port

	<p style="text-align: center;"><b>Note</b></p> <p>In order to expose WatchPAT's Micro USB port:</p> <ol style="list-style-type: none"> <li>1. Disconnect the Oximetry module by disconnecting the Oximetry module connector.</li> <li>2. Gently slide the WP200 out of the wrist strap until a click is heard and the Micro USB port is exposed.</li> </ol>
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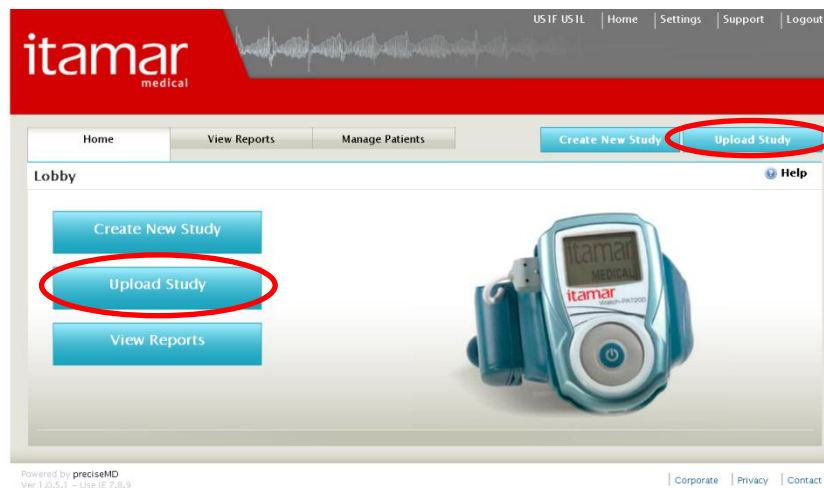


Figure 15: Upload Study Selection

Proceed by selecting the “Proceed with upload” button (see Figure 16).

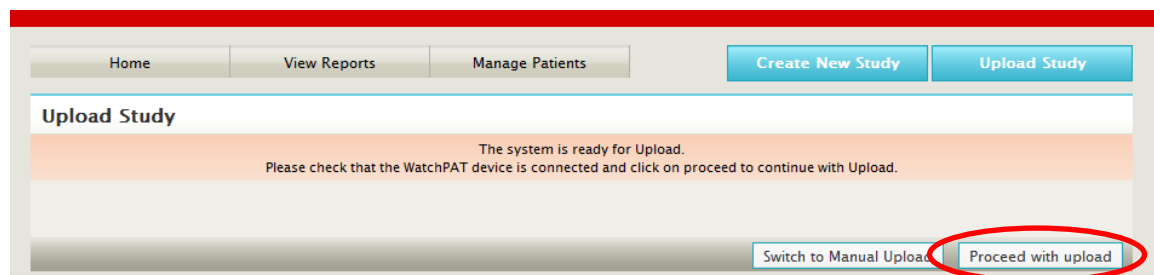


Figure 16: Upload Study Dialog box

A small PC-resident program will be downloaded the first time remote access is requested from CloudPAT (see Figure 12) and select “Run”. During the upload process you will see a screen informing that upload is in progress.

If more than one Specialist is defined for the current Office and no Specialist was previously designated (while creating the new study), you will be prompted to select a Specialist at this time (see Figure 17) from a list of Specialists which were defined for your office.

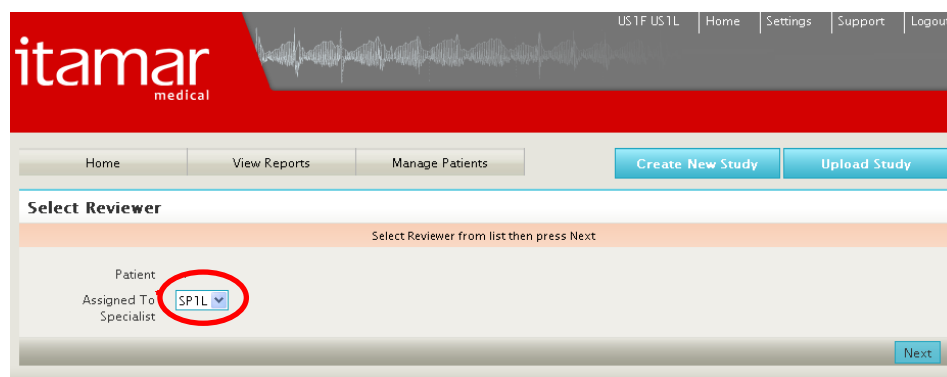


Figure 17: Select Specialist Dialog box

While uploading the following dialog (see Figure 18) will be displayed.

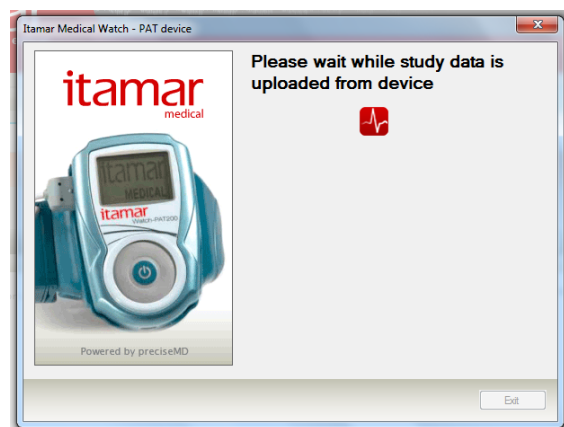


Figure 18: Patient sleep study upload in progress



### Note

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 upload is successful you will receive the message: “Upload Complete: Study uploaded successfully. The analyzed data file will be ready shortly under Reports. Data has been sent to be reviewed by [*Specialist’s name*]” (see Figure 19).

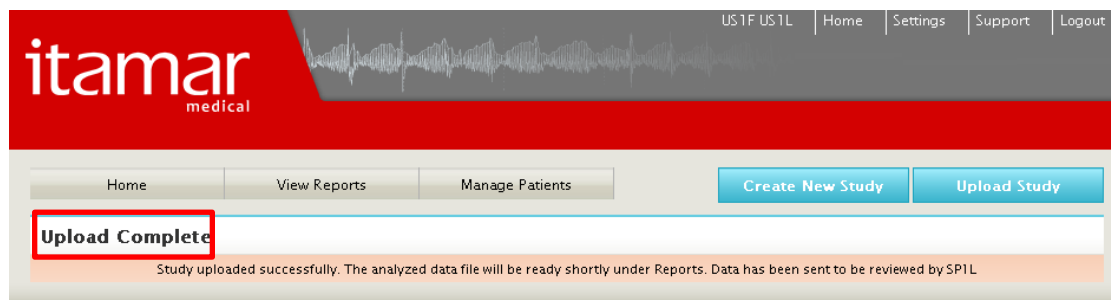


Figure 19: Upload complete screen

If an error is reported, you will need to try again (see Figure 20).



Figure 20: Upload failed screen

### 3.3.2. Manual Mode

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 log.dat (if it exists) 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 21).

See Appendix C: Uploading study from zzzPAT to CloudPAT Guide.

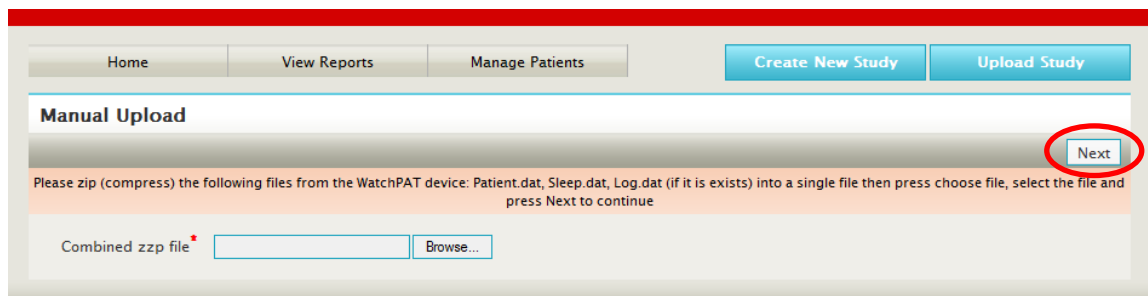


Figure 21: Manual Upload

In both modes at the end of a successful upload you will see the following screen:

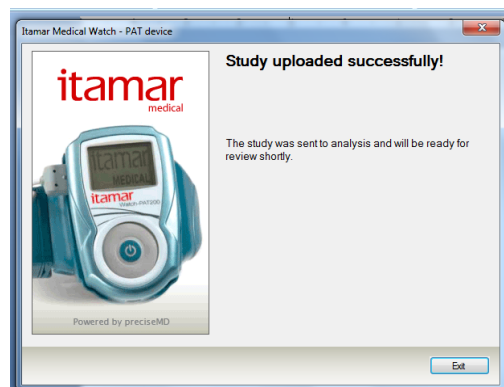



Figure 22: Successful upload screen

### 3.4. Viewing Reports

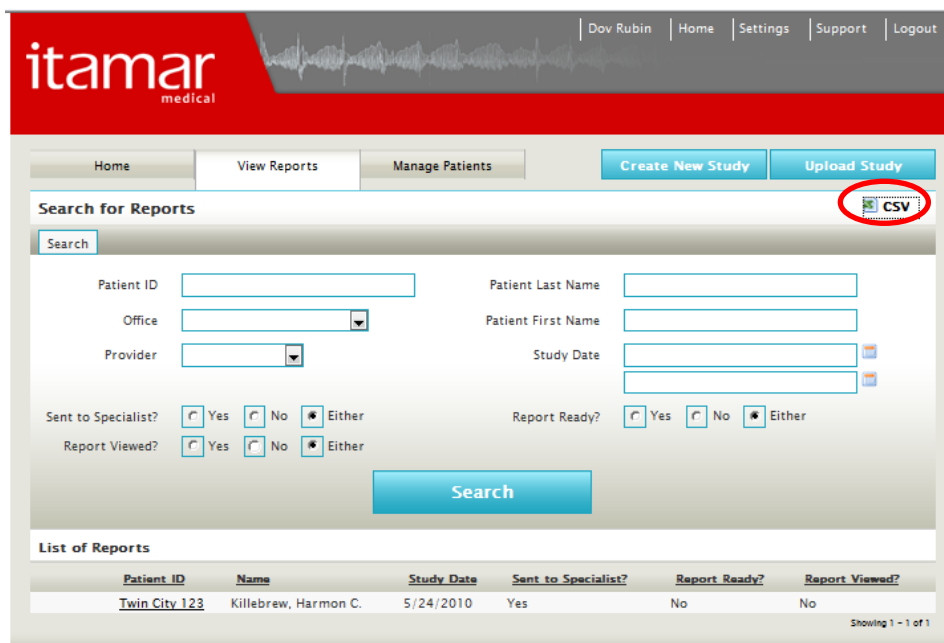
After a patient sleep study has been sent to your Specialist for reviewing and Board-certified interpretation, you will receive an email notification that your patient sleep study report is available. Alternatively, you may poll the system by pressing “View Reports” from the main screen which will display the newest studies as well as a list of previously viewed sleep study reports (see Figure 23).

