CloudPAT™

CloudPAT™ Featured with SleePATh™ Module

Addendum to Web Software Operation Manual
for Software Version 2.8
Itamar Medical REF OM2200001

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

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1	July 2018	Release	All	All
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3	Jan 2019	Note re: filling compliance usage gaps CPAP Compliance, <u>Under 30 Days</u>	3 5.5	8 17
4	July 2019	Integration with ResMed Message to non-complying patients Usability shortcuts in funnel License agreement	4.1 5.7 5.5 Appendix C	9 19 17 26

	Note
	This Operation Manual is an Addendum to Web Software Operation Manual OM2200000 describing additional functionality introduced with the release of CloudPAT™ Software Version 2.8.
	Web Software Operation Manual OM2200000 is applicable unless changes are specified in this Addendum.

1   Introduction to CloudPAT™ Version 2.8

1.1   Intended Use of WatchPAT™ devices

There's no change to the intended use of WatchPAT™ devices vs OM2200000.

1.2   zzzPAT S/W – Definition

There's no change to zzzPAT S/W – Definition vs OM2200000.

1.3   CloudPAT S/W – Definition

There's no change to CloudPAT S/W – Definition vs OM2200000.

1.4   CloudPAT Version 2.8 Overview

Refer to the basic functionality of CloudPAT Version 2.8 to OM2200000.

The CloudPAT horizon is expanded beyond a tool for conducting WatchPAT Sleep Study and now includes **monitoring of treatment compliance and effectiveness by integrating information from CPAP provider**.

	Note
	The expanded capabilities are Available only for patients with CPAP devices given by specific DME providers.

The following CloudPAT version 2.8 expanded capabilities are available:

   a. Integration with ResMed Compliance Data Server
   b. Message to non-complying patients
   c. Usability shortcuts in Enhanced Patient Care Pathway Funnel Widget

Web Software Operation Manual OM2200000 together with this manual provides the information necessary for routine use of CloudPAT Version 2.8 software.

1.5 Terminology

- **API -** Application Programming Interface
- **PAP Compliance Data Server –** Data server system that collects usage & other measurements from PAP devices and provides API for obtaining summary of compliance data for specific identified patient
- **PAP Compliance Data -** Usage & other measurements from PAP devices, including hours of usage per night and Residual AHI per night.
- **PAP -** Positive Airway Pressure
- **CPAP -** Continuous Positive Airway Pressure
- **Residual AHI -** Apnea Hypopnea Index as calculated by the PAP device/provider.

1.6 Minimum requirements

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

2 SleePATh™ Module Overview

SleePATh Module is a Patient Care Pathway dashboard enabling physicians to track their patients' sleep apnea, CPAP compliance and treatment effectiveness*. Physician can easily focus on the patients group of interest based on their care pathway status.

With the introduction of SleePATh™ Module, CloudPAT integrates Check-in procedure and STOP-BANG screening questionnaires, initiation of WatchPAT sleep study, sleep data management including study analysis, obtaining PAP daily usage compliance data and daily AHI score from PAP device for monitoring treatment effectiveness.

Need Sleep Study	Data Acquisition	Study Analysis	PAP Compliance	Treatment Effectiveness
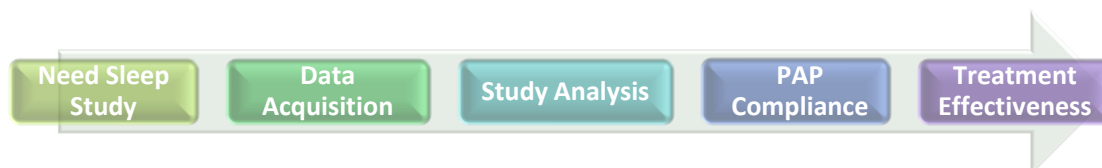
Refer to section 2 SleePATh™ Module Overview for detailed description.

Available only for patients with CPAP devices given by specific DME providers.

3 Overview of PAP Compliance Data in CloudPAT*

CloudPAT is configured to interface with PAP Compliance data servers for obtaining patients' daily PAP Compliance Data, including usage (h) per night and residual AHI per night.

