ResMed

Leo

User Guide

Contents

Welcome

The Leo wireless monitoring system monitors a patient's vital signs, including heart rate, respiration rate, and body posture.

Indications for use

Leo is a wireless multi-parameter remote monitoring system intended for healthcare professionals' continuous collection of physiological data at home and in healthcare settings. Data is transferred wirelessly from the Leo sensor patch to a remote cloud server via a mobile application for storage and analysis and is displayed on the mobile application. This data includes heart rate, respiration rate, and body posture.

The Leo multi-parameter remote monitoring system is indicated for the non-critical pediatric population (2 to 21 years).

Contraindications

- The Leo system is not intended for use on critical care patients.
- The Leo system is not intended for patients with active implantable devices, such as defibrillators or pacemakers.

Intended use and principles of operation

The Leo system collects and reports data on respiratory function, heart rhythm, and body posture. A healthcare provider may use this data to make clinical decisions about diagnosis and treatment. The Leo system comprises of a wearable sensor patch, a charging cable, and a companion mobile application. The sensor patch is a multi-use device.

The patient or parent/caregiver are the intended operator of the device. The device is not provided sterile. Please read the entire guide before use. Access this user guide online at ResMed.com. For more information about the device's clinical benefits, safety, and performance, contact ResMed support using the contact information in this guide. The Leo system does not have essential performance. However, the clinical functions were tested during EMI and they met the pass criteria.

Heart rate monitoring

- Uses ECG to detect heart rate (HR) only.
- Cannot be used to detect the absence of a heart rate.
- Provides intermittent HR readings of 30-200 beats per minute (BPM) without excessive movement.
- Cannot be used to detect any forms of arrhythmia or any other conditions usually detected through an ECG.

Respiration rate monitoring

- Uses impedance pneumography to detect respiratory rate (RR).
- Provides intermittent RR readings of 5–60 breaths per minute (BrPM).
- Due to the nature of impedance pneumography, RR readings may often appear as not available. This situation is more likely to happen when the patient is moving.

Body posture

- Uses a 3-axis accelerometer to detect body posture.
- Provides intermittent body posture, including upright, supine, lateral, and prone.

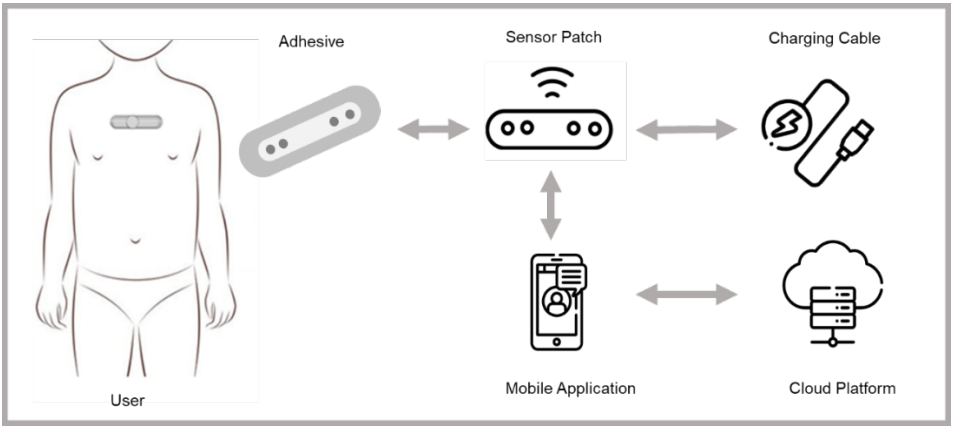
⚠ WARNINGS

- In the US, Federal law restricts this device to sale by or on the order of a physician.
- The sensor patch is not intended to communicate an emergency.
- Call your physician right away if you or your dependent needs care. Information from your sensor patch can be delayed, and your care team may not be aware of your condition.
- The Leo data alone should not be used to make a diagnosis or treatment plan. Consult your healthcare provider for a complete evaluation of your condition.

- The sensor patch and its components may be a choking hazard. Do not put the sensor patch or its components where it may block a patient's airway.
- Do not ingest any sensor patch component, including the adhesive or hydrogel.
- Do not attempt to modify or service the sensor patch or any of its components.
- If the sensor patch is dropped, gets wet, or shows any signs of damage, stop using the device immediately.
- Do not use the sensor patch as a bandage for a wound. The sensor patch is not intended to be used as a bandage.
- In case of skin discomfort including skin irritation or redness, remove the sensor patch immediately.
- The sensor patch is not designed to be waterproof. Remove the sensor patch before bathing or swimming. The sensor patch should not be submerged in water.
- Do not use the sensor patch near life-supporting devices that may be affected by electromagnetic interference, such as pacemakers. The system is not designed for use with pacemakers, implantable defibrillators, or neuro-stimulators.
- The system is not designed for use near magnetic resonance imaging (MRI) equipment. The sensor patch must be removed from any patient about to undergo an MRI.
- The sensor patch is a radio frequency (RF) emission device and should not be used in RF-sensitive areas.
- The system is not designed for direct X-ray exposure. The sensor patch must be removed from any patient undergoing an upper torso X-ray.
- The system is not designed for use near X-ray computed tomography (CT) equipment. The sensor patch must be removed from any patient undergoing a CT scan.
- The system is not designed to be used as an apnea monitor. Clinicians should not rely on the respiration monitoring for detection of cessation of breathing and should always follow hospital guidelines and best clinical practices, including monitoring additional parameters that indicate the patient's oxygenation status.
- The system is not designed for use on an airplane. Do not record data using the Leo system while on an airplane.

