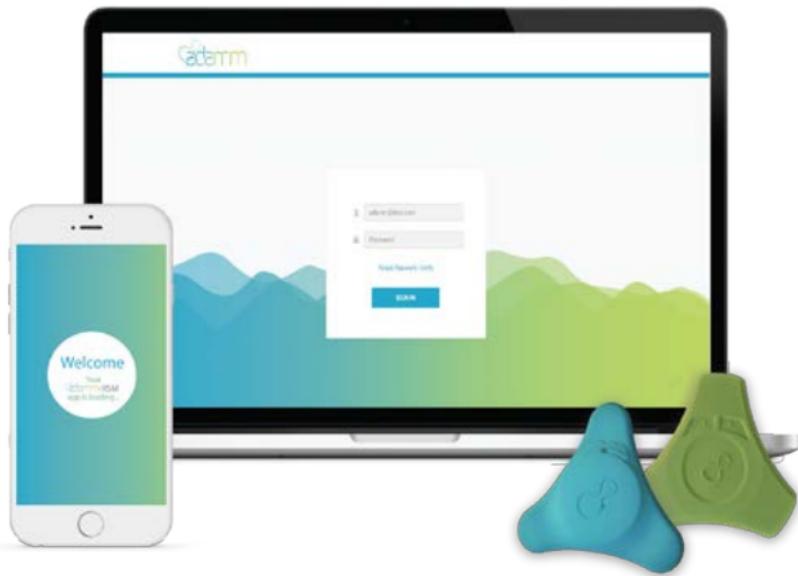




## User Manual



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# INTRODUCTION

## Intended Use

The ADAMM-RSM™ is a patch type wearable system that monitors various physiological characteristics specifically for studies, trials, research and health & wellness applications. Sensors in the wearable pick up data such as coughing, respiration, heartbeat, temperature and other parameters of interest. The data collected will be dependent on the product model and one or more parameters may not be available. The information is transmitted from the wearable via Bluetooth and Wi-Fi. Bluetooth, if provided, requires pairing with a smart device (e.g., a phone or a tablet), and additionally, the data service on such a device may be used to forward the information to a cloud-based database. If Wi-Fi is used, the wearable sends data to the cloud-based database directly and requires the use of a

Wi-Fi service, e.g., home Wi-Fi. The cloud data can be used to create new accounts, see the data in a larger format or set up data sharing. Additionally, the ADAMM-RSM™ wearable device may not be used to relied upon to indicate emergency or life-threatening situations or to indicate treatment.

## Concepts

The ADAMM-RSM™ system has three major components:

- ADAMM-RSM™ Wearable
- Mobile Device App (optional)
- Database and Webserver (optional)

## Limited Product Warranty

Health Care Originals, Inc. (HCO) warrants to the original purchaser that the ADAMM-RSM™ system shall be free from defects in materials and

workmanship when used normally in accordance with the guidelines contained herein for a period of ONE (1) YEAR from the date of delivery to the original purchaser. Please refer to the 'Warranty, Liabilities and Privacy' leaflet which may contain additional benefits based on a specific location that the product is sold and used and where such additional benefits are only applicable if the product was purchased from an authorized source for that location and is used in the specific location.

## **Remedies**

If such a defect arises and a return authorization is received by HCO within the applicable Warranty Period, HCO will, at its option and to the extent permitted by law, either (1) repair the Product at no charge, using new or refurbished replacement parts or (2) replace the Product with a new or refurbished Product. Any replacement Product will be warranted for the remainder of the original warranty period or ninety (90) days, whichever is longer, or for any additional period that may be required by applicable law. To the extent permitted

by law, these are the original purchaser's sole and exclusive remedies.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY HCO IN CONNECTION WITH THIS PRODUCT, AND HCO HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.

HCO SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS, EXPENSES OR DAMAGES.

## **How to Obtain Warranty Service**

To obtain warranty service, a return authorization must be obtained by calling the authorized distributor for the address of the inspection center

and the return shipping and handling fee. It is your responsibility to backup any data you may have stored in the Product. While every effort will be made to restore data, it is likely that it may be lost or reformatted during warranty service, and HCO will not be responsible for any such loss.

## **Exclusions and Limitations**

HCO does not warrant that the operation of the Product will be uninterrupted or error-free.

This Limited Product Warranty applies only to the original purchaser of the Product.

This warranty does not apply: (a) to consumable parts, such as batteries or protective coatings that are designed to diminish over time, unless failure has occurred due to a defect in materials or workmanship; (b) to cosmetic damage, including but not limited to scratches, dents and broken ports unless failure has occurred due to a defect in materials or workmanship; (c) to damage caused by use with a third party component or product

not supplied from HCO to the original purchaser of the Product; (d) to damage caused by accident, abuse, misuse, fire, liquid contact, earthquake or other external cause; (e) to damage caused by operating the Product outside these published guidelines; (f ) to defects caused by normal wear and tear or otherwise due to the normal aging of the product; (g) if any serial number has been removed or defaced from the Product; (h) if HCO received information that the product has been stolen or the user is unable to deactivate passcode-enabled or other security measures designed to prevent unauthorized access to the Product; or (i) operating the product (1) outside the permitted or intended uses described by HCO, (2) not in accordance with instructions provided by HCO, or (3) with improper voltage or power supply.

This warranty does not apply to a Product or part of a Product that has been serviced, altered, refurbished, covered, or modified by anyone other than HCO.

## Data, Privacy & 3rd Party Software

### Permitted Use and Restrictions

Third Party Technology. Any and all third-party technology provided, made available, linked to, or otherwise accessible through the Licensed Software (“**Third Party Technology**”) is provided solely as a convenience to you and is not under the control of HCO. HCO does not endorse, recommend, or otherwise make any representations or warranties with respect to any Third-Party Technology. HCO does not have any responsibility or liability to you for any Third-Party Technology which you access and you use at your own risk.