To obtain the patients' daily PAP Compliance Data, first the patient has to be identified by the PAP Compliance data servers (see 4.1).
CloudPAT is obtaining PAP compliance data **daily** for all identified patients actively using PAP device. Subsection 4.2 describes how to identify if patient is actively using PAP device.

Patient's daily PAP device usage and residual AHI (provided by PAP device) are displayed in CPAP Compliance section in Patient Details screen (see 4.2.4).

Patients' PAP Compliance data is also used for generating the data for the SleePATh dashboard – Compliance Chart and Patient Care Pathway funnel chart (see 5.4 Patient Care Pathway Funnel Chart and 5.6 Compliance Chart*).

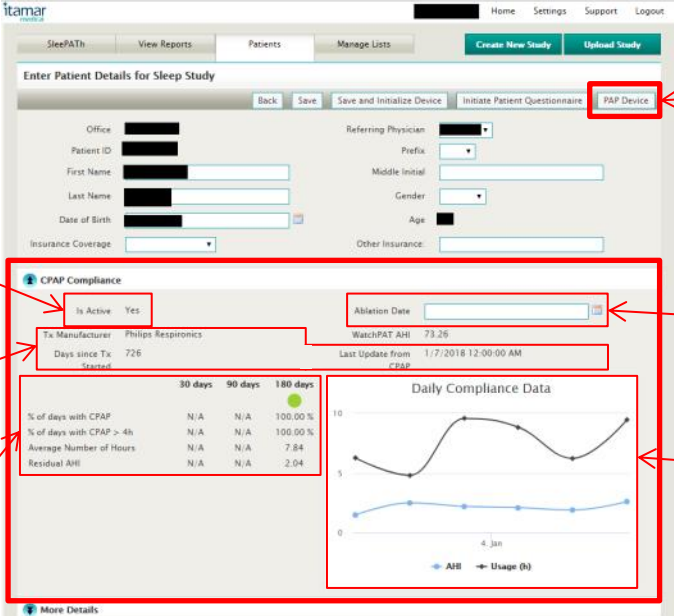|	**Note**
	PAP Compliance data will be available one day after patient's identification by PAP Compliance data servers.

	Note
	Gaps in daily usage compliance data are considered as zero (0) minutes of usage.
	Residual AHI is only calculated from daily data received from CPAP Compliance Data Server

* Available only for patients with CPAP devices given by specific DME providers.

4 Patient Detailed Compliance Data*

The following enhancements were implemented to Patient Details Window to enable the connection between patients and their PAP data:

1) PAP Device Button
2) CPAP Compliance Section

Figure 1 - CPAP Compliance in Patient Details Window

* Available only for patients with CPAP devices given by specific DME providers.

4.1 PAP Device Button

CloudPAT patients must be identified by the PAP Provider server prior to reception of their CPAP data.

	Note
	Patients with ResMed CPAP Devices are automatically identified (within 1 day) once their matching details are entered in both CloudPAT and ResMed data server.

Clicking on the PAP Device button opens the PAP Device window, automatically filling-in the Last Name, First Name and Date of Birth as entered to the CloudPAT system.
Select the Manufacturer from the pull down list.

	Note
	If ResMed AirView is selected, the device serial number is mandatory.

Clicking on Submit button, CloudPAT system sends the patient details to the PAP Compliance server. If patient is uniquely identified by the PAP Compliance Server, the Device Serial Number of the PAP device allocated to the patient is returned and included in Patient Details. The window is automatically closed.
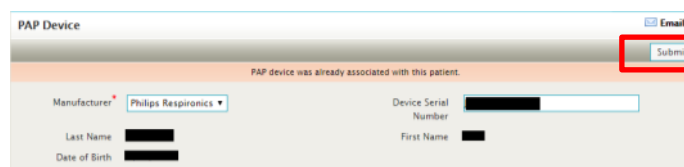

Figure 2 - PAP Device Window

When the PAP device Window is reopened for the patient, after successfully identified by the PAP Compliance server, the Device Serial Number is displayed, together with the message that the PAP device was already associated with this patient.

	Note
	It is strongly recommended to confirm that the PAP Device Serial Number of the patient matches the number displayed in the window.
	If mismatch found, report to your administrator.