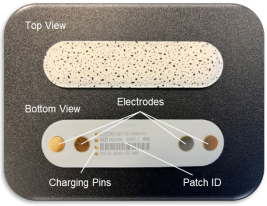
About the Leo system

The Leo system (model 22601) is comprised of the following:

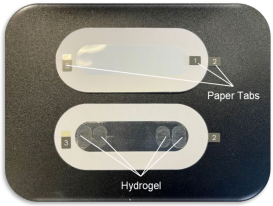


Item	Description
Sensor patch	Collects and transmits vital signs data from patients to the mobile application
Adhesive	Uses a double-sided tape to adhere the sensor patch to the chest
Charging cable	Uses a USB-A port to charge the sensor patch
Mobile application	Uses **Bluetooth® Wireless Technology** to communicate with the sensor patch to start/stop recording, download data from the sensor patch, and upload data to the cloud. It also displays vital sign data.
Cloud platform	Stores and processes the sensor patch data; generates and sends the data report to the mobile application.

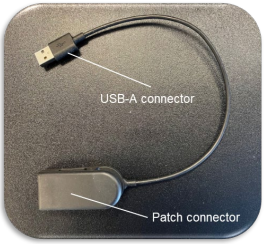
Sensor patch



Adhesive



Charging cable



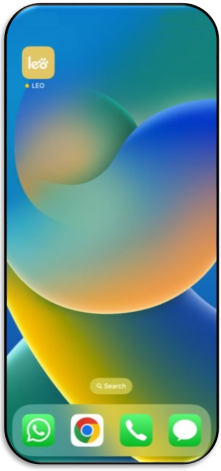
Setting up Leo

The following steps will be performed by the patient if aged 12-21 years or by the patient's parent or caregiver for patients under 12 (or if assistance is otherwise needed).

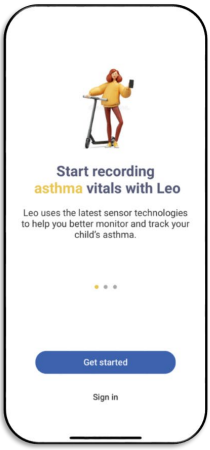
Install the Leo mobile app

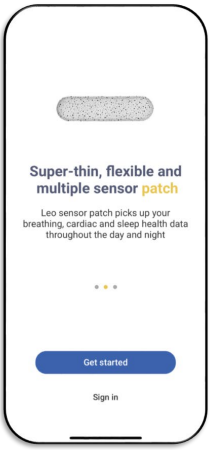
The sensor patch sends collected data to the Leo mobile app for processing via Bluetooth® Wireless Technology. The Leo mobile app is only available on the iOS App Store and not on Android.

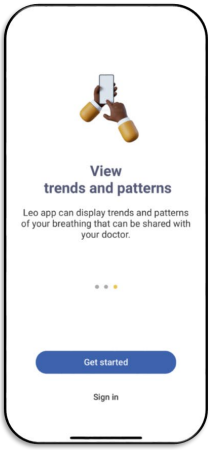
1. Download and install the Leo mobile app on your phone.
2. Locate and tap the Leo mobile app icon.



