

Patient Safety Connection Center - Internet Analysis Software

SATSCREEN OXIMETRY REPORTING USER'S MANUAL

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1 Introduction

This document is the user guide for the Patient Safety's Connection Center and Internet Analysis software, a software device designed by Patient Safety, Inc.

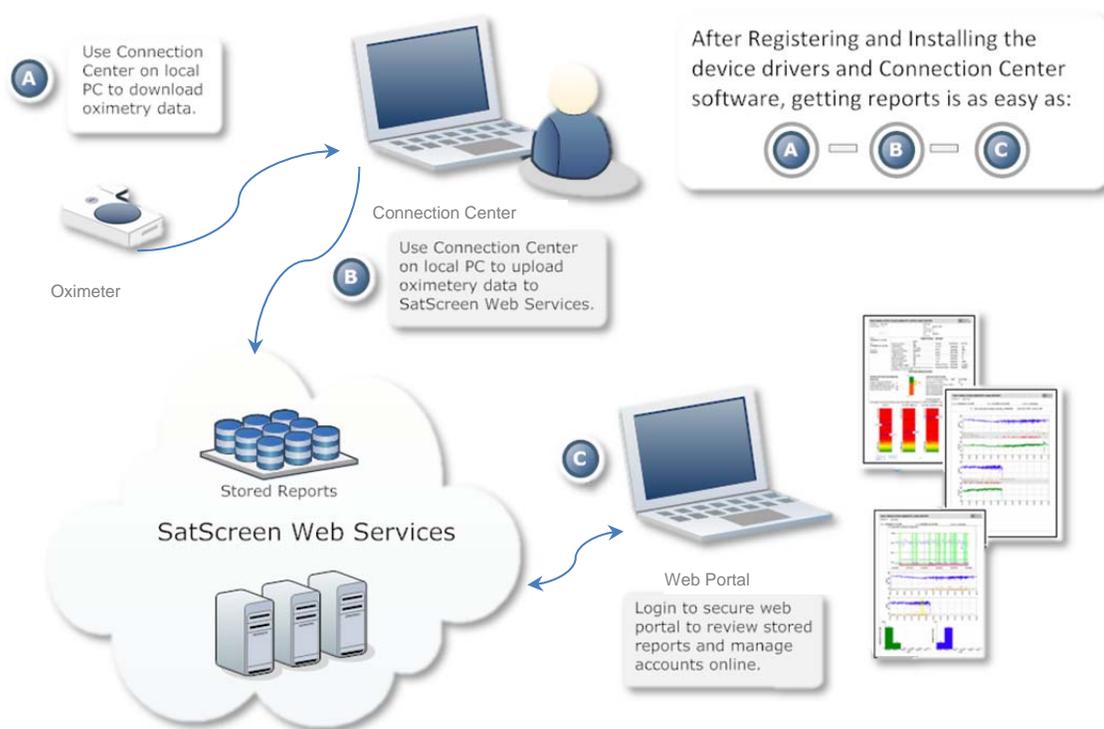
It is recommended that you read this instruction manual carefully before use.

- This manual serves as a reference.
- Read and understand the entire manual before using the device.
- Please, read carefully the precautions with  symbols, to ensure that the software is used in best conditions and in complete safety.

1.1 SatScreen System Overview

Welcome to Patient Safety Connection Center & Internet Analysis Software Services!

The SatScreen system consists of the oximetry device, the Connection Center application, SatScreen Web Services, and the Web Portal with the workflow shown below.



The Connection Center software features a patient-centric interface which allows for the downloading and management of data collected from oximetry devices and sleep data collection systems. Patient Safety's Connection Center allows users to quickly and easily bind patient information with a study. Data is then communicated to the Internet Analysis Services which analyzes data and generates a SatScreen report within minutes.

The Web Portal is an internet-based component which allows users to log in to view archived reports, edit patient information, and manage their customer account and/or user profile.

In addition to traditional reporting of oximetry data, Patient Safety designs software which identifies and provides detailed information relating to cyclical patterns, blood-oxygen desaturations, baseline oxygen saturation levels, and motion artifact.

2 Intended Use

Patient Safety's Connection Center and Internet Analysis software is intended to be used as an aid in the diagnosis of sleep and respiratory related sleep disorders.

