# ADI CARDIOPULMONARY MANAGEMENT (CPM) SYSTEM

## Clinician Instructions for Use – Device and Mobile Application

DOC #: CFU0001

READ ENTIRE INSTRUCTIONS FOR USE BEFORE OPERATING THE ADI CPM SYSTEM


Revision C – March 2021

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**DISCLAIMER**: Information, operation, specifications, and product appearance may change without notice.

**SYMBOLS GLOSSARY:** The symbols glossary is located at the end of this Instructions for Use guide

## Contents

# GLOSSARY & ACRONYMS

| | |
|---|---|
| ΔZ | Delta Impedance / Change in Impedance from Position 1 to Position 2 |
| ADI | Analog Devices, Inc. |
| Alignment Tool | The mechanical subsystem of the CPM System that interfaces with the Wearable device to aid in the proper placement of the wearable. |
| Base Station | The mechanical subsystem of the CPM System that stores, protects, and charges the wearable device when not in use, as well as acts as a pass-through for data from the wearable device to the cloud platform. |
| BLE | Bluetooth Low Energy |
| BP | Blood Pressure |
| HF | Heart Failure |
| Clinical Care Team (CCT) | Referring to any group of medical professionals who have clinical responsibility for the care of patients using the CPM System, including but not limited to physicians, nurses/nurse call centers, physician assistants, and medical assistants |
| CPM | Cardiopulmonary Management |
| CPM System | Cardiopulmonary Management System; including electrical hardware, firmware, software, mechanical, cloud, and backend components. |
| ECG | Electrocardiogram |
| Electronics Housing | The plastic enclosure of the electronics in the CPM Device |
| EMC | Electromagnetic Capability |
| EU | European Union |
| FCC | Federal Communications Commission |
| FDA | Food and Drug Administration |
| HCP | Healthcare Provider |
| HF | Heart Failure |
| HR | Heart Rate |
| ICD | Internal Cardioverter Defibrillator |
| IEC | International Electrotechnical Commission |
| IP | Ingress Protection |
| ISO | International Standards Organization |
| LED | Light Emitting Diode |
| MR | Magnetic Resonance |
| MRI | Magnetic Resonance Imaging |
| Packaging | Any parts that are not necessary in the function of the CPM System which provide labeling, protection, and storage of the CPM Wearable device and Mechanical Subsystems before and during delivery to the end-user. |
| PCB | Printed Circuit Board |
| PHI | Protected Health Information |
| PII | Personally Identifiable Information |
| Position 1/Position 2 | The body position of the user wearing the device during one half of the measurement. Users move through 2 positions, usually sitting upright and then lying supine, throughout the course of one measurement. |
| RR | Respiration Rate |
| rTV | Relative Tidal Volume |
| TI | Thoracic Impedance |
| TV | Tidal Volume |
| Wearable Device | The piece of the CPM System that attaches to the user's body and contains the electronics modules which measure biological signals of interest. |

## WARNING AND PRECAUTION SYMBOLS

**WARNING**

This graphic will appear if there is a **WARNING**. Warnings indicate hazardous situations that could result in serious injury if not avoided.

**CAUTION**

This graphic will appear if there is a **PRECAUTION**. Precautions indicate situations that may result in minor injury to the user or damage to the device if not avoided.

**IMPORTANT**

This graphic will appear if there is a **MANDATORY ACTION**. Special attention is drawn to these actions, as if they are not completed the device may not function as intended.

# PART 1. GENERAL SYSTEM INFORMATION

## 1. INTRODUCTION

The ADI Cardiopulmonary Management (CPM) System is a non-invasive wearable device that acquires physiological data and derives parameters associated with the presence and progression of cardiopulmonary conditions. The CPM System collects, derives, and transmits measurements to a Clinical Care Team daily and with high accuracy, enabling healthcare providers to more closely monitor patient status and aid in clinical decision making. The CPM System is not intended to be used as a diagnostic tool. The device is designed for use in outpatient clinics and home settings and is attached to the body with gentle reusable adhesives for several minutes each day, after which it is placed on a wireless-enabled Base Station to store and charge the device as well as to transmit data to the secure cloud platform.

The device has the capabilities to measure heart and lung auscultation sounds, thoracic impedance, single lead ECG, skin temperature and body position. From this, additional parameters are derived and trended.

## 2. INDICATIONS AND CONTRAINDICATIONS FOR USE

The ADI At-Home CPM (Cardiopulmonary Management) System is intended for adults undergoing monitoring for cardiopulmonary conditions under the direction of a licensed medical professional to measure, record, and periodically transmit physiological data.

The ADI At-Home CPM System monitors, derives, and displays:

- ECG (Computer generated analysis of potential patient cardiac abnormalities which must be confirmed by a physician with other relevant clinical information)
- Heart and Lung Auscultation Sounds
- Skin Temperature
- Thoracic Impedance (including Changes in Thoracic Impedance)
- Respiration Rate and relative changes in Tidal Volume
- Heart Rate
- Diastolic Heart Sounds
- Body Position (including Tilt Angle)

The ADI At-Home CPM System is indicated for patients:

- Taking diuretic medication
- Living with heart failure
- Recovering from a coronary artery disease-related event
- Living with Chronic Obstructive Pulmonary Disorder (COPD)

The ADI At-Home CPM System is contraindicated for:

- Those patients requiring attended, in-hospital monitoring for life threatening arrhythmias

# 3. WARNINGS AND PRECAUTIONS

## 3.1 General

**WARNING**

- **The CPM System is NOT intended to be used as a diagnostic tool. Rather, CPM System outputs are intended to provide insight into how patients are trending. The Clinical Care Team should confirm any CPM System information with other relevant clinical information and analyses.**
- This device is **NOT** intended to be used as an apnea monitor. Do not rely on the respiration monitoring function of the device for detection of the cessation of breathing.
- Do **NOT** use if the patient has allergies or skin sensitivities to silicone-based adhesive.
- Do **NOT** use if the patient has skin breakdown and/or open wounds in the area that the device is placed as determined by the care team.
- The CPM System is **NOT** compatible for use with MRI machines.
- Keep out of the reach of children, those who may be mentally compromised or unstable, and pets. Use with caution if the patient has a history of ingesting small objects. Smaller parts of the system such as the adhesive disposable and liners may be choking hazards and harmful if swallowed.
- Avoid getting any of the CPM System components wet, including the Device, Base Station and charger. The device is **NOT** meant to withstand water ingress. Do **NOT** shower or bathe with the device.
- Use **ONLY** the charging cords, adaptors, and accessories provided with the system in the original packaging. Any other adaptors or cords may damage the device, cause the device to malfunction, and have electrical hazards or affect EMC performance.

**CAUTION**

- The device is **NOT** meant to be worn between readings. It should be removed immediately following each measurement and returned to the base station.
- The CPM System is for prescription use only. Federal law restricts this device to sale by or on the order of licensed practitioners.


- Each device is configured for a specific patient. Do NOT exchange devices or otherwise use a device on an individual not assigned to the specific device.


- Clinicians should always refer to and use EMR data as the primary source of patient information. If there is a mismatch between CPM System data and the EMR, the EMR data should be used.
- Use caution when using the device on patients with sensitive skin in the left chest/sternal area where the device is placed.
- Remove the device if any pain or discomfort occurs. A topical skin cream may be applied (in consultation with a healthcare provider) if discomfort, redness, itching, or rash persists after the device is removed. Patients should consult their healthcare provider and stop using the device for future measurements if these symptoms occur.
- Do **NOT** change, modify, or disassemble any parts of the ADI CPM System – the system contains no user-serviceable components. Any changes, modifications, updates, or servicing of the system will ONLY be performed by the manufacturer. Do not use if the CPM System has been modified in any way.
- If the system shows signs of damage, discontinue using it and contact CPM System Support.
- The CPM System has not been validated in a pediatric population.
- This device may not fit or function as intended on patients who meet the medical definition of obese or morbidly obese.

### 3.2 Implant Information

**WARNING**

- Do **NOT** place the electrodes of the CPM Device directly on top of implanted devices such as pacemakers, defibrillators, or loop monitors.
- Do **NOT** wear the device while externally communicating with implanted devices or external defibrillators.
- Use with caution if the patient or you have an implant such as a pacemaker or an ICD. Maintain a distance of at least 8 inches or 20 centimeters away from the CPM Base Station when plugged in. Failure to do so could result in an unintended shock to you or the patient.
- If a mobile device and CPM Device are both in close proximity (within 6in) to the chest of a patient with an implantable and the Mobile App is actively communicating over BLE with the CPM device, there may be a low likelihood that the combination of both RF sources in such close proximity may interfere with the implantable.

### 3.3 Blood Thinner and Steroid Precautions

**CAUTION**

If the patient is currently taking a blood thinner or steroid, they may be at greater risk for bruising. If bruising is seen after use, clinicians should be consulted immediately. Use special care in observing skin changes such as bruising or bleeding when prescribing this device to patients on blood thinners or steroids.

# 4. DETAILED DESCRIPTION OF THE SYSTEM

The ADI CPM System consists of the following components:

- The **measurement hardware** that is used by the patient to collect data daily, including
  - the **CPM Device** wearable;
  - the cloud-connected **CPM Base Station** used to charge and store the device;
  - **Disposable Adhesives** which attach the device to the body**;**
  - and an **Alignment Tool** used to repeatably locate the device on the body.
- A **mobile app** used by the Clinical Care Team to guide initial device setup and collect patient calibration information.
- **Cloud Software** for the Clinical Care Team that is used to view measurement data and trends.

## 4.1 System Components

### *CPM Device*

The CPM Device (also known as the “wearable” or “patch”) contains several sensors: five electrodes, a round acoustic sensor (electronic stethoscope), an accelerometer to measure tilt, and a temperature sensor. The device works with the supplied adhesives to stick to the body and acquire measurements. The device has an adjustable length to accommodate differences in chest circumference and breast size, configured by clinicians during an initial baseline and fitting visit.

The CPM Device is intended to be used for a less than 5-minute period in the morning and/or at night (up to two measurements per day) while the patient is stationary and is not intended to be worn between uses.

The CPM Device is **NOT** disposable and is intended to be used for up to one-year.

This device is battery powered and is plugged in to charge via a magnetic charging cable. A multicolored LED bar and large button on the electronics housing communicate the status of the system and initiate measurements with the device, respectively.

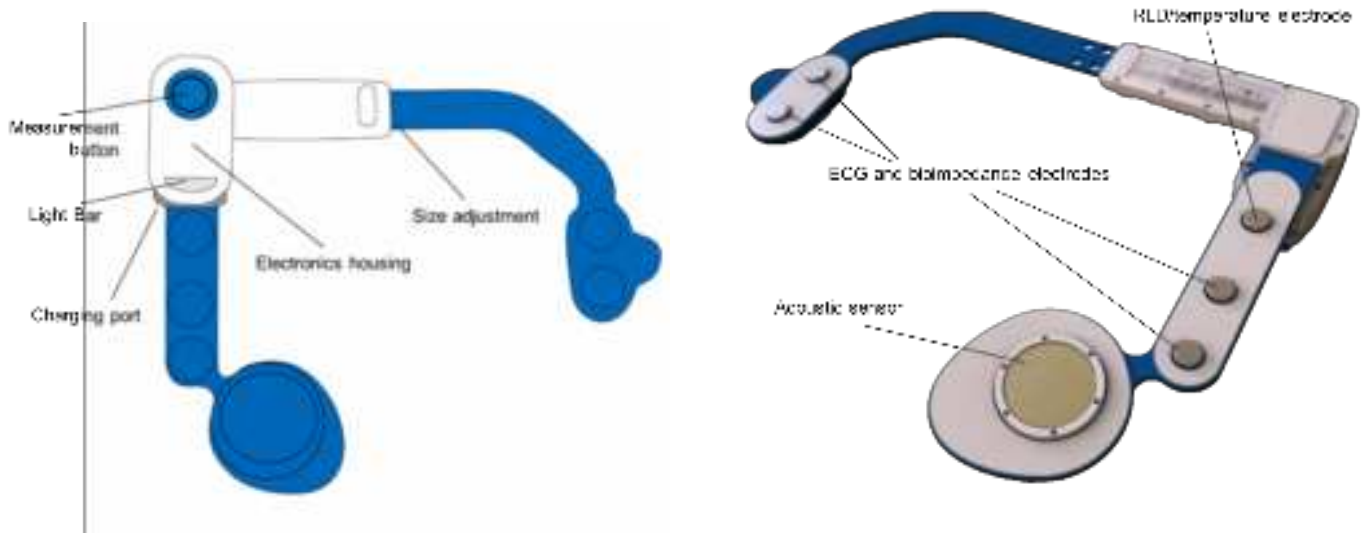



*Figure 1 a-b. Renderings of the CPM Device a) front side (left) and b) back/sensor side (right)*

### *Adhesive Disposables*

The adhesive disposables attach to the CPM Device with gentle hook and loop material like that found on an infant diaper. The skin-side adhesive is a low-tack medical silicone. Hydrogel material is embedded in the adhesive stack, and these hydrogel areas overlay the metal electrodes on the device to create a robust electrode-skin contact. Finally, there is a double-sided silicone adhesive that aligns with the acoustic sensor.

