



The Circadia C300 System™

Instructions for Use

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Introduction

This manual provides the necessary instructions to operate and receive valid measurements from the Circadia C300 System. In addition, it contains the regulatory and safety information as well as technical specifications of the system. Do not operate the Circadia C300 System without completely reading and understanding these instructions.

The Circadia C300 System (the “System”) consists of the Circadia Contactless Cardiorespiratory Monitor, Model: C300 (the “Monitor”), the Circadia Clinical Intelligence Platform application (the “CIP App”), and the Circadia Cloud Service (the “Cloud Service”). The purpose of the Circadia C300 System is to measure respiratory rate (RR) and heart rate (HR) from a patient while seated or lying in bed, under no-motion conditions, including spot measurements. The System is intended as an adjunct to standard care and not intended to replace other physical vital signs parameters and patient information, for retrospective data analysis, to detect changes in vital signs over time. The system is intended to be used by healthcare professionals and data are intended to be reviewed by healthcare professionals to inform patient care. The System is not intended for active monitoring of RR and HR, as it does not provide alarms for timely response in life-threatening situations. The System may be used for long-term unsupervised use, and it may be used to obtain on-demand spot-check measurements. It is designed to automatically discard values for HR and RR that may be inaccurate or artefactual. The system is not indicated to monitor heart rate in patients with arrhythmias, such as atrial fibrillation.

The System is also intended to monitor motion, user presence or absence in the vicinity of the Monitor, and exits from the vicinity of the Monitor. Presence and exit data are available in real time, but should not be used as a sole basis for medical decisions or patient care management, and should not replace standard care practices. The CIP App is a cloud-based web application that operates on both mobile and desktop devices, and allows a user to visualize long-term data from multiple connected Monitors.

For optimal monitoring performance, the Monitor must be placed to the side of the patient, at a distance of 3 ft or less from the patient’s chest, with no other motion in the direct vicinity.

The successful operation of the System assumes basic knowledge of using iOS mobile devices (tablets and smartphones).

Quick start

1. **Download and Install App**
 - 1.1. Using an iOS mobile device, go to your device's app store.
 - 1.2. Search for "Circadia CIP" (Developer: Circadia Technologies, Ltd.) and download it.
2. **Launch the App**
 - 2.1. Tap the Circadia CIP icon on your home screen.
3. **Login to the App**
 - 3.1. Enter your login credentials provided by Circadia Health.
 - 3.2. **Note:** If you do not have your credentials, contact Circadia Health Customer Support (support@circadia.health).
4. **Enter One-Time Password (OTP)**
 - 4.1. A One-Time Password (OTP) will be sent to your registered mobile phone number.
 - 4.2. Enter the OTP in the app.
5. **Set up your 4-digit PIN**
 - 5.1. Choose and enter a 4-digit PIN for future quick sign-ins.
 - 5.2. **Note:** Your PIN will be used for easy and secure access in the future.
6. **Complete App Setup**
 - 6.1. The CIP App setup is now complete.
 - 6.2. You will be directed to the dashboard.
7. **Circadia Monitor Setup**
 - 7.1. Circadia Monitors will be installed and configured by the Circadia Health Team. If your CIP App does not display the Monitors, contact Circadia Health Customer Support.
 - 7.2. Ensure the Monitor stays connected to power using the provided power cable.
 - 7.3. Ensure the Monitor is at a distance up to 3 ft to the patient, pointed at their chest.
8. **Start Monitoring**
 - 8.1. Data will stream automatically from the Monitor, and will be visible in the CIP App .
 - 8.2. It may take several hours before data is being displayed: The Monitor only collects RR and HR while the patient is at rest in bed.
 - 8.3. For best performance, ensure the Monitor has direct line of sight to the patient, and no other motion is present in the Monitor's detection range (5 ft).
 - 8.4. To measure RR and HR on-demand, ensure correct Monitor placement, and ask the patient to lie still. RR and HR will be displayed (updating minutely) in the CIP App.

Indications for use

The Circadia C300 System is intended for the measurement of respiratory rate and heart rate, including spot measurement.

The system is indicated for adult patients in clinical settings, such as skilled nursing and long-term care facilities.

The system is not indicated for active patient monitoring, and does not provide alarms for timely response in acute life-threatening situations. The system is not intended to monitor heart rate in patients with arrhythmias.

The system is intended to be used by healthcare professionals (HCPs) and data are intended to be reviewed by HCPs to inform patient care.

The system also monitors patient motion, and patient presence or absence near the device (exits).

Safety Information, Warnings and Cautions

To ensure essential performance, the device must be positioned within 3 feet of the patient and used under no-motion conditions. Under these conditions, the device accurately monitors respiratory rate (RR) and heart rate (HR) with an error not exceeding $\pm 5 \text{ min}^{-1}$. While motion is present or when the patient is outside the detection range, RR and HR data will not be displayed. Loss of Wi-Fi connectivity may interrupt data transmission, during which no RR or HR data will be received.

Safety Warnings and Cautions

- **WARNING:** The Circadia Monitor is not water-proof, drip-proof or splash-proof despite good isolation of internal electronics from the outside. Direct contact with water should be avoided in all situations. For cleaning, follow the detailed information in the Cleaning Section of this manual.
- **WARNING:** Do not use the Circadia System during magnetic resonance imaging (MRI).
- **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- **CAUTION:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from the C300 Monitor and the included power plug cable. Otherwise, degradation of the performance of the Monitor can occur.
- **WARNING:** Use of cables or accessories other than those specified, may result in increased emissions or decreased immunity of the equipment and may result in non-compliance of the system with the requirements of IEC 60601-1-2.
- **WARNING:** Always inspect the equipment for visible signs of wear. If evidence of wear is found, remove the affected equipment from use and contact Circadia Health Customer Support (support@circadia.health) for replacement or servicing.
- **CAUTION:** Do not use the Circadia Monitor within 6 inches of magnetically susceptible devices. The magnet provided with the Circadia Monitor could interfere with the proper operation of such devices.