The Connection Center/Internet Analysis software is used for analysis (semi-automatic and manual rescoring), display, redisplay (retrieve), edit, summarize, to generate user defined reports, networking and managing of data received from devices that are typically used to evaluate sleep- and sleep related respiratory disorders. The Patient Safety Connection Center/Internet Analysis software also provides scoring of desaturation events as they related to sleep breathing disorders.

Patient Safety's Connection Center/Internet Analysis is intended to be used as an information and decision management tool to import/record and transmit/transfer data typically captured to evaluate sleep and respiratory related sleep disorders.

The Connection Center/Internet Analysis software itself is not a diagnostic tool. It is an information and decision management tool which allows Health Care Providers (HCP) to upload, view, and score data related to a sleep study and provide output reports to a physician.

This software is to be used under the supervision of a physician, sleep technologist, or clinician (Referred to herein as "Health Care Provider" or "Qualified Health Care Provider").

3 Precautions

3.1 Precautions

- ⚠ The Connection Center/Internet Analysis software and its outputs are intended only as an aid to patient assessment. It must be used by a Qualified Health Care Provider, in conjunction with other methods of assessing clinical signs and symptoms.
- ⚠ Read this manual and the manufacturer's instruction manual for the pulse oximeter before operating the medical device and software.
- ⚠ If reported SpO2 values exceed 100%, refer to the manufacturer's manual for the pulse oximeter for important information regarding measuring range and accuracy. If indicated, contact the nearest distributor or authorized service facility to determine whether your medical device is in need of service.
- ⚠ The user is responsible for ensuring accuracy of patient information they bind to the device recording(s).
 - Maintaining a log with a device number or unique device ID, patient information, and release/return dates is recommended.
- ⚠ The study start time and date are maintained on the device's internal clock. The device clock must be set to the correct time prior to releasing the oximeter to the patient.
- ⚠ Clear the device once all test data has been retrieved. Errors may occur if too many recordings are stored on the device and/or the device's memory becomes full.
- ⚠ The user is responsible for ensuring patient test data has been retrieved from the device before clearing the device recordings. Verify that the patient recordings have been downloaded and report(s) have been generated prior to clearing the device. Once the recording device's memory has been cleared, this data can no longer be retrieved from the device.
- ⚠ It is the Health Care Provider's responsibility to abide by the regulations and laws set forth by the Health Care Provider's applicable regulatory and governing bodies when using the Connection Center/Internet Analysis software and its outputs.

3.2 System Requirements

Compatible System Types:

- 32-bit Operating Systems
- 64-bit Operating Systems

Compatible Windows Edition(s):

- Windows XP
- Windows Vista
- Windows 7

Other

- Personal computer with 2.4 GHz or higher processor;
- 101+ Mb Available Hard Drive; 300+ Mb if .NET Framework needs to be installed
- Microsoft .NET Framework v.3.5 or higher
- Mouse or other pointing device
- USB port
- High-speed Internet Connection (1.5 Mbps upload; 12 Mbps download or higher is recommended)

*The Patient Safety Connection Center software is a small executable. Installation files require less than one Mb of disk space on your hard drive. The Patient Safety Connection Center software will also require approximately 1Mb per case downloaded for storage of oximetry data files and patient information. This does not apply if user chooses to delete these files.

Please refer to the Microsoft Windows Recommended System Requirements for more information.

<http://www.microsoft.com/windowsxp/pro/upgrading/sysreqs.mspx>

<http://www.microsoft.com/windows/products/windowsvista/editions/systemrequirements.mspx>

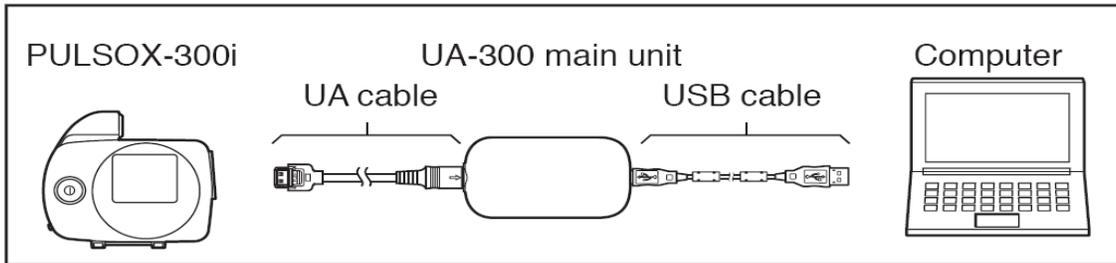
3.3 Compatible Devices

The Connection Center / Internet Analysis software must be used with an approved compatible device. Compatible device(s) are listed below.

