

ResTraxx[™] System User Guide

English

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Introduction

Welcome to the *ResTraxx™ System User Guide*. This guide is designed to provide you with the information you need to effectively use ResTraxx System.

ResTraxx System comprises two parts: ResTraxx Online and ResTraxx Wireless.

ResTraxx Online is a web-based application designed for healthcare professionals involved in the care and management of patients with obstructive sleep apnea. It provides healthcare professionals with the ability to remotely monitor patients' usage of ResMed Positive Airway Pressure (PAP) flow generators via the internet.

With ResTraxx Online, each patient's sleep therapy information is available any time, anywhere.

The data collected facilitates timely intervention and optimizes patient acceptance of treatment.

ResTraxx Wireless is a module that connects directly to ResMed compatible flow generators (see "Compatible Flow Generators" on page 43), to allow upload of data for a set time period.

Notes:

- The recommendations indicated in this guide are intended as guidelines only, and should not replace the care and judgment of a trained clinician or healthcare professional.
- ResTraxx System should only be used by or under the direction of an appropriate healthcare professional.
- This guide is based on version R10 software. Since updates and improvements to the ResTraxx System software occur from time to time, it is not always possible to update the user guide immediately.
- You must have Adobe Acrobat Reader® 5.0 or later to display and print the online agreement and some ResTraxx Online reports.



CAUTION

US federal law restricts this device to sale by or on the order of a physician.

Indications for Use

ResTraxx System is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been wirelessly transmitted from the patient's home to the care giver.

It is intended to be used in the home only and with compatible S7 Elite[™], AutoSet Spirit[™], AutoSet Respond[™], S8[™] Series CPAP Systems, VPAP[™] III, VPAP III ST, VPAP ST, VPAP Malibu[™], VPAP Auto and VPAP Auto 25 positive airway pressure flow generators.

How to Use This Guide

Organization

This user guide is organized into the following sections:

ResTraxx System Overview

This section provides you with a basic understanding of the system; its intended use, the benefits, security and the system requirements. This is where you'll find information on how the system works and what you need to get up and running.

Software Navigation

This section provides information on the "look and feel" of ResTraxx Online. This is where you'll find information on the icons used, fields and field formats.

Note: All patient names and detailed information used as examples within this guide are fictitious and any resemblance to individuals living or dead is purely coincidental.

Quick Start Guide for Patient Setup

This section contains information about how to set up a patient's details and monitoring schedule quickly, for previous users of ResTraxx applications.

Quick Start Guide for Monitoring Patients

This section contains information about how to monitor compliance and troubleshoot compliance issues, once you have set up patient monitoring schedules.

Menus

These sections contain information about how to use the menus in ResTraxx Online to set up and manage patients, and to set up user accounts. The menus are:

- Exceptions contains information about creating exception, fault and compliance summary reports.
- Patient contains information about creating and searching for patient information; entering threshold settings, device and mask details; creating monitoring schedules; monitoring compliance; and adding patient notes.
- Account Management contains information about setting up user accounts and loading physician's details.

Installing and Using ResTraxx Wireless

This section contains the information you need to attach and maintain the ResTraxx Wireless module required to transmit flow generator usage data.

Note: The ResTraxx and S8 ResTraxx devices function in the same way. The term "ResTraxx Wireless" applies to both devices. See "Compatible Flow Generators" on page 43 to view compatible flow generators for each device.

Troubleshooting

This section contains information about solving issues that may arise during use of ResTraxx Wireless.

Technical Specifications

This section contains specifications for ResTraxx System.

Conventions

The following conventions are used in this guide.

<enter></enter>	Indicates a key press.
<ctrl +="" s=""></ctrl>	Indicates a combination of keys to be pressed at the same time.
"Anthem"	Quotes indicate an entry to be typed in. Type it into the correct field.
[OK]	Indicates a button to be selected in a window or from a menu on the screen.

If you are using this guide in pdf format, you can navigate using the hyperlinks in the Contents and Index. Click on the topic you require to display the appropriate section of the text. Cross-references are also linked within the pdf, allowing you to display a reference by clicking on it; eg, click on "Field Definitions" on page 12' to jump to that point in the text.

ResTraxx System Overview

System Overview

ResTraxx System comprises two parts: ResTraxx Online and ResTraxx Wireless.

ResTraxx System allows a large number of flow generators to be monitored at any given time in patients' homes, in a variety of different geographical locations. Figure 1 illustrates ResTraxx System with multiple flow generators.

ResTraxx Wireless, when attached to a compatible flow generator, wirelessly transfers data from the flow generator through a nationwide messaging network to ResTraxx Online. ResTraxx Online provides the software that enables this data to be stored in a database.

ResTraxx Online also enables healthcare professionals to retrieve and view the stored information in an easy-to-interpret manner, using standard web browsers and custom-designed web screens.

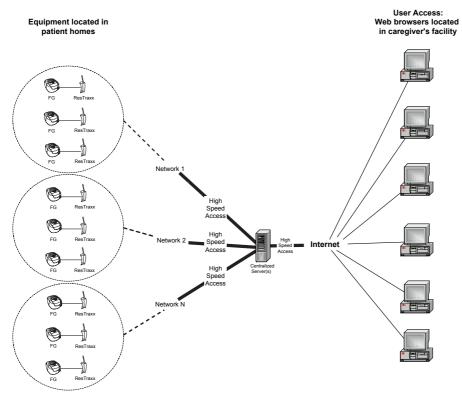


Figure 1: ResTraxx System configuration

System Requirements

Requirements for Equipment in the Patient's Home

The following requirements must be met for wireless transfer of usage data to occur:

- A prescribed and compatible ResMed flow generator must be used (see "Compatible Flow Generators" on page 43).
- The correct ResTraxx Wireless module must be connected to the flow generator.
- Flow generator(s) with ResTraxx Wireless connected must be located in a coverage area. See "Set up Monitoring" on page 15 for details about verifying wireless coverage.

Requirements for Equipment in the Caregiver's Facility

These requirements refer to the hardware, software and codes a caregiver or healthcare professional needs to run ResTraxx Online.

Hardware

Any Intel-based PC hardware that allows a connection to the internet can be used.

Software

Internet connection software:

- · A direct connection or dial-up networking within Windows®
- Other connectivity software for your modem
- · Network connection to the internet
- · Windows XP operating system.

Browser software:

- Microsoft® Internet Explorer® 6.0 (with 128-bit SSL)
- · Javascript must be enabled.

Note: Pop-up blockers must be turned off in order to access Help and display confirmation popups.

Other software:

· Adobe Acrobat Reader 5.0 or higher.

Authorization Codes

Appropriate authorization codes provided by ResMed are required to access ResTraxx Online.

Security

The Health Insurance Portability & Accountability Act of 1996 (HIPAA), as defined in the federal regulation (45 CFR, parts 160 and 164), mandates the way patient information is exchanged between healthcare organizations. The ResTraxx system has been developed to help your organization comply with HIPAA security requirements. This ensures that only those who need to view records are granted access when logging onto ResTraxx Online via a web browser.

ResTraxx Online contains features that allow organizations to set different levels of access to their user base. Access levels such as Master Authority and Read-Only are examples of the flexibility available in the system. See "Authority Levels and Accessibility" on page 35 for information about access levels.

In addition, ResTraxx System provides the following security:

• Information transmitted from the wireless network contains no patient-identifying data.

