acurable

AcuPebble™ SA100/Ox100

User Manual

(Instructions for Use and Technical Information)

1. About AcuPebble SA100/Ox100

1.1 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 professionals in the patient's evaluation.

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.

AcuPebble Ox100 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA).The device is primarily intended for home setting use (although it can also be used in healthcare settings) under the direction of a Healthcare Professional (HCP).

Figure 1: AcuPebble sensor (left and middle) and finger sensor (right - Ox100 only)

Figure 2: Image illustrating positioning of AcuPebble sensor

1.2 Description of the Device

The AcuPebble SA100 system consists of a single miniature electronic wireless multi-use wearable device, to be worn during sleep on the neck. The AcuPebble Ox100 system is composed of two devices, one to be worn during sleep on the neck, and another one on the finger. The neck sensor attaches to the body with a single use double coated medical tape. The finger sensor can be slid on. Both sensors are used to extract information during sleep about a variety of physiological processes/channels which are relevant for the diagnosis of obstructive sleep apnoea (OSA). In both cases, the sensors transmit signals to a mobile base station (i.e. mobile phone or tablet), although in the case of the neck worn sensor, transmission occurs continuously, whereas in the finger sensor transmission only occurs after the user takes it off at the end of the study. Transmission in both cases 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. They both operate with small Li-polymer batteries. 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). The devices can be recharged using a standard micro-USB connector. The signals transmitted to the mobile phone can be uploaded to the Cloud, once the user stops the signal acquisition within the app, and there they are fully processed by algorithms that, amongst others, automatically determine diagnostic indexes. The outputs from both sensing devices are displayed in a Web app platform that can be accessed by physicians to aid the diagnosis.

The ring sensor is used to measure peripheral oxygen saturation (SpO2). The principle of operation is as follows: two light emitting diodes with different wavelength shine light through the finger. Two photodiodes detect the transmitted light and convert it into an electrical signal. Characteristics of the received infrared and red electrical signals are computed with electronic circuits. Using those measured characteristics, a scientifically well established algorithm based on what is known as the Beer Lambert law is used to calculate the SpO2 value.

Illustrative images of the wearable sensors are shown in Figures 1 and 2.

2. How to use AcuPebble SA100/Ox100

The AcuPebble SA100/Ox100 system 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.

2.1 Using the AcuPebble mobile application

2.1.1 Set up the 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 SA". 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 SA" 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.

2.1.2 Conduct a sleep study

You 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 your own mobile phone or tablet, you need to activate the sleep study using a code before being able to conduct it.
- If the sleep study is conducted using a mobile phone or tablet already setup, you can undertake the sleep study directly.

2.1.3 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, or a mobile device with an internet connection, the patient will upload the data.
- Otherwise, the healthcare professionals will upload the data after the patient returns the AcuPebble SA100/Ox100 system.

2.2 How to use the AcuPebble neck sensor

2.2.1 How to put on the neck sensor

The AcuPebble neck 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.

2.2.2 How to change the adhesive

The AcuPebble neck sensor'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 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.

2.2.3 Sensor location

The AcuPebble neck 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 sensors will be provided in the form of an animated video.

2.3 How to use the finger sensor

2.3.1 How to put on the finger sensor

The finger sensor should be worn as follows:

- Slide the sensor on to the index finger until it fits comfortably and does not feel loose.
- The sensor will turn on automatically and begin to work after a few seconds.

If the finger sensor is worn for less than 2 minutes, the recording will not be saved.

2.3.2 Removing the finger sensor

At the end of the sleep study:

- Remove the finger sensor when instructed by the mobile application.
- A countdown will begin on the sensor's display. When the countdown reaches zero, the data is ready to be uploaded.

3. Charging the Batteries

The batteries in the AcuPebble sensors are expected to last over 12 hours when used for sensing after having been fully charged. We advise that you charge the batteries for at least an hour before carrying out an overnight test. The batteries can be charged by connecting a micro-USB charger to the micro-USB connector (DC port. See Figure 3 below). 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 micro-USB charger.

Whilst the AcuPebble neck sensor 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 finger sensor will display a charging icon while charging is in progress. When charging is complete, the device will switch off.

The battery level of the finger sensor can be checked during use by touching the button on the front of the sensor. The app will also warn you if either battery is not sufficiently charged to carry out an overnight test.

