

CloudPAT Itamar Medical OM2200005 Web Software Operation Manual

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1 Introduction to CloudPAT

1.1 Intended Use of the CloudPAT (CP) [®]

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

1.2 zzzPAT & WatchPAT Interface S/W – Definition

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

1.3 CloudPAT S/W – Definition

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

1.4 Overview

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

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

1.5 Terminology

CloudPAT supports various types of users and entities.

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

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

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

1.6 Minimum Requirements

An internet connection using a PC workstation with Microsoft Win10 and above, running at a minimum upload speed of 1 Mbps and supported browser (Edge, Chrome or Firefox) is required.



< Note

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

2 Setting CloudPAT Access

2.1 Obtaining an Account

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

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

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

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

2.2 Accessing CloudPAT

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

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

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

ronen.prov			
	ider		
orgot your usern	ame?		
SSWORD			
		Ø	
rgot your passw	vord?		
& Need help si	igning.in?	SIGN IN	
	LSSWORD	ISSWORD Ingot your password? Need help signing in?	ASSWORD Argot your password? Argot help signing in? SIGN IN

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

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

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

To set up login restrictions, please contact CloudPAT Support.

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

2.3 Setting [Initial] Password

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

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

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

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

CloudPAT supports additional security measures, and allows users to log in with MFA through a text message sent to the patient's mobile phone. This option needs to be enabled by the system's admin upon request.

Change Password	×
* OLD PASSWORD	
ø	
* NEW PASSWORD	* RETYPE NEW PASSWORD
ø	Ø
Cancel	Save

Change Password Screen

迩

Note

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

2.3.1 Forgot Password / User Name

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

Forgot Password	
Please fill in your username to co you don't know your username pl	ntinue with password recovery. If lease contact us.
* USERNAME	
K Need help signing in?	
Cancel	Continue

Forgot Password Screen

If you happen to forget your User Name, simply click on the "Forgot your username?" link on the Sign In screen, enter your Email and an email will be sent to you with the associated User Name.

Forgot Usernam	e		
Please fill in your email address and associated usernames will be sent to you			
* EMAIL			
& Need help signing in?			

Forgot User Name Screen

2.3.2 Contact Us

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

Contact Us		×
The latest CloudPATio client can be downloaded Download the latest WatchPAT \oplus 300 device driv	here ers here	
© General Inquiry	NAME	
	* OFFICE	
°] 	• MESSAGE	
Send Study for Clinical Support		
∘ &		
By Phone		
Request for record removal from CloudPAT server		
	Cancol Send	

Contact Us Screen – General Inquiry

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

The "General Inquiry" creates a ticket for Itamar-Medical personnel to address.

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

	ræn	US and Canada: TEL: 1 888 748 2627	
0	General Inquiry		
0			
Send St	udy for Clinical Support		
0	C		
	By Phone		
0			
Request	for record removal from CloudPAT server		

Contact Us Screen – By Phone

If enabled, the "Contact Us" menu has the option to send a study to consultation with ZOLL's clinical support. This option is available only if the user is viewing the "Patient Details" screen, and the patient has at least one uploaded study when selecting the Contact Us menu option. If enabled, the "Contact Us" menu has the option to request for record removal from CloudPAT servers. Once this office setting is turned on, this option will allow users to specify the desired criteria for the removal.

2.3.3 Email Preferences

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

User Email Preferences		×
toggle off all options that you prefer not receive email notifica	ations for	
There is a new study awaiting interpretation	Indication about a study that has been assigned for your interpretation.	
The report has been unlocked	Indication about a study that has been locked by you has been unlocked.	
The study has been reassigned	Indication about a study that has been assigned for your interpretation is now re-assigned.	
There is a new study awaiting pool interpretation 🦲	Indication about a study that has been assigned for a pool.	
Daily Interpretation Pool Summary	Periodic summary email in relations to pending pool studies.	
A new study has been uploaded	Indication that a study you have initialized has been uploaded to CloudPAT.	
Analysis has failed	Indication that a study you have initialized has failed to run analysis.	
A new report has been completed	Indication that a study you have initialized has been interpreted and locked.	
Screening Uploaded	Indication that a screening study you have initialized has been uploaded to CloudPAT.	
Cancel	Save	

Email Preferences

3 Using CloudPAT as a Provider

3.1 Main Access Screen

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

- Dashboard monitors patient progress and gives physicians and staff better control over patient care.
- New Patient 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 predetermined instructions.
- Patients enables the user to see which sleep studies have been performed on patients, alter the patient's information and/or generate a follow-up sleep study for an existing patient.
- Devices Displays a table of the associated devices. Also allows access to more details for a particular device.
- Managing Referring Physicians allows the user to directly manage the referring physicians associated with the office.
- Configuring Managed Lists allows the user to manage the following lists: Medications, Diseases, Statuses, and Insurers. The user may also search for existing entries from global and local office level lists or add new ones.

3.2 Dashboard

The Dashboard includes the following items:

3.2.1 Enhanced Patient Care Pathway

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

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

Each stage is comprised of 1-3 sections that, when combined, equals to the number of patients in the first section of the previous stage.

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

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

The results can be filtered by Office, Referring Physician and Last Status Update.

The following stages are displayed in the chart:

- 1. Patients checked in: The 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 who have returned the device, and the WP study was uploaded to CloudPAT but not yet analyzed.
 - b) WP not assigned: Patients not yet assigned a WatchPAT device.
- 3. Tested with WP:
 - a) Tested with WP (main): Patients that have successfully completed the WatchPAT Study and the data was successfully analyzed.
 - b) WP Study Failed: Patients' WP study was uploaded to CloudPAT, but no AHI was calculated.
 - c) Not tested yet: Patients' WP study not yet uploaded to CloudPAT.
- 4. Sleep Apnea:
 - a) Apnea Positive (main): Patients positively diagnosed with sleep apnea, i.e., AHI above the office-defined threshold.
 - b) Apnea Negative: Patients with AHI below the threshold.
 - c) Report Not Ready: Patients with successfully uploaded studies to CloudPAT but the report is not ready.





3.2.2 Screening Patient Care Pathway

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

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

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

 Screening Patients Screening Not Load 	Created 🔵 Screening Assig ded	gned 🔵 Screenin	ig loaded 🌘	NA 🌒 No	WatchPAT 🔵 Assig	ned WatchPAT 🌒	Screening Not Assigned
Screening Created				1.	2		
Screening Assigned			9				3
Screening loaded		6			3		
Assigned WatchPAT	4		1	1			



3.2.3 Sleep Apnea Severity Scale

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

- 1. No Apnea
- 2. Mild Apnea
- 3. Moderate Apnea
- 4. Severe Apnea

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



Sleep Apnea Severity Scale

3.2.4 Central Sleep Apnea bar chart

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

Central Sleep Apnea

The specific SA Threshold of each of the participating offices will be used for the calculation AHIc as a percentage of total AHI



Central Sleep Apnea bar chart

3.2.5 Screening Patients STOP BANG bar chart

The Screening Patients STOP BANG bar chart shows information based on data received from SleePATh screening, within these ranges: 0 - 2, 3 - 4, 5 - 8.

Screening Patients STOP BANG

*Includes only the patients in screening stage without a WP device initialization process.



Screening Patients STOP BANG chart

3.2.6 Screening Patients ESS bar chart

The Screening Patients ESS bar chart shows information based on data received from SleePATh screening within these ranges: 0 - 5, 6 - 10, 11 - 12, 13 - 15, 16 - 24.

Screening Patients ESS

*Includes only the patients in screening stage without a WP device initialization process.



Screening Patients ESS bar chart

3.2.7 Longest AFib duration pie chart

Disclaimer: The WatchPAT is not intended to be used as a diagnostic device for any cardiac arrhythmia and is not intended to replace traditional methods of diagnosis for cardiac arrhythmias.

The Longest AFib duration is a pie chart indicating AFib episodes duration with WP patients according to four levels:

- 1. Not Enabled
- 2. Not Detected
- 3. Less than one min
- 4. Greater than one min

When a section is selected, the respective query in the patients table will display. In cases where the longest AFib episode detected is shorter than 60 seconds, review of the peripheral arterial tonometry signal for an irregular rhythm in the location of the episode is recommended. The WatchPAT may not detect short AFib episodes (<60 seconds).