- Information accessed by the internet is secured using Secure Socket Layer (SSL) encryption technology.
- Information stored on the centralized servers is located in a secure data center and protected by firewalls, intrusion detection systems and other securing mechanisms.
- A login session times out after a pre-defined period if ResTraxx Online does not detect any activity.

The Online Agreement

The first time you log in to ResTraxx Online you will be asked to read and accept the online agreement.

You will need Adobe Acrobat Reader 5.0 or later to view or print the agreement. If you do not have Adobe Acrobat Reader installed, you can download a free copy from the Adobe web site.

Software Navigation

This section provides you with information about using ResTraxx Online. This is where you find information on the screens, the icons used, features, functions, and step-by-step procedures.

ResTraxx Online Interface

The ResTraxx Online interface is designed to be intuitive and easy to use in a web environment. It puts the information you need right at your fingertips through a series of menus, screens, fields and buttons.

Components of the ResTraxx Online interface are identified below.

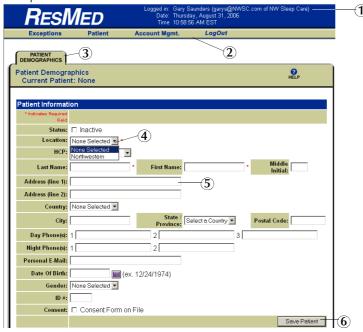


Figure 2: ResTraxx Online interface

- 1. User information 2. Main menu bar 3. Submenu screen
- 4. Drop-down menu 5. Data fill-in field 6. Button

Main Menu

ResTraxx Online makes options accessible from a main menu bar at the top of the screen.



Figure 3: Main menu options bar

The main menu provides access to all of the application features via drop-down menus. Some menu options also have submenus.

The main menu options available in ResTraxx Online are:

- Exceptions Menu (page 21)
- Patient Menu (page 24)
- Account Management Menu (page 35)
- LogOut (page 14).

Note: Screens displayed through tabs and sub-tabs are based on your user permissions. See "Authority Levels and Accessibility" on page 35.

Using ResTraxx Online

Use the <Tab> key to move from field to field.

Fields that require entries are indicated by a red asterisk after the field.



Figure 4: Required fields

Field Formats

Use the following formats when entering data in ResTraxx Online:

Names:

Type in the first or last name with leading upper case and following lower case letters; for example, "John", "Forrester".

Note: The name field only accepts alphabetic letters and the punctuation marks comma (,) hyphen (-) and apostrophe ('). Numbers and other special characters are not accepted.

· Dates:

The American style is used for all dates in the system. For example, 4/7/2002 is April 7, 2002, not 4 July, 2002.

· Phone numbers:

The American style is used with a three-digit area code, a three-digit central office code, and a four-digit phone number. The country code is not used. Use dashes to separate the parts of a phone number; eg, 312-444-1515.

· Email addresses:

If a patient's email address is provided, enter it in one of the following formats:

"username@host.com"

"username@host.net"

"username@host.org"

Field Definitions

These are the fields used to enter patient information:

- Address (line 1): the name and number of the street where the patient resides. This field accepts numeric and alphabetic characters.
- Address (line 2): more specific mail delivery information, such as a company name, building or suite number, etc. This field accepts numeric and alphabetic characters.
- Date Of Birth: the patient's date of birth, displayed in mm/dd/yyyy format.
- City: the name of a place where a US Postal Code has been assigned, or the location of real property, a lock box or regional office. This field accepts numeric and alphabetic characters.
- Consent Form: used to indicate that a patient has signed consent, privacy and/or confidentiality form(s) on file.
- Country: the name of the country where the patient resides. Select the appropriate country from the drop-down menu.
- Day Phone(s): the telephone number where a patient can be reached during normal daytime hours, with area code first.
- First Name: the name indicated as the first or 'given' name of the patient as provided on medical forms. Use upper and lower case, as appropriate. This is a required field.

- Gender: the gender of the patient. This information is not required, but is relevant as it provides a means of identifying a specific patient when two or more patients have the same name.
- HCP: the name of the health care provider for a specific patient.
- ID #: a unique identifier assigned to each patient. The ID # consists of four numeric and/or alphabetic characters. This information is not required, but is relevant as it provides a means of identifying a specific patient when two or more patients have the same name.
- Last Name: the name indicated as the family or last name of the patient as provided on medical forms. Use upper and lower case, as appropriate. This is a required field.
- Location Providing Care: indicates the location providing care for a specific patient. This is a required field.
- Middle Initial: the first letter of the patient's middle name as provided on medical forms.
- Night Phone(s): the telephone number where a patient can be reached during evening hours.
- Personal E-Mail: the electronic mailing address of the patient, if available.
- State: the state name as designated by the US or Canadian Postal Service. Select the country first to activate the state drop-down menu.

Log in to ResTraxx Online

To use ResTraxx Online:

- 1. Log on to the internet (if you don't have a constant connection).
- 2. Open your browser window and access the Web site at www.restraxxonline.com.

Note: If you are typing the Web site address in manually, ensure there is an "s" in the URL https (ie, https://www.restraxxonline.com) and that there is a padlock icon at the bottom of the browser screen.



Figure 5: Login screen

- 3. Enter your user name and press <Tab>.
- 4. Enter your password and press <Enter> or click [Log In]. The Welcome screen of ResTraxx Online is displayed.

Notes:

- New feature announcements and tips on using the system are periodically posted on this screen.
- You can access the Restraxx Online User Guide from this screen.

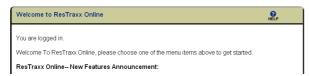


Figure 6: Welcome screen

Log out of ResTraxx Online

When you have finished, you can exit from anywhere in ResTraxx Online by clicking [LogOut] in the main menu bar at the top of the screen.



Figure 7: Main menu

When you click [LogOut] the logout screen appears.

Note: You should always close your browser window after logging out, unless you plan to immediately log in again.



Figure 8: LogOut screen

To log in from this screen, select [Click Here to Log In again].

A login session times out after 30 minutes if ResTraxx Online does not detect any activity.

Quick Start Guide for Patient Setup

To set up a patient, you need to access and enter data in several screens. The process below is provided to help you quickly set up numerous patients in the system. For step-by-step procedures and illustrations please refer to the relevant section in the user guide.

Log in

- 1. Enter "www.restraxxonline.com".
- 2. Log on to the system using your user name and password.

Add/Edit Patient Records

- 1. Select [Patient] from the menu bar.
- 2. Select [Patient Add/Search], enter specific patient information and select [Search]. If patient is not found select [Add Patient], enter all required information and click [Save Patient].
- 3. Click the [Threshold Settings] sub-tab.
- 4. Add the physician, threshold settings, device and mask details.
- 5. Click [Save Settings].
- 6. Click [Submit] to continue or [Cancel] to exit.

Set up Monitoring

Note: To verify wireless coverage in the USA, go to www.usamobility.com and follow the steps on the website to check two-way coverage. To verify wireless coverage in Canada, go to www.pagenet.ca and follow the steps on the website to check two-way coverage.

- 1. Click the [Monitoring] sub-tab.
- 2. With the [Schedule] radio button selected, enter data in all fields.
- 3. Click [Save Schedule].
- 4. Click [Submit] to continue or [Cancel] to exit.

Note: Monitoring allows you to schedule a request for retrieval of data for dates that have not yet occurred. For more information, see "Monitoring Screen" on page 27.