You have the option to review subsets of your patient studies by selecting Yes/No for the different options (Sent to Specialist, Report Ready or Report Viewed), or by entering a specific Patient ID, name, etc.



**Note**

Click on the CSV icon (see Figure 23) if you want to obtain an Excel file containing the "List of Reports".



**Search for Reports**

Search

Patient ID  Patient Last Name

Office  Patient First Name

Provider  Study Date

Sent to Specialist? ☐ Yes ☐ No ☒ Either

Report Viewed? ☐ Yes ☐ No ☒ Either

Report Ready? ☐ Yes ☐ No ☒ Either

**Search**

**List of Reports**

Patient ID	Name	Study Date	Sent to Specialist?	Report Ready?	Report Viewed?
Twin City 123	Killebrew, Harmon C.	5/24/2010	Yes	No	No

Showing 1 - 1 of 1

Figure 23: Viewing Sleep Study Reports

After selecting a Patient ID, you will be brought to the following screen (see Figure 24) from which you can review the Board-Certified sleep study report.

**Report Details** Back

Patient	<a href="#">Killebrew, Harmon C.</a>	Office	Itamar Medical sales team
Provider		Bracelet Study	Unknown
Patient ID	Twin City 123	Bracelet ID	
Study Date	5/24/2010	Comments	<div></div>
Assigned To	Specialist, Demo	Insurance Coverage	

**Status:**

Analysis Ready? Yes

Report Ready? No

**Files:**

Analysis File [analysis69.pdf](#) Excel File [report69.xls](#)

Figure 24: Report Details for reviewing sleep study reports

Simply click on the “Analysis File” link for a details report complete with comments and diagnosis from the Specialist and/or click the Excel File link to download an equivalent file in Excel format. Depending on the default setting for your institution, an unofficial and un-reviewed version of the sleep report may be available right after uploading your patient study.

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

### 3.5. Managing Patient Information

You may use this function in order to manage patient information or see all studies that have been recorded for a particular patient.

You may browse or edit patient details by pressing “View Reports” from the main screen which will display the Search for Patients screen (see Figure 25). You may press on the Search button in order to see all patients or you may search by Patient ID, name, etc.

Figure 25: Search for Patients screen

After selecting Search, you will be brought to the following screen (see Figure 26) from which you can select the specific Patient to manage.

Patient ID	Name	Date of Birth	Insurance Coverage	Study Date
TestAllPatientF	Levi, Rami Jr.	7/30/1974		5/15/2011
PID4567890123456	LN 3456789012345, FN 3456789012345 .	12/31/1970		6/27/2009
050505	ManualEvents, TestUpload .	7/10/2003		6/27/2009
07261_1	MCh, StraightSBPCon .			3/17/2012
0000000000	Not initialized, Patient details .	1/1/1900		3/12/2012
0000000000	PatientFirst, PatFirst .	8/4/1975		10/14/2010

Figure 26: Search for Patients screen



### Note

Click on the CSV icon (see Figure 26) if you want to obtain an Excel file containing the "List of Patients".

After selecting a Patient ID, you will be brought to the following screen (see

Figure 30) from which you can **edit** the Patient details.

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

1. **Save** – saves your changes to the Patient record.
2. **Save and Initialize Device** – loads WatchPAT with the current patient information while saving your changes (if any) to the Patient record.

The bottom of the screen lists all studies for the specific patient and you may select the Study Date link in order to view the corresponding Report Details screen (see Figure 24).

Study Date	Analysis Ready?	Sent to Specialist?	Report Ready?	Report Viewed?
6/27/2009	Yes	No	No	No

Figure 27: Manage Patient Details screen

## 4. Using CloudPAT as a Specialist

### 4.1. Main Access Screen

When you sign in CloudPAT as a Specialist you will be presented with the Specialist's Home screen (see Figure 28).

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

3. **Review studies** – reviews new or displays completed studies.
4. **Manage templates** – defines new or edits existing templates used for Clinical diagnosis and recommendations while reviewing studies.

Figure 28: Specialist's Home screen

## 4.2. Studies

### 4.2.1. Reviewing a Study

After a patient sleep study has been sent for interpretation, you will receive an email notification that a sleep study is waiting for your interpretation. Alternatively, you may poll this site by pressing on the “New” tab from the main screen which will display the new studies screen (see Figure 29). You may also select the “Completed” tab for viewing completed sleep study reports. You have the option to review subsets of your studies by selecting a particular Office, Patient name, etc. (see Figure 29).



#### Note

Click on the CSV icon (see Figure 29) if you want to obtain an Excel file containing the "Results".

Patient ID	Patient	Office	Current Doctor	Study Date	Waiting (days)
OffC-P3	OfficeC	ProvC	6/27/2009	99	

Figure 29: Study selection screen



After selecting a Patient ID while on the “New” studies tab, you will be brought to the following screen (see Figure 30) from which you can review the new sleep study.

The screenshot shows the Itamar Medical web application interface. At the top, there is a red header with the 'itamar medical' logo and a navigation bar with links for 'SP1L', 'Settings', 'Support', and 'Logout'. Below the header, there are two tabs: 'Studies' and 'Templates'. The 'Studies' tab is active, and the page is titled 'PATIENT:'. Below the title, there are several buttons: 'Back', 'Download to zzzPAT', 'Save', 'Save and Lock Report', and 'Preview report'. The main content area is divided into several sections: 'Analysis File' with a link to 'analysis424.pdf', 'Warnings' with a dropdown menu showing 'Inconclusive REM.', 'Load Manual Events and Reanalyze' with a text input and a 'Browse...' button, 'Category (for statistics)' with a dropdown menu, 'Diagnosis Template' with a dropdown menu, 'Diagnosis' with a large text area, 'Recommendation Template' with a dropdown menu, and 'Recommendations' with a large text area.

Figure 30: Review a new 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. 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 30).
2. **Preview report** - after you fill in the Diagnosis and Recommendations sections you can click the “Preview report” button in order to see the first page of the final report with your interpretation included (see Figure 31, sections “Summary & Diagnosis” and “Recommendations”). You may use the Diagnosis and Recommendations templates if you wish to insert an already defined paragraph in the corresponding section.
3. **Download to zzzPAT** - if you wish to see more details on the study’s signals you can use the “Download to zzzPAT” function in order to download a copy of this study to your local computer. Once the study files are downloaded, you can use the “Import Packed study” zzzPAT’s function (see zzzPAT’s OM) in order to open the study, view the signals and edit the Respiratory events or sleep stages if needed.

4. **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 events file (see zzzPAT’s OM) and then point to this file when clicking on the “Load Manual Events and Reanalyze” button (see Figure 30). 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.
5. **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.
6. **Save** – saves your input without locking the report.



### Note

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.

**Sleep Study Report**

OfficeA1Header1

OfficeA1Header2

**Patient Information**

First Name: Jama	Last Name: Dean	ID: sample
Birth Date: 08/01/1990	Age: 21	Gender: Female
Insurer:	BMI: 19.0 (W=121 lb, H=67")	
Neck Cir.:	EPworth:	
Address:		

**Sleep Study Information**

Study Date: 02/26/2010	H/A Version: 2.2182/4.3.61.3
------------------------	------------------------------

**Referring Physician Information**

First Name:	Last Name: ProvA	E-mail:
Work Phone:	Mobile Phone:	Fax:

**Medical Information**

Medical History

Frequent arousals,

Medications

Thyroid hormone replacement,

Comments

**Summary & Diagnosis**

Suppine related apnea

**Recommendations**

refer to ENT.

Figure 31: First page of sleep report

### 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 32) 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.
2. **View report** - you can click on the “View report” button in order to see the three page final report (with your interpretation included).

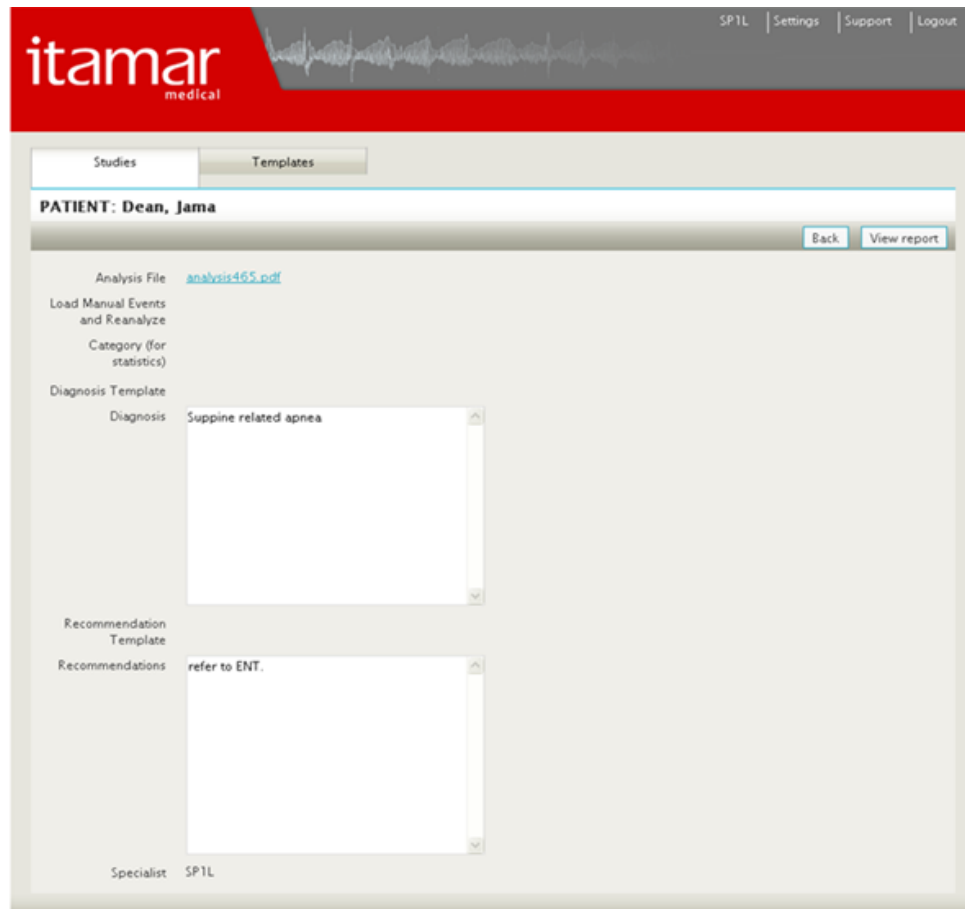


Figure 32: View a completed study

### 4.3. 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 or Recommendations and which can be used with a click of a button in order to facilitate the Reviewing process.



### Note

Click on the CSV icon (see Figure 33) if you want to obtain an Excel file containing the "Templates".

Selecting the Templates tab will open up the Template Search screen (see Figure 33).

Name	Type	Text
SP1 - D1	Diagnosis	test diagnostics
SP1 - D2	Diagnosis	test diagnostics number 2
SP1 - r1	Recommendation	first recommendation of SP1
SP1 - r1	Recommendation	first recommendation of SP1 version 2
SP1 - r2	Recommendation	2nd recommendation of SP1

Figure 33: Search a template screen

### 4.3.1. Managing Templates

Clicking on the “New” button will open up a new template for editing (see Figure 34).