The adhesive stack consists of two tear-apart adhesive islands, one for each side of the device, which align with the shape of the CPM Device. The adhesive stack includes a liner material that protects the skin-side adhesive and hydrogel when not in use.

The adhesives are disposable items for single person use only and can be disposed of in the trash after use. They are meant to be used in conjunction with the CPM Device for up to a week at a time. Adhesive refills will be provided to patients throughout their prescriptions as needed.

*Figure 2 a-b. a) Adhesive packs. b) Rendering of the CPM Adhesive Disposable.*

### *Alignment Tool*

The CPM System features an alignment tool accessory intended to repeatably fit the device onto the patient's body. The alignment tool positions the device relative to the clavicular notch and ensures consistent device placement.

The placement guide comes in two pieces (the "Alignment Strap" and the "Housing Attachment Mechanism") and its length is configurable by the clinical team during the initial set-up visit of the CPM System. The tool snaps onto the electronics housing of the CPM Device and is held using the index finger at the clavicular notch to help keep the device in place reliably. The guide is removed after the device is positioned.

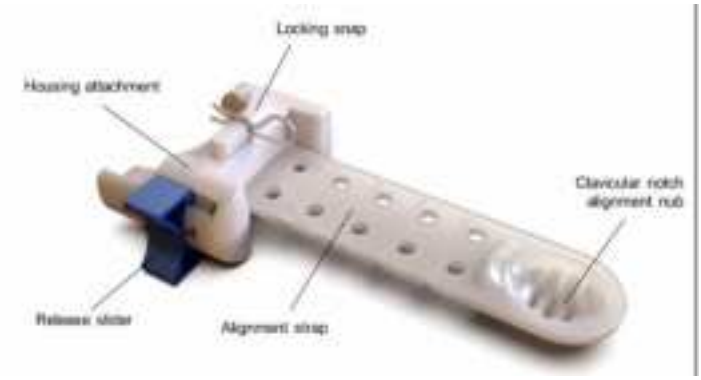



*Figure 3. The CPM Alignment Tool.*

### *Base Station*

A Base Station is supplied with the CPM System. The Base Station provides a place to store the device and extra adhesive disposables, charges the device, updates the device's firmware, and uploads collected data to a secure cloud platform. The data transfer first occurs between the CPM Device and CPM Base Station via USB and then subsequently from the CPM Base Station to the cloud platform via cellular network where the CPM Analytics Engine will process the raw measurement data. All data are anonymized, and no identifiable information is communicated by or stored on either the CPM Device or CPM Base Station. Personal Identifiable Information (PII) and Protected Health Information (PHI) are stored in an isolated partition in the Cloud, only accessible to authorized organizations as per business associate agreements.

The Base Station includes a charging cord with a wall adapter and connects to the CPM Device via a magnetic attachment head. The Base Station is also equipped with LEDs to indicate power supply, docking, and network connectivity status. A mirror on the base station assists in placement of the device, and the device-shaped wells aid in replacing and changing the adhesives.


*Figure 4 a-b. The CPM Base Station in its a) open configuration with CPM Device stored inside and b) closed configuration.*

### *Mobile Application*

The clinical care team uses the CPM Mobile Application to set up the CPM Device for patients. The app enables the clinical care team to view physiological parameter information in real-time to ensure the device is operating properly, verify the placement of the device on the patient, perform the baseline measurement, and input clinician's observations such as blood pressure or weight.

The clinical care team can use either default settings or customize single-parameter threshold settings for trend analysis performed by the CPM Analytics Engine. These analyses are displayed on the CPM Web Services interface.


*Figure 5. Log-in screen of the CPM Mobile Application.*

### *Cloud Software*

The Clinical Care Team can view patient reports, compliance, notifications, trends, and derived measurement data via the CPM Cloud Software, accessed via URL link or through your organization's EMR (depending on system implementation). The Software does not modify the data or control functions of the CPM measurement hardware. Further information regarding the Cloud Software and Web Application can be found in the separate Web Application User Guide.


*Figure 6. Log-in page of the CPM Web Application.*

**WARNING**

The information presented to the clinical care team as part of the CPM Web App is **NOT** intended to be used to take immediate action but rather to inform clinical decisions for the monitored patient.

## 4.2 How the System Works

*Figure 7. System Architecture Diagram of the CPM System.*

After a patient is enrolled into the CPM System, a clinician will fit the device in the clinic for the patient by securing the CPM Device at the appropriate length, and then will take a baseline measurement using the CPM Mobile Application. The alignment tool will also be fitted appropriately if needed.

At home, after the device is placed correctly and a measurement is initiated, the device acquires raw measurement data for under 5 minutes. Once the device is charging in the Base Station, data are automatically transmitted from the CPM Device to the Base Station, and then forwarded to the CPM Cloud Services platform via wireless network. These data are then processed to generate derived measurements from the raw measurement data, and data will then be visible on the Web Application. This system is designed for use in outpatient clinic and home environments.

## 4.3 Measurement Parameters

The CPM Analytics Engine derives the measurements listed below from raw measurement data acquired from the CPM Device's sensors and electrodes. The derived measurements, along with trending information about these measurements, are then displayed on the CPM Web Application for viewing by the clinical care team. The clinical relevance of selected parameters is described in the following section.

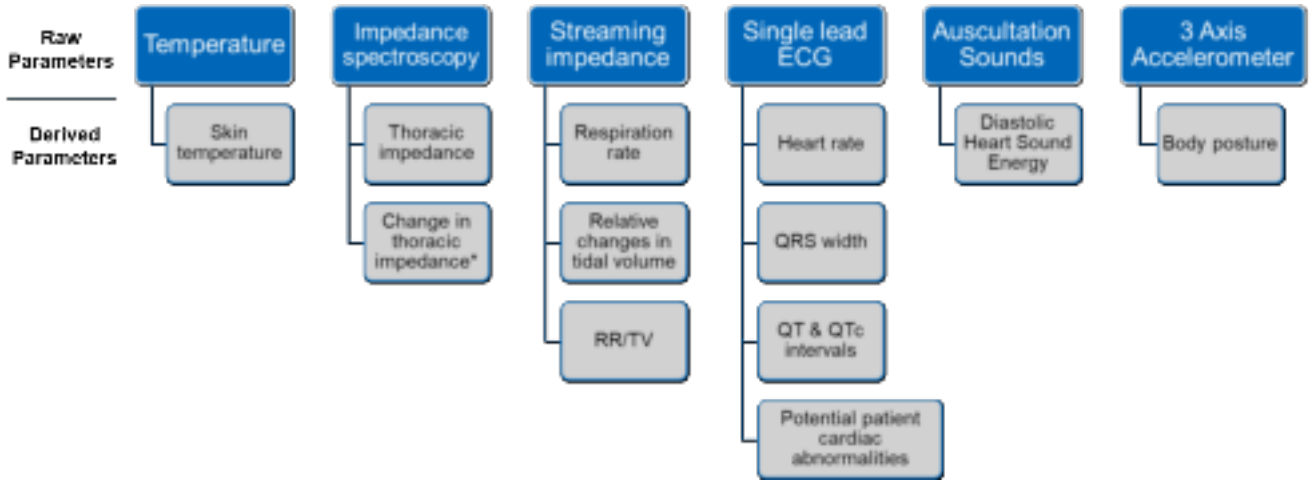



*Figure 8. Raw and derived measurements from the CPM Analytics Engine.*

***Thoracic Impedance (TI)***

Thoracic Impedance, measured in ohms (Ω), has been demonstrated[1] to be a surrogate measurement for the fluid content in the thoracic cavity and lungs, with lower values indicating a greater hydration or fluid level and higher values meaning a patient is dryer. It is important to note that the differences in TI between different individuals can be caused by a variety of factors (i.e. body type, fat content, placement of CPM Device electrodes, etc.) **The day-to-day change of TI values in an individual rather than the values themselves should be used as the clinically relevant parameter.**

**CAUTION**

The CPM System is not intended to directly measure thoracic fluid content.

***Change in thoracic impedance (ΔZ)***

ΔZ, measured in ohms (Ω), is a calculation of the difference in average thoracic impedance from one measurement position to the other. Literature has shown that this measurement can provide insight into short-term fluid settling behavior in the thoracic cavity[2]. Healthy patients should have ΔZ values close to 0.

***Relative changes in tidal volume (rTV)***

rTV acts as an analogue for the standard clinical tidal volume measurement. Increasing values can mean an increase in lung tidal volume, while decreasing values can mean a decrease in lung tidal volume. **Please note that rTV values are not displayed in liters (L) or other standard units – it is meant to be used to track day-to-day changes in lung capacity rather than tidal volume value itself. Values should never be compared between subjects.**

[1] Weyer, S., et al., Bioelectrical impedance spectroscopy as a fluid management system in heart failure. Physiol Meas, 2014. 35(6): p. 917-30.
[2] S. Dovancescu et al., "Sensitivity of a wearable bioimpedance monitor to changes in the thoracic fluid content of heart failure patients," Computing in Cardiology 2013, Zaragoza, 2013, pp. 927-930.

**WARNING**

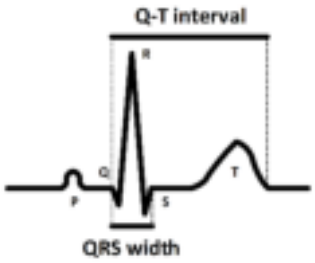
This device is **NOT** intended to be used as an apnea monitor. Do not rely on the respiration monitoring function of the device for detection of the cessation of breathing.

***Respiration Rate/Tidal Volume (RR/TV)***

This is a metric that computes the ratio of respiration rate and relative tidal volume. An upward trend can indicate an increase in respiration rate and/or a decrease in tidal volume, suggesting a rapid shallow breathing pattern.

***QRS Width***

QRS width, measured in milliseconds (ms), represents ventricular depolarization. It is calculated as the difference between QRS onset and offset, which is determined based on a metric representing the QRS-like morphology in the single-lead ECG waveform. The reported value is the mean value from the lowest-angle posture.




***QT Interval and QTc***

The QT interval is the time from the beginning of the QRS complex to the end of the T wave resulting from ventricular repolarization. QTc is the corrected QT interval, accounting for the effects of heart rate. It is calculated using the equation $QTc=QT/\sqrt{RR}$. QT interval and QTc are both measured in milliseconds (ms) and are calculated from the ECG waveform.

***Potential cardiac abnormalities***

The CPM System is intended to detect and flag ECG tracings demonstrating an irregularly irregular rhythm such as that seen in an atrial fibrillation.

Other types of arrhythmias not exhibiting this characteristic are **NOT** intended to be detected and will not be flagged by the CPM System. An example of an abnormal rhythm flag can be found below.

**NOT DETECTED** – Normal Sinus Rhythm

**DETECTED** – "Abnormal Rhythm"

**NOT DETECTED** – Pre-Ventricular Contraction (PVC)

**WARNING**

This is NOT a final diagnosis of Atrial Fibrillation or any other cardiac abnormality. A clinician should always confirm the CPM System's analysis with other relevant clinical information, including a clinical 12-lead ECG if deemed necessary.

***Diastolic Heart Sound Energy***

Diastolic heart sounds represent the energy of heart sounds during diastole as measured by the CPM System's acoustic sensor. In healthy subjects, this value should be stable across days, while increasing values can indicate an increase in diastolic sounds. **These values are not displayed in standard units and may vary among individuals and depending on sensor placement. Values should be used to track day-to-day changes and should never be compared between subjects.**

***Skin Temperature***

Provided in °F and °C by the CPM System, this measurement offers a way to detect changes across multiple days in skin temperature. When other trended CPM system parameters show a certain behavior, skin temperature trends can provide additional information to determine whether such changes are associated with a change in temperature. For example, if a patient's heart rate is showing an increasing trend, the clinical team can determine whether th is trend is associated with a change in skin temperature and take the steps they deem necessary to validate these observations.

**CAUTION**

Skin temperature provided by the CPM Device is not intended to be used to assess core temperature and should be confirmed through other means before diagnosing a patient with a fever.

## 4.4 Parameter Thresholds

The CPM System allows clinicians to manage "thresholds" related to many of the parameters captured by the CPM Device. These thresholds can be manipulated either by using the mobile app or the web software and allow a way for clinicians working with the web software to easily visualize whether physiological parameters are out of range from what would be considered normal or expected – in other words, alerts for any values that are outside of threshold values ("breached" thresholds) will be flagged and displayed.

There are two types of thresholds – "absolute" and "relative". Absolute thresholds refer to parameters where individual values are well understood and could be compared from patient to patient. Minimum and maximum thresholds can be set. Heart rate, respiration rate, QTc interval, and QRS width are the CPM System's absolute thresholds. Relative thresholds refer to parameters that are meant to look for changes only within a single patient and do not translate to a population. These thresholds are set not according to absolute number but relative to the Baseline measurement (a percentage increase or decrease from Baseline). Thoracic impedance, relative changes in tidal volume, and diastolic heart sound energy are relative thresholds for the CPM System.

