acurable

AcuPebble® SA100

User Manual

(Instructions for Use and Technical Information)

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Document control

Document name	User Manual
Document reference	ACU-IFU-SA-US
Document version	1.8
Issue date	2021-10-06
Document classification	Customer Confidential
Status	Issued

Device version

DEVICE COMPONENT	VERSION
AcuPebble SA100 sensor	100
AcuPebble SA100 adhesives	1.0
AcuPebble SA100 mobile application	1.1
AcuPebble SA100 web application	1.0
AcuPebble SA100 algorithms	1.0

Glossary

TERM	DEFINITION
A/D	Analog-to-Digital
AASM	American Academy of Sleep Medicine
ACU	Acurable
AHI	Apnea-Hypopnea Index
BLE	Bluetooth Low Energy
bpm	beats per minute (cardiac)
CE	Administrative marking which indicates that a product may be sold freely in any part of the European Economic Area
CI	Confidence Interval
CISPR	Comité International Spécial des Perturbations Radio
dBm	Decibel-Milliwatts
DC	Direct Current
e.i.r.p.	Effective Isotropic Radiated Power
EEG	Electroencephalogram
EMC	Electromagnetic Compatibility
ES6	ECMAScript 6
GHz	Gigahertz
GFSK	Gaussian frequency shift keying
HCP	Healthcare Professional
HF	High Frequency

TERM	DEFINITION
IFU	Instructions for Use
IP	Ingress Protection
ISM	Industrial, Scientific and Medical
kPa	Kilopascal
Li-Po	Lithium Polymer
LoA	Limits of Agreement
mA	Milliampere
mAh	Milliamp Hour
MHz	Megahertz
ODI	Oxygen Desaturation Index
OSA	Obstructive Sleep Apnea
PPG	Photoplethysmogram
QR	Quick Response code
RF	Radio Frequency
SA	Sleep Apnea
UK	United Kingdom
US	United States
μ	Bias
σ	Standard deviation

1. Introduction

Thank you for purchasing this product. Before using it, please read this user manual carefully. We would be grateful for any feedback and/or suggestions you have on this product, to help us improve it in the future.

Our telephone-hotline offers help at:
Mon-Fri 09:00-18:00 **+44 (0)208 191 7590**

Send us a message by email at any time:
support@acurable.com

Or send us a letter at:
Acurable, Finsgate, 5-7 Cranwood Street, London EC1V 9EE

The AcuPebble SA100 sensor MUST be used with the adhesive provided by Acurable Ltd. The performance of the system largely depends on this specific adhesive and hence cannot be guaranteed if an alternative one is used.

The device is not guaranteed if the enclosure is opened. Trying to repair it or modify it will void the guarantee.

Acurable Ltd., Finsgate, 5-7 Cranwood Street, London EC1V 9EE, United Kingdom

2. About this user manual

It is very important that you read each paragraph that you see with this icon, since it is used in the following sections to indicate potential danger. This danger could be to the patient, property, data, or connection with other devices. This user manual is part of this medical device and it must be kept available.

Acurable does not consider itself responsible for the effect on basic safety, reliability and performance of the system if:

- The system has been modified in any way or form.
- The system has been used outside the remit and/or operating conditions specified in this user manual.
- The system has not been used in accordance with this user manual.

This user manual is only intended to be used by healthcare professionals with the relevant clinical training as determined by the responsible healthcare organisation.

2.1 Explanation of symbols used

This warning symbol is used to represent potential danger to patients, property or data loss.

This symbol is used to indicate paragraphs that are essential to read, since they make reference to potential danger.

The CE icon and the number next to it indicate that AcuPebble SA100 complies with the regulations for medical products in the European Community.

This device complies with the IEC 60529, with an IP Rating of at least “22”. This means that it is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

This device works with a nominal 3.7 volts DC.

Protection class: Type BF applied part (device in contact with the patient).

HF transmitter with integrated Bluetooth Smart protocol.

This symbol represents a landline phone number is provided as contact method.

This symbol represents a mobile phone number is provided as contact method.

This symbol represents an email address is provided as contact method.

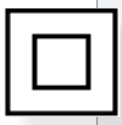
This symbol represents sections of this user manual that are self-contained in the mobile application, so the user can choose not to read them here, and follow the mobile application instead.

Never dispose of the device in domestic waste.

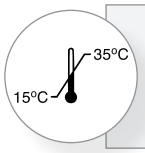
General prohibition sign.

Do not re-use.

This is a medical device.



This equipment meets the safety requirements specified for Class II equipment according to IEC 61140.



Use in temperatures above 15°C (59°F) and below 35°C (95°F).

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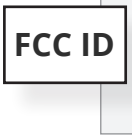


A unique identifier assigned to a device registered with the United States Federal Communications Commission (FCC).

Federal Law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

3. Safety Warnings

This equipment needs to be installed and put into service in accordance with the information provided in this user manual.

AcuPebble SA100 is not intended to be used with patients with pacemakers or other implantable devices.

AcuPebble SA100 is not intended to be used with patients with known or suspected arrhythmias.

This device has not been validated in patients with congestive heart failure or patients with neuromuscular disorders. Patients with significant cardiopulmonary or neurological disorders need to be excluded from using the device.

Use only adhesive provided by Acurable Ltd. The performance of the system is linked to the properties of this adhesive. The system is not expected to work with any other.

Choking hazard. Keep away from small children.

No modification of this system is allowed.

If the enclosure is broken, dispose of the system.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment 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 the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment should be used no closer than 30cm to any part of the equipment. Otherwise, degradation of the performance of this equipment could result.

This equipment has not been tested for safety in oxygen rich environments.

This device is not intended to be used continuously on the skin for more than 30 days.

Do not shower while wearing this device.

The micro-USB DC power port is solely intended for connection to a CE marked (or marked as per equivalent national legal frameworks) micro-USB charging device.

Do not use in subjects with a known allergy to acrylate.

Do not try to open the system enclosure.

Do not try to replace the battery.

Do not try to put on the sensor whilst charging the battery.

Do not re-use the adhesive once it has been pulled off the body.

- The performance of this device has not been tested under extreme weather conditions. Hence, we recommend to use it indoors and in temperatures above 15°C (59°F) and below 35°C (95°F), humidity above 20% and below 75%, and atmospheric pressure above 70 kPa and below 106 kPa. For usage outside this temperature, humidity and atmospheric pressure range, please do contact Acurable Ltd.
- This device is at least IP22 in terms of water ingress. This means that it is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water. The system has however not been designed to be used under water.
- Cleaning of the system with autoclave has never been tested. Hence we cannot guarantee this will not affect its performance.
- Follow the manufacturer's instructions when cleaning the device.
- Once the seal is opened the system is non-returnable.

- The system contains a Lithium-Polymer battery. This cannot be disposed of in domestic waste. Please return the system to your distributor or your local municipal collecting point when you wish to dispose of it.
- This device is not designed to be used in Explosive Environmental Conditions.
- The lay operator or lay responsible organisation should contact Acurable or Acurable's representative:
  - For assistance in setting up, using or maintaining the system; or
  - To report unexpected operation or events.
- This device is not intended to be used as a cardiac monitor.
- This device is not validated for use in the pediatric population.
- The pulse rate should only be used for informative purposes and not to infer clinical decisions. The pulse rate has been validated in a [50bpm, 120bpm] range.
- Home sleep testing (HST) devices are recommended for patients with suspected moderate or severe sleep apnea[1].

[1] For a full set of guidelines and recommendations on the use of different types of systems in different diagnostic contexts, please refer to "Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(3):479–504". AcuPebble SA100 has been validated for diagnosis using a HST device as a reference gold-standard. It has not been validated against PSG. Hence it should not be used in situations in which the patient would have been originally referred for PSG assessment, rather than HST assessment.

4. About AcuPebble SA100

4.1 Intended Use / Indications for Use

AcuPebble SA100 is indicated to sense, record, and interpret a patient's physiological signals (including respiratory pattern) during sleep for the purpose of prescreening patients for obstructive sleep apnea (OSA) syndrome. The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders (although it can also be used in clinic). Results are used to assist the healthcare professional's in the patient's evaluation.

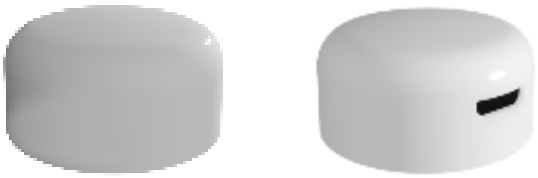


Figure 1: AcuPebble sensor

The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

Figure 2: Image illustrating positioning of AcuPebble sensor

4.2 Description of the Device

The AcuPebble sensor is a miniature electronic wireless wearable device, enclosed in a plastic case which is intended to be worn attached to the body with double coated medical tape. AcuPebble extracts and interprets multiple physiological channels from physiological body sounds, with the whole system having been designed to optimize the transmission of weak acoustic signals generated by different physiological processes. The sensed signals are interfaced with very low power electronic blocks which optimise both the quality of the signal and the wireless transmission to a mobile base station (i.e mobile phone or tablet). Transmission is carried out using a commercial Bluetooth Low Energy (BLE. 2.402-2.480 GHz frequency band, GFSK modulation and less than 4dBm radiated power) integrated circuit.

AcuPebble operates with a small Li-polymer battery (80mAh capacity), which has been tested for safety as per EN 62133:2013 (and a gap analysis to prove safety has been done for the subsequent version of the standard EN 62133:2017). In continuous operation, the system can function for over 23 hours (although note that for the intended purpose less than half of this is needed). Hence the average current through the system is less than 4mA. The device can be recharged using a standard micro-USB connector. Photos illustrating the device are shown in Figure 1 and 2.

The signal transmitted to the mobile phone can be uploaded to the Cloud and is automatically processed by the AcuPebble SA100 algorithms running on a server, which can extract physiological biomarkers. When worn on the neck (anywhere between the Adam's apple and the suprasternal notch. See Fig. 1), the AcuPebble algorithms are able to extract conventional obstructive sleep apnoea diagnostic indexes (AHI and ODI as per the American Association of Sleep Medicine, for both 3% and 4% oxygen desaturations with respect to baseline) from which the presence and severity of the disease can be obtained following the clinically worldwide established thresholds (i.e. 5, 15 and 30). Note that because of the nature of the condition, the automatic interpretation of the signals does not take place in real time. Block diagrams of the system are shown in Figure 3 and Figure 4.

AcuPebble SA100 is not intended to be used with patients with pacemakers or other implantable devices, or with patients with known or suspected arrhythmias. This device has not been validated in patients with congestive heart failure or patients with neuromuscular disorders. Patients with significant cardiopulmonary or neurological disorders need to be excluded from using the device.