Request History

Request History may be useful in the following situations:

- When you need to look at data from a patient who has already been on CPAP for a while, and you wish to see what problems they have been encountering.
- When a payor requires data on a specific timeframe, such as Medicare's 61st day compliance requirement, to ensure use of the flow generator.
- If a fault occurs due to coverage issues, Request History can be used when the patient is back in a coverage area.

To request a patient's history:

- 1. In the [Monitoring] sub-tab, select the [Request History] radio button.
- 2. Select a start date up to 365 days in the past, and an end date prior to today's date.
- 3. Enter the flow generator and ResTraxx Wireless serial numbers.
- 4. Click [Download] to retrieve the data.

5. Click [Submit] to continue or [Cancel] to exit.



Figure 9: Request history screen

Compliance

Once you have started monitoring a patient, data should begin to be displayed on the calendar within 24 hours, assuming the device is switched on and in the coverage area.

A session of flow generator data is recorded within a period of 24 hours, starting at 12 noon. For example, if a patient starts using their flow generator at 10 pm on January 1, their data will be displayed after 1 pm PST on January 2.

The calendar is accessed via the Compliance sub-tab.

To see more specific data for a given day, click on the colored box in the calendar. A report-style format displays pressure, leak, efficacy, hours of usage, and mask on and off times.

The calendar uses a series of symbols, defined in the Symbol Legend box (see "Usage History" on page 28 for more information).

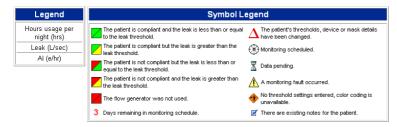


Figure 10: Calendar symbol legend

Quick Start Guide for Monitoring Patients

The process below is provided to help you quickly monitor compliance and troubleshoot compliance issues, once you have set up patient monitoring schedules. For step-by-step procedures and illustrations please refer to the relevant section in the user guide.

Check Patient Compliance

Create an Exception Summary report to check compliance for all your patients.

- 1. Select [Exception Summary] from the [Exception] menu.
- 2. Enter filter criteria.
- 3. Click [Search] to refresh the screen and display exceptions data for the criteria entered.

The Exception Summary report shows efficacy and compliance results for each day that patients are monitored, and lets you 'manage by exception': the icons quickly show you the patients who are trouble-free, and those patients who are 'exceptions' and are having compliance problems.

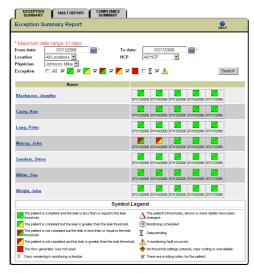


Figure 11: Checking patient compliance

View a Patient's Details

In the Exception Summary report, click on a patient's name to show their Patient Usage History report.



Figure 12: Viewing details for a specific patient

The Patient Usage History report provides a full calendar view. You can move between months, and move between patients. (These patients are those listed in the Exception Summary report.)

Identify Causes and Troubleshoot Non-compliance

From the Usage History report, click on the day you wish to view in more detail. This displays the Daily Therapeutic report for the patient.



Figure 13: Identifying causes of non-compliance

The Daily Therapeutic report gives you compliance and efficacy data, as well as showing device settings and mask events.

View Patient Progress and History

Use the Therapeutic History report to see the patient's progress and history.

1. Select the [Compliance] sub-tab.

2. Select the [Therapeutic History Report] radio button.



Figure 14: Therapeutic History Report radio button

3. Select the report type (Current Patient or Multiple Patients) and enter the start and end dates for the report (the maximum range is 31 days).

If you select the start date first, the end date is calculated automatically.



Figure 15: Therapeutic History report type

- 4. Click [NEXT: Set Criteria].
- 5. Enter the criteria that you want to report on.



Figure 16: Criteria for Therapeutic History report

6. Click [Show Report] to create the Therapeutic History report.

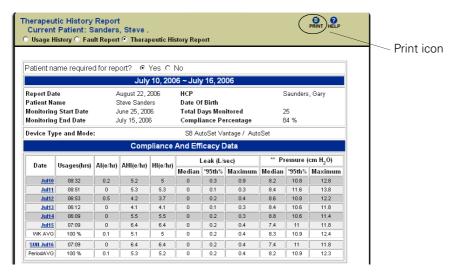


Figure 17: Therapeutic History report

Click the print icon to open the report in PDF format for saving or printing.

Exceptions Menu

The Exceptions menu allows you to access Exception Summary, Fault Report and Compliance Summary data. Compliance data is compiled by date. Fault data is compiled into one of two types—New or All.

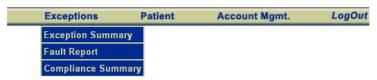


Figure 18: Exceptions menu options

Exception Summary Report Screen

Use the Exception Summary Report screen to create a summary report for all patients being monitored. The Exception Summary report's parameters are location, physician, healthcare provider (HCP) and exceptions. The report displays a graphical representation of patients' usage and leak rate compared to their threshold settings for a selected date or range of dates.

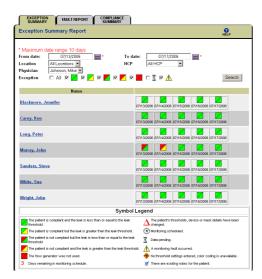


Figure 19: Exception Summary Report screen

To create an Exception Summary report by date:

- 1. Select [Exception Summary] from the Exceptions menu.
- 2. Select the desired dates (within a ten-day range) using the calendar.
 - From date: Start of the report.
 - To date: End of the report.

Note: If you set the To date first, a From date occurring 10 days before the To date displays automatically.

- 3. Select filter criteria, or use the default values.
 - · Location: Only displays patients in the selected location.
 - HCP: Only displays patients assigned to the selected HCP.
 - Physician: Only displays patients assigned to the selected physician through the Threshold Settings screen.
 - Exception: Only displays patients whose status corresponds to the selected icons. You can select one, multiple or all exceptions to display.

4. Click [Search] to refresh the screen and display exceptions data for the criteria entered. Compliance information is displayed on the screen via a colored graphical symbol indicating the usage and leak.

Note: Moving the cursor over the graphical symbol will provide a description relative to the patient's threshold settings.

5. Click the underlined patient name to display a patient's Usage History report.

Compliance Summary Report

The Compliance Summary Report screen allows you to create a graphical compliance report of a group of patients sorted by location, HCP or physician.

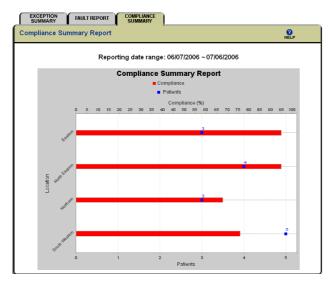


Figure 20: Compliance Summary Report screen

To create a Compliance Summary report:

- 1. Select [Compliance Summary] from the Exceptions menu.
- 2. Select the desired range of dates using the calendar.
- 3. Select filter criteria from the drop-down menus.
 - Location: Only displays patients in the selected location.
 - HCP: Only displays patients assigned to the selected HCP.
 - Physician: Only displays patients assigned to the selected physician through the Threshold Settings screen.
- 4. Click [Show Report] to display graphical compliance data for the criteria entered.

Fault Report Screen

The Fault Report screen allows you to create a report of fault-related data for all patients at a specific location.

