| | Name / Title | Signature | Date |
|---|---|---|---|
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| History Of Changes | | |
|---|---|---|
| **Revision** | **Description Of Changes** | **Effective Date** |
| 1 | Initial version | 05-March-2020 |
| 2 | Compliance information update, correction of terminology, some syntactic changes | 24-April-2020 |
| 3 | Refined compliance info per Clause 5 Review | 27-April-2020 |
| 4 | Refined Patch low battery indication | 12-June-2020 |
| 5 | Revised according to app changes, added provider portion | 16-Nov-2021 |
| 6 | Updated to Wesper Lab user manual, included charging, cleaning and re-adhesion information | 18-Nov-2022 |
| 7 | Added information regarding shelf-life and charging lifetime, clarifications regarding patch lifetime | 8-Feb-2023 |
| 8 | Added information and guidance regarding chargerless configuration | 31-Jul-2024 |
| 9 | Updated images of pairing flow in the app. Revisions for clarity | 17-Sep-2024 |

**Purpose** :

The purpose of this document is to describe the Instructions for Use for the Wesper Lab device.

# Wesper Lab

## User Manual

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## Manufacturer



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# 1. Introduction

Use of This Manual

This manual covers the operation and maintenance of Wesper Lab. The user of this device should be fully familiar with the contents of this manual before using the device.

**PLEASE RETAIN THIS USER MANUAL FOR FUTURE REFERENCE.**

# 2. Safety

## *2.1. Typesof Warnings, Cautions and Notes*

Three types of special messages appear in this User Manual:



**Warning:** A warning indicates precautions to avoid the possibility of personal injury or death.



**Caution:** A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.



**Note:** A note provides other important information.

# 3. GeneralWarningsand Cautions

## 3.1. *Warnings*



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Wesper Lab Patches, including cables specified by Wesper. Otherwise, the performance of this equipment could be negatively impacted.

## 3.2. *Cautions*



Do not expose the Patches or Patch charger to direct heat or flammable products.



Do not immerse or expose the Patches or Patch charger to water or other liquids.



The Patches are intended for use on adult patients.



Do not use the Patches if they show any sign of damage.



Replace the device if it is not working properly.



Use of the Patches or Patch charger in any way other than that described in this manual is prohibited.



Do not fully immerse the Patches into alcohol or solvents.



Do not allow the Patches or Patch charger to get wet.



Damaged Patches are to be discarded according to electronic waste disposal regulations in your region.



Use of Wesper Lab Patches adjacent to or stacked with other monitoring equipment should be avoided as the presence of other equipment could result in improper operation. If such use is necessary, the Wesper Lab Patches and the other equipment should be observed to verify that they are operating normally.



Use of accessories, transducers, and cables other than those specified or provided by Wesper could result in increased electromagnetic emissions or decreased electromagnetic immunity of Wesper Lab Patches and result in improper operation.


Do not use thePatches orPatch charger if outside the appropriate temperature range, as specified in Section 7.1.1 Environmental and Storage Conditions.


Do not use the Patches if the casing is damaged.


Do not use the Patches if the lights on the Patch do not light up during initial pairing.


Do not use the Patches if the lights on the Patch do not change color during initial pairing.


Do not use the Patches if there is no measurement indication.


Use only authorized pulse oximeters, a list of which can be found at www.wesper.co/oximeter .

# 4. ConditionsforUse

## *4.1. Indications for Use*

The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel. Wesper Lab is intended to be used for adult sleep studies at home or clinical environment. The device does not monitor or diagnose the patient and does not issue any alarms.

## *4.2. Contraindications*

Use of this device is contraindicated for pediatric patients, including infants and neonates.

# 5. System Overview

## *5.1. Why Wesper?*

Wesper Lab is a digital recording device designed to collect sleep data in adult patients as prescribed by a healthcare professional.

Wesper Lab uses a set of adhesive Patches to record physiological parameters during sleep. The kit is coupled with a compatible pulse oximeter to collect information about pulse rate and oxygen desaturations. This information is wirelessly transmitted and stored using the Wesper mobile application. The data is then forwarded to the Wesper Cloud for use by the care provider. Wesper Lab is simple to use. A replaceable adhesive layer is used to attach the Patches to the patient's skin, and the App is configured to record data in a few simple steps. The collected data is delivered to the patient's healthcare provider who can analyze the information as they normally would for any physiological recording device. The patches and pulse oximeter are rechargeable, so data can be taken separately for multiple nights per the healthcare provider's prescription.

## *5.2. Wesper in Brief*

Wesper Lab uses an FDA-cleared pulse oximeter and a proprietary set of flexible, thin, wireless, reusable, and wearable adhesive Patches designed to record sleep disorder data in adult patients.

The Patches consist of a battery-powered physiological recording system encapsulated in layers of fabric (top layer), silicone (bottom layer), and medical-grade skin adhesive. The adhesive is safe for adult patient use. It is strong enough to keep the Patches affixed to the body throughout a single night, and replaceable to allow the patches to be used for multiple nights. Both the Patches and the pulse oximeter can be recharged to allow for use over multiple nights.

The Patches collect multiple physiological parameters related to sleep quality, including sleep position and respiratory effort. The pulse oximeter records oxygen saturation levels and pulse rate. Data from the Patches and the pulse oximeter is transmitted via low-energy Bluetooth (BLE) throughout the night to a companion mobile application installed on the patient's personal mobile device. The data is then uploaded to a secure cloud-based server after the recording has ended.

Clinicians can access this data for interpretation and use it as additional information to support diagnosis of sleep apnea.