### Collection and Use of Patient Information

a. Privacy. You agree that you will not use the Licensed Software to transmit, access, or communicate any data or other information pertaining to the treatment of patients (“**Patient Information**”) that you do not have the right to

transmit, access, or communicate under all applicable federal and state privacy laws including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 as modified by the Health Information Technology for Economic and Clinical Health Act and all rules, regulations, and related laws and acts promulgated under and in connection therewith (collectively, "**Privacy Laws**").

b. Use of Patient Information by HCO. Patient Information may be stored by HCO and/or its licensees and service providers in connection with providing the Licensed Software and its related services. You grant HCO the perpetual, non-exclusive, worldwide, royalty-free irrevocable license to use, copy, print, display, reproduce, modify, publish, post, transmit, distribute, and preserve any Patient Information collected using the Licensed Software in accordance with all applicable Privacy Laws. Further, HCO may also use or disclose such data if required to do so by Law or if HCO determines that such use or disclosure is reasonably necessary to (1) comply with legal process, (2) enforce this Agreement, (3) respond to

claims that any such data violates the rights of others, or (4) protect the rights, property, or personal safety of HCO.

## **Representations & Warranties**

In addition to the other representations and warranties contained in this Agreement, you represent, warrant, and covenant to HCO the following:

a. You, your practice, and all goods and services provided in connection with your use of the Licensed Software will comply with all applicable Privacy Laws;

b. You are legally authorized in accordance with all applicable Privacy Laws to provide any and all Patient Information that you provide to the Licensed Software for all uses contemplated under this Agreement;

c. You are at least 18 years old and have full power, capacity, and authority to enter into this Agreement; this Agreement has

been duly and validly authorized, accepted, agreed to, and delivered by you (or your authorized representative) and constitutes your legal, valid, and binding obligation, enforceable against you in accordance with this Agreement; and you have full legal authority to bind Your Organization to this Agreement, if applicable; and

d. The performance by you of this Agreement and your use of the Licensed Software does not and will not conflict with or violate (1) any law, rule, regulation, order, judgment, decree, agreement, instrument, or obligation applicable to you, or (2) if you are an entity, any provision of your organizational or governing documents.

## **Disclaimer of Warranties**

THE LICENSED SOFTWARE AND ANY THIRD PARTY TECHNOLOGY ARE PROVIDED ON AN “AS IS” AND “AS AVAILABLE” BASIS WITHOUT WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT, AND IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR

PURPOSE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, HCO MAKES NO WARRANTY, REPRESENTATION, OR GUARANTY THAT: (1) THE LICENSED SOFTWARE MAY BE RELIED UPON FOR ANY REASON AS TO ANY INFORMATION OFFERED OR PROVIDED WITHIN OR THROUGH THE LICENSED SOFTWARE REGARDING TREATMENT OF MEDICAL CONDITIONS, ACTIONS, DIAGNOSES, PROCEDURES, APPLICATION OF MEDICATION, OR OTHER PROVISION OF HEALTHCARE SERVICES; (2) THAT THE USE OF THE LICENSED SOFTWARE WILL BE UNINTERRUPTED OR ERROR FREE; OR (3) THAT THE LICENSED SOFTWARE OR THIRD PARTY TECHNOLOGY WILL MEET YOURSPECIFIC REQUIREMENTS.

FURTHER, HCO ASSUMES NO LIABILITY FOR OR RELATING TO THE DELAY, FAILURE, INTERRUPTION, OR CORRUPTION OF ANY DATA OR OTHER INFORMATION TRANSMITTED IN CONNECTION WITH USE OF THE LICENSED SOFTWARE THAT IS REASONABLY DETERMINED TO BE BEYOND HCO'S CONTROL. YOUR USE OF THE LICENSED SOFTWARE, AND ANY THIRD-

PARTY TECHNOLOGY IS AT YOUR OWN RISK. TO THE EXTENT THAT HCO MAY NOT DISCLAIM ANY WARRANTY AS A MATTER OF APPLICABLE LAW, THE SCOPE AND DURATION OF SUCH WARRANTY WILL BE THE MINIMUM PERMITTED UNDER SUCH LAW.

## **Limitation of Liability**

Except as provided in this warranty and to the maximum extent permitted by applicable law, HCO is not responsible for direct, special, incidental, indirect or consequential damages resulting from a breach of express or implied warranty or condition, or under any other legal theory, including but not limited to loss of use; loss of revenue; loss of actual or anticipated profits (including loss of profits on contracts); loss of the use of money; loss of anticipated savings; loss of business; loss of opportunity; loss of goodwill; loss of reputation; loss of, damage to, compromise or corruption of data; or any indirect or consequential loss or damage howsoever caused including the replacement of equipment

and property, any costs of recovering, programming or reproducing any program or data stored in or used with the Product; or any failure to maintain the confidentiality of the information stored in the Product.

## General Warnings and Precautions

### Warning:

- No modification to the ADAMM-RSM™ wearable is permitted.
- Do not wear the ADAMM-RSM™ wearable without the consent of your healthcare provider if you have implanted defibrillators.
- Do not wear the ADAMM-RSM™ wearable without the consent of your healthcare provider if you have been implanted with any battery powered medical devices or are currently using any other wearable battery powered medical devices or intend to use such devices simultaneously with the use of ADAMM-RSM™.
- Do not wear the ADAMM-RSM™ wearable if you are pregnant or breast feeding.
- May be used in hospitals except for near active High Frequency (HF) SURGICAL EQUIPMENT and the

Radio Frequency (RF) shielded room of a Medical Electrical (ME) SYSTEM for magnetic resonance imaging, where the intensity of Electromagnetic (EM) DISTURBANCES is high.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ADAMM-RSM Equipment, including the charging cradle and permanently attached 0.75M USB cable and any other cable specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- If you are wearing an ADAMM-RSM™ wearable and plan on traveling on an airplane, discontinue use during the flight and resume use afterwards.
- All components of the ADAMM-RSM™

wearable should be kept out of the reach of children, pets, or anyone who may swallow the wearable, its components, or otherwise be at risk of being harmed by the components. If the wearable or any component is swallowed, seek emergency medical attention immediately.