If patient was not identified, or uniquely identified, by the PAP Compliance Sever, the system returns with error message, and PAP data for this patient is not available.

4.2 Patient Compliance section

The Patient Compliance section includes the following subsections:
   a. Is Active indicator
   b. PAP Device information
   c. Ablation Date field
   d. Compliance statistics table
   e. Daily Compliance chart

The Patient Compliance section is available only after the patient is identified by the PAP Provider server and PAP data is received for the patient.

4.2.1 Is Active indicator

Is Active field provides indication that user is actively using CPAP based on the time from the last CPAP update. When patient enters Inactive state, system stops polling for compliance data.

	Note
	When patient is In Active = No, and regained CPAP usage, the operator shall re-establish retrieval of compliance data clicking on PAP Device button and submit connection request to the server.

4.2.2 PAP Device Information

This subsection provides information on the CPAP Device Manufacturer, number of days since device has been set up for patient, and date/time of last update from CPAP.

4.2.3 Ablation Date field

User can update the patient's ablation date. The ablation date will be marked on graph and used as a period filter of the dashboard.

4.2.4 Compliance statistics table

After patient is associated with PAP device, the system retrieves the patient's compliance data. The Compliance section provides the following specific CPAP compliance data and effectiveness of the therapy over last 30, 60 and 180 days:

1) **% of days with CPAP:** Days for which CPAP use was recorded
2) **% of days with CPAP > 4h:** CPAP use was recorded for more than four hours
3) **Average Number of Hours:** Average number of hours only on days CPAP use was recorded (including nights of no use)
4) **Residual AHI:** Average AHI, only on days CPAP use was recorded

Compliance color coded icon is provided for each period:

- RED- Less than four hours per night of average use
- ORANGE - Average AHI is over 10 and is at least half of the AHI observed in the WatchPAT study
- YELLOW - Average AHI is over 10 but is less than half of the AHI observed in the WatchPAT study
- GREEN - Average AHI is under 10

4.2.5 Daily Compliance Chart

Patient Daily Compliance Data graph shows usage behavior and treatment effectiveness displaying CPAP hours of use and AHI per night over the last 180 days. Operator can zoom in marking the period of interest, and zoom out clicking on Reset Zoom button in the graph area.
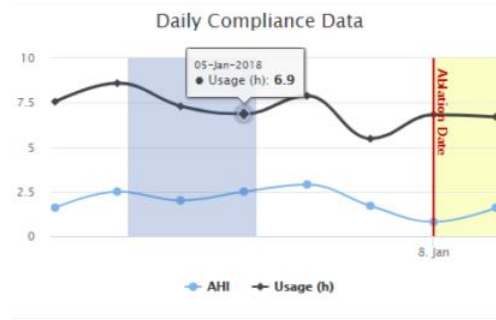
Figure 3 - Compliance Graph Tooltip, period of interest and Ablation Date mark