This document explains the use of the Wesper Lab and its associated smartphone App.

## *5.3. Device Description*

### *5.3.1. Main Components*

Wesper Lab consists of four components: the Patches, an FDA-cleared pulse oximeter, the Wesper smartphone App, and a Patch charger.

#### *5.3.1.1. The Wesper Lab Patches*



The Wesper Lab Patches are two thin reusable Patches that are attached to the patient's stomach (abdomen) and right side of the rib cage (thorax) with adhesive before the patient goes to sleep.

The Patches reliably and continuously record the patient's physiological data, including sleep position, respiratory effort, and other data relevant to sleep quality.

This data is automatically stored in the Patches' on-device memory and is also continuously transmitted to the Wesper App when the smartphone is nearby. Data is then transmitted from the smartphone to the Cloud, where it can be analyzed by Wesper's data analysis software.

##### *5.3.1.1.1. Essential Performance*

Essential performance of the Wesper Lab Patches is defined as a functioning patch being able to both collect accurate physiological data, and successfully deliver this data to the Wesper mobile application.

Accuracy and data delivery may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the indications for use (Section 7.1). If issues are experienced, move the

Wesper Lab patchesaway fromthe source of any electromagnetic disturbances.

***5.3.1.2. The Wesper App***




The Wesper App is used with the Patches; it automatically collects and forwards physiological information from the Patches.

***5.3.1.3. The Pulse Oximeter***

A pulse oximeter is a small device that measures blood oxygen saturation and heart rate, typically at the finger or ear lobe. When used as part of the Wesper system, the data produced by the pulse oximeter is transmitted to the Cloud and can be analyzed, along with the data from the Patches, by Wesper's software. Please consult www.wesper.co/oximeter for a list of authorized oximeters that work with the system.

***1.***

#### *5.3.1.4. The Patch Charger*

**Note:** Based on necessity and expected usage period, your kit may not contain a charger.

The Patch charger is a wireless charging platform which can be used to recharge the battery of the two Wesper Lab Patches. The charger is a small, low-profile pad with two impressions matching the profile of the Patches on its top surface. When the Patches are placed in these impressions, they are charged using wireless induction charging. The Patch charger receives power from the included 5V power supply and USB-C cable.

##### *5.3.1.4.1. Essential Performance*

Essential performance of the Wesper Lab Charger is defined as being able to deliver energy to up to two Wesper Lab Patches.

Performance of the charger may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the indications for use (Section 7.2). If issues are experienced, move the Wesper Lab charger away from the source of any electromagnetic disturbances.

### *5.3.2. Data Capture – Automatic and Continuous*

While the patient is sleeping, the Patches continuously record and transmit physiological data to their personal mobile device. The data is automatically uploaded from the phone to the Wesper Cloud, where it is analyzed and then delivered to the patient's healthcare provider for scoring and interpretation.



### *5.3.3. Patch ConnectionLoss*



**Warning:** The Wesper Lab Patches should be used no closer than 30 cm (12 inches) to any equipment in the intended use environment which emits EM radiation. Otherwise, degradation of the performance of the patches could occur.

If Bluetooth connection loss occurs during recording, for example, due to EM disturbances, the patches will continue to record data and will automatically send data accumulated during a connection loss when the connection is re-established.

If the connection loss lasts for a large portion of the night, the patient may need to wait a few minutes in the morning while Wesper sends all recorded data to the Cloud to ensure the integrity of the sleep study. At this point, the patient may remove the Patches, but it's important they're kept close to the patient's mobile device to ensure successful completion of the study.

A progress bar on the App shows when the data has been successfully delivered.

If any connection loss persists at completion of the test, data may be lost, and a new study must be initiated on a future night. If connection loss becomes a persistent issue, the patient may consider moving potential sources of disturbances, or may make alternative sleeping arrangements.

### *5.3.4. Patch Low-Battery Indication*

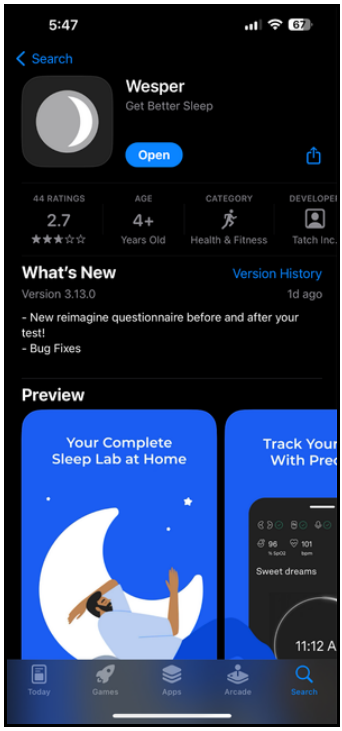
When the user connects a Wesper Patch to the mobile App (see Section **6 Using Wesper** *),* the system automatically runs an internal test to determine if the Patch has sufficient battery capacity to sustain a full night's session. Should the battery level be insufficient, the user will be notified with a patch LED indication (see section **6.7.2 Patch Low Battery Indication** ), at which point the user will need to recharge the Patch using the Patch charger before another session can be started. If no charger is provided with your kit, please contact your healthcare provider for further instructions.

# 6. Using Wesper

## *6.1. First-timeUse:Install the Wesper App*

If it is not installed already, install the Wesper App.

Open the Apple App Store or Google Play Store and search for “Wesper” in the search bar. Install the Wesper App by tapping on the download icon next to the app icon.