Enter details about the Template

Save & New Delete List Save

Name \*

Type \*

Text \*

Figure 34: 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 33) will open up the Template screen for editing (see Figure 35).

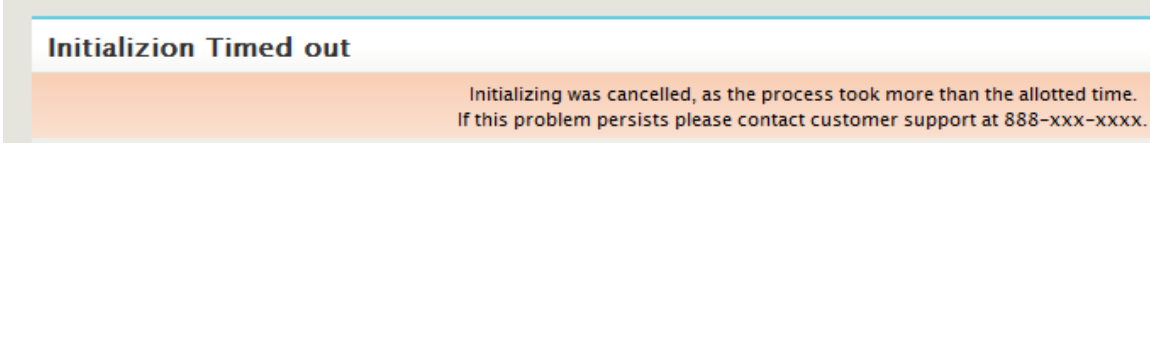
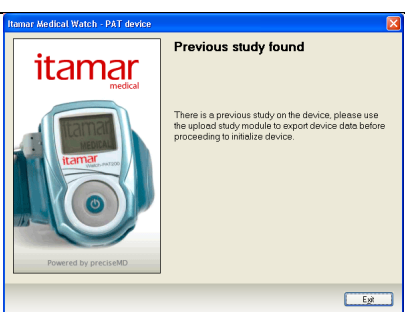
Here are the main actions that can be selected from this screen:

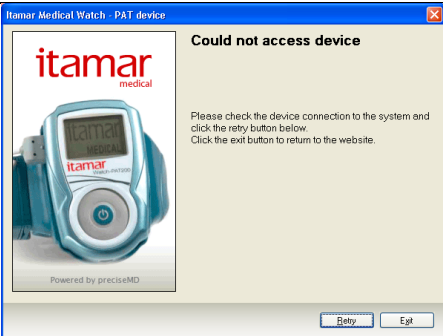
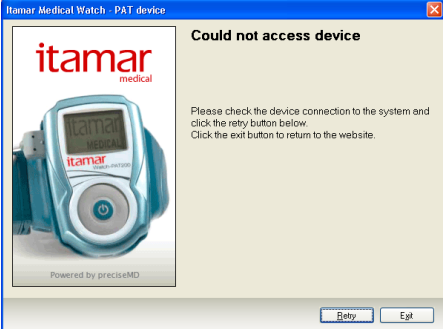
1. **Save & New** – Saves the template and creates a duplicate copy.
2. **Delete** – Deletes the template.
3. **List** – Returns to the list of templates.
4. **Save** - Saves the template.

The screenshot displays the 'Enter details about the Template' interface. At the top, there is a red header with the 'itamar medical' logo and a navigation bar with links for 'SP1L', 'Settings', 'Support', and 'Logout'. Below the header, there are two tabs: 'Studies' and 'Templates', with 'Templates' being the active tab. The main form area is titled 'Enter details about the Template'. On the right side of this form, there are four buttons: 'Save & New', 'Delete', 'List', and 'Save'. The form contains three labeled fields: 'Name' with a text input containing 'ENT', 'Type' with a dropdown menu showing 'Recommendation', and 'Text' with a large text area containing 'Refer to ENT for consultation.'. Each label has a red asterisk indicating a required field.

Figure 35: Existing Template screen

## 5. Troubleshooting

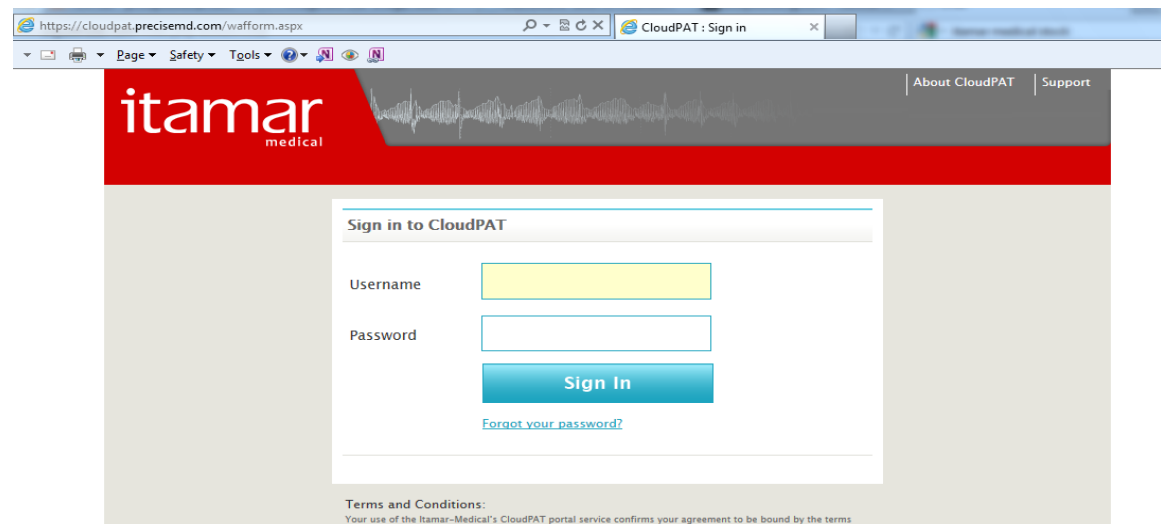
Trouble	Possible Cause	Solution	Error Message
<b>New Study screen</b>			
Creating a new study timed out	You took too long in replying to a message that there is another study resident on WatchPAT.	Re-run the initialization process a little quicker. If the problem persists it could be an internet connectivity problem so contact Support.	
Previous Study found	There is a sleep study still on WatchPAT that has not been uploaded from the device.	Press Exit and upload this old study.	

Could not access device.	The PC does not recognize WatchPAT.	Make sure WatchPAT is connected to the PC via the USB. Select Retry.	
Trouble	Possible Cause	Solution	Error Message
<b>Upload Study screen</b>			
Failed to Send.	The station may not have Internet access.	Save the data (using "Save" option) and send it later.	
Failed to Send.	The Itamar Upload service is temporarily unavailable.	Save the data (using "Save" option) and send it later.	
Could not access device.	The PC does not recognize WatchPAT.	Make sure WatchPAT is connected to the PC via the USB. Select Retry.	

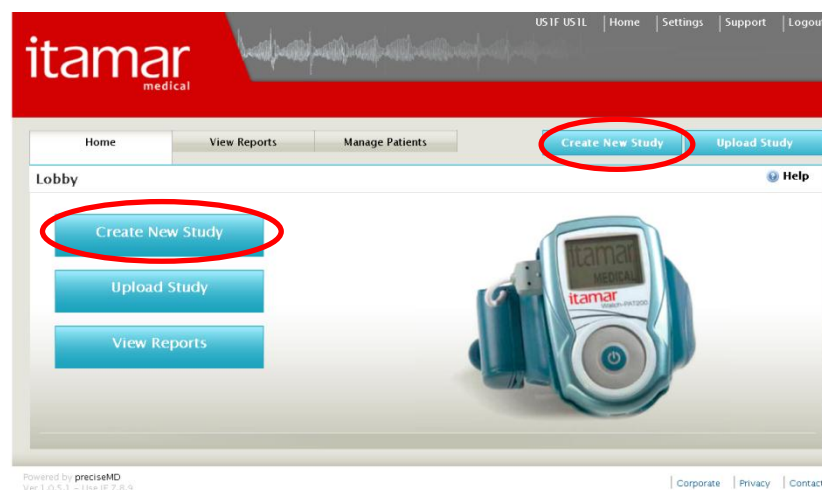
## 6. Appendix A: Initializing WatchPAT via CloudPAT Guide

This guide will give you step-by-step instructions on how to initialize a WatchPAT device using CloudPAT.

1. Go to <https://cloudpat.precisemd.com> and the following screen should appear:



2. Enter the Username and Password that was emailed to you and click "Sign In".
3. Clicking on the "Create New Study" from the main screen will start the process of device initialization using CloudPAT.



4. Thereafter, the following screen will open up. The only mandatory field is "Patient ID", but you may put as much patient information as you like, including date of birth, gender, etc. Make sure to select a specialist in the "Sent to Specialist" field, otherwise you will be prompted to select a specialist while uploading (in case you have several specialists to choose from).



Home View Reports Manage Patients Create New Study Upload Study

Enter Patient Details for Sleep Study

Back Save Save and Initialize Device

Office Itamar Medical sales team Current Doctor Rose, Mark

Patient ID\* Alpha-numeric 17 Prefix Mrs.

First Name Queen Middle Initial R

Last Name Elizabeth Gender Female

Date of Birth 04/21/1926


Insurance Coverage Aetna Other Insurance: Royal NHS Insurance

Send to Specialist Tirosh, Roy

More Details

Diseases

Medications

5. Clicking the button  next to either “More Details”, “Diseases”, or “Medications” allows even more patient details to be entered.

Send to Specialist Specialist, Demo

More Details

Additional Patient Details

Height (in) 70 EPworth Score 6

Weight (lb) 174 Neck Circ (in) 16

Address

City

State

Zip Code

Country

Comments Any comments about medications, etc can be entered here for the interpreting physician.

Sync Clock ☒ Make sure your clock is in the right timezone for where the test will be conducted, especially if drop shipping the device.

Bracelet Study ☒ Chain of Custody for occupational workers or clinical research

Diseases

Medications

6. After the “Patient ID” (mandatory) and any of the other patient details you want to enter are completed, you will now select “Save and Initialize Device” in the upper right portion of the CloudPAT screen

Mr. Phillip Dukes | Home | Settings | Support | Logout

itamar medical

Home | View Reports | Manage Patients | Create New Study | Upload Study

Enter Patient Details for Sleep Study

Back | Save | **Save and Initialize Device**

Office: Itamar Medical sales team

Current Doctor: Tirosh, Roy MD

Patient ID\*: HST12-12212

Prefix: [Dropdown]

First Name: Phil

Middle Initial: [Text Field]

Last Name: Dukes

Gender: Male [Dropdown]

Date of Birth: [Text Field]

7. The following screen will appear. Click on **“Proceed with initialization”**

Mr. Phillip Dukes | Home | Settings | Support | Logout

itamar medical

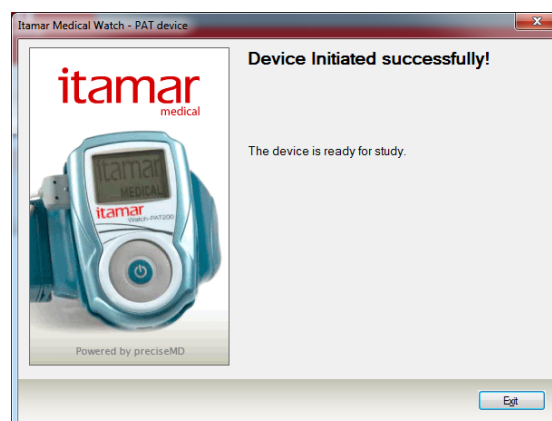
Home | View Reports | Manage Patients | Create New Study | Upload Study

Initialize Device

The Patient's information is now ready for initialization.  
Please check that the WatchPAT device is connected and click on proceed to continue with Initialization.