**CAUTION**

Thresholds should only be set and/or changed by licensed medical professionals to suit the clinical needs of their patients. Threshold changes apply only to individual patients.

### 4.5 Device Use and Duration

The ADI CPM System is intended for long term (up to one year) once-or-twice daily monitoring. The device is not meant to be worn between measurements and should be removed and returned to the Base Station directly following data collection. Measurements should be initiated in the morning as soon as the patient wakes up, and/or in the evening just before the patient goes to sleep. The care team will instruct the patient how often and for how long to use the CPM System depending on the device prescription. Each measurement takes less than 5 minutes, with half of the measurement in Position 1 (usually an upright seated position) and half of the measurement in Position 2 (usually a reclined Supine position). Measurements are initiated by the patient with the large button on the CPM device electronics housing.

**IMPORTANT**

The CPM System can be used for up to one year after the date of prescription.

The two measurement positions are determined by the clinical care team during the baseline reading; these must be repeated for all measurements to ensure accurate data collection.

**IMPORTANT**

As prescribed by the care team, patients should take measurements

- First thing in the morning; **AND**/**OR**
- Right before bed

### 4.6 Device Placement and Location

The CPM Device is placed on the upper left chest area. The device spans the left lung, with the larger side of the device (the side with the electronics housing, the “medial island”) on the sternum and the smaller (“lateral”) island near the left mid-axillary line. The CPM alignment tool can be used to aid in this placement of the device.

**IMPORTANT**

**Accurate** and **consistent** placement is key to acquiring good signals from the device. Patients should try to place the device consistently to within 2 cm of baseline placement.

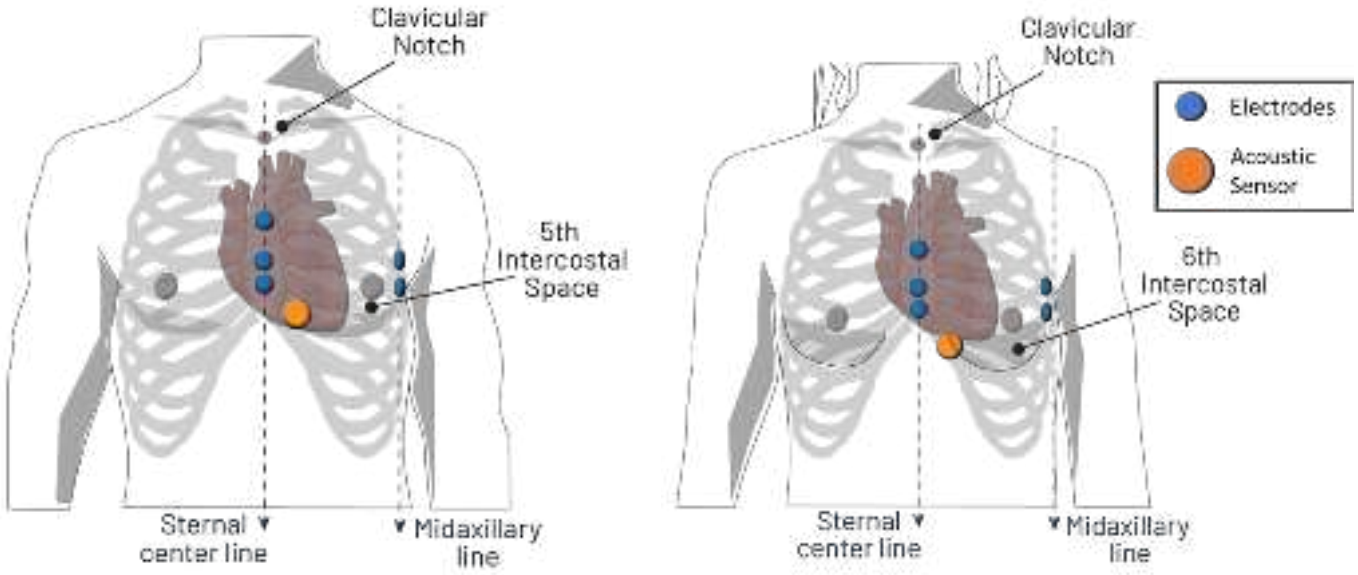



*Figure 9 a-b. Sensor locations of the CPM Device on a) men and b) women.*

### *Guidance for Correct Clinician Placement*

Acoustic sensor (**place first**):

- Locate the 5th (for men) or 6th (for women) intercostal space or the area directly below where the breast tissue attaches to the chest wall.
- You can auscultate this position with a stethoscope for clear heart sounds if desired. If you cannot hear heart sounds here, try moving the sensor slightly higher or to the left (towards the apex of the heart).
- For women, the breast can fall on top of the sensor. Lift the left breast to place the sensor.

Electrodes:

- Span the left lung
- Two “pairs” of electrodes near the 3rd and 4th intercostal spaces

Larger (medial) island:

- Vertical on the sternum or left sternal border

Smaller (lateral) island:

- Vertical under the armpit near the mid-axillary line
- Center connecting bridge horizontal and not tensioned

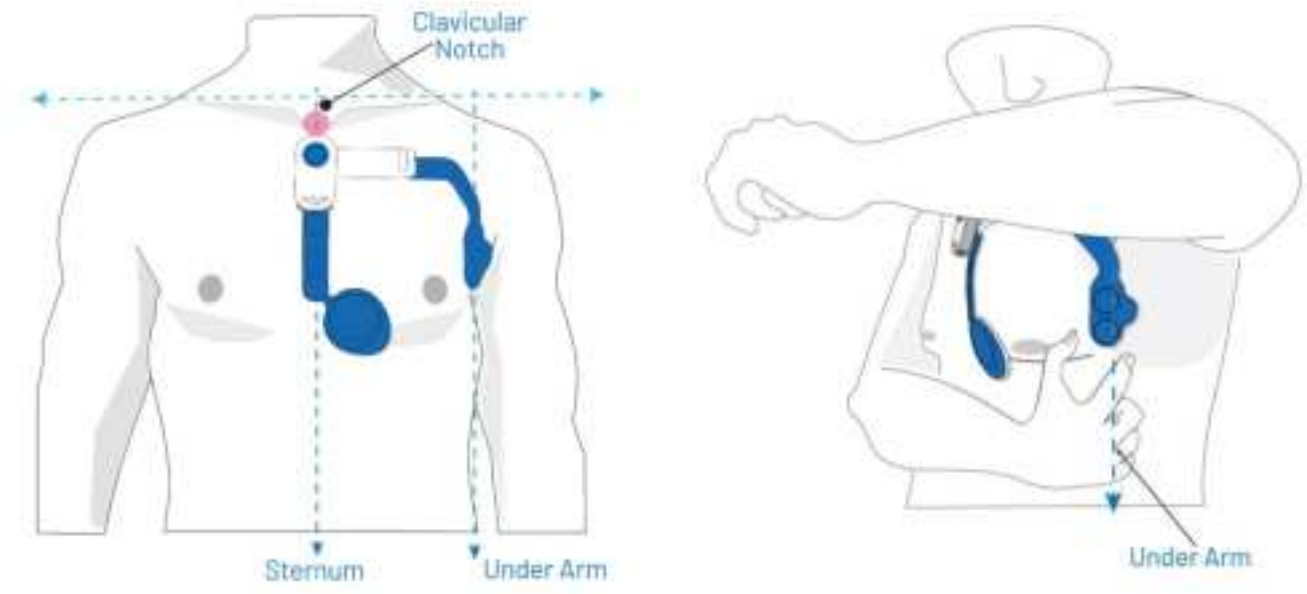



*Figure 10. Correct CPM Device placement on men.*

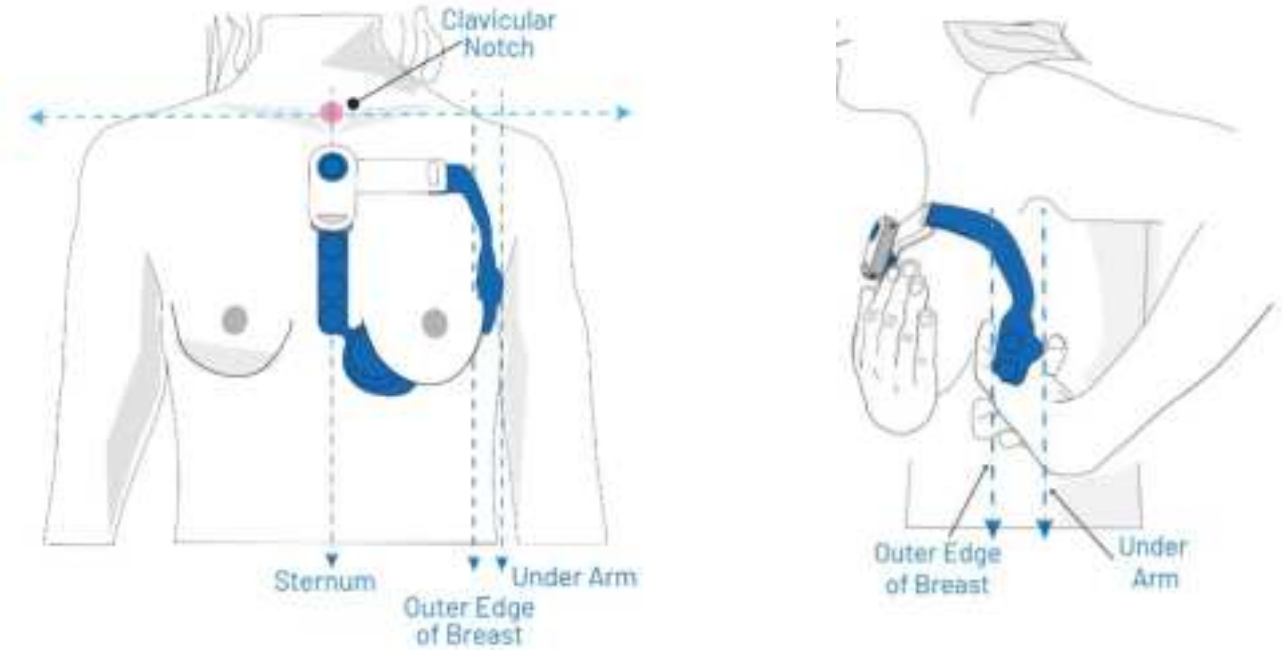
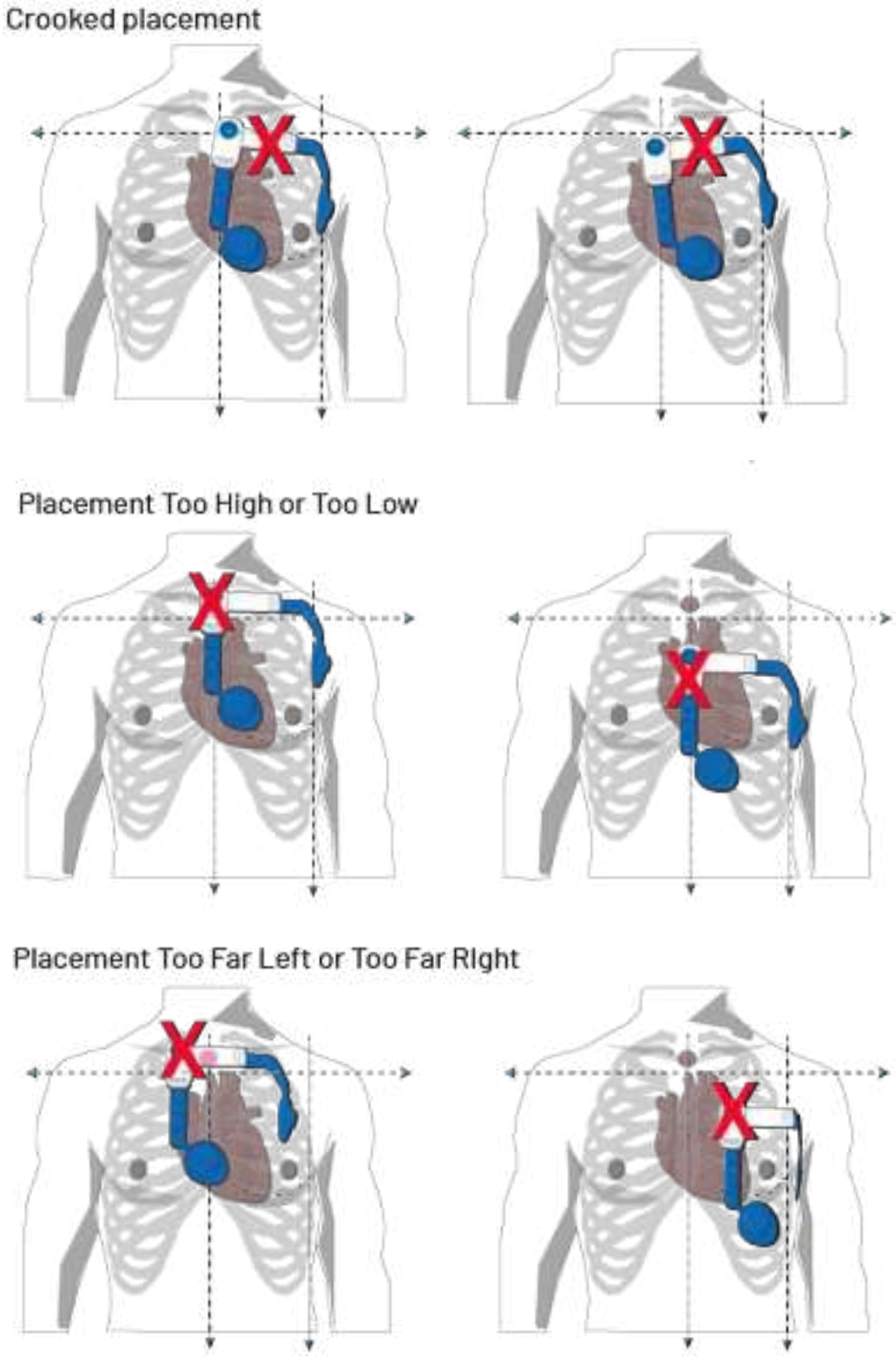
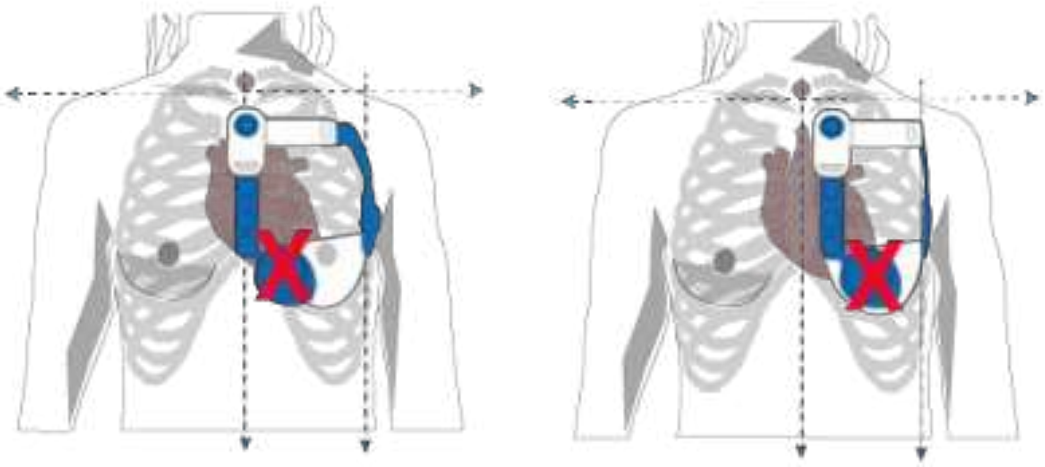