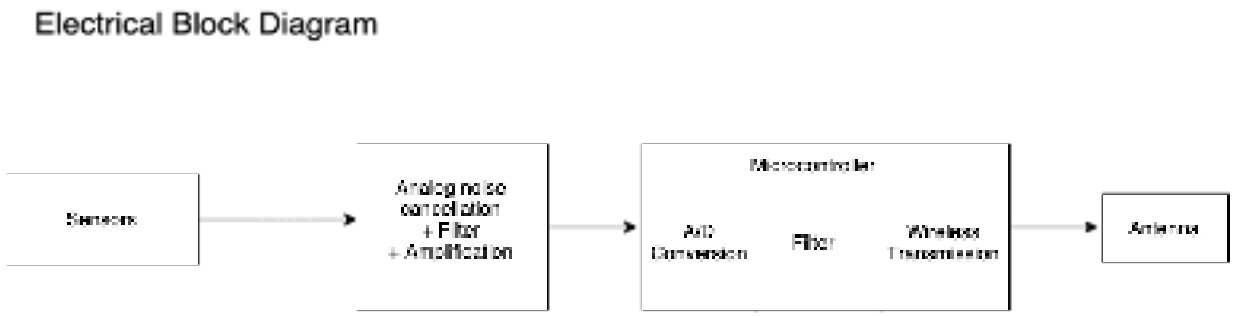


Figure 3:AcuPebble electrical block diagram

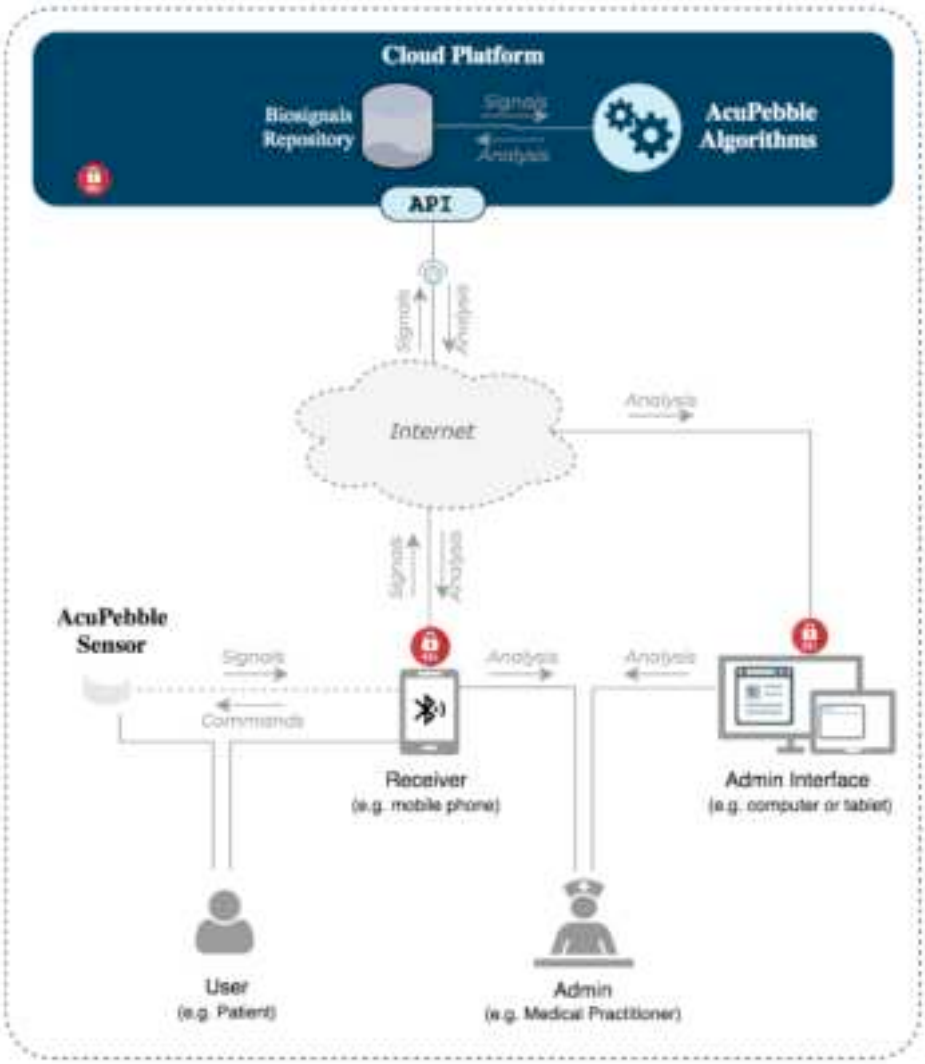


Figure 4: Full system diagram

4.3 Risks and Benefits

- Risks:
  - AcuPebble SA100 attaches to the body with a medical grade adhesive. If the patient is allergic to the adhesive this might cause a minor allergic reaction.
  - As with any medical device, the outputs of AcuPebble SA100 are not 100% accurate (refer to Section 20 for limits of accuracy obtained in clinical validation).
- Benefits:
  - AcuPebble SA100 can be used by patients themselves unsupervised at home, without the need of prior training. The device can also save interpretation time leading to faster subsequent interventions.
  - As per the patient's feedback, the device is significantly more comfortable to wear and use than current home-diagnosis gold-standard methods.

5. System Requirements

5.1 System requirements for running AcuPebble SA100's mobile application

AcuPebble SA100 can only be used with certain types of mobile devices. Performance and usability can both be affected if this is not the case. Check with your distributor whether the one you have would be suitable, or alternatively to get a suitable one for you.

A Wi-Fi or mobile network connection is required in order to set up the application and upload patient test results.

- Minimum:
  - Bluetooth 4.0 (Hardware BLE support)
  - Support for Android 6.0+ and iOS
  - 1 GB storage
  - Wi-fi
- Recommended:
  - Bluetooth 4.2

5.2 System requirements for charging AcuPebble SA100 sensor's battery

AcuPebble can only be used with a micro-USB charger with the CE mark (or marked as per equivalent national legal frameworks) which is able to provide more than 80mA of current. DO NOT use any charger which does not bear this mark. Should this be the case, the safety and performance of the system is not guaranteed.

5.3 System requirements for accessing AcuPebble SA100's web application

A computer with a compatible web browser installed and an internet connection is required in order to access the web application interface. Acurable Ltd does not guarantee the compatibility of the web application with browsers and versions not specifically listed as compatible. If you want to use a different browser or version, please first contact your distributor to verify its compatibility with AcuPebble SA100's web application.

- List of compatible web browsers:
  - Recommended: Chrome 63+, Firefox 67+, Safari 11.1+, Edge 69+
  - Minimum requirement: ES6 compatible browsers

6. How to use AcuPebble SA100 step by step

The AcuPebble SA100 sensor works together with a mobile application. It is worth noting that most of the instructions contained in this manual do not need to be read if the instructions in the mobile application are followed. More specifically, sections 6.3, 6.4 and 6.5 are covered in the app.

In addition, this symbol has been added to all those sections that are also self-contained in the mobile application.

6.1 When receiving your AcuPebble SA100

When unpacking AcuPebble SA100, check to make sure that all items are in good condition, and that all third party ordered accessories correspond to the delivery note.

6.2 Setting up AcuPebble SA100 for the first time

The AcuPebble SA100 sensor operates in combination with a mobile application. The mobile application should be installed in a mobile receiver, for example a mobile phone or tablet, compatible with the minimum requirements specified in this document.

- If you want to use the patient mobile phone or tablet to conduct the sleep study, make sure it is compatible with the minimum requirements.
- If you want to provide a mobile receiver to the patient to conduct the sleep study:
  - Acurable can procure a phone or equivalent receiver device and set up the system for you.
  - You can send us your mobile receiver(s) and we will set it up for you.
  - Alternatively, if you prefer to do it yourself, please follow the instructions below carefully.

6.2.1 Set up the AcuPebble SA100 mobile application

- Switch on the mobile receiver device (eg: mobile phone or tablet).
- Connect the mobile device to a wi-fi or mobile network to access the Internet.

- Open Google Play (for Android devices) or the App Store (for iOS devices) and search for "AcuPebble SA100". Alternatively you can open the mobile device web browser and enter the following URL in the navigation bar, then press "Enter": **https://acurable.com/products/sleep-apnoea/download**
- Press the "Download" button and download the app to the mobile device.
- After installing the application, a new icon with the text "AcuPebble SA100" will appear on your mobile device main menu. Press it to open the application.
- The mobile device and application are now ready to conduct sleep studies. The app will not allow the user to proceed unless the sensor is considered to be ready to complete a full night test, and it will guide the user on actions to be taken if this is not the case.

6.3 Using the AcuPebble SA100 mobile application

There are 3 steps required to complete a sleep study with AcuPebble SA100:

- Create a sleep study
- Conduct a sleep study
- Upload a sleep study

In the following subsections we detail each step.

6.3.1 Create a sleep study

Healthcare professionals can create a new sleep study using the AcuPebble SA100 mobile or web applications.

- The steps to create a sleep study using the web application are detailed in Appendix C.
- The steps to create a sleep study using the mobile application are detailed in Appendix D.

6.3.2 Conduct a sleep study

Patients can conduct a sleep study using their own mobile phone/tablet, or using a mobile receiver already setup.

- If the sleep study is conducted using the patient's own mobile phone or tablet, the patient needs to activate the sleep study using a code before being able to conduct it. The steps to activate the sleep study using the patient's mobile phone are detailed in Appendix E.
- If the sleep study is conducted using a mobile phone or tablet already setup, the patient can undertake the sleep study directly.

The steps to conduct a sleep study are detailed in Appendix F.

6.3.3 Upload a sleep study

After conducting the sleep study, the data recorded needs to be uploaded for analysis.

- If the sleep study is conducted using the patient's own mobile phone or tablet, the patient will upload the data.
- If the sleep study is conducted using a mobile phone or tablet already setup, the healthcare professionals will upload the data after the patient returns the AcuPebble SA100 system.

The steps for both the healthcare professional and patient to upload a sleep study using the mobile application are detailed in Appendix G.

6.3.4 Terminating the operation

The operation of the system can be terminated by fully closing out the app in the mobile receiver (phone or tablet). The specifics on how to do this will depend on the exact model of your phone/tablet. If you need any assistance on this please contact either your terminal manufacturer or Acurable.

6.4 Attaching the sensor

6.4.1 How to put on the sensor

AcuPebble SA100 sensor is attached to the body with a medical grade adhesive. Every adhesive is single use. Once the adhesive is detached, it CANNOT be used again. Hence, if by mistake the sensor is attached in the wrong location, and needs to be repositioned, the adhesive MUST be replaced, regardless of the time it was in the wrong position. Also, if the adhesive is mistakenly touched in the middle while peeling or positioning the sensor, it must be replaced.

Prior to attaching the sensor, the location where it is going to be placed must be cleaned and dried. This can be done with either water and soap, or, if in clinical settings, with typically used alcohol wipes.

DO NOT use wipes with chlorhexidine to wipe the neck, since this affects the performance of the adhesive and the sensor will fall off.

This is especially important if the patient has used any kind of cream or makeup in that location. The skin must be totally free of those. Also, if the sensor is intended to be attached on a hairy surface, this must be shaved.

For use on intact skin only.

The sensor enclosure, together with the adhesive, is a floating applied part (i.e. a part that in normal use necessarily comes into physical contact with the user).