Longest AFib Duration in Sleep

*The WatchPAT® is not intended to be used as a diagnostic device for any cardiac arrhythmia and is not intended to replace traditional methods of diagnosis for cardiac arrhythmias.





3.3 Managing Patients

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

You can enter filters to limit the search results.

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

You may click on the Export button for various csv export options of the list of patients to your PC. There is an option to toggle between single (latest) study per patient to multiple (show all studies).

You may choose "Select all" and "Un-Select all" in some of the dropdown search fields.

	WP Patients	Screening Patient:	5									
ø	Find	A «	List o	of Patients		All Stud	ies 💦 Last Study		DIPC	RT TO CSV IMPORT	SHOW 10 V	69
	PATIENT ID		_	PATIENT ID 💠	NAME ©	DATE OF BIRTH 💠	OFFICE \$	PATIENT CREATED DATE	STUDY DATE 🔅	STATUS 🗘		
	ronen		D	ronen111			Ronen Office	08-14-2022	08-14-2022			
A	FIRST NAME		D	ronen special ch	üüüÿääæçéééillőœ		Ronen Office	08-11-2022	08-11-2022	_	۵	
Q9	LAST NAME			ronen_wp300			Ronen Office	08-04-2022		-		
=				ronen102			Ronen Office	04-06-2022		•		
	STATUS		D	ronen101			Ronen Office	04-05-2022	04-05-2022			
			۵	ronen100			office	04-04-2022	04-04-2022		۰	
	INTERPRETING PHYSI	KIAN V		ronen12	LN, FN		office	04-30-2021		•		
	PATIENT CREATED DA	те		ronen005			office	04-27-2021		•		
	From	То		ronen003	123456789012345, 123456789012345		office	04-20-2021		•		
	REFERRING PHYSICIA	N		ronen002	Watson, Emma	04-06-2009	office	04-11-2021		_		
	SCREENING ORIGINAT	TED					< 1 2 : Total 17	>				
	<u>Clear</u>	Search										

Patient Table Screen

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

If the office enables Screening Patients, there is a Screening Patients Table, which does not include any of the study related search fields and columns.

a Screening Status as search field and column can be added.

There are additional search fields called STOP BANG and ESS, with the same values from the dashboard.

CloudPA By itar	AT [®] <u>Patients</u> \ Pa	atient Card							Contact Us R New Patient	Hello, ronen hansis 🗸
2	1 Created 04.06-2022	in Tesi	2 ing (initiated)		3 Study Loaded		4 Sent to Interpretation		5 Study Complete	d
Å	PATIENT ID ronen102	NAME Mr. Ronen 102	orr Ro	nen Office	GENDER Male	DATE OF BIRTI 07-04-200	1 D	AGE 22		
	REFERRING PHYSICIAN	COUNTRY CODE +1	MOBILE 31088	E PHONE 8999111	EMAIL ronen102@test.com					
:= Stu	dies & Initializations	Diseases & Medications Attached	Files App	Questionnaires						Initialize Device
	PERSONAL DETAILS			CONTACT INFORMAT	ION		INSURANCE INF	ORMATION		
	HEIGHT(IN)	71		STREET	street 1		INSURANCE PROVIDER			
	WEIGHT(LB)	177		СІТҮ	city 1		GROUP NUMBER	-		
	BMI	24.69		ZIP CODE	zip 1		OTHER INSURANCE	-		
	NECK CIRC.(IN)	16		STATE	Alaska		INSURANCE ID NUMBER	-		
	EPWORTH SCORE	18		COUNTRY	-		PRE-AUTH NEEDED	No		
	STOP BANG SCORE	5		HOME PHONE	-		PRE-AUTH NUMBER	-		
	PACEMAKER	No		ADDITIONAL PHONE NUMBER			PATIENT'S FINANCIAL RESPONSEBILITY			Rev
	PREFERRED PATIENT LANGUAGE			NOTIFICATION	No		BILLING COMMENT		E Log	edit _

Patient Details Screen

Subject to office setting, a Provider user has the ability to delete patients from the CP office using a designated "Remove Patient" button. A confirmation message will be displayed before the patient is deleted.

				4		5
Created 10-09-2022	In Testir 10-	ng (initiated) 09-2022	Study Loaded 10-09-2022	Sent to Inter 03-21-2	pretation 024	Study Completed
PATIENT ID	NAME	OFFICE	GENDER	DATE OF BIRTH	AGE	
REFERRING PHYSICIAN	COUNTRY CODE	MOBILE PHONE	EMAIL			
						Initialize Remov Device Patien
Idies & Initializations	vetails WPT Disea:	ses & Medications	Attached Files SleePATh™	HSAT Medical Order Form		

Remove Patient button

Providers can change a Patient's ID for uploaded studies only once, with the following conditions:

- The patient has one study
- There are no manual events
- The study is not in in-testing stage

Providers can disable all SleePATh services from the Patient Card, in the SleePATh tab.

In case of manual events, if the analysis has been edited or changed, an icon will appear on the patients table with the description of: "The automatic analysis events or stages have been edited."

Clo		Patients		PAT® Academy Masterclass with Pro Friday, Sept 13 in Birmingham Discover and Unlock the hull Potential of PAT® Technology in steep agness disponsis and use WatchPAT® with confidence	f. Adrian Williams	WP300 Operations	General Inquiry	Hello,
•	WP Patients	Screening Pa	atients					
ø	Find		Last Status Update Two Weeks		All Studies Last Study	Import	Exports SHO	
8	PATIENT ID		PATIENT ID 💠 NAME ≑	DATE OF BIRTH + INSURANCE PROVIDER + OFFICE +	REFERRING PHYSICIAN PATIENT CREATED DATE	PATIENT SYSTEM ID	STATUS \$	
	FIRST NAME		-		07-30-2024		•	
Ē			-		07-29-2024		•	
B	LAST NAME		-		07-29-2024		•	
		_			07-29-2024		•	
Ŕ	PATIENT SYSTEM ID				07-29-2024		•	
Ċ,	BOET FOUCATION FU				07-25-2024		•	
	FOST EDUCATION ED	~		07-08-1999	07-31-2024			5
A	OFFICE			07-08-1999	07-31-2024		-	2 🗊
\odot	1 selected Offices			07-08-1999	07-31-2024			
~	WPT PARTNER			07-14-1999	08-06-2024		•	
U	WPT Partner			07-21-1999	08-06-2024			63
R	Select a status			08-05-1999	08-05-2024	-	-	6
•	INTERPRETING PHYS	ICIAN		08-05-1999	08-05-2024		-	5
	Clear Search			08-20-1999	08-05-2024		Sh	ow All Results

Manual Events Indicator Icon

3.4 Creating a New Patient

When creating a new patient, erroneous fields and empty mandatory fields will be highlighted in red. It is possible to configure specific fields as additional mandatory fields by contacting the system administrator.

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

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

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

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

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

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

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

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

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3.4.1 Creating a New WatchPAT Patient

In order to prepare the WatchPAT[™] device for a new patient please select "New WP Patient".