**Proceed with initialization**

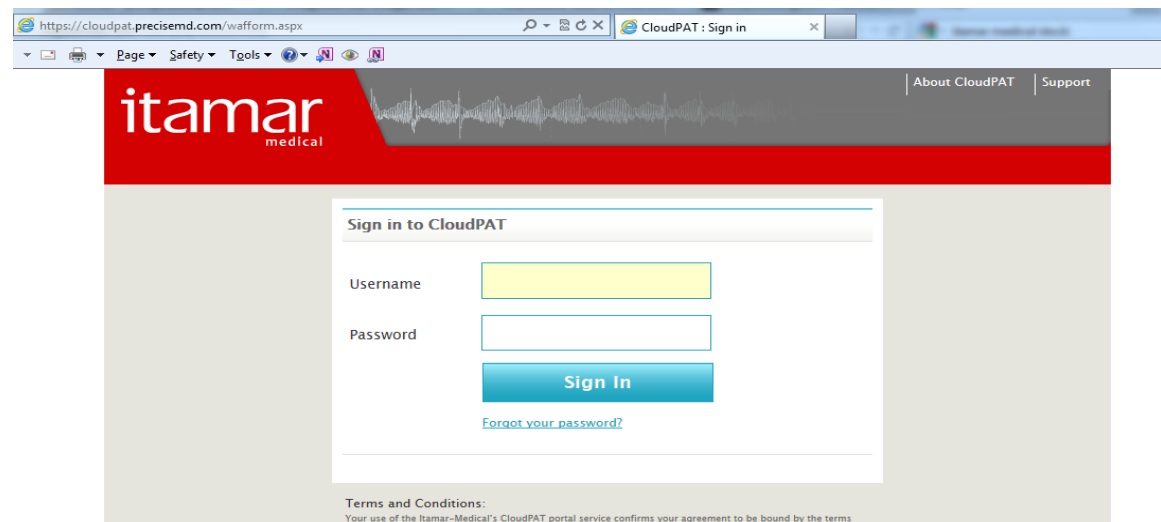
8. The following screen will then appear and initialization is complete.



## 7. Appendix B: Uploading study from WatchPAT to CloudPAT Guide

This guide will give you step-by-step instructions on how to upload a study directly from the WatchPAT device to CloudPAT.

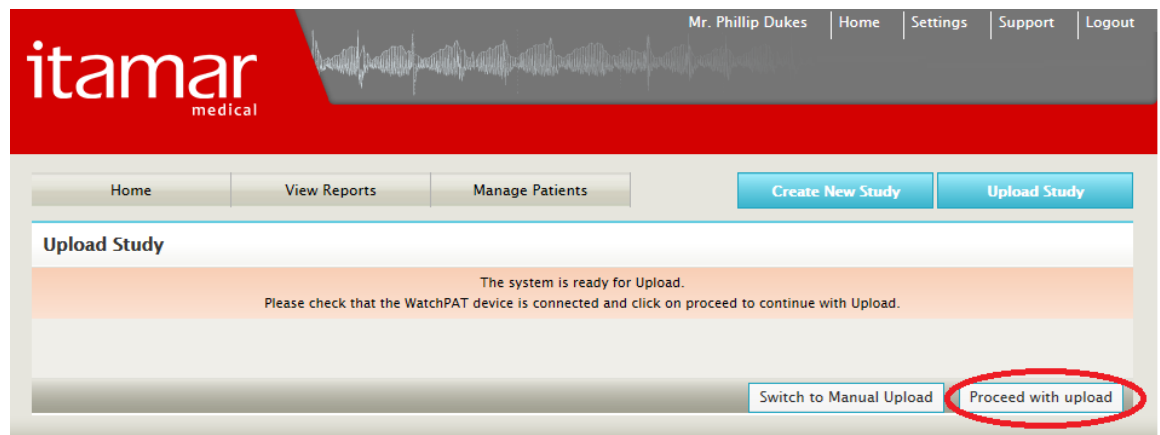
1. Go to <https://cloudpat.precisemd.com> and the following screen should appear:



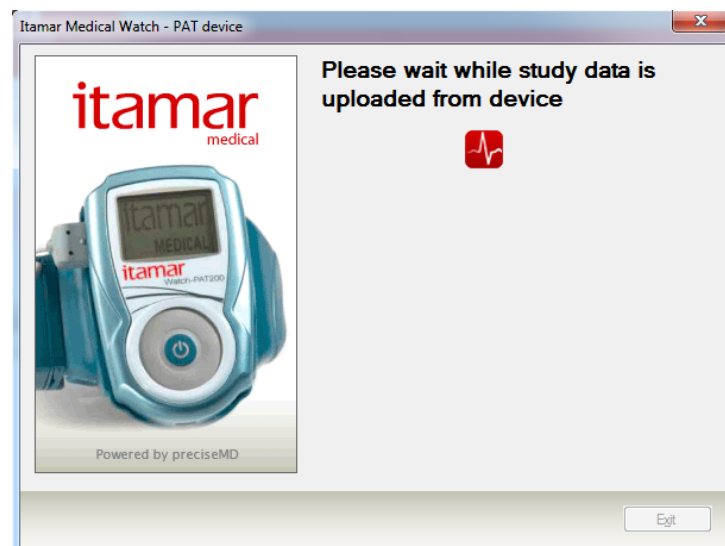
2. Enter the Username and Password that was emailed to you and click **“Sign In”**
3. Clicking on the **“Upload Study”** from the main screen will start the process of uploading a study from the WatchPAT device to CloudPAT.



4. Thereafter, the following screen will open up. We will select **“Proceed with upload”** when uploading directly from the device.



5. 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.



6. The study will automatically attach itself to the associated patient if the device was initialized via CloudPAT.
7. Now, the study must be assigned to a sleep specialist. Then, click **“Next”**

The screenshot shows the Itamar Medical web application interface. At the top, there is a red header with the 'itamar medical' logo and a navigation bar with links for 'Mr. Phillip Dukes', 'Home', 'Settings', 'Support', and 'Logout'. Below the header, there is a secondary navigation bar with buttons for 'Home', 'View Reports', 'Manage Patients', 'Create New Study', and 'Upload Study'. The main content area is titled 'Select Reviewer' and contains the instruction 'Select Reviewer from list then press Next'. A dropdown menu labeled 'Assigned To Specialist' is set to 'Specialist, Demo'. A red circle highlights the 'Next' button in the bottom right corner.

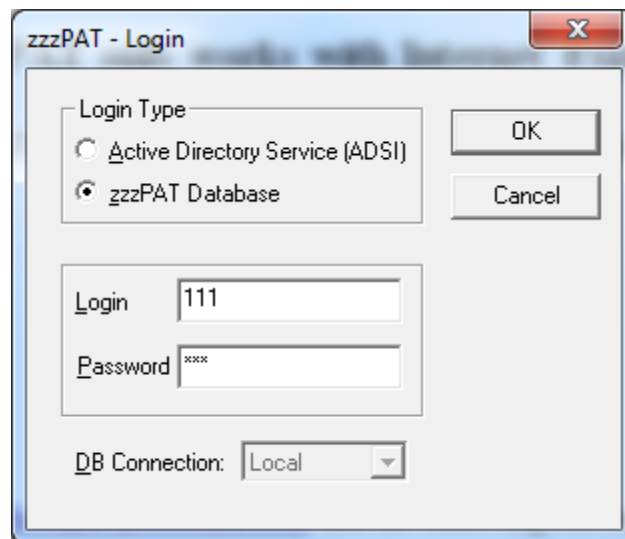
8. The following screen will appear and the process is complete

The screenshot shows the Itamar Medical web application interface after a successful upload. The main content area displays 'Upload Complete' in a large, bold font, which is highlighted with a red circle. Below this, a message states: 'Study uploaded successfully. The analyzed data file will be ready shortly under Reports. Data has been sent to be reviewed by Specialist, Demo'. The navigation bar and header are identical to the previous screenshot.

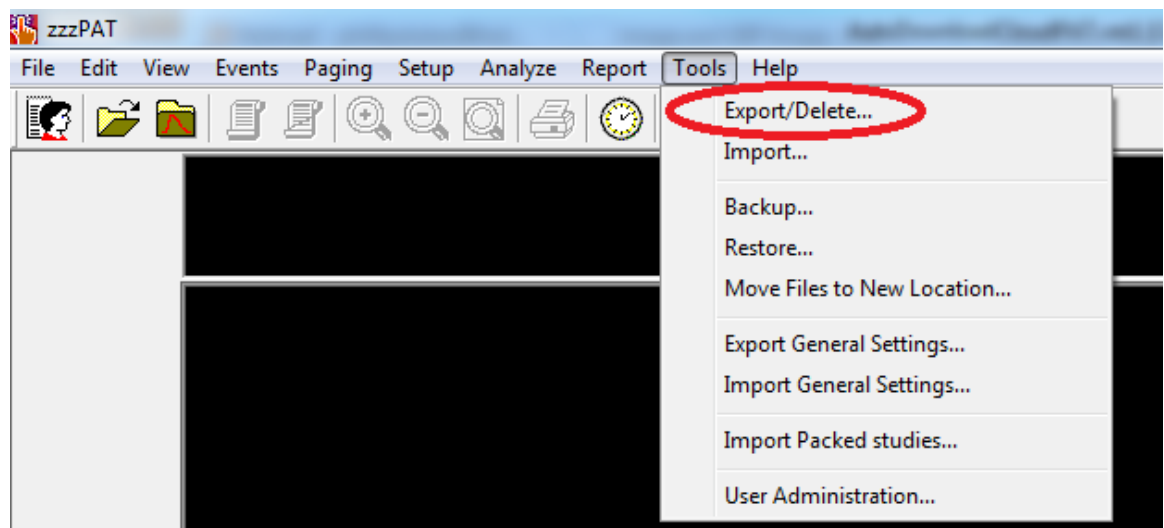
## 8. Appendix C: Uploading study from zzzPAT to CloudPAT Guide

This guide will give you step-by-step 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.