3. Swipe through the welcome screens for other information.

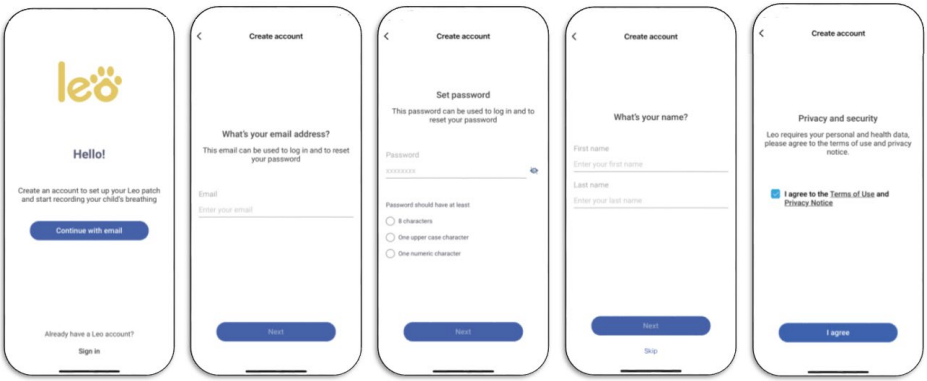






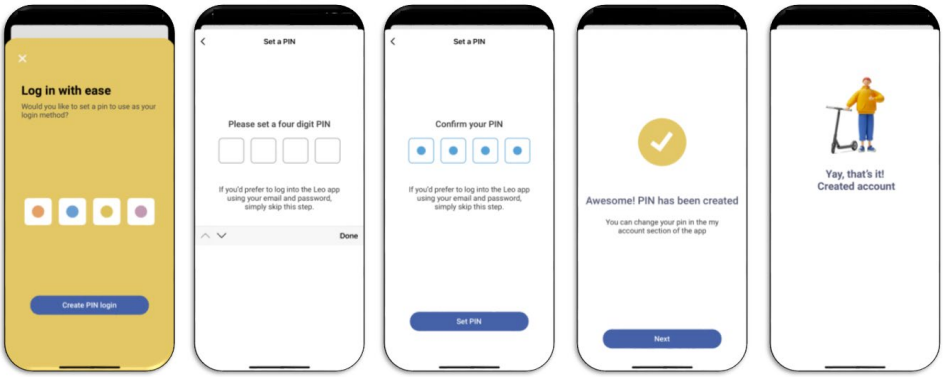
Create an account on the Leo mobile app

To use the Leo mobile app the first time, an account must be created using an email address and password. You can only use the Leo mobile app once you have logged on with an account.



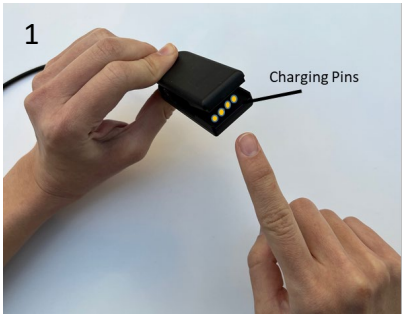
Set up a PIN as a login method

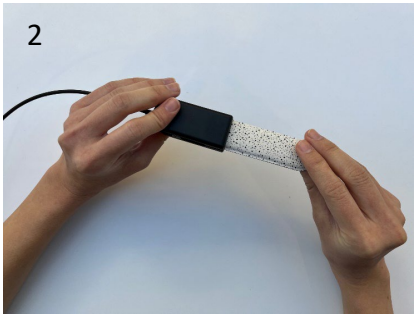
Once an account is created, you can set up a 4-digit PIN to use as a login method for ease of signing in the Leo mobile app.



Charge the sensor patch

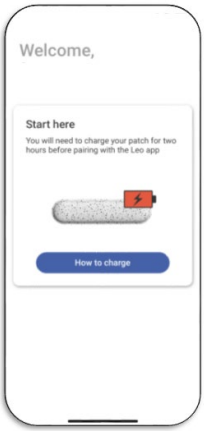
The sensor patch is rechargeable and requires charging before first use.





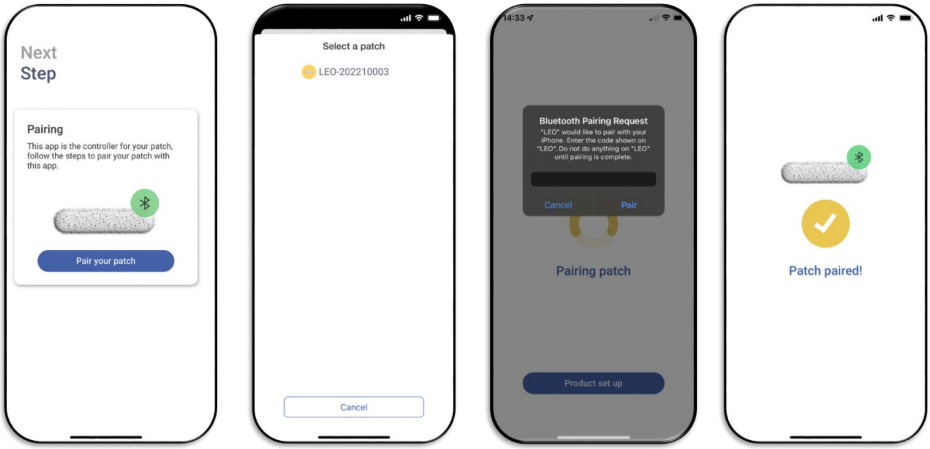
1. Pinch the end of the charger to open and locate the four charging pins.
2. Align the charging cable pins to the sensor patch pins on the bottom of the sensor patch. Release the clip to close and secure the sensor patch.
3. Plug the other side of the charging cable into a USB-A charging port. Leave for 4-5 hours to charge. The red LED light will turn off to indicate the charging is complete.