Performance Warnings and Cautions

- **WARNING:** The C300 System is not to be used for life critical monitoring where failure to operate could result in patients' death or severe injury.
- **WARNING:** The system is not indicated to monitor heart rate in patients with arrhythmias, such as atrial fibrillation.
- **WARNING:** The C300 System is adjunctive to and not intended to replace other physical vital sign parameters and patient information.
- **WARNING:** The C300 System should not be used as the sole basis for medical decisions or patient care management, and it is not intended to directly diagnose or inform treatment.
- **WARNING:** The Circadia System is intended for use with adult patients (21 years and above) and has not been validated for pediatric patients.
- **WARNING:** The Circadia System is not intended to be used as an apnea monitor or for detection of cessation of breathing.
- **WARNING:** Care needs to be taken when positioning the Circadia Monitor next to the patient. Please follow the detailed setup guide for more information. Failure to do so might negatively impact the performance of the System.
- **WARNING:** For optimal monitoring performance, the C300 System Monitor must be placed to the side of the patient, at a distance up to 3 ft from the patient. At higher distances, monitoring performance may be reduced.
- **WARNING:** Any sources of motion within the Circadia Monitor's detection range (5 ft) may negatively impact the performance of the System.
- **WARNING:** Inaccurate RR, HR, or presence/absence/exits readings might be caused by: Incorrect positioning of the Circadia Monitor, patient motion, irregular respiration patterns, interference of other RF transmitting devices, motion in the detection range (5 ft) of the Monitor.
- **WARNING:** Do not use the System to measure RR or HR of patients who cannot hold still during critical measurements (e.g., patients suffering from uncontrollable limb movement).
- **WARNING:** Use of the Circadia System on patients with irregular cardiac rhythms may result in a lower number of HR measurements, or may result in no HR measurements at all.
- **WARNING:** The C300 system will not output HR when the numerical difference between HR and RR is less than or equal to 10 min^{-1} .
- **WARNING:** The C300 System is intended for patients who do not require critical care or continuous vital sign monitoring.
- **CAUTION:** As the Circadia Monitor has no internal battery, it needs to be plugged into a power socket at all times to deliver targeted operation.
- **CAUTION:** The room where the Circadia Monitor is installed must have a stable Wi-Fi network coverage and active internet connection to deliver the essential performance of the Monitor.
- **CAUTION:** Data are intended to be interpreted by a healthcare practitioner.
- **CAUTION:** The Circadia System can only be sold, or ordered to be sold, by a physician. The System is only applicable for users with a valid prescription.

Cleaning, Disinfecting, and Service Warnings and Cautions

- **WARNING:** The Circadia Monitor is serviced by Circadia Health only, warranty can be void if the screws or back disc are found to be tampered with.
- **CAUTION:** Do not clean the Circadia Monitor with any chemical other than those specified in the Cleaning Section of this manual.

Compliance Warnings and Cautions

- **WARNING:** Any changes or modifications not expressly approved by Circadia Health shall void the warranty for this equipment and could void the user's authority to operate the equipment.
- **CAUTION:** Comply with local laws regarding the disposal of the Circadia Monitor.

Cybersecurity Warnings and Cautions:

For inquiries or concerns regarding data and cybersecurity, contact: security@circadia.health

- **WARNING:** Do not share login information (e.g., password) of your Circadia Cloud account.
- **CAUTION:** Regularly apply/allow security updates to your mobile device's operating system. Firewalls and antivirus software are recommended for the mobile device.
- **CAUTION:** The Monitor uses secure Wi-Fi connectivity to communicate with the Circadia Cloud. No open ports or physical interfaces require user configuration.
- **CAUTION:** Circadia Monitors, as well as your mobile device, should be used only on secure, encrypted Wi-Fi networks (WPA2/WPA3).
- **CAUTION:** Firmware updates for the Circadia Monitor are provided over-the-air by Circadia Health and applied securely and automatically. Only authorized updates should be installed. Circadia Health ensures that Monitor firmware is updated automatically.
- **CAUTION:** Regularly update the CIP App to ensure device security and performance. Enable automatic updates and use only official app stores.
- **CAUTION:** Do not attempt to make unauthorized changes to the system, such as modifying software, altering settings, or performing resets intended to restore functionality, without explicit approval from Circadia Health.
- **CAUTION:** Circadia systems monitor for unusual activity. Users will be notified if security-related anomalies (e.g., communication errors, failed updates) are detected.
- **CAUTION:** The system includes safeguards against known CVEs as defined in the SBOM (Software Bill of Materials) and is maintained by Circadia Health.
- **CAUTION:** Circadia Monitors do not store patient data locally. No backup or restore is required.
- **CAUTION:** Circadia Health personnel will never request your password or login information. If you receive unexpected or confusing emails, phone calls, or other forms of communication, notify Circadia Health immediately (security@circadia.health).
- **CAUTION:** When an incident is reported by the user to Circadia Health:
 - Circadia Health will confirm receipt within 24 hours
 - Recommended actions will be provided to the user within 15 days, if applicable.
 - If applicable, Circadia Health will disclose the reported cybersecurity vulnerability or incident to relevant Information Sharing and Analysis Organizations (ISAOs) within 30 days of initial reporting.
- **CAUTION:** The software version of each deployed Circadia Monitor can be accessed by contacting Circadia Health customer support.

Contraindications:

No contraindications are known.

About the Circadia C300 System technology

Overview

The Circadia C300 System consist of:

- The Circadia Contactless Cardiorespiratory Monitor, Model: C300 (the “Monitor”)
- The Circadia Clinical Intelligence Platform application (the “CIP App”),
- The Circadia Cloud Service (the “Cloud Service”).

Respiratory rate (RR), heart rate (HR), motion, and presence data are measured by the Monitor through radar technology: Both respiration and the heartbeat cause chest wall movement, which is measured using the Monitor’s radar sensor. The radar signal works through textiles such as clothing and blankets, and works best when the Monitor points directly towards the patient’s chest with direct line of sight, and no other sources of motion present. Other motion in the Monitor’s detection range (5 ft) is registered as user motion. User presence or absence near the Monitor, as well as exits, are monitored continuously from motion data. RR and HR can only be obtained when a user is at rest (no motion), and within the Monitor detection range, with no other disturbances present. When these conditions are not met, or when the sensor signal is of insufficient quality, the Monitor will discard RR or HR measurements, and they will not be displayed. Large gaps in RR data and/or HR data may be experienced, and the Monitor is not guaranteed to output a value for RR or HR at any given time. User data is continuously being streamed to the Circadia Cloud and can be reviewed retrospectively from the CIP App.

Contents of the C300 System packaging

Figure 1 shows the contents of the C300 System packaging. Contents may vary depending on the chosen mounting option.

This Box Contains

*Depending on chosen mounting option

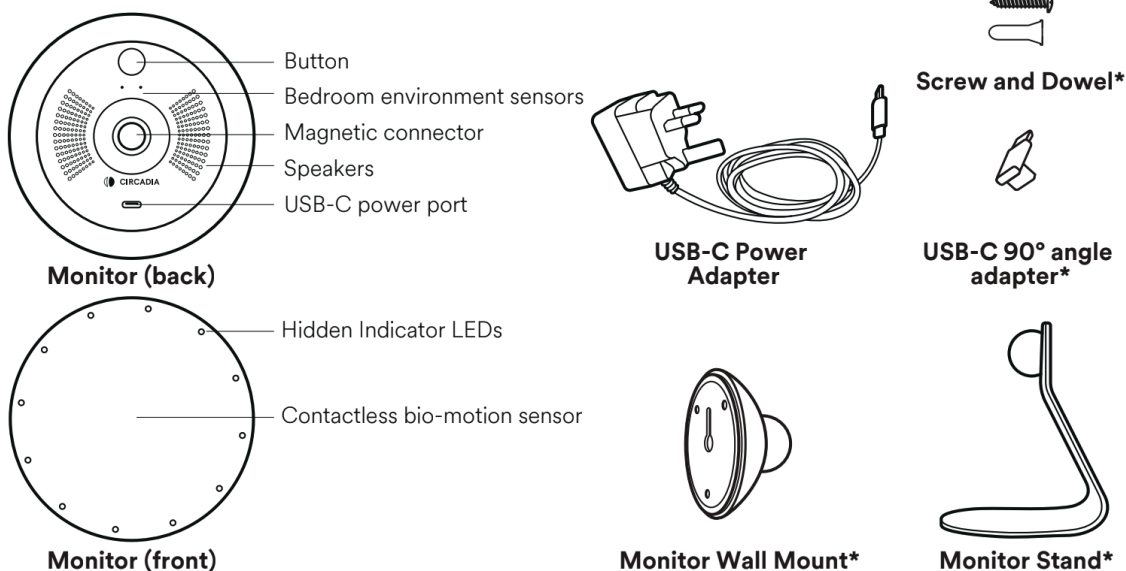


Figure 1: Contents of the C300 System packaging.