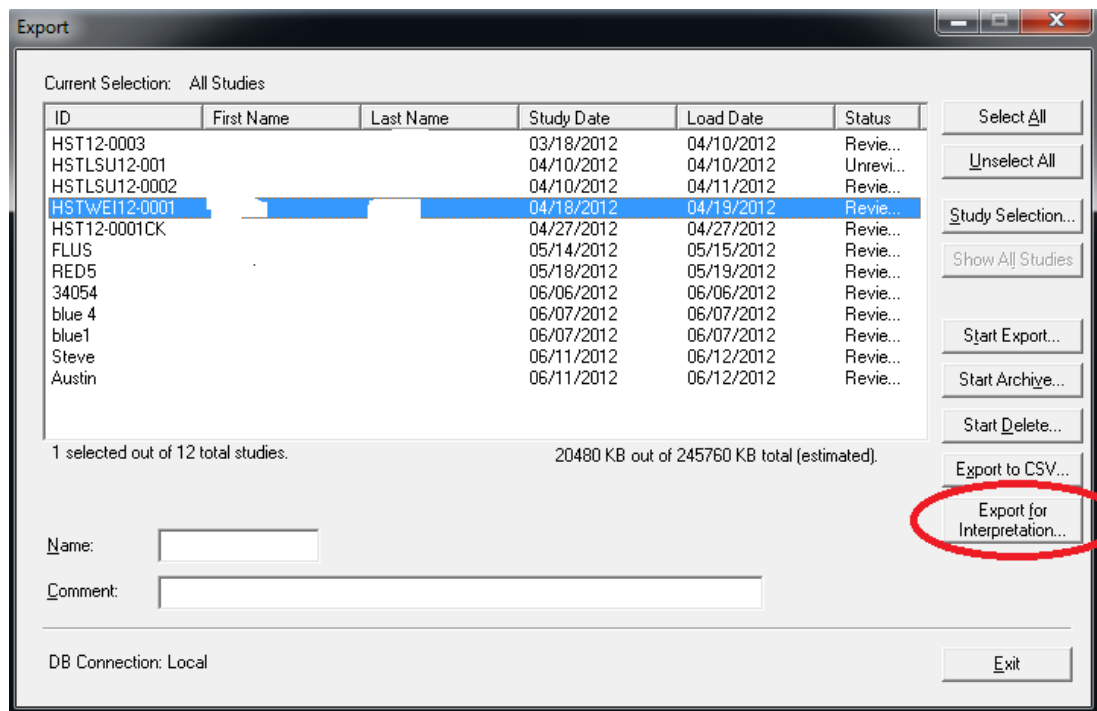
1. Open zzzPAT (default Login and Password: “111” for both entries)



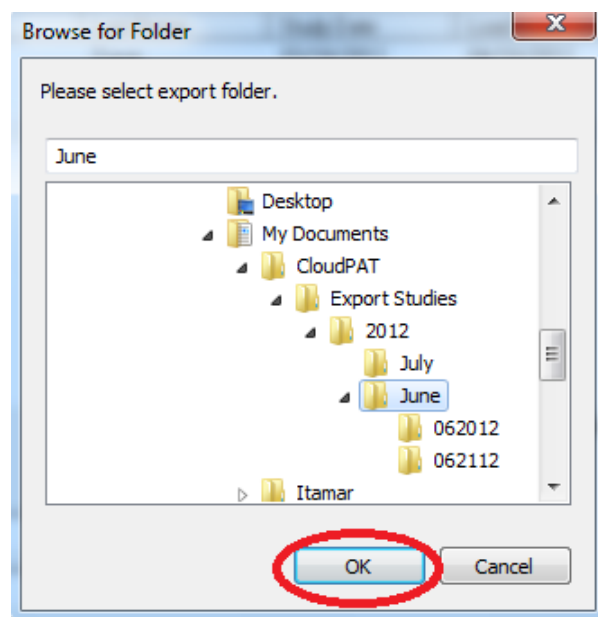
2. Select “Export/Delete” under “Tools”



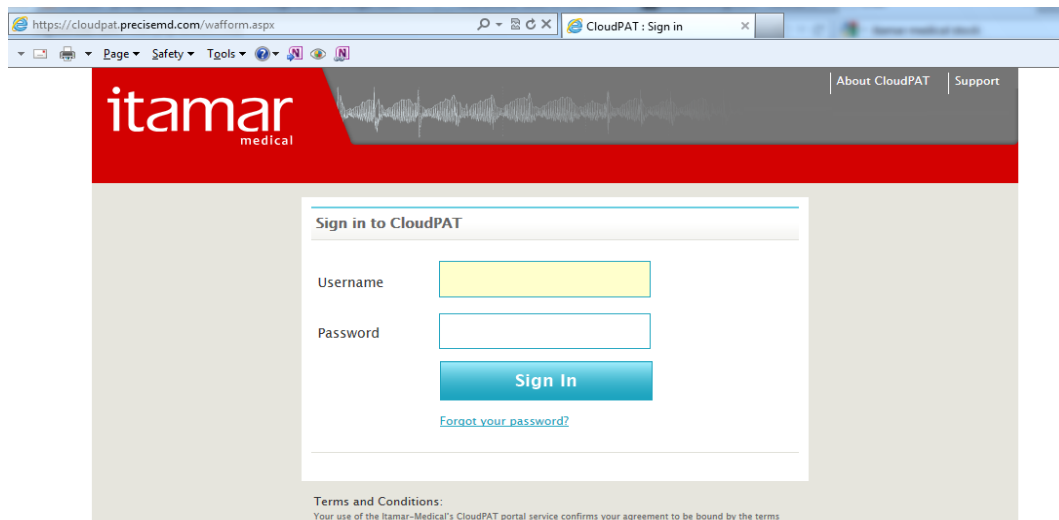
3. Highlight the study that you want to export to CloudPAT and select “Export for Interpretation”



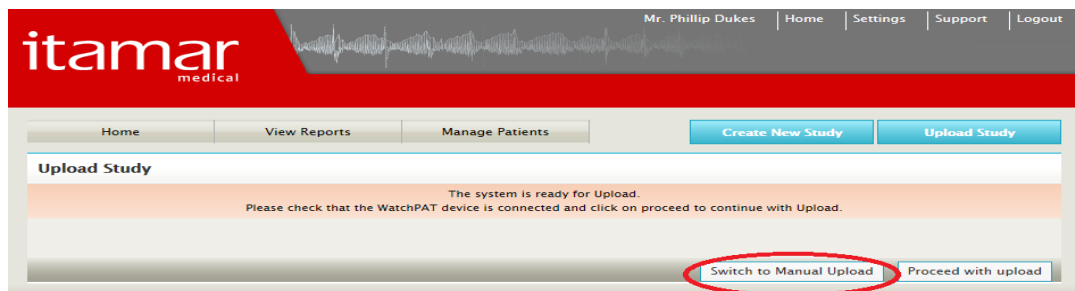
4. You will now be asked to save this file to your hard drive. Generally, I choose a folder called "CloudPAT" that I create prior to this step. After selecting the folder to save the exported file, click "OK".



5. Now go to <https://cloudpat.precisemd.com> and the following screen should appear:



6. Enter the Username and Password that was emailed to you and click "Sign In".
7. Uploading a .zzp exported for interpretation study using CloudPAT is performed by following these steps:
8. Select "Upload Study" from Home screen.
9. Thereafter, the following screen will open up. Select "Switch to Manual Upload".

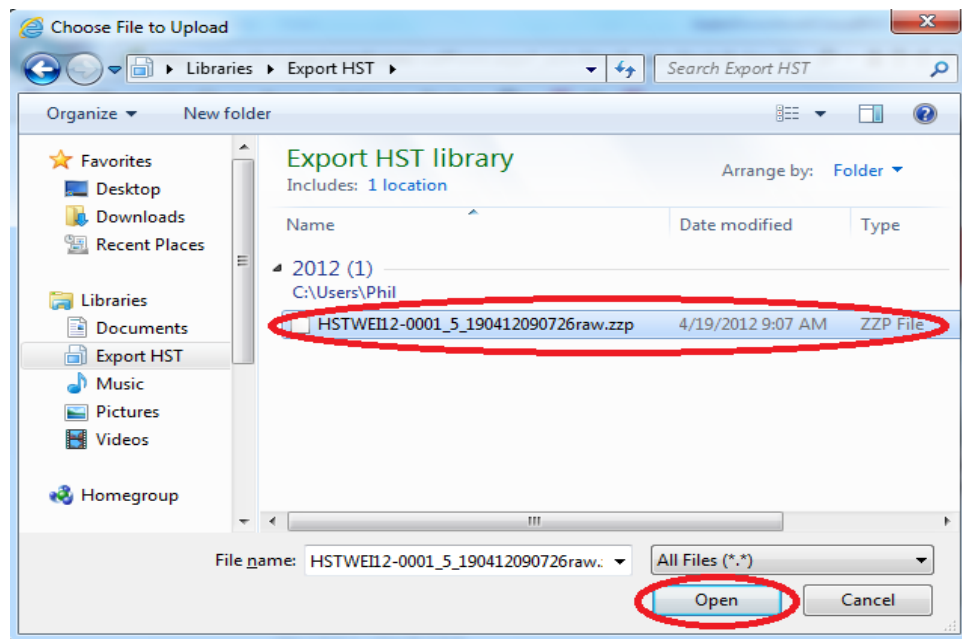


10. Now you need to find the file that was exported out of zzzPAT by selecting "Browse".



11. The file will end in .zzp. Select the file that you want to upload and select "Open".





12. Select “Next”.

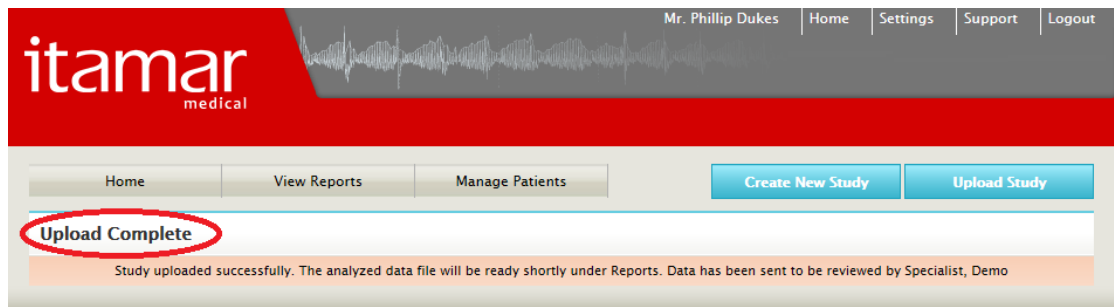


13. Depending on your connection speed to upload and the size of the study data file, the upload time will vary between 2 and 5 minutes. If an error is reported, you will need to try again.

