

Home Diagnosis of Obstructive Sleep Apnea and Snoring



Convenient

Comfortable

Comprehensive

Self-administered at home



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Business hours: Monday through Friday, 9am - 7pm ET

Do you suffer from any of these symptoms?

- Loud snoring
- Waking with a headache
- Restless nights
- Clinching of teeth
- Trouble concentrating
- Dry mouth
- Irritable
- Depression
- Rapid weight gain
- Heartburn
- Sexual dysfunction
- Hypertension

If so, you may be suffering from a sleep disorder.

Why should you take a Watch-PAT home sleep study?

A full and restful nights sleep is vital to one's individual health. If you have symptoms related to sleep disorders, it is important to find their causes and treat them as soon as possible. To fully understand many sleep related problems, an overnight sleep study is needed. Problems that can be diagnosed from an overnight sleep study include sleep apnea, snoring, REM related problems, bruxism and different behavioral changes.

Historically, an overnight sleep study has been performed in a hospital or sleep lab. You spend the night in the facility with up to a dozen wired sensors attached to your body and a sleep tech watching you sleep on a closed circuit camera to determine if you have sleep problems. **The Watch-PAT is an easy home sleep test that allows you to sleep in your own bed and get results in just a few days.** If left untreated, sleep disorders can lead to heart attacks, strokes and even death. Other long term physical and psychological complications can include obesity, high blood pressure, diabetes, depression, poor work performance and strained personal relationships. A Watch-Pat home sleep study will determine if you have symptoms related to a sleep disorder so you can be treated.

What will the Watch-PAT home sleep study tell you?



The Watch-PAT device uses 3 easy-to-apply sensors to measure 6 channels of information to monitor your quality of sleep. The cause of most sleep disturbance is identified by measuring breathing, snoring, body position and Sleep Stages.

Sleep disturbances are reported as either the Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI), which is the number of times you wake up per hour of sleep. Most of these awakenings are too short to remember as they last only for a number of seconds. It is considered normal to wake up 5 times per hour; waking 5-15 times per hour is considered mild sleep apnea; 15-30 times per hour is considered moderate sleep apnea and over 30 awakenings per hour is considered severe sleep apnea and indicates a sleeping problem that requires urgent intervening treatment.

The Watch-PAT sleep study also reports your snoring level, the amount of time that you slept, your heart rate, your desaturation levels, your REM (rapid eye movement) sleep stages and the overall quality of your night's sleep.

When your health care professionals receive the results from your Watch-PAT test, they will be able to determine the most appropriate treatment for you. Possible treatment methods may include oral appliances, CPAP, lifestyle changes and surgery. Generally, these treatments result in an improved quality of life.

The steps for Watch-PAT testing:

- 1 Talk to your physician, who will perform a medical evaluation and likely prescribe a home sleep study.
- 2 **1st Line Medical** will contact your health insurance provider on your behalf to confirm coverage and benefits.
- 3 **1st Line Medical's** customer service personnel will contact you to review your insurance coverage and benefits and arrange delivery of a Watch-PAT home sleep study kit.
- 4 You Watch-PAT home sleep test will arrive at your home with a 24/7 toll-free tech support hotline number and a patient orientation video. Unpack the box, follow the directions and wear the device for one night while you sleep. It is battery-operated and completely portable, so you are free to get up and move about during the study.
- 5 Upon awakening the next morning, remove, repackage and return the Watch-PAT to **1st Line Medical** using the original packaging and the prepaid return label provided for you.
- 6 The information from the Watch-PAT home sleep test will be interpreted and provided to your physician within 5 business days.
- 7 You will schedule a follow up appointment with your doctor to discuss the results and consider all treatment alternatives that are appropriate for you.
- 8 As with any medical condition, consult your physician for additional information and answers to your questions and concerns. More information about Watch-PAT home sleep testing and a patient video are available at www.1stlinemedical.com.



An Independent Diagnostic Testing Facility (IDTF).
Providers of At-Home Sleep Study Services.

