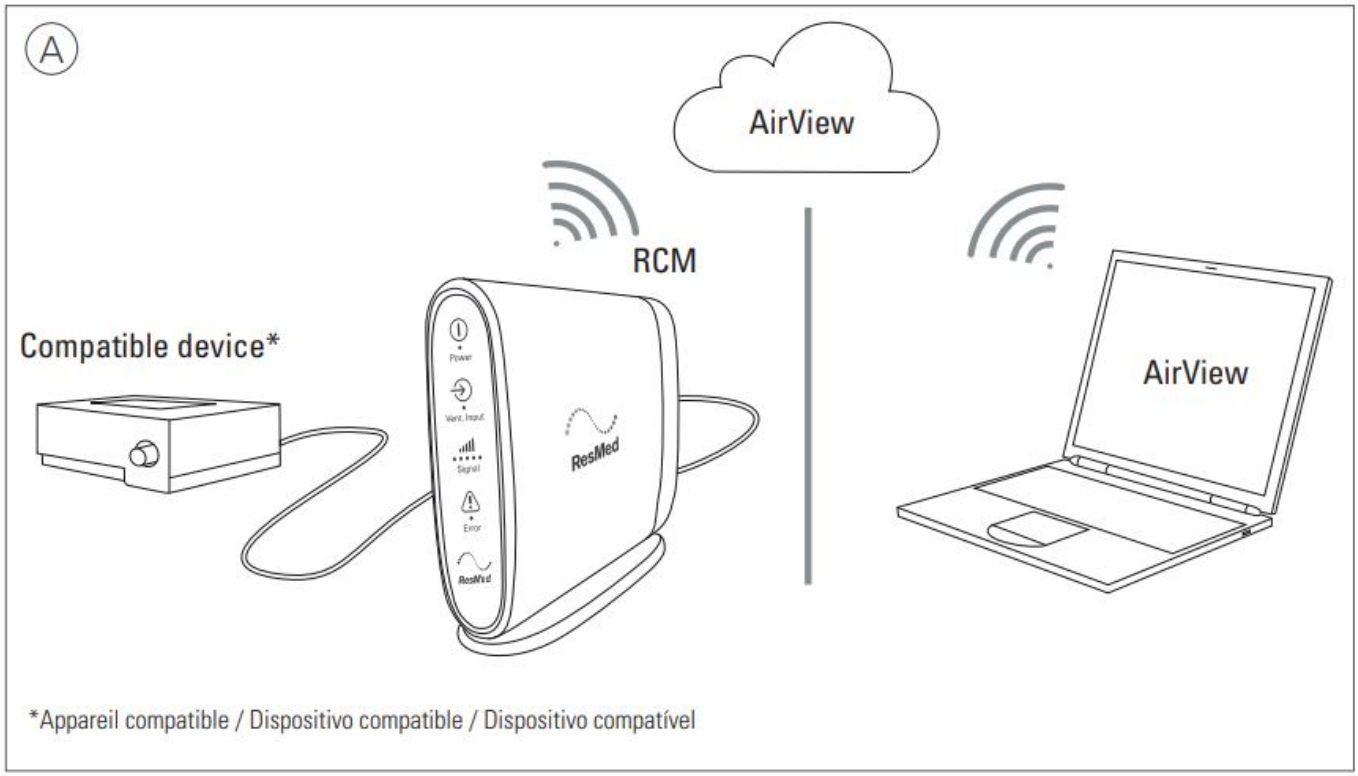
ResMed RCM1 Connectivity Module for Ventilators User Guide

Contents

ResMed RCM1 Connectivity Module for Ventilators

Introduction

Refer to illustration



ResMed Connectivity Module (RCM) provides cellular connection between a compatible ResMed ventilation device and the ResMed AirView™ system.
RCM sends therapy and device data recorded in the ventilation device to the cloud-based AirView system once a day from home, wirelessly and automatically, to assist the remote display of patient data.
RCM also sends data to AirView on demand when requested via AirView (eg, for remote display and troubleshooting).