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

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

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

Note

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

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

PAT [®] Patient	Patient Card								Contact	Us Helk
()		2					_			
Created 01.05-2022		in Texting (initiated)		Study Loaded		Sent to Interpre	riation		Study Co	mpleted
PRIMATIO *	PREMOX	PRST NAME	LAST NAM		owner.		GENDER		DATE OF BRITH	
ronen102	Mr. v	Ronen	102		Romen Office		Male		07-08-2000	
AGE	REFERENCE PHYSICIAN	COUNTRY	CODE MOBILE PHONE	EMAL.						
22		× +1	× 31066999111	ronen102@test.com						
Personal Details	els Diseases & Medications Ad	tached Files App Quer		N		INSURANC	E INFORM/	ATION		
Studies & Initializations De PERSONAL DETAILS HEIGHTUN)	ih Danases & Medications An	tached Files App Quee CO	INTACT INFORMATIC	DN street 1		INSURANCE PR		ATION		
20udes & Initializations Dev PERSONAL DETAILS HEIGHT(JR) WEIGHT(LB)	All Diseases & Medications All	Eached Files App Control CO STRE CTTV		DN street 1 city 1		INSURANCE PE		ATION		
Studies & Intelligations Dee PERSONAL DETAILS HEIGHT(JN) WEIGHT(L8) BMI	ah Dawase & Medicators A 21 177 2469	CO CO STRI CTT ZIP 1	NOTACT INFORMATIC RET Y CODE	DN street 1 city 1 zip 1		INSURANCE PR GROUP NUMBE OTHER INSURA	EE INFORM/ Iovider In Ince	ATION		×
Definition & biologications Def PERSONAL DETAILS HEIGHT(JR) WEIGHT(JR) BMI NECK CIR(JR)	Timesen & Molloutiers Annotation 71 71 1777 2469 16 16	torbed File App Cases CO STM ZIP+ STA	NTACT INFORMATIC RET Y CODE	Street 1 city 1 zip 1 Alaska		INSURANCE PR GROUP NUMB OTHER INSURA	EE INFORM/ Iovider IR INCE			
Todas & Hitelevien PERSONAL DETAILS HERHITUR HERHITUR HERHITUR HERHITUR HERK CIRC.(IN) EPWORTH SCORE	Timesen B Medication An 71 71 177 2469 16 19	CCO STREE CCO STRE CPT 291 STAI	torodor INTACT INFORMATIC EET Y code net Avritev	SN street 1 city 1 zip 1 Alaska		INSURANCE PR GROUP NUMBE OTHER INSURA INSURANCE ID PRE-AUTH NEE	EE INFORM/ IOVIDER IR INVIDER INVIDER			
Patient & brokkrytene PERSONAL DETAILS PERSONAL DETAILS PERSONAL OPENIN PERSONAL DETAILS P	A Disease & Medicators A	CCO	NTACT INFORMATIC REF Y CODE SE ARTRY ME RUNNE	2N street 1 chy 1 2ip 1 Alaska		INSURANCE PR GROUP NUMBE OTHER INSURA INSURANCE ID PRE-AUTH NEE	CE INFORM/ Iovider IR INCE INUMER DED			

WP Patient Card

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3.4.2 Creating a New Screening Patient

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

Cloud	PAT [®] Patients \ Se	creening Patient Card						Hello, A New Patient 🕥 Upto	ad Study
•	1 Screening Creat		2 Screening Assigned		3 Screening Loaded	Pending Screen	ing Deck., 👻	4 Pending WatchPAT**	
A P	REFERENCE PHYSICIAN	NAME COUNTRY CODE	OFFICE office+Q MOBILE PHONE	GENDER EMAR	DATE OF BIRTH		AGE		
R A	Details Diseases & Medications	+972 Attached Files App Questionnaires		qa.com				Initialize Screening Device Pote	to nt
Q,	PERSONAL DETAILS		CONTACT INFORM	ATION		NSURANCE INFOR	MATION		
A	HEIGHT(IN)		STREET			ISURANCE PROVIDER			
©	WEIGHT(LB)		CITY		G	ROUP NUMBER			
	BMI		ZIP CODE		0	THER INSURANCE			
0	NECK CIRC.(IN)		STATE			ISURANCE ID NUMBER			
R	EPWORTH SCORE		COUNTRY		P	RE-AUTH NEEDED	No		
	STOP BANG SCORE		HOME PHONE		P	RE-AUTH NUMBER			
•	PACEMAKER	No	ADDITIONAL PHONE NUMBER			ATIENT'S FINANCIAL ESPONSEBILITY			
	PREFERRED PATIENT LANGUAGE		NOTIFICATION	No		ILUNG COMMENT		Edit 🖉	
	PATIENT E2E APPOINTMENT	No	EMERGENCY CONTACT NAME						

Screening Patient Card

3.5 Importing Patients

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

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

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

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- Home Phone
- Country Code + Mobile Phone
- Email
- Number of Nights
- Bracelet Study
- Address
- State
- Work Phone
- Pacemaker
- Prefix
- DOB
- Logistics Comments
- STOP BANG
- Height
- Weight
- Epworth Score
- Neck Circ

3.6 First Time Installation

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

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

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

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

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

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

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

CloudPATio provides two modes of installation:

- 1. A regular user installation making it operational only for the current Windows logged in user.
- 2. Admin user installation making it operational for any Windows logged in user. Admin installation shall require admin credentials for install, un-install and upgrade.

CloudPATio presents a taskbar icon when running allowing to terminate it from there.

Whenever there is a newer optional version, a suggestion to upgrade will be presented. Occasionally there may be a mandatory version that would have to be installed within a certain timeframe.





Double click the downloaded installation file.



Start the CloudPATio Installation

Follow the installation instructions:

	Installer La	nguage	×
	3	Please select a language.	
		English / English	~
		OK	Cancel
		Language Selection	
💮 CloudPA	Tio Setup		– 🗆 X
		Welcome to Cloud Setup will guide you through the It is recommended that you do before starting Setup. This will relevant system files without the computer. Click Next to continue.	PATio Setup he installation of CloudPATio. ose all other applications I make it possible to update having to reboot your
			Next > Cancel

Running the Installation Wizard

😚 CloudPATio Setup —	×
License Agreement	
Please review the license terms before installing CloudPATio.	
Press Page Down to see the rest of the agreement.	
Your use of the Itamar-Medical λ€ [™] S CloudPAT portal service confirms your agreement to be bound by the terms and conditions contained in this agreement as well as any rules for use of the services. It also acts as your acknowledgment of your receipt and understanding of the disclosures in this agreement and your agreement allowing all disclosures or other information required under applicable law to be sent electronically. Terms and conditions of this agreement may change from time to time. Itamar-Medical has the right to terminate this agreement and/or your access to the CloudPAT portal service at any time, at our convenience and without cause. In no event will Itamar-Medical be liable for any direct or indirect, damages or lost profits arising from your use of our CloudPAT portal service as well as any interruption in	\$
If you accept the terms of the agreement, dick I Agree to continue. You must accept the agreement to install CloudPATio.	•
Kullisort Install System V3.05 Kack I Agree Can	icel

License Agreement Screen

💮 CloudPATio Setup	– 🗆 X
	Completing CloudPATio Setup
	CloudPATio has been installed on your computer. Click Finish to close Setup.
	< Back Finish Cancel

Installation Completion Screen

3.7 Initialize WP200U/WP300 Device

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

- Bracelet Study (available only if office setting permits) from this screen you may require a Tamper Proof Bracelet to be used as Positive Chain of Custody in Occupational Testing (e.g., truck drivers. See WatchPAT[™] Operation Manual for further details).
- If the office setting permits a Multiple Nights Study: in order to record up to 3 nights with same WatchPAT device, select the number of nights needed. There are two options for Multiple Nights Study:
 - Two nights when no charging is needed between the nights (maximum length of study is approximately 8 hours)

- Three nights when charging is necessary between the nights (maximum length of study is approximately 10 hours)
- The Request Script option informs the Interpreting Physician that a script is requested.
- An associated interpreting physician may be selected for the study, and the option to change this selection will be allowed later.
- As part of the WP300 initialization process, there is an option to trigger a device test operation This operation can also be invoked from the WP300 Operations Menu, by selecting the Device Test option.

Click on the Initialize Button once all inputs are set.

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

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



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

When initializing a WP300 device, if an issue with the battery was detected, a warning message will appear. The user should consider putting in a new battery in this case.

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

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

An office can configure a mandated interpretation selection as part of the device initialization process. After the initialization is completed, a new entry is added to the Initializations section under the Studies & Initializations tab.