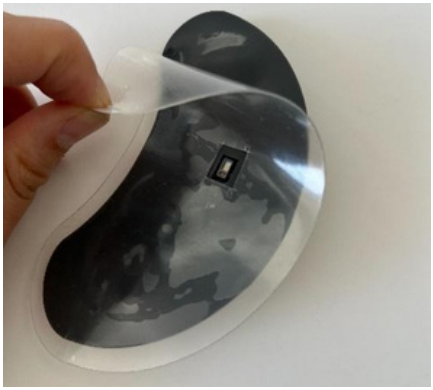



## *6.2. Check Patches Before Starting a Session*

### *6.2.1. Apply New Adhesive Layer to Patches*

**Caution:** Do not reuse old adhesive for a new Wesper Patch application.

If the Patches have a previously used adhesive layer applied, remove this adhesive layer by peeling it from the bottom of the patch. Discard the used adhesive layer.



Next, place the patch onto a flat surface with its glass sensor window facing up. Remove the thin plastic film from one side of a new adhesive cutout and stick this side onto the exposed bottom layer of the patch.

Use both hands to lower the adhesive onto the Patch, taking care to ensure that the adhesive cutout lines up well with the Patch bottom layer, and that the Patch's sensor window is not obstructed with adhesive. Press the adhesive into the patch, removing any air bubbles in between the adhesive and the bottom layer of the patch.






Repeat this processfortheotherpatch.

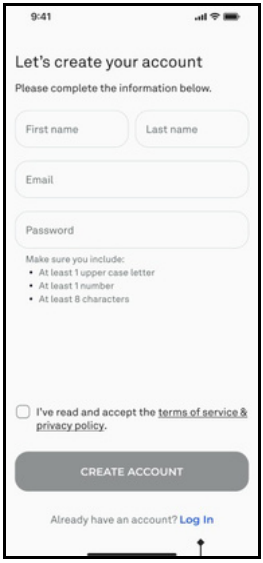
### *6.2.2. Charge Patches*

| | |
|---|---|
| | **Note:** Based on necessity and expected usage period, your kit may not contain a charger. |
| | **Caution:** Do not start a Wesper session using patches which are not fully charged. |

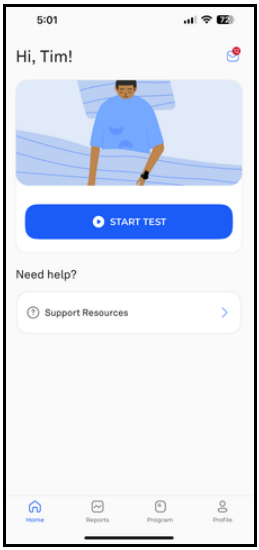
Ensure that patches are fully charged before starting a session. See section **6.12 Charging The Patches** for Patch charging instructions.

## *6.3. Begin a new Wesper Session*

Open the Wesper App. If you have not already set up an account, follow the instructions displayed in the app.




Once logged in, tap the “Start Test” button to begin a new session.

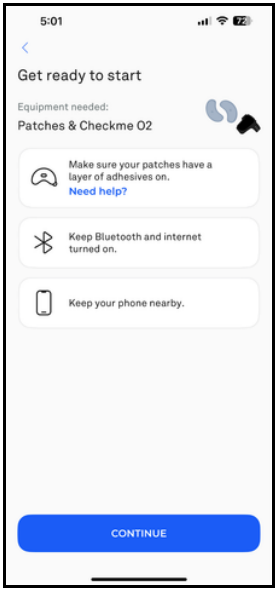



## *6.4. Activate and Apply the Patches*

**Caution:** Do not allow the Patches to get wet.

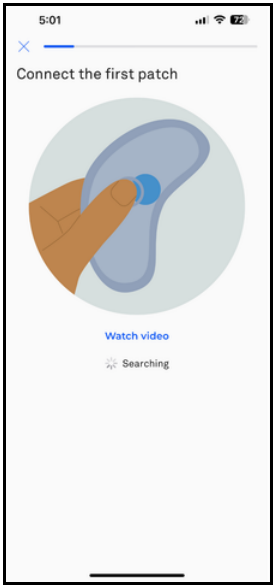
**Caution:** The Patches must be applied in the following order: right side of the rib cage (thorax), then the stomach (abdomen).

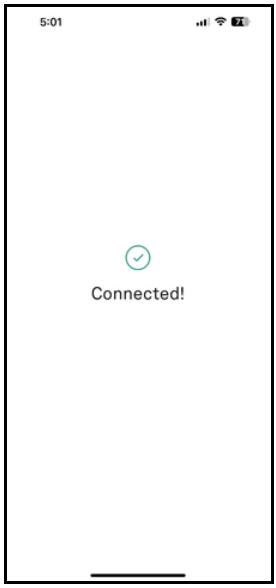
Ensure that the patient's chest and abdomen are clean and dry before pressing "Continue" to set up both patches.




### *6.4.1. Turn on Patch 1 (Pairing)*

When directed by the app, press the button on the first Patch to connect.