CAUTION

In the US, Federal law restricts this device to sale by or on the order of a physician.

Compatible devices
RCM is compatible with the following ventilation devices:

- Astral™ 100/150
- Stellar™ 100/150.

Intended use
RCM is intended to be used in the home environment, for the collection and transmission of respiratory data to AirView. RCM will not control any clinical devices, nor provide interpretation of data.
RCM is not intended for use on an aircraft.

General warnings and cautions

The following are general warnings and cautions. Specific warnings, cautions and notes appear with the relevant instructions in the guide.

WARNING

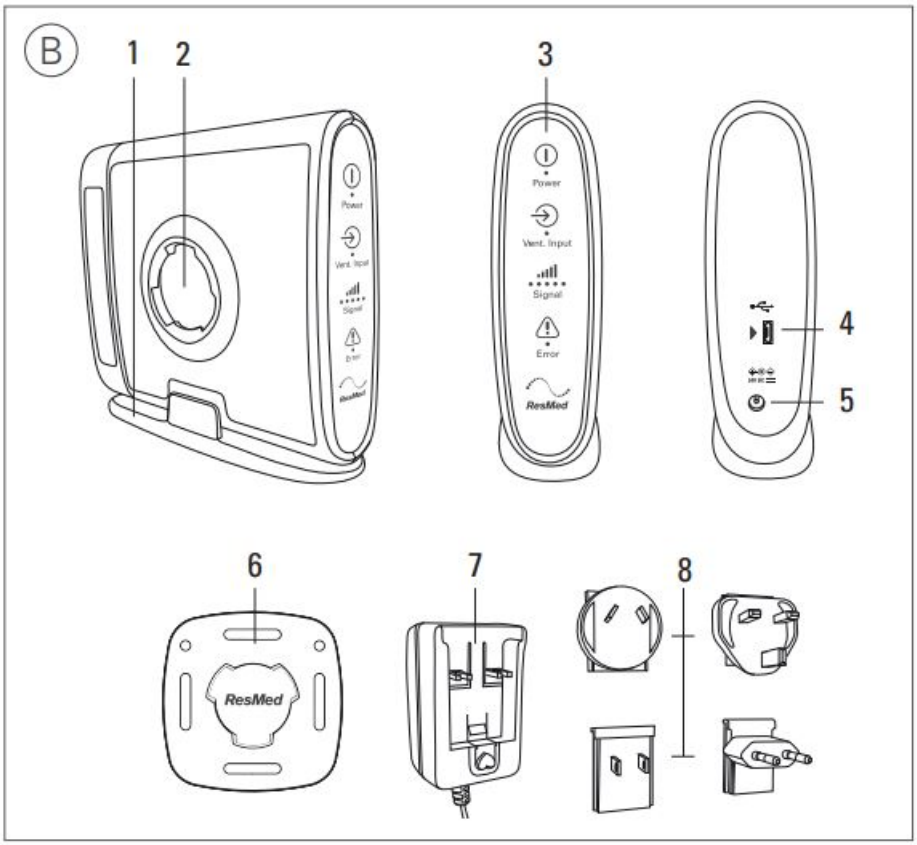
- Only use the power supply unit and plug blade attachments provided with RCM.
- Beware of electrocution. Do not immerse RCM or any of its components in water. Always unplug RCM before cleaning and make sure that all parts are dry before plugging it back in.
- Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized ResMed service agent.

CAUTION

Do not use RCM outdoors.