These instructions are also provided in the mobile app Welcome screen. Tap **How to charge** to go through the instructions. To finish, the mobile app will prompt you to pair the patch.



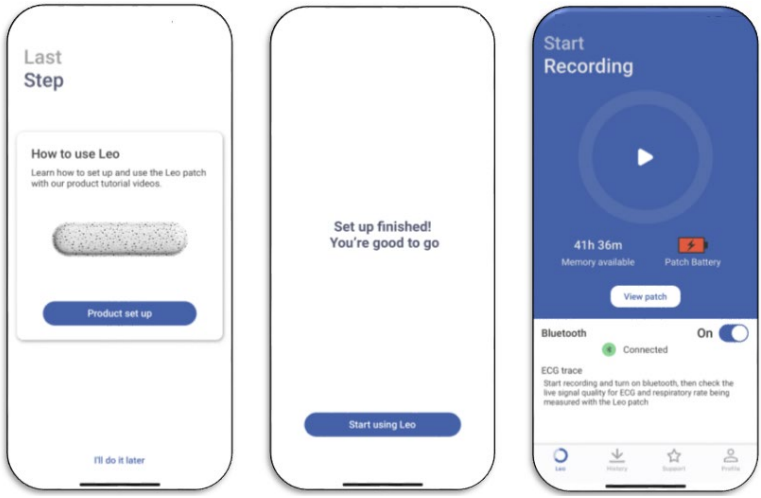
Pair the sensor patch with the mobile app

Once the sensor patch is fully charged, open the Leo mobile app and follow the steps for pairing the sensor patch to your smartphone. You will need the serial number and six-digit pairing PIN printed on the back of the sensor patch.



Product setup

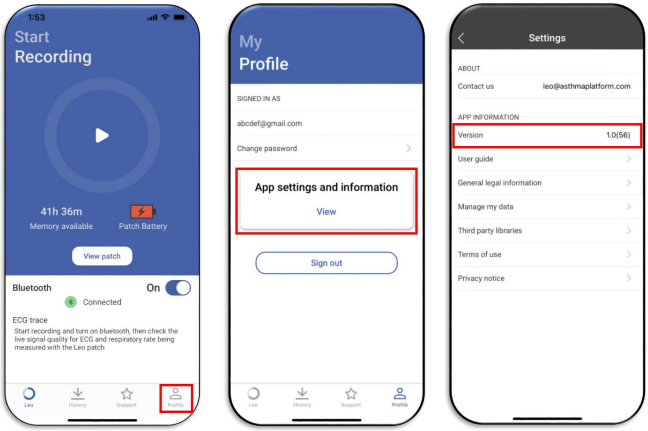
As an optional last step during set-up, the mobile app has instructions for Product set-up. Tap the **Product set up** icon to go through these instructions. These instructions are also presented in the later sections of the User guide under **Applying the Sensor Patch** and **Removing the Sensor Patch** sections.



Identify the Leo mobile app version

To identify the Leo mobile app version, follow the steps below

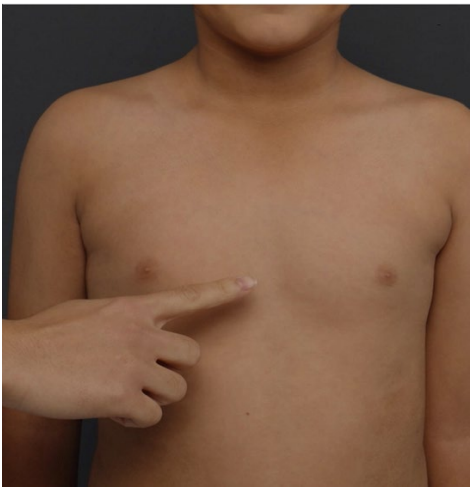
1. Tap the profile icon to open the **My profile** page
2. In the **My Profile** page, tap **App Settings and Information**.
3. In the **Setting** page, identify the app version.



Applying the sensor patch

Identify the sensor patch location on the body.

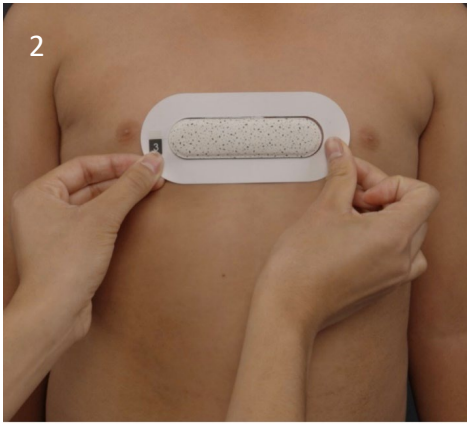
For the best signal, the sensor patch should be applied to the middle area of the chest (see image below). For patients with developed breasts, place the sensor patch a little higher on the chest. Before applying the sensor patch, clean the skin with an alcoholic swab and let the skin dry completely.