*Figure 11. Correct CPM Device placement on women.*

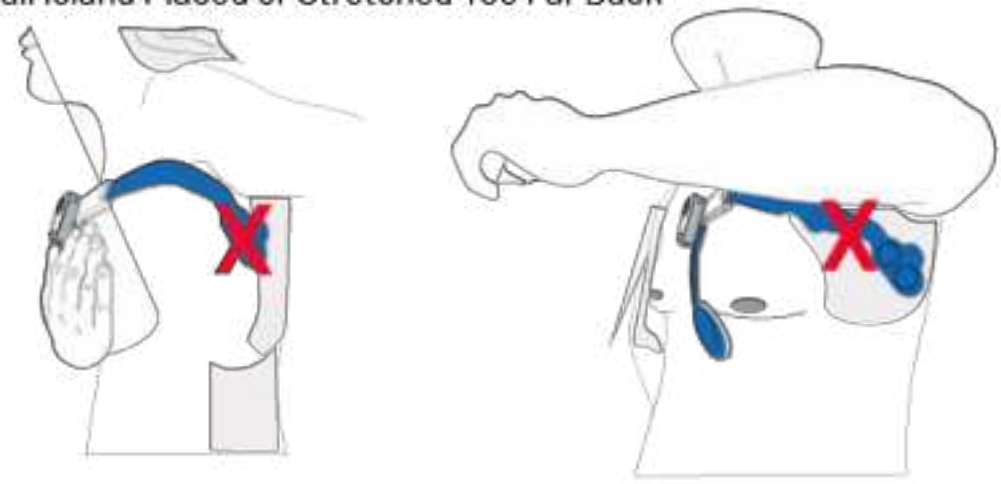
***Incorrect CPM Device Placements***



Female Placement On Top of Breast Tissue



Small Island Placed or Stretched Too Far Back



**IMPORTANT**

Ensure:

- The lateral island does not sit on top of breast tissue.
- There is a full adhesive seal around the acoustic sensor. If the sensor peels up, you may have to re-place the device in a slightly different position to accommodate body curvature.
- There is no gapping under the sensors of the device. Any gapping is likely to lead to poor electrode contact. Press firmly on and around all electrodes before initiating a measurement.

# PART 2. IN-CLINIC INSTRUCTIONS FOR USE

## 5. GETTING STARTED

The ADI CPM System packaging contains:

1. CPM Device (packaged in the Base Station)
2. CPM Base Station
3. CPM Device alignment tool strap
4. CPM Device alignment tool housing attachment mechanism
5. Charging cable and wall adaptor
6. Locking snaps for CPM device (2)
7. Base Station adjustment plates (5)
8. Box of 15 adhesive disposables
9. Patient User Manual

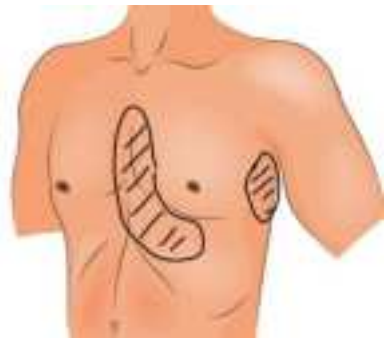

*Figure 12. CPM System main packaging with included components labeled.*

## 6. BASELINE MEASUREMENT PREPARATION AND DEVICE SETUP

### 6.1 Before meeting your patient for the baseline reading

1) Ensure that you have login credentials for the mobile app.
2) Ensure that the mobile app is installed on the phone and that the phone is sufficiently charged. The CPM mobile application is compatible with Android operating systems.
3) Charge the CPM Device using the Base Station.

## 6.2 Preparing the skin



**IMPORTANT**

This step ensures good adhesion to the skin and improves data quality.

*Figure 13. Areas to be trimmed under the CPM Device.*

- Trim chest hair where the CPM Device adhesive patches contact the body (about a 6” long x 2” wide area at the sternum, under the left nipple, and a 4” long x 2” wide area on the left side of the chest).
- Trimming may not be needed in all cases. If baseline data collection proves to be an issue, it may be necessary to remove the CPM Device, trim, and retry placing the device.
- Patients may have to periodically trim hair at home depending on their length of device use.
- In certain cases, patients may be instructed by clinicians to wet the skin in the area under the device electrodes with a damp cloth before placing the CPM Device, especially in cases of extremely dry skin. **Clinicians should give these instructions to the patient only if they are having severe difficulties with electrode contact errors during the Baseline measurement that cannot be resolved by pressing down on the electrodes, replacing the device, or trimming hair.**

**IMPORTANT**

**NO** creams or lotions should be applied to the skin and skin should be dry of water immediately prior to the application of the device except for special circumstances. **Patients should follow any special directives given by the Clinical Care Team for these circumstances.**

## 6.3 Fitting and sizing the CPM Device

1) Extend the CPM Device to the desired length by holding the device up to the patient’s body and gently pulling the flexible material out of the rigid housing in the middle of the device. You can use a tape measure if desired. The device should extend to the anterior- or mid-axillary line on the left side of the patient’s chest.

2) Before locking this position **permanently** in place, hold the device to the patient’s chest to ensure that the measured size is appropriate (i.e. not too long or short, as illustrated below).

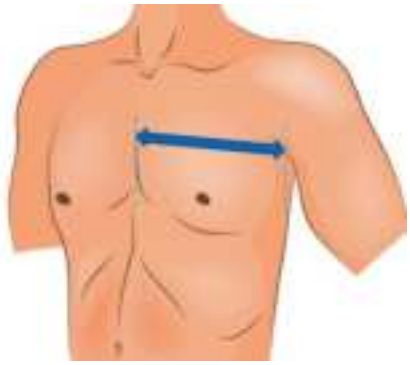


*Figure 14. Distance to be measured for CPM Device sizing.*

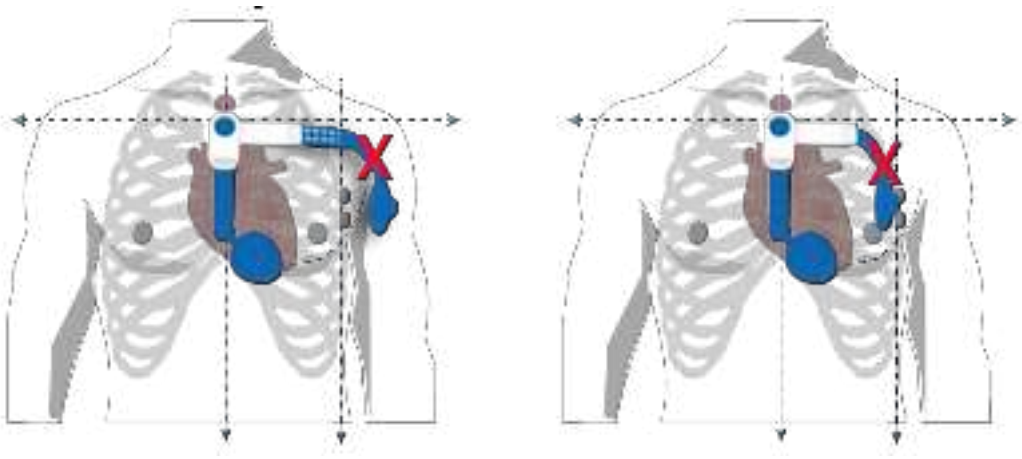


*Figure 15 a-b. CPM Device incorrect sizing that is a) too large and b) too small.*

3) Insert the two snaps into the top and bottom of the device as shown.

4) Match the adjusted device size with the appropriate Base Station adjustment plate. One adjustment plate is included for each possible device length.

5) Drop the adjustment plate into the Base Station's right side well. The sized wearable should now sit snugly inside the Base Station.

*Figure 16. Inserting the top snap into the CPM Device.*

*Figure 17. Inserting the correct adjustment plate into the Base Station*

## 6.4 Pairing the CPM Device to the Mobile App

1) Make sure you are connected to a network and Bluetooth is enabled on the phone with the CPM Mobile Application downloaded. Log into the app.

2) Patients ready for a baseline reading should already be enrolled and searchable in the mobile application. Search for the patient using the filters available on the landing page of the app. You can search for patients by last name, first name, date of birth, or patient display ID.

3) Once a patient is selected, enter the required information and provider details and “Confirm Patient” on the bottom right of the screen.

4) Put the CPM Device into Bluetooth Advertising Mode by pressing and holding the large blue button until the LED begins to flash blue (~10s).

5) Tap “Connect to a device nearby”.

6) A popup window will list devices in range. Select “Assign Device to Patient” and select the appropriate device from the list using the Device ID printed on the back of the CPM Device.

7) The message “Device assigned and connected!” should display on the screen.

**IMPORTANT**

Ensure that the battery charge is greater than 20% before proceeding.

## 7. IN-CLINIC SETUP AND BASELINE

**IMPORTANT**

**Correct placement of the CPM Device is at your (the clinician’s) discretion.** You must achieve ideal placement and data quality for the Baseline reading, as it will act as a baseline for the cloud analytics as well as training for patients.

**IMPORTANT**

**A Baseline is required for measurements to appear on the web application.**

**Before** the measurement…

- The patient should remove their shirt and/or bra.
- Apply an adhesive disposable to the CPM Device. See Replacing the Adhesives on the device on page 37 for instructions on how to place adhesive disposables on the CPM Device.
- Remove the clear liners from the skin side of the device and **place them back into the Base Station**.

**IMPORTANT**

Always place liners back into the Base Station during measurements.

## 7.1 Taking a Baseline Reading using the CPM Mobile App

1) Apply the device to the patient as described on page 17: Device Placement and Location. Press down around all sensors to ensure good contact with the skin.

2) Select “Take Reading” and then “Start Reading” in the app.

**3)** The “pre-screen data check” will now begin. Ensure that the patient is in your desired First Position. Look at the data to confirm that ECG and impedance are readable. With headphones, you may also listen to the auscultation sounds for quality. **Use noise cancelling headphones for good heart sound quality.**

**IMPORTANT**

**Scroll down** to view all the pre-screening data.

4) When ready, select “Perform Reading” on the bottom right of the screen. This step determines the tilt that the patient must achieve in Position One for each subsequent measurement. The patient should have back support (to avoid core muscle engagement being captured with the device) provided either by a chair, pillows, or a hand on the small of the back.