- Do not bite, bend, puncture, break, or otherwise pierce the exterior housing of the wearable to expose electronics.
- Do not share your wearable with others to avoid damage to your wearable, potential harm to others, and/ or risk of contamination.
- Do not use a wearable if it shows outward signs of being damaged. Contact the distributor for options to have it repaired.
- Do not make any modifications to any components of the ADAMM-RSM™ System, unless otherwise instructed by Health Care Originals, Inc. and its approved affiliates.
- If connected to other devices/system through the same user interface (i.e. mobile phone), while connected to the ADAMM-RSM™ app via a Bluetooth or Wi-Fi connection, please note that performance of either or both Bluetooth or Wi-Fi

connected devices/system could potentially be affected.

- Please note that the ADAMM-RSM™ mobile apps may connect automatically to available internet service on a mobile device using its data service and counts in the data usage of the mobile device.
- Please note that the ADAMM-RSM™ wearable may connect automatically when authenticated to a Wi-Fi service and the use of this connection counts in the data usage of the Wi-Fi service.
- Do not use this wearable to obtain or broadcast notifications of life-threatening conditions.

**For Your Safety** The ADAMM-RSM equipment is compliant with the following (See section on test levels at end of manual, pg. 27 - 30):

- IEC 60601-1-2:2014Ed.4 Electromagnetic Compatibility
- IEC 60601-1:2005 Ed.3+A1;C1:2014 Medical Electrical Equipment
- FCC 47CFR PT 15 SPT B\*AEI Radiated and Spurious Emissions & Conducted Emissions
- EN 55032:2015 Radiated Emissions:

- CENELEC EN61000-3-2\*CEI Conducted Emissions
- CENELEC EN61000-3-3\*CEI Limitation of Voltage Changes, Fluctuations & Flicker
- EN 55024:2011+A1 ESD, EFT, Mag Field,
- ETSI EN 301 489-1:2017 Ed.V2.1.1 Electromagnetic Compatibility
- CAN/CSA-C22.2 No. 60601-1:14, Third Edition

**Caution:**

- The wearable is meant to be reusable for a period up to 1 year. If it becomes necessary to clean it, hand-wash gently in a mild soapy solution.
- The adhesive with the wearable is intended to reduce discomfort associated with harsher adhesives however, this increases the risk that the wearable may detach if placed under strain especially during rigorous movement.
- You may experience slight discomfort and/or itchiness as a result of wearing acrylic adhesive materials. If you experience discomfort or irritation, beyond mildly tolerated symptoms, please remove wearable immediately.
- For mitigation of the risk of discomfort or

irritation, use a new adhesive each time you put on the wearable, and wear it in a different place within the designated area every time you wear it.

- It is possible to experience mild soreness and/or redness after the removal of wearable. If you experience this affect, do not wear the in the same area.
- Adverse skin reactions may occur due to the nature of this product containing acrylic adhesives. Should adverse or allergic reactions occur and persist beyond two to three (2-3) days, stop using and contact the distributor for further consultation.
- While wearing the wearable if you feel that it is getting warm and/or hot, remove immediately and have it checked.
- Do not wear while swimming or immersed in water or while wearable is connected to an energy source (e.g. electrical outlet, power sources and backup batteries). This includes while charging the wearable.
- Wearable will not be damaged while showering or bathing if properly sealed and does not have signs of outward damage. Do not submerge in

more than 18 inches of water.

- Connectivity and data transmission of wearable may be interrupted while under water. It may be necessary to replace the adhesive if the wearable gets submerged under water while wearing. Thoroughly dry the wearable before replacing the adhesive.
- Handle the ADAMM-RSM™ system with care and according to the instructions in this manual.
- Incorrect handling, use of excessive force, excessive bending, or dropping of the ADAMM-RSM™ may cause malfunction and/or permanent damage to the wearable.
- Keep the wearable away from excessive heat exposure, as this may cause damage to the wearable.
- To ensure optimal performance of the ADAMM-RSM™ wearable, do not wear it while undergoing any medical imaging procedures such as MRI, CT, X-ray, PET, etc.
- If any component of your ADAMM-RSM™ fails to operate after attempting all suggested troubleshooting methods, contact your distributor for repair options.

- Do not dispose of the wearable in trash as it contains rechargeable batteries and other components that are recyclable but are not allowed in the landfill.

Please refer to the relevant section on disposal.

- If the wearable becomes unresponsive and unable to link to a network, check the troubleshooting guide.
- When traveling in a car, data collected by the wearable may not be transmitted to the server, due to the unavailability of Bluetooth or the specified Wi-Fi network.
- When traveling on an airplane, data collected by the wearable will not be transmitted to the server, due to the unavailability of Bluetooth or the specified Wi-Fi network.  
ADAMM-RSM™ is in flight safe mode provided that wireless communications are set to off and the wearable is not manually forced to sync. As setting the wireless communications to off may not be a feature of your particular wearable, it is advised to keep the wearable off once onboard an aircraft.

## General Information

- ADAMM-RSM™ is tested for electrical safety in accordance with IEC 60601-1-1.
- Electronic components are RoHS compliant.
- Wearable housing and adhesives are Class IV and medical grade respectively.
- Software failure, firmware failure, or battery failure has no adverse effect on the end user. Failure would cause loss of data collection and transmission. In the event this occurs, contact your distributor for repair options.