Stick adhesive to the sensor patch

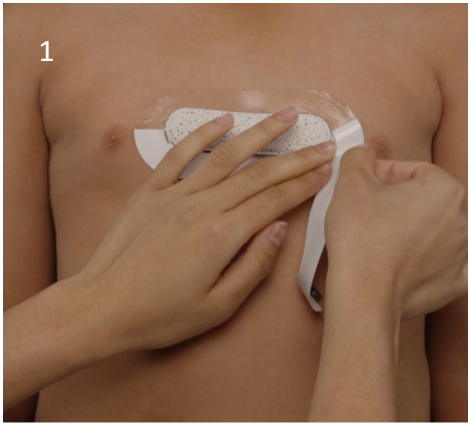
1. Locate the labels (1), (2), and (3) on the adhesive, then peel off the paper cover labelled (1) and turn over the sensor patch so the bottom is facing up.
2. Align the adhesive and the sensor patch and place the adhesive onto the sensor patch. Ensure the adhesive is attached firmly by applying pressure with your fingers.

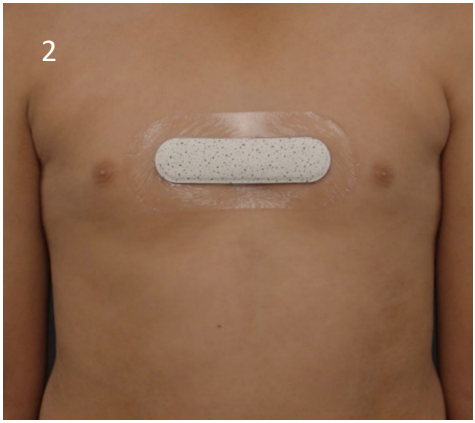
Attach the sensor patch with adhesive to the chest



1. Peel off the paper cover labelled (2) from the adhesive.
2. Attach that side of the adhesive to the upper middle chest region and press firmly to secure the sensor patch.

Remove the label from adhesive





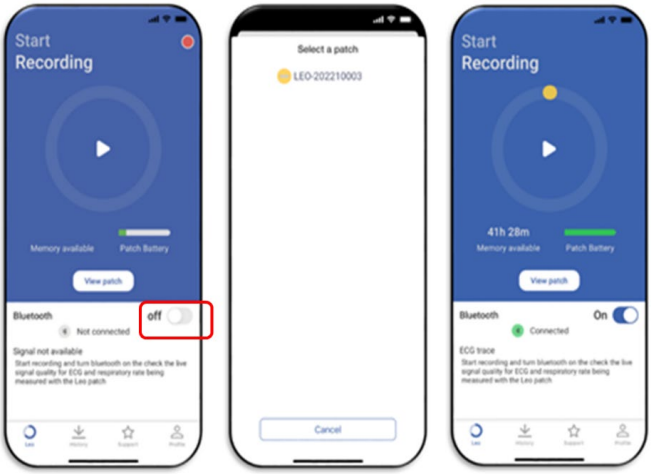
1. Peel off the final paper cover labelled (3) from the adhesive.
2. You are now ready to start recording using the mobile app.

Using Leo

The following steps are to be performed by the patient if aged 12-21 years or by the patient's parent or caregiver for patients under 12 (or if assistance is otherwise needed).

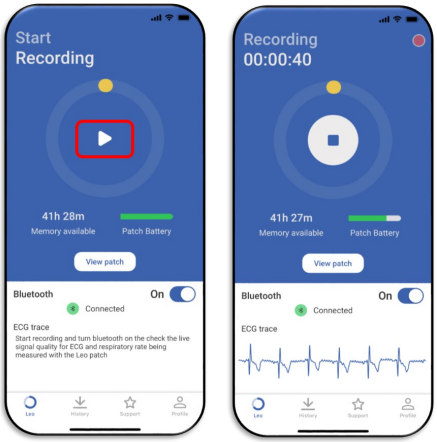
Connect the sensor patch to the mobile application

When the patient is ready for recording and all setup steps have been completed, bring the smartphone with the Leo mobile application within Bluetooth® connection range of the sensor patch. Connect the sensor patch by swiping the Bluetooth button to On. Follow the steps below:



Start recording

In the Leo mobile application, tap the play button to start recording. Verify that the mobile application displays raw data collected by the sensor patch.*



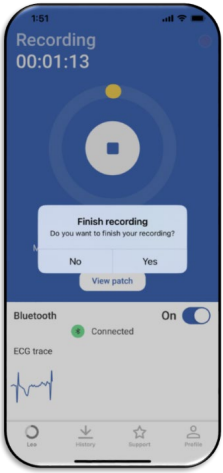
*The raw data display is not intended for interpretation or analysis, only to show that the recording is active

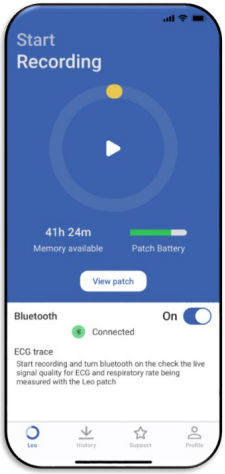
Daily activities

Allow the patient to continue with their normal activities for 24 hours. The smartphone with the Leo mobile application is not required to be connected to the sensor patch during this time.