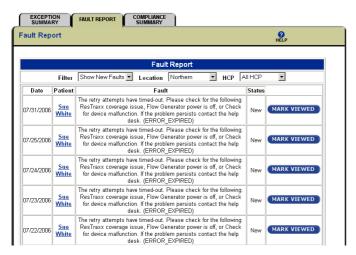


Figure 21: Fault Report screen

To create a fault report:

- 1. Select [Fault Report] from the Exceptions menu.
- 2. Select the type of fault filter you wish to use from the drop-down menu.
 - Show All Faults: lists all entries, regardless of viewing status.
 - Show New Faults: displays entries where [Mark Viewed] has not been selected.
- 3. Select filter criteria from the drop-down menus.
 - Location: Only displays patients from the selected location.
 - HCP: Only displays patients assigned to the selected HCP.
 The screen refreshes and displays Faults data for the criteria entered.
- 4. Once you have viewed the information, you can click [Mark Viewed] to change the status to 'Viewed'.

Note: Viewed entries only appear when [Show All Faults] is selected.

5. If desired, click the underlined patient name to display additional patient information.

Patient Menu

Use the Patient menu to search for and/or add patient-specific data.



Figure 22: Patient menu options

Patient Menu Sub-tabs

Once a patient file is added or retrieved, submenu options become available through a series of tabs across the top of the screen. When selected, each sub-tab screen displays specific information related to the patient.

The sub-tabs are:

- · Patient Demographics
- Threshold Settings
- Monitoring
- Compliance
- · Notes.



Figure 23: Patient menu sub-tabs

When selected, each sub-tab displays a screen that allows you to view, add, or modify specific information related to the patient. For example, the Threshold Settings sub-tab contains a history of the patient's threshold settings, device and mask details.

Search for a Patient

Use the Patient Search screen to locate a patient record in the system. To search for a particular patient's data, select [Patient Add/Search] from the Patient menu. The Patient Search screen is displayed.

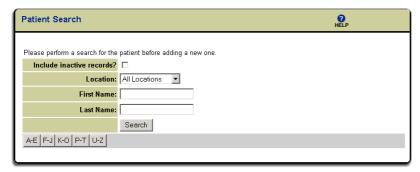


Figure 24: Patient Search screen

There are multiple ways to search for a patient. The quickest way to search is by location, followed by the patient's full name.

To search for a patient by location:

- 1. Select the desired location from the drop-down menu.
- 2. Click [Search] to display the search results.

To search for a patient by partial or full first/last name:

- 1. Enter one or more letters of the patient's first/last name in the appropriate field.
- 2. Click [Search] to display the search results.

To search for a patient alphabetically by last name:

1. Click on the appropriate letter range. The search results are displayed automatically.

To search for all patients:

- 1. Leave First/Last Name fields blank.
- 2. Select [Include Inactive Patients] option to include both active and inactive patients.
- 3. Click [Search] to display the search results.

Add a New Patient

To add a new patient:

- 1. First search for a patient (page 24). If the patient is not listed, click [Add Patient] to add a new patient.
- 2. The Patient Demographics screen is displayed. Add the patient's details.
- 3. Click [Save Patient] to save the patient information.

Notes:

- The Patient Demographics screen is the main data entry point for ResTraxx Online. To maximize the benefit of the automated functions within ResTraxx Online, enter all patient information as completely as possible.
- See "Field Formats" on page 12 for information about the correct format for entering data in ResTraxx Online.

Patient Demographics Screen

Use the Patient Demographics screen to view or record a patient's personal and contact information. Information added to many of these fields is automatically entered into other screens in ResTraxx Online.

To display a patient's demographic information, conduct a Patient Search (page 24). The patient name is displayed as an underlined field in the Search Results section. Click on the patient name.

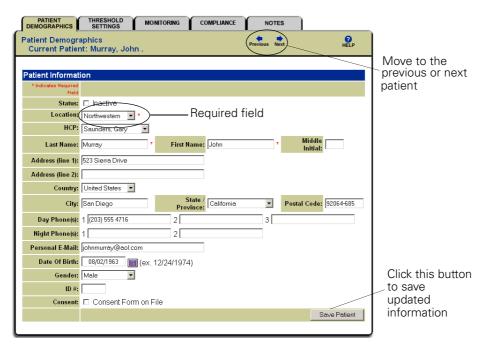


Figure 25: Patient Demographics screen

The information for the current patient is displayed. At this point you can view and/or make changes to the patient information.

Modify Patient Information

To modify a patient's information:

- 1. Select the appropriate field and type over the existing information, or select a different option in the drop-down menu.
- 2. Click [Save Patient] to save the updated information.

Threshold Settings Screen

To enter threshold settings for an existing patient, locate the patient's information and use the Threshold Settings sub-tab to enter the threshold settings. The threshold settings data entered provides ResTraxx Online with the information necessary to track and report on patient compliance.

To enter or modify threshold settings:

1. Conduct a Patient Search (page 24).

2. Click the [Threshold Settings] sub-tab.

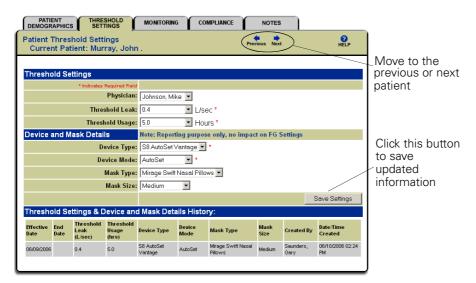


Figure 26: Threshold Settings screen

- 3. Edit existing information or enter new information as completely as possible.

 Click the "Next" or "Previous" arrows (if available) to display the threshold settings for the next or previous patient.
- 4. Click [Save Settings] to save the data to the system.
- 5. When the confirmation message appears, click [Submit] to save your changes or [Cancel] to exit.

Monitoring Screen

The Monitoring screen provides the mechanism for collecting information stored in the memory of the flow generator for a specific patient.

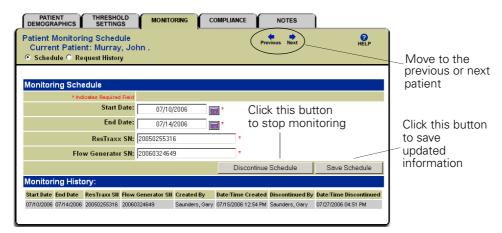


Figure 27: Monitoring screen

To enable or disable an existing patient's monitoring schedules:

- 1. Conduct a Search for a Patient (page 24).
- 2. Click the [Monitoring] sub-tab.
- 3. Edit existing information or enter new information as completely as possible.

Note: If the ResTraxx serial number or flow generator serial number is entered incorrectly, you will receive a fault message. Enter the correct serial number for transmission to commence.

Click the "Next" or "Previous" arrows (if displayed) to display the schedule for the next or previous patient.

- 4. Click [Save Schedule] to save the monitoring schedule or [Discontinue Schedule] to disable a current monitoring schedule.
- 5. When the confirmation message appears, click [Submit] to continue or [Cancel] to exit.

Note: The Monitoring screen allows you to schedule a request for retrieval of data for dates that have not yet occurred. The system records your request and, when the scheduled date occurs, it retrieves the data. For example, if you wanted to set up a patient for a 30-day monitoring schedule, you would choose as a start date the first day on which the patient should use the flow generator. You would then set the end date for 30 days later.

Request History

Request History may be useful in the following situations:

- When you need to look at data from a patient who has already been on CPAP for a while, and you wish to see what problems they have been encountering.
- When a payor requires data on a specific timeframe, such as Medicare's 61st day compliance requirement, to ensure use of the flow generator.
- If a fault occurs due to coverage issues, Request History can be used when the patient is back in a coverage area.