5 SleePATh™ Module

SleePATh Module is a Patient Care Pathway dashboard enabling physicians and provide office admins to track their patients' sleep apnea, CPAP compliance and treatment effectiveness. Physician can easily focus on the patients group of interest based on their care pathway status. Refer to Figure 4 for typical SleePATh dashboard layout.
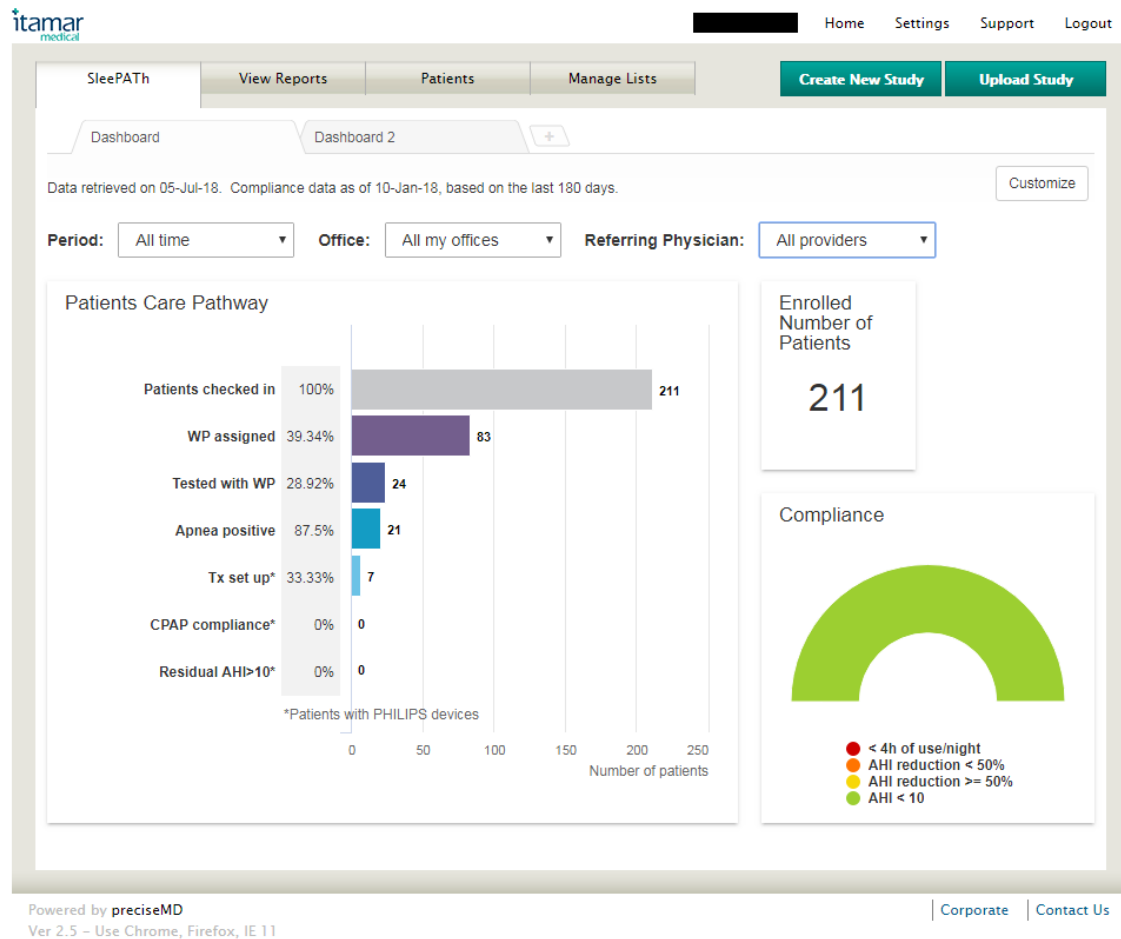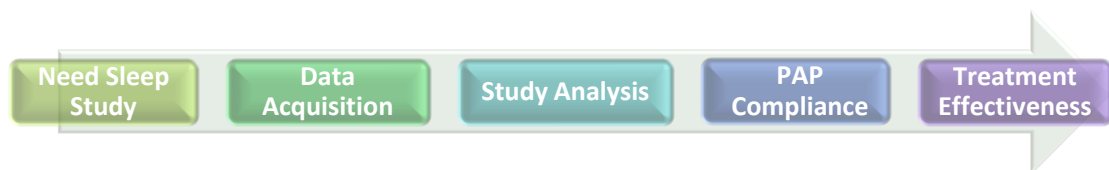

Figure 4 - Typical SleePATh Dashboard

With the introduction of SleePATh™ Module, CloudPAT now covers 5 stages of Sleep Patient Care Pathway:

 a) Patient Checked-in
 b) Initiation of WatchPAT sleep study
 c) Sleep data upload and study analysis
 d) Monitor PAP daily usage compliance data
 e) Monitor daily AHI score from PAP device for monitoring treatment effectiveness.

The SleePATh dashboard is customizable, and can include the following widgets:
1) Patient Care Pathway Funnel
2) Compliance Chart*
3) Number of Enrolled Patients

*Available only for patients with CPAP devices given by specific DME providers. Compliance is assessed after 30 days since PAP device setup.*

	Note
	Offices that do not have the connection to the compliance module should not add the Compliance Cart to their dashboard although is included in the available dashboard widgets as chart will always be empty.

Users can create their own dashboards.