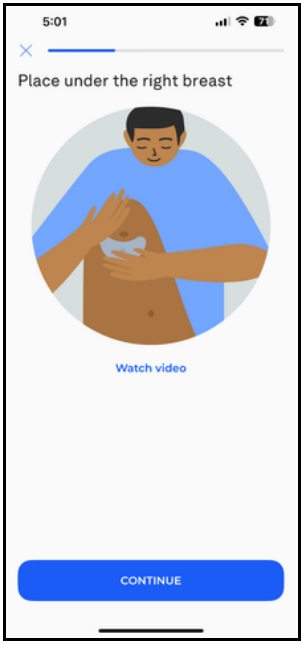



**Caution:** Do notuse aPatchifthe lights on the Patch do not light up or change color during initial pairing.

### *6.4.2. Apply Patch 1 to Ribcage (Thorax)*

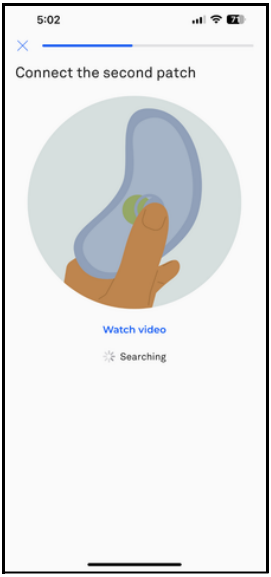
**Caution:** Only apply Wesper Lab Patches to intact skin.

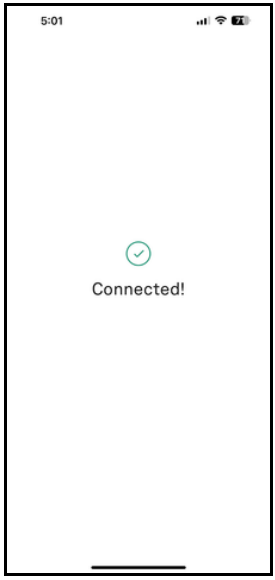
Once paired, remove the adhesive liner and attach the Patch to the right side of your ribcage in the position and orientation shown on the app.




### *6.4.3. Turn on Patch 2 (Pairing)*

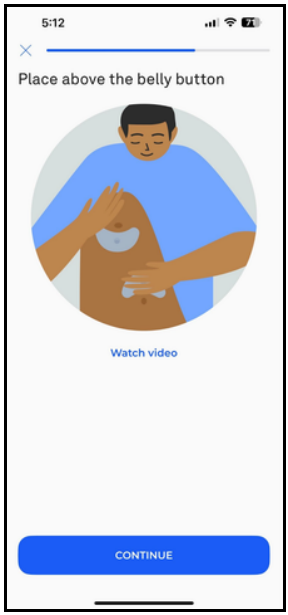
When directed by the app, press and hold the button on the Patch for three seconds. The light on the Patch will cycle between green, blue, and, red before settling on solid green, to indicate that the Patch is powered on and connected.




### *6.4.4. Apply Patch 2 to Stomach (Abdomen)*

Peel off the adhesive liner from the Patch and attach it to your stomach in the position and orientation shown in the App.

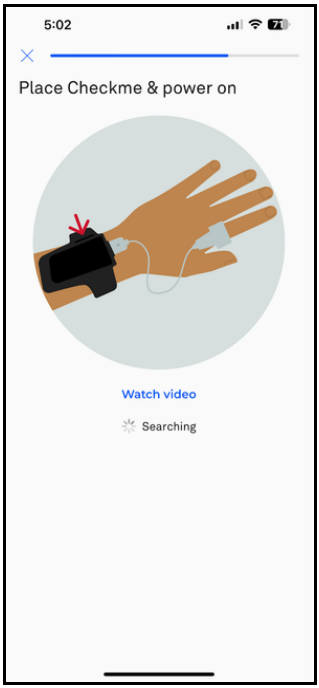


## 6.5. ConnectandActivateYourPulse Oximeter

Caution: Use only authorized pulse oximeters, a list of which can be found at www.wesper.co/oximeter .

Caution: Read the pulse oximeter's IFU before using with Wesper Lab

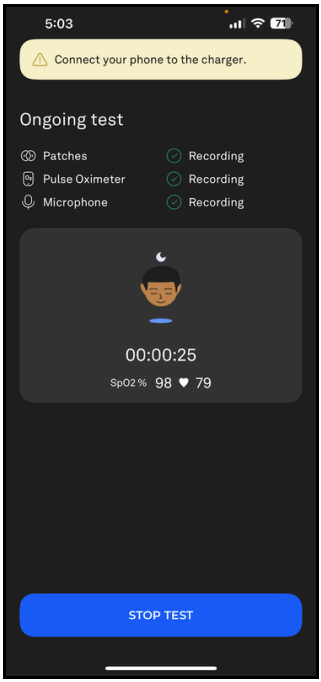
When prompted by the Wesper App to connect the authorized pulse oximeter, follow the instructions provided with the pulse oximeter to connect it to the app.




## 6.6. Sweet Dreams

A final set of screens finishes the session setup. Ensure that your patches are in the correct position, then begin the session.

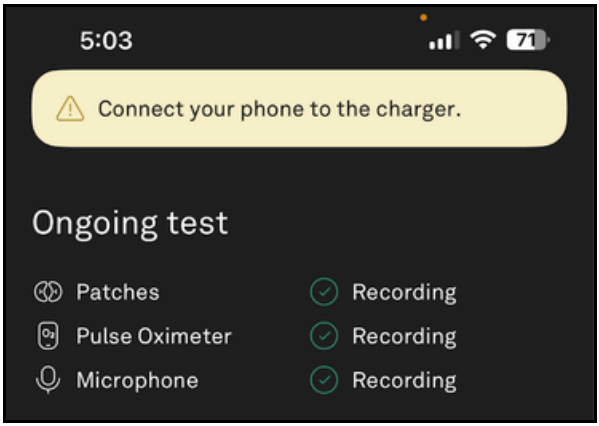
**Note:** Make sure that your phone is connected to its charger and is near you before going to sleep.