ADAMM-RSM™ is:

- IPX7, protected against water submersion.
- IPX4, protected against water spray.
- No installation or maintenance beyond battery charging and cleaning is required.
- The battery is rechargeable. It is to be recharged only via placement in the charger provided for this purpose.
- No cable or electrical connection is to be made

- with the wearable while it is being worn. The charging system uses USB power for charging.
- The wearable comes with a charging cradle and a built-in USB Type A cable for connection to a USB source. USB source should be rated for 500mA or higher and accommodate USB Type A male connection.
- The ADAMM-RSM™ wearable should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ADAMM-RSM™ wearable should be observed to verify normal operation in the configuration in which it will be used.
- ADAMM-RSM contains the following radios:
  - Wi-Fi operating to 802.11b/g/n Standard on 2.4GHz Band
  - Bluetooth built to 4.2 BR/EDR/LE Standards and operating in LE mode on 2.4GHz Band
- The MAC addresses of both radios are printed on the packaging and retrievable via a USB data connection with a PC.

## Special Attention

- *While wearing the wearable if you feel that it is getting warm and/or hot, remove immediately and have it checked.*
- *Always wear the wearable so that it can be removed unassisted very quickly.*

## GENERAL DESCRIPTION

### ADAMM-RSM™ Wearable\*

The heart of the ADAMM-RSM™ system is the patch-type wearable. The soft, semi-flexible wearable is designed to be worn comfortably on the front, back, or side of the upper torso. The wearable is a low power computer with sensors and communication peripherals. Using skin-safe peel-and-stick double-sided adhesive, it attaches to the user's body on the upper torso.

The sensors inside the wearable gather several types of raw data and the wearable then processes that data to determine respiration, activity level, heart rate, skin temperature, and abnormal breath events (including cough and wheeze). One or more of these may not be available depending on product model. The wearable includes two different communication avenues - Wi-Fi and Bluetooth Low Energy (BLE) with the mobile app.



*ADAMM-RSM™ (Model A)*

If activated for this application, you can record limited voice memos related to changes, feelings, behaviors – anything you might notice and want to record.

The wearable includes a rechargeable battery and comes with a USB charging station which requires USB power supply with Type A port. The wearable remains active when placed in the charging station and will continue to monitor you for coughing only while charging.

## **Wearable Functionality While Charging**

- When the wearable is placed in the charging cradle, it remains active and can detect coughing.
- If it is being charged at night, the charging cradle should be placed at or near the same level as the participant's head to best use this feature. The charging indicator light (see page 14) should be facing the participant. Do not place on the bed or in such a manner that participant can come into contact with it while asleep and damage themselves or re-orient the wearable.
- If it is being charged in a location where other persons are present, false readings (false positives) may develop should they be the ones coughing (cough false positives due to others coughing occurs in this use case only).
- The indicator lights do not function when charging while powered off – always remember to power ON for charging and always press Wi-Fi sync button at the start of charging.
- Wearable will automatically switch to battery operation if the charger is unplugged while the wearable is ON.

## **Wearable Functionality When Not Being Worn**

The wearable continues to function for a period of time if left powered on but not mounted on the body. During this time incorrect data may be collected. It is advised to wear the wearable as soon as it is removed from the charging cradle.

# PARTICIPANT GUIDE

## Key Features of ADAMM-RSM™ Wearable (Model A)



1 "ON" Check Button

2 Power Button

3 Sync Button

4 Indicator Light A

5 Indicator Light B

6 Charging Contacts

7 Indicator Light C

Note: wearable colors may appear different in print from actual wearable.

## “ON” Check Button

1

- ADAMM-RSM™ wearable does not have an indicator light to show that it is on. Therefore a button has been provided for this purpose
- “ON” Check Button 1 is located on the top left of the wearable.
- To use this check, briefly press and let go of the button. If a vibration is felt shortly afterwards, then the wearable is ON. If no vibration is felt, then the wearable may be OFF.

## Power Button

2

- Power button is located on the top right of the wearable and can be felt when pressing down on the device.
- This button can be used for powering ON, powering OFF and restarting the ADAMM-RSM™ wearable:  
**1) Powering ON:** Press the “Power button” 2 for 1 second and observe “indicator light B” 5 blinking BLUE followed by GREEN color within 20-25 seconds. If this does not happen, try again by pressing the button for 1 second. If the issue still

persists, follow the steps below for restarting the wearable.

**2) Powering OFF:** Press and hold down the “Power button” **2** for 8 seconds and observe a short duration vibration. The vibration indicates the shutdown cycle has commenced. The wearable takes 40-50 seconds to shut down and power OFF completely, so it is important not to press any other buttons during this time.

**3) Resetting:** Keep the “power button” **2** pressed continuously for 20 seconds, disregarding the vibration, to allow the wearable to restart. After this, follow “Powering ON” steps to power ON the wearable. Restarting can only be done if your device is already powered ON.

### Wi-Fi & Bluetooth (BTLE) Sync Button

- Wi-Fi and Bluetooth sync button **3** is located in the center of the wearable. Simply press in this area and feel the button action.
- Press this button to enable Wi-Fi or BTLE on ADAMM-RSM™ wearable. During this time the “indicator light A” **4** will flash BLUE in color.
- Wi-Fi sync is only to be used while the wearable is

powered ON and being charged at the same time.  
BTLE may be used at any time.

NOTE: A Wi-Fi hotspot device is available as an option.

During Wi-Fi syncing, the wearable connects to this hotspot to send data wirelessly for storage.

## Indicator Lights

The system uses LED indicator lights to indicate the following:

- **Indicator Light A** 

1. Quick Flashing Blue: Wi-Fi Sync in progress
2. Solid BLUE: Wi-Fi connection established.

- **Indicator Light B** 

1. Slow Flashing RED: Low Battery – please charge wearable.
2. Flashing BLUE for short duration: Boot-up/Power ON – no action required.
3. Solid RED: Self-test failed – if restarting or resetting the wearable does not change the Self-test failed, check the troubleshooting guide for remedies. If none works, please

- contact your distributor for repair options.
4. GREEN for short duration: Self-test successfully passed – no action required.
- 
- **Indicator Light C** 
    1. Flashing RED: Wearable is connected to live USB supply and charging – leave charging until fully charged.
    2. Solid RED: Wearable charging is completed and charger is still connected – only disconnect charger if solid red.

