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Rx only Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

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EN ISO 13485:2016
See appendix B for contact information of the regulatory authorized representative
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1. **Introduction to CloudPAT**

1.1. **Intended Use of the CloudPAT (CP)**

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

1.2. **zzzPAT & WatchPAT Interface S/W – Definition**

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

1.3. **CloudPAT S/W – Definition**

1. The CloudPAT (CP) is a HIPAA-compliant web-based cloud application providing management system for sleep disordered breathing patients from diagnostic to treatment compliance.

2. The CloudPAT utilizes sleep study data done with the cleared WatchPAT (WP) device for diagnostic. CloudPAT uses WatchPAT Interface package for using the WatchPAT device.

3. The CloudPAT is intended to display and store the medical device data without controlling or altering its functions or parameters of the device; The CloudPAT do not modify, interpret, or add value to the data or the display of the data.

4. The CloudPAT allows the management of the study flow by different practitioners, including preparing and uploading the study by sleep technicians/physicians from one side to reviewing and interpreting of the study by sleep specialist on the other side.

1.4. **Overview**

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. 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.

- **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.

- **Patient** – the person who undergoes the sleep study.

1.6. 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.

<table>
<thead>
<tr>
<th>Note</th>
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<tbody>
<tr>
<td>Figures included in this Operation Manual are for reference only and actual design and appearance might be different in the final product.</td>
</tr>
</tbody>
</table>

2. Setting CloudPAT Access

2.1. Obtaining an account

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

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

<table>
<thead>
<tr>
<th>Server location</th>
<th>Direct link</th>
</tr>
</thead>
<tbody>
<tr>
<td>United state</td>
<td><a href="https://cloudpat.itamar-medical.com/">https://cloudpat.itamar-medical.com/</a></td>
</tr>
<tr>
<td>European union</td>
<td><a href="https://cloudpat-eu.itamar-medical.com/">https://cloudpat-eu.itamar-medical.com/</a></td>
</tr>
<tr>
<td>United Kingdom</td>
<td><a href="https://cloudpat-uk.itamar-medical.com/">https://cloudpat-uk.itamar-medical.com/</a></td>
</tr>
</tbody>
</table>

Access to CloudPAT starts with the Sign In screen also including a link to Itamar’s Terms and Conditions screen where Username and Password are entered.

![Sign In screen](Image)

Figure 1: Sign In screen

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.

An office you belong to may restrict CloudPAT access to specific IP address range or to a particular country group within US, EU & UK.

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

To setup login restrictions, please contact CloudPAT Support.
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.

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 !, $, #, %).

The new password shall be different to any of the user’s past passwords.

![Change Password screen](image)

Figure 2: Change Password screen

**Note**

All asterisk (*) tagged fields are mandatory and should be filled.
2.3.1. Forgot Password / User Name

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

Figure 3: Forget Password screen

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

Figure 4: Forget User Name screen
2.3.2. User Settings & Support

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

![Contact Us Form](Figure 5: Contact Us screen – by form)
For administration support and help with any problems you experience with CloudPAT, please contact us by clicking the “Contact Us” link from any window.

The Contact Us using a form creates an e-mail sent to Itamar-Medical CloudPAT Support.

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

![Contact Us](image)

**Figure 2: Contact Us screen – by phone**
3. Using CloudPAT as a User

3.1. Main Access Screen

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

- **Dashboard** - monitors patient care progress allowing the physicians and their staff a better control over the process.

- **New Study** – prepares a new patient & initializes WatchPAT™ device for a new sleep study.

- **Upload Study** – uploads sleep study files from WatchPAT™ device to the CloudPAT web server and subsequent redirection (e.g., interpretation by an Interpreting Physician/) according to pre-determined instructions.

- **Patients** – enables the user to see which sleep studies have been performed on patients, alter the patient’s information or generate a follow-up sleep study for an existing patient.

- **Devices** – shows a table of the associated devices also allowing drilling down to particular device.

- **Managing Referring Physicians** – allows the user to manage the referring physicians associated with the office directly.

- **Configuring Managed Lists** - allows the user to manage the following lists: Medications, Diseases, Statuses, Insurers, enables the user to search for existing entries from global and office level lists and add new ones.