5.1 Creating and modifying dashboard

To create a new dashboard, click on the "+" tab, and assign a name to the dashboard.
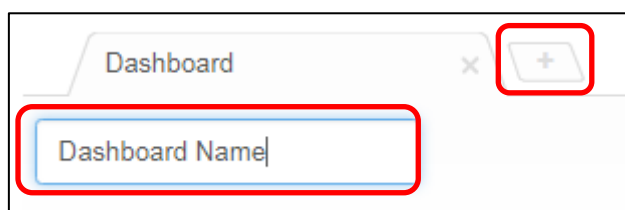
Clicking on *Add widget* button, a popup window is displayed, allowing the selection of a widget. Clicking on a widget will place it on the dashboard, and user can arrange the layout of the dashboard screen by dragging it to desired location.
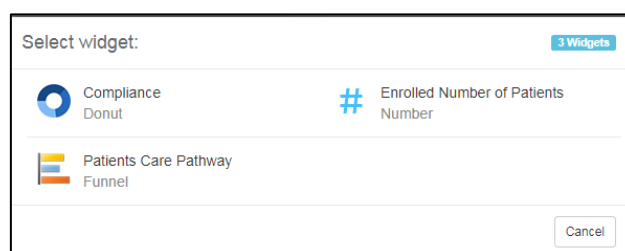

Figure 5 - Dashboard widgets selection popup

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

To switch between dashboard, click on the desired tab.

5.2 Data included in dashboard

The dashboard provides information on the data which was used to create the statistics.
Data retrieved on: CloudPAT's system time.
Compliance data as of*: the most recent date compliance data was obtained.
Based on the last 30 **days***: days used for the analysis of PAP compliance and treatment effectiveness.

Data retrieved on 01-Jul-18. Compliance data as of 09-Jan-18, based on the last 30 days.
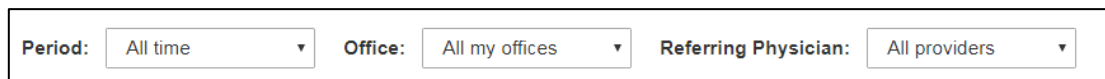
Figure 6 - Dates of data used for dashboard display

* Currently available only for patients with CPAP devices given by specific DME providers. Compliance is assessed after 30 days since PAP device setup.

5.3 Define patient group

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

Figure 7 - Dashboard patient population group filter

5.4 Patient Care Pathway Funnel Chart

Patient Care Pathway Funnel (see Figure 8) is a bar chart that provides statistics on the selected patient group, along seven stages starting from their check-in towards assessment of their treatment effectiveness.
For each stage along the pathway, the total number of patients in this stage is provided as well as the percentage of them from the previous stage.
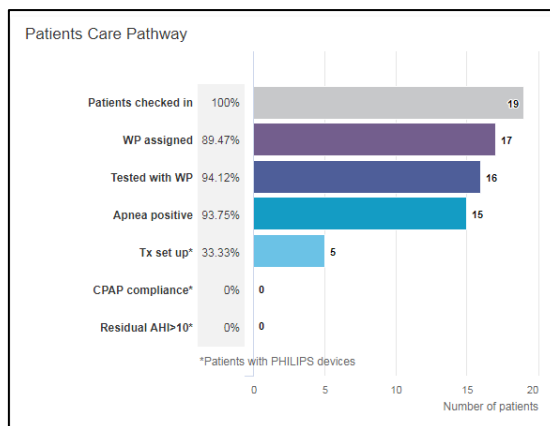
Figure 8 - Patients Care Pathway Funnel Chart

The following stages are displayed in the funnel

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

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

3) **Tested with WP**: Number of patient successfully completed the WatchPAT Study and successfully analyzed, and their percentage out of the patients assigned with WatchPAT.

4) **Apnea positive**: Number of patient that were positively diagnosed with sleep apnea, i.e. AHI above threshold[1], and their percentage of all WP tested patients.

5) **Tx Setup***: Number of patients provided with CPAP devices, and their percentage out of the patients diagnosed with Sleep Apnea.

6) **CPAP compliance*:** Number of patients that have slept with CPAP at least 4 hours per night over at least 21 out of the last 30 days or with average use of 4 hour per night over the last 30 days and their and percentage out of number of patients provided with CPAP device.