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



Note

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

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

Initialize Device		×
WatchPAT ONE	INTERPRETING PHYSICIAN	NUMBER OF NIGHTS 1 V BRACELET STUDY
WatchPAT 300	TEST DEVICE	
WatchPAT 400		
WatchPAT ONE-M	* Battery should remain in the device until st	udy completion.
	Cancel	Initialize

Initialize WatchPAT 200U/300 Device Screen

3.8 Initialize WatchPAT[™] ONE Device

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

- Enter the WatchPAT[™] ONE's Device serial number.
- Enter the PIN and PIN Type (hint) provided to the patient. Pin Type can be pre-set as an office setting.
- If there is a mobile number for the patient and the office setting for "Use last four digits of patient's mobile number" is enabled, the PIN would be auto populated from the last four digits of the patient's mobile number.
- Enter the max number of PIN Retries (default: 7, can be pre-set as an office setting).
- Accept default or change the Email for Notification, indicating the email for notification on study completion and upload to CloudPAT.
- Optional: Select the desired Interpreting Physician that the study will be sent to. If Interpreting Physician is not assigned, they can be selected after study is successfully uploaded to CloudPAT.
- An office can configure a mandated interpretation selection as part of the device's initialization process.
- Click on the "Initialize" button to complete the initialization process.

ll.	* SERIAL NUMBER	* PIN
WatchPAT Witcher m		**The last four digits of the Mobile Number
VINE	* MAX NUMBER OF PIN RETRIES	* PIN TYPE
	7	Mobile Number V
WatchPAT	* EMAIL FOR NOTIFICATION	**As configured for your office
300	() Add	
WatchPAT 400		REQUEST SCRIPT
WatchPAT ONE-M		

Initialize WatchPAT ONE Screen

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

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

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

Init	ializa	ations									
	INITIALIZATION DATE SERIO			SERIAL #	SERIAL # DEVICE TYPE			STATUS			
~	× 01-08-2021 12:44:04				WatchPAT One			WP1 Registered			
		DEVICE TYPE	WatchPAT One		PIN TYPE	Pin		ASSIGNED PATIENT NAME	Mr. Erik Smidth		
		LOAD DATE			PIN	1234		Unregister			
		🙏 Retrieve Test			MAX NUMBER OF PIN RETRIES 3						
				Reset Retries							

Reset Available PIN Retries

3.9 Initialize WatchPAT[™] ONE Multi-Night Device

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

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

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

nitialize Device		
	* NUMBER OF NIGHTS	* DEVICE SERIAL NUMBER
	2 ~	
ONE CONE		enter here the serial number that is presented on the box.
	* PIN	* PROBE2 SERIAL NUMBER
WatchDAT	**The last four digits of the Mobile Number	
500	* MAX NUMBER OF PIN RETRIES	* PIN TYPE
	7	Mobile Number V
		**As configured for your office
<u>H</u>		
WatchPAT	* EMAIL FOR NOTIFICATION	
400		
A. A	④ Add	
	REQUEST SCRIPT	
WatchDAT		
		Cancel Initialize -
		Initialize

Initialize WatchPAT ONE Multi-Night Screen

3.10 Initializing a WP400 device

Click on the Initialize Device button, select WatchPAT400 option and input the desired settings on the screen:

- Enter the WatchPAT[™] 400's Device serial number.
- Enter Probe Serial Number.
- The PIN field is always the last 4 digits of the mobile number for WatchPAT400, and the PIN type is always Mobile Number. If there is no mobile number saved for the patient, in the WP400 Initialization screen a message will show saying that it is needed.

• Accept default or change the Email for Notification, indicating the email for notification on study completion and upload to CloudPAT.

• Optional: Select the desired Interpreting Physician that the study will be sent to. If Interpreting Physician is not assigned, they can be selected after study is successfully uploaded to CloudPAT.

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

• Click on the "Initialize" button to complete the initialization process.

 \times

Initialize Device		×
WatchPAT WatchPAT	* SERIAL NUMBER	* PROBE SERIAL NUMBER
UNL	**The last four digits of the Mobile Number	Mobile Number v
WatchPAT 300	* EMAIL FOR NOTIFICATION	
		INTERPRETING PHYSICIAN
WatchPAT 400	REQUEST SCRIPT	
WatchPAT ONE-M		
	Car	cel Initialize
	Initialize WatchPAT400	Screen

3.11 Device Initialization Details

In the Patient Card, under the "Devices and Initializations" tab, users can click on the caret for each initialized device to see the device details.

Here, information about the initialized devices can be seen, and additional functionality.

INITIALIZATION DA	ATE SERIAL	# PROBE SERIAL #	DEVICE TYPE	INTERPRETING PHYSICIAN	STATUS
05-15-2025 07:57	:23		WP400		Registered
DEVICE TYP	E WP400	PIN TYPE	Mobile Number	ASSIGNED PATIENT	
LOAD DATE		PIN			
🔟 Retrie	eve Test				
01-30-2025 08:11	:16	-	WP1		Completed
01-30-2025 08:11	:16 E WP1	PIN TYPE	WP1 Mobile Number	ASSIGNED PATIENT	Completed
01-30-2025 08:11 DEVICE TYPE LOAD DATE	E WP1 01-30-2025 08:13:20	PIN TYPE PIN	WP1 Mobile Number	ASSIGNED PATIENT NAME	Completed
01-30-2025 08:11 DEVICE TYPE LOAD DATE	:16 WP1 01-30-2025 08:13:20 02:000 00:00:00:00:00:00:00:00:00:00:00:00	PIN TYPE PIN MAX NUMBER OF PI RETRIES	WP1 Mobile Number	ASSIGNED PATIENT NAME Unregister	Completed

Device Initialization Details Screen

3.12 Uploading a Study

This section covers uploading studies from the device or manually.



Note

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

3.13 Normal Upload Mode (WP200U/WP300)

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

Proceed by selecting the "Proceed with upload" button.

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

Open Windows Command Proc	essor?
	wants to open this application.
Always allow	to open links of this type in the associated app
	Open Windows Command Processor Cancel

Allowing Windows Command Processor

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



Patient Sleep Study Upload in Progress



Note

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



Note

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

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

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

📀 upload succeed! Redirecting to patient page...

Successful Upload Notification

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

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

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

By the end of the wp300 study upload process, if there is a newer firmware version, a suggestion will appear to perform the upgrade straight from CloudPAT. Once accepted, it will trigger the upgrade operation. This operation can also be invoked from the WP300 Operations using the Firmware Upgrade option.

If you attempt to upload a WP300 study to a patient who already has a study with the same date, a message will be displayed.

Clou	dPAT [®] Pat	ents \ Patier	nt Card							Contact Us	Hello, Victoria Victo
e	Crez 08-11-	Created in Te			tiated) 2		3 Study Losded 08-11-2022	Sent to Int	erpretation	5 Study Compl	eted
A	PATIENT ID ronen special ch		NAME ùûliÿàāæçéèé	eiiôœ	OFFICE Ronen Office		GENDER	DATE OF BIRTH	AGE -		
с,	REFERRING PHYSICIA	N	COUNTRY CODE		MOBILE PHONE		MAIL				Initialize Device
	Studies & Initializations	Details Dise	ases & Medications	Attached Hies	App Questionnaires						
	STUDY DATE	SERIAL #	AHI ODI	VALID SLEEP TIME	# OF NIGHTS	ANALYSIS READY	INTERPRETING PHYSICIAN	MIN DESAT FOR AHI	MIN DESAT FOR ODI	REPORT READY	
	> 08-11-2022			0 hrs, 0 min	1	Yes		× 3% ×	4% 1	No	< 🗸
							< 0 >				
	INITIALIZATIO	ONS									
	INITIALIZAT	ON DATE		SE	RIAL #	DEVICE TYPE		INTERPRETING PHYSICIAN		STATUS	
	08-11-2022	15:51:34		•		WatchPAT 300				E Log	🖉 Edit
	08-11-2022	15:48:52		•		WatchPAT 300					

In-Row Editing in Study Details Screen

3.14 Manual Mode (WP200U/WP300)

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

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

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

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

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

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

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On attempt to load a study that has been initialized not in CP 3.0, while the user is connected to more than one office, CP will present a dropdown of the user's connected offices, allowing the user to select the desired office and then create the patient and the study under this office.

슈 Upload Study	^
Please zip (compress) the following files from the WatchPAT device into a single file:	
 Patient.dat Sleep.dat Log.dat (if it exists) 	
E	
Click or drag file to this area to upload	
Support for a single file upload. The uploaded file has to be a ZIP(compressed) file!	
)

Upload Study Screen

3.15 Manual Upload of WatchPAT ONE Study

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

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

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

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

Initia	lizations									
	INITIALIZATION DATE SER			DEVICE	DEVICE TYPE		STATUS			
~	✓ 01-08-2021 12:44:04			WatchPAT One		WP1 Regi	WP1 Registered			
	DEVICE TYPE	WatchPAT One		PIN TYPE	Pin		ASSIGNED PATIENT NAME	Mr. Erik Smidth		
	LOAD DATE			PIN	1234		Unregister			
	1 Retrieve Test			MAX NUMBER OF PIN RETRIES 3						
				Reset Retries						

Manual Retrieval of WP1 Study

3.16 Searching Studies and Reports

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

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

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

The table including the search results is customizable and includes the majority of the search fields. Search results can be exported to CSV files.