Overview of Display Parameters in the CIP App

Display Parameter	Description
RR (br/min)	Respiratory rate, in breaths per minute (br/min)
HR (bpm)	Heart rate, in beats per minute (bpm)
Motion	Motion, in number of minutes per hour that substantial motion was detected from within the Monitor's 5 ft detection range
Bed Exits	Bed Exits, in number of times that an exit was detected from the Monitor's 5 ft detection range
Moving Avg.	Smoothed RR or HR data, using a moving average filter

Operation

Initial installation and configuration of the Circadia Monitor

The Circadia Health team will ensure the installation and Wi-Fi configuration of all Monitors. All installed Monitors should be visible in the CIP App. In case of connectivity issues, please contact Circadia Health Customer Support (support@circadia.health). In case you need to re-install or replace one of the Monitors, follow the instructions below.

1. **Placement:** Position the Monitor such that it faces the patient's chest with a clear line of sight (no other obstructions but clothing and bedding), at a distance of 1.5 to 3 ft from the patient's chest. Optimal placement is at the bedside, to the side of the patient.
2. **Mounting options:** The Monitor may be placed at the bedside using the provided Stand. Alternatively, the Monitor may be wall-mounted at the bedside, using the provided Wall Mount, as shown in Figure 2. While installing the Wall Mount, make sure the bed is at maximum elevated height. Connect the Circadia Monitor to either the Stand or the Wall Mount using the magnetic connector.
3. **Wall mounting surface:** When using the Wall Mount, ensure the wall surface is structurally sound and capable of holding a screw and wall plug prior to installation. Avoid mounting on weak, damaged, or crumbly surfaces. Test by pressing firmly on the area and lightly tapping—if the surface flexes, cracks, or produces a hollow sound in areas not intended for anchors, choose a more suitable location.
4. **Positioning:** Ensure that:
 - a. The Monitor is pointed towards the patient's chest
 - b. The distance between the Monitor and the patient is approximately 1.5 - 3 ft
 - c. No objects obstruct the view
 - d. No electronic devices are placed directly near or in front of the Monitor
 - e. No other persons are present in front of or directly behind the Monitor
 - f. No moving mechanical objects (e.g. fans) are placed within the detection range (5 ft)
5. **Power:** Connect the Monitor to power using the supplied power adapter. When using the Wall Mount, also use the 90° USB-C connector, as shown in Figure 2: plug the angled adapter into the back of the Monitor and attach the power cable.
6. **Network Connectivity:** If previously configured, the Monitor will automatically connect to Wi-Fi.

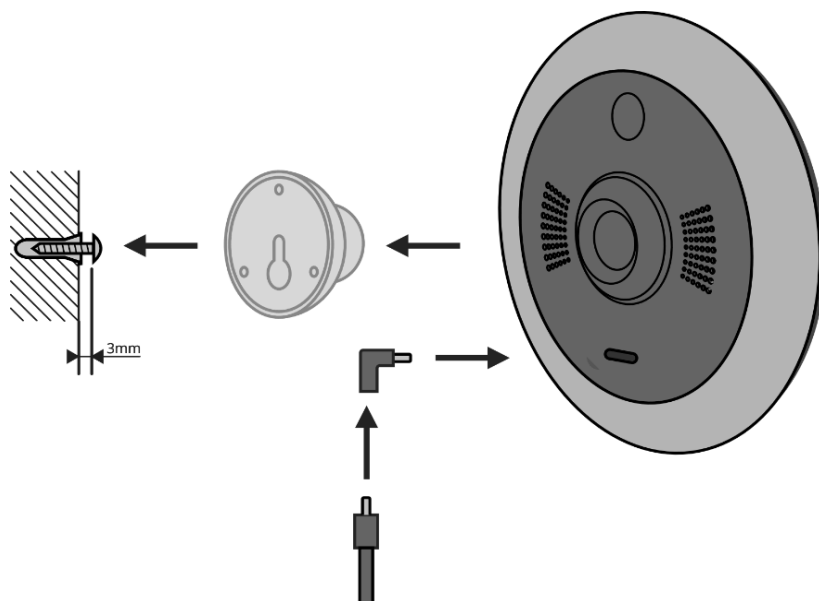


Figure 2: Wall Mount Set-Up

Initial download and use of the CIP App

1. Using an iOS mobile device, download and install the “Circadia CIP” (Developer: Circadia Technologies, Ltd.) from the device's app store. Launch the App.
2. Open the CIP App and login with your credentials. If you have not received log in details, reach out to Circadia Health Customer Support.
3. On your first login, a One-Time Password (OTP) will be sent to your registered mobile phone number. Enter the OTP in the CIP App.
4. Create a 4-digit PIN, for future quick sign-in. The 4-digit PIN is stored locally on your mobile device.
5. After successful login and PIN creation, the CIP App is ready for use.

Navigating the CIP App

After logging into the CIP App, use the tabs in the menu bar in the left of the screen to navigate to:

- **Clinical**, for an overview of all patients in your facility
- **Watchlist**, to view patients your have previously added to your list
- **Consents & Devices**, to view patient monitoring consent status and Monitor online status
- **Motion & Exits**, to view and configure motion and exit notifications

At the bottom of the menu bar, you will find:

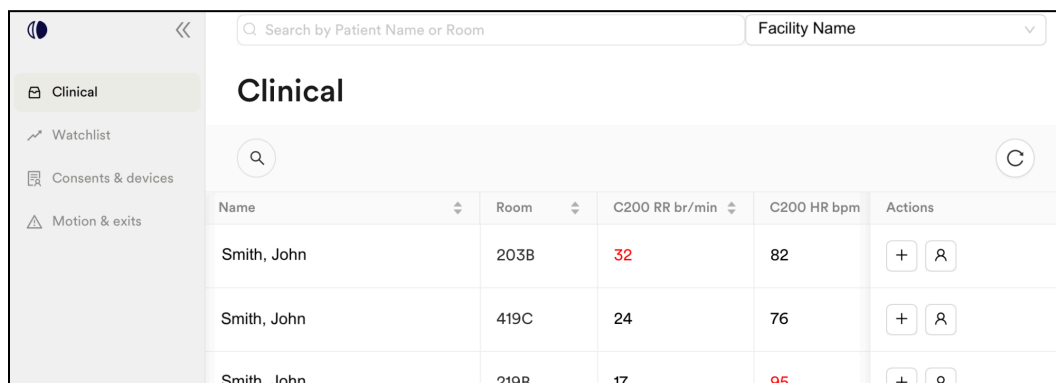
- **Settings**, to set your preferences or find more information
- **Help**, to find troubleshoot or reach out to Circadia Health Support directly

Alternatively, search for a patient by their name or room number in the top **Search Bar**.