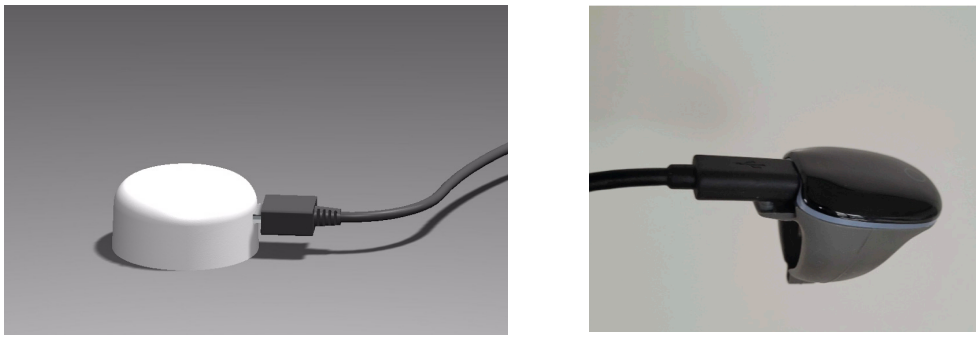
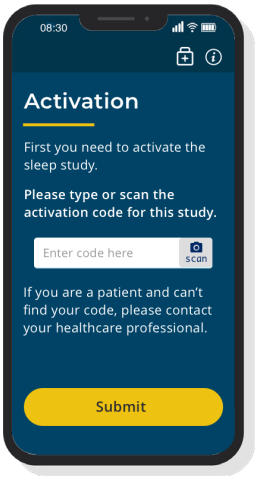
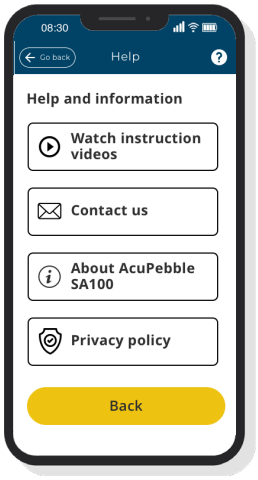


Figure 3 : Sensors connected to micro-USB charger

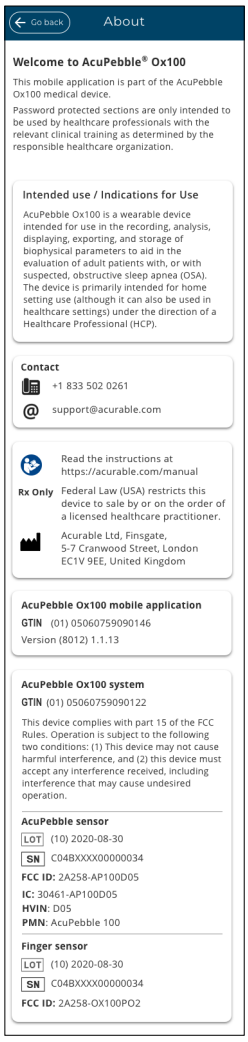
4. Regulatory Information

Regulatory information about AcuPebble SA100 can be accessed within the mobile application, by tapping the information icon in the top right hand corner of the screen and then selecting "About AcuPebble SA100" or "About AcuPebble Ox100".





The information is displayed as shown below:



5. 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 (neck sensor): 2A258-AP100C04
FCC ID (finger sensor): 2ADXK-8326

AcuPebble SA100/Ox100 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/Ox100 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.

6. ISED Compliance

Innovation, Science and Economic Development Canada (ISED) regulatory information

This device complies with Innovation, Science and Economic Development Canada's licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Avis de conformité à la réglementation d'Innovation, Sciences et Développement économique Canada (ISDE)

Le présent appareil est conforme aux CNR d'Innovation, Science et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produiredе brouillage; (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

IC ID: 30461-AP100D05

7. 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 **+1 833 502 0261**

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, United Kingdom

7. Safety Warnings

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

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 either 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.

The neck sensor is not intended to be used continuously on the skin for more than 30 days.

Do not shower while wearing the system.

The micro-USB DC power port is solely intended for connection to a micro-USB charging device.

Prolonged continuous use of the finger sensor may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.

The finger sensor is only intended to be worn during sleep and ideally for a maximum of 8 hours. If wearing for longer inspect the application site for skin integrity every 8 hours.

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 either of the sensors whilst charging the battery.

Do not use during an MRI examination.

Do not use with a defibrillator.

Do not place the finger sensor in pressure vessels or a gas sterilization device.

Do not squeeze the sensor part of the finger sensor or apply excessive force to it.

Do not wear nail polish while wearing the finger sensor.

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

- The performance of this system 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 system 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, and should not be submerged in water or other liquids.
- 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 system.
- Once the seal is opened the system is non-returnable.
- The system contains Lithium batteries. These 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 system 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 system is not intended to be used as a cardiac monitor.
- This system 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].
- A functional tester may not be used to assess the accuracy of the SpO2 sensor or a device.
- The finger sensor is not intended to be used under motion conditions or low perfusion conditions.
- The finger sensor is only intended to be used as part of the AcuPebble Ox100 system for sleep apnea diagnosis.
- The AHI and ODI parameters have been calculated only using acoustic signal. SpO2 was not used in the estimation algorithm.

[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".

WEARABLE MEDICAL DEVICES