- Export to CSV: Including patients' details.
- Export Summary Report: Including some analysis information.

IdPAT® By itamar	Patients									Contact Us	Hello,	d Study
WP Patients	Screening Patients	1										
Find	¥ «	ist of	Patients		All Stu	idies 📃 Last Study			EXPORT TO CSV IMPORT	SHOW [10 👻	69
PATIENT ID	Add/Remove Filters	_	PATIENT ID 💠	NAME 0	DATE OF BIRTH \$	OFFICE \$	PATIENT CREATED DATE 💠	STUDY DATE	STATUS 🗘			_
ronen	Serial # Date Of Birth	۵	ronen111			Ronen Office	08-14-2022	08-14-2022				
FIRST NAME	Study Date Study Load Date Study Close Date	۵	ronen special ch	üüüÿääæçéééëilőœ		Ronen Office	08-11-2022	08-11-2022	_	۵		
LAST NAME	Waiting For Interpretation Interpreting Physician		ronen_wp300			Ronen Office	08-04-2022		-			
	Pool Referring Physician		ronen102	102, Ronen	07-04-2000	Ronen Office	04-06-2022		•			
STATUS	Insurance Provider Office	D	ronen101			Ronen Office	04-05-2022	04-05-2022				
Select a stat	 Wpt Partner Patient Created Date 	۵	ronen100			office	04-04-2022	04-04-2022			٩	Þ
INTERPRETING	Custom Status		ronen12	LN, FN		office	04-30-2021		•			
	Screening Originated Sleep Apnea		ronen005			office	04-27-2021		-			
From	Compliance Period		ronen003	123456789012345. 123456789012345		office	04-20-2021		•			
REFERRING P	Report viewed		ronen002	Watson, Emma	04-06-2009	office	04-11-2021		_			
SCREENING OF	RIGINATED					< 1 2 Total 1	7					
Clear	Search											

• Export History: Including progress bar changes.

Viewing Sleep Study Reports

3.17 Study Management

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

3.17.1 Understanding the Study Screen

This screen presents information about the study.

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

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

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

If the office settings allow it, you can see the Analysis File under "Files".

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



Note

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

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Ø		Created 8-14-2022			In Testing (i 08-14-2	nitiated)		Study Loaded 08-14-2022		Ser	at to Interpretation 08-14-2022		5 Study Complete	•
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300	STUDIES	IS Details	Diseases	e metiications	Attached Hiles	App Ques	oorman es							
	STUDY	ATE	SERIAL #	AHI	ODI	VALID SLEEP TI	ME # OF NIGHTS	ANALYSIS READY	INTERPRETING PHYSICIAN	N	MIN DESAT FOR AHI	MIN DESAT FOR ODI	REPORT READY	
	 ✓ 08-14-2 	022 🖸		22.4 (3%)	15.0 (4%)	5 hrs, 19 min	1	Yes	sp Ronen		3%	4%	Yes	
	ASSIGNME	NT DATE	08-1	4-2022			BRACELET STUDY				ERROR / WARNINGS			_
	LOAD DAT		08-1	4-2022			BRACELET ID				Rerun Analysis			
	LOCK DATE		08-1	4-2022			REQUEST SCRIPT							
	⊕ RAW	Data 🔛 RT	F										E Log	/ Edit
	Interpreta	ion History												

Study Details Screen

3.17.2 Attaching Files to a Patient

Once a patient is created, the user can choose to add documents to the patient record. These documents will be available for the Interpreting Physician to review when preparing the report. To attach a file – enter a description and select the file to be uploaded using the upload area.

Clo	udPAT	Patients \ Patient Card	b					×	
	s, ZOLL İtamar	<u></u>					WP300 Operations	A New Patient	🕥 Upload Study
		1	2	🗄 Upload File	×			5	
69		Created 12-09-2024	In Testing (initia	Description		Sent to Interpretation			
8	PATIENT ID	PREFIX	FIRST N#			GEN	DER	DATE OF BIRTH	
A	~	-	× •	Click or drag file to this area to uploa	d	· ·			ä
Ċ,	AGE	REFERRING PH	YSICIAN	Support for a single file upload. Please upload one of types: BMP, JPEG, TIF, TIFF, PNG, DOCX, XLSX, PI	the following DF, TXT!				
:=	Studier & Initiali	zatione Dataile WRT Direct	arer 8 Medications		_				
	studies & mitian	Zauons Details WP1 Disea	ases or medications	Back	Save				
La	ATTACH	ED FILES							
R		FILE NAME		DESCRIPTION	UPLOAD DATE		UPLOADED	BY	
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	0 ±	e-Order_Dec_09_2024_11_28_13		e_order File	12-09-2024 11:2	8:14		-	
	0 ±	e-Order_Dec_09_2024_11_29_39		e_order File	12-09-2024 11:2	9:39	~	-	
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	⊙ Add								
							Can	cel Save & Initia	lize Save

Attach File Screen

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

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

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

Clo		Patients \ Pat	tient Card						C WP300 Operations	Contact Us Hello	Upload Study
ø		1 Created 12-09-2024	In T	2 esting (initiated)	Study	3 Loaded	Sen	4 at to Interpretation		5 Study Complete	ed
8	PATIENT ID		PREFIX	FIRST NAME	LAST NAME		OFFICE •	GEND	ER	DATE OF BIRTH	
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:=	_										
	Studies & Initializ	ations Details N	WPT Diseases & Me	dications Attached Files	SleePATh™ HSAT I	Medical Order Form					
R	ATTACHI	D FILES									
R		FILE NAME			DESCRIPTION		UPLOAD DATE		UPLOADED	BY	
	0 ±	e-Order_Dec_09_202	4_11_22_57		e_order File		12-09-2024 11:22:58				
	0 ±	e-Order_Dec_09_202	4_11_28_13		e_order File		12-09-2024 11:28:14				
	0 4	e-Order_Dec_09_202	4_11_29_39		e_order File		12-09-2024 11:29:39			i i i i i i i i i i i i i i i i i i i	
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	④ Add										
									Can	cel Save & Initia	lize Save

Deleting Attached Files

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3.17.3 Changing Interpreting Physician

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

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

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

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

Offices may turn on an Eligibility Check for Interpreting Physicians. This would compare the states where the interpreting physician is board certified in with the Patient's state of residence and would allow a study assignment only if they match.

3.17.4 Interpretation Pools

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

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

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

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

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

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

If the Eligibility check is configured for the office, an interpretation pool could be assigned only if it includes at least one member that is certified to interpret in the patient's state and only certified members could pull the study.

Whenever a pool member is configured as the Default Assignee, they would be assigned to any new study assigned for this pool, getting these studies added to their Studies table. The default assignee shall be able to return studies back to the pool for other members to pull them.

3.17.5 View Analysis File

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

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

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

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

Offices have the option to enable a setting to allow providers to download the statistics.XML file (including the full set of the analysis information).

Offices also have the option to enable downloading EDF file of an analysis.

Note

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

3.17.6 Request for a Script

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

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

3.17.7 Changes of Study Parameters

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

Some of the parameters will require running the analysis again:

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

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



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

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

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3.18 Using CloudPAT as an Office Admin

The Office Admin is a role designed to manage and administrate the Office, and has further capabilities without relying on Itamar Admin for operations.

An Office Admin has the following capabilities and permissions:

Creating office Providers:

An Office Admin can create Office Providers by navigating to the "Access" tab and clicking the "New" button, then fill the Provider Details fields.

Creating Office Interpreting Physicians:

An Office Admin can create Office Interpreting Physicians by navigating to the "Access" tab and clicking the "New" button, then fill the Interpreting Physician Details fields.