Clinical Tab

Use the CIP App Clinical tab to:

- View all patient names and room numbers for your selected floor or unit, as shown in Figure 3
Note: Change the floors and units shown in the Clinical tab under Settings
- View a patient's last respiratory rate (RR) and heart rate (HR), displayed as an hourly average
- Search for a patient by their name or room number via the Search Bar at the top of the screen
- Tap the '+' icon to add the patient to your watchlist
- Tap on a patient's name or on 'View Profile' to open up their Patient Profile



The screenshot shows the 'Clinical' tab in the CIP App. At the top, there is a search bar labeled 'Search by Patient Name or Room' and a dropdown menu for 'Facility Name'. Below the search bar is a table with the following columns: Name, Room, C200 RR br/min, C200 HR bpm, and Actions. The table contains three rows of patient data. The first row shows 'Smith, John' in room '203B' with a respiratory rate of 32 and a heart rate of 82. The second row shows 'Smith, John' in room '419C' with a respiratory rate of 24 and a heart rate of 76. The third row shows 'Smith, John' in room '219B' with a respiratory rate of 17 and a heart rate of 95. Each row has a '+' icon and a person icon in the Actions column. On the left side of the screen, there is a sidebar with icons for 'Clinical', 'Watchlist', 'Consents & devices', and 'Motion & exits'.

Name	Room	C200 RR br/min	C200 HR bpm	Actions
Smith, John	203B	32	82	+ [Person Icon]
Smith, John	419C	24	76	+ [Person Icon]
Smith, John	219B	17	95	+ [Person Icon]

Figure 3: Clinical tab in the CIP App, showing respiratory rate (RR) and heart rate (HR) for all patients on the selected floor or unit.

Patient Profile

Navigate to Patient Profile by tapping the patient name in the Clinical tab. Use the Patient Profile to view details such as room number, date of birth, gender, and date of admission. Tap on the Patient Profile tabs to review Circadia Monitor data:

- **Vitals:**
 - View the patient's last respiratory rate (RR) and heart rate (HR), or review historical RR and HR data in the graphs, as shown in Figure 4
 - Choose between different historic time durations (1, 3, 5, or 30 days), to view recent minutely vital sign data, or hourly and daily average RR and HR data further in the past
 - A moving average line shows smoothed RR and HR data for ease of interpretation
- **Motion & Bed Exits:**
 - View the patient's Motion (average number of mobile minutes per hour), or Exits (average number of exits from the Monitor's detection range, per hour), as shown in Figure 5
 - Choose between different historic time durations (1 day, 3 days, 5 days, 30 days), to view average Motion or Exit data from different time periods
 - View a list of historic Motion and Exit notifications for the selected patient
 - View current Motion and Exit notification settings for the selected patient
 - Tap '+ Add New' to configure new Motion or Exit notification settings

For detailed instructions on the configuration of new motion or exit notifications, review the 'Motion & Exits' tab section of these Instructions.

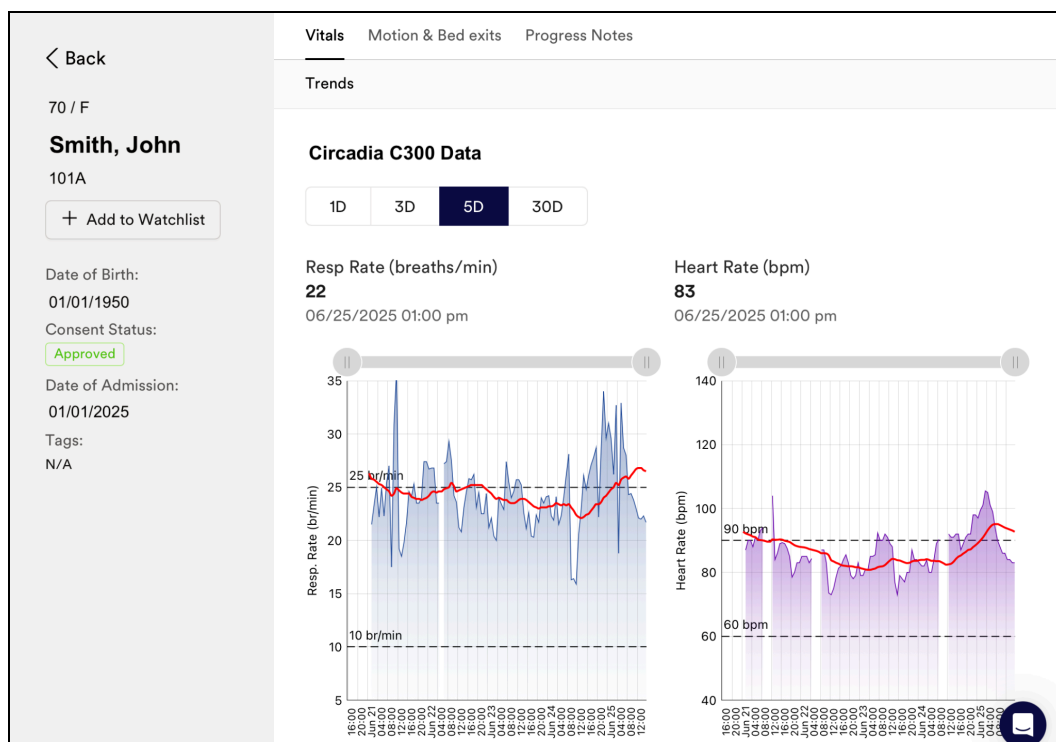


Figure 4: Patient Profile screen in the CIP App. The Vitals tab shows a patient's respiratory rate and heart rate, over the past five days (5D).