3.3.1 Approved Compatible Devices:

Manufacturer	Model
Konica Minolta	PULSOX UA-300i Oxygen Saturation Monitor

3.3.2 Components for Connecting the Konica Minolta PULSOX UA-300i to the Computer.



The PULSOX UA-300i Oxygen Saturation Monitor should be used with approved accessories. Refer to the current Konica Minolta PULSOX UA-300i manufacturer's user manual for instructions for use, approved accessories, and other important product and safety information.

- Konica Minolta PULSOX -300i Oxygen Saturation Monitor
- UA Cable
- UA-300 USB Adapter
- USB Cable
- Computer w/ functioning USB port

4 Installation

NOTE: First time users must first visit the www.patientsafetyinc.com website and [Register](#) to use SatScreen prior to installing the Connection Center.

Make note of the username and password established during registration as user authentication is required to analyze test data and generate a SatScreen report.

Once registered, the Connection Center can be installed on as many computers as needed. ORGANIZATIONS SHOULD ONLY REGISTER ONCE to avoid multiple accounts and invoices. Visit the Support section of the patientsafetyinc.com website to download and install additional copies of the software.

4.1 Install the Connection Center & Device Drivers

4.1.1 Visit the PatientSafetyInc.com Support Page: Downloads Center

- Click on the link to download the Connection Center Installer Package.

The download process may take several minutes

4.1.2 Click "Run" when prompted.

If you receive a message in your browser notifying you that the file is not commonly downloaded, select "run anyway" or "actions" > "run anyway".



4.1.3 The Installer will guide you through the installation.



Click "continue anyway" or "install" on user account control or windows security messages.

4.1.4 Plug in the oximeter when prompted.



If a "found new hardware" message appears in the lower right corner of the screen, click on the message to begin the hardware installation wizard.

4.1.5 Once finished, double click on "Patient Safety Connection Center" desktop icon to launch the program.



5 Getting Started

5.1 Set-up and First Time Use

First time users will need to log in to the Connection Center to enable analysis and reporting features. A “**Not Logged In**” message will in the upper left corner of the Import Wizard Screen until this information has been updated and stored.

The internal clock on new oximeters will be set to the manufacturer's default. The device clock will need to be set from the Connection Center if the oximeter is new, or when it is stored without battery.

5.1.1 Save Log In Credentials to the Connection Center:

- Go to **Options > Settings**, enter the username and password, and select the  button.
- Alternately, a log in prompt will appear during the download process when the user attempts to download a study and generate a report. This information is then stored in the Connection Center under **Options > Settings**.
- If the username and password are correct, a “**Welcome, ...**” message will appear in the upper left corner of the Import Wizard page. This information will be stored in the Connection Center by default.

5.1.2 Setting the Device Clock

- While the Connection Center is open, connect the oximeter to the computer and turn it ON.
- Click on the [Set Device Clock](#) link in the Tasks Menu
- It will automatically sync to the date/time on your computer. Click “Ok”.

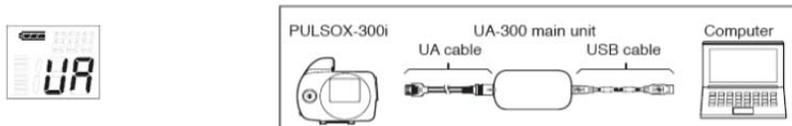
5.2 Downloading Oximetry Data & Generating Reports

5.2.1 Collect Data



Review the overnight oximetry instructions with the patient. Have the patient wear the oximeter overnight and return it for data download.

5.2.2 Turn the oximeter ON & connect it to the computer



Use the enclosed cables and adapters to connect the oximeter to the computer.

When the device is on & connected, the screen should display “UA”.

5.2.3 Launch the Patient Safety Connection Center



Double click on your desktop shortcut.

The Connection Center will open to the Import Wizard. Here, you may enter standard report information, select report(s) to create, and generate the report from a single screen.