Stop recording

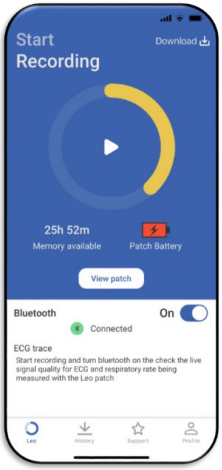
After recording the data, with the sensor patch connected to the smartphone, hit the Stop Recording button. Verify that the mobile application stops displaying the ECG trace.

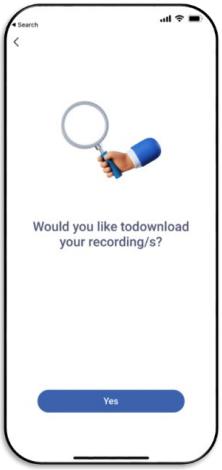


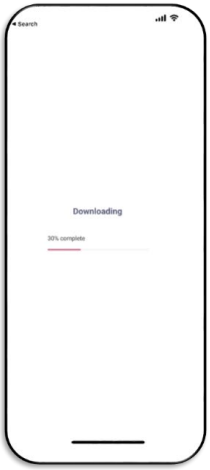


Data download

To download the data, the sensor patch must be charging to avoid battery runout. Once the sensor patch is connected to the charger, the mobile application should indicate a red battery icon, and the Download option will be enabled. Tap the **Download** button and follow the steps to download the data. During the data download, the phone must be left close to the sensor patch, and the Leo mobile application must not be closed or minimized.

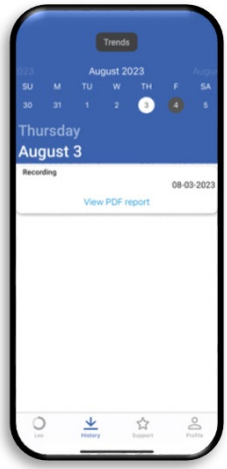






If the smartphone is out of range of the sensor patch during the data download process, the Bluetooth connectivity will be lost, and the data download will be paused. If this occurs, bring the smartphone within Bluetooth range of the sensor patch and resume the data download.

Once the download is complete, the data will be automatically sent to the cloud for processing. A push notification will be sent in the mobile application once the data report is available in the History tab on the mobile app.

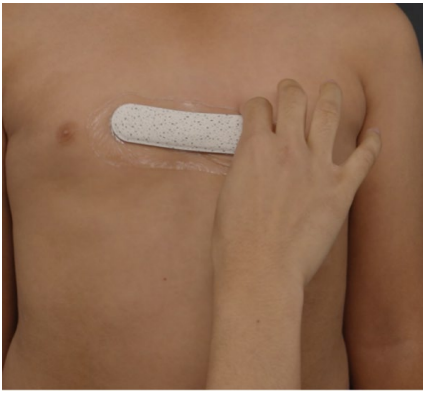


Removing the sensor patch

The following steps are to be performed by the patient if aged 12-21 years or by the patient's parent or caregiver for patients under 12 (or if assistance is otherwise needed).

Remove the sensor patch from the skin

Once the recording is complete, the sensor patch may be removed carefully by rolling off the outer adhesive. Work at removing the adhesive around the sensor patch first before removing the sensor patch.



Remove the adhesive from the sensor patch

Peel the used adhesive from the sensor patch and clean the sensor patch with alcoholic wipes. The adhesive is single-use and should be discarded after single use. If the sensor patch is to be used again, install one of the provided new replacement adhesives using the steps above.

Clinician use only

Using the Leo data report

The Leo data report is to be used by the patient's physician only. Do not attempt to interpret or take action on the data if you are not a qualified medical professional.