14. Now, the study must be assigned to a sleep specialist. Then, click “Next”.



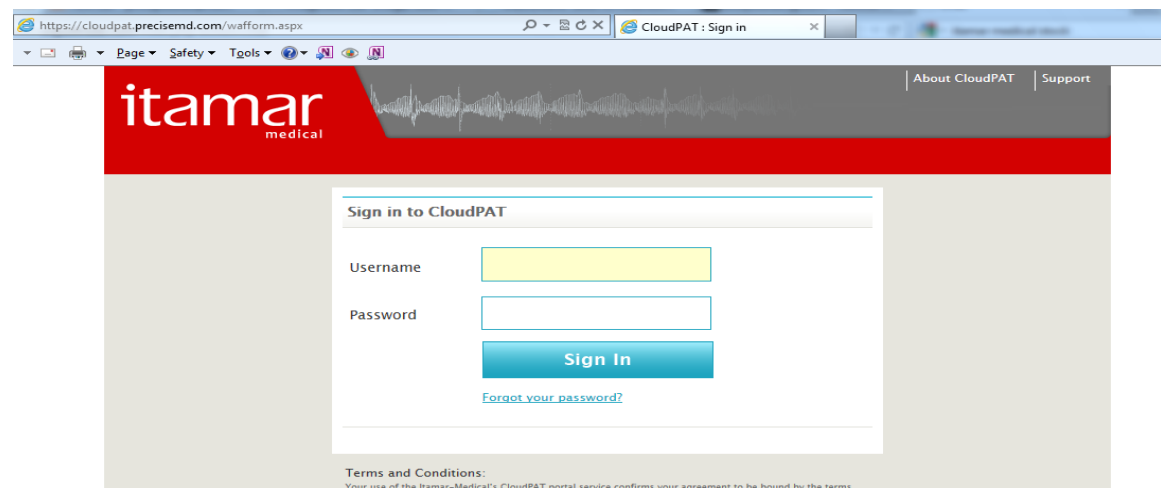
15. The following screen will appear and the process is complete.



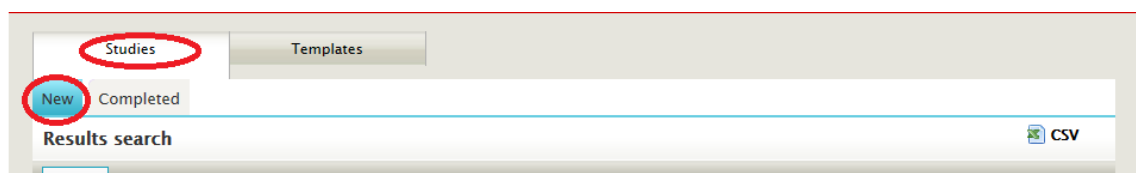
## 9. Appendix D: Interpretation and editing of events by the Specialist Guide

This guide will give you step-by-step instructions on how to view, download to zzzPAT, edit events, upload to CloudPAT, and generally interpret a study using CloudPAT.

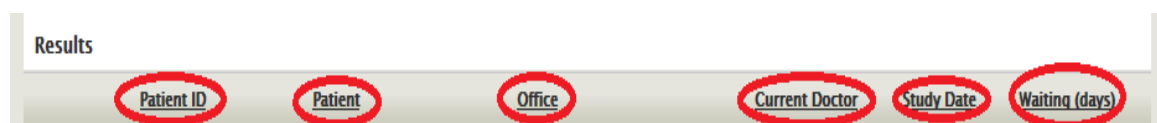
1. Go to <https://cloudpat.precisemd.com> and the following screen should appear:



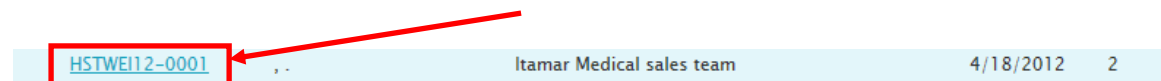
2. Enter the Username and Password that was emailed to you and click “Sign In”.
3. After logging in to CloudPAT, the following screen will appear. Note (circled in red) at the top left corner to options “Studies” and “Templates”. Choose “Studies”. Beneath “Studies”, there are two options “New” and “Completed”.



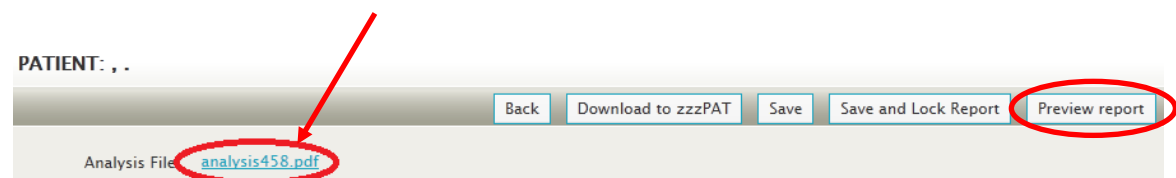
- a. "Completed" Studies are studies that have been interpreted
- b. "New" Studies are studies that have been uploaded to CloudPAT and are in the queue awaiting interpretation. These studies can be sorted by clicking “Patient\_ID”, “Patient”, “Office”, “Current Doctor”, “Study Date”, or “Waiting (days)”. See below:



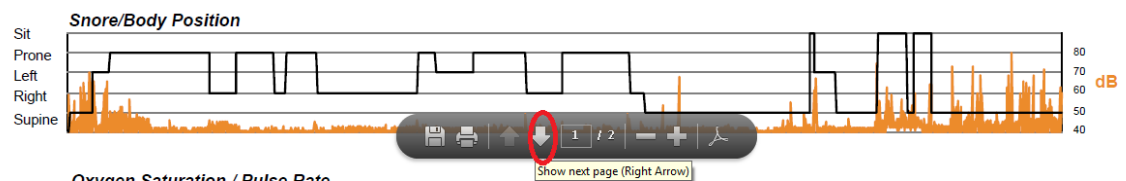
4. Once you have sorted, searched, and identified the study to interpret, the next step is to open the file by clicking on the “Patient ID” name.



5. The next steps for the interpreting specialist is to “Preview Report” (1st page of report that is the dictated impression and recommendations from the custom template and is blank until selections are made), “Download to zzzPAT” (to review the raw data), and “Save and Lock Report” (completed review and interpretation of raw data).
6. To view the auto analyzed 2 page report that the technician uploaded, double click the “Analysis File”.

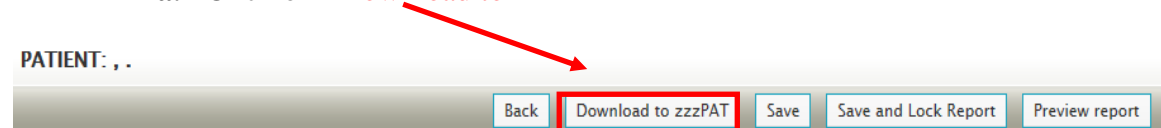


7. This will open a new window in Internet Explorer to a 2 page pdf document. At the bottom of the new page, you can scroll to view both pages of the sleep report:

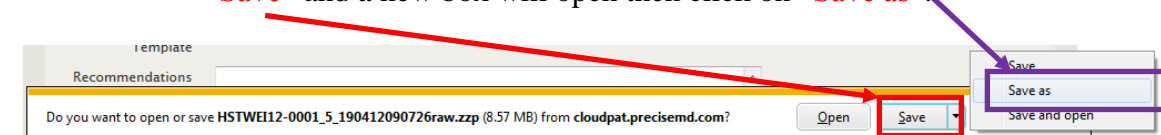


8. To download the raw data for review, follow these steps:

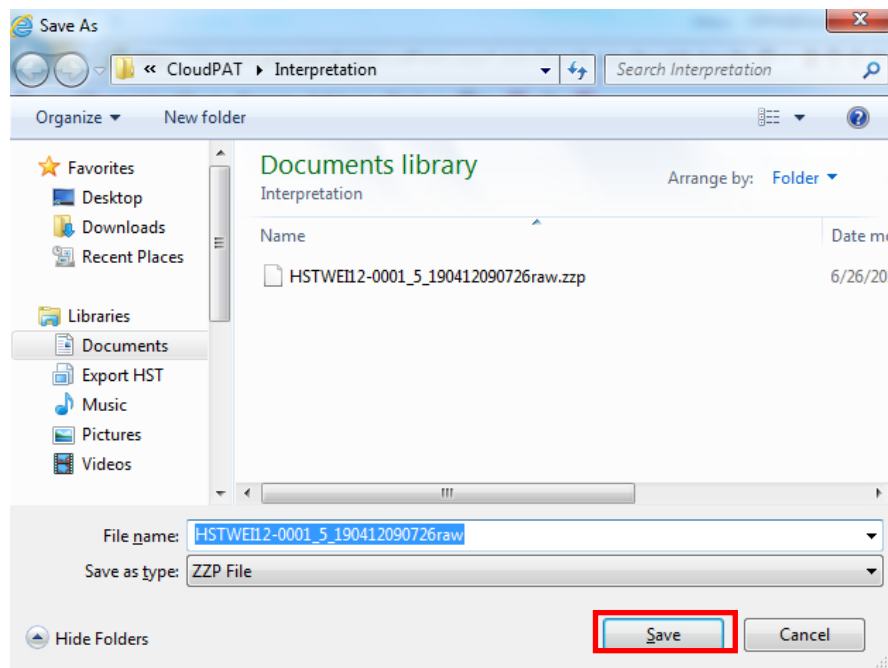
- a. Click on “Download to zzzPAT”



- b. 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”.

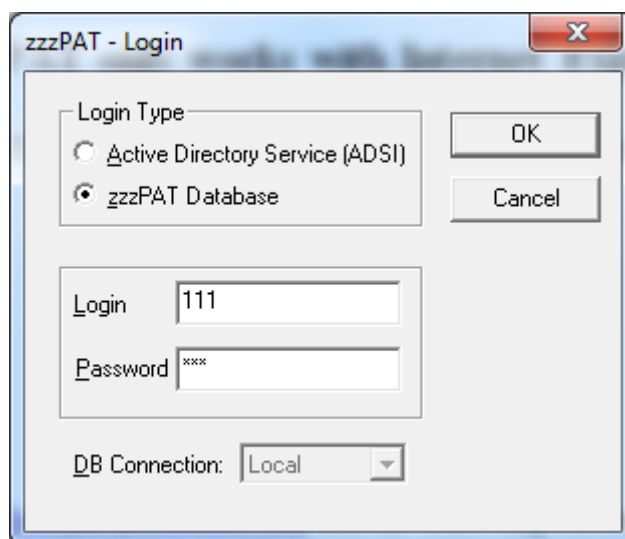


- c. From here you will need to save the file to your hard drive. I do this by creating a new folder in “Documents” called “CloudPAT” so that I can find the zzp file for import into zzzPAT in subsequent steps.