5.2.4 Enter Patient Information & Select Stud(ies)

- Add patient identifiers
- Enter:
 - First name
 - Last name
 - Dob (mm/dd/yyyy)

Patient Identifiers
 First Name: Patient ID:
 Last Name: Birth Date:
 Comments:
 Available: 2 sleep studies that satisfy the criteria.
 Show sleep studies that match criteria Show all records

**If desired, select Interpreting/Referring clinicians through the Change link(s) in the left hand menu. Selections will be stored as defaults until changed again or removed.*

Add the clinician's email address to invite them to view their patients' reports through the Web Portal and receive notifications when new studies are available.

- Select a Study to Download
- Check the create box next to the patient's study or studies.

Create	Date	Recordings	Duration
<input checked="" type="checkbox"/>	05/20/2011	6 hr (00:52:33 - 07:51:02) 0 min (07:51:14 - 07:51:15)	6:58:30
<input checked="" type="checkbox"/>	05/19/2011	0 min (00:28:02 - 00:28:03) 6 hr (00:29:59 - 07:14:30) 0 min (07:14:40 - 07:14:56)	6:44:48

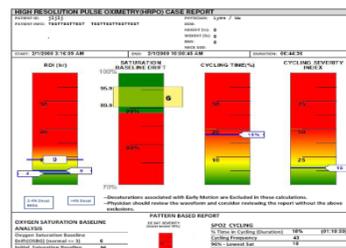


Verify patient information is accurate and associated with the correct device recording(s) before generating the report.

5.2.5 Generate the Report



- Click on Start Downloads
- This may take a few minutes; do not disconnect/turn off the oximeter or close out of the program during this time. Once data is uploaded successfully, the printable pdf report will open.



If there is a Not Logged In message in the upper left corner of the Connection Center, you may receive a prompt asking you to log in during the download process. You may also log in prior to starting the download by going to Options > Settings.

- Archived reports:
- To access the report at a later time, click on the View All Reports button in the Connection Center.

Or, log in at www.patientsafetyinc.com to review your SatScreen Reports from anywhere using our secure web portal.



Clear the device once test data has been retrieved.



Verify that all valid patient recordings have been downloaded and report(s) have been generated prior to clearing the device.

5.3 Managing Device Data



Internal functions of the recording device can be managed from within the Connection Center. These options become available in the **Tasks** menu on the left side of the Connection Center when the device is connected to the computer and turned on.

5.3.1 Clearing the Device

- While the Connection Center is open, connect the oximeter to the computer and turn it ON.
- Click on the [Clear Device Recordings](#) link in the Tasks Menu of the Connection Center.
- A prompt to confirm this action will appear. Verify that the patient recordings have been downloaded and report(s) have been generated, then click “Ok” to confirm.
- ALL files stored on the recording device will be deleted.

5.3.2 Setting the Device Clock

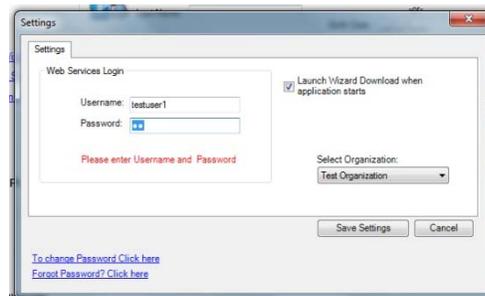
- While the Connection Center is open, connect the oximeter to the computer and turn it ON.
- Click on the [Set Device Clock](#) link in the Tasks Menu
- It will automatically sync to the date/time on your computer. Click “Ok”.
- The date and time on the clock will be updated to the new date and time.

6 Settings

6.1 Settings Page

To access the settings page, click on **Options** in the upper left corner of the Patient Safety Connection Center and select **Settings**. The settings page allows users to:

- Log in to utilize web service features, such as generating reports, viewing archived reports, and storing patient and physician information.
- Change a password.
- Submit a forgot password request.
- Select a sub-organization or location to upload studies to. (if applicable)



6.2 Web Services Login

The Web Services Login provides a secure connection between Patient Safety Connection Center and Patient Safety's web services.

Once created, the username and password can be saved and stored in Patient Safety Connection Center, allowing the user to add new patients and physicians, access archived reports, and utilize Patient Safety's web services.

Login credentials are created during registration. Organization administrators may invite additional users to set up new accounts.

6.3 Change Password and Forgot Password Requests.

Users may change a password or submit a request to establish a new password from the Connection Center Settings Page.

6.3.1 To change a password:

- Select the [Change Password](#) link.
- Complete the corresponding form.