5) The device will perform “sweeps” for approximately 10 seconds. During this time, if there is an electrode contact error, the app will indicate that the CPM Device must be adjusted. The device will then continue to perform a reading for approximately one minute, and audio and visual data will stream through headphones and on the app screen.

**IMPORTANT**

**DO NOT hit “skip and continue” on contact error dialog boxes until you feel you have exhausted all other troubleshooting techniques for bad contact. Bad contact flagged by the CPM System is likely to cause poor data quality and inaccurate web application outputs.**

***Data Quality: what to look for***

**ECG:**

- No clipping, clean
- Minimal drift in the baseline of the ECG (fairly flat)
- Clear QRS complex and T- wave waveform showing characteristics of lead 1 ECG tracing

**Auscultation Sounds:**

- Heart sounds clearly heard using noise-cancelling headphones with a consistent volume
- Periodic waveform aligning with heartbeat in ECG
- No sporadic spikes or flat periods in the waveform

**Thoracic Impedance:**

- Values between 10 and 250 (Ohms)
- Value is not steadily increasing (drifting) over time (indicating the device may be peeling off)
- Clear oscillation caused by breathing

*Figure 18 a-d. a) Good data b) Clipping, bad electrode connection, noisy acoustic signal c) No sensor connection d) Steadily increasing thoracic impedance indicating sensors are peeling off.*

6) When Position 1 is complete, review the data and proceed using the “Looks Good Continue” button.

7) Move the patient into your desired Second Position.

**IMPORTANT**

The default for Position Two is at least 50 degrees less than Position One. You can override this default by selecting “Skip and Continue” when the tilt error pop-up box appears.

8) Select the “Continue Reading” button and repeat the steps above for the second position. When you are reviewing your reading, ensure that “Reading is a Baseline” is checked at the top of the screen.

**Note: If you would like to save a reading taken with the mobile application as a non-baseline, normal reading, uncheck the “Reading is a Baseline” button before saving.**

**IMPORTANT**

**Do not plug the device in to the Base Station until you complete the ENTIRE Baseline workflow**. Otherwise the CPM Device will disconnect from the application and you will not be able to enter thresholds and/or patient details from the app.

9) Review and Confirm the thresholds. **These thresholds should match the clinical needs of the patient and will only apply to this specific patient.** They will also appear and be editable on the Web Application. Default thresholds should already be set by your organization’s policy. Then select “Confirm Settings and Continue”.

**CAUTION**

Thresholds changed in the mobile app will only apply to this specific patient and should ONLY be selected by a licensed medical professional.

10) Review and Confirm your Patient's details and medical information. These will appear on the Web Application if/when completed. When finished, select "Confirm and Save".

11) The baseline reading is now complete. Return the CPM Device to the Base Station to upload the Baseline reading to the cloud.

## 7.2 Removing the CPM Device from the body

**Gently and slowly** peel the CPM Device from your patient's chest using the tabs on the device. Avoid touching the sticky parts of the adhesive, replacing the device back on top of the clear liners in the Base Station immediately. Ensure that the hydrogel and acoustic discs remain intact and on the device during removal.

For those with loose skin, it may help to hold down the skin near the device as you are peeling off the CPM device adhesive to lower the chances of bruising or skin tears.

**CAUTION**

Carefully examine your patient's chest for adverse effect (e.g. bruising, skin irritation) after removing the CPM Device. Be especially observant of skin changes during the use of the device if your patient is on blood thinners and/or steroids.

## 7.3 Charging the CPM Device

1) While in the Base Station, connect the magnetic charging adapter to the device, snapping it into the bottom of the CPM Device electronics housing. Make sure that the Base Station is plugged into a wall outlet.

2) Ensure that the device is charging by verifying that the Base Station's top and bottom LEDs as well as the CPM Device's light bar are illuminated.

**3)** Close the lid of the Base Station when the CPM Device is not in use to prevent dust build-up. **Before shifting the Base Station, ensure that the magnetic clasp on the front of the Base Station is securely fastened.**

**IMPORTANT**

Always connect the CPM Device in the Base Station to charge when not in use.

*Figure 19 a-c. a) Plugging in the Base Station b) The CPM Device charging with LEDs illuminated c) Base Station clasp..*

## 8. THE ALIGNMENT TOOL

It is recommended that the alignment tool be given to the patient to help consistently locate the CPM Device at home until they are comfortable using the device**. The alignment tool should be assembled and fit to the patient during the baseline visit, before the CPM Device is removed.** This can either occur before or after the baseline reading.

### 8.1 Assembly and fitting

1) Once the device is placed on the patient and skin contact is strong under all device sensors, remove the two pieces of the alignment tool (strap and snap-on mechanism) from the packaging.

2) Snap the plastic piece onto the CPM Device electronics housing, aligning the two nubs with the indents on the device. Make sure that the blue quick release slider is in the “up” position and the silver pin is in place.

3) Once the housing attachment mechanism is in place, push the quick release slider down to lock the component securely in place on the CPM Device.

4) Gently press the protruding bulb of the flexible strap into the patient's clavicular notch, fitting it comfortably into the bottom of the notch.

**CAUTION**

Bruising can occur when the alignment tool is applied with excessive pressure at the base of the clavicular notch. Take special precaution for those patients who are on blood thinners or steroids.

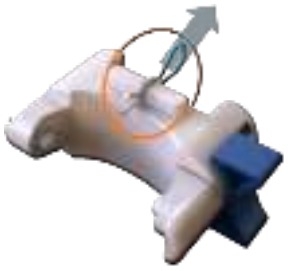
5) Visualize, count, or mark where the strap meets the top of the snap-on mechanism.

6) Using scissors, cut the alignment strap at the notch **below** the point you just identified. Discard the piece below the cut. You may want to cut a longer than necessary length at first and then trim.

7) Slide the alignment strap into the slot at the top of the snap-on mechanism.

8) Once satisfied with the fit of the strap, move the blue slider up to release the snap-on mechanism from the electronics housing.

9) Remove the silver pin from the locking snap and press the locking snap down firmly with the alignment strap inserted into the slot to permanently secure the alignment guide inside the housing attachment mechanism.



10) The alignment tool should fit as shown below.

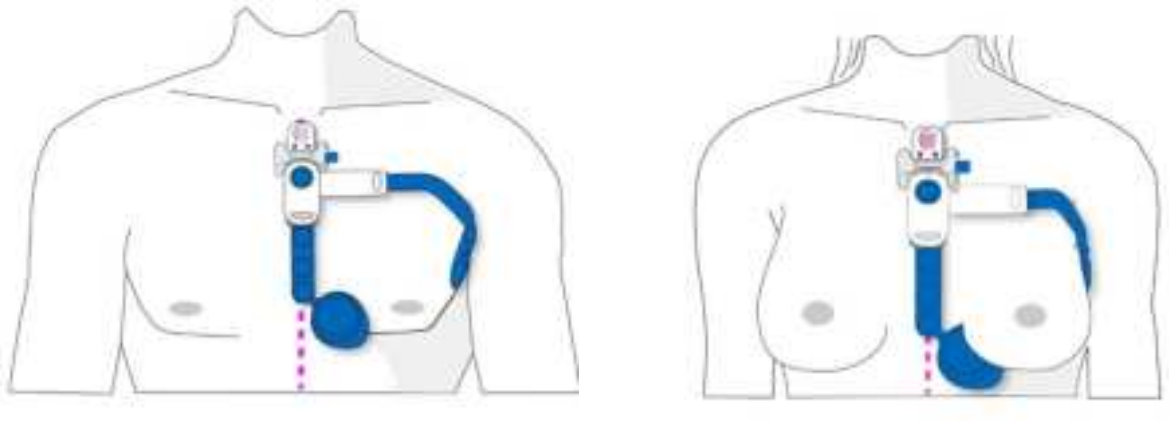


*Figure 20 a-b. Fit of the alignment tool with the CPM Device on a) men and b) women.*

## 8.2 Using the tool

1) Snap the alignment tool onto the CPM Device electronics housing, aligning the two nubs on the alignment tool with the divots on the sides of the electronics housing. Slide the blue quick-release slider down to secure the alignment tool onto the device.

2) Expose the skin side adhesive by removing the clear liners and placing them back into the Base Station. Holding the device with the alignment tool attached, place the knob of the alignment tool **gently** into the clavicular notch.

3) Stick the CPM Device onto the skin in the location described on page 17, first placing the larger middle island. Women may have to lift their breast to properly place the device.

4) Remove the alignment tool before starting the measurement with the app or the button by sliding up the blue slider to release the arms of the tool from the electronics housing.

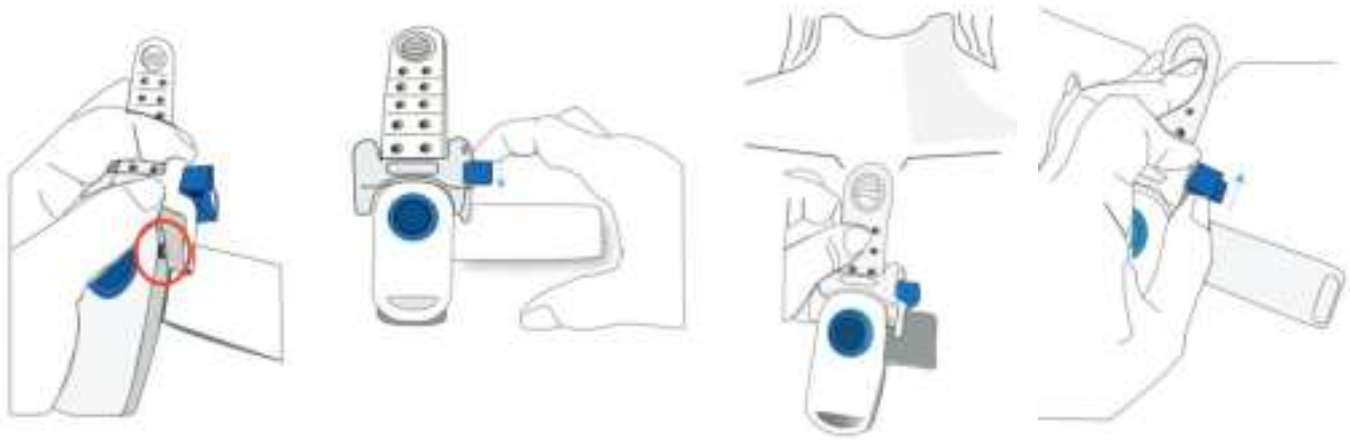


*Figure 21 a-d. Using the alignment tool to place the CPM Device.*

# PART 3. AT-HOME CPM SYSTEM USE

This section of the Clinician Instructions for use is intended to help you train your patient on how to use their CPM System at home.

## 9. HOME SETUP

**IMPORTANT**

The CPM Device and Base Station should be located near your patient's place of sleep, on a **sturdy table,** with the Base Station plugged in and the lid closed when not in use. Placing the Base Station near a window is ideal for achieving consistent and strong cellular signal.

**CAUTION**

Ensure that the Base Station is in a stable position and is not at risk of falling.

1) Place the CPM Base Station on a **sturdy table** near where the patient sleeps.
2) Attach the power adapter to the CPM Base Station (the adaptor is on the bottom right of the Base Station).
3) Plug in the Base Station's power adapter to an electrical outlet nearby.
4) Open the Base Station, ensuring that the CPM Device is seated inside with the magnetic charger connected. The Base Station power LED as well as the device charge LED should be illuminated.
5) Five (5) adhesives at a time can be stored (in their packaging) until ready to use in the Base Station compartment behind the mirror. **Note that the initial CPM patient kit includes five (5) adhesives in the Base Station adhesive storage compartment, while adhesive refill packaging contains fifteen (15) adhesives at a time. Always keep adhesives that do not fit inside the Base Station in a safe and dry location.**

*Figure 22 a-c. a-b) Plugging the Base Station into the wall and c) Magnetic charging and LED indications in the Base Station.*

*Figure 23. Adhesive storage compartment in the Base Station.*

## 10. PATIENT MODE MEASUREMENTS

**IMPORTANT**

For best results, take measurements at the same time each day (recommended at morning wake-up).

### 10.1 Measurement preparation

1) Ensure that the room is quiet (**e.g. no talking, no loud machines in the background such as air conditioners, fans, radios, TVs, etc**.).
2) The patient should **remove their shirt and/or bra** to expose the chest. *For men*: trim chest hair if needed.
3) Remove the CPM Device from the Base Station, checking that the device charge LEDs on the device and Base Station are green or yellow. Replace the adhesives if needed (instructions on page 37).
4) Peel off the two clear liners to expose the skin adhesive and then place them back into the Base Station, aligning their shapes to the appropriate wells.
5) Place the device as designated by the clinician (guidelines given on page 17), pressing down around all the sensors. Use the alignment tool (use is described on page 33) and/or Base Station mirror to help, if needed.