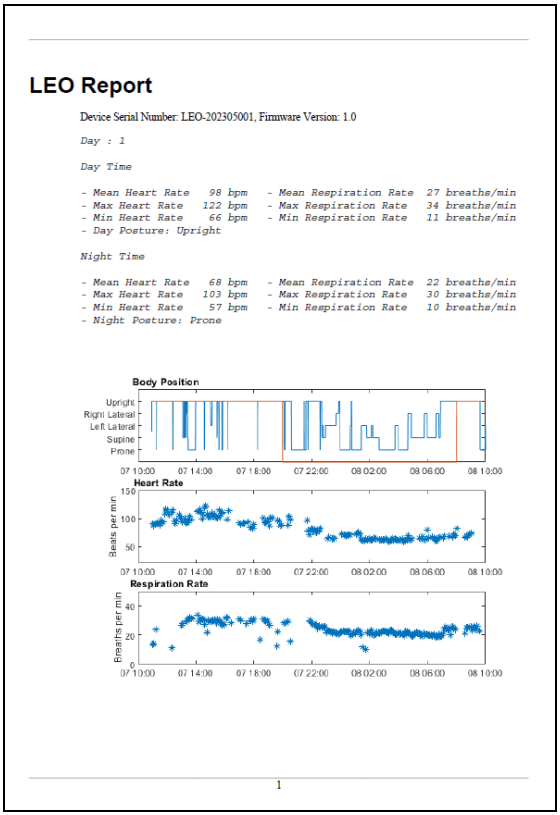


Figure 1: Leo data report example

The Leo data report includes the following sections:

Section	Description
LEO Device Information	Lists the Leo device serial number and firmware version.
Data Statistics	Lists the Day and Night-time statistics, including mean, maximum, and minimum heart and respiration rates. It also lists the average body posture during the day and night.
Graphs	This section has 3 graphs: 1. Body posture in the upright, right lateral, left lateral, supine or prone position. 2. Heart rate trace over a 24-hour period averaged using 5 min window. 3. Respiration rate trace over a 24-hour period averaged using 5 min window.

Troubleshooting guide

Issue	Troubleshooting steps
The smartphone is not able to pair or connect with the sensor patch	• Ensure the phone's *Bluetooth*® Wireless Technology setting is On. • Ensure the phone is within recommended signal range of the sensor patch. • Ensure there are no signal-blocking obstructions between the phone and sensor patch. • Ensure the sensor patch is charged and has power. • If the above do not address the issue, power Off and On the phone to reset it.
The sensor patch does not record data	• Ensure the sensor patch is charged and has power. • Ensure the Start Recording button has been pressed. • Ensure the recording is not paused. • Ensure the correct side (sensor-side) of the sensor patch is installed on the patient's chest. • Ensure that the sensor patch is positioned on the chest as shown in the instructions for use.

Technical specifications

Performance specifications

Item	Description
Heart rate	30-200 beats per minute (bpm) ± 3 bpm
Respiratory rate	5-60 breaths per minute (BPM) ± 3 BPM
Body posture	Classified as: Upright, Supine, Lateral, Prone

Sensor patch and mobile app specificaions

Item	Description
Patch weight	15g
Patch size	90mm x 25mm x 4mm (L x W x H)
Patch duration of use (single charge)	40 hours
Patch Ingress Protection (IP) rating	IP 22 IP 22 rating
Patch IEC 60601 Applied Part type	 Type BF
Mobile app compatible smartphone operating systems	iOS version 16 and above

Sensor patch storage and operating conditions

Parameter	Storage range	Operating range
Temperature	-10° to 60°C (14° to 140°F)	0° to 40°C (32° to 104°F)
Pressure	1013 to 700 hPa	1013 to 700 hPa
Humidity	5 to 95% relative humidity (non-condensing)	5 to 95% relative humidity (non-condensing)

Service life

Sensor patch	12 months*
Charging cable	24 months

*Adhesives may need to be replaced depending on storage duration

Symbol descriptions

The following symbols may appear on your product or packaging.

Caution. The current situation needs operator awareness or action to avoid undesirable consequences (ISO 7000-0434A).

Manufacturer. The medical device manufacturer (ISO 7000-3082).

Date of manufacture. The medical device manufactured date (YYYY-MM-DD) (ISO 7000-2497).

Serial number. The manufacturer's serial number to identify a specific medical device (ISO 7000-2498).

Operating instructions. The operating instructions should be considered when operating the device or control close to where the symbol is placed (ISO 7000-1641).

Temperature limit. Temperature limits to which the medical device can be safely exposed (ISO 7000-0632).

Atmospheric pressure limitation. The range of atmospheric pressure to which the medical device can be safely exposed (ISO 7000-2621).

Humidity limitation. The range of humidity to which the medical device can be safely exposed (ISO 7000-2620).

MR unsafe. The device is unsafe for magnetic resonance exposure (such as MRI) (ASTM F2503-13).

Type BF Applied Part. Type BF applied part complying with IEC 60601-1 (IEC 60417-5333).

Non-ionizing electromagnetic radiation. Indicates equipment or systems, eg, in the medical electrical area, including RF transmitters (IEC 60417-5140).

Electronic Waste. Indicates that this device is e-waste and should only be disposed of in accordance with local regulations.

Federal Communications Commission. The United States Federal Agency regulating communication, including RF. Indicates FCC wireless certification.

IP 22

Ingress Protection rating 22. The device is protected from safety risks due to dripping water when tilted up to 15 degrees.

Medical Device. Indicates that this device is a Medical Device.

See the symbols glossary at ResMed.com/symbols.