The sensor can be attached by peeling off the adhesive, holding it from the sides and fixing it to the desired location, applying a slight pressure for a couple of seconds.

In the mobile app, the instructions to put on the sensor are provided in the form of an animated video. Appendix A details each one of the instructions provided to the user.

6.4.2 How to change the adhesive

AcuPebble SA100's adhesive can be changed as follows:

- Peel off the old adhesive.
- Take a new one, place it on a table with the yellow side facing up and press your finger down on the white tab to hold it in place.
- Peel off the yellow backing paper WITHOUT touching the sticky side of the adhesive. If that part is touched, throw it away and start again.
- Keep your finger on the white tab, and with your other hand place the bottom of the AcuPebble SA100 sensor (the one with a little hole in the middle) on to the adhesive. Keep pressing down for a few seconds so that the adhesive sticks firmly to the sensor.

In the mobile app, the instructions to replace the adhesive will be provided in the form of an animated video. Appendix B details each one of the instructions provided to the user.

6.4.3 Sensor location

The AcuPebble SA100 sensor should be placed on the neck above the suprasternal notch (2 or 3 cm, where the trachea can be felt around that area above the notch). If this location is not possible, the closest to it, whilst as far as possible from arteries.

In the mobile app, the instructions detailing the location to put on the sensor will be provided in the form of an animated video. We detail in Appendix A each one of the instructions provided to the user.

When removing the adhesive from the neck a slight redness might appear on the location it was placed (similar to the redness that appears when taking off many other plasters in other parts of the body). Unless the patient has got an unknown allergy to acrylate this effect should not cause discomfort and should be temporary.

6.5 Accessing diagnostic data

The diagnostic data can be accessed via a secure web application. The steps to access diagnostic data are detailed in Appendix H.

Depending on the service plan the user has contracted with Acurable, the user may be able to access additional information:

- A graphic representation of the signals
- The patient's heart rate, and/or a graphic representation of it

We cannot guarantee the heart rate will be at all times accurate, since the signal might be corrupted by artefacts. Hence this should not be used for diagnostic purposes.

6.5.1 Historic information

In the web app, there is also the option of accessing a historic list of patients tested, so that the information about a specific patient can be clicked on directly without having to manually enter the identifier number (Note that this list is still identifier based, since no personal information is recorded by the system).

7. Charging the Battery

The battery in AcuPebble SA100 sensor is expected to last over 15 hours when used for sensing after having been fully charged. We advise that you charge the battery for at least an hour before carrying out an overnight test. The battery can be charged by connecting a CE marked micro-USB charger to the micro-USB connector (DC port. See Figure 3 below). DO NOT use any device that does not show the CE mark. If you do not own a suitable charger, you can ask your distributor to get one for you. Note that the DC port is solely intended for connection to the CE marked micro-USB charger.

Whilst the battery is being charged, and until it is fully charged, a shining orange light will be seen through the enclosure. You might need to surround the enclosure with your hand to see it properly under very bright room lighting conditions. The app will guide you through this.

The app will also warn you if the battery is not sufficiently charged to carry out an overnight test.

Figure 5 : AcuPebble SA100 sensor connected to micro-USB charger

7.1 Battery levels

AcuPebble SA100 sensor uses a Lithium-Polymer battery. The shelf-life of the device is going to depend on how often the device is charged, since the battery is able to provide enough capacity for it to operate for up to 500 recharging cycles. Hence, assuming daily use, the device is expected to function for over a year; less frequent use may result in longer operation. However, the device should not be left unused for long periods of time. Following the recommendations of the battery manufacturers if the device is stored for extended periods, this should be fully charged, fully discharged and fully charged again, at least once every 90 days.

The system will warn about power limitations prior to starting any test. Please do charge the batteries if this warning appears.

If after charging the device, this warning persists immediately after disconnecting it from the charger, please contact Acurable Ltd to arrange for a replacement, since that might mean that the device has reached the end of its life.

7.2 Expected life (Expected failure time)

Once the battery reaches capacity/voltage levels that would not allow a test to be completed, this would be detected by the mobile app, in the same way the app detects when the battery is not charged to a level that would allow the device to operate continuously for a full test duration. Should the patient have the device when this happens, the only effect this will have is that a new sensor will need to be provided for the app to allow the test to take place.

8. Software Updates 

Whenever there is a software update available for the system, an alert will appear when accessing the “doctor/authorised person” mode of the app. The update must be completed before the user can continue with the application.

If the research version of the app is used, the same will happen when opening the app.

9. Security

To ensure data is kept secure, all healthcare professionals accessing the AcuPebble SA100 system through either the web or mobile applications must have a registered user account, which is accessed using a unique email address and secure password. In addition, users are encouraged as best practice to enable two-factor authentication to further protect the security of their accounts.

10. Troubleshooting

PROBLEM	POSSIBLE REASON	WHAT TO DO
I cannot login to the mobile application.	**Either:** **· the internet connection is not working, or** **· your login/password are not valid**	· Go to the phone/tablet settings and make sure the phone/tablet is connected to the internet via Wi-Fi and that the Wi-Fi signal strength is good. Otherwise try moving closer to the Wi-Fi router. · Then make sure your login details are correct. If you don't have login details, contact your organisation so they can create them for you. If you have login details but have forgotten them, use the reset option in the application to create a new password.
The wireless communication seems to be failing and I cannot connect the mobile application to the sensor.	**Either:** **· the sensor is too far away** **· there are other electronic devices close to the sensor** **· the sensor is not charged** **· the mobile phone/ tablet you are using has the bluetooth disabled, or** **· the mobile application does not have permission to use bluetooth**	· Move the sensor next to the mobile phone/ tablet, and move any other electronic devices more than 30cm away from the sensor and mobile phone/tablet. · Charge the sensor by connecting it to a power supply, then verify your phone/ tablet settings to make sure the bluetooth is enabled. · Finally, access the AcuPebble SA100 mobile app settings and make sure all the permissions are enabled.
I charged the sensor but the mobile app still says it is not charged.	**Either:** **· you did not charge the sensor enough, or** **· the charger you used was not compatible so the sensor did not charge**	· Charge the sensor again. Make sure the charging light is on and that the charger is a CE marked micro-USB charger providing over 80mA of current.

PROBLEM	POSSIBLE REASON	WHAT TO DO
The sensor light does not come on when charging.	**Either:** **· the charger is not properly plugged into the sensor, or** **· the light is on, but you cannot see it due to high ambience luminosity**	· Make sure the charger is properly attached to the sensor and the electricity socket. · You may need to shield the sensor with your hand to see if the light is on: 
The sleep study does not upload.	**Either:** **· the internet connection is not working, or** **· it is too slow to complete the upload**	· Go to the phone/tablet settings and make sure the phone/tablet is connected to the internet via Wi-Fi and that the Wi-Fi signal strength is good. Otherwise try moving closer to the Wi-Fi router. · If the upload starts successfully but never finishes, try using a different Wi-Fi network or wait a few minutes and try again.

If the problem persists or you experience an issue not described above, please contact your distributor for further assistance.

11. Cleaning and Maintenance

11.1 Cleaning and disinfection

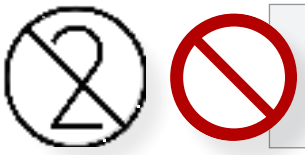
Regardless of whether a sleep apnea patient is known to have an infectious disease or not, since the AcuPebble SA100 sensor is reusable, for hygiene reasons, it should be cleaned in-between uses by different users. In order to do this, wipe the enclosure of the sensor with an alcohol wipe (70% isopropyl alcohol).

With the adhesive on, this device is at least IP22 in terms of water ingress. This means that it is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

After cleaning, the device must be visually examined in a well-lit area. If the device appears visibly soiled, then further cleaning is required and the process should be repeated. If after several attempts the device cannot be satisfactorily cleaned, or any signs of damage to the enclosure are noted, the device must be taken out of use and disposed of safely, as described in section 16.

If the adhesive is not on, make sure not to get any liquid into the hole at the bottom of the enclosure. If by mistake liquid gets into that hole, do not use the system. Contact your distributor, or Acurable directly.

With the adhesive off, this device complies with IP protection class “20”. This means that the device is NOT waterproof. Also protect it from dust and dirt. Do not use autoclave for cleaning.



DO NOT reuse the adhesive.

11.2 Use and maintenance of AcuPebble SA100 sensor’s battery

The AcuPebble SA100 sensor operates with a rechargeable Lithium-Polymer battery. This battery has been tested for safety by the battery manufacturers as per IEC 62133-2. The battery offers a long lifetime (approximately 500 charges), is not susceptible to memory effects and is ecologically friendly. Every charging cycle is counted as a complete charge. It takes approximately 2.5 hours (150 minutes) to charge a full battery.

When the battery is being charged an orange light will shine through the device enclosure. This light will switch off when the battery is fully charged. Note that it is not necessary to fully charge the battery for the system to be ready for a night test. The mobile app will however only let the user continue with the tests once the battery has reached enough level of charge.

Never dispose of the device in domestic waste. It is strictly forbidden to dispose of Li-Po batteries in domestic waste. Please return it to your distributor or hand them in at your local waste disposal point.

Always charge the device with CE marked (or marked as per equivalent national legal frameworks) devices.

11.3 Expected life of the device

If used and stored according to these instructions for use, the AcuPebble SA100 sensor can be re-used up to 500 times. Once the battery reaches capacity/voltage levels that would not allow a test to be completed, this would be detected by the mobile app, in the same way the app detects when the battery is not charged to a level that would allow the device to operate continuously for a full test duration. Should this happen, the device must be replaced.

Before every use, the device must be visually examined in a well-lit area. If the enclosure appears corroded, cracked or otherwise damaged, the device must be taken out of use and disposed of safely, as described in section 16.

12. Storage and Transport

Always carry and store the AcuPebble SA100 sensor with an adhesive on and in a pouch, box or some other kind of alternative protective cover.

Once opened, make sure to always store and transport the AcuPebble SA100 sensor with an adhesive on, and in a separate protective bag or container, to prevent, for example, a thin-pointed object from breaking the adhesive and penetrating the hole at the bottom of the enclosure. Additionally, the sensor should be wrapped up in bubble envelopes.

The following environmental conditions must be respected during transport and storage:

- Temperature between -25oC and +70oC (-13oF and +158oF).
- Humidity between 20% and 75%.
- Atmospheric pressure between 70 kPa and 106 kPa.

Additional environmental conditions:

- If the device is going to be stored for more than 3 months but less than a year, the storage temperature should be between -5°C and 25°C (23°F and 77°F).
- If the device is going to be stored for less than three months the storage temperature should be between -10°C and 40°C (14°F and 104°F).
- During long periods of storage, the device should be fully charged, fully discharged and fully charged again at least once every 180 days.