**IMPORTANT**

For best results, apply the device as consistently as possible during each use, in the location used to take the baseline reading.

### 10.2 Patient mode workflow

**IMPORTANT**

Stay stationary and do not speak for the duration of the measurement.


**1)** Once the device is securely adhered to the body, move into the first position (Position One) specified by the clinical care team during the baseline measurement. Press the large blue button on the CPM Device until a small beep is heard, **about 2 seconds.**

2) The device will start by checking to see if the patient is in the right position and for electrode contact quality for a maximum of 1 minute. The measurement will then proceed for 1 minute. The LED bar will blink purple and a tone will sound every 5 seconds throughout this time.

- *If there are measurement errors with positioning or contact, the LED will blink yellow (tilt) or orange (contact) and chimes will sound. See the section on lights and sounds for how to resolve these errors.*

3) There will be an audible alert and the LED bar will flash pink when the first position is complete.

4) Move to the second position (Position Two) specified during the clinic visit. When in position, press the button for about 2 seconds, the same as in the first position. After 30 seconds, the device will automatically proceed with the measurement even if the button was not pressed.

5) After checking for contact and tilt errors in this position, the measurement will proceed for one minute more, with the LED bar blinking purple and a chime sounding every 5 seconds throughout this time.

6) After the second position is complete, the device will chime and the LED light will flash green, indicating the measurement is finished.

7) At this point, the device can be gently removed and placed back in the Base Station to charge. The data will automatically upload to the cloud if there is cellular connectivity.

**IMPORTANT**

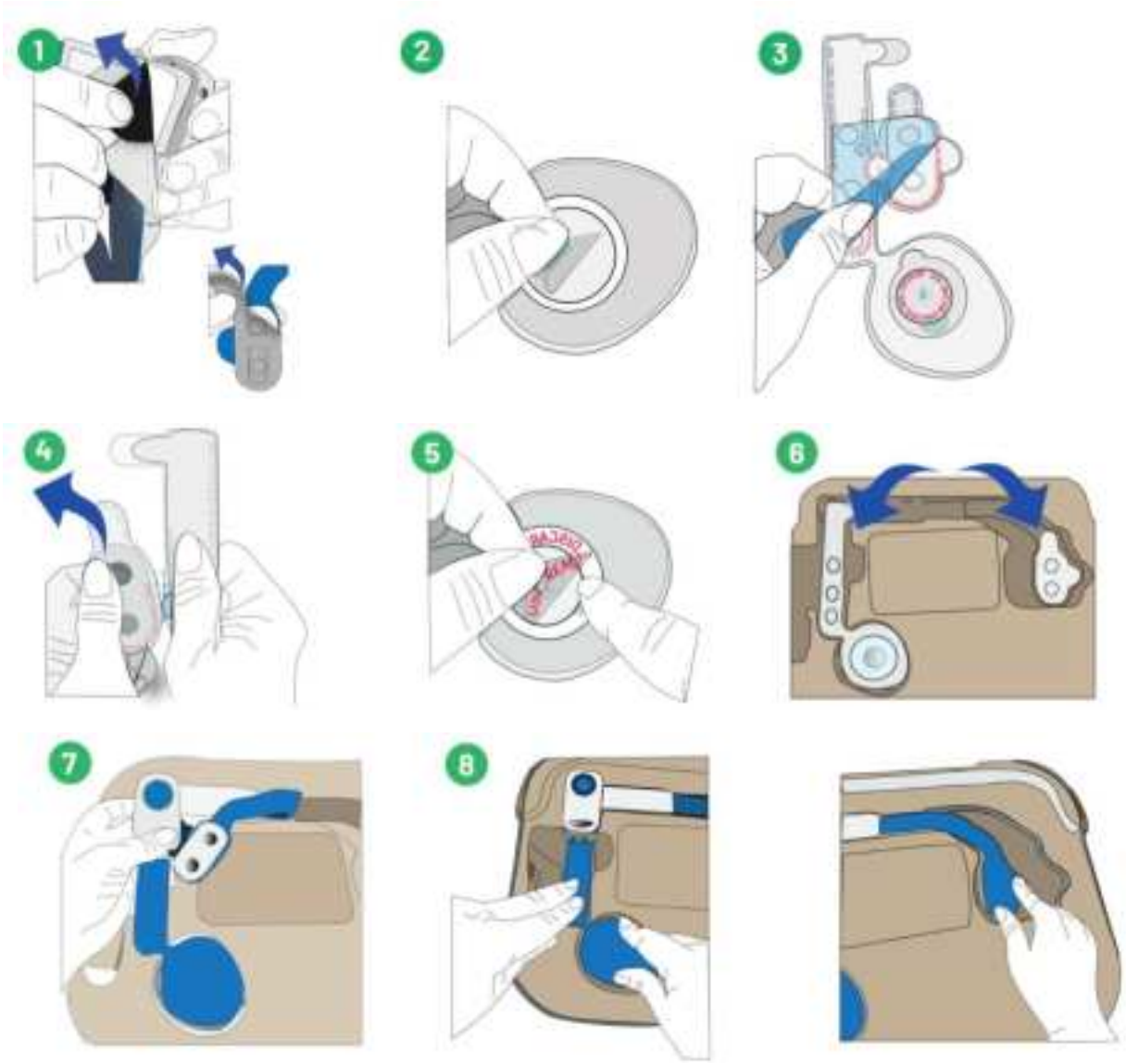
If the patient is having undue trouble with the device (e.g. excessive beeping, cannot place the device, thinks there is something wrong with the device), they should contact the support team for help.

## 11. REPLACING THE ADHESIVES ON THE DEVICE

**IMPORTANT**

**Replace the adhesive patches on the device…**

- Every week, **OR**
- After more than 5 uses, **OR**
- When the device no longer adheres well enough to the skin to complete a measurement, **OR**
- When significant dirt, lint, hair, or dust is visible on the skin-side adhesive.



1) Gently pull the non-adhesive tabs on the used adhesive on the two islands to separate them from the from the device.

2) **Also remove the small disc-shaped adhesive from the acoustic sensor using the blue tab.** Discard the **three pieces** of used adhesive disposables in the trash. Remove and throw away the old clear liners (2) from the Base Station as well, if they are still seated inside.

3) Remove a new adhesive disposable from its pouch using the tear notch on the packaging. Remove the hydrogel protector sheet. This sheet is labeled with a "1", as shown. Discard the protector sheet.

4) Tear along the perforation to separate the adhesives for each side of the device. The perforation is labeled "Separate Here" with a "2", as shown.

5) Remove the acoustic protector sheet, labeled with a "3" as shown. **Make sure to hold down the blue tab so that the adhesive disc does not come up with the liner**. Discard this protector sheet.

6) Place both pieces of the separated adhesive sheet into the Base Station, aligning the shapes with the wells.

7) Place the CPM Device on top of the adhesives in the Base Station. It may help to put the rigid plastic part of the device into the wells first.

8) Gently press down on both islands to secure the disposables on the device.

**IMPORTANT**

**When removing the clear liners for the first time on newly replaced adhesives, peel them off slowly and gently to ensure that the five hydrogel discs and round acoustic adhesive remain on the device.**

# PART 4. LIGHTS, SOUNDS, AND TROUBLESHOOTING


*Figure 24. Locations of the light bar on the CPM Device and Base Station LEDs.*

## 12. CPM DEVICE LIGHTS AND SOUNDS

The CPM Device is equipped with a LED light bar on the electronics housing below the blue button. The device also has a speaker which will play tones as indicated below during certain device events.

### 12.1 Bluetooth Advertising

| |  Blue Flash |  Green |
|---|---|---|
| **Description** | **Bluetooth (BLE) Advertising**<br>Put into this mode using a long (10s) button press.<br><br>**For clinical use only; disabled for at-home use.* | **Connected to Bluetooth** |
| **Actions** | Ready to connect to CPM Mobile App | Ready to take a measurement using the CPM Mobile App |

### 12.2 Battery and Charging

When the CPM Device is plugged into the Base Station to charge, the LED bar will “breathe” green.

To get a sense of the charge of the device when it is NOT plugged into the Base Station, tap the blue button on the device and it will blink green, yellow, or red depending on device charge as shown below. The light will blink twice and then stay on for 5 seconds to indicate the charge.

| |  Green “Breathing” |  Green |  Yellow |  Red |
|---|---|---|---|---|
| **Description** | **Actively Charging** Only when docked, LED “breathes” | **Good battery level (>75%)** Only when woken up | **Ok battery level (10% - 75%)** Only when woken up | **Low Battery Level (<10%)** Only when woken up |
| **Actions** | Device is ready to take a measurement when unplugged from the Base Station. | Device is ready to take a measurement. | Device is ready to take a measurement. | Dock to the Base Station until the light is yellow or green. The battery is too low to take a measurement. |

Green/Yellow/ Red Blink x5

| | |
|---|---|
| **Description** | **Plug the device in** Only after a reading has been attempted and/or completed. The LED color will vary depending on the battery charge of the device (good = green, ok = yellow, red = low). If the light flashes red, the battery is too low to take a measurement. |
| **Sounds** | Three notes, once every minute for 5 minutes |
| **Actions** | Return the device to the Base Station. |

### 12.3 Notifications and alerts during a measurement

| |  Purple Light |  Pink Flash |  Green Flash x2 |
|---|---|---|---|
| **Description** | **Active reading is taking place** CPM Device is currently recording data. A tone will play every 5 seconds. | **Move to the next position** | **Error resolved / measurement position beginning / measurement complete** |
| **Sounds** | Single note every 5 seconds | 3-note tone | 2 tones |
| **Actions** | Remain still and quiet for the duration of the measurement and do not touch the sensors. | Move to the next position specified by the Clinical Care Team and press the blue button on the electronics housing to start the second half of the measurement. | |

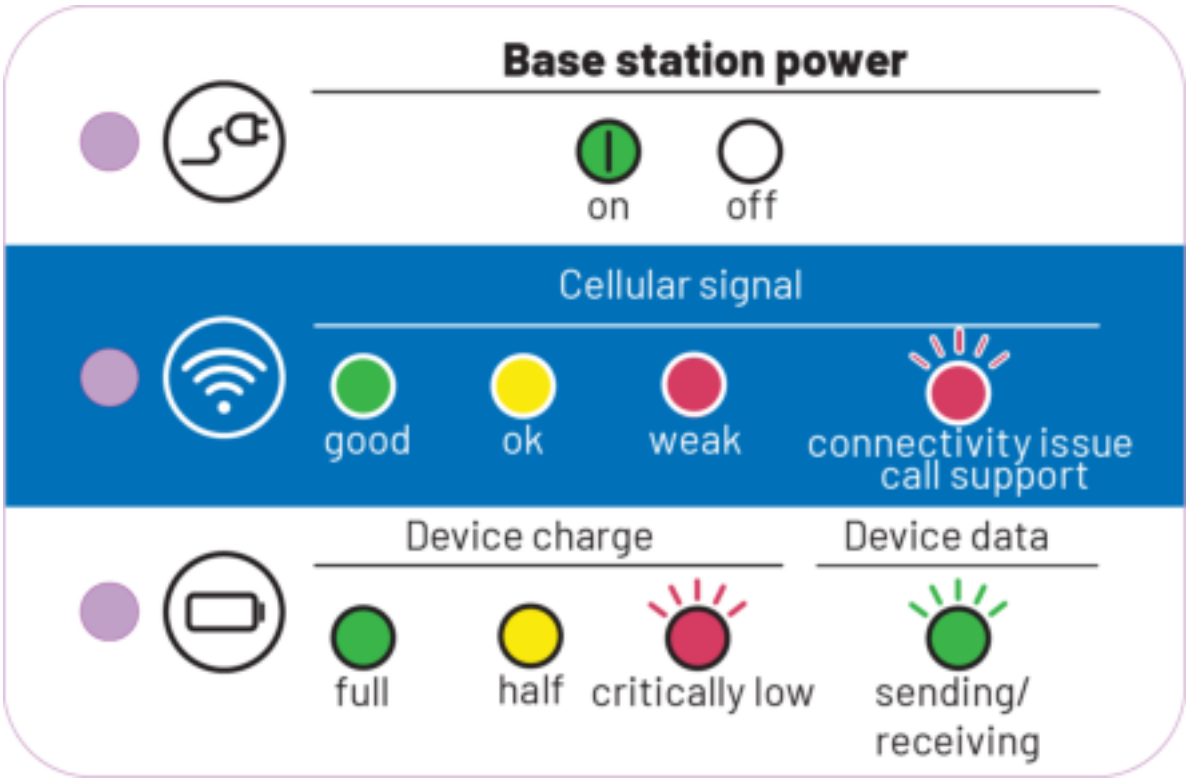
| |  Yellow Flash |  Yellow Flash |  Orange Flash |
|---|---|---|---|
| **Description** | **Tilt Error – Lean forward** You are leaning too far back and need to lean forward. | **Tilt Error – Lean backward** You are leaning too far forward and need to lay back further | **Electrode Contact Error** The electrodes are not contacting the skin well |
| **Sounds** | 3 ascending notes | 3 descending notes | 4 flat notes |
| **Actions** | Lean forward until the LED flashes green and the error goes away; otherwise it will resolve after 20 seconds.  Lean Forward | Lean backward until the LED flashes green and the error goes away; otherwise it will resolve after 20 seconds.  Lean Backward | Press down on the parts of the device with the electrodes until LED flashes green and the error resolves. You may also have to replace the adhesives, dampen skin, or remove and replace the device.  Press Down |

### 12.4 Errors

| |  Red Light |
|---|---|
| **Description** | **Critical Device Error**<br>Malfunction or needs reset |
| **Actions** | Connect the device to the Base Station and contact the clinical care team or logistics partner for support or replacement device |

## 13. BASE STATION INDICATIONS

The CPM Base Station has three embedded multicolored LEDs. They are labeled on the Base Station as follows below, with the LEDs at the left of the label.