7) **Residual AHI>10 *:** Number of patients with High Residual AHI (reported by the CPAP) and their percentage out of the patients maintaining CPAP compliance.

   * Only for patients with CPAP devices by specific DME providers are included in the statistics. Compliance is assessed after 30 days since PAP device setup.

If the specific office or all offices that has been chosen to be displayed are not one of the specific DME providers, only the first 4 bars will be displayed, and the compliance stages will be hidden.

Clicking on any of the bars in the Patient Care Pathway bar chart will display a list of patients included in the chosen group, based on the selected criteria (see 5.3 Define patient group). Clicking on a patient within the list displays the Patient Details window.

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

5.5 Enhanced Patient Care Pathway Funnel Chart

The Enhanced Patient Care Pathway Funnel is a stacked bar chart that provides statistics on the selected patient group, along four stages starting from their check-in towards assessment of their Sleep Apnea (see Figure 9).

For each stage along the pathway, the total number of patients in this stage is provided as well as the percentage of them from the previous stage. Each stage is built from 1-3 subsections, main/first section and additional 1-3 complementary sections, that all together sum to the number of patients in the main/first section of the previous stage. The first (main) section is assigned with unique color, while the complementary sections are in gray levels.
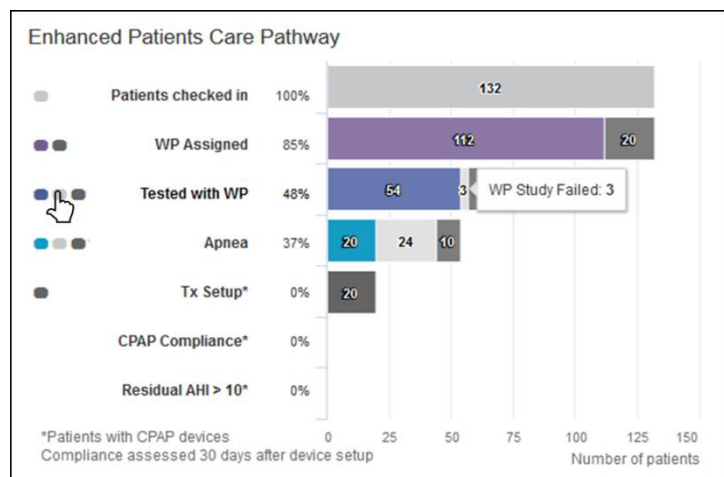

Figure 9 - Enhanced Patient Care Pathway Chart

The following stages are displayed in the funnel

1) **Patients checked in**: Number of patients in selected group (percentage is always 100%).
2) **WP assigned**:
    a. WP assigned (main): Patients assigned with initialized WatchPAT device, including patients returned the device and WP study was uploaded to CloudPAT but yet not analyzed.
    b. WP not assigned: Patients yet not assigned with WatchPAT device.
3) **Tested with WP**:
    a. Tested with WP (main): Patients successfully completed the WatchPAT Study and successfully analyzed.
    b. WP Study Failed: Patients that their WP study was uploaded to CloudPAT but no AHI was calculated.
    c. Not tested yet: Patients that their WP study yet not uploaded to CloudPAT.
4) **Apnea**:
    a. Apnea Positive (main): Patients that were positively diagnosed with sleep apnea, i.e. AHI above the office-defined threshold.
    b. Apnea Negative: Patients that their AHI is below the threshold.
    c. Report not ready[2]: Patients that their study was successfully uploaded to CloudPAT but their report is yet not ready.
5) **Tx Setup*:**

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

a. <u>Tx Setup</u>: Number of patients provided with CPAP devices, and their percentage out of the patients diagnosed with Sleep Apnea.

b. <u>Tx not set up</u>: Patients that yet not provided with CPAP device.

6) **CPAP compliance*:**

a. <u>Complying</u>: Number of patients that have slept with CPAP at least 4 hours per night over at least 21 out of the last 30 days or with average use of 4 hour per night over the last 30 days and their and percentage out of number of patients provided with CPAP device.

b. <u>Inactive</u>: Patients that there is no data on device usage for more than 30 days.

c. <u>Not Complying</u>: Number of patients that have **not** slept with CPAP at least 4 hours per night over at least 21 out of the last 30 days or with average use of 4 hour per night over the last 30 days and their and percentage out of number of patients provided with CPAP device.

d. <u>Under 30 Days</u>: Patients that have been on CPAP device for fewer than 30 days.