Creating Office Sleep Physicians:

An Office Admin can create Office Sleep Physicians by navigating to the "Access" tab and clicking the "New" button, then fill the Sleep Physician Details fields.

Clo	UCCONT , ZOLL Itamar	Access		1 Ampatrit	WatchPAT® Arrhy Detection Feature	thmia Click Here to Learn more		WP300 (Contact U Operations 옷 Ne	s Hello, w Patient	(†) Upload Stu	idy
	Find		List of Client Logins						① New Exp	orts Hov		69
Ø	USER ROLE		NAME 🗘	LOGIN ID 👙	ROLES 🗘	ACTIVE 🗘	EMAIL USED FOR ANOTHER USER	0 EMAIL	Provider			
R	LAST NAME								Interpreting Physi Sleep Physician	tian		
冎	ACTIVE					No Data						
Q	LOGIN ID											
≔												
R	FIRST NAME											
A	OFFICE											
	EMAIL											
	EMAIL USED FOR A	NOTHER USER										
	<u>Clear</u> Search											



Office admins have full control over SleePATh settings.

3.19 SleePATh Questionnaires

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

The SleePATh settings can be configured by an Itamar administrator or by an Office Admin user granted with this permission, also including the possibility to create Y/N custom questions for both screening and the study questionnaires, to be added in any of the sections. Changes in the SleePATh settings are captured in Audit Trail screen.

The provider can turn questionnaires On/Off from the App Questionnaire tab and select elements from Bedtime, Morning, Assessment Questions, Risk Assessment (STOP BANG) that will later show in the patient's mobile application.

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

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

The Patients Table includes an icon to indicate the App Questionnaires status (In Progress, Completed, Aborted, NA).

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

The answers are added to the sleep report and are also available in the Studies & Initializations tab.

CloudP/ Byita	nar Patients \ Patient Card				Contact Us Hells
Sh	dies & Initializations Details Diseases & Medications Attached Files	App Questionnaires			Device
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8			Nease assign a referring physician, if you wan	t your patient to get a personalized experience	
A				ACTIVATE STUDY QUESTIONNAIRES	
0	Study Questionnaires				
-					
	Bedtime				
	⊕ BEDTIME QUESTIONNAIRE *		13/13 💌		
	Morning				
	MORNING QUESTIONNAURE *		12/12		
	Assessment				
	MAIN SLEEP COMPLAINTS		1/1 💌		
	PRIOR SLEEP DIAGNOSIS		6/6 🔽		
	SLEEP PATTERN		14/14 🔽		🔳 Log 🖉 Edit
	GENERAL BACKGROUND		7/7 🕑		

App Questionnaires

Office Admins have full control over sleePATh settings through the "sleePATh" Tab under Office settings.

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3.19.1 Learning center:

Learning center is a mobile APP service that allows the office to send the patients educational information pre and post sleep study and to get confirmation that the patient viewed the information.

Pre-Study:

The pre-study education process is triggered during the device initialization process.

It may include the following items: Educational Videos, About sleep apnea, Common symptoms, Associated risks, Treatment options, FAQs, Healthy sleep habits.

Once checked by the provider, the relevant content will be available for the patient in the mobile application.

Post-Study:

The post-study education process may be triggered or the interpreting physician after the study has been locked in a similar fashion.

It may include the following items: Educational Videos, Sleep Apnea, Common Symptoms, Associated Risks, Treatment Options, FAQs, Patient Preferred Therapy (Survey), Healthy sleep habits and the patient's treatment preference.

Cla		WatchPAT Arrhythmia Detection Does the beat go on?		Contact Us Hello, mich	nael.ohayon 🗸
	zoultamar	SIGN UP NOW!	ZOLL İtamar	WP300 Operations R New Patient	Upload Study
•				Initialize Device F	emove Patient
Ø	Studies & Initializations Details Diseases & Medication	ns Attached Files SleePATh™ Orders			
٨	Questionnaires Learning Center Communicat	tion Activate Services			
А	Unlock and Resend Entry Code		Deactiv	ate Journey	
Ċ,	*Send a new entry-code to unlock login		*Abort slee	path process after init device	
≣	SleePATh™ ∖ Learning Ce	nter			
R	Activate Learning Center				
Ŕ	The patient will access the Learning Center in the app with the or that you have chosen.	content modules			
ť.	PRE-STUDY EDUCATION Sent: 01-30-2025	Download Report	POST-STUDY EDUCAT	пол	
• ©	> About sleep apnea	Sent: 01-30-			
	> Common symptoms	Sent: 01-30-			

SleePATh Learning Center

3.20 IDTF Customers - HSAT Order Form

There exists an optional tab called "HSAT Order Form" if the office is a ZOLL IDTF customer submitting orders using CloudPAT. This tab enables the creation of a sleep test order in a PDF format.

Any of the Patient Information fields that were entered/modified in the e-Order tab will update the Patient Details tab and vice versa.

There are several sections, and each section holds different fields. Certain logic is applied to the form to ensure the IDTF has the information it needs to process the order.

The logic for submitting an E-order: Once the E-Order button is pressed, CP executes a validation of input data, then the user shall put in the "Prescriber Login" field the User Name of the logged inuser, and in the "Prescriber Password" field the password of the logged in user. A PDF is then created with the entered data under the Attached Files tab.

You may attach PDF files to be included in the output PDF.

Orders can be updated and repeated.

If the "Path to Therapy" setting is turned on, the form will include a checkbox called "Information Sharing". If turned on, a selection of a therapy provider from the dropdown will be mandatory for producing the pdf. This will send the study to the chosen therapy provider.

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CIC	», zoul îtamar		ralleni	Calu	SIGN UP	NOW!	ZOLL İtan	nar	WP300 Operations	A New Patient	🗘 Upload Study
	Studies & Initializa	ions Details	IDTF	Diseases & Medications	Attached Files	SleePATh™	HSAT Medical Order Form				
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\$ \$									Zin		
	*City:						*State:		Code:	ancel Save & Initial	ize Save

HSAT Order Form

3.21 Viewing Reports

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

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

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

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

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

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

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

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

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

dPAT [®] By itamar	Patients \ Patien	t Card					Contact Us	Hello,
	Created 08-11-2022	In Testing (init 08-11-2022	tiated) 2	3 Study Loaded	Sent to Inte	rpretation	5 Study Completed	
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Download Buttons for the Reports



Note

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

3.22 Managing Devices

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

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

3.22.1 Devices Table

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

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

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

Clo		Devices	Expect	more from your HSAT	Introducing the WatchPAT® Arrhyth Detection Featur	e nmia Click Here to Learn more		C WP300 Operations	ontact Us Hello,	V Upload Study
								€New	Exports SHOW	
ø	SERIAL #		SERIAL # 🔅	DEVICE TYPE	OFFICE 👙	DEVICE ASSIGNEE	STATUS 🗘	STATUS CHANGE DATE	FIRMWARE VERSIO	N ‡
A	DEVICE TYPE			WatchPAT 300	Ronen Office		Available	08-23-2022 18:12:08		
	Device Type			WatchPAT 300	Ronen Office		Assigned	08-17-2023 14:39:46	4.2.1023	
A	STATUS			WatchPAT 300	korenNEW		Assigned	10-31-2023 13:58:29		
				WatchPAT 300	korenNEW		Out of Service			
Ŷ	OFFICE		_	WatchPAT 300	korenNEW		Assigned	08-22-2022 04:15:30		
	Office						ann 11 18 70			_
=	STATUS CHANGE DA	ATE	_	WatchPAT 300	korenNEW		Assigned	08-22-2022 04:35:43		
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æ	DEVICE ASSIGNEE		_	WatchPAT 300	korenNEW		Available			
100	FIRMWARE VERSIO	N	-	WatchPAT 300	korenNEW		Assigned	07-20-2022 21:11:16		
			-	WatchPAT 300	korenNEW		Assigned	07-20-2022 21:36:47		
			-	WatchPAT 300	korenNEW		Assigned	07-20-2022 23:25:02		
			-	WatchPAT 300	korenNEW	-	Assigned	08-22-2022 03:41:32		
	<u>Clear</u> Search		-	WatchPAT 300	korenNEW		Assigned	08-22-2022 06:51:44		