### Power

- When the Base Station is plugged into an electrical wall outlet, the power LED will illuminate green indicating that the Base Station is powered.
- If it is not powered, all LEDs will be off.

### Cellular Signal

- This light may take up to a minute to illuminate after the Base Station is powered as signal is being acquired.
- When the Base Station is powered, the cellular signal LED will illuminate green, yellow, or red based on the strength of the cellular connectivity in your home. The signal may transiently change from one color to another over time, as cellular signal changes in the area.
- If the LED is showing weak signal (solid red), move the Base Station to an area with better cellular service such as near a window.

**IMPORTANT**

If the cellular signal LED is flashing red, data is likely not being sent to the cloud. **Contact the service team for help immediately.**

### Device Charge and Data Transfer

- When the CPM Device is plugged into the Base Station, the device charge LED will illuminate green, yellow, or red based on the battery charge of the CPM Device. Flashing red indicates a critically low battery level. This LED may take up to one minute to illuminate after the Base Station is powered on.
- The device charge LED should be green or yellow before taking a measurement.
- Data being sent or received by the CPM Device and Base Station, including over-the-air updates, are also indicated by this LED. When sending data, this LED will blink green. When finished, it will return to solid color indicating the charge of the CPM Device.

## 14. BUTTON PRESSES

**WAKE**

Press the button on the CPM Device once, quickly, to wake it. The LED will flash with the color indicating the charge of the device. **You do NOT need to do this to take a measurement**.

**HIBERNATE MODE**

To put the device to sleep, plug it into the Base Station.

**BLE ADVERTISING MODE***

Press and hold the button on CPM Device for 10 seconds, or until the blue LED comes on and begins blinking indicating it is searching for a connection. The LED light bar will flash blue until a connection is made, and then should beep and stay sold green once a connection is made to the CPM Mobile Application.

* Only for clinician use. This mode is disabled for at-home use.

**START A PATIENT MODE MEASUREMENT (OR SECOND MEASUREMENT POSITION)**

Press the button for 1-3 seconds (a small beep will sound) and then release. Ensure the device is on the body before initiating a measurement.

**RESET DEVICE**
If the device stops functioning as expected, you can reset the device. Use a paperclip in the pinhole on the back of housing of the CPM Device. The device should shut off and then reboot after a few seconds.

## 15. GENERAL TROUBLESHOOTING / FAQS


### 15.1 Physician Q&As

**Q: I am having trouble connecting the new CPM Device to Bluetooth via the CPM Mobile App.**

**A:** The mobile phone's Bluetooth may not be on. Make sure Bluetooth is turned on before proceeding.

**A:** Make sure that the CPM Device is advertising (the LED bar on the device will be flashing blue). To put the device into advertising mode, hold the button on the device down until the LED begins flashing blue (about 10 seconds). **The device will go to sleep if not paired within several minutes.**

**A**: Make sure you are paired to the correct device by matching the device ID on the device sticker to the paired device shown on the app.

**A:** Ensure that the CPM Device is sufficiently charged to take a measurement (> 20%, the LED on the device should be green or yellow when plugged into the Base Station).

**A:** Check that the app is responsive. If it is not, force quit and restart the app and try pairing the device again.

**Q: No data from my patient is appearing on the server, but after getting in touch with the patient, they say that they have been taking measurements consistently with no issue and their device is connected to a plugged-in Base Station.**

**A:** This is likely a cellular connectivity issue. First, ask the patient to ensure that the device is charging by looking at the Device and Base Station LED indications. Then ask them to look at the cellular connectivity LED on the Base Station. If the LED is yellow or red, ask the patient to follow the following steps:

1) Reboot the Base Station by unplugging and then re-plugging in the Base Station.
2) Move the Base Station to a spot in the house with better connectivity – try near a window.
3) Call the clinical care team to replace the Base Station with one that has a SIM card with a better fit for the area.

**Q: No size of the CPM Device fits my patient.**

**A:** Your patient may be outside the range of body types that the CPM Device was designed for. This device was designed to accommodate about 95% of the population, but very large or very small people, or those with large breasts, may not be able to wear the device.

**Q: I initiated a patient mode measurement while trying to put the device into Bluetooth pairing mode and now I can't pair the CPM Device to the Mobile App.**

**A:** Plug the CPM Device into the Base Station to charge to stop the measurement. Then unplug and attempt to pair the device again.

**Q: How do patients get more adhesives when they run out?**

**A:** Adhesives are provided on a prescription basis in boxes of 15. Patients will receive replacement adhesives for the duration of the device prescription length. Patients should contact the support team if they are running low on adhesive disposables.

**Q: Can the CPM System be used near other electronic or medical equipment such as telephones, televisions, computers, etc.?**

**A:** Yes, although some sources of Electromagnetic Interference (EMI) can temporarily disrupt data transmission or cause the CPM System to transmit more slowly.

**Q: Is data secure when transmitting from the CPM Device to the Mobile App, the Device to the Base Station, or the Base Station to the Cloud platform?**

**A:** Yes, many measures have been taken to comply with data privacy and cybersecurity guidelines. The data is transmitted securely with no identifying information and stored privately and securely.

## 15.2 Patient Q&As

**Q: The CPM Device is not lighting up when plugged into the Base Station to charge.**

**A:** The Base Station might not be plugged in. Ensure that the charging adaptor is connected to both a wall outlet and the Base Station and the power LED is lit up on the Base Station. If power to the Base Station is confirmed, try re-plugging in the magnetic charging adaptor to the CPM Device. If still nothing happens, the device might be out of battery. Wait a few minutes to see if the device boots up. If not, contact the support team.

**Q: Nothing happens when I am trying to start a measurement and/or the button is pressed on the CPM Device.**

**A:** First, make sure that the CPM Device is **not** connected to the Base Station when trying to start a measurement. Also ensure that the battery of the CPM Device has been charged to over 20% by looking at the LED color while the

device is charging. If it is red, it is NOT yet ready to take a measurement, and you should continue to charge the device until the LED bar is yellow or green.

**Q: The device visually does not stick well to my body or is obviously peeling up.**

**A:** *For men:* The CPM Device is not intended to be used on patients with a large amount of chest hair – men that do have chest hair may need to trim in the area of the device. Ensure that this is done before the initial placement of the CPM Device and as hair grows back throughout the prescription duration of the CPM System.

**A:** The adhesive disposables may have been used too many times or may be dirty. Replace the adhesive disposables and try again if this is the case by following the instructions in this document.

**Q: I lost the clear protective liners for covering the adhesive.**

**A:** Replace the current set of adhesives on the device so that they can be covered when not in use.

**Q: I pressed the button accidentally/too early and a measurement started before the device was on my body. How do I get the device to stop beeping?**

**A:** Plugging the device into a Base Station will quiet it and stop the measurement.

**Q: The CPM Device continues to beep, indicating there are errors, during a measurement.**

**A:** The most common cause of beeping during measurements are electrode contact errors. See the Lights and Sounds Indications section of this document for more information about how this is communicated by the device. If you are experiencing an electrode contact error:

- Press down around all the sensors to ensure that the entire adhesive surface of the device is contacting your skin.
- Ensure that the adhesive disposable is placed correctly on the device, checking that you can see all the round metal electrodes (5) under the clear hydrogel and that there is no air gap between the metal and the hydrogel.
- In rare cases, patients may have extremely dry skin and need to slightly dampen the skin under the device adhesives in order to achieve good electrode contact. This can be done using a baby or wet wipe.
- The hydrogels may be dried out, preventing good measurement data. Remove the CPM Device, replace the adhesive disposables using the instructions in this document, and try again.

**A:** Tilt errors may also be causing continuous beeping while trying to take measurements. These errors always appear first and will automatically go away after 20 seconds. **Patients should contact their healthcare provider or clinical care team immediately if they are no longer able to achieve the two positions outlined in the initial baseline office visit.**

**A:** Note that after a period of time, about 1 minute, all errors will be disregarded, and the measurement will continue. However, these measurements may give poor data quality.

**Q: Can I shower with the CPM Device or get it wet?**

**A:** The CPM System is designed to be surface-cleanable using an alcohol wipe or damp cloth. This device is NOT meant to be used in the shower or any other very wet environment.

**Q: Can I travel with the CPM System?**

**A:** Traveling with the CPM System is encouraged, especially if you are travelling for a longer period of time. There is a leather strap on the CPM Base Station to allow patients to easily carry the Device inside the Base Station. Please note that the CPM System contains lithium ion batteries, which may need to be declared before traveling by plane. Make sure that the CPM Device and Base Station are plugged in to charge immediately as soon as they have arrived at the destination. Also note that the hydrogels on the device adhesives are only meant to withstand the temperature range given in the Specifications Table in this document and may lose their efficacy or tack if left in hot or cold environments for a sustained period of time.

If you are travelling to an area where your Base Station does not have cellular coverage, the CPM system will still record data up to approximately a month's worth of measurements. This data will be available to your clinical team once the CPM system is back in a coverage zone.

**Q: A piece or part broke off the device, base station, or alignment tool.**

**A:** Contact the support team for a replacement part if the device is not working or electronics and/or sharp edges are exposed.

**Q: What do I do if I think I am having a medical emergency or decompensation event?**

**A:** If you think this is a life-threatening emergency, call 911 immediately. Otherwise, call your primary care physician, cardiologist, or pulmonologist immediately. ***This device is NOT meant to warn clinicians of medical emergencies or diagnose decompensation events. Patients should use their own best judgement while using this device and should not wait for the clinical care team to call with results from the CPM System. Care regimens for patients with cardiopulmonary conditions should be continued as they would be with or without the CPM System.***

# PART 5. CLEANING AND MAINTENANCE OF THE SYSTEM

## 16. CLEANING

Cleaning is recommended after every several uses of the CPM Device. Gentle cleansers can be used to clean the Base Station, Device, and Alignment Tool as follows:

***In the clinic***
Wipe any exposed surfaces of the CPM Device, Base Station, or Alignment Tool with **isopropyl alcohol** or **alcohol prep pads** to clean the device and/or remove any dirt, stains, lint, etc.

***At home***
Wipe any exposed surface of the CPM Device, Base Station, or Alignment tool with alcohol prep pads, **baby wipe,** or a **water-dampened cloth** to clean the device and/or remove any dirt, stains, lint, etc.

**IMPORTANT**

Do not use cleansing agents on the adhesive disposables, as this degrades the adhesive and the device's ability to stick to the skin.

Also, to preserve cleanliness of the system:

- Always replace the clear liners onto the skin-side adhesive before storage in the Base Station. This prevents dirt, hair, lint, and dust from sticking onto the adhesive and degrading their adhesion.
- Always close the lid of the Base Station and the Base Station's adhesive storage compartment after using the CPM Device. This provides a second level of defense from dust, hair, lint, and dirt and keeps unused adhesives clean.
- Replace the adhesives as soon as there is visible dust, hair, dirt, or lint on the pads, or at least once per week and discard them in the trash as soon as they are removed from the CPM Device.
- Make sure the skin is clean before placing the CPM Device on a patient's chest.

## 17. ADHESIVE DISPOSAL

The CPM System Adhesive disposables can be disposed of after they are used in normal residential conditions (e.g. home garbage cans). Do NOT dispose of the CPM Device or Base Station at home. **CPM Adhesives must be used by their use-by date listed on the packaging.**

## 18. MAINTENANCE AND RETURN OF THE SYSTEM

No maintenance on the part of the user is required for this device. When the use duration of the device is completed, return this device with all the contents that came with the system (Base Station with charging cords, extra adhesives, etc.).