7) **Residual AHI*:**

a. <u>Residual AHI>10</u>**:** Number of patients with High Residual AHI (reported by the CPAP) and their percentage out of the patients maintaining CPAP compliance.

b. <u>Residual AHI<=10</u>

* Only for patients with CPAP devices by specific DME providers are included in the statistics. Compliance is assessed only after 30 days since PAP device setup.

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

Shortcut icons are located to the left of each bar title to make selecting small sections easier.

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

5.6 Compliance Chart*

The Compliance half-pie chart displays the overall compliance and treatment effectiveness for the selected group of patients.

	Note
	*The Compliance Chart is relevant **only** for specific DME providers. If these DME provides are not among the offices assigned to the user, the Compliance Chart will be empty. Therefore, it is not recommended to add to the dashboard.*

1) **< 4h of use/night**: None-complying patients that are failing to use the PAP for 4h/night on average. The color of the half pie segment for this category is Red (●).
2) **AHI reduction < 50%:** Patients with none effective treatment, that are using the PAP for more than 4h/night on average, but their Residual AHI (reported by the PAP device) is not reduced to 50% of what it was diagnosed with WatchPAT. The color of the half pie segment for this category is Orange (●).
3) **AHI reduction >= 50%:** Patients with effective (but not optimal and >= 10) treatment, that are using the PAP device and get their Residual AHI reduced to below 50%, but are still have not reached optimal AHI level. The color of the half pie segment for this category is Yellow (●).
4) **AHI < 10:** Patients with Optimal treatment that are using the PAP device and have reached target Residual AHI levels. The color of the half pie segment for this category is Green (●).

Clicking on any of the half-pie segment displayed in the Compliance chart will display a list of patients included in the chosen group, based on the selected criteria (see 5.3 Define patient group). Clicking on a patient within the list displays the Patient Details window.

* Available only for patients with CPAP devices given by specific DME providers.

5.7 Message to non-complying patients

CloudPAT can be used to communicate with non-complying patients. CloudPAT defines non-complying as either inactive (no usage data for more than 30d) or insufficient usage (<4h/day).
Email message, based on an **office-defined template**, can be manually sent to a specific patient from the patient details form, or to a selected list of patients, included in a filtered list.
Office may define the **maximum frequency** of such notifications.
Patients are by default **opt-out**, to avoid getting these messages.

	Note
	Please contact CloudPAT Support at CloudSupport@itamar-medical.com *for creating message template and defining the maximum frequency of messages.*

5.7.1   Patient Details Window

Patient Details Window now includes a checkbox to prevent non-compliance notification messages from being sent.
By default, this checkbox is selected and patient will not get notifications.
The patient's email address must be entered for them to receive notifications.

5.7.2   Message from Patient Window

Patient window includes a new button, "Send Non-Compliance Email" that is displayed if the patient is Inactive or doesn't comply with CPAP usage over the last 30d.

If a message was sent to a patient within the specified frequency time frame, the following message will be displayed:

Email was sent on May 16, 2019, fewer than 7 days ago.

5.7.3   Message from Filtered List of Patients Window

The Non-Compliance email can be sent to a list of patients by clicking on -> "Inactive" or "Not complying" segments of the CPAP Compliance bar in the Enhanced Patient Care Pathway Funnel Chart or clicking "< 4h of use/night" segment in the Compliance half-pie chart. (See Figure 10)

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The Button is part of the Refined Search section. List can be refined applying additional filters.

Figure 10 - Send Non-Compliance Email button in Refined Search in Filtered Patient Group

Appendix A: Troubleshooting

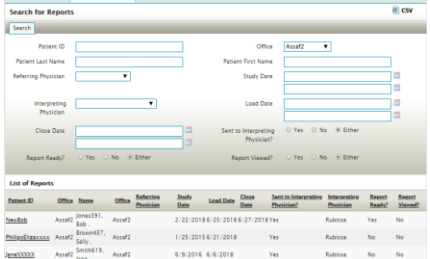|	**Note**
	Make sure you are using Chrome, Firefox, Edge or Internet Explorer 11 or above as your browser.