Request History does not allow you to view dates in the future.

To request a patient's history:

- 1. On the [Monitoring] sub-tab, select the [Request History] radio button.
- 2. Select a start date up to 365 days in the past, and an end date prior to today's date. Up to 30 days of data can be downloaded at a time.
- 3. Enter the Flow Generator and ResTraxx serial numbers and then click [Download].
- 4. Click [Submit] to retrieve the data or [Cancel] to exit.
- 5. Once you have started monitoring a patient, data should begin to be displayed on the calendar within 24 hours, assuming the device is switched on and in the coverage area. The calendar is accessed via the Compliance sub-tab.

Note: A session of flow generator data is recorded within a period of 24 hours, starting at 12 noon. For example, if a patient starts using their flow generator at 10 pm on January 1, their data will be displayed after 1 pm PST on January 2.

Compliance Screen

The Compliance screen displays the patient's usage history, and can also generate a fault report that shows any system faults.

The Patient Compliance Calendar provides historical information comparing a patient's actual usage of the flow generator with that prescribed by the physician.

Note: You must have Adobe Acrobat Reader 5.0 or later to display and print some ResTraxx Online reports.

Usage History

To view a patient's usage history:

1. Conduct a Search for a Patient (page 24).

2. Click the [Compliance] sub-tab. (You can also select a patient from the Exceptions Summary report — see "Exception Summary Report Screen" on page 21.)

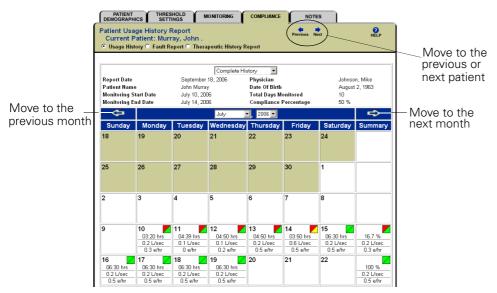


Figure 28: Patient Usage History Report screen

The Compliance screen opens with the Patient Usage History report. This displays compliance data in calendar form with daily and weekly summary results indicating:

- actual usage (in hour format)
- actual leak (L/sec)
- apnea index (events/hour)

Colored graphical symbols indicate the patient's compliance and leak, compared to the threshold settings.

To get more information:

- Click the arrows at the top of the report to move from month to month, or select the month and year from the drop-down menu.
- Click the "Next" or "Previous" arrow to display the usage history for the next or previous patient. (The patients listed depend on whether you accessed the patient usage history from the Patient Search screen or from the Exceptions Summary report.)
- Click on a specific day to display additional detailed information for that date. See Daily Therapeutic Report (page 30).
- Select [Complete History] from the drop-down menu to view all information for the patient.
- Select [Most Current Schedule] from the drop-down menu to view only information associated with the most recent monitoring schedule.

Color-coded symbols enable easy identification of patients who have fallen outside the threshold parameters entered by the clinician in the Threshold Settings Screen (page 26).

Usage and leak data are displayed graphically, using the following codes:

- The patient is compliant and the leak is less than or equal to the leak threshold.
- The patient is compliant but the leak is greater than the leak threshold.
- The patient is not compliant but the leak is less than or equal to the leak threshold.
- The patient is not compliant and the leak is greater than the leak threshold.
- The flow generator was not used.
- 3 Days remaining in monitoring schedule.

Figure 29: Compliance coding

The calendar also uses the following symbols:

- Δ The patient's thresholds, device or mask details have been changed.
- (M) Monitoring scheduled.
- 🥈 Data pending.
- A monitoring fault occurred.
- No threshold settings entered, color coding is unavailable.
- There are existing notes for the patient.

Figure 30: Calendar symbols

The Exception Summary Report screen (page 21) provides summary data for multiple patients for any particular day of therapy. This allows you to identify patients requiring immediate attention. This screen displays a graphical representation of patients' usage and leak rate compared to their threshold settings for a selected date or range of dates. Based on the color(s) of the boxes and the symbols displayed, you can easily target those patients who have not met compliance thresholds or have exceeded the leak threshold, and choose to review a more detailed record.

Daily Therapeutic Report

More detailed information on the patient's usage history is available in the Daily Therapeutic report.

Note: You must have Adobe Acrobat Reader 5.0 or later to display and print this report.

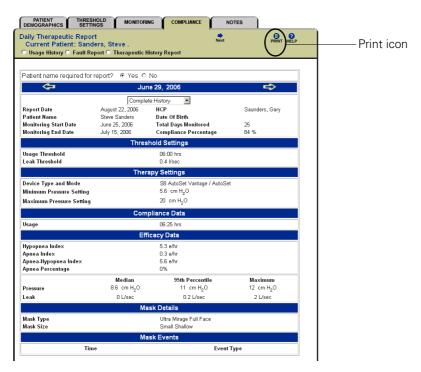


Figure 31: Daily Therapeutic Report screen

To view the Daily Therapeutic report:

- 1. From the Patient Compliance Calendar, click on a specific day to display the report.

 Data displayed includes: Threshold Settings, Therapy Settings, Compliance Data, Efficacy, Mask Data and Mask Events.
- To view the patient's entire monitoring history, select [Complete History] from the drop-down menu.
- To view the patient's most current monitoring history, select [Most Current Schedule] from the drop-down menu.
- Click the print icon to open the report in PDF format for saving or printing.
- 2. Click the [Compliance] sub-tab or the [Usage History] radio button to return to the calendar.

Therapeutic History Report

The Therapeutic History report displays summary data for single or multiple patients for multiple days. The data provided includes Compliance and Efficacy Data.

Note: You must have Adobe Acrobat Reader 5.0 or later to display and print this report.

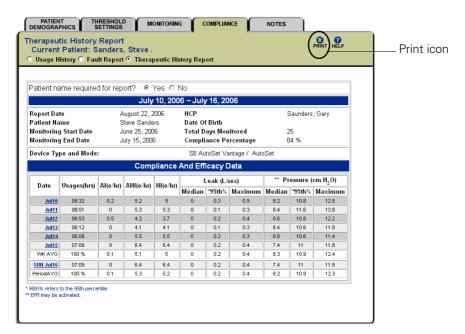


Figure 32: Therapeutic History Report screen

To view the Therapeutic History report:

- 1. Select [Therapeutic History Report] to display the setup page.
- 2. Specify whether you want to report on the current patient or on multiple patients, and specify the range of dates to report on.
- 3. Click [Next: Set Criteria].
- 4. Select the settings, usage and leak data on which you want to report.
- 5. Click [Show Report] to display the report.

Note: To generate a Daily Therapeutic report for a particular patient on a particular day, click on the desired day in the Therapeutic History report.

Patient Fault Report

The Patient Fault report on the Compliance screen allows you to view a patient-specific fault report.

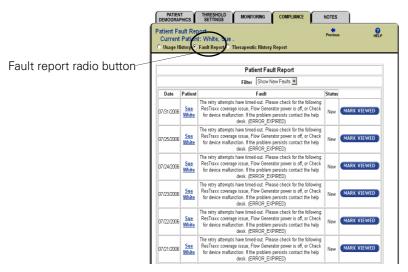


Figure 33: Patient Fault Report screen

- 1. Conduct a Search for a Patient (page 24).
- 2. Click the [Compliance] sub-tab. The Patient Usage History Report screen is displayed.
- 3. Click [Fault Report]. The Patient Fault report is displayed.
- 4. Use the Filter drop-down menu to select [Show New Faults] or [Show All Faults]. Fault information includes date, fault notes and status of the item on the report.
- 5. Once you have viewed the report information, you can click [Mark Viewed] to change the status to 'Viewed'.