For shipping, the device must be protected by placing it in its original packaging or, alternatively, by covering it with protective wrapping. The device, once protected, should be placed inside a standard cardboard shipping box, with padding or equivalent to avoid sudden vibrations or movements. Additionally, if the shipment contains 3 or more sensors, the shipping box should comply with the labelling requirements for international transportation of new small size Li-Po batteries contained in equipment, specifically:

- For all transport methods, the shipping box should have affixed the UN3481 handling mark.
- For air transport, the shipping box should also have affixed a transport document containing a General warning statement and an Air-waybill notice.
    - General warning statement: “The package contains Li-Po cells or batteries; the package must be handled with care and a flammability hazard exists if the package is damaged; special procedures must be followed in the event the package is damaged, to include inspection and repacking if necessary; For emergency information, call (+1) 833 502 0261.”
    - Air-waybill notice: “Li-Po batteries, in compliance with Section II of PI967”.

13. Warranty

Acurable will only guarantee the Safety, Operation and Reliability under the following conditions:

- The device is used according to the instructions.
- The device is stored in a suitable environment.
- The device is not physically modified.
- The system is not put to charge more than once a day.

The system is guaranteed for 12 months.

Details about warranties will be specified in your contract with the manufacturer (or authorised representative when relevant).

14. Travel or International Use

This medical device has been authorised for use in Europe. Use outside the US or Europe might result in infringement of national laws and hence must be not authorized.

15. Accessories

AcuPebble SA100 requires the following accessories to operate:

- A CE marked (or marked as per equivalent national legal frameworks) micro-USB charger providing over 80mA of current (alternatively it can be charged with a micro-USB cable connected to a device with a suitable port).
- A CE marked (or marked as per equivalent national legal frameworks) mobile phone or tablet or computer.

AcuPebble SA100's distributors can procure any of these accessories for you, or alternatively you can purchase them separately yourself. However, note that:

Acurable Ltd. does not guarantee the Safety, Reliability and Operation of AcuPebble SA100 if non-CE marked (or equivalent) devices are used.

16. Disposal of Parts

AcuPebble SA100 devices must be disposed of according to local regulations for environmental protection. Since the devices do contain Li-Polymer batteries, domestic disposal is not allowed.

Never dispose of the device in domestic waste. It is strictly forbidden to dispose of Li-Polymer batteries in domestic waste. Please return the device to your distributor or hand them in at your local waste disposal point.

17. Information about Radio Equipment Electromagnetic Compatibility

17.1 Wireless transmission

AcuPebble SA100 uses nRF52832 transceiver for fast and reliable data transmission. This transceiver chip is non-adaptive and uses GFSK frequency modulation in the frequency range 2.402 GHz to 2.485GHz. This is an ISM band which is available globally and is intended to ensure communication compatibility everywhere in the world. The effective radiated power when in operation of this integrated circuit is less than 7dBm e.i.r.p., with a maximum transmission power of +4dBm. The maximum data rate is 26 kbps and the transmission of data is encrypted using the AES-CCM encryption scheme.

The device is classified as Group 1, Class B as per EU and British Standard BS EN 55011:2016 (CISPR 11:2015); this is equipment suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and Manufacturer's declaration- electromagnetic emissions

Emissions test	**Compliance**	Electromagnetic environment- guidance
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment		
RF emissions, CISPR 11	**Group 1**	The equipment 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 equipment
RF emissions, CISPR 11. Electromagnetic radiation disturbance limits	**Class B Complies**	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

For any further technical information about this integrated circuit you can also contact the manufacturers (https://www.nordicsemi.com/).

17.2 Electromagnetic Compatibility (EMC)

This product emits radio frequency energy, but the radiated power is very low, and has been tested and found to be in compliance with CISPR-11.

Although not affecting safety, other portable and mobile RF communications may however affect the optimum performance of the device, resulting in inconclusive sleep apnea test results (and consequently the requirement of having to repeat the test). The reason for this is that the device may suffer from interference from other equipment, even if that equipment complies with CISPR-11 radio requirements. To minimize the probability of this, wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. should be kept at least a distance "d" away from the equipment. The distance d can be calculated from the Table below.

Recommended separation distances to portable and mobile communication equipment

Rated power of the transmitter (W)	Separation distance (d) according to the transmission frequency (m)		
	150kHz to 80MHz d=1,2(P) 1/2	**80 MHz to 800 MHz d=1,2(P) 1/2**	**800 MHz to 2.5 GHz d=2,3(P) 1/2**
The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

17.3 FCC Compliance

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.

Acurable has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment.

FCC ID: 2A258-AP100C04

AcuPebble SA100 is an electronic device. As for all electronic devices, its operation could be somewhat affected by interference from other electronic devices. Examples of typical devices which may cause interference include RFID tags, televisions, other cell phones, etc. In some cases, since electromagnetic signals are not visible, interference might be the result of non-obvious sources. In extreme cases, this interference might lead to data loss which could result in an invalid test. Should this be the case you can try to prevent this from happening again by:

- Placing all other electronic devices as far as possible from the sensor, as you can in the bedroom; or even better, outside the bedroom, if this is at all possible.
- Placing the mobile phone (or smart device where the app is running) as close as possible to where you are sleeping. The closer the mobile phone is to the sensor the stronger the signal it will get.

AcuPebble SA100 has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

18. Information about Safety Testing

This device has been tested for safety and found to be compliant as per European/British Standards BS EN 60601-1:2006+A12:2014 and its associated relevant collaterals.

19. Adverse Events

No adverse events have been reported whilst using this product so far. However, it is important to note that this device should not be used by patients with a known allergy to medical adhesives, since the device is attached to the body with one, which cannot be replaced by any other form of attachment. Slight transitory redness typical of the one left when pulling an adhesive from the body (like conventional bandages) is not considered an adverse event.

20. Summary of Clinical Evaluation Results

The efficacy of AcuPebble SA100 sensor and accompanying software was evaluated in a clinical trial, carried on in the Royal Free Hospital (UK). The trial was approved by London Centre National Ethics Committee (UK) as well as the UK Medicines and Healthcare Products Regulatory Agency.

In the course of this trial, the diagnostic performance of AcuPebble SA100 was compared with the diagnosis of the gold-standard method for home sleep diagnosis, in 150 consecutive patients. Patients used AcuPebble SA100 whilst also following the conventional home diagnostic pathway. More specifically, under the conventional pathway, patients who are being referred for diagnosis are issued with a limited cardio-respiratory polygraphy device. After undertaking their study at home and completing a comprehensive sleep questionnaire, the patient is required to return the device the next day. The data is uploaded and subsequently analysed by a member of the sleep and ventilation team. In the context of the trial, the multi-channel polygraphy signals for each patient were manually marked by two experts sleep physicians, who also computed the following indexes:

- AHI (for 3% desaturations): Apnea Hypopnea Index as defined by the AASM.
- AHI (for 4% desaturations): Apnea Hypopnea Index, considering as hypopnea events that meet the AASM definition for reductions in flow, but have desaturations equal or greater than 4%.
- ODI (for 3% desaturations): Oxygen Desaturation index, defined as the number of times per hour of sleep that the blood's oxygen level drops by more than 3% from baseline.
- ODI (for 4% desaturations): Oxygen Desaturation Index, defined as the number of times per hour of sleep that the blood's oxygen level drops by more than 4% from baseline.

The clinical team was completely blind to the outputs of AcuPebble.

AcuPebble's software automatically and independently generated four diagnostic outputs corresponding to four equivalent diagnostic indexes:

- ACU-AHI3: Average number of apnea plus hypopnea events per hour, with hypopneas defined using the AASM criteria for reduction in flow, but considering 3% reduction in oxygen saturation.
- ACU-AHI4: Average number of apnea plus hypopnea events per hour, with hypopneas defined using the AASM criteria for reduction in flow, but considering 4% reduction in oxygen saturation.
- ACU-ODI3: Number of times per hour of sleep that the blood's oxygen level drops by more than 3% from baseline.
- ACU-ODI4: Number of times per hour of sleep that the blood's oxygen level drops by more than 4% from baseline.

Note that, although the top index (i.e. AHI-3% desaturation) is the one recommended for the AASM, AcuPebble SA100 generates four different outputs (and their corresponding diagnosis) to accommodate for a wider variety of criterias used in different sleep clinics around the world. It is up to the individual clinic/physician to decide which one of those indexes (together with its corresponding diagnosis) to follow.

For all of the indexes, the presence and severity of the disease follows the usual diagnostic convention: Normal if the diagnostic index is in the 0 to 5 range, Mild Sleep Apnea in the range 5 to 15, Moderate 15 to 30 and Severe over 30.

The comparative evaluation results are shown in Tables I to IV:

**Table I: ACU-AHI3 Based Diagnosis:
Blind Evaluation Results
(Hypopnoeas defined using the AASM reduction in flow criteria and 3% oxygen desaturations, in both AcuPebble and Gold-Standard)**

Statistic	Value	95% CI
Sensitivity	92.73%	82.41% to 97.98%
Specificity	96.84%	91.05% to 99.34%
Positive Likelihood Ratio	29.36	9.62 to 89.64
Negative Likelihood Ratio	0.08	0.03 to 0.19
Disease prevalence	36.67%	28.96% to 44.92%
Positive Predictive Value	94.44%	84.78% to 98.11%
Negative Predictive Value	95.83%	89.94% to 98.34%
Accuracy	95.33%	90.62% to 98.10%

**Table II: ACU-AHI4 Based Diagnosis:
Blind Evaluation Results
(Hypopneas defined using the AASM reduction in flow criteria and 4% oxygen desaturations, in both AcuPebble and Gold-Standard)**

Statistic	Value	95% CI
Sensitivity	95.92%	86.02% to 99.50%
Specificity	97.03%	91.56% to 99.38%
Positive Likelihood Ratio	32.29	10.58 to 98.59
Negative Likelihood Ratio	0.04	0.01 to 0.16
Disease prevalence	32.67%	25.24% to 40.79%
Positive Predictive Value	94.00%	83.69% to 97.95%
Negative Predictive Value	98.00%	92.65% to 99.48%
Accuracy	96.67%	92.39% to 98.91%

**Table III: ACU-ODI3 Based Diagnosis:
Blind Evaluation Results
(Hypopneas defined using the AASM reduction in flow criteria and 3% oxygen desaturations, in both AcuPebble and Gold-Standard)**

Statistic	Value	95% CI
Sensitivity	91.03%	82.38% to 96.32%
Specificity	93.06%	84.53% to 97.71%
Positive Likelihood Ratio	13.11	5.61 to 30.62
Negative Likelihood Ratio	0.10	0.05 to 0.20
Disease prevalence	52.00%	43.70% to 60.22%
Positive Predictive Value	93.42%	85.87% to 97.07%
Negative Predictive Value	90.54%	82.48% to 95.11%
Accuracy	92.00%	86.44% to 95.80%

**Table IV: ACU-ODI4 Based Diagnosis:
Blind Evaluation Results
(Hypopneas defined using the AASM reduction in flow criteria and 4% oxygen desaturations, in both AcuPebble and Gold-Standard)**

Statistic	Value	95% CI
Sensitivity	97.96%	89.15% to 99.95%
Specificity	92.08%	84.99% to 96.52%
Positive Likelihood Ratio	12.37	6.35 to 24.08
Negative Likelihood Ratio	0.02	0.00 to 0.15
Disease prevalence	32.67%	25.24% to 40.79%
Positive Predictive Value	85.71%	75.50% to 92.11%
Negative Predictive Value	98.94%	93.03% to 99.85%
Accuracy	94.00%	88.92% to 97.22%

AcuPebble also gives as an output the classification of apnea versus hypopnea events. In order to evaluate the performance, the classification of events for 10 randomly chosen patients with moderate or severe sleep apnoea was individually compared with the blind classification of the doctor (N=3164). The accuracy of the classification, was 90.20% with (89.11%, 91.22%) confidence interval. Recall and Precision values are shown in Table V.