Using the Watch-PAT is as easy as 1 ~ 2 ~ 3 ~ 4



1 Put the device on your wrist.



2 Put on the 2 finger sensors.



3 Put on the snoring and body position sensor.



4 Push the button.

NOTICE OF HEALTH INFORMATION & FINANCIAL POLICIES

This notice describes how information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

COMMITMENT TO PRIVACY:

1st Line Medical, Inc. is dedicated to maintaining the privacy of your healthcare information and we are required by law to maintain the confidentiality of information that identifies you. Any use of healthcare information beyond the uses described below requires your individual written authorization. The Health Insurance Portability and Accountability Act (HIPAA) obligates us to provide you with a copy of our Privacy Notice, outlining our privacy practices and how we safeguard your health information. We abide by the terms of the Privacy Notice currently in effect, and reserve the right to revise or amend the notice, as needed.

YOUR HEALTH INFORMATION RIGHTS:

Although your health record is the physical property of the healthcare facility that compiled it, the information belongs to you. You have the right to:

- Request a restriction on certain uses and disclosures of your information;
- Obtain a paper copy of the notice of privacy practices;
- Inspect and copy your health care record;
- Obtain an accounting of disclosures of your health information;
- Request confidential communication;
- Amend your healthcare record;
- Revoke your authorization to use or disclose health information except to the extent that action has already been taken.

We will use your health information for payment.

In order to determine your eligibility for services, we will contact your insurance company and disclose healthcare related information. Also, we may bill you or a third-party payer for services that you receive from our company. The health information that identifies you, your diagnosis, equipment, and supplies may be included on this bill.

Product: Watch-PAT200 Home Sleep Test Kit
Part Number: WP200HST
Price (USD): \$385.00
Price is subject to change.

Responsibility for Payment:

1st Line Medical, Inc. will make every effort to bill your insurance company directly. You are responsible for full payment for services rendered by us. Any charges not covered by your insurance company, includ-

ing co-payments, deductibles, non-covered services, and out-of-network services will be your responsibility except where not allowed by law. It is your responsibility to know the requirements of your health plan. In the event of a denial of any insurance billed, you will be responsible for all fees charged.

To our Managed Care Patients:

If you receive any services at 1st Line Medical, Inc. and the fees are denied because you did not obtain prior authorization from your primary care physician, you will be personally responsible for those fees.

We will use your health information for healthcare operations.

We may use your health information to evaluate the quality of care you receive from us, to conduct cost management assessments, and to plan business activities. This information is used in an effort to continually improve the quality and effectiveness of the healthcare services we provide.

Business Associates: There are some individuals who are under contract with us and, from time to time, are engaged in the improvement or financial enhancement of our business. So that your health information is protected, however, we require any business associate to appropriately safeguard your information.

Public Health: As required by law, we may disclose your health information to public health or legal authorities charged with preventing or controlling disease, injury, or disability.

Law Enforcement: We may disclose health information for law enforcement purposes as required by law, or in response to a valid subpoena.

Health Oversight Activities: We may disclose health information to health oversight agencies for activities authorized by law, including surveys, audits, and compliance inspections.

Worker's Compensation: We may release your health information to the extent necessary to comply with laws relating to workers compensation or other similar programs established by law.

OUR RESPONSIBILITIES:

We are required to:

- Maintain the privacy of your health information;
- Provide you with a notice as to our legal duties and privacy practices with respect to information we collect and maintain about you;
- Abide by the terms of this notice;
- Notify you if we are unable to agree to a requested restriction;
- Accommodate reasonable requests you may have to communicate health information by alternative means.

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We reserve the right to change our practices and to make the new provisions effective for all protected health information we maintain. Should our information practices change, we will mail a revised notice to your address on file. We will not use or disclose your health information without your authorization, except for treatment, payment, and healthcare operations.

We will use your health information for treatment.

Information obtained by our company will be documented in your healthcare record and will be used to provide you with healthcare related services. The prescription that your physician has ordered will be part of the record and will determine the equipment and supplies that you receive.