6.3.2 To request a new password,

- Select the [Forgot Password?](#) link.
- A section will appear below the log in section. Submit your username here. You will receive an email with instructions for re-setting your password.

6.4 Selecting an Organization

If the organization has varying levels of access, select a specific sub-organization (i.e., "location") from the **Select Organization** dropdown to upload studies to.

Study access will then be restricted to users with permissions for the specified location or a higher-level organization.

7 Advanced Features

7.1 Adding Detailed Patient Information



Tasks

[Use Import Wizard](#)

[Display Main Screen](#)

[Add Patient Information](#)

Defaults

Interpreting Physician
Jinyun Wu
1937424547
Dayton, OH

Referring Physician
Amy Lynn
4195343500
Toledo, OH

Patient Safety Connection Center

Patient Information	Referring Physician	Interpreting Physician	Review Patient Information
Patient ID: <input type="text" value="555666444"/> <input type="button" value="Lookup"/>	Date Required By: <input type="text" value="2/ 2/2010"/>		
First Name: <input type="text" value="John"/> Middle Initial: <input type="text"/> Last Name: <input type="text" value="Doe"/>			
Address: <input type="text" value="125 Place Park"/>			
Address2: <input type="text" value="Apt. 25Q"/>			
City: <input type="text" value="Columbus"/>	State: <input type="text" value="OH"/>	Postal Code: <input type="text" value="43220"/>	
Email: <input type="text" value="sleepy@patientsafety.com"/>		Home Phone: <input type="text" value="(555) 555-5555"/>	
Gender: <input type="text" value="Male"/>	Marital Status: <input type="text" value="Married"/>		
Date Of Birth: <input type="text" value="2/ 2/2010"/>	Height(ft): <input type="text" value="5"/> in <input type="text" value="5"/>		
Neck size(in): <input type="text" value="18"/>	Weight: <input type="text" value="220"/>		
Insurance Medicare ID: <input type="text" value="646465ML8"/>			
Primary Group ID: <input type="text" value="665465464"/>		Secondary Group ID: <input type="text"/>	
Patient ID: <input type="text" value="6546-65"/>		Patient ID: <input type="text"/>	
Other: <input type="text"/>		Other: <input type="text"/>	
<input type="button" value="Return to Wizard"/>		<input type="button" value="Save and Next"/>	
<input type="button" value="Review Profile"/>			

Patient information should be entered before the study is downloaded and bound to the patient's case report. This information is used in SatScreen analysis reports. The patient information screen can be accessed by clicking on [Add Patient Information](#) or [Edit Patient](#)

for a patient with a  status. Once the patient's study has been downloaded from the device and submitted for analysis, the user can no longer make changes to the patient information associated with that download.

7.1.1 Patient Information

- Patient First Name, Last Name, and Date of Birth (mm/dd/yyyy) are required fields. Other information on this screen is populated on to SatScreen reports as well.
- Once patient information is entered into the appropriate fields, click "Save & Next" or "Review Profile" to save the entry.

 **Verify patient information is accurate and associated with the correct device recording(s) before generating the report**

7.2 Sending Studies to Physicians

Invite physicians to set up practice profiles so that they can receive notifications when new studies are available for review.

Using the Connection Center, select the physician, fill in his or her email address, and upload the study. If an email address has been entered for the physician, uploading a study to a new physician will send an invitation to view assigned studies through Patient Safety's secure Web Portal. Then, the invited physician can enter practice information to set up an account login. Once the physician's practice account is established, new study notices are sent to the registered email address and the physician can click on the email link or log in to access reports.

NOTE: Physician information will always default to the most recently selected interpreting and referring physician. If you do not want the physician to have access to a study, remove the physician or specify another physician using the [Change](#) link.