Table V: Hypopnea versus apnoea classification performance of AcuPebble versus gold-standard (human marker)

Statistic	Value	95% CI
Recall for Apnea Events (Sensitivity)	90.70%	89.38% to 91.90%
Precision (Positive Predictive Value)	94.44%	93.45% to 95.29%
Accuracy	90.2%	89.11% to 91.22%

For apnea events (N=426), the accuracy of classification between central and obstructive apnea was 81.7% with 95% confidence interval from (77.68% to 85.25%).

When central apnea events are detected AcuPebble also outputs a warning of potential Cheyne-Stoke apnea patterns if:

1. There are episodes of at least three consecutive central apneas separated by a crescendo and decrescendo change in breathing amplitude with distances between two consecutive ones of less than 80 seconds.
2. There are five or more central apneas per hour associated with the crescendo/decrescendo breathing pattern recorded over a minimum of two hours of sensing.

In addition to automatic diagnosis of sleep apnea, AcuPebble SA100 also outputs the heart rate (with one sample every two seconds). The performance of the heart rate output was evaluated for the same 150 patients, using as an index test the heart rate obtained from the PPG signal of the polygraphy system. Two hours of data per patient were used for the comparison. The same two hours were taken for all the patients, unless the PPG signal was too corrupted to generate the output, in which case, the time was shifted to the nearest non-corrupted interval.

For the complete dataset of 150 subjects, the Bland-Altman comparison is plotted below. A bias of -0.46 bpm, a standard deviation of 3.59 bpm and LoA of [-7.51, 6.58] are obtained for the heart rate comparison.

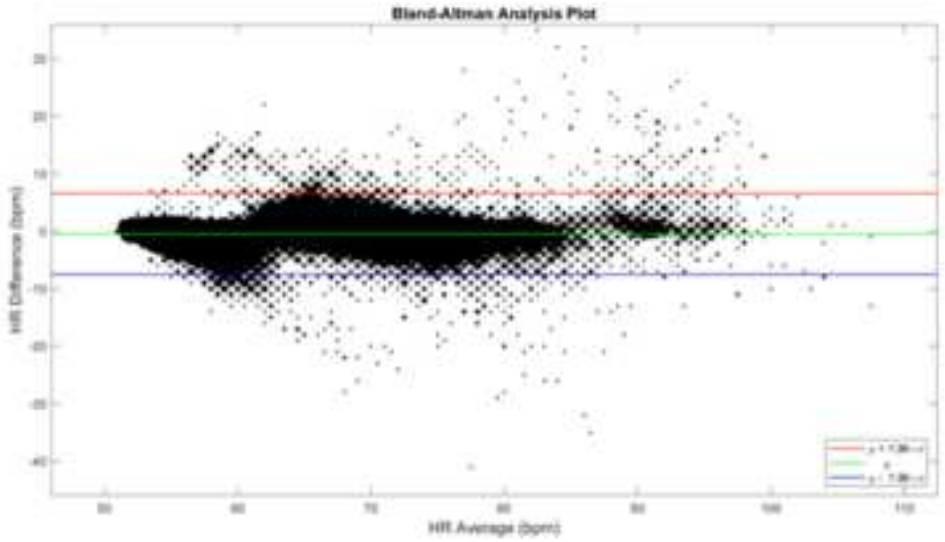


Figure 6: Heart Rate- Illustration of Bland-Altman plot for the 150 evaluation subjects.

Table VI lists the percentage of subjects with bias and standard deviation within a certain range.

Table VI: Heart Rate - Percentage of subjects with bias and standard deviations within different ranges

Bias (μ)			**Standard Deviation (σ)**		
≤ ±1 bpm	=≤ ±3 bpm	≤ ±5 bpm	≤ 2 bpm	≤ 5 bpm	≤ 8 bpm
62.0%	94.0%	98.7%	28.7%	93.3%	98.7%

The following table lists the percentage of samples in the complete dataset with LoA within a certain range.

Table VII: Heart Rate - Percentage of samples with limits of agreement within different ranges

Limits of Agreement (μ ± 1.96 × σ)				
≤ ±1 bpm	≤ ±2 bpm	≤ ±3 bpm	≤ ±4 bpm	≤ ±5 bpm
53.9%	70.9%	80.5%	86.6%	90.8%

21. Contact

For questions, problems, feedback, or should you need any help with the system, contact us! We will be happy to hear from you.

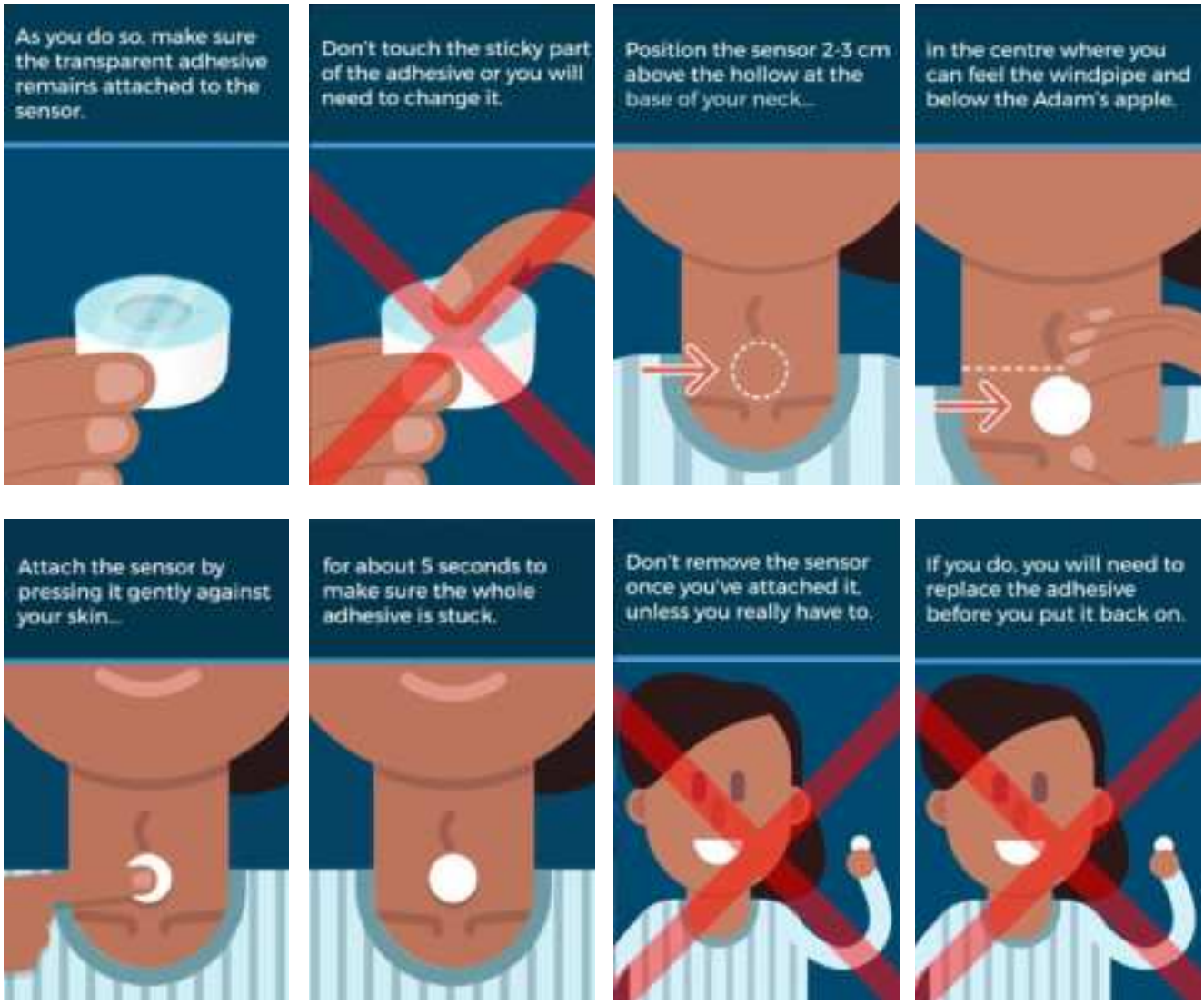
Our telephone-hotline offers help at:
Mon-Fri 09:00-18:00 **+44 (0)208 191 7590**