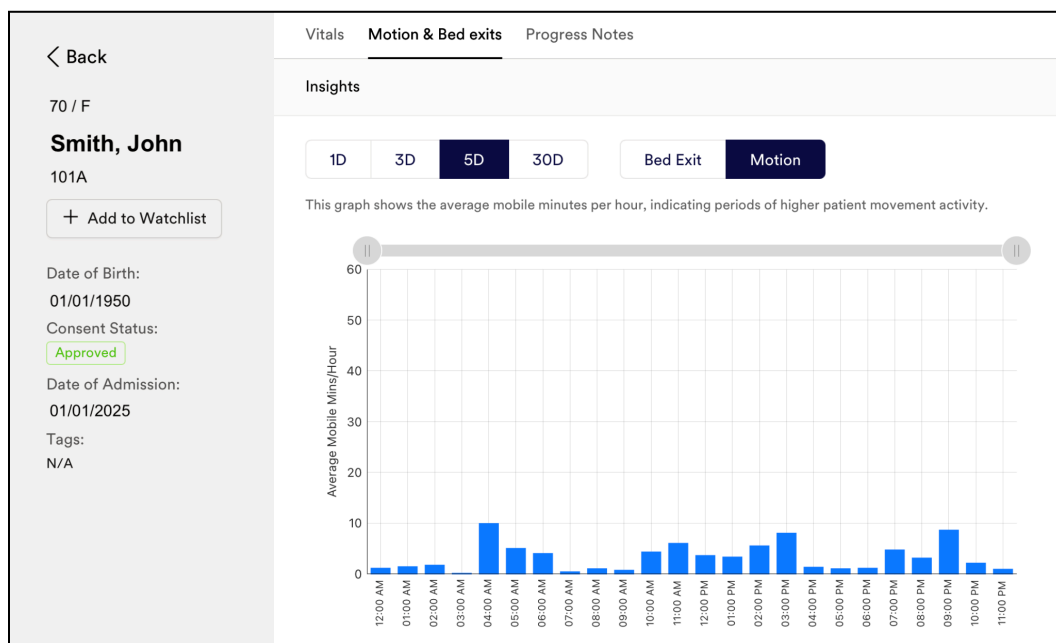


Figure 5: Patient Profile screen in the CIP App. The Motion & Bed Exits tab shows a patient's average number of exits per hour, over the past five days (5D).

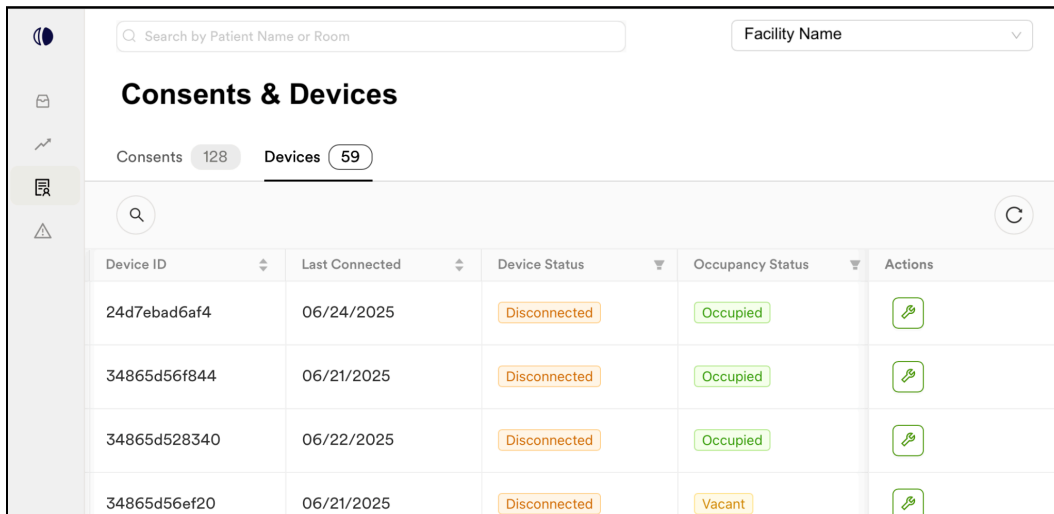
Watchlist Tab

The CIP App Watchlist tab offers identical functionality as the Clinical tab, but shows only patients that were manually added to your Watchlist. Add patients to your Watchlist from the Clinical tab. In Watchlist, tap the 'X' icon to remove a patient from your personal watchlist. You can view all patients from the Clinical tab.

Consents & Devices Tab

Use the Consents & Devices tab to:

- View the device ID of Circadia Monitors assigned to patient rooms, as shown in Figure 6
- View the connectivity status of each Circadia Monitor
- View the occupancy status of each bed equipped with a Circadia Monitor
- Report any issues such as missing Circadia Monitors, missing power adapters, or connectivity issues, directly to Support at Circadia Health
- View and manage consent status for all patients



Device ID	Last Connected	Device Status	Occupancy Status	Actions
24d7ebad6af4	06/24/2025	Disconnected	Occupied	
34865d56f844	06/21/2025	Disconnected	Occupied	
34865d528340	06/22/2025	Disconnected	Occupied	
34865d56ef20	06/21/2025	Disconnected	Vacant	

Figure 6: Consents & Devices tab in the CIP App. The Devices subtab shows all Circadia Monitors in your facility, their assigned room number, connectivity status, and occupancy status.

Motion & Exits Tab

Use the Motion & Exits tab to:

- View a list of historic Motion and Exit notifications for all patients on your floor / unit, in the Notifications subtab
Note: you will only receive notifications for patients in the floors / units you have set in 'Floor Selection', in the CIP App 'Settings'
- View, modify, or disable/enable current Motion and Exit notification settings for each patient in the Settings subtab, as shown in Figure 7
Note: Notification settings are applied across your facility, and other users of the CIP App may also receive the notification, depending on their floor / unit

- View the number of Exits detected per shift (Morning, Afternoon, Evening) for each patient, in the Facility Report subtab
- Tap '+ Add New' to configure new motion or exit notification settings

Configuring new Motion or Exit notification settings:

- To configure new Motion or Exit notification settings, tap '+ Add New' in the Motion & Exits Tab, in Patient Profile
- In the Notification Configuration screen, select the patient you want to configure notifications for
- You can view Exit and Motion data, in the same manner as in the Patient Profile
- To configure new notification settings (as shown in Figure 8):
 - Select whether or not you want to receive a Push Notification
 - Select whether or not you want a sound to ring
 - Select whether you want to receive a notification for an Exit, or for a High Motion event
 - Select the time period during which you would like to receive notifications. Choose from:
 - Day Time: 7AM - 3PM
 - Afternoon: 3PM - 11PM
 - Nocturnal: 11PM - 7AM
 - All Day: Midnight - Midnight
 - Custom: Choose the start and end time of the notification period
 - You can add multiple notification settings per patient at once, by selecting '+ Add More'
 - Delete notification settings by selecting 'Delete'
 - Save new notification settings by selecting 'Save'