3.2. Dashboard

The Dashboard includes the following items:

3.2.1. Enhanced Patients Care Pathway

The Enhanced Patients Care Pathway 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.

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 that together sum to the number of patients in the first section of the previous stage.
Clicking on any of the sections of the bars will display a list of patients included in the chosen group, based on the selected criteria and clicking on a patient within the list would display the Patient Details screen.

Tooltip is displayed next to the segment when mouse hovers over the icon. The results can be filtered by Office, Referring Physician and Period. The following stages are displayed in the funnel:

1) **Patients checked in**: Number of patients in selected group (percentage is always 100%).

2) **WP assigned**:
   a. **WP assigned (main)**: Patients assigned with initialized WatchPAT device, including 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) **Sleep Apnea**:
   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 ready**: Patients that their study was successfully uploaded to CloudPAT but their report is yet not ready.

---

**Figure 7 - Enhanced Patients Care Pathway**
3.2.2. Sleep Apnea Severity Scale

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

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

When clicking on a section it shall open the respective query in the patients table and the Sleep Apnea filter shall include the four levels.

Figure 43 - Sleep Apnea Severity Scale
3.3 Create new study and manage patients

In order to prepare WatchPAT™ device for a new study select “New Study” from the Home screen.

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

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

You can enter filters to limit the search results.

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

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

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

Figure 8: Patients Table screen
Clicking on a row shall open the patient’s details screen.

Figure 9: Patient Details screen

3.4 Preparing for a New Study

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

- The mandatory fields are Patient ID and a selection of an office if the user is associated with more than one office.
- The Patient ID cannot be changed once a device was initiated.
- Erroneous fields and empty mandatory fields will be highlighted in red. The user may attach files which will be associated to the next WP study once successfully uploaded to CloudPAT.
- You can save the patient record at any stage and return to it later from the “Patients” screen.
- Filling in the patient name is recommended for easier patient management.
- Pacemaker – select this option if the patient has an implantable pacemaker. The CloudPAT will automatically detect segments where the PAT pulses seem to be paced and exclude these segments from the analysis.

Note

Some types of pacemakers are excluding the use of the WatchPAT device. See the device’s Operating Manual for more details.

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

Note

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

![Create New Study screen](image)

**Figure 10: Create New Study screen**

### 3.5 Importing Patients

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

The Patient ID shall be unique per Office and the following fields are supported:

- Patient ID (Mandatory)
- Office (Mandatory)
- Last Name
- First Name
- Referring Physician
- Gender
- Insurance Provider
- Other
- Status
- Custom Fields
- City
- ZIP
- Country
- Home Phone
- Mobile Phone
- Email
- Number of Nights
- Bracelet Study
- Address
- State
- Work Phone
- Pacemaker
• Prefix
• DOB

3.6 First Time Installation

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

CloudPATio (CloudPAT Input/Output) is a Windows application developed in Java and installed on the desktop computer for managing patient sleep data of Itamar Medical WatchPAT (WP) devices. This is including the initialization and upload of studies, and launch of the Study Viewer application.

Please note that the installation package size may reach a few hundreds of MBs because it includes some pre-requisites such as Java JDK and AWS SDK (without installing them).

CloudPATio can be initially downloaded and installed as part of a required operation or deliberately though the Contact Us screen.
You should download the PC-App and run its installation - follow the installation instructions.

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

Figure 11: Download CloudPATio screen.
Double click the downloaded installation file.

![CloudPATio (9).exe](image)

Figure 12: Start the CloudPATio installation.

Follow the installation instructions:

![CloudPATio Setup](image)

Figure 13: Running the installation wizard
Figure 14: License Agreement screen

Figure 15: Installation Completion screen
3.7 Initialize WP200U/WP300 Device

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

- **Bracelet Study** (available only if office setting permits) - from this screen you may require a *Tamper proof Bracelet* to be used as Positive Chain of Custody in Occupational Testing (e.g., truck drivers. See WatchPAT™ Operation Manual for further details).

- If the office setting permits 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)

- **Request Script option** would instruct the Interpreting Physician that a script is requested if option is selected.

- You may select an associated interpreting physician for the study and you will be able to change the selection later on.

Click on the Initialize button once all the inputs were set.