Send us a message by email at any time:
support@acurable.com

Or send us a letter at:
Acurable, Finsgate, 5-7 Cranwood Street, London EC1V 9EE

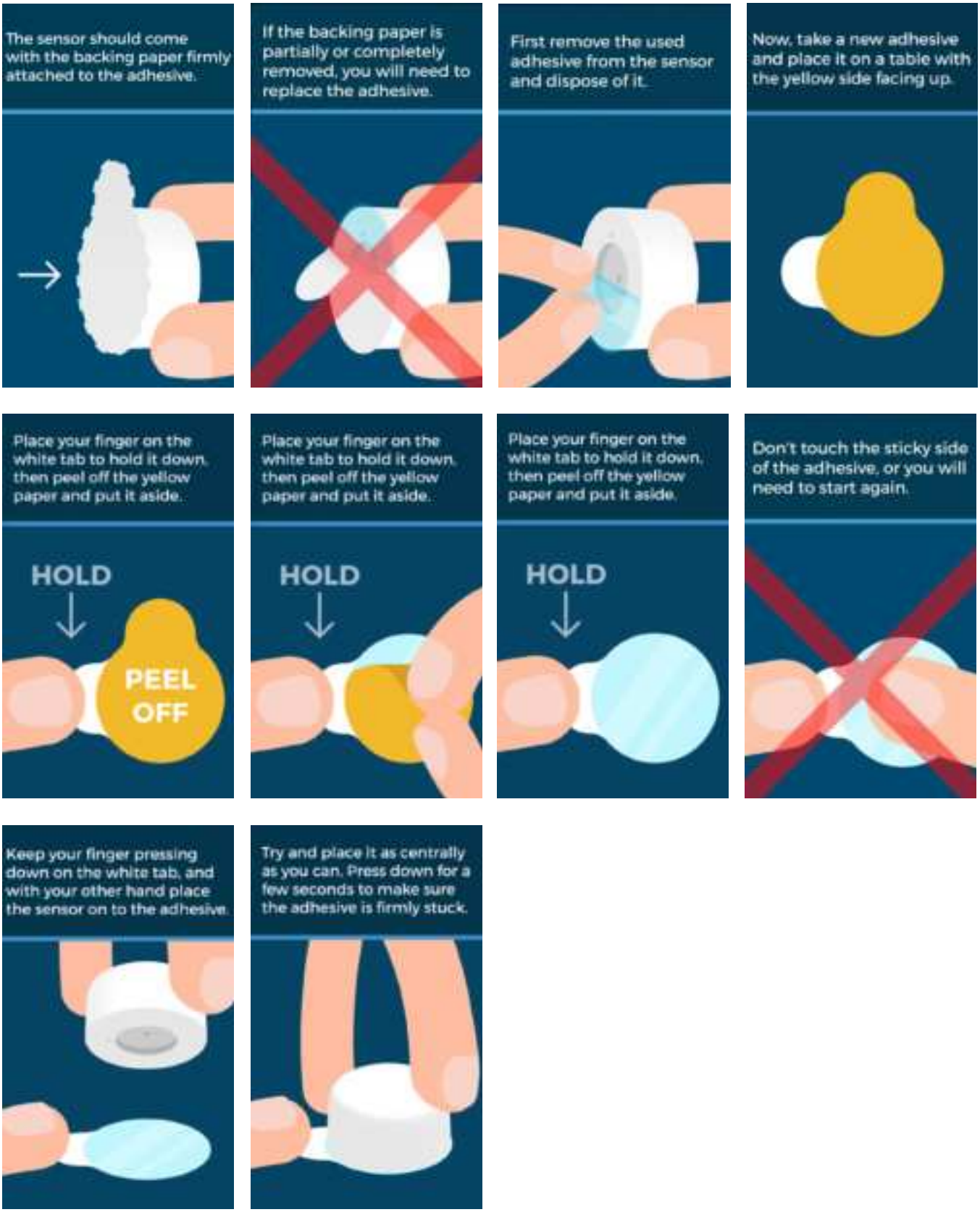
Appendix A: How to put on the sensor

Instructions on how to put on the sensor are given in a video in the mobile app, as shown in the screens below:



Appendix B: How to replace the adhesive

The steps for replacing the adhesive are explained in a video in the mobile app, as shown in the screens below:

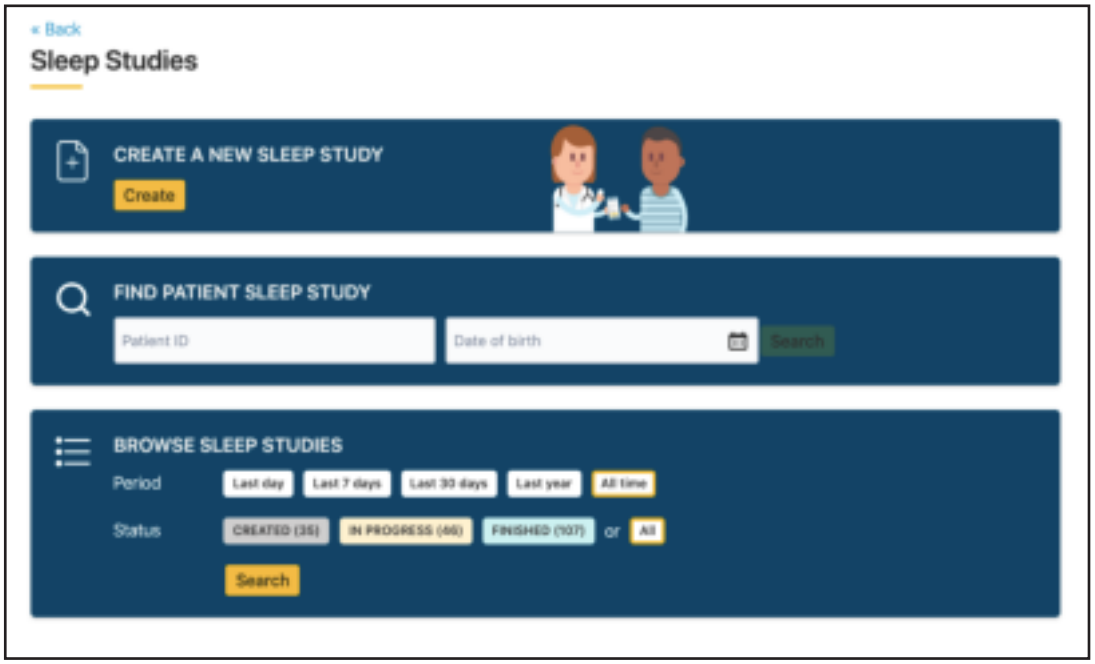


Appendix C: Create a sleep study using the web application

1. Go to the web app at **https://cloud.acurable.com**.

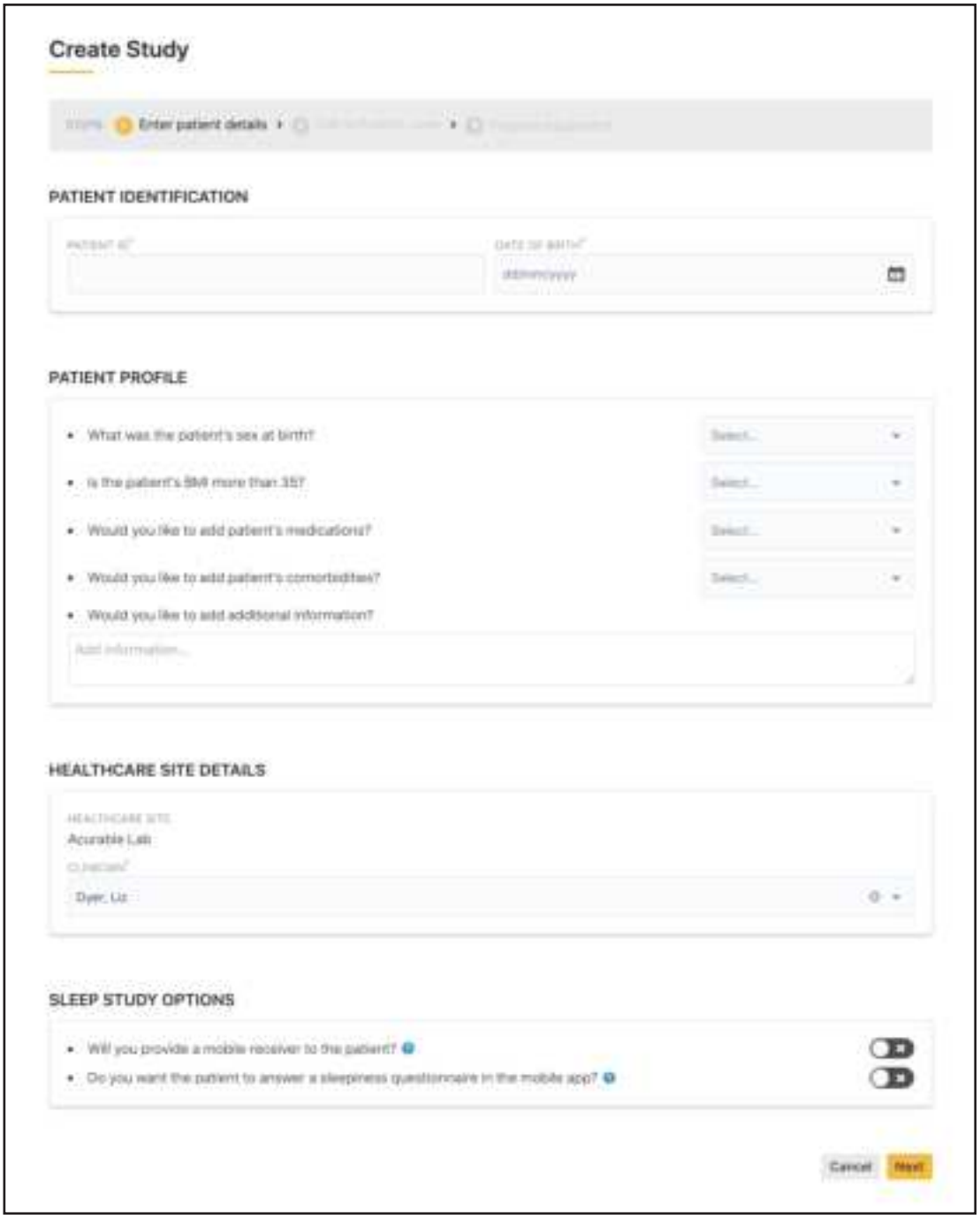
2. Enter your login details and press “Log in”. If you’ve forgotten your password, you can reset it.

3. Select “Studies” in the main menu, then click on “Create”.



4. Complete the form with the following information:

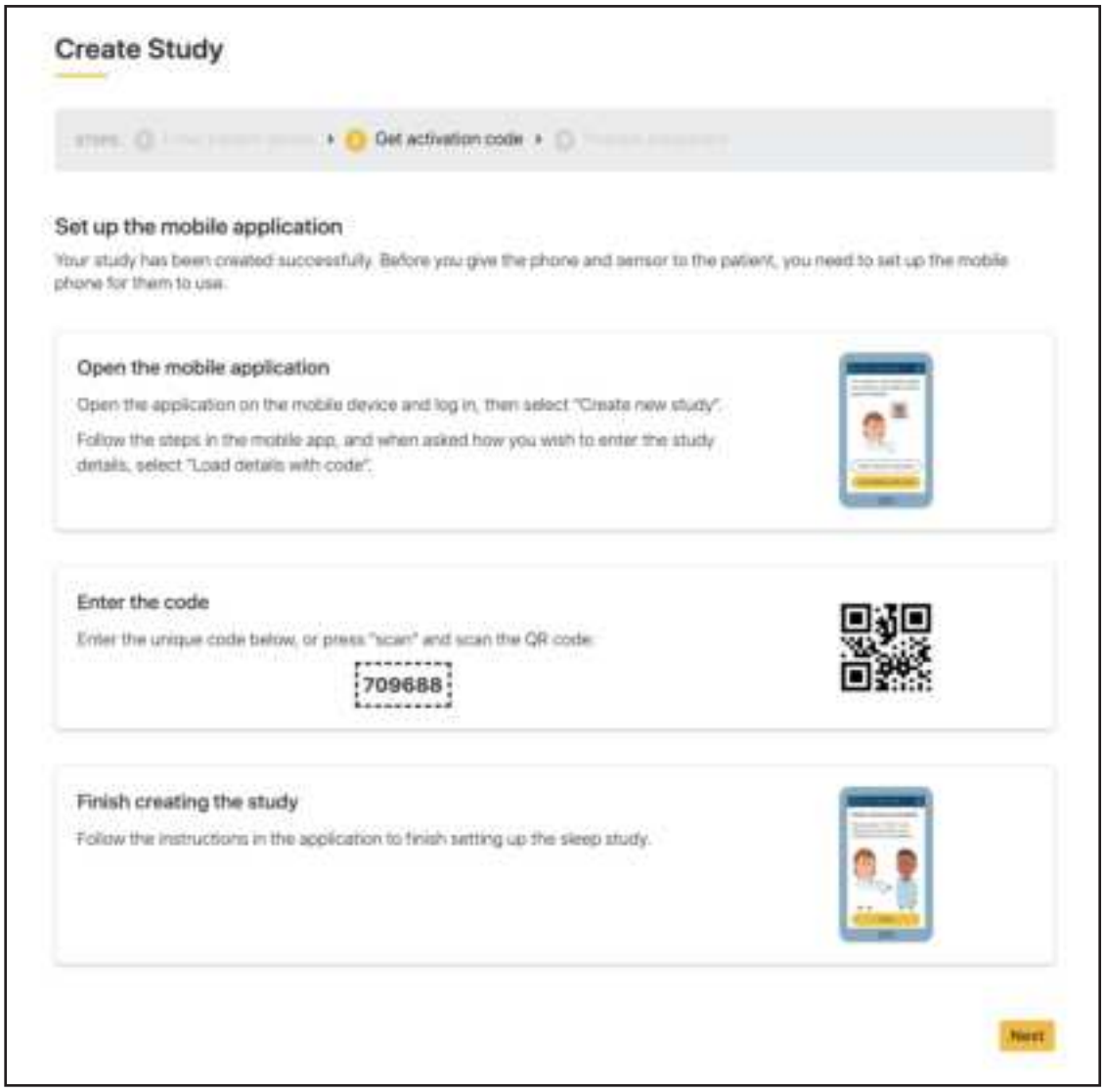
- **a.** Patient identification: enter the patient ID and date of birth.
- **b.** Patient profile: answer the questions to provide more detail about the patient.
- **c.** Healthcare site details: select the healthcare site and requesting clinician for the study.
- **d.** Sleep study options: confirm which device the patient should use and whether they need to complete a sleep questionnaire.