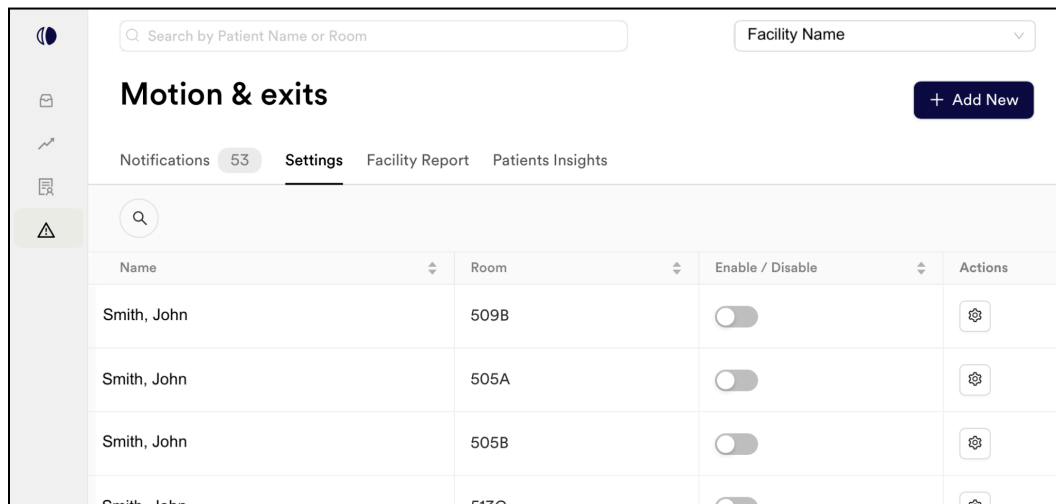


Figure 7: Motion & Exits tab in the CIP App. Use this tab to view notifications and configure notification settings, for exit events and high motion events, of all patients.

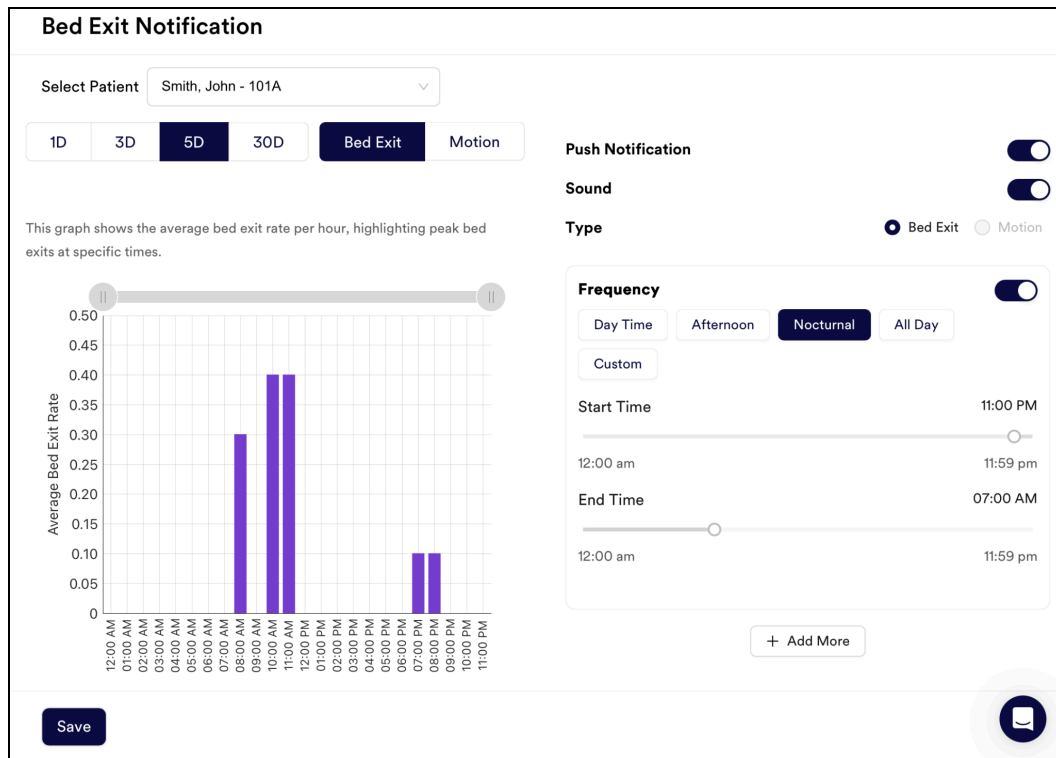


Figure 8: Notification configuration screen, under the Motion & Exits tab in the CIP App. Configure what type of notifications you want to receive, and at what times, for individual patients.

Settings

Use the Settings tab to:

- Change your CIP App password under 'User Profile'
- Change your CIP App PIN under 'User Profile'
- Select units/floors to select which patients you see in the Clinical tab, and to select for which patients you receive notifications
- Enable or disable all notifications under 'Notification Settings'
- View the CIP App version. Version history is maintained by Circadia Health.
- Select 'Support' to:
 - Provide Feedback on the C300 System
 - View Circadia Health's Support team contact details, or use the Live Chat feature to contact Support directly
 - View Circadia Health's Privacy Policy
 - View the Intended Use of the C300 System
 - Access additional resources and materials such as these Instructions for Use
- Tap 'Log Out' to log out of the CIP App.

Patient Monitoring and Data Review

Start monitoring

Whenever the Monitor is connected to power and connected to Wi-Fi with internet connection, it will continuously attempt to measure RR and HR data. Captured data are transmitted over Wi-Fi and stored in the Circadia Cloud service. Data can be reviewed from the CIP App. There is no need to start or stop recording. The Monitor will take up to 60 seconds to initialize and lock on to the patient, before it will capture RR and HR. When the Monitor cannot reliably measure RR or HR (for example during patient movement) it will not display a value in the CIP App and simply show "--" until data are collected. For graphs showing RR and HR data, gaps may be visible if no measurements could be obtained.

For successful RR and HR measurement, ensure that:

- The Monitor is positioned correctly as described in Section "Initial installation and configuration of the Circadia Monitor". Ensure the Monitor distance to the patient does not exceed 3 ft.
- The Patient holds still during critical spot measurements
- No person other than the patient is within 5 ft of the Monitor

If low numbers of RR data or HR data are obtained, ensure that the above criteria are met, and that no motion is present in the direct vicinity of the Monitor (5 ft). If RR or HR data are still not obtained with sufficient frequency, position the C300 Monitor nearer to the patient.

Review Respiratory and Heart Rate data

From the Settings tab, first select the units/floors for which you want to view patients. Next, from the Clinical tab, tap on the patient name to open their Patient Profile to begin review of RR and HR data.

Performing a Respiratory Rate and Heart Rate spot measurement

To perform a spot check measurement of RR and HR, first ensure the Monitor is positioned correctly. Next, ask the patient to lie still in bed and relax, and to try not to move or speak. RR and HR data will be displayed in the Patient Profile as soon as they are available. It may take up to several minutes until data are displayed.

Motion and Exit Data Review and Notifications

Motion and Exit data are monitored continuously. View a patient's activity data in Patient Profile.

The C300 System can notify healthcare professionals when high levels of motion are detected in the Monitor detection range (5 ft), and/or when exits from the detection range are detected. By default, activity notifications are disabled. To receive notifications, configure motion and or exit notifications for individual patients from their Patient Profile, or from the Motion & Exits tab.

Note that motion and exit notifications will be received by all users of the CIP App assigned to the same facility and unit/floor. You will only receive notifications for patients on the unit/floor you have selected. You can change your assigned floors/units in 'Settings'.