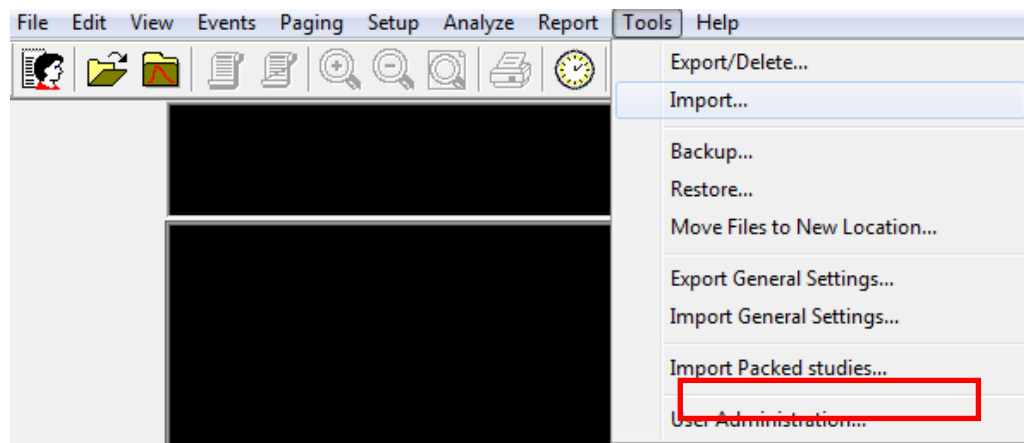


d. We are now ready to open zzzPAT to review the raw data.

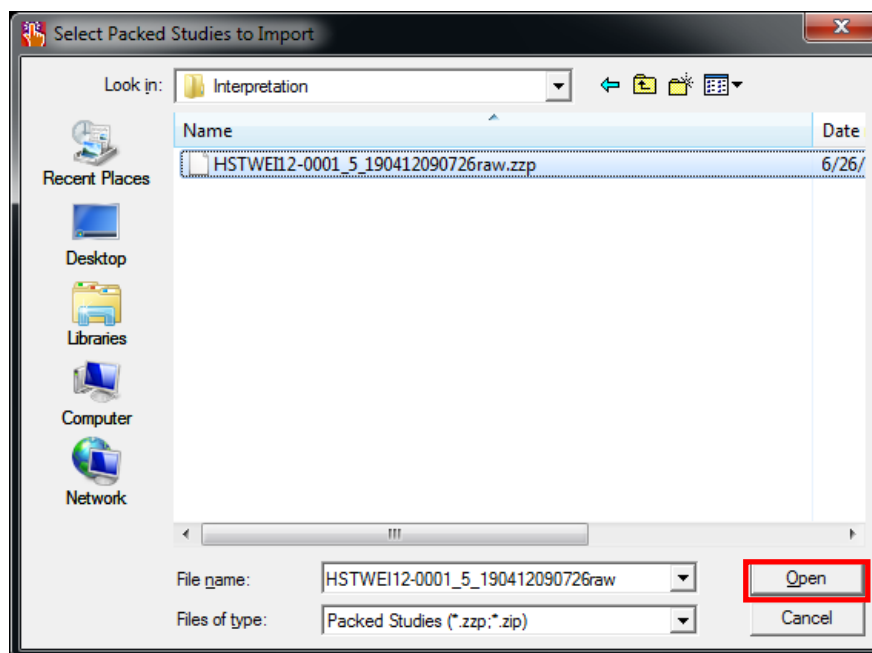
9. To review the raw data open zzzPAT software and put in the Login and Password “111” for both entries (default values).



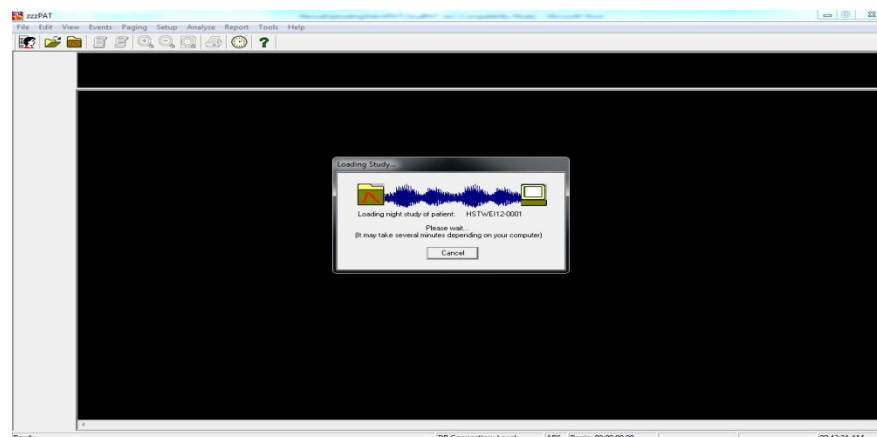
10. Select “Import Packed studies” under “Tools”



11. The following box will open and we need to highlight the zzp file to import and select “Open”.



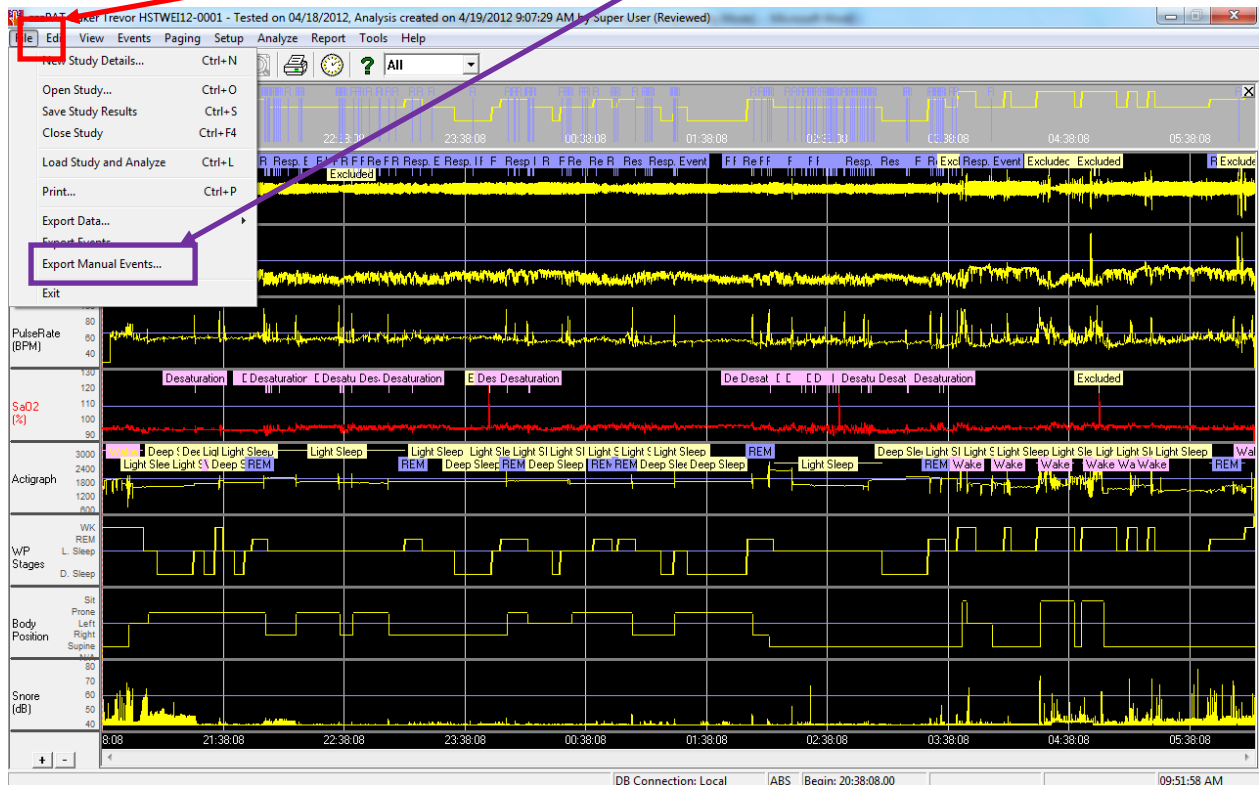
12. A new box will now open and the imported study will now be loaded and analyzed.



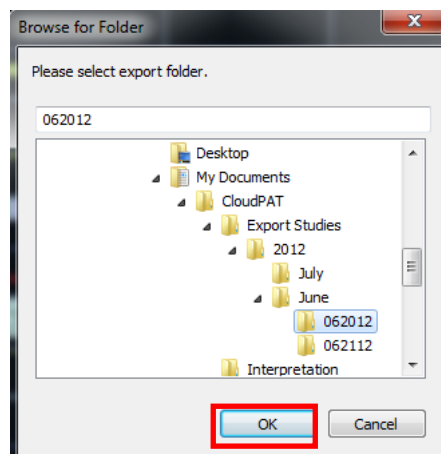
13. The study is now available to be reviewed and manually edited by the interpreting physician.

14. If changes are made, the study will need to be uploaded to CloudPAT by following the steps below:

- e. Add and/or Delete events per your training
- f. Go to **File** and select “Export Manual Events...”



c. A new box will open and we will now save the changes to our CloudPAT folder and select “OK”



d. The manually edited changes now need to be uploaded to CloudPAT. To do so follow these remaining steps:

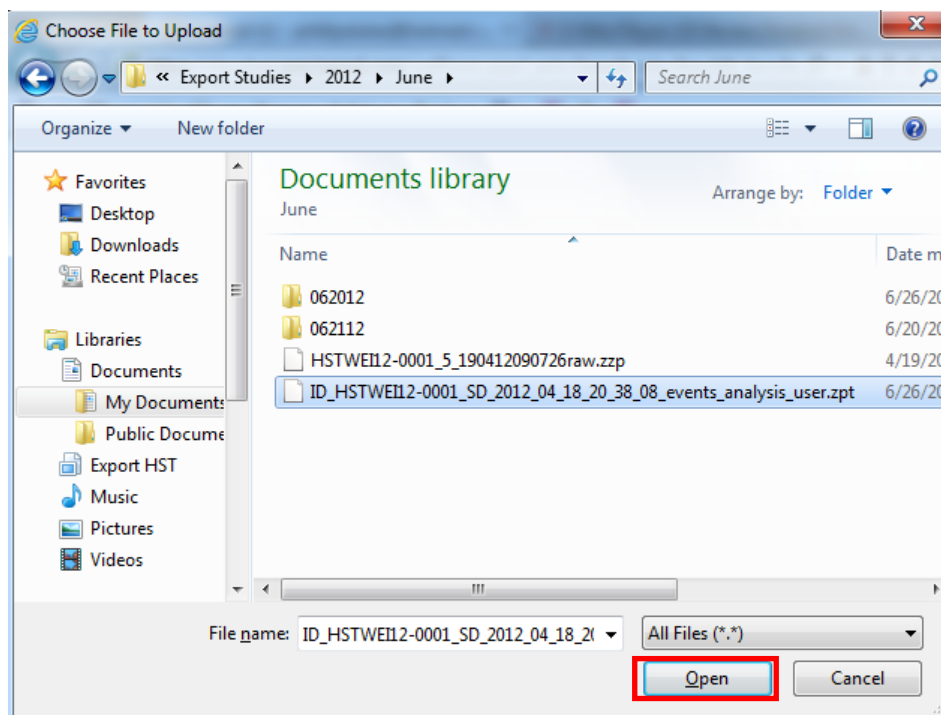
- i. Click on “Browse”

Load Manual Events  
and Reanalyze

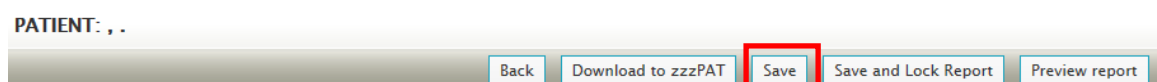
C:\itamar medical\zzzpat

Browse...