5. Re-enter the patient ID and date of birth, to confirm they are correct.

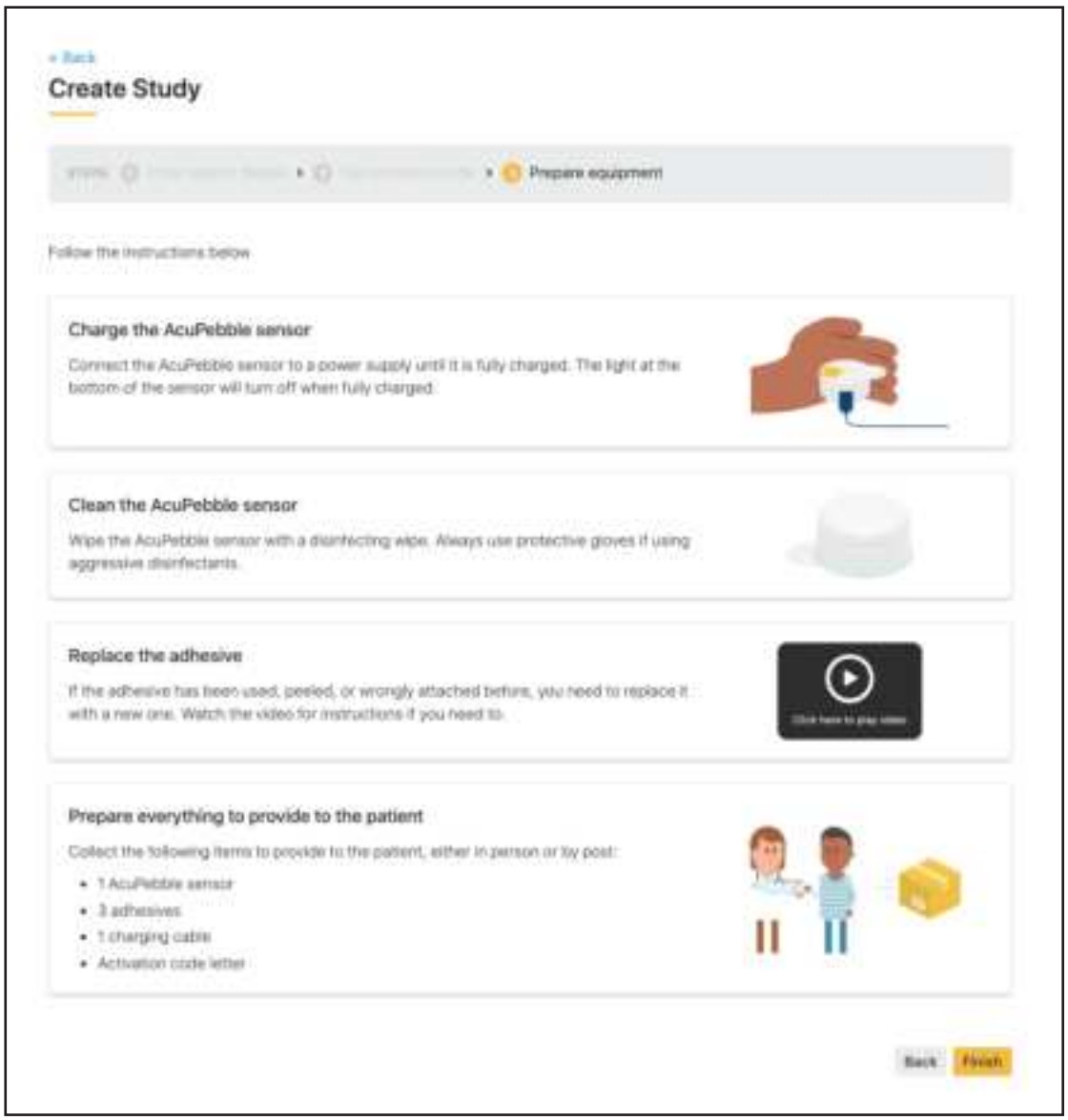
6. If the patient will be using their own phone to conduct the study: Print the activation code with instructions to send to the patient with the sensor.

7. If the patient will be using a hospital phone to conduct the study: An activation code will be displayed on screen in the web app. You will need to enter this in the mobile app on the hospital phone before giving it to the patient (see Appendix D).



8. Follow the instructions provided to prepare the equipment to be supplied to the patient. You will need to:

- **a.** Charge the sensor.
- **b.** Check the adhesive, and replace if necessary.
- **c.** Clean the sensor.
- **d.** Prepare all the equipment for posting or handing to the patient.

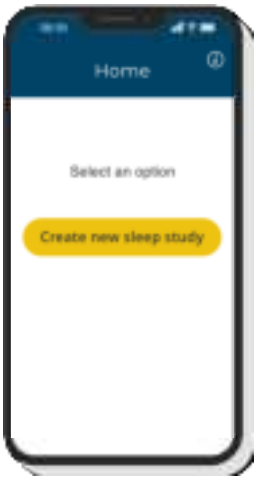


Appendix D: Create a sleep study

Patients can conduct a sleep study using their own mobile device (***patient mode***), or using a mobile device already setup (***hospital mode***).

For studies to be conducted in *hospital mode*, you can use the mobile app to create or load a study directly (previously created on the web app) on the device that the patient will use.

Enter your login details and press “Login”. If you’ve forgotten your password, you can reset it. If you haven’t received your login details, please contact your administrator or Acurable representative.



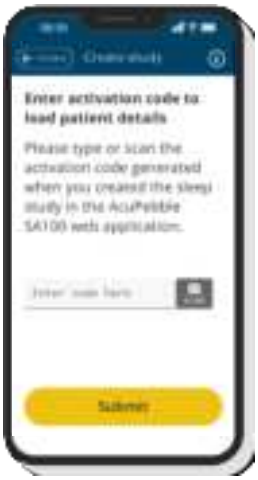
Select the option to create a new sleep study.

Press “Start”, and the app will check the battery levels of the sensor and mobile phone and connectivity between the devices. If any action is required, the next screen will explain what you need to do.

When the test is complete, press “Continue” to carry on.

Check that the sensor has a new, unpeeled adhesive. If it does, press “Yes”. If it doesn’t, press “No” and the app will provide video instructions explaining how to replace the adhesive.

If you created the study in the web app (appendix C) and have an activation code, select “Load details with code”. Otherwise, choose “Enter details manually” to enter the study details directly in the app.



If you selected "Load details with code":
Step 1 - Type in the activation code, or press "scan" and scan the QR code. Then press "Submit". If the code is recognised, you can continue. If not, check the code and try again.

Step 2 - Enter the patient's date of birth and press "Submit". The app will check that the date of birth matches that entered when creating the study. If it does, you can continue. If not, you can check and try again.

If you selected "Enter details manually":
Step 1 - Enter the patient ID and date of birth, and press "Submit".
On the following screen, you will need to re-enter these details.

Step 2 - Answer the questions in the app to complete the patient profile for the study.

Review the information and check that all the details are correct. You can go back and edit them if you need to.

The study has now been created, and the sensor and mobile phone can be provided to the patient to conduct the study (Appendix F).

Appendix E: Activate a sleep study

If the study is to be conducted in *patient mode*, the patient will first need to install the AcuPebble SA100 app on their own mobile device from the App Store or Google Play (see section 6.2.1). When they open the app, they will be asked to activate their sleep study, using the code that was generated by the web app (Appendix C) and supplied to them with the sensor.

When the patient has installed the mobile app on their own phone, they will need to type or scan the activation code supplied with the sensor in order to start the study, then press “Submit”.

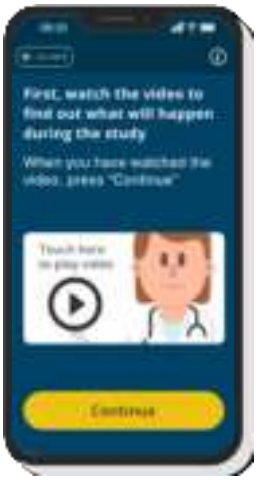
Next, they should enter the date of birth of the person undertaking the study, and press “Submit”.

The mobile app will check the code and the date of birth entered, and if they match a new study in the system, the patient can press “Continue” to begin the sleep study. If there is a problem, they will be advised on how to get help.

Appendix F: Conduct a sleep study

In both *patient* and *hospital mode*, once a sleep study has been created (Appendix D) or activated (Appendix E), the patient should follow the instructions in the mobile app to conduct the study.

When they are ready, the patient should press “Start”. The app will then check the battery charge levels of the sensor and mobile phone, and the connectivity between devices. If any action is required, the next screen will explain to the patient what they need to do.



Once the app has confirmed the battery levels and sensor connection are adequate, the patient will be asked to watch a video, which explains how the study will work and what will happen.

The app explains how to check that the sensor has a new, unpeeled adhesive. If the patient presses “Yes”, the app continues to the next screen. If they press “No”, a video explains how to replace the adhesive, which the patient must do before continuing.

The patient will be asked to confirm they are about to go to sleep. If they press “Yes”, they can continue. If they press “No”, they will be asked to wait and return to the app when they are about to go to bed.

The patient should now put on the sensor, following the video instructions provided in the app. They can watch the video as many times as they need to.

The app will next give the patient the option to set an alarm for the following morning. If they press “Yes”, the app will take them through how to do this step by step. If they say “No”, it will continue to the start of the study.