Stop monitoring

The Monitor is designed to remain powered on at all times, with patient assignment to a specific Monitor (bed) managed through the software. In normal operation, there is no need to switch off the device.

If you do need to turn the Monitor off, unplug the power adapter from the wall socket.

To resume monitoring, reconnect the power adapter to the wall socket. The Monitor will automatically power on, reconnect to Wi-Fi, and resume data collection without additional user action.

Troubleshooting

The Monitor shows as Disconnected in the CIP App

The Monitor must be connected to power, and must have an ongoing Wi-Fi network connection with internet connection to operate. If the Monitor shows as Disconnected, it is either not connected to power, or is not able to connect to the internet.

To troubleshoot, first ensure the Monitor is connected to power, by following the Installation Instructions. If LED lights on the front of the Monitor do not come on, the Monitor may be defective. The Monitor may not collect patient data. Contact Circadia Health Customer Support (support@circadia.health) for further troubleshooting or for replacement of the Monitor.

If the Monitor is connected to power, LED lights on the front of the Monitor will come on. If LED lights are green, the Monitor is connected to power and has an active internet connection. The Monitor will soon show as Connected in the CIP App.

If LED lights are showing, but a different color than green is shown, read the guidance below.

The Monitor displays a ring of constant red lights

If the Monitor is not able to connect to the internet, all LEDs show a constant red. This may occur when:

- Your Wi-Fi network is down
- There is an issue with your internet provider
- There is no Wi-Fi coverage in the room
- The Monitor was configured with incorrect Wi-Fi credentials

Please contact maintenance or IT at your facility to troubleshoot your internet connection and Wi-Fi network. If this does not solve the issue, please reach out to Circadia Health Customer Support for further instructions.

The Monitor displays a ring of constant blue lights

If the Monitor shows a solid ring of blue LEDs, the device is in Configuration Mode. Return the device to normal operating mode by pressing the button on the back of the Monitor once. If the Monitor's LEDs continue to display a solid blue ring, please reach out to Circadia Health Customer Support for further instructions.

Data from the Monitor has gaps, or no data is being collected

The Monitor will only record respiratory rate (RR) and heart rate (HR) when the user is near the device, at rest, and no other motion is present. If no RR or HR data are visible, and the Monitor is connected, it

simply has not been able to measure data. Data will appear once the intended use conditions are met, typically while the patient is resting in bed.

To improve the monitoring performance, ensure the Monitor is placed and oriented as per the instructions. Try placing the Monitor closer to the patient for better results. Ensure the Monitor has direct line-of-sight to the patient's chest. Ensure no other motion is present in the direct vicinity (5 ft) of the Monitor.

To ensure an HR or RR measurement (such as during a spot check measurement), position the Monitor as per the installation instructions, and instruct the patient to lie still in bed and relax. RR and HR data will be displayed typically in 1 - 2 minutes.

Data may have visible gaps due to interruptions in internet connection. Please note that the device must be connected to Wi-Fi with an active internet connection in order to operate. Please troubleshoot any Wi-Fi or internet connectivity issues with maintenance or IT at your facility. Please ensure minimum separation distance recommendations to other RF emitters are being met.

Expected service life

The expected service life of the Circadia Monitor is 4 years. Service life of the Monitor can be extended by 4 years through device servicing. Device servicing can only be performed by authorized Circadia personnel.

If, during its service life, a Monitor or power supply becomes visibly damaged, or malfunctions in any way, remove the affected device from use and contact Circadia Health Customer Support (support@circadia.health) for replacement or servicing.

System maintenance

No calibration or maintenance is required during the lifetime of the Circadia Monitor, other than the device servicing, performed by Circadia-authorized personnel.

Cleaning

1. Clean the Circadia Monitor before applying it to a new user. The Monitor can be disinfected using isopropyl alcohol and damp cloth.
2. The body of the Monitor is made from ABS plastic and aluminum. Do not use acetone or other plastic abrasives when cleaning the device.
3. Care must be taken when cleaning the back of the device: Do not spill any liquids into the speaker or sensor holes as this might lead to internal shorts and subsequent failure of the device.
4. Any visible damage to the casing should be reported to Circadia Health Customer Service for servicing (support@circadia.health).

Disposal

When disposing of the Circadia Monitor at the end of its expected service life, the appropriate laws need to be followed for proper disposal of printed circuit boards, plastics and metal parts.



The Circadia Monitor must not be disposed of together with common household waste.

Mobile Device Requirements

The CIP App operates on iOS mobile devices. iOS devices must run on iOS 14 or higher.

Wi-Fi network requirements

The System requires a stable wireless network connection to function, with at least 5 kbps of average bandwidth required per Monitor. The Monitor can be configured to Wi-Fi networks with one of the following security protocols: WEP, WPA, or WPA2.

Specifications

	Performance Specifications	Properties
Respiratory Rate (RR)	Mean accuracy rate (abs. error $\leq 5 \text{ min}^{-1}$)	100%
	Mean accuracy rate (abs. error $\leq 2 \text{ min}^{-1}$)	89%
	Respiratory rate detectable range	7 - 38 RPM
Heart Rate (HR)	Mean accuracy rate (abs. error $\leq 5 \text{ min}^{-1}$)	95%
	Mean accuracy rate (abs. error $\leq 2 \text{ min}^{-1}$)	89%
	Heart rate detectable range	40 - 140 BPM*
RR and HR performance were clinically tested by comparison against clinician-scored reference data: capnography and electrocardiography, respectively. To ensure accurate monitoring, the device must be positioned within 3 ft of the patient and used under no-motion conditions. *The C300 system will not output HR when the numerical difference between HR and RR is less than or equal to 10 min^{-1}		

RPM, Respirations per minute; BPM, Beats per minute;

Signal acquisition and RF transmitters	Properties
Sensor type	FMCW radar
Frequency of operation (Sensor)	58.0 - 61.5 GHz
Transmitted power (Sensor)	8 dBm
Sampling rate (Sensor)	16.667 Hz
Frequency of operation (Wi-Fi module)	2.41 - 2.49 GHz
Maximum transmitted power (Wi-Fi module)	20 dBm
Receiver sensitivity (@30.8% PER, Wi-Fi module)	-97 dBm
Supported protocols (Wi-Fi module)	IEEE 802.11 b/g/n
Recommended distance from the communication hub (Wi-Fi router)	20 m

Electrical Specifications	Properties
Supply voltage (Monitor)	5 V
Maximum current consumption (Monitor)	1000 mA
Power connector (Monitor)	USB-C

Supply voltage (Wall adapter)	100-240 V @50/60 Hz
Maximum current output (Wall adapter)	2000 mA

Physical characteristics	Properties
Dimensions (length x width x height; Monitor)	130 mm x 130 mm x 20 mm
Weight (Monitor)	150 g
Cable lead length	2.7 m

Environmental Specifications	Properties
Operating temperature	+10°C to +40°C
Operating humidity	10% to 70%
Operating altitude	Up to 2000 m
Operating atmospheric pressure	700 to 1060 hPa
Storage temperature	-20°C to +80°C
Storage humidity	10% to 70%
Storage atmospheric pressure	700 to 1060 hPa

Safety compliance	Standard	Equipment classification
Safety compliance (Power adapter)	IEC 60950-1	Mode of operation: Continuous operation
Safety compliance (Monitor)	IEC 60601-1	
EMC Compliance (Monitor)	IEC 60601-1-2	Degree of protection against liquid ingress: IP20
	AIM Standard 7351731 ANSI C63.27 AAMI TIR69 2017(R2020) Common Electromagnetic (EM) emitters - FDA Guidance 'EMC of Medical Devices' 2022	EMC classification: Class B, Group 1, Professional Healthcare Facility Environment

EMC emissions

Guidance and Manufacturer's Declaration - Electromagnetic emissions

The Circadia Monitor is intended for use in the electromagnetic environment specified below. The customer or the end user of the Monitor should assure it is used in such an environment.