- ii. Find the saved file, highlight it, and click **“Open”**



- iii. Now click **“Save”**



- iv. The manually edited study is now saved to CloudPAT and is ready for interpretation using the customizable template system:

Record saved [6/26/2012 8:11:56 AM].



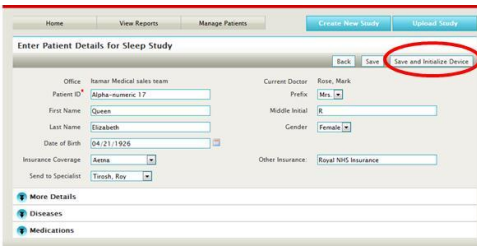
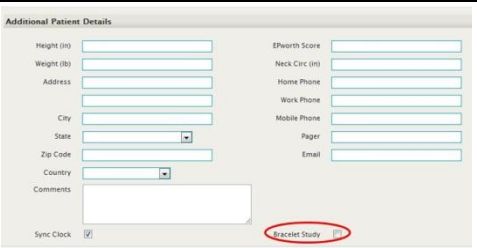

15. Preview the new report. Enter your Diagnosis and Recommendations and click on “Save and Lock Report” to complete the process and alert the provider that the study is complete.






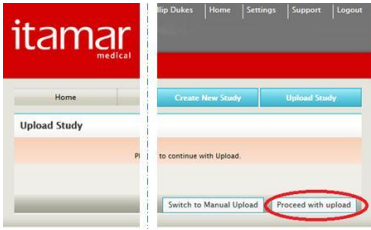
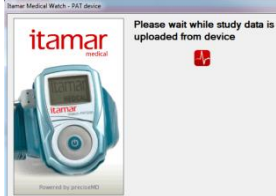

## **10. *Appendix E: CloudPAT Assistant “cheat sheets”***

**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...	<p>Do you have...?</p> <ol style="list-style-type: none"> <li>1. PC workstation w/internet access?</li> <li>2. Internet Explorer 7.0 or higher?</li> <li>3. Username &amp; Password?</li> <li>4. Minimum upload speed of 1 Mbps</li> </ol>	<p>Problems or Questions?</p> <p><b>Select Support</b> or Call: +1-888-748-2627</p>
Logging in	1.	Enter CloudPAT via the Web	<p>Log in to: <a href="http://www.cloudpat.precisemd.com">www.cloudpat.precisemd.com</a></p> <ul style="list-style-type: none"> <li>• Enter your Username &amp; Password</li> <li>• <b>Select Sign In</b></li> </ul>	
Connecting	2.	Create (initialize) new Sleep Study using CloudPAT	<ul style="list-style-type: none"> <li>• <b>Select "Create New Study"</b></li> <li>• Slide WatchPAT out of its "cradle" to reveal the USB connection.</li> <li>• Connect WatchPAT to any USB port.</li> </ul>	
Patient Detail Entry	3.	Patient Detail Entry	<ul style="list-style-type: none"> <li>• Only one (1) patient field is mandatory: <b>"Patient ID"</b></li> <li>• Select your Board-certified interpreter under <b>"Send to Specialist."</b></li> <li>• If no <b>Specialist</b> was selected for study interpretation, you will be prompted to select one when eventually uploading a study.</li> <li>• <b>Select "Save &amp; Initialize Device"</b> OR</li> </ul>	
	4.	OPTIONAL Chain of Custody Bracelet	<ul style="list-style-type: none"> <li>• For more patient detail entry, <b>select "More Details"</b> opening another screen</li> <li>• <b>Select</b> the box <b>"Bracelet Study"</b> for occupational testing using a Chain of Custody bracelet.</li> <li>• <b>Select "Save &amp; Initialize Device"</b></li> </ul>	
Success?	5.	Initialization complete	<ul style="list-style-type: none"> <li>• <b>Select: "Proceed with initialization"</b></li> <li>• <b>1st time usage:</b> a small PC-resident program will be downloaded. <b>Select: "Run"</b></li> </ul>	

## Upload Sleep Study from WatchPAT to CloudPAT

		Step	Action(s)	Comment
Minimum	0.	Before you start...	Do you have...? 1. PC workstation w/internet access? 2. Internet Explorer 7.0 or higher? 3. Username & Password? 4. Minimum upload speed of 1 Mbps	Problems or Questions? <b>Select Support</b> or Call: +1-888-748-2627
Important Notes	1.	Enter CloudPAT via the Web	Log in to: <a href="http://www.cloudpat.precisemd.com">www.cloudpat.precisemd.com</a> <ul style="list-style-type: none"> <li>Enter your Username &amp; Password</li> <li>Select Sign In</li> </ul>	
Study Preparation	2.	Upload a Sleep Study-WatchPAT to CloudPAT	<ul style="list-style-type: none"> <li><b>Select "Upload Study"</b></li> <li>Slide WatchPAT out of its "cradle" to reveal the USB connection.</li> <li>Connect WatchPAT to any USB port.</li> </ul>	 
Internet Connection required	3.	Connect WatchPAT to USB port	<b>Select: "Proceed with upload"</b> <ul style="list-style-type: none"> <li><b>1<sup>st</sup> time usage:</b> a small PC-resident program will be downloaded.</li> <li><b>Select: Run</b></li> <li>If <b>no Specialist</b> was pre-selected for Study interpretation, you will be prompted to select one <u>after</u> the study has uploaded.</li> </ul>	
	4.	Upload in progress	Depending on your connection speed, upload time will vary between two (2) and five (5) minutes. If an error is reported, you will need to try again.	
Success?	5.	Upload result	<b>"Upload Complete":</b> Study uploaded successfully. Data has now been sent for analysis to your Specialist (and after you have now been prompted to select a Specialist). <b>"Upload Failed":</b> try again or call Support	

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

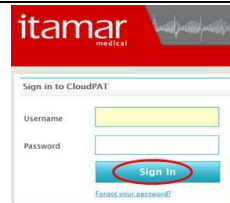
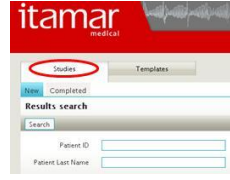


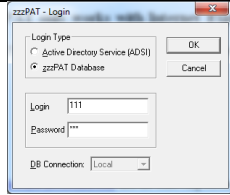
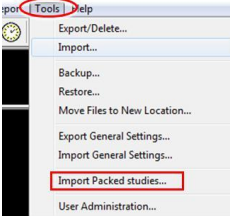
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CloudPAT

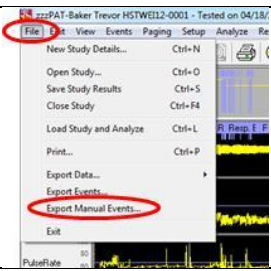
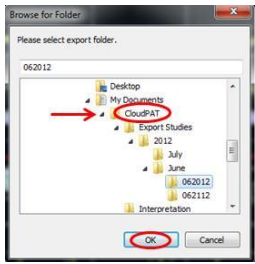
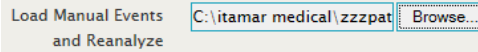


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Operation Manual

**Specialist: Board-certified physician review of raw sleep study data**  
*Download study for scoring & interpretation*

		Step	Action(s)	Comment
Preparation	1.	Before you start...	Do you have...? 1. PC workstation w/internet access 2. Internet Explorer 7.0 or higher? 3. Username & Password? 4. zzzPAT familiarity & installed	Problems or Questions? <b>Select Support</b> or Call: +1-888-748-2627
Login	2.	Enter CloudPAT via the Web	Log in to: <a href="http://www.cloudpat.precisemd.com">www.cloudpat.precisemd.com</a> <ul style="list-style-type: none"> <li>Enter your Username &amp; Password</li> <li><b>Select Sign In</b></li> </ul>	
Find study	3.	Select patient study	You may <ul style="list-style-type: none"> <li>Analyze a study ("Studies") or</li> <li>Create custom forms ("Templates").</li> </ul> <b>Select</b> the patient you want to analyze. Various Sort options are available at the bottom	
View	4.	View auto-analyzed suggestions	<ul style="list-style-type: none"> <li>To view the auto analyzed, 2-page report that the Provider uploaded, <b>select</b> "Analysis File."</li> <li>To view patient information, <b>select</b> "Preview Report"</li> </ul>	
Analyze	5.	Analyze & save Sleep Study raw data	To download the raw data for review: <ul style="list-style-type: none"> <li><b>Select</b> "Download to zzzPAT"</li> <li>Browse for a Folder you created prior to this step (suggestion: name it "CloudPAT")</li> <li>If/when scoring results are satisfactory, diagnosis, and recommendations have been entered, <b>select</b> "Save and Lock Report."</li> <li>You are done.</li> </ul>	
Work zzzPAT	6.	Start zzzPAT	Open zzzPAT (default Login and Password: "111" for both entries)	
Import Study	7.	Manual Study Upload	<ul style="list-style-type: none"> <li><b>Select</b> "Import Packed studies" under "Tools"</li> <li>Get to "Select Packed Studies to Import"</li> <li>Go to your previous CloudPAT Folder</li> <li>Highlight the .zzp file to Import</li> <li><b>Select</b> "Open"</li> <li>Edit/Score as usual with zzzPAT</li> </ul>	

**Specialist: Board-certified physician review of raw sleep study data**  
*Score, Interpret, Upload Changes, Save & Lock Report*

		Step	Action(s)	Comment
Score raw data	1.	Manually edit and score the sleep study	<ul style="list-style-type: none"> <li>• Add and/or Delete Events per your training</li> <li>• The changes now need to be saved on your local disk.</li> </ul>	
Save locally	2.	Save Event changes on local disk	<ul style="list-style-type: none"> <li>• Select "File"</li> <li>• Select "Export Manual Events..."</li> <li>• A new box will open;</li> <li>• Save the changes to your <u>local</u> CloudPAT Folder</li> <li>• Select "OK"</li> </ul>	
Upload	3.	Upload Event changes to CloudPAT	<ul style="list-style-type: none"> <li>• The manually edited changes now need to be uploaded back to CloudPAT.</li> <li>• Select "Browse"</li> <li>• Find the saved file, highlight it, select "Open"</li> </ul>	
Save Cloud	4.	Save Event changes on CloudPAT	<ul style="list-style-type: none"> <li>• Select "Save" from the CloudPAT toolbar.</li> <li>• Your manually edited study is now saved on CloudPAT, ready for diagnosis using your customizable template system</li> </ul>	
Lock & Notify	5.	Lock report; notify Provider	<ul style="list-style-type: none"> <li>• Preview the new report.</li> <li>• Enter your Diagnosis and Recommendations</li> <li>• Select "Save and Lock Report" to complete the process</li> <li>• Provider will be alerted automatically that the study is complete.</li> </ul>	

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## **12. Appendix G: Regulatory Representative**

Itamar Medical's authorized regulatory representative is:

	MEDES Ltd.
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