## 6.7. Warning Messages

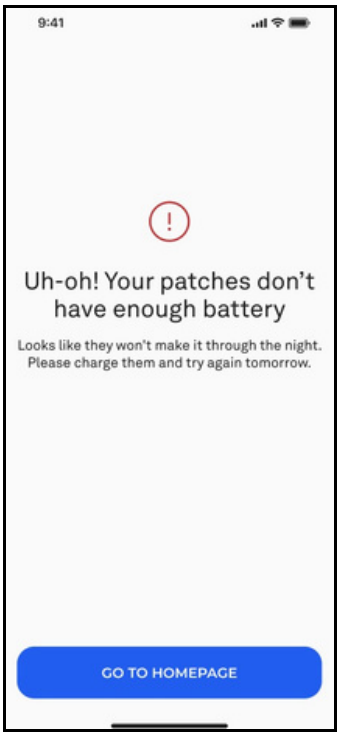
### 6.7.1. Phone Not Connected to Charger

If the phone is not charging, a warning message appears at the top of the screen:



### *6.7.2. Patch Low Battery Indication*

If the Patches are not properly charged the app will prevent you from starting a session during the session setup flow.

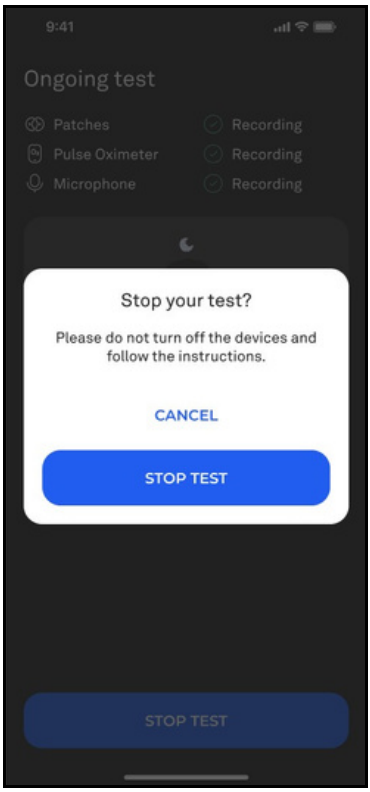


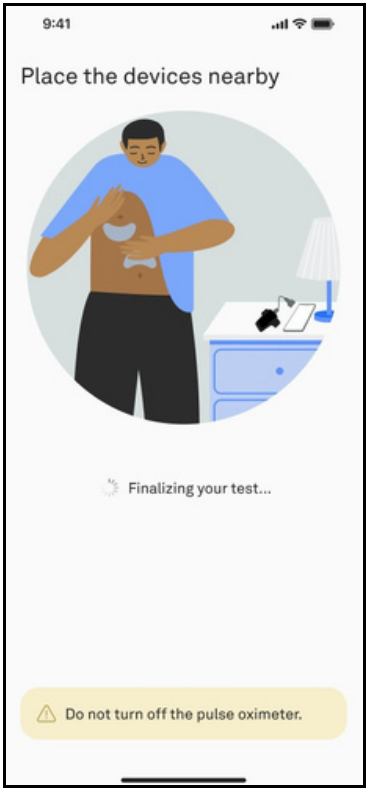

Place the Patches on the Patch charger and charge them fully (see section **6.10 Remove the Patches and Adhesive** ) before attempting another test. If a charger was not provided with your kit, contact your healthcare provider for further instructions.

If you receive this warning message when using a patch which was recently charged or that hasn't yet been used, contact Wesper support.

## *6.8. End the Test, Remove Patches and Adhesive*

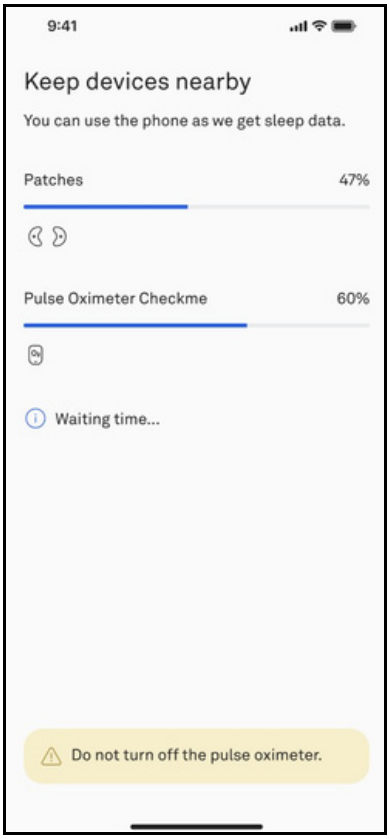
When you awake in the morning, press the "STOP TEST" button and follow the prompt to end the test session. Remove the patches and oximeter (without turning them off) and place them nearby.




## *6.9. Wait for Wesper Data to Upload*

After the session ends, any data remaining on the patches will be transferred to the cloud. Keep the patches close to your mobile device while this process completes.


9:41
Keep devices nearby
You can use the phone as we get sleep data.
Patches
47%
Pulse Oximeter Checkme
60%
Waiting time...
Do not turn off the pulse oximeter.

## 6.10. Charge Your Pulse Oximeter

**Note:** Based on necessity and expected usage period, your kit may not contain a pulse oximeter charge cable.

If applicable, charge the pulse oximeter using the provided charge cable so that it can be used for another test.