Trouble	Possible Cause	Solution	Error Message
Patient Details screen			
PAP Device not found for patient	CloudPAT Patient details not matching patient's details on Compliance Server	Change patient's details entered in CloudPAT to match patient's details on Compliance Server	No patient has been found. Please verify the information.
PAP Device not found for patient	Partial CloudPAT Patient details	Update patient's details on CloudPAT to include First and Last name, Date of Birth or PAP device serial number.	Please enter full name and date of birth, or the device serial number.
PAP Device not found for patient	Multiple patients on Compliance Server match CloudPAT Patient details	Include PAP device serial number Update patient's details PAP device serial number.	Multiple patients have been found. Please refine the search fields.
Patient's Compliance	Patient state is In Active	Click on PAP device and submit to restart data retrieval for the	

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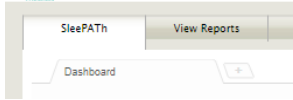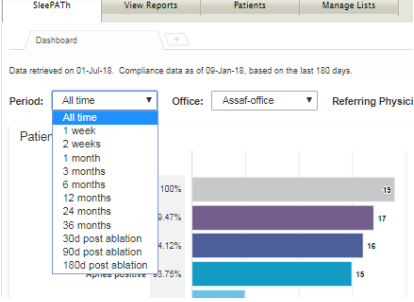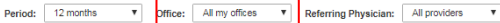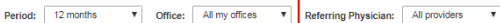| Trouble	Possible Cause	Solution	Error Message
data not updated		patient.	
PAP Device button not available	Patient has no study	Upload WP study	
PAP Device button not available	Office not configured to be Philips or ResMed DME	Contact your Administrator	
CPAP data not presented for patient	PAP Device not associated to patient	Click PAP Device button.	
CPAP data not presented for patient	CPAP Data yet not obtained from PAP server	Wait 1 day to allow daily batch retrieval of the data.	
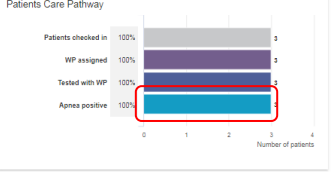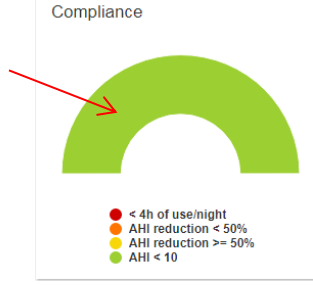
Appendix B: New CloudPAT Assistant "cheat sheets"

Provider: Obtain Patient PAP Compliance Data*

		Step	Action(s)	Comment
Locate Patient	1.	**Identify the desired patient**	• Search the patient, highlight the patient and click to open Patient Details screen.	
	2.	**Verify that PAP data can be obtained**	Verify that the patient has at least one WP Study.	
PAP Device	3.	**Open PAP Device window**	Click on PAP Device button	
Connect	4.	**Search patient in PAP Compliance server**	• Verify that all patient details are displayed on the window • Submit button.	

Available only for patients with CPAP devices given by specific DME providers.

<u>Provider</u>: Create list of patients' group from SleePATh dashboard

		Step	Action(s)	Comment
Dashboard	1.	**Open dashboard**	Click on SleePATh tab in the main menu.	
Period	2.	**Select the period of interest**	Click on the Period pull down menu and select desired period.	
Office	3.	**Select the Office of interest**	Click on the Office pull down menu and select desired office. *If you have only one office skip this step.	
Physician	4.	**Select the Referring Physician of interest**	Click on the Referring Physician pull down menu and select desired Referring Physician.	
Stage	5.	**Select the state of Patients Care Pathway**	Within the Patients Care Pathway chart, click on the bar graph associated with the desired state in pathway.	
Compliance	6.	**Select the compliance and effectiveness group**	Within the Compliance half-pie chart, click on the segment associated with the desired compliance and effectiveness group.	
List	7.	**Get list of patients**	List of Patients window is opened. Data can be exported to excel clicking on CSV icon.	

Appendix C: License Agreement

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