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Customers have the right to:

- Be given timely, appropriate and quality professional services without discrimination.
- Be provided with proper products and services as ordered by a qualified health care professional.
- Receive products in proper operating conditions according to manufacturer's specifications.
- Receive fair treatment, including honoring cultural, spiritual, and personal preferences.
- Request a detailed explanation of any bill for product or services.
- Be communicated with in a way that can be reasonably understood.
- Refuse equipment or services, accepting full responsibility for that refusal.
- Choose their own provider for equipment and services.
- Be assured of confidentiality, to review records, and to approve or refuse the release of protected health information.
- Have competent and qualified people carry out the services for which they are responsible.
- Voice their grievances and recommend changes without fear of reprisal.
- Report concerns about patient safety without fear of reprisal.

It is the responsibility of the Customer to:

- Dial "911" whenever a life threatening medical emergency arises.
- Provide complete and accurate information regarding your history and billing information.
- Comply with your physician's orders and plan of care.

- Use and care for the equipment provided and not allow use by anyone other than authorized patient.
- Contact the Company if any equipment malfunctions or is defective, and allow our staff to correct the problem.
- Advise us of any changes in your status, including address, medical condition, billing information.
- Assume payment responsibility for services not covered by your insurance carrier, except where not allowed by law.
- Maintain a safe home environment for the proper utilization of equipment.
- Pay for the replacement costs of any equipment damaged, destroyed, or lost due to misuse, abuse, or neglect.

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**INDEPENDENT DIAGNOSTIC TESTING FACILITY
(IDTF) PERFORMANCE STANDARDS**

Below is a list of the performance standards that an IDTF must meet in order to obtain or maintain their Medicare billing privileges. These standards, in their entirety, can be found in 42 C.F.R section 410.33(g).

1. Operate its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.
2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 calendar days.
3. Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mail box, hotel or motel is not considered an appropriate site.
 - (i) The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.
 - (ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

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4. Have all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. A catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers, must be maintained at the physical site. In addition, portable diagnostic testing equipment must be available for inspection within two business days of a CMS inspection request. The IDTF must maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

5. Maintain a primary business phone under the name of the designated business. The primary business phone must be located at the designated site of the business, or within the home office of the mobile IDTF units. The telephone number or toll free numbers must be available in a local directory and through directory assistance.

6. Have a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a non-relative owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must –

(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least \$300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations.

7. Agree not to directly solicit patients, which include, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Nonphysician practitioners may order tests as set forth in §410.32(a)(3).

8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

9. Openly post these standards for review by patients and the public.

10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must be accessible during regular business hours to CMS and beneficiaries and must maintain a visible sign posting the normal business hours of the IDTF.

15. With the exception of hospital-based and mobile IDTFs, a fixed base IDTF does not include the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization.

(ii) Leasing or subleasing its operations or its practice location to another Medicare enrolled individual or organization.

(iii) Sharing diagnostic testing equipment using in the initial diagnostic test with another Medicare-enrolled individual or organization.

16. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

17. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.

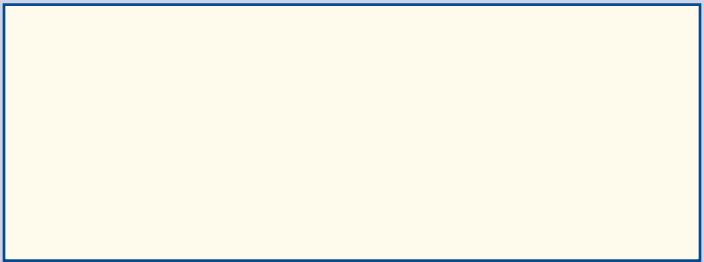
FOR MORE INFORMATION:

Please contact 1st Line Medical, Inc.'s Privacy Officer, at 866-720-8080, if you require additional information and/or want to pursue your rights, including:

- Requesting restrictions;
- Inspecting and copying your record;
- Securing an accounting of disclosures;
- Requesting additional disclosures;
- Revoking authorizations at any time;
- Filing a complaint

If you believe your privacy rights have been violated, you may contact our company's General Manager. You may also file a complaint with the Secretary of Health and Human Services (Office of Civil Rights) to: DHHS, Office of Civil Rights, 200 Independence Avenue, S.W., Room 509F HHH Building, Washington, DC 20201. There will be no retaliation for filing a complaint.

Your Prescribing Health Care Professional:



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