Notes Screen

Use the Notes screen to enter and view user-generated notes and system-generated notes.

- User-generated notes are manual entries that are entered directly into the Notes page by the
 user. User-generated notes are used to document patient-related information as part of a
 permanent record.
- System-generated notes are automatically generated by the system whenever changes are made to patient information. System-generated notes are recorded in the System Change Log with the date, time, the user who made the changes, and a description of the changes.

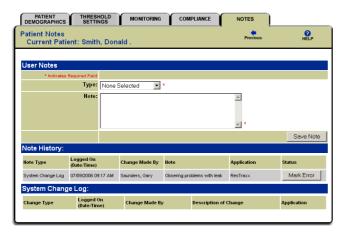


Figure 34: Notes screen

To create user-generated notes:

- 1. Conduct a Search for a Patient (page 24).
- 2. Click [Notes].
- 3. Select the note type from the drop-down menu.
- 4. Enter your information in the Note field and click [Save Note].

To mark a note as an error:

1. Click [Mark Error].

You cannot delete notes, as the patient information in ResTraxx Online constitutes medical records.

Note: Notes are stored in descending date order, from the most recent to the oldest.

Account Management Menu

Use the Account Management menu to access data loading and permission-based user options.

Note: Only options that you are authorized to access are displayed. If you don't see what you expect, check to make sure you are logged on with the proper authority level.

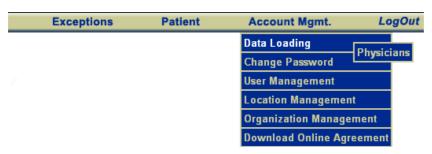


Figure 35: Account Management menu

The following submenu options are available in the Account Management menu:

- Data Loading
- · Change Password
- · User Management
- · Location Management
- Organization Management
- · Download Online Agreement.

The Account Management main screen also displays the available options:

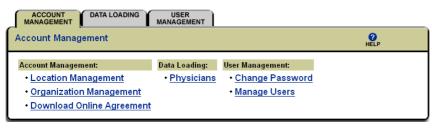


Figure 36: Account Management main screen

Authority Levels and Accessibility

Account Management has sections that can be accessed based on a user's authority level. There are five different levels of authority and accessibility:

• Default User Account: Can change their own password and add, view and modify patient demographic information and patient notes. Access to Account Management and patient information at any other level is denied.

Note: Default User Account is the minimum authority level and must be assigned to all user accounts.

• Data Administrator: Can change their own password; access the Physician Data Loading section; and add, view and modify patient demographic information and patient notes. Access to Account Management and patient information at any other level is denied.

- Health Care Provider: Have full access to Patient Menu (add, view and modify patient demographic information, threshold settings, monitoring, compliance and patient notes) and can change their own password. Access to Account Management at any other level is denied.
- Master Authority: Full access and ability to establish users (using User Management) and locations (using Location Management), and access to all account management data, including changing a user's password. Master Authority authorizes access to the Patient Demographics and Notes screens in the Patient menu, and to all screens in the Account Management menu. Must have Health Care Provider authority to access the Exceptions menu and for full access to patient information (Threshold Settings, Monitoring and Compliance sub-tabs).

Note: Individuals with Master Authority have access to all Account Management information, and can change their own authority level or that of other users. (To do so, they must have Default User authority.)

Read Only User: Assigns view-only permissions to user in Exceptions menu and Patient menu.
 Can change their own password.

Only options a user has authority to access are displayed. If you don't see what you expect, check to make sure you are logged on as a user with the proper authority level.

Note: All users must have Default User Account access. Master Authority Users must also have Data Administrator access. Access to Master Authority, Default User, Data Administrator and Health Care Provider is required for full system access.

Data Loading

When you select the Data Loading tab, the Physician option is displayed on the screen. Select this option to input multiple records of physician data during initial start up or whenever new non-patient-specific information is obtained.

Note: Only Data Administrator or Master Authority users can access this tab. If you don't see what you expect, check to make sure you are logged on with the proper authority level.

To add physician information:

- 1. Select [Data Loading] then [Physicians] in the Account Management main screen.
- 2. Conduct a search to ensure the physician does not already have an entry in the system.

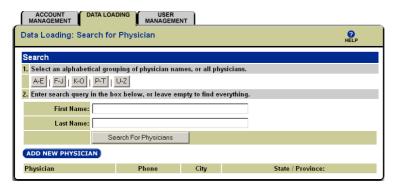


Figure 37: Search for a physician

3. Click [Add New Physician].

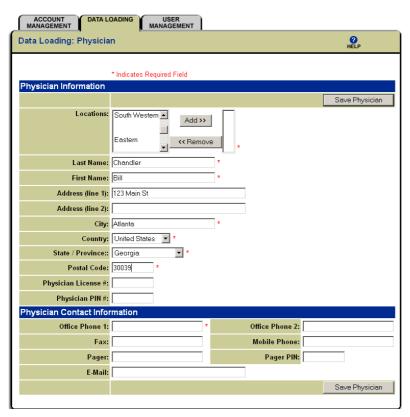


Figure 38: Add a physician

- 4. Enter the physician's information in the required fields.
- 5. Select the appropriate location(s) and click [Add]. The Location field indicates where the physician data is available.

Note: You must select at least one location. Selecting more than one location will make this physician available to users at the other locations.

- 6. Click [Save Physician].
- 7. Repeat steps 1-6 for each additional physician.

Note: Enter all information as completely as possible to take advantage of the automated functions.

Change Password

The system administrator sets initial passwords. To ensure system security, you should log in to the system and change your password in the Change Password screen as soon as possible.

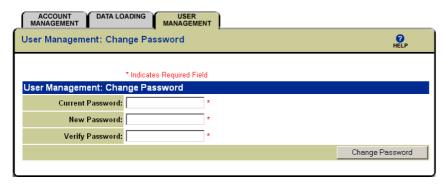


Figure 39: Change Password

To change your account password:

- 1. Select [Change Password] from the Account Management main screen or drop-down menu.
- 2. Enter your current password in the Current Password field.
- 3. Enter your new password in the New Password field.
- 4. Re-enter your password in the Verify Password field.
- 5. Click [Change Password] to initiate the change.

Guidelines for Passwords

- · Passwords do not expire automatically.
- Passwords are displayed as asterisks on the screen to ensure security. If you enter a password incorrectly, you will be returned to the Login screen.
- Passwords are case sensitive. For example, "xp45RbDg" is not the same as "Xp45rBDg".
- A user's password and login name cannot be the same. If you enter your login name as the password, a system error displays.
- Passwords can be any length and may contain any character except 'Enter', 'Space', and 'Tab' For example, "MarySue23" is a valid password, but "Mary Sue 23" is not a valid password.
- If you forget your password, a new password must be set by your system administrator.
- Your personalized password ensures that only you can access your confidential account information. Keeping your password secure and private is a part of your job.
- It is recommended that you change your password every 60–90 days, or as recommended by your system administrator to maintain system integrity.

User Management

Use the User Management tab to access permission-based user options in order to add, modify and inactivate user credentials.