## **Wearable Charging**

- Reveal the charging connections by removing the adhesive completely from the back of the wearable.
- Place the wearable in the charging cradle, close it and secure with strap. Follow pictures below on placing wearable in cradle to ensure that contacts on the back of the wearable match the contacts in the charging cradle.
- The indicator light, “indicator light C” will light up once

a live USB source is connected to the cradle and the wearable is powered on:

- RED flashing - indicates wearable is charging
- Steady RED - indicates wearable is fully charged
- The wearable contains rechargeable batteries and should be charged for 10 to 12 hours before first usage. The charging time is typically 3 to 4 hours.
- Charging of the wearable is done via a charging cradle that uses USB power. A USB wall adapter has been provided – connect the charging cable to it and connect the wall adapter to an electrical outlet.
- Wearable should NEVER be worn while charging.



Place wearable firmly on the inside cover so that the contacts on the wearable and cradle face each other as shown. Then close the cradle down on the cover and secure the cover with the strap.

The cradle may have an integral cable as shown below or a Micro USB jack.



When the wearable is in the cradle, it can stand upright.

## Getting Started

- Upon powering-up from off state, the wearable will go through a Self-test during which time “indicator light B” will flash BLUE. Once the test is successfully completed, the “indicator light 2” will turn GREEN for a few seconds.
- If the Self-test fails, “indicator light B” will stay solid RED light. In this case, please Restart and or Reset the wearable to execute a self-test again. If restarting or resetting the wearable does not change the Self-Test failed, then contact your distributor for repair options.

## Using the Wearable

- The ADAMM-RSM™ wearable is designed to be worn anywhere on the upper torso, in the area below the base of the neck and the top of the stomach. It can be worn on the front, side, or back of the body. Observe the following guidelines when applying the wearable to your body.

- Each time the wearable is being used, it is recommended to wear it on a different location within the prescribed area to reduce the likelihood of skin irritation.
- Skin surface where the wearable is to be applied should be clean and free of any lotions, creams, powders, or any other substances that could interfere with sticking the wearable on.
- Position the wearable to minimize the amount of body hair under the sensor. Excessive body hair may need to be shaved and or trimmed before placing the wearable to allow for close contact with the skin.
- The wearable should be positioned so that it minimizes the interference with the participant's lifestyle.
- When wearing during sleep – choose a comfortable position within the defined area to attach the wearable.

# **INSTALLING AND USING THE MOBILE DEVICE APP**

**Apps change over time so screen layout may be different!**

## **Getting Started**

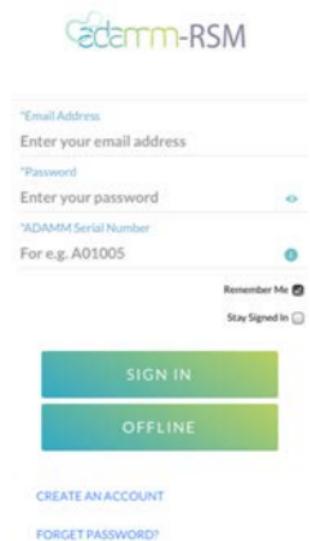
1. Locate and install the ADAMM-RSM™ mobile device app from the relevant app store for your mobile device – search for ‘HCO RSM’ if your search is not yielding the required result. Pay particular attention to the app version, as there may be more than one app for this wearable. App may not be visible or function with incompatible devices.

2. Launch the App. This is how it will show as the app loads.



- 3.** Navigate to the ‘Login’ screen and select ‘Create an Account/ Registration’

*If the account has already been created, this screen is used to login to the app in which case the following steps 4 & 5 would not be required. Please have the wearable serial number handy as the first six (6) characters are required.*



4. The screen that appears next is the ‘Registration’ screen. Please scroll down, filling in the information, and then select ‘Register’. Note: this screen requires the Wearable Serial Number to be known before registration can be completed. The entire serial number is required. Depending on the information provided by the Administrator, placeholder information may be entered here instead of personal data however, the wearable serial number is important.

The screenshot shows a mobile application interface for 'Adamm-RSM'. At the top left is a back arrow labeled 'Back'. The title 'Adamm-RSM' is centered above a series of input fields. The first field is labeled 'Alias' with the placeholder 'Enter your Alias'. The second field is labeled 'Email Address' with the placeholder 'Enter your email address'. The third field is labeled 'Password' with the placeholder 'Enter your password'. The fourth field is labeled 'Confirm Password' with the placeholder 'Re-enter your password'. The fifth field is labeled 'ADAMM Serial Number' with the placeholder 'For e.g. A0101P0101000000001'. Below these fields is a date input field labeled 'Setup Date (YYYY-MM-DD)' containing the value '2021-06-29'. At the bottom of the form is a link 'READ THE PRIVACY POLICY' and a checkbox labeled 'I agree with the Privacy Policy'. A large green button at the bottom right is labeled 'Register'.

5. After selecting 'Register' the data is displayed again as the 'User Profile' screen for double checking. If it is correct, select 'Save'. The 'User Profile' screen may be selected at any time to update information and save it.

The image displays two screenshots of a mobile application's 'User Profile' screen. The top screenshot shows the initial data entry screen with fields for First Name (Sarah), Last Name (Martin), E-mail address (s.martin@example.com), Device Serial Number (A0101P010100000004), Date of Birth (1989-12-22), Gender (Female), and Phone Number (Enter your phone number). The bottom screenshot shows the same screen after data entry, with the 'Gender' field now populated with 'Female' and the 'Phone Number' field showing 'Enter your phone number'. A large green 'Save' button is visible at the bottom of the screen.