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

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

<table>
<thead>
<tr>
<th>Note</th>
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<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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

As long as there is no Interpretation choice (no physician is selected) the report is not sent for interpretation and final report cannot be generated.

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

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

To prevent 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.

---

Figure 16: Initialize WatchPAT 200U/300 Device screen
3.7.1 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” and that you should upload the study before proceeding. This behavior prevents you from accidental overwriting a study that was not uploaded.

### 3.8 Initialize WatchPAT™ ONE Device

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

- Enter the WatchPAT™ ONE’s Device serial number.
- Enter the PIN and PIN Type (hint) provided to the patient. Pin Type can be pre-set as an office setting.
- Enter the max number of PIN Retries (default:3, can be pre-set as an office setting).
- Accept default or change the Email for Notification, indicating the email for notification on study completion and upload to CloudPAT.
- Optional: Select the desired Interpreting Physician that the study will be sent to. If Interpreting Physician is not assigned, they can be selected after study is successfully uploaded to CloudPAT.

Click on the “Initialize” button to complete the initialization process.
After the initialization is completed, a new entry is added to the Initializations section under the Studies & Initializations tab.

If patient exceeded max PIN retries, you may reset the counter entering the registered entry in Intialization section and click on “Reset Available PIN Retries” button.

If there is been a mistake with the registration, you may click on the Unregister button to cancel it.
3.9 UPLOADING A STUDY

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

<table>
<thead>
<tr>
<th>Note</th>
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<tbody>
<tr>
<td>WatchPAT ONE studies are automatically uploaded to CloudPAT once sleep study is completed.</td>
</tr>
</tbody>
</table>

3.10 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 click on the “Upload Study” button from any screen.

Proceed by selecting the “Proceed with upload” button.

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

![Figure 19: Allowing Windows Command Processor](image)

During the upload process you will see a screen informing about the various steps of the upload.
Figure 20: Patient sleep study upload in progress

**Note**

When a multi-night study is loaded all the night recordings are loaded automatically.
A notification message will be presented to the user as soon as the process completes.

![Successful upload notification](image)

**Figure 21**: Successful upload notification

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

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

![In-row editing in Study Details screen](image)

**Figure 22**: In-row editing in Study Details screen

### 3.11 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”.

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

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

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

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

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

Figure 23: Upload Study screen

**3.12 Manual upload of WatchPAT ONE study**
In the rare occasions that WatchPAT ONE (WP1) study was not automatically uploaded to CloudPAT after sleep study recording was completed, you may upload the study manually via the ‘Initializations’ section.

Select the relevant WP1 registration entry and click on ‘Retrieve Test’ button.

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

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

Figure 24 - Manual Retrieval of WP1 Study
3.13 Searching studies and reports

Clicking the “Patients” icon gets the user to a search screen that enables viewing all or a subset of the studies and reports available to the current user while clicking on the table’s icon shall perform a table refresh.

The following filters are available: Patient ID, First Name, Last Name, Email, Office, Status, Custom Status, Period, Sleep Apnea, Serial #, Study Date, Study Load Date, Study Close Date, Waiting for Interpretation, Interpreting Physician, Patient Created Date, Referring Physician, Insurance Provider, Report Viewed (indicates if the report file has been opened by a provider from the office).

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

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

Search results can be exported to a CSV format.

Figure 25: Viewing Sleep Study Reports

3.14 Study management

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

3.14.1 Understanding the Study screen

This screen presents information about the study.
The more frequently used fields are displayed on the collapsed row.

Changing the Minimum % of Desaturation for AHI/RDI calculation and assigning interpreting physician can be done through this row using the pencil icon for edit and check mark icon for saving.

Clicking on the caret would expand to include all the additional information of the study including errors or warnings returned from the analysis, Bracelet information and if Request Script was checked or not.

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

There is an office setting controlling if to show some analysis information in the study’s row or not.

![Note](image)

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.

![Figure 26: Study Details screen](image)

### 3.14.2 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 upload area.
The user can also remove or download the attached files by clicking on the respective buttons next to them.
3.14.3 Changing Interpreting Physician

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

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

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

Notification of a new study will be sent to the Interpreting Physician. Notification is also sent to the previous Interpreting Physician indicating that the study has been reassigned.