The Location drop-down menu displays the location information that the particular user is able to access.

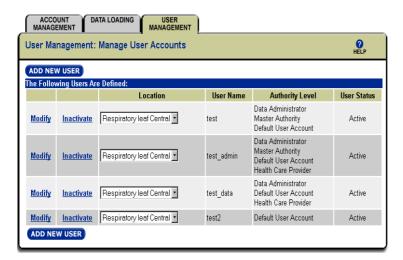


Figure 40: User Management tab

To add a new user:

- 1. Select [User Management] from the Account Management drop-down menu, or [Manage Users] from the main screen.
- 2. Click [Add New User].

The User Management screen is displayed.

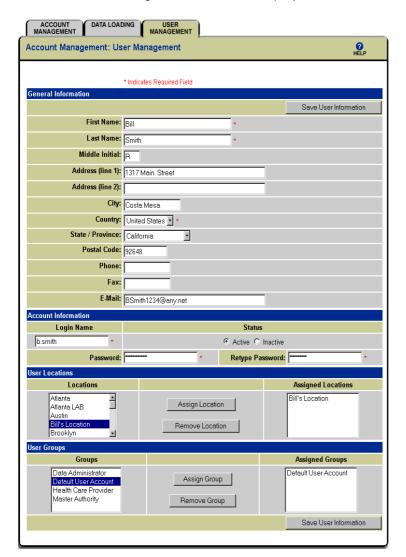


Figure 41: User Management screen

- 3. Enter the user's name, address and contact information in the General Information section.
- 4. Enter Account Information for the user in the appropriate fields.
- 5. Select the location(s) the user will have access to in the User Location and click [Assign Location]. You must select at least one location.
- 6. Select the levels of authority the user will be assigned to in the User Groups section and click [Assign Group]. (See "Authority Levels and Accessibility" on page 35 for more information.)
- 7. Click [Save User Information].

To modify a user's information:

- 1. Locate the user in the User Name column on the User Management screen.
- 2. Click the [Modify] link to the left of the user's name. The user's information screen displays.
- 3. Modify the information as appropriate.
- 4. Click [Save User Information].

To make a user's account inactive:

- 1. Locate the user in the User Name column on the User Management screen.
- Click [Inactivate] to the left of the user's name. The user's account will be changed to "Inactive" status.

Notes:

- a. Each user entered into the system (regardless of location and organization) must have a unique user name. It is recommended that users' email addresses are used. If you try to add a user name that already exists, the name will not be accepted.
- b. Only users with Master Authority logins can enter this part of the system.

Location Management

System users are assigned to one or more locations. Specifying locations adds an extra level of security by separating patient information in the system on a per location basis. The Location Management screen is used by users with Master Authority to add, modify and activate or inactivate locations.

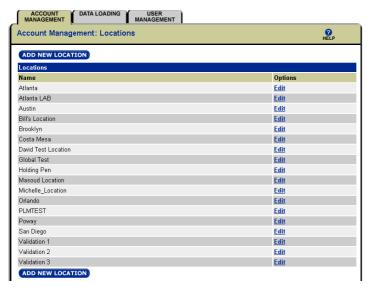


Figure 42: Location management screen

Note: Only users with Master Authority logins can enter this part of the system.

To access information on locations:

1. Select [Location Management] from either the Account Management drop-down menu or from the Account Management main screen.

To view or change location information:

- 1. Click the [Edit] option on the Location Management screen.
- 2. Enter the appropriate information on the resulting screen, and then click [Save Location].

To add a new location:

- 1. Click [Add New Location] on the Location Management screen.
- 2. Enter the appropriate information on the Edit Location screen and then click [Save Location].

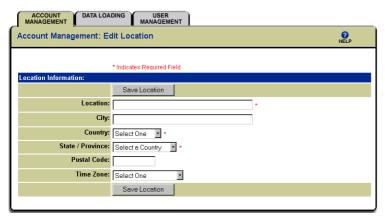


Figure 43: Edit Location screen

To activate or inactivate a location:

- 1. Click the [Edit] option on the Location Management screen.
- 2. Click [Active] or [Inactive], as required, then click [Save Location].

Installing and Using ResTraxx Wireless

A ResTraxx Wireless module must be connected to a prescribed and compatible flow generator in order for the wireless transfer of usage data to occur. Compatible flow generators are listed below.

Note: The ResTraxx and S8 ResTraxx devices function in the same way. The term "ResTraxx Wireless" applies to both devices.

Compatible Flow Generators

The compatible flow generators for each ResTraxx Wireless module are listed below.

ResTraxx

- S7 Elite
- · AutoSet Spirit
- AutoSet Respond
- VPAP III
- VPAP III ST
- VPAP Malibu

S8 ResTraxx

- S8 Elite
- S8 AutoSet Vantage
- S8 Elite II
- S8 AutoSet II
- VPAP ST
- VPAP Auto
- · VPAP Auto 25.

Connecting ResTraxx Wireless to a Flow Generator

Connecting ResTraxx Wireless to a compatible flow generator is the first step in setting up for wireless transfer of data. Once ResTraxx Wireless is connected to the flow generator, transmission and collection of patient usage information can be scheduled in ResTraxx Online.

When providing ResTraxx Wireless to a patient, it is important that you familiarize them with the information below. Ensure that the patient has also been given the appropriate quick reference guide for their ResTraxx Wireless.

It is recommended that you set up a patient's file in ResTraxx Online before attaching ResTraxx Wireless to the flow generator.

Note: The flow generator should be set to the user's local time to ensure accurate reporting of data.



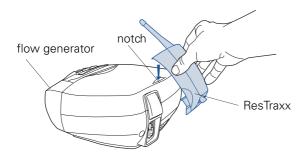
CAUTION

Do not transport a flow generator with a ResTraxx Wireless module attached.

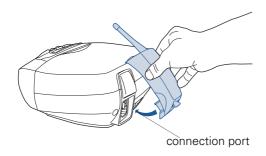
ResTraxx

Note: See "Compatible Flow Generators" on page 43 for a list of flow generators compatible with this device.

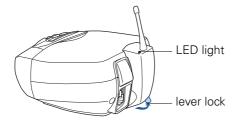
- 1. Switch the flow generator to OFF at the power switch.
- 2. Slide the lever on the back of the ResTraxx to the left.
- 3. Place the top catch of the ResTraxx onto the notch at the back of the flow generator.



4. Push the 15-pin connector on the ResTraxx onto the connection port at the back of the flow generator.



5. Slide the lever on the back of the ResTraxx to the right to lock it into place.



6. Turn the main power switch at the back of the flow generator ON.

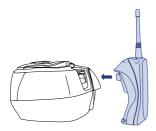
S8 ResTraxx

Note: See "Compatible Flow Generators" on page 43 for a list of flow generators compatible with this device.

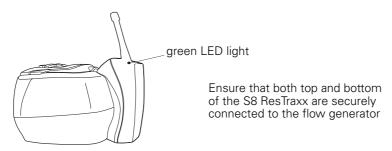
- 1. Make sure the flow generator is not plugged in at the power outlet.
- 2. Remove any module attached to the flow generator. Store the module in the S8 ResTraxx pouch.



3. Align the S8 ResTraxx with the back of the flow generator.



4. Push the top and base of the S8 ResTraxx onto the flow generator simultaneously.



5. Plug the flow generator into the power outlet.

Initialization

Approximately 15–20 seconds after the flow generator is turned on, a green LED status light on top of the ResTraxx Wireless module lights up, then begins to blink.