## 6.11. Charging The Patches

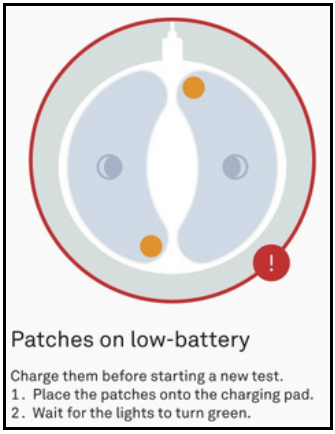
**Note:** Based on necessity and expected usage period, your kit may not contain a Patch charger.

Set up the Patch charger in a convenient location. Turn on the Patch charger by plugging in an authorized power supply.

**Warning:** The use of a non-authorized power supply may result in damage to Wesper Lab equipment, and/or increase the risk of exposure to mild electric shock.

**Warning:** Wesper patches are rated for 300 charging cycles, after which battery performance may degrade. Continued use of a device that exceeds its use life may result in reduced effectiveness and/or malfunction.

Place the Patches onto the powered Patch charger so that they can be recharged for another test. Ensure that each patch is centered in one of the cradles on the charger. When charging, the charging light will turn orange. Once the patches are sufficiently charged, the charging light will turn green.



If the orange charging light does not illuminate, try reseating the Patch on the charging cradle. If the issue persists, contact Wesper support.

## *6.12. Cleaning The Patches*



Caution: Do not reuse a patch which is contaminated with blood or bodily fluids after cleaning

The patches must be cleaned before each use. Follow this procedure for cleaning the patches:

- Remove and discard any adhesive strips, such that the back of the patch feels smooth
- Run a clean, dry, microfiber cloth over the patch (both back and front) to remove any visible debris or dust
- Dip the micro-fiber cloth in a solution containing 70% isopropyl alcohol by volume (sometimes referred to as “rubbing alcohol”)
- Gently apply the alcohol onto the back of the patch using the micro-fiber cloth
- Allow patch to air-dry for 5 minutes before applying a new adhesive strip

Before applying the patches, inspect them for any blood or bodily fluid which may remain on the patch after cleaning, as well as any visible cracking, discoloration, delamination or other forms of visible damage. If necessary, the cleaning procedure may be repeated, using more pressure with the microfiber cloth. If blood or bodily fluids remain on the patch after multiple cleanings or any visible damage is observed, discard the patch.

## *6.13. Access Output Data (Healthcare Providers Only)*

Healthcare providers with access to Wesper Lab output data should see Appendix A – Wesper Lab Output Specification for more information on how to parse and view Wesper Lab data.

# 7. GeneralSpecifications

## *7.1. Wesper Lab Patches*

The Wesper Lab patches are intended for use in the home or clinical healthcare environment.

The patient and any healthcare professional involved in the use of Wesper Lab should assure that the following conditions are met with regards to storage and usage.

**Note:** Any portion of the standards quoted below which are not explicitly listed are not applicable to the Patches.

### *7.1.1. Environmental and Storage Conditions*

**Warning:** The Wesper Lab Patches should be used no closer than 30 cm (12 inches) to any equipment in the intended use environment which emits EM radiation. Otherwise, degradation of the performance of the patches could result.

**Operating Temperature:** 10°C to 40°C (storage temperature: -20°C to 45°C)
**Operating Relative Humidity:** 15% to 90%, non-condensing (storage up to 90%)
**Atmospheric Pressure:** 700 hPa to 1060 hPa
**Altitude:** Up to 3000m above sea level

### *7.1.2. Electromagnetic Compatibility*

The Patches comply with IEC 60601-1-2: 2014, 4th edition, clauses 7 and 8 with the following specifications and parameters:

| Standard/Category | Emissions Class and Group/Immunity test level |
|---|---|
| Radiated Emission<br>CISPR 11 | Class B Group 1 |
| Electro-Static Discharge Immunity<br>IEC 61000-4-2 | 8kV Contact /<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| Radiated, Radio-Frequency, Electromagnetic Immunity<br>IEC 61000-4-3 | 10V/m, 80-2700MHz (Home healthcare)<br>80%, 1 kHz, AM |
| Immunity to Proximity fields from RF wireless communications equipment IEC 60601-1-2:2014, Section 8.10 | As per Table 9 of IEC 60601-1-2: 2014 |
| Power Frequency Magnetic Field Immunity IEC 61000-4-8 | 30A/m<br>50 Hz and 60Hz |

### *7.1.3. Radio Specification*

Wesper Lab Patches use an FCC-compliant 2.4GHz Bluetooth Low-Energy Transmitter/Receiver FCC ID: 2AAQS-ISP1507 [Additional ID for PCBA Revision Pending Testing Q4 2024] with the following key characteristics:

| Property | Value |
|---|---|
| Center frequency | 2.4GHz |
| Range of transmitted frequencies | 2.36 – 2.5GHz |
| Nominal bandwidth | ±200KHz |
| Range of transmission powers | -40 to +3dBm |
| Nominal transmission power | +0dBm |

### *7.1.4. Shelf Life*

Wesper Lab Patches can be stored indefinitely under the storage conditions described in Section **7.1.1 Environmental and Storage Conditions** .

The patches are shipped with their battery charged, after which they have 2 months to remain unused before the battery will passively deplete below acceptable levels. If this occurs, you will encounter a Low Battery indication (see 5.3.4), preventing you from starting a nightly session.

At any point prior to the elapsing of the 2-month period or after, you may follow instructions specified in 6.12 to charge your patches, after which you can proceed to use them as instructed.

#### *7.1.5. Reusable*

Depending on the patient usage period, the Wesper Lab Patches can be used and recharged over the course of multiple nights. In these cases, after the patient ends each night test they should charge the patches according to the instructions in ***6.11 Charging the Patches*** . Additionally, a fresh adhesive layer must be applied to the Patches before starting another test.