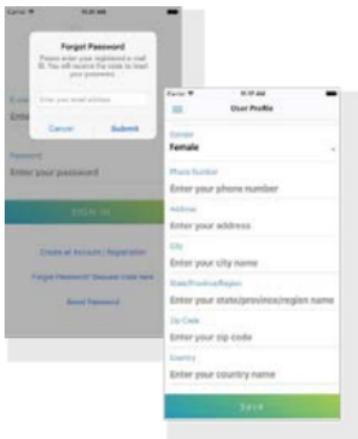
Field	Value
First Name	Sarah
Last Name	Martin
E-mail address	s.martin@example.com
Device Serial Number	A0101P010100000004
Date of Birth (YYYY-MM-DD)	1989-12-22
Gender	Female
Phone Number	Enter your phone number
Address	Enter your address
City	Enter your city name
State/Province/Region	Enter your state/province/region name
Zip Code	Enter your zip code
Country	Enter your country name

Carrier 11:16 AM User Profile  
Carrier 11:17 AM User Profile

Save

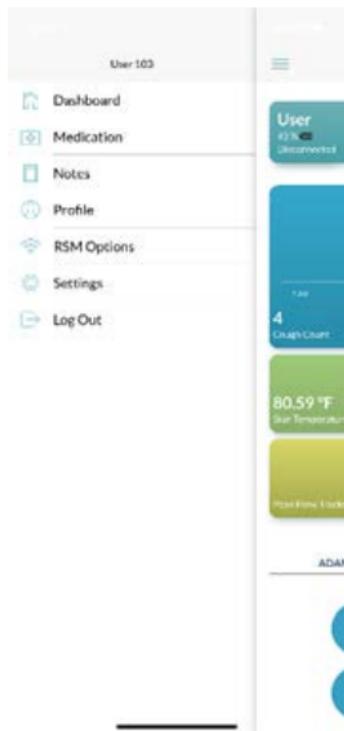
## Password Reset

Password Reset is an option available on the ‘Login’ screen. It requires that the registered email address and the first six (6) characters of the serial number be entered in the ‘Forgot Password’ screen to receive a code via that email which must be entered on the ‘Reset Password’ screen. Access to the original email that was used to setup the account is required. The password cannot be changed without account access. In the event of loss of account access, the entire account may need to be cancelled with loss of data.



## Menu

The menu is available either using the top left icon or if available, using the left screen feature.



## Dashboard

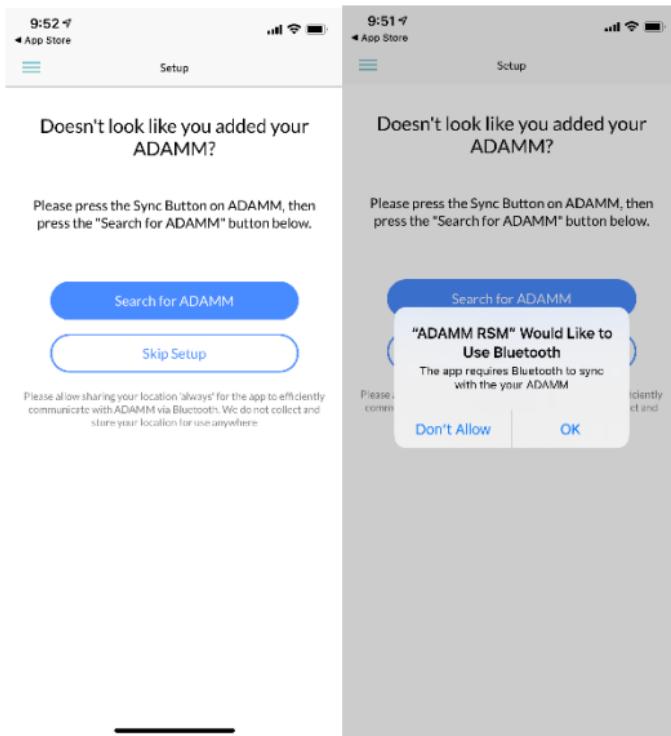
The Dashboard shows the information available at the last sync. Please sync with the wearable to get the most recent information, including the most recent battery capacity left. The Dashboard screen scrolls down for additional information.



- Touch a symptom box to expand out the data.
- Depending on product model, this information may not be updated automatically and some of this information may not be updated even after syncing.
- *iOS devices are never updated automatically.*

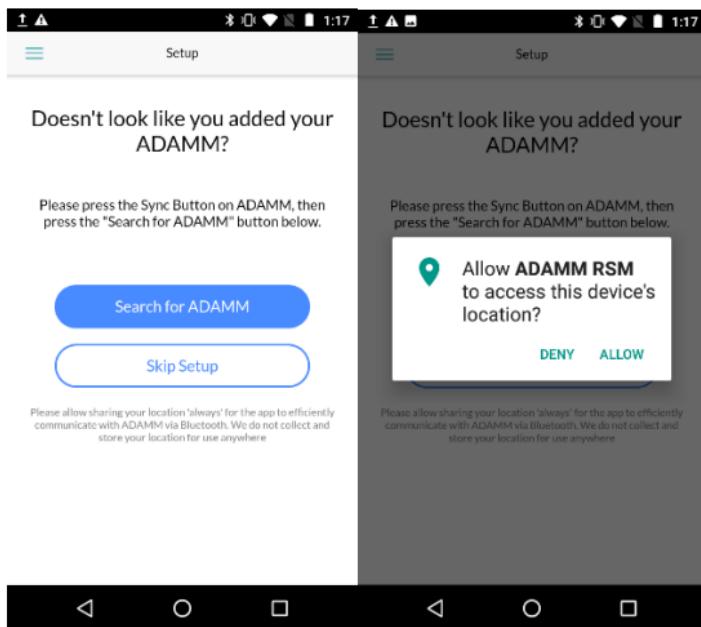
## Search for ADAMM (IOS)

Click Search for ADAMM. On the ADAMM device, press top left for RSM model A to search. Click allow when the app asks for Bluetooth permission.