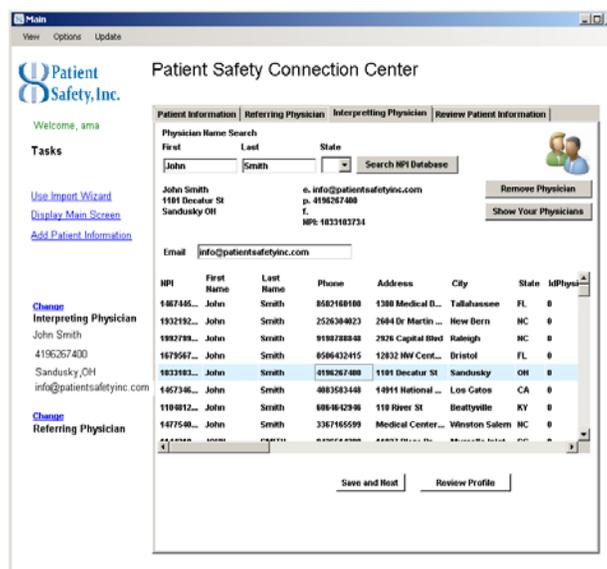
7.2.1 Select the Interpreting or Referring Physician for a Study



- Open the Connection Center .
- In the Import Wizard, select the Change link above the corresponding physician field.

7.2.2 Add or Change the Physician

- Click **Show Your Physicians** to select from a stored physician list.
- Alternately, use the Physician Name Search engine to look up any physician in the NPI database. The number of results returned can be reduced or increased by entering more or less specific information.
- Select the physician from the list and add a practice email address, or a direct email address.
- The physician's name and contact details should appear in the physician section on the left side of the Connection Center. Click Save & Next or Review Profile to save changes.



- Once the physician(s) are added, click on the Use Import Wizard Link. Fill in the patient information, select the patient's study(ies), and select the "Start Download" button.
- If an email address has been entered for the physician, a notification will be sent to the email address for the physician to set up an account. If the physician has an existing account, an email will be sent notifying him/her that the study is available to review.

7.2.3 Removing a Physician

- The physician will remain as the default referring or interpreting physician unless he/she is removed. To remove a physician, select the corresponding Change link, click



. Leave blank or select a new physician for the patient's study.

7.3 Main Screen Display

The program default is to bring the user to the Import Wizard upon the start of the application. However, the Main Screen has added utility for managing patients and devices. From this page, the user can:

- Use the visual indicators to help manage patients or view reports uploaded from their workspace;
- Modify device settings.
- Delete sleep studies from the local machine
- Export sleep study data

7.3.1 Visual Indicators of Upload Status

- Patient Safety's Connection Center helps users stay organized and easily manage patients by providing visual indicators and reminders for each patient's case status.

Possible States for Incomplete Sleep Studies	
 (555) 444-3333 DEMO THREE print forms import data	Signifies a patient is available for import.
 (555) 555-1111 TEST TWO print forms import data	If a required on date is specified in the detailed patient information section, SatScreen reminds the user by highlighting the patient's name and phone # in red.
 (555) 555-5555 JOHN DOE 1/1/0001 upload data	The  symbol indicates that the patient's study has been downloaded from the device, but upload for report generation has not been completed yet. The user can still modify patient information or re-import device recordings at this point, but the report will not be available until the study is uploaded successfully.

Possible States for Completed Sleep Studies



(555) 555-5555
Demo Patient2
9/9/2009
[case report](#)

Click on this icon to view the patient's analysis report.

7.3.2 Exporting Sleep Study Data

- In the Main Screen Display, right-click on the icon next to a Completed Sleep Study.
- The option to export to EDF or Compumedics, will appear.

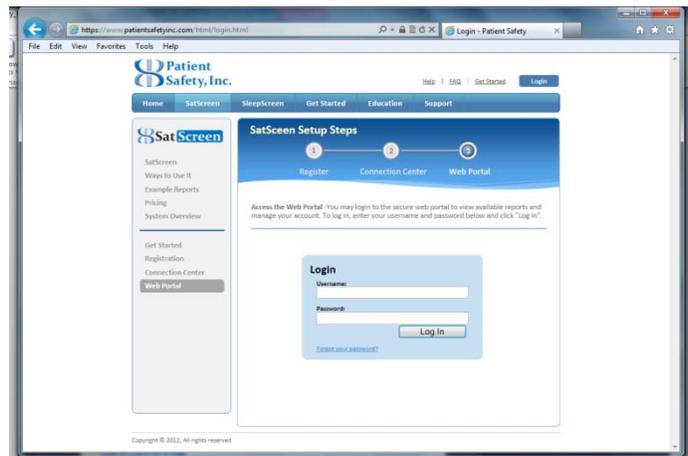
7.3.3 Deleting Locally Stored Sleep Study Data

- In the Main Screen Display, right-click on the icon next to a Completed Sleep Study.
- Select "Delete" from the menu. The sleep study will be deleted from the local computer.