Note: Any user interface errors and symbols not referenced in this user manual are explained in the mobile application user interface.

Compliance information

This device conforms to the following medical device technical standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-11
- ISO 10993 (cytotoxicity, sensitization, and irritation or intracutaneous reactivity)

This device was developed under the following medical device quality system standards:

- IEC 62304/82304
- ISO 13485
- ISO 14971

Both the sensor patch and Leo mobile application have a country of origin of Australia.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

2BC8M-LEO1

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Servicing, maintenance, cleaning, and disposal

The sensor patch does not require regular physical servicing or maintenance by the user. The sensor patch may be cleaned with an alcohol wipe or a clean, dry rag if dirty. Do not use soap and water to clean the sensor patch.

The Leo mobile application may receive software updates for the mobile application or the sensor patch firmware. App or firmware updates may be automatically applied when the smartphone client is connected to the internet and to the sensor patch. It is recommended to check for any app or firmware updates before using the Leo system.

The sensor patch and its components are considered electronic waste and should be disposed of according to your local e-waste regulations. Check with your healthcare provider if they offer disposal services.

Quality of service

Bluetooth® Wireless Technology uses several low-level data handling techniques to ensure the integrity of data transmission to and from the sensor. Additionally, the sensor patch uses its own, higher-level data handling measures to ensure that signals are received accurately. If the sensor patch is not able to establish a reliable wireless connection for any reason, it has been designed to internally record data for automatic retransmission when a reliable connection can be established.

This is a wireless device. Wireless devices can cause interference with other medical electrical equipment. This device uses Bluetooth® Wireless Technology to communicate securely and reliably in areas with high levels of radio interference. This technology uses advanced frequency hopping techniques to maintain high levels of accuracy in the most saturated radio environments and was selected specifically for these features.

Electromagnetic compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the information provided in this user manual.

The sensor patch is designed to automatically resume normal operation in the unlikely event of interference from common electromagnetic systems (for example, anti-theft systems, metal detectors and radio frequency identification readers). Move away from the system and the sensor patch will resume normal operation. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

The following tables provide recommended separation distances between portable and mobile RF communications equipment and the sensor patch.

Guidance and manufacturer's declaration – Electromagnetic emissions

The sensor patch is intended for use in an electromagnetic environment as specified below. The customer or the user of sensor patch should ensure it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The sensor patch uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The sensor patch is suitable for use in all establishments, including domestic establishments.

Recommended separation distances between portable and mobile RF communications equipment and the sensor patch

The sensor patch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the sensor patch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the sensor patch as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 0.35\sqrt{P}$	$d = 0.35\sqrt{P}$	$d = 0.70\sqrt{P}$
0.01	0.035	0.035	0.070
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and manufacturer's declaration – Electromagnetic immunity

The sensor patch is intended for use in an electromagnetic environment as specified below. The customer or the user of the sensor patch should ensure it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the sensor patch than the recommended separation distance calculated using the equation applicable to the frequency of the transmitter. For these equations and the resulting recommended separation distances, see the table, 'Recommended separation distances between portable and mobile RF communications equipment and the sensor patch'. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment caused by fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the sensor patch is used exceeds the applicable RF compliance level above, the sensor patch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the sensor patch.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Transmitter technical specification	Value
Radio frequency	2.4GHz
Modulation	GFSK
Channels	40 channels, 2MHz/channel, FHSS
Transmit power	-2 dBm
Protocol	Bluetooth Smart
Power source	One non-replaceable, rechargeable lithium iron phosphate battery. Under normal use conditions, the sensor battery is expected to last for at least 24 hours of use between charges.
RF transmission	Bluetooth Low Energy

Mobile application security

The Leo app uses security features to help protect your privacy and prevent unauthorized access to your data. Security features include:

- Unique keys for Bluetooth pairing
- Application-level encryption for the transmission of data, in addition to Bluetooth® Wireless Technology security
- Data encryption

Protecting your smart device against malware also helps keep your data secure. ResMed recommends the following:

- Enable personal identification number (PIN) or fingerprint security on your smart device. Refer to your smart device user instructions for information on enabling either feature.
- Avoid unsafe modification of the smart device's operating system.
- Consider enabling remote data wipe on your smart device. Remote data wipe is a function available on your smart device for remotely erasing personal data in the event that your device is lost or stolen. Refer to your smart device user instructions for information on enabling this feature.
- Keep your operating system up to date with security patches.

Support information

The Leo system is a medical device intended for distribution to and use by the public. Report any serious incidents to the competent authority and to the following entities:

Support contact information

Phone	1 (800) 424-0737
Web form and email	https://www.resmed.com/en-us/contact-us/

Legal manufacturer:

ResMed Pty Ltd
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153
Australia

USA distributor:

ResMed Corp
9001 Spectrum Center Blvd, San Diego, CA 92123
USA

ResMed.com