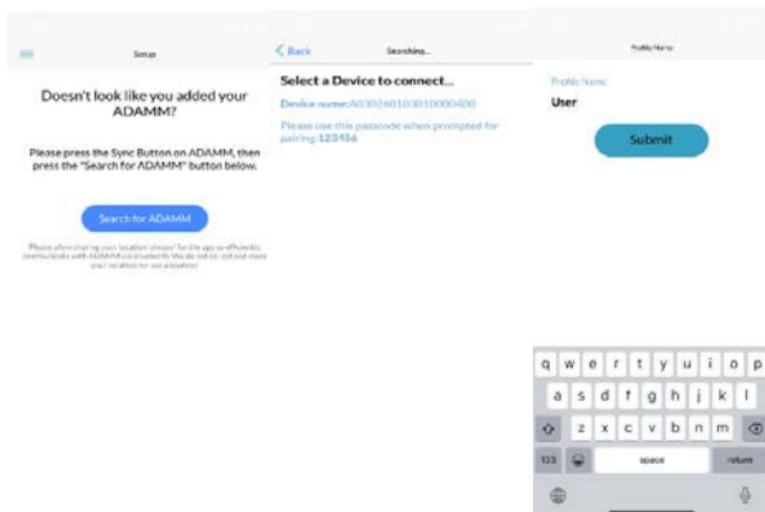
## Search for ADAMM (Android)

Click Search for ADAMM. On the ADAMM device, press top left for RSM model A to search. Click allow when the app asks for location permission.



## Syncing the Wearable with the Mobile Device

If syncing has not been performed before, upon first sync, a prompt to search for a wearable, as well as enter a customized name for the wearable appears. Please follow additional phone instructions to switch on Bluetooth and pairing with a wearable.

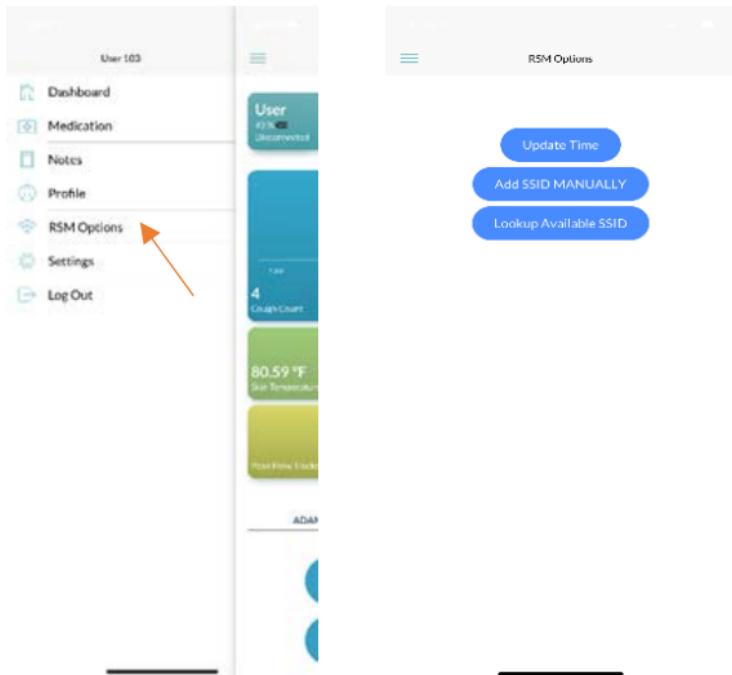


If the wearable has been synced before, follow the instructions on the Dashboard screen to re-sync with the wearable. Selecting ‘Sync Device’ shows the ‘Syncing Device’ graphic momentarily and then switches to the ‘Searching’ screen where if a wearable is found, it is shown with the prompt to select that wearable.



## Wi-Fi Setup

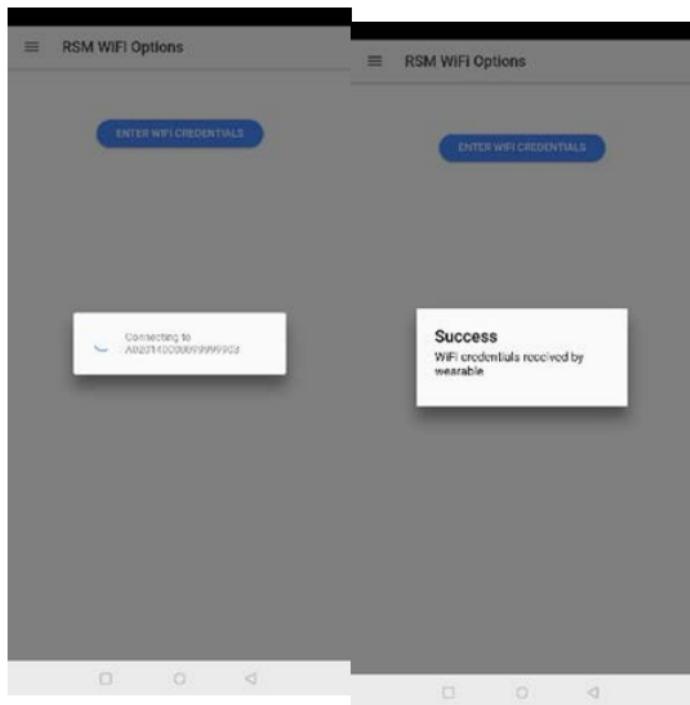
1. Go to the Menu and select 'RSM Options' to switch to the 'Add SSID MANUALLY', 'Lookup Available SSID' and 'Update Time' page.



2. Enter the SSID or Wi-Fi name followed by the Wi-Fi password. Select 'Next' to continue. A new screen pops up asking to sync the wearable i.e. press the manual sync button on the wearable to start the Bluetooth process. After pressing the sync button to initiate syncing, select submit on the screen.



3. If the syncing is successful a Success message is displayed.



4. In the event that the wearable was unable to be updated with the Wi-Fi information, a Connection Error will be displayed. Follow the instructions on the screen and repeat the process.