Note

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 two Interpreting Physicians have seen it.

3.14.4 View analysis file

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

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

Users of such offices can click the analysis file link 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.

Note

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.
3.14.5 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.

3.14.6 Changes of Study Parameters

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

Some of the parameters will require running the analysis again:
- AHI index – according to 3% or 4% desaturations.
- Pacemaker.
- Gender
- Date of Birth

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

Note

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

Warning message will appear in desaturation threshold is not 4% for Medicare insured patient.

Figure 29: Rerun Analysis indication
### 3.15 App Questionnaires

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

The provider shall be able turning questionnaires On / Off from the App Questionnaire tab and select / de-select groups of items from the Assessment module while the Bedtime and Morning sections are mandatory.

Once questionnaires are turned on for an office, it would change the App experience by displaying the questionnaires menus.

When using questionnaires, Email and Mobile fields become mandatory and CP shall issue an error message on attempt to Initialize WP1 Device if empty.

The patients table shall include an icon to indicate the App Questionnaires status (Pending /Ready).

When clicking on the "Resend Entry Code" button it shall send an SMS message to the patient’s mobile phone with a new entry code to be used in the APP.

The answers shall be added to the PDF report file.

---

![App Questionnaires](image-url)

**Figure 44: App Questionnaires**
3.16 Viewing reports

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

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

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

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

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

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

![Image of PDF report](image)

Figure 30: Download button for the PDF report

**Note**

Contact Itamar Medical support for other file type options of report availability.
3.17 Manage Devices

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

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

3.17.1 Devices Table

You can search for a device using designated filter fields and it is possible to add / remove device columns to the table.

Once a study is being uploaded from the device, its status would change into Available.

Figure 31: Devices Table screen
3.17.2 Devices Details

Clicking on a Device row would open the Device Details screen including showing additional information.

A device could be set as Out of Order through the by clicking on the Out Of Order button.

Initialization of a device that is marked as Out of Order shall be prohibited. A device can be moved between offices by using the Office dropdown.

![Device Details](image)

Figure 32: Devices Table screen
3.18 Manage Referring Physician

It would be possible to manage the referring physicians as a provider on the office level without waiting for this to be set by system administrators.

A referring physician may be added, edited, or set to inactive by the provider.

3.18.1 Referring Physicians Table

You can search for a referring physician using designated filter fields and it is possible to add / remove device columns to the table.

![Referring Physician Table screen]

Figure 33: Referring Physician Table screen
3.18.2 Referring Physician Details

Clicking on a referring physician row would open the Referring Physician Details screen including showing additional information.

A Referring Physician could be set to Inactive by using the designated checkbox.

If the user is associated to multiple office, it would be possible to move a referring physician to one of the other offices.

![Figure 34: Referring Physician Details screen](image-url)
3.19 Managed Lists

Managed Lists include medications, diseases, statuses and insurances.

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

Clicking on the “Managed Lists” icon will open up a search screen allowing searching for items including global, office specific or both, while items in the global list cannot be changed.

Figure 35: Managed Lists
4. Using CloudPAT as an Interpreting Physician

4.1. Main Access Screen

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

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

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

![Figure 36: Interpreting Physician’s Home screen](image)

4.1.1. Studies Assigned to the Interpreter

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 selecting “Unlocked” Status in the filter of the main screen which will display all unlocked studies waiting for you. You may also select the “Locked” status for viewing completed (signed) sleep study reports. You have the option to review subsets of your studies by selecting a particular Office, Patient name, etc.
**4.1.2. Reviewing a Study**

When you filter for “Unlocked” status, clicking on the study you want to, will display the study details screen from which you can review the new sleep study.

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

1. **Interpretation Details tab including:**
   - Input fields for the interpreter to fill in the Diagnosis and Recommendations. You may use the Diagnosis and Recommendations templates if you wish to insert an already predefined paragraph in the corresponding section.
   - Errors/Warnings – in case of errors or warnings returned from the analysis, a message will appear in the Errors/Warnings box.
   - Change Min Desat for AHI/RDI – change the value used for analysis. Change becomes effective only after saving. At this event, a message shall show indicating that rerun analysis is required to take into account the new setting. Click on “Rerun Analysis” button to see the results based on the new threshold.
   - NPI – you can add the NPI to the report if have one. If you have more than one NPI, select the right NPI number that matches the office details.
   - Add attachments like 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 a file – enter a description and select the file to be uploaded using the upload area. The user can also remove or download the attached files by clicking on the respective buttons next to them.