# PART 6. SYSTEM SPECIFICATIONS

## 19. TECHNICAL SPECIFICATIONS

### MEASUREMENT PARAMETERS

**Impedance**

| | |
|---|---|
| **Range:** | 50 – 250 Ohms |
| **Accuracy:** | 0.5 Ohms |
| **RMS Current Injection:** | 9 uA |
| **Respiration Rate Derived Range:** | 6 – 40 breaths per minute (+/- 1 breath per minute) |

**ECG**

| | |
|---|---|
| **Sampling Rate:** | 1 kHz |
| **Digital Resolution:** | 16 bits |
| **Input Dynamic Range:** | +/- 5 mV |
| **Input Offset Dynamic Range:** | +/- 300 mV |
| **Heart Rate Derived Range:** | 30 – 200 beats per minute (+/- 5 beats per minute) |

**Heart Sounds**

| | |
|---|---|
| **Sampling Rate:** | 5 kHz |
| **Diginal Resolution:** | 16 bits |
| **Frequency Range:** | 10 Hz – 1 kHz |

**Temperature**

| | |
|---|---|
| **Range:** | 34 – 43 °C |
| **Precision:** | 0.3 deg °C |

**Tilt**

| | |
|---|---|
| **Range:** | 0° – 360° |
| **Precision:** | 5° |

## Electrical (Power) Requirements

### Wearable

| | |
|---|---|
| **Max Power Consumption:** | 150 mW |
| **Nominal Power Consumption:** | 0.4 mW |
| **Battery Type:** | Li-Ion Polymer Battery, HCP - 451223 |
| **Nominal Rating:** | 3.7 V, 85 mAh |
| **Max Rating:** | 3.96 V, 90 mAh |

### Base Station

| | |
|---|---|
| **Max Power Consumption:** | 5 W |
| **Nominal Power Consumption:** | 1 W |

### Base Station Charger

| | |
|---|---|
| **Part Number:** | CUI-SWM12-5 Series |
| **Max Power Consumption:** | 12 W |
| **Nominal Power Consumption:** | 0.1 W |
| **Adaptor Type:** | Barrel Plug (2.1 mm ID x 5.5 mm OD) |
| **Input:** | 90 – 264 VAC at 50/60 Hz |
| **Output:** | 5 V |

## Wireless Transmission Specifications

### Bluetooth Transmission

| | |
|---|---|
| **Frequency:** | 2.4 GHz |
| **Protocol:** | Bluetooth Low Energy |
| **Peak Output Power:** | 0 dBm |

### RF Transmission

| | |
|---|---|
| **Frequency Range:** | 700 MHz, 1700 MHz, 1900 MHz |
| **Protocol:** | LTE CAT-M with 2G backup |
| **Peak Output Power:** | 22 dBm |
| **BLE Operating Range:** | 20 ft |

## DIMENSIONS

### Wearable

| | |
|---|---|
| **Width:** | 10.75 in |
| **Height:** | 8.5 in |
| **Depth:** | 1.25 in (at electronics housing) |
| **Weight:** | 100g |

### Base Station

| | |
|---|---|
| **Width:** | 14.5 in |
| **Height:** | 11.25 in |
| **Depth:** | 2 in |
| **Weight:** | 3.5 kgs |

## ENVIRONMENTAL AND OTHER SPECIFICATIONS

### Device and Base Station Operating Conditions

| | |
|---|---|
| **Temperature:** | 0 – 40 °C |
| **Relative Humidity:** | 30 - 95 % |
| **Pressure:** | 700 -1060 hPa |
| **IP Rating – Device:** | IP42 |
| **IP Rating – Base Station:** | IP22 |

### Adhesive Operating Conditions

| | |
|---|---|
| **Temperature:** | 0 – 40 °C |
| **Relative Humidity:** | 30 - 95 % |
| **Pressure:** | 700 -1060 hPa |

### Device and Base Station Storage Conditions

| | |
|---|---|
| **Temperature:** | -10 – 45 °C |
| **Relative Humidity:** | 10 - 60 % |
| **Pressure:** | 500 -1060 hPa |

**Adhesive Storage Conditions**

| | |
|---|---|
| **Temperature:** | 10 – 27 °C |
| **Relative Humidity:** | 40 - 60 % |
| **Pressure:** | 500 -1060 hPa |

**Shipping and Transport Conditions**

| | |
|---|---|
| **Temperature:** | -30 – 60 °C |
| **Relative Humidity:** | 5 - 93 % |
| **Pressure:** | 700 -1060 hPa |

**Other Specifications**

| | |
|---|---|
| **Wearable Shelf Life:** | 6 months |
| **Base Station Shelf Life:** | 6 months |
| **Adhesive Shelf Life:** | 6 months |
| **CPM System Operating Life:** | 1 year |
| **Wearable Battery Life Expectancy:** | > 80% after 500 charge-discharge cycles |
| **Wearable Battery Operation Time:** | 1.5 days |
| **Adhesive Reuse:** | 5 uses |
| **Data Storage Capacity:** | 256 MB |

## 20. STANDARDS AND TESTING COMPLIANCE

| | |
|---|---|
| **IEC 60601-1-2** | Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests |
| **IEC 60601-1-11** | Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment |
| **IEC 60601-2-27** | Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment |

| | |
|---|---|
| **IEC 62133-2** | Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems |
| **BS EN 60601-1-6** | Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance. Collateral Standard. Usability |
| **BS EN ISO 10993-10** | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |
| **EN ISO 10993-5** | Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity |
| **ANSI AAMI EC57** | Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms |
| **AAMI TIR69** | Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems |
| **ISO 27000-1** | Information technology — Security techniques — Information security management systems — Requirements |
| **ISO 14117** | Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices |
| **AAMI/ANSI/IEC 62304** | Medical Device Software – Software Life cycle processes - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices |

**EMC guidance and manufacturer's declarations**

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC 60601-1-2 ed 4.0 (2014-02).

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment (e.g: cell phones) can affect the behavior of medical electrical equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity.
- The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed in order to verify normal operation in the configuration in which it will be used.

The ADI CPM system complies with all applicable and required standards for electromagnetic interference:

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the ADI CPM System in the presence of high-frequency surgical equipment or MRI.
- However, it is good practice to avoid using the ADI CPM System in extremely close proximity to other equipment.

| **Guidance and Manufacturer's Declaration – Electromagnetic Emissions** |
|---|

| The ADI CPM system is intended for use in the electromagnetic environment specified below. The customer or user of the ADI CPM system should ensure that it is used in such an environment. | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Electromagnetic Environment - Guidance** |
| RF Emissions CISPR11 | Class B | The ADI CPM system 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. |
| CE Emissions CISPR11 | Group 1 | |
| Harmonic Emissions IEC 61000-3-2 | Class B | The ADI CPM system 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 |
| Voltage Fluctuations / Flicker Emissions IEC 61000-3-3 | Compliant | |

| **Guidance and Manufacturer's Declaration – Electromagnetic Immunity** | | | |
|---|---|---|---|
| The ADI CPM system is intended for use in the electromagnetic environment specified below. The customer or user of the ADI CPM system should ensure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance** | **Electromagnetic Environment - Guidance** |
| Electro-Static Discharge Immunity Test 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%. |
| Electrical Fast Transient / Burst – IEC 61000-4-4 | ±2kV 100 kHz rate | ±2kV 100 kHz rate | Mains power quality should be that of a typical commercial or hospital environment |
| Conductive Surge – IEC 61000-4-5 | ± 0.5 kV, ±1 kV, (Line to Line) ± 0.5 kV, ±1 kV, ±2kV (Line to Ground) | ± 0.5 kV, ±1 kV, (Line to Line) ± 0.5 kV, ±1 kV, ±2kV (Line to Ground) | Mains power quality should be that of a typical commercial or hospital environment |
| Power Frequency / Immunity to Magnetic Field IEC 61000-4-8 | 50Hz/60Hz 30 A/m | 50Hz/60Hz 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Voltage Dips and Interruptions IEC 61000-4-11 | 100 V/60Hz, 240V/ 50Hz<br><br>0% $U_T$ for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°,270°,315°; 0% $U_T$ for 1 cycle; 70% $U_T$ for 0.5 s; 0% $U_T$ for 5 s | 100 V/60Hz, 240V/ 50Hz<br><br>0% $U_T$ for 0.5 cycle at 0°, 45°, 90°,135°, 180°, 225°, 270°, 315°; 0% $U_T$ for 1 cycle; 70% $U_T$ for 0.5 s; 0% $U_T$ for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source. |

| **Guidance and Manufacturer's Declaration – Electromagnetic Immunity** | | | |
|---|---|---|---|
| The ADI CPM system is intended for use in the electromagnetic environment specified below. The customer or user of the ADI CPM system should ensure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance** | **Electromagnetic Environment - Guidance** |

| | | | |
|---|---|---|---|
| Radiated Immunity Test<br>IEC 61000-4-3 | 10 V/m, frequency 80MHz-2700 MHz<br><br>385-5800MHz PM 18Hz, 217Hz | 10 V/m<br><br>9-28 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the ADI CPM System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommend separation distance**<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[3] should be less than the compliance level in each frequency range[4]. Interference may occur in the vicinity of equipment marked with the following  |
| Conducted Immunity Test<br>IEC 61000-4-6 | 3 V (0.15 MHz - 80 MHz)<br><br>6 V (ISM and amateur radio Bands between 0.15 MHz and 80 MHz) | 6 V (150 kHz- 80MHz) | |
| NOTE 1: At 80 MHz and 800 MHz, 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 | | | |

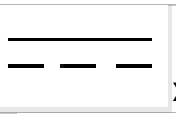
**FCC Compliance Information**

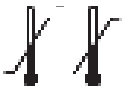
Wearable Sensor and Transmitter devices comply with Part 15 of the Federal Communications Commission (FCC) Rules – Radio Frequency Devices: Operation is subject to the condition that (1) this device does not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation. Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. The monitor is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

[3] Field strengths from fixed transmitters, such as base stations for radio (cellular/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 due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ADI CPM System is used exceeds the applicable RF compliance level above, the ADI CPM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ADI CPM System.

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

# PART 7. SYMBOLS GLOSSARY

| | |
|---|---|
| IP42 | Ingress protection rating, IP42 |
| IP22 | Ingress protection rating, IP22 |
|   | MR Unsafe |
|   | Single Patient – Multiple Use |
| $R_x$ Only | Prescription use only |
| MD | Medical Device Information |
|  | Date of Manufacture |
|  | Manufacturer |
| SN | Serial Number |
| REF | Catalogue Number |
|  | Class II Device |
|   | Electrical Information: Rated Supply Voltage, Nature of Supply, and Frequency |
|   | Electrical Information: Rated Supply Voltage, Nature of Supply, Frequency |
|  | Type CF applied part; compliant with IEC 60601-1 |
|  | General Warning or Precaution |
|  | Prohibition |

| | |
|---|---|
|  | General Mandatory Action Sign |
|  | Refer to Instruction Manual |
|  | FCC ID (7 to 25 characters in length) |
|  | Batch Code |
|  | Wireless Transmission Symbol |
|  | Upper and Lower Temperature Limits |
|  | Keep away from rain |
|  | Keep away from sunlight |
|  | Use-by Date |
|  | Protect from heat and radioactive elements |
|  | Do not use if package is damaged |
|  | Non-sterile |
|  | Humidity limitations |
|  | Atmospheric pressure limitations |
|  | Fragile, handle with care |
|  | Do not dispose of in trash |

# PART 8. **FCC Compliance Statement (USA)**

## I. BASE STATION

**FCC ID:** 2AZELADCP1P0BS

**Compliance Statements:** 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.
2. This device must accept any interference received, including, an interference that may cause undesired operation.

**FCC Compliance Information**
Wearable Sensor and Transmitter devices comply with Part 15 of the Federal Communications Commission (FCC) Rules – Radio Frequency Devices: Operation is subject to the condition that (1) this device does not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

**INFORMATION TO THE USER**

For Class A and Class B digital devices, information to the user is required to include the following statements (Section 15.105):

For a Class A digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

For a Class B digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

NOTE: This equipment 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.

The users manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.

**Warnings & Cautions**

- Patients with implants such as pacemakers or defibrillators should use caution to maintain a distance of at least 8 inches or 20 centimeters away from the CPM Base Station at all times when it is plugged in. Failure to do so could result in an unintended shock or malfunction of your implant.

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

- This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body.

• Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
• This equipment should be installed and operated with a minimum distance of 20cm between the radiator and your body.

**WARNING:** Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment and may void the warranty.

- Note: The product is integrated with pre-certified Cellular transmitter with FCC ID: N7NWP77B. Module grant conditions are not violated, and RF exposure evaluation for user separation distance of 20cm from transmitter antenna to user is evaluated

## II. WEARABLE DEVICE

**FCC ID:** 2AZELADCP1P0WB

**Compliance Statements:** 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.
2. This device must accept any interference received, including, an interference that may cause undesired operation.

**FCC Compliance Information**
Wearable Sensor and Transmitter devices comply with Part 15 of the Federal Communications Commission (FCC) Rules – Radio Frequency Devices: Operation is subject to the condition that (1) this device does not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

**INFORMATION TO THE USER**

For Class A and Class B digital devices, information to the user is required to include the following statements (Section 15.105):

For a Class A digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

For a Class B digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

NOTE: This equipment 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.

Note: RF exposure evaluation for CPM wearable is performed for considering separation distance of 5mm from transmitter antenna. The RF exposure evaluation meets the SAR exclusion limits specified in clause 4.3.1 of FCC KDB 447498 D01 General RF Exposure Guidance v06“