## Wearable Adhering

Follow these steps to apply the wearable to your body\*:

1. Determine where on your body you want to apply the wearable. The wearable can be applied anywhere on the upper torso (front or back).
2. Make sure the skin surface where the wearable will be applied is clean and free from any lotions, powders, or other substances that could interfere with the adhesive.
3. Select your adhesive pad and locate the side with the white liner. The other side is an oversized clear plastic liner that is easy to hold and prevents the adhesive from deforming.



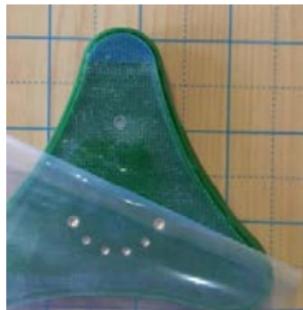
4. Peel the white liner away from the adhesive pad. This exposes the adhesive that is meant to stick to the wearable. Use the large clear spaces of the plastic liner for holding.



5. Hold the clear liner and align the adhesive pad with the edges of the wearable, and press the adhesive pad into place, making sure it aligns with the profile of the wearable.



6. Peel the clear liner off the other side of the wearable. This exposes the adhesive that is meant to stick to your skin. Press the wearable firmly onto your skin in the desired location.



7. Make sure the wearable is securely in place and will be comfortable in that location.
8. The adhesive is designed for single use and one time application. Therefore, repositioning it reduces the stickiness of it.

## **Wearable Removal and Cleaning**

Follow these steps to remove the wearable from your body:

1. Gently peel the wearable away from your skin.
2. In some instances, the wearable may come off leaving the adhesive on the skin – gently peel the adhesive away.
3. Remove the adhesive from the wearable by grasping the blue tab and pulling away from wearable.
4. If necessary, clean the wearable with mild soap and water.

## TROUBLESHOOTING

The following are simple troubleshooting guides. Most issues are resolved by performing a hard reset as outlined on page30 under the Power Button section.

RedflashingLED indicator light 7 nevergoessolid red when charging for more than 3 hours:

- Shut down, restart wearable and see if it goes solid red after ½ hour.
- Ensure the charger is properly connected to the power source.

The adhesive does notadhereproperly—thewearablekeeps falling off:

- Ensure the correct side of the adhesive is adhered to the wearable and your skin.
- Excessive activity or heavy clothing could cause the wearable to fall off.
- Another type of adhesive may be best suited for your activity level.

**Low Battery indication:**

- If the wearable starts vibrating on its own, it is indicating low battery.
- Please charge the wearable until full capacity.

## **Guidance and Manufacturer's Declaration**

ADAMM-RSM Monitoring Wearable  
Information for accompanying documents in the scope of IEC60601-1-2:2014

Model: ADAMM-RSM without 5V DC USB Power Supply

### **Important information regarding Electro Magnetic Compatibility (EMC)**

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical

devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2:2014 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by Health Care Originals (HCO) conform to this IEC60601-1-2:2014 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by HCO, with the exception of cables sold by HCO as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent

or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.

- Refer to further guidance below regarding the EMC environment in which the device should be used.
- The MEDICAL ELECTRICAL EQUIPMENT ADAMM-RSM needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this documentations.
- The Essential Performance of ADAMM-RSM is to collect coughing, accelerometer data, audio data, calculating respiration and heart rate, skin temperature and using the memory function.

The ADAMM-RSM equipment may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>		
ADAMM-RSM is intended for use in the electromagnetic environment specified below. The customer or the user of ADAMM-RSM should assure that it is used in such environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF Emissions CISPR 11	Group 1	ADAMM-RSM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	ADAMM-RSM 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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
ADAMM-RSM is intended for use in the electromagnetic environment specified below. The customer or the user of ADAMM-RSM should assure that it is used in such environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floor 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 for power supply lines	±2kV for power supply lines	Mains power quality for a 5VDC USB power supply for charging and powering ADAMM-RSM should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	Line to N ±1kV	Line to N ±1kV	Mains power quality for a 5VDC USB power supply for charging and powering ADAMM-RSM should be that of a typical commercial and/or hospital environment.

<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic environment - guidance</b>
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% $U_T$ for 0.5 and 1 cycle	0% $U_T$ for 0.5 and 1 cycle	Mains power quality for a 5VDC USB power supply for charging and powering ADAMM-RSM should be that of a typical commercial and/or hospital environment.
	70% $U_T$ for 30 cycles	70% $U_T$ for 30 cycles	
	70% $U_T$ for 25 cycles	70% $U_T$ for 25 cycles	
	30% $U_T$ for 25 cycles	30% $U_T$ for 25 cycles	
	0% $U_T$ for 300 cycles	0% $U_T$ for 300 cycles	
Power frequency (50/60 Hz) & Battery magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note:  $U_T$  is the A.C. mains voltage prior to application of the test level.

<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
ADAMM-RSM is intended for use in the electromagnetic environment specified below. The customer or the user of the ADAMM-RSM should assure that it is used in such environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance Level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	10 Vrms; $U_T$ 230VAC 50Hz 10 Vrms $U_T$ 230VAC 50Hz: ISM Bands	10 Vrms; $U_T$ 230VAC 50Hz 10 Vrms $U_T$ 230VAC 50Hz: ISM Bands	Portable and mobile RF communications equipment should be used no closer to any part of ADAMM-RSM, than 30cm
Radiated RF IEC 61000-4-3	10 V/m; 80-1000 MHz 3 V/m; 1000-6000 MHz	10 V/m; 80-1000 MHz 3 V/m ; 1000-6000 MHz	

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

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

- Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 ADAMM-RSM is used exceeds the applicable RF compliance level above, ADAMM-RSM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating ADAMM-RSM.
- Over the frequency range of the ISM Bands, field strengths should be less than 10 V/m.

## CONTACT INFORMATION

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HCO11007-A-0-P