The following messages appear on the flow generator LCD display, indicating the initialization and registration status.

- · ResTraxx Initializing
- ResTraxx Registered.

Registration can take up to 15 minutes.

After registration, a standby message appears on the flow generator LCD display and the ResTraxx Wireless LED light becomes solid, indicating that ResTraxx Wireless can begin downloading and transmitting information. Download depends on the time period set in the Monitoring Screen (page 27).

While ResTraxx Wireless is downloading, the following message is displayed on the flow generator LCD display:

"ResTraxx Downloading"

When downloading is complete, the following message is displayed:

"ResTraxx Download Done"

Note: Items such as televisions, computers or large metal objects may block reception to and from ResTraxx Wireless. Do not place these items on top of, under or near a ResTraxx Wireless module.

ResTraxx Wireless LED Status Light

The green LED status light on the top of ResTraxx Wireless lights up at initialization. The blinking pattern of the light indicates the following:

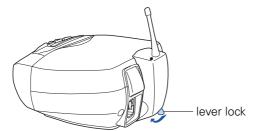
- Solid light (no blinking)—normal operation; download and transmission can occur.
- Single blinks—registration is occurring. Will also occur if ResTraxx Wireless loses its connection to the transmission network.
- Double blinks—ResTraxx Wireless cannot communicate with the flow generator to which it is attached.

See "Troubleshooting" on page 49 for possible causes and solutions if the ResTraxx Wireless LED is blinking.

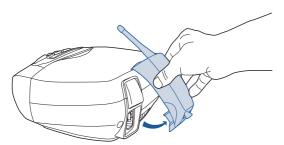
Detaching a ResTraxx Wireless Module

ResTraxx

- 1. Switch the flow generator to OFF at the power switch.
- 2. Slide the lever on the back of the ResTraxx to the left.



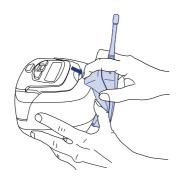
3. Carefully pull the ResTraxx away from the flow generator.



4. Store the ResTraxx in its pouch.

S8 ResTraxx

- 1. Unplug the flow generator from the power outlet.
- 2. Detach the S8 ResTraxx from the top of the flow generator then carefully pull it away.



3. Reattach the ResScan Data Card module or blank module to the flow generator. If you do not have a module for your flow generator, order a replacement from your equipment supplier.



4. Place the S8 ResTraxx in its protective pouch.

Cleaning a ResTraxx Wireless Module

ResTraxx Wireless is designed to give you years of trouble-free operation. If the device appears dirty, disconnect it from the flow generator and wipe the outside with a clean dry cloth.

Note: Avoid exposing ResTraxx Wireless to moisture and extreme temperatures.



- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean any part of ResTraxx Wireless. These solutions may cause damage and reduce the life of the product.
 - Do not use liquids to clean any part of ResTraxx Wireless.
 - Inspection and repair should only be performed by an authorized service agent. Under no circumstances should you attempt to service or repair the device yourself.

Troubleshooting

If there is a problem, try the following suggestions. If the problem cannot be solved, contact your equipment supplier or ResMed.



CAUTION

Service and repair should only be performed by an authorized service agent. Under no circumstances should you attempt to service or repair the unit yourself. Do not attempt to open the unit.

Problem	Possible Cause	Solution
After the "ResTraxx Initializing" message is displayed, the light starts the short blink sequence and never leaves this state. Transmission of usage data is disrupted or does not occur.	ResTraxx Wireless is not connected properly.	Re-attach ResTraxx Wireless.
	Patient has traveled out of a coverage area.	Determine when patient will be in coverage area again.
	Flow generator is not in a coverage area for the wireless service.	Determine if coverage is possible.
	Inadequate network signal at location of ResTraxx Wireless.	Move ResTraxx Wireless to a different location. Elevating or moving the device near a window may help. Ensure that there are no electric motors nearby (eg, fans, air conditioners).
	Incorrect ResTraxx serial number entered into Restraxx Online.	Check for fault messages. Re-enter serial number in Monitoring Screen (page 27).
	Incorrect flow generator serial number entered into ResTraxx Online.	Check for fault messages. Re-enter serial number in Monitoring Screen (page 27).
	Restraxx Wireless is not registered with the paging network.	Contact your equipment supplier.
Flow generator and ResTraxx Wireless not working (ResTraxx LED light does not come on and there is no display on the flow generator LCD). Transmission of usage data is disrupted or does not occur.	Power cord is not plugged in properly.	Check that the power cord is plugged firmly at the back of the flow generator and into a working power outlet.
	Flow generator not switched on.	Check that the switch at the back of the flow generator unit is in the ON position.
	Faulty power outlet.	Try another power outlet.

Problem	Possible Cause	Solution
The LED light on ResTraxx Wireless does not come on after power up.	The connector on ResTraxx Wireless is not completely inserted into the connection port at the back of the flow generator.	Turn the flow generator OFF. Ensure that the connector on ResTraxx Wireless is completely inserted into the connection port at the back of the flow generator. Turn the flow generator back ON.
	Faulty LED.	Contact your equipment supplier.
The light on ResTraxx Wireless starts the two short blink pattern and stays in this state for over an hour.	Incompatible flow generator.	Make sure that you have connected ResTraxx Wireless to a compatible ResMed flow generator. See "Compatible Flow Generators" on page 43. Contact your equipment supplier. It may be necessary to upgrade your flow generator or obtain a later model.
	Component failure.	Contact your equipment supplier.

Technical Specifications

Computer for Accessing ResTraxx Online

Computer/processor: Intel-based PC

Operating system: Windows XP

Internet Explorer: 6.0

Adobe Acrobat Reader: 5.0 or above

ResTraxx

Dimensions (H x W X D): 8.4" x 2.5" x 2.3" (attached to flow generator; including aerial)

Weight: 0.35 lbs

Power Supply:

Maximum current derived from the flow generator at 24V: 350 mA when transmitting; 40 mA in standby mode.

Housing Construction: Flame retardant engineering thermoplastic **IEC 60601-1 Classification:** Class II (double insulation), Type CF

Electromagnetic Compatibility

Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments.

Environmental Conditions

Operating Temperature: +41°F to +104°F Operating Humidity: 10%–95% non-condensing Storage and Transport Temperature: -4°F to +140°F

Storage and Transport Humidity: 10%-95% non-condensing

Symbols on the ResTraxx



Attention, consult accompanying documents



Type CF applied part



Class II equipment



Non-ionizing electromagnetic radiation



Drip proof

S8 ResTraxx

Dimensions (H x W X D): 8.1" x 2.5" x 1.3" (attached to flow generator; including aerial)

Weight: 0.32 lbs

Power Supply:

Maximum current derived from the flow generator at 12V: 700 mA when transmitting; 80 mA in standby mode.

Housing Construction: Flame retardant engineering thermoplastic **IEC 60601-1 Classification:** Class II (double insulation), Type CF

Electromagnetic Compatibility

Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments.

Environmental Conditions

Operating Temperature: +41°F to +104°F
Operating Humidity: 10%–95% non-condensing
Storage and Transport Temperature: -4°F to +140°F
Storage and Transport Humidity: 10%–95% non-condensing

Symbols on the S8 ResTraxx



Non-ionizing electromagnetic radiation



Drip proof

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