Emissions test	Compliance	Guidance on intended electromagnetic environment
RF emissions CISPR 11	Group 1	The Monitor was tested for compliance for a Professional Healthcare Facility.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	CONFORMS	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	CONFORMS	

EMC immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Circadia Monitor is intended for use in the electromagnetic environment specified below. The customer or the end user of the Monitor should assure it is used in such an environment.

Immunity Test	IEC 60601-1-2:2014 test level	Compliance level	Guidance on intended electromagnetic environment
Electrostatic Discharge (ESD) IEC 61000-4-2	Air Discharge: $\pm 2, \pm 4, \pm 8$ & $\pm 15\text{kV}$ Contact Discharge: $\pm 8\text{kV}$	Air Discharge: $\pm 2, \pm 4, \pm 8$ & $\pm 15\text{kV}$ Contact Discharge: $\pm 8\text{kV}$	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	$\pm 2\text{kV}$	$\pm 2\text{kV}$	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 0.5\text{kV}$ & $\pm 1\text{kV}$ L-L	$\pm 0.5\text{kV}$ & $\pm 1\text{kV}$ L-L	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 UT = 100VAC & 240VAC	100% reduction in UT for 10ms 100% reduction in UT for 20ms 30% reduction in UT for 500ms 100% interruption in UT for 5s	100% reduction in UT for 10ms 100% reduction in UT for 20ms 30% reduction in UT for 500ms 100% interruption in UT for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field immunity IEC 61000-4-8	50 Hz, 30 A/m 60 Hz, 30 A/m	50 Hz, 30 A/m 60 Hz, 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

RF immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Circadia Monitor is intended for use in the electromagnetic environment specified below. The customer or the end user of the Monitor should assure it is used in such an environment.

Immunity test	IEC 60601-1-2: 2014 test level	Compliance level	Intended electromagnetic environment
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz 6Vrms ISM bands	3Vrms 150kHz to 80MHz 6Vrms ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = (3.5/V1) \sqrt{P} < 80\text{MHz}$ $d = (3.5/E1) \sqrt{P} 80\text{ MHz to } 800\text{ MHz}$ $d = (7.0/E1) \sqrt{P} 800\text{ MHz to } 2.7\text{ GHz}$ 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 ¹ , should be less than the compliance level in each frequency range. ² Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m, 80MHz to 2.7GHz	3 V/m, 80MHz to 2.7GHz	
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.			

¹Field strength 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 Circadia Monitor is used exceeds the applicable RF compliance level above, the Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Monitor.

²Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance

Recommended separation distances between portable and mobile RF communications equipment and Circadia Monitor.

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

Rated maximum output power P of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	V1 = 3Vrms 150kHz to 80MHz $d = 1.2 \sqrt{P}$	E1 = 3V/m, 80MHz to 800MHz $d = 1.2 \sqrt{P}$	E1 = 3V/m, 800MHz to 2.7GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Wireless Coexistence immunity

Standards: IEEE/ANSI C63.27-2021
AAMI TIR69 2017(R2020)

Summary of Test Results: In Compliance

Protocols that operate at the 2.4 GHz frequency, as well as devices in adjacent frequency bands:

Band (MHz)	Service	Modulation	Maximum Power (W)
2400-2483	WLAN	Pulse modulation: 217 Hz	2
	802.11 b/g/n		
	RFID 2450	Data rate: up to 3 Mbps	
	LTE band 7		

Test Results:

Coexistence test	Standard	Interference signal	Summary of test result
Wi-Fi coexistence	IEEE/ANSI C63.27	- Three routers with cell phones connected via Wi-Fi - One cell phone with Bluetooth turned on and searching for signal	The EUT was fully functional without any disruption due to the wireless interference.

Symbols and certifications

The following symbols and marking can be observed on the device or packaging. See below for their brief explanation.

	Consult instructions before use		For indoor use only
	The certified power adapter to be used with Circadia Monitor is classified as Double Insulated (Class II)		Keep dry
	Do not dispose together with common household waste. Take to a dedicated collection point at end-of-life for proper recycling.	5V $\overline{\text{---}}$ 1.0A	Use with a 5.0 V 1.0 A DC power supply
	Non-ionizing electromagnetic radiation		Atmospheric pressure limitation
	Manufacturer		Storage temperature range
	Date of manufacture		Storage humidity limitation
FCC	Federal Communications Commissions (FCC) licensing	CE	CE declaration of conformity
FCC ID:	Identification number of FCC registered components	UK CA	UK Conformity Assessed (UKCA) marking
R _x Only	Prescription use only	REF	Catalog number
	Device contains strong magnet	LOT	Batch code
	This device is known to pose hazards in all MR environments.	QTY	Quantity
IP20	Degrees of protection provided by enclosures (IP20)	SN	Serial number

Warranty

Circadia Health provides a limited warranty for the Circadia Monitor. Please refer to your initial service agreement, or contact Circadia Health Customer Service.

Contacting Customer Service

In case of any issues, feel free to contact us through one of the following channels:

- **Email:** support@circadia.health
- **Phone:** +1 800 985 5596 (Mon - Fri, 9 am - 5 pm; PST)

FCC Compliance



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

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

RF Exposure Information: This device complies with FCC RF exposure limits for general population/uncontrolled environments. A separation distance of at least 20 cm must be maintained between the Antenna and all persons.

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

FCC Identification:

FCC ID: 2BPIS-C300

Contains FCC ID: 2AC7Z-ESPS3WROOM1

Declaration of conformity



Circadia Technologies Ltd. hereby declares that the product "Circadia Contactless Cardiorespiratory Monitor" complies with the essential requirements of the following European Directives:

- 2014/30/EU (Electromagnetic Compatibility Directive, EMC)
- 2014/35/EU (Low Voltage Directive, LVD)

A written Declaration of Conformity is available upon request from Circadia Health.



The Circadia C300 System™



Manufactured by:

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Circadia Technologies, Ltd. licenses its technology to Circadia Health, Inc.

REF C300

R_x Only

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