If the patient chose to set an alarm:
The app will display a series of screens allowing them to enter and confirm the time at which the alarm should go off.

When they are ready, the patient can press "Start recording" and place the mobile phone next to the bed as instructed, then go to sleep as normal.

When the patient wakes up in the morning, they should stop the recording. If they set an alarm but wake up before it goes off, they can stop the recording earlier and the alarm will then be cancelled.

When they have stopped the recording, the patient must confirm if the sensor was still attached to their neck when they woke up. If they press "Yes", they can continue to the next screen. If they press "No", they may need to repeat the test the following night. The app will provide instructions if this is the case.

If the patient experienced any issues while conducting the study, or would like to make any comments, they can do so on this screen and then press "Send". If they have no feedback, they should press "Skip" to continue.

If the study is being conducted in *patient mode*:
They will now need to upload the study by following the instructions in the app (see Appendix G).

If the study is being conducted in *hospital mode*:
The sleep study is now complete, and the patient should return the sensor and mobile phone, so that the study can be uploaded for analysis (see Appendix G).

Appendix G: Upload a sleep study

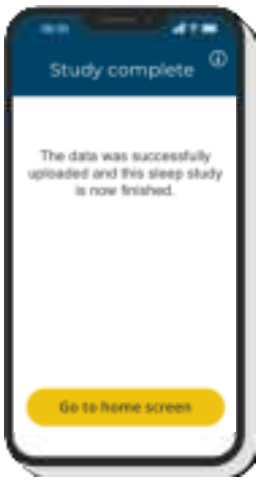
When the study has been conducted, it needs to be uploaded for analysis. This can be done by a healthcare professional or other authorised representative if the study was conducted in *hospital mode*, or the patient can do it themselves if the study was conducted in *patient mode*.

If the study was conducted in *hospital mode*:

When the patient returns the phone after conducting the study, enter your login details and press “Login” to start.

Enter the patient ID and date of birth for the study to be uploaded and press “Submit”. If these details match the study conducted, you can continue. If not, the app will ask you to verify the details before uploading the data.

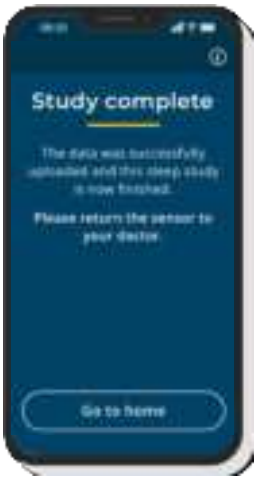
When you press “Continue”, the data will first be compressed and then uploaded, and the app will display the progress on the screen. This requires an internet connection, so if the device is not connected the app will explain what to do.



When the study has been uploaded, you can return to the home screen to create a new study. The requesting clinician will receive an email when the patient test result is available to view in the web application (see Appendix H).

If the study was conducted in *patient mode*:

After completing the study, the patient can press “Continue” to start uploading the data. The data will be compressed and uploaded, and the app will display the progress on the screen. The upload requires an internet connection. If the mobile phone is not connected, the app will explain what the patient needs to do.



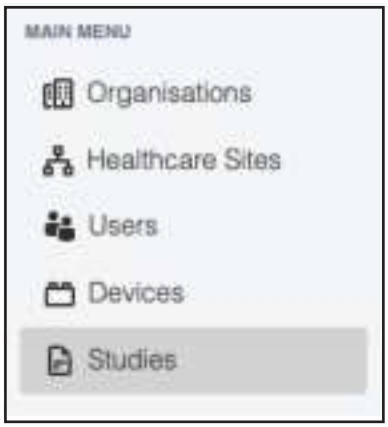
When the upload is finished, the sleep study is complete. The patient should now return the sensor.
If the patient needs to conduct another study, they can press “Go to home” to start again with a new activation code.

Appendix H: Accessing diagnostic data

1. Go to the web application at https://cloud.acurable.com.

2. Enter your login details in the web application and press “Login”. If you’ve forgotten your password, you can reset it.

3. Select “Studies” in the main menu.



4. You can search for patient results using any of the following criteria:

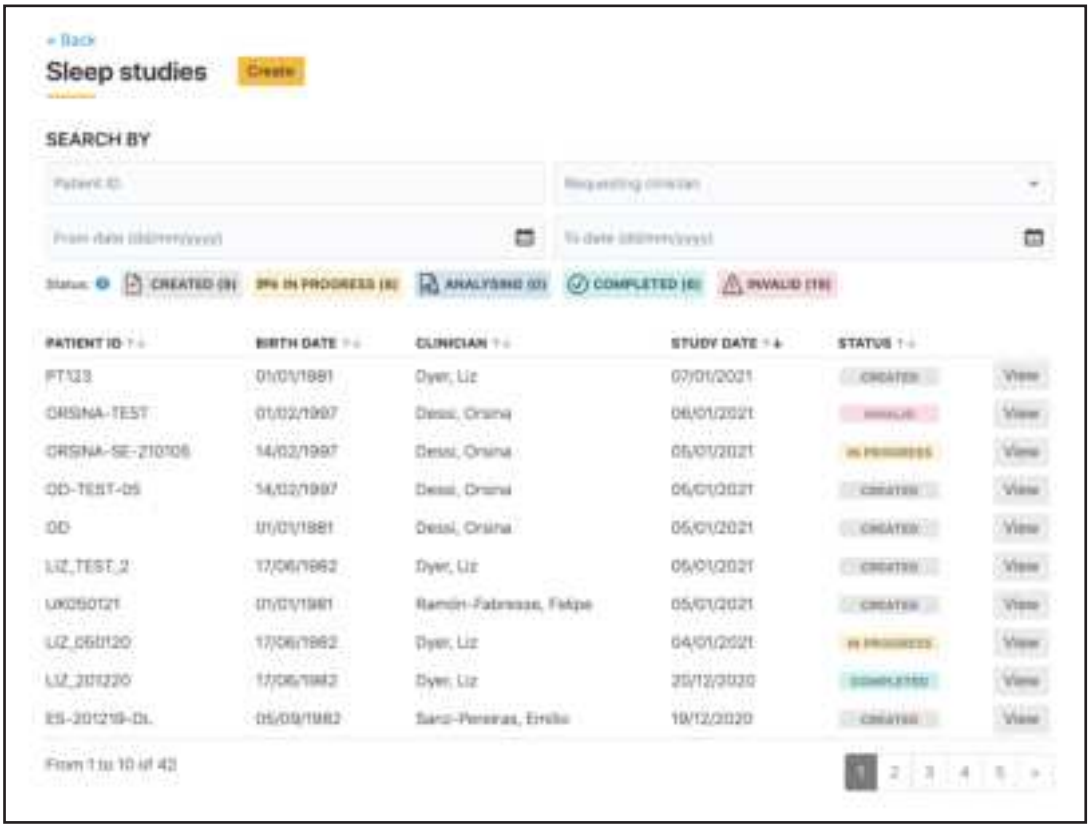
Patient ID

Requesting clinician

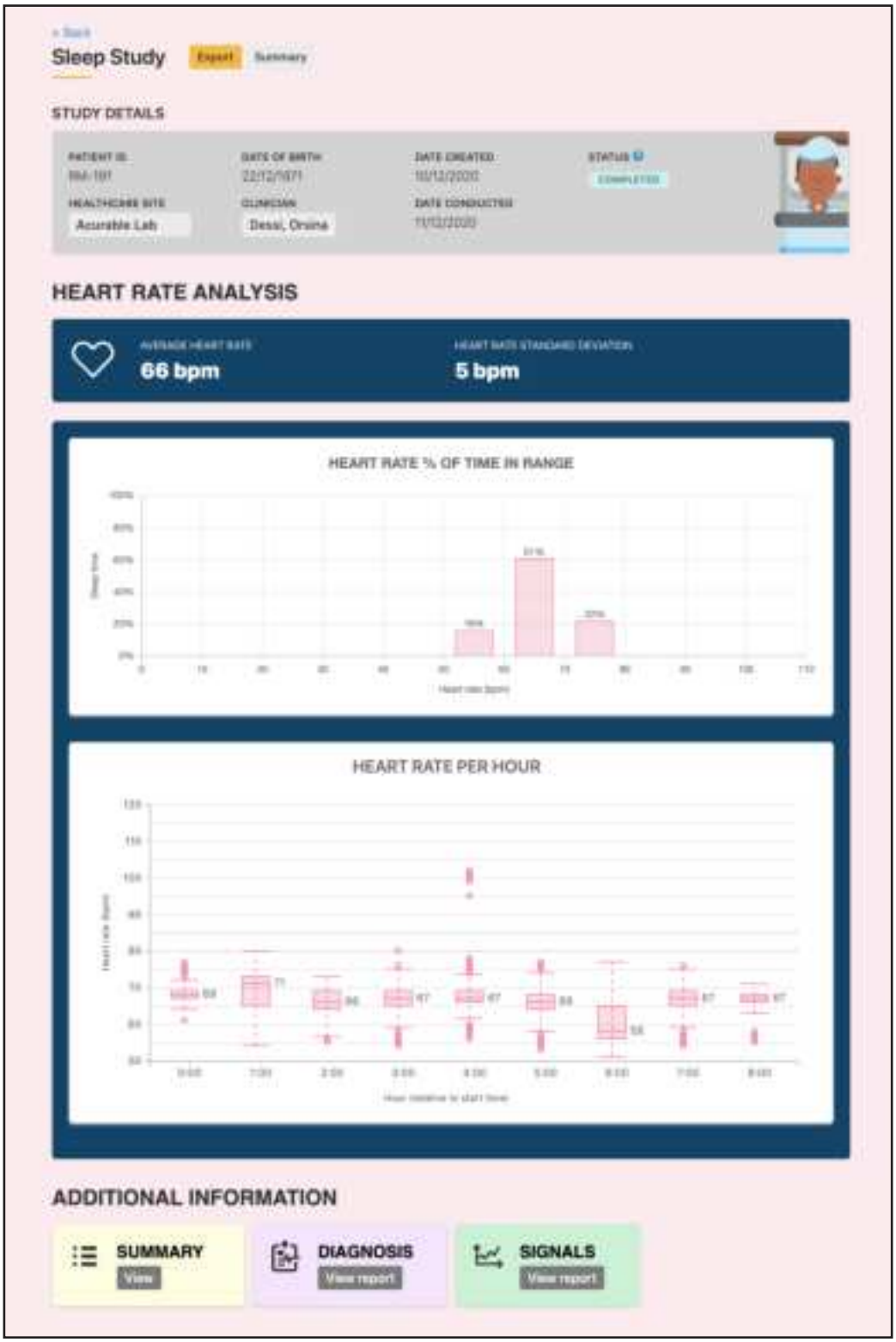
Study date

Status

Click “View” to select the study you need.



5. Once a study has been selected, a summary screen will appear presenting the results (refer to Section 20 for information on clinical validation of the results). You can click “Export” to download a summary of the results as a PDF. Additional reports are also available, which provide further detail about the patient’s sleep study. Access to some of these options will depend on the contractual agreement with Acurable. Examples of screens are shown below.



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