2. **Therapy tab:**
   - Allowing the interpreter to produce a Therapy Prescription which once enabled shall retrieve the patient information allowing the interpreter to edit the data and select prescription items from lists.
   - Once the Generate Scrip button is clicked, an auto-generated PDF file shall be created and displayed, including the submitted information to be appended to the report during the Save and Lock operation.
   - The supported therapies are CPAP and Oral Appliance.
3. **Patient Details tab**– patient details are displayed.

4. **Office Details tab** – by clicking the “Office Details” button, you can see the following details of the office that sent the sleep study: Address, Phone and Minimum % Desaturation for AHI/RDI calculation.

5. **Patient Attached Files tab**: Showing files that were attached by the provider.

6. **Preview report** button- You can click the “Preview report” button in order to see the 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. It would also include the patient information as well as your interpretation as it was last saved.

7. **Open in Viewer button** (RECOMMENDED) - This utility avoids the need to install zzzPAT on the PC, to download the study to the PC and upload the results. If you wish to see more details on the study’s signals or to review and edit the events, you can use the “Open in Viewer” function in order to invoke the zzzPAT utility viewer on your local computer with study data. Refer to **zzzPAT Operation Manual** for description of the operation can capabilities of the Viewer.

**Note**
On your first use of Open in viewer on your PC, installation of a small PC-app, CloudPATio will be done (if not installed already as part of device initialization / study upload process.)
8. **Download Study Files button (Legacy)** - Manually download the study to zzzPAT, and manually upload editing results to CloudPAT. This legacy option is kept in CloudPAT during the migration to **Open in Viewer** method.

   ![Note]

   Make sure to upload the correct manual event file. The filename will be comprised of
   
   ID_[patient ID]_
   
   SD_[study Date & time]_
   
   events_analysis_user.zpt
   
   other file will generate an error during the post upload analysis and will not change the analysis file

9. **Save** – saves your input without locking the report.

10. **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.

   ![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.

11. **Unlock a Report** – interpreting physicians can unlock their own locked studies by clicking on the Lock icon on the List of Studies screen. An audit trail record shall be added to the study indicating the user and the time and the previously locked report will be added.

12. **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.

![Image](image1.png)

**Figure 37: Interpretation Details screen**

### 4.1.3. Viewing a Completed Study

When you filter for “Locked” status, clicking on the study you want to, will display the study details screen.

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

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

![Image](image2.png)

**Figure 38: A completed Study screen**
4.2. Manage Templates & NPIs

This section explains how to manage the lists of templates and NPIs each Interpreting Physician has. Clicking on the “Settings” icon will open up a table in which you can browse for templates and NPIs. You can narrow down your search by using the “Type” field.

Figure 39: Templates & NPIs screen

4.2.1. Templates

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

You may have a number of predefined templates for Clinical diagnoses and for Recommendations which can be used with a click of a button in order to facilitate the Reviewing process. Using a template will fill the relevant section (diagnosis or recommendation) in the report. After choosing a template you may edit the text.

Clicking on the “New” button will open up the New Setting Details screen. Please select the Type, put the Name, decide if Active or not and for Templates put in the template’s text.
Clicking on an existing setting entry will open it for editing.

**New Settings Details**

- **Type**: Diagnosis
- **Name**: depression
- **Active**: On

Text:

As a medical diagnosis, depression denotes a prolonged state of dejection, emotional emptiness, self-recrimination, lack of energy, apathy, anxiety, sleep disorders, and lack of appetite.
4.2.2. NPIs

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

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

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

4.2.3. Signature

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

Figure 42: Interpreter Signature screen
Appendix A: License Agreement


Appendix B: Regulatory Representative

Itamar Medical’s authorized regulatory representative is:

<table>
<thead>
<tr>
<th>EC</th>
<th>REP</th>
<th>Arazy Group GmbH</th>
</tr>
</thead>
</table>

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