Devices Table Screen

3.22.2 Device Details

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

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

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

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

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

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SERIAL #		ASS	IGNED PATIENT ID			
105904		No				
OFFICE				FIRMWARE VERSION		
-	***	•		4.2.1023		
HISTORY	[(and a second	[1		
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0	09-03-2023	Study	(tonen:23:02-23)			
0	09-03-2023	Study	(ronen-23-02-23)			

Devices Table Screen

3.23 Managing Referring Physician

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

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

3.23.1 Referring Physicians Table

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

			Discolution	Expect more from your HSAT	Introducing the	Click Hara to	Co	ontact Us Hell	о,	×
CIC	JUCIPAI "zollitamar	Referring	Physicians	- funder	WatchPAT [®] Arrhythmia Detection Feature	Learn more	WP300 Operations	名 New Patient	(†) Upload S	Study
	Find	8 «					⊕ New	Exports SH	low 25 🗸	8
ø	LAST NAME		NAME \$		OFFICE \Leftrightarrow	STATUS \$	SPECIALTY 🗢		LICENSE 🗘	
				•		Active	<u>سنيند ت</u>			
8	FIRST NAME					Active				
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	Select a value					Active				
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	Search									

Referring Physician Table Screen

3.23.2 Referring Physician Details

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

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

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

5,					
PREFIX	FIRST NAME			MIDDLE INITIAL	
Dr. v	Sam			J	
* LAST NAME		SUFFIX		JOB TITLE	
Shoval		MD	~		
* OFFICE					
office					\sim
EMAIL		* ACTIVE	SPE	CIALTY	
		\checkmark	C	Cardiologist	~
NPI / LICENSE		INS	TITUTE		
1234567890123					
ADDITIONAL PHONE NUM	BER	МО	BILE PHO	NE	

Referring Physician Details Screen

3.24 Managing Lists

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

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

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

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

ZOLL. itamar

Clou	udPAT® By itamar	Managed Lists	3		Helk	√ Dipload Study
	Find		List of Managed Lists		New EXPORT TO CSV SHOW 25	
	LIST TYPE		NAME ¢	OFFICE \Diamond	TYPE 🌣	
≌			United Health		INSURANCE	
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	Office		Statins		MEDICATION	
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S.	VIEW GLOBAL		Sleep apnea		DISEASE	
:=	With Global	~	Schizophrenia		DISEASE	
	Clear	Search	ronen status	office	CUSTOM_STATUS	
			ronen ins	office	INSURANCE	
			RLS		DISEASE	
			PLMD		DISEASE	
			Peptic ulcer		DISEASE	
			Patient Pay		INSURANCE	
			Oxygen therapy		MEDICATION	
			Other Private		INSURANCE	
			Osteoporosis		DISEASE	
			office1_medication1	office	MEDICATION	
			office1_disease1	office	DISEASE	

Managed Lists

3.25 SleePATh Communications Tab

If a patient belongs to an office which has enabled "Active Communications", an additional tab will be added to the patient card, called "Communication", under "SleePATh" tab.

This service sends texts to the patient, which are daily reminders, reminding the patient to complete the study.



3.26 Using CloudPAT as a Therapy Provider

The Therapy Provider is a role designed for sleep physicians for treating patients.

Users who are defined as Therapy Providers will have an additional menu item called "Therapies" which leads to the therapies table.

The therapies table contains all the patients that were assigned to the therapy provider, and their studies have been locked.

There, the therapy provider can choose to accept the therapy by clicking the "Accept Therapy" button. Clicking on the "Accept Therapy" button, or clicking on the patient's row again will navigate into the therapy screen.



Therapies Table

4 Using CloudPAT as an Interpreting Physician

4.1 Main Access Screen

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

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

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

Clou	dPAT [®] By itamar	Studie	es												Co	intact Us	Hello	*
														EXPO				
B	PATIENT ID			-	PATIENT ID	PATIENT :	OFFICE 0	REFERRING PHYSICIAN	a STUDY DATE	STUDY LOAD DATE	VALID SLEEP TIME	ahi o	ODI 0	WAITING FOR 0				
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옲				6	1234567890123456	123456789012345. 123456789012345	office		04-21-2021	04-21-2021	4 hrs, 58 min	24.10 (3%)	16.10 (4%)	482			D	
	LAST NAME			₿	ronen001		office		01-02-2020	04-11-2021	4 hrs. 58 min	23.90 (3%)	16.10 (4%)				Ø	
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	Al									<	0 >							
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	STUDY LOAD DA	n - 5																
	INCLUDE POOL S	TUDIES																
	Clear	Se	arch															

Interpreting Physician's Home Screen

4.1.1 Studies Assigned to the Interpreter

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

CloudPAT supports an option to send Interpreting physicians a summary of their pending studies through a daily email.



Note

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

4.1.2 Reviewing a Study

When you filter for "Unlocked" status, select the study you want, and the screen will display the study details for you to review. Here are the main actions that can be selected from this screen:

- 1. Interpretation Details tab including:
- Input fields for the interpreter to fill in the Diagnosis and Recommendations. You may use the Diagnosis and Recommendations templates if you wish to insert an already pre-defined paragraph in the corresponding section. Multiple templates can be used.
- Errors/Warnings in case of errors or warnings returned from the analysis, a message will appear in the Errors/Warnings box.
- Change Min Desat for AHI/RDI change the value used for analysis. Change becomes effective only after saving. If this occurs, a message will display indicating that rerun analysis is required for the new setting. Click on "Rerun Analysis" to see the results from the new threshold.
- NPI you can add the NPI to the report if have one. If you have more than one NPI, select the right NPI number that matches the office details.
- Add attachments like prescriptions or any other files to the report. If you add PDF files, they will be added to the report itself. Any other files will be available to download in the office. To attach a file – enter a description and select the file to be uploaded using the upload area. The user can also remove or download the attached files by clicking on the respective buttons.
- Interpretation History section listing interpretation related operations done on the study
- Interpretation Comments section facilitates communication between interpreting physicians and pool members about the study.
- Interpreting Physicians and Sleep Physicians can delete their Interpretation Comments.
- A Sleep Physician can navigate from the Study Details screen back to the respective Patient Details screen by using a button called "Go to the Patient Record".
- It is possible for the interpreting physician to add a statement to the sleep report that the study was manually scored / analyzed alongside with the interpreting physician name by clicking on a designated button.
- 2. Therapy tab:
- Allows the interpreter to produce a Therapy Prescription which when enabled retrieves patient information which can be edited and prescription items selected from the list.
- Once the Generate Script button is clicked, an auto-generated PDF file shall be created and displayed, including the submitted information to be attached to the report during the Save and Lock operation.
- The supported therapies are CPAP and Oral Appliance.

Cloud _{By} i	PAT [®] itamar <u>Studies</u> \Pa	atient				Contact Us
	Interpretation Details Therapy	Patient Details Office Details Interpreter	Attached Files	O Rer	un Analysis	C Open in Viewer
8	Enable Script Prescription					Create Script
	Patient Information		Prescription		Interpreting Phys	ician Details
	FIRST NAME*		DIAGNOSIS*		PHYSICIAN NAME*	MD Hansis
	LAST NAME*		LENGTH OF PRESCRIPTION*		NPI*	
	PATIENT ID	ronen400	TREATMENT TYPE*		LICENSE	
	GENDER		PATIENT EDUCATION		ADDRESS	
	DATE OF BIRTH	MM-DD-YYYY			STATE	
	BMI		CLINICAL NOTES		CITY	
	STOP BANG SCORE				ZIP CODE	
	PATIENT MOBILE PHONE		HUMIDIFIER*		PHONE	
	NECK CIRC. (CM)		CPAP MASK / INTERFACE / DELIVERY SYSTEM*		FAX	
			PRESSURE RA Cancel 3 Save	& Lock		

Therapy Tab

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

کر Note

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

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

Note

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

ID_[patient ID]_

SD_[study Date & time]_

events_analysis_user.zpt

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

- 10. Save saves your input without locking the report.
- 11. Save and Lock Report When you are satisfied with your interpretation select the "Save and Lock Report" button. At this point the study report will be automatically digitally signed with your name, tagged as completed and be available for the Physician's review.
- 12. In order to comply with part 11 regulations, an office may require a re-entry of the password upon locking the study.