#### *7.1.6. Water Ingress Protection*

Wesper Lab Patches are rated IP22 as per IEC 60601-1. This provides protection against small amounts of liquid droplets that may fall in contact with the Patches. However, any large amount of excess water (for example, water flow during a shower) may reach the electronics which reside within the Patch and may cause mild electric shock.

#### *7.1.7. Disposal*

The Wesper Lab Patches are electronic devices. Follow local guidelines to determine the appropriate method for disposal of electronic waste.

### *7.2. Patch Charger*



**Note:** Based on necessity and expected usage period, your kit may not contain a charger. If one was not provided, please disregard any conditions, compatibility or environmental limitation information provided in this section.

The Wesper Lab patch charger is intended for use in the home or clinical healthcare environment.

The patient and any healthcare professional involved in the use of Wesper Lab should assure that the following specifications are met with regards to storage and usage.

**Note:** Any portionofthe standardsquoted below which are not explicitly listed are not applicable to the charger.

### *7.2.1. Charger Power Supply*

Only power supplies in compliance with the IEC 62368-1 standard for product safety are authorized for use with the Patch charger.

**Warning:** The use of a non-authorized power supply may result in damage to Wesper Lab equipment, and/or increase the risk of exposure to mild electric shock.

The Patch charger must be used with a power supply matching the following specifications.

| Power Supply Voltage (V) | Power Supply Current (mA) | Power Supply Connection Type |
|---|---|---|
| 5VDC ± (0.1 V) | 500mA (max) | USB-C |

### *7.2.2. Environmental and Storage Conditions*

**Warning:** The Wesper Lab Charger should be used no closer than 30 cm (12 inches) to any equipment in the intended use environment which emits EM radiation. Otherwise, degradation of the performance of the charger could result.

**Warning:** The Wesper charger is rated for 1000 charging hours, after which performance may degrade. Continued use of a device that exceeds its use life may result in reduced effectiveness and/or malfunction.

**Operating Temperature:** 10°C to 40°C (storage temperature: -25°C to 55°C)
**Operating Relative Humidity:** 15% to 90%, non-condensing (storage up to 90%)
**Atmospheric Pressure:** 700 hPa to 1060 hPa
**Altitude:** Up to 3000m above sea level

### *7.2.3. ElectromagneticCompatibility*

The charger complies with IEC 60601-1-2: 2014, 4th edition, clauses 7 and 8 with the following specifications and parameters:

| Standard/Category | Emissions Class and Group/Immunity test level |
|---|---|
| Radiated Emission<br>CISPR 11 | Class B Group 1 |
| Electro-Static Discharge Immunity<br>IEC 61000-4-2 | 8kV Contact /<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| Radiated, Radio-Frequency, Electromagnetic Immunity<br>IEC 61000-4-3 | 10V/m, 80-2700MHz (Home healthcare)<br>80%, 1 kHz, AM |
| Immunity to Proximity fields from RF wireless communications equipment IEC 60601-1-2:2014, Section 8.10 | As per Table 9 of IEC 60601-1-2: 2014 |
| Power Frequency Magnetic Field Immunity IEC 61000-4-8 | 30A/m<br>50 Hz and 60Hz |

### *7.2.4. Shelf Life*

Wesper Lab Charger can be stored indefinitely under conditions described in Section ***Environmental and Storage Conditions*** .

### *7.2.5. Water Ingress Protection*

The Wesper Lab Patch charger is rated IP22 as per IEC 60601-1. This provides protection against small amounts of liquid droplets that may fall in contact with the charger (for example, negligible amounts of water sprayed while brushing teeth). However, any large amount of excess water (for example, a glass of water spilled onto the charger) may reach the electronics inside the charger and may cause mild electric shock.

### *7.2.6. Disposal*

The Wesper Lab Patch charger is an electronic device. Follow local guidelines to determine the appropriate method for disposal of electronic waste.

## *7.3. Authorized Pulse Oximeters*

A list of approved pulse oximeters can be found at www.wesper.co/oximeter .

| Vendor | Model | FDA 510 (k) Number |
|---|---|---|
| Nonin, Inc. | WristOx2 3150BLE | K102350 |
| Shenzhen Viatom Technology Co., Ltd. | Oxiband (Checkme) O2 Pulse Oximeter | K191088 |

## *7.4. Smartphone*

The Wesper iOS App is compatible with iPhone 7 or newer running iOS 15 or higher. The Wesper Android App is compatible with Samsung Galaxy and Google Pixel phone models running Android 9 or later.

# 8. Label andSymbols

## *8.1. Wesper Lab Patches*

### *8.1.1. Device Label*




### *8.1.2. Symbols on the Wesper Lab Patches*

The following symbols may appear on the Wesper Lab Patches.



Do not expose this device to moisture




Prescription Only



This device is in compliance with FCC regulations

## *8.2. Wesper Lab Charger*



**Note:** Based on necessity and expected usage period, your kit may not contain a charger.

### *8.2.1. Device Label*



### *8.2.2. Symbolsonthe WesperLabCharger*

The following symbols may appear on the Wesper Lab Charger.

| | |
|---|---|
|  | Do not expose this device to moisture. |
|  | This device is in compliance with FCC regulations. |

# 9. Troubleshooting

If you encounter issues with the Wesper Lab patches or the app, please visit www.wesper.co/support for more information.