7.4 Returning to the Import Wizard from the main screen

7.4.1 To return to the Import Wizard:

- Select the [Import Data Wizard](#) link on the left side of the screen.
- Another option is to select the  icon for the desired patient in the **Patients without Case Studies** queue.
- The Import Wizard displays a summary for the selected patient and allows for the import of data from the portable monitoring device.



8 Patient Safety Web Portal

The screenshot shows a web browser window with the Patient Safety, Inc. logo and a user welcome message. The main content area is titled "List of Studies by Status" and includes a search bar and a table of study entries. The table has columns for Date, Patient Name, Physician Interpreting, Physician Referring, Type Of Study, and Edit. Two studies are listed: "Test 1" from 05/15/2010 and "Test 2" from 10/10/2010, both of type "SatScreen". Below the table, there are status summaries: "Pending Scoring (29)", "Pending Interpretation (4)", and "There are no completed studies." and "There are no invalid studies."

Date	Patient Name	Physician Interpreting	Physician Referring	Type Of Study	Edit
05/15/2010	Test 1			SatScreen	
10/10/2010	Test 2			SatScreen	

8.1 Viewing Case Studies

The study report can either be viewed locally, through the Main Screen in the Connection Center, or through the Patient Safety Web Portal. Through the Patient Safety Web Portal, the user can log on from anywhere and view studies uploaded to his/her organization's database.

8.2 Accessing Studies through the Internet

Studies that have been previously uploaded to the web services through the Connection Center can be viewed online.

8.2.1 To access Patient Safety's Web Portal:

- Click on the **View all Reports** button, located next to the "Start Download" button on the Import Wizard; or,
- Use the Log in link on Patient Safety Website:

<http://www.patientsafetyinc.com>

Log in with your Patient Safety username and password.

Once logged on, a list of available studies will appear.

8.3 Search Archived Reports

Use the search toolbar or expand the site index to search for a patient or group of patients.

8.4 Open Archived Reports

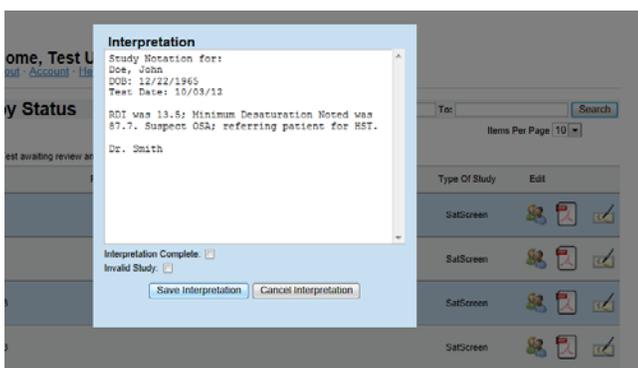
Click on the PDF icon next to the desired patient study to view the report.

8.5 Edit Patient Information

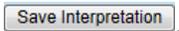
Post-upload corrections to patient information can be made by selecting the Patient icon in the edit column next to the desired patient. Note that changes made here will be reflected in other study listings with the same patient ID.

8.6 Interpretations & Updating Reviewed Status

You may add notation to the first page of the SatScreen report the next time the study is opened. You may also mark studies as completed or invalid to communicate that the study has been reviewed this to other users in your organization.



8.6.1 Adding an Interpretation/Study Notation to the study:

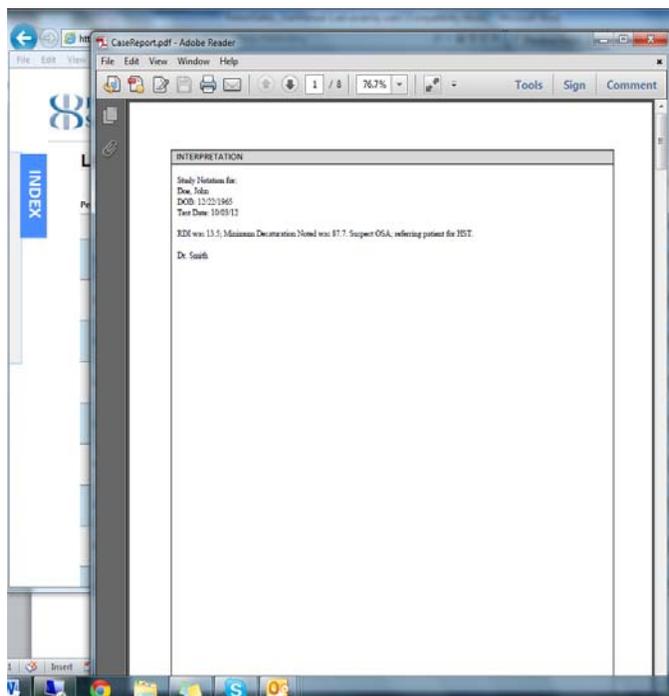
- Click on the  icon
- Enter desired text and click 
- Click on Corresponding PDF icon. Study notation will be appended as a cover page for the analysis report.