Note

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

- 13. Unlock a Report interpreting physicians can unlock their own locked studies by clicking on the Lock icon on the List of Studies Screen. An Audit Trail Record will be added to the study indicating the user and when the previously locked report will be added.
- 14. Notifications you may receive notifications which will be displayed on the screen in the following cases:
- If a script was requested by the office, a "Study requires a script" notification will be displayed on the screen. Also, a reminder will appear before locking the report.
- If the office changed one of the following analysis parameters: Minimum % Desaturation for AHI/RDI calculation, Pacemaker, Gender, Date of Birth, or a rerun of the analysis is required to update the analysis result. In case rerun was not initiated by the office, a notification that rerun is required will be displayed on the screen and the "Rerun Analysis" button will appear. You won't be able to lock the report before re-running the analysis.
- 15. Summarized PDF report CloudPAT enables to produce a patient letter based on the PDF report through the WP Interface. This enables a button in Studies and Initializations called "Patient Letter", and clicking on it will open a more summarized version of the PDF report. this feature is enabled only for offices that turned it on through Office Settings.
- 16. Re-generate report after patient changes CloudPAT enables to re-generate the Sleep Report through the WP Interface in cases where edits were made to the patient details (e.g., height, weight, age, name, DOB etc.) with no need to re-run the analysis.

Fonen007	NAME	orniz Ronen Hansis	GENDER	DAIT OF	BARTH	A62 -					
RETERENE PRESEN shimponn	COUNTRY CODE	NOBLE PROM	EMAR								
Interpretation Details Therapy	Patient Details Office Details	Interpreter Attached Files Diseases & M	edications	0.4	na destan	© Proview	Den in Viewer	Download Study			
ERROR / WARNINGS		MIN DESAT FOR AHI	3%	MIN DESAT FO	R ODI 4%		NPI Philo	91			
DIAGNOSIS TEMPLATE				RECOMMENDATION TEMPLATE							
	orig diag			RECOMMENDATIONS	orig reco						
DIAGNOSIS								9			
DIAGNOSIS			9/5000				INTERPRETATION COMMENTS				
DIAGNOSIS	RY		.9/5000	INTERPRETATION COMM	ENTS						

Interpretation Details Screen

4.1.3 Viewing a Completed Study

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

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

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

Cloud By	PAT [®] <u>Studies</u> \ Patient	t							Contact Us H	ello,
	PATIENT ID ronen100	NAME	office	GENDER	DATE OF	BIRTH	AG	ε		
	REFERRING PHYSICIAN	COUNTRY CODE	MOBILE PHONE	EMAIL						
\$					RELEASE O Rerun		View Report	Open in Viewer	ن Download Stud	y Files
*	Interpretation Details Therapy Patien	nt Details Office Details Interpr	reter Attached Files							
	POOL STATUS ronen it is for you to	o take								
	ERROR / WARNINGS		MIN DESAT FOR AHI	3% ~	MIN DESAT FO	R ODI	4% ×	NPI	123344	
	DIAGNOSIS TEMPLATE				RECOMMENDATION TEMPLATE					
		ronen 15:30				ronen	15:00			
	DIAGNOSIS				RECOMMENDATIONS					
				11/2500					1	1/2500
	INTERPRETATION HISTORY					INTERPRETATION COMMENTS				
	UPDATE DATE USER ACTION	INTERPRETER / POOL			UPDATE DATE	USER		MESSAGE		
	04-04-2022 04:59:35	ronen pool								

A Completed Study Screen

4.2 Manage Templates & NPIs

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

Clo	udPAT Byitamar	Interpreter Setting	gs				Hello	¢.
	Find	«	List of Settings			New EXPORTTO CIV	arear 25 v	89
	1175		NAME	TYPE ‡	TEXT 2	ACTIVE ‡		-
E			Phil001	NPI		Ves		
	NAME		Reco	RECOMMENDATION	Reco	Yes		
	Active Series 2 works	.v Search	CHAP Recommendation	RECOMMENDATION	If a patient is not able or willing to undergo CIT-1, the short setm (1-4 month) hermacotherapy, complementary and integrative health CR4 treatment or bolic, and be considered. Although the history and evaluation for considered a bibrough help history and evaluation for considered a bibrough help interventions are also encouraged. If pharmacotherapy is recommended, knopharmacole interventions are also encouraged. If pharmacotherapy is historical good on domain or pharmacotherapy is reconstructed. (MRAc) can be considered, though the secons list for complex layer heated bahaviors with the NBK4 shoul also be discussed.	s Hoal _{Ves}		
			depression	DIAGNOSIS	As a medical diagnosis, depression denotes a prolonge state of dejection, emotional emptiness, self-recriminati lack of energy, apathy, anxiety, sleep disorders, and lack appetite.	d on, Yes c of		
			Get CPAP	RECOMMENDATION	The following is the CPAP script:	Yes		
			90210	NPI		Ves		
			ronen diag	DIAGNOSIS	ronen diag details	Yes		
					< 💽 > Total 7			



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 several of predefined templates for Clinical diagnoses and for Recommendations which can be used with a click of a button 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 the New Setting Details screen.

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

Settings Details		×
* Туре	* Name	Active
Diagnosis v	Mild	\sim \bigcirc
Text		
This is a template for a mild diagnosis		
		39 / 2500
Back		Save

New Setting Details Screen

Settings Details		>
* Туре	* Name	Active
Diagnosis	diag_ronen	$\checkmark \bigcirc$
Text		
No care is needed.		
		18 / 2500
Back		Save

Existing Template Screen

4.2.2 NPIs

You can manage a list of NPI to be used later in the report by selecting Type = NPI in the search fields. Click on "Search" to see the list of all NPIs currently in the system. You can also enter text in the NPI field to limit the search results. Clicking on an existing NPI will display the NPI's details screen, where you can edit the NPI number and save the changes.

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

4.2.3 Signature

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

			Hello,
	~	New EXPORTTO CSV SHOW 25	Change Password
User Settings	^	ACTIVE \$	G Logout
UPLOAD SIGNATURE IMAGE		Yes	Version 3.0.0 Interpreter Chrome, Firefox, Edge, IE11
		Ves	
		r willing to undergo CBT-I, then short-term otherapy, complementary and integrative , or both can be considered.	
Image file can be one of the following types BMP, JPEG, JPG, GIF, TIFF, PNG and max 600px wide		onsidered, a thorough sleep history and	
Cancel Save		fications for pharmacotherapy are irmacological interventions are also Yes	
' nonbenzedi	azepine be	nitiated, Iow-dose doxepin or nzodiazepine-recentor adonists (NBRAs) can	

Interpreter Signature Screen

4.2.4 States Eligibility

Interpreting Physicians can add the list of states in which they are board certified by selecting the States Eligibility from the User menu.

4.3 Using CloudPAT as an Interpreting Physician Assistant

The Interpreting Physician Assistant is able to see the Interpreting Physician's data as read-only, and is a role meant to help the interpreting physician staff administration.

The Interpreting Physician Assistant has access to read the following:

- Studies Table
- Study Details
- Templates and NPIs Table
- Setting Details
- Pool Managers Table
- Pool Details

The Interpreting Physician Assistant has the following regulations/definitions:

The login procedure is identical to other roles. If the Interpreting Physician Assistant user is not connected to any interpreting physician – the user will not be able to log in.

The Interpreting Physician Assistant cannot create new patients or upload a study.

The Interpreting Physician Assistant receives the same emails (direct and pool related, all as bcc) as their parent but the link will lead to a read-only record.

The Interpreting Physician Assistant will see all the studies that belong to the parent – if studies are added to the parent the Interpreting Physician Assistant will see them, and if a study is taken away from the parent, The Interpreting Physician Assistant will not be able to see it.

One Interpreting Physician user can have multiple assistants connected to it.

The Interpreting Physician Assistant user role can be linked to numerous parents (Interpreting Physicians). This can be done via the "Select Parent" dropdown menu, which supports multi selection.

5 Appendices

This chapter includes the following appendices:

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

Appendix A. License Agreement

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

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

Appendix B. Regulatory Representative

Itamar Medical's authorized regulatory representative is:



Arazy Group GmbH

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