# Appendix A:WesperLab Output Specification

Wesper Lab data is provided as a set of two files which contain all information necessary to parse and view the patient's sleep data.

These files are:

1. CSV (Comma-separated values) file, containing all numerical data
2. Standard XML (eXtensible Mark-up Language) file, containing relevant artifact marking information

CSV File Specification:

The CSV file is formatted such that each column contains data from a different signal type, and each row represents a single sample. The columns are specified as follows:

| Column Name in File | Signal Type | Units |
|---|---|---|
| Time | Time | Seconds (since beginning of test) |
| Position | Body Position | Discrete Fields:<br>0 = Right<br>1 = Supine<br>2 = Left<br>3 = Prone<br>4 = Upright<br>5 = Unknown |
| THX | Thoracic Respiratory Effort | Unitless |
| ABD | Abdominal Respiratory Effort | Unitless |
| SUM_FLOW | TATCH-SUM-FLOW TATCH- | Unitless |
| SUM_PRESSURE | SUM-PRESSURE Functional | Unitless |
| SpO2 | Oxygen Saturation | Percent |
| Pulse | Pulse Rate | Beats Per Minute |

Below is an example snapshot of the CSV file from a sample study from the beginning and middle (ellipsis were introduced for brevity, they do not appear in the original file):

```
Time,Position,ABD,THX,SUM_Flow,SUM_Pressure,SpO2,Pulse
0,1,98.8502944424401,20.8193919150304,2120.17307716701,4495133.87714384,97,84
0.1,1,1025.21333045974,1214.62943306474,2067.31373933444,4273786.09684093,97,84
0.2,1,1904.1571071556,2350.14005787075,1931.88021550457,3732161.16705798,97,84
0.3,1,2709.2425893176,3394.36060521603,1741.68074728617,3033451.82546731,97,84
0.4,1,3418.23973000087,4319.41892959781,1507.32423140786,2272026.33858929,97,84
0.5,1,4014.28471736965,5103.96693997969,1241.24707706468,1540694.30632162,97,84
0.6,1,4486.38067919006,5733.77213453799,956.383400853945,914669.209428958,97,84
0.7,1,4829.35952196169,6201.65893709554,665.155569482626,442431.931613756,97,84
...
...
...
21400.1,1,14.6082927226905,8.08139830186587,0.18330575092522,0.0336009983222587,96,67.2
21400.2,1,14.2227627839575,8.33529196654512,-0.45067508140507,-0.203108028999466,96,67.4
21400.3,1,13.4057422271685,8.38259863457775,-1.0844746607316,-1.17608528976891,96,67.6
21400.4,1,12.1737919085489,8.21531352049053,-1.70226121099711,-2.89769323046535,96,67.8
21400.5,1,10.5543098930226,7.82950854672947,-2.28946983640971,-5.24167213182991,96,68
21400.6,1,8.58436589145759,7.22579986476243,-2.83158223827852,-8.01785797213441,96,68.2
21400.7,1,6.31027654887745,6.41037741431755,-3.31305610432877,-10.9763407504301,96,68.4
21400.8,1,3.78769803719596,5.39635551036651,-3.71689208612113,-13.8152867798699,96,68.6
21400.9,1,1.08179259352694,4.20507719742579,-4.02507445706966,-16.2012243849546,96,68.8
21401,1,-1.73298439366266,2.86688902708581,-4.21993752757485,-17.8078727366345,96,69
```

In this snapshot, it's shown that:

- The time resolution is 100ms
- The patient was on their back in the beginning and middle portions
- SpO2 values are around 96-97%
- Pulse values start high (84 BPM) and then trend lower (68 BPM in the middle portion)

XML File Specification

The XML file is standard format and contains a variety of information.

For the provider, the information necessary for study interpretation are annotations of where the system has detected artifacts. This can be found inside the XML file using the following hierarchy:

```
<TatchStudy>
 <ScoredEvents>
   <ScoredEvent>
     <Name>Artifact</Name>
     <Input>THX </Input>
     <Start>0.1</Start>
     <Duration>30221.5</Duration>
     <Family>Signal</Family>
   </ScoredEvent>
 </ScoredEvents>
</TatchStudy>
```

Under TatchStudy->ScoredEvents, there will be a collection of <ScoredEvent> tags. Under each one, there will be the following four tags:

| Tag Name | Contents | Notes |
|---|---|---|
| Name | Type of event | For artifacts, this tag will always have the contents "Artifact" |
| Input | The CSV column / signal type this event is referring to | Matches CSV column names mentioned above |
| Start | Time-stamp in seconds (since the start of the test) where the event starts | |
| Duration | Duration in seconds of the event | |
| Family | Class of data to which the event is applied | Deprecated – will always say "Signal" |

All events marked "Artifact" should be applied to their respective signal types, and the event periods specified.

# Audit trail

## Details

| | |
|---|---|
| FILE NAME | 8b Wesper User Manual - 7/31/25, 11:01 AM |
| STATUS | Sig n ed |
| STATUS TIMESTAMP | 2025/07/31<br>19:11:03 UTC |

## Activity

| | | |
|---|---|---|
| SENT | ciaran@wesper.co sent a signature request to:<br>• Motti Perlman (motti@wesper.co) | 2025/07/31<br>15:01:39 UTC |
| SIGN E D | Signed by Motti Perlman (motti@wesper.co) | 2025/07/31<br>19:11:03 UTC |
| COMPLETED | This document has been signed by all signers and is complete | 2025/07/31<br>19:11:03 UTC |

The email address indicated above for each signer may be associated with a Google account, and may either be the primary email address or secondary email address associated with that account.