8.6.2 To lock notes from further editing:

- Check the “Interpretation Complete” box prior to saving.
- Notes will be locked from additional editing.
- Study will move to the **Completed Studies** queue in the Sleep Study Listings Page.

8.6.3 To mark a study as invalid:

- Check the “Invalid Study” box prior to saving.
- Notes will be locked from additional editing
- Study will move to the **Invalid Studies** queue in the Sleep Study Listings Page.



9 FAQs & Trouble-shooting

9.1 "How do I install the oximeter drivers if I don't have an Installation CD?"

A copy of the Konica Minolta PULSOX-300i driver is included in the Connection Center Installer. To install the Connection Center, visit www.patientsafetyinc.com.

9.2 "I am getting a message that says I need to install .NET Framework to continue with installation"

Make sure that .NET 3.5 or later has been installed on your computer. You can download the most recent version through the Microsoft Download Center website.

9.3 "The report says 'Warning: Error Artifact Exceeds 10%'."

Error in SatScreen reports is excluded from analysis. The error message included in the reports is intended to serve as a flag for the clinician to review the raw data. Depending on the duration of the study, the % Error and/or its underlying cause, it is important to review the raw data to determine if there is sufficient amount of valid data to form conclusions from the results.

9.3.1 Common causes of error:

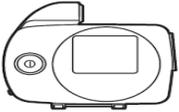
- Excessive movement that is not associated with a respiratory event arousal.
- Diminished signal, e.g. excessive pressure or very poor circulation caused by laying on the probe, acrylic nails or dark nail polish, or the probe is not situated on the finger properly.
- This will typically show up in the raw data as repeated periods where the signal drops to zero, or a significant change in the signal's baseline just after a movement.
- No signal, e.g. if the probe falls off, the patient takes it off, starts the study early or forgets to turn it off when they wake up.

9.3.2 Tips for minimizing error:

- Wear oximeter on ring or pinky finger of non-dominant hand.
- Secure the probe.
 - Place the probe on the finger (cable facing the back of the hand), then use a cloth probe cover over top of the probe to hold it in place.
 - Alternatively, use a small strip of medical tape to tape the probe cord loosely to the back of the hand. Do not tape the probe onto the finger as this may restrict bloodflow
- Do not turn oximeter on until ready to sleep, then lay still for 5 min prior to sleep to obtain a baseline.
- If the patient gets up during the night, ask them to turn the oximeter off when getting out of bed, and be sure to turn it back ON when returning.

9.4 "The Connection Center says 'Device Not Connected'"

Check the following:

<p><i>Oximeter should be in the ON position.</i></p>	 <p>Turn it on by pressing down the round button next to the display screen.</p>  <p>The display screen should say "UA".</p>
<p><i>Check connections.</i></p>	<p>Un-plug and re-plug in the cables connecting the oximeter to the UA 300 adapter and from the adapter to the computer, making sure that they are securely fastened. <i>*The diagram in Getting Started shows how the cables connect to each component. Excessive force when inserting the cable connectors into the components.</i></p>
<p><i>Install or Re-install the drivers</i></p>	<p>Refer to the Patient Safety support center to download and reinstall the Connection Center, or, refer to the installation guide for the operating system used. <i>*You may need to install the oximeter drivers for each USB port you wish to use.</i></p>
<p><i>Contact the Device Manufacturer</i></p>	<p>If you've followed the steps above and you still see the "Device Not Connected" message > contact the device manufacturer's/distributor's technical support line for additional support.</p>



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11 Manufacturer Contact Information



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Technical support for the Connection Center / Internet Analysis Software is included free of charge. Service hours are offered from 8:00 am to 5:00 PM ET.

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