RCM at a glance

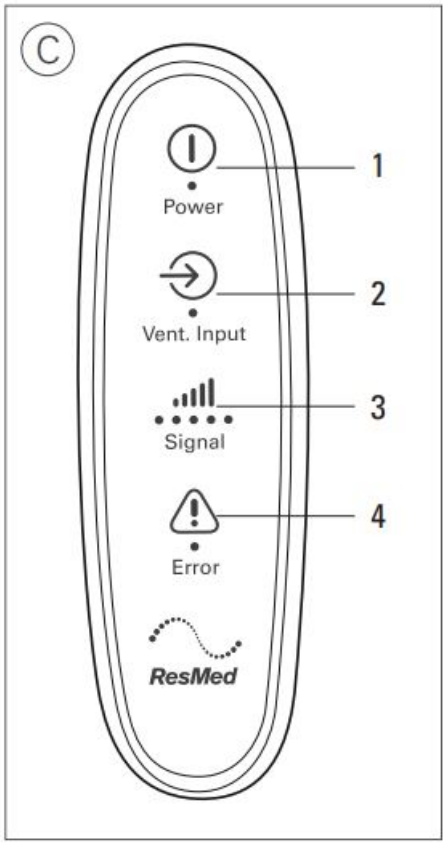
Refer to illustration



1. Stand
2. Wall mounting socket
3. Indicator panel
4. Micro-USB port
5. Power inlet
6. Wall mount
7. Power Supply Unit (PSU)
8. Plug blade attachments
9. USB cable (not shown)

Indicators

Refer to illustration



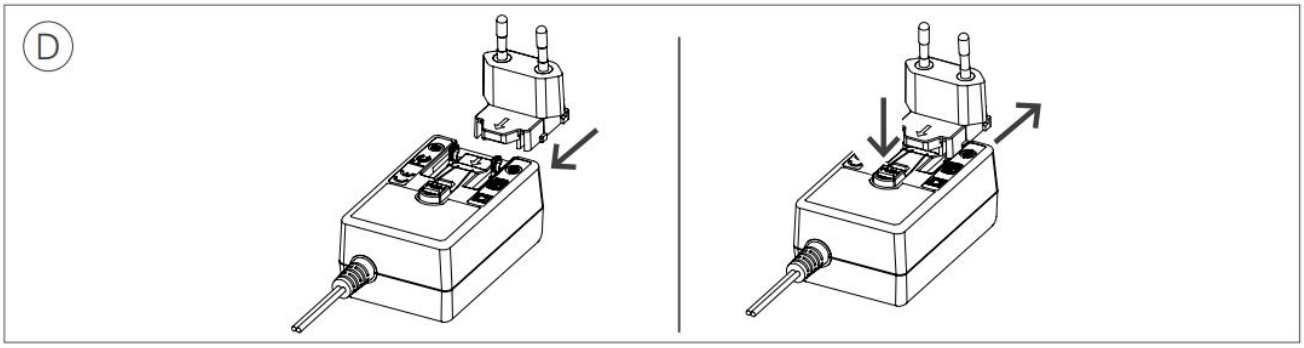
RCM provides indication of the current operating state. When the Power and Vent. Input indicators illuminate and you have network reception, RCM is ready to use.

Indicator	Status
1 Power – Green Indicates whether RCM is powered on.	On: The power is on. Off: The power is off.
2 Vent. Input – Blue Indicates whether RCM is connected to the powered-on ventilation device.	On: Connected to the ventilation device. Off: Disconnected from the ventilation device. Blinking: Establishing connection to the ventilation device.
3 Signal – Blue Indicates connectivity to the cellular network and the signal strength.	On: Connected to the cellular network. The signal strength is indicated by the number of blue dots (more dots mean a stronger signal). Off: No cellular network detected.
4 Error – Yellow Indicates whether RCM has an error.	On: An error has occurred. Off: No error

Note: The Vent. Input and Signal indicators will dim in 5 minutes and will return to full brightness when RCM is connected to the ventilation device or powered on again.

Assembling the PSU

Refer to illustration



1. Insert the plug blade attachment suitable for your region into the PSU.
2. To remove the plug blade attachment from the PSU, press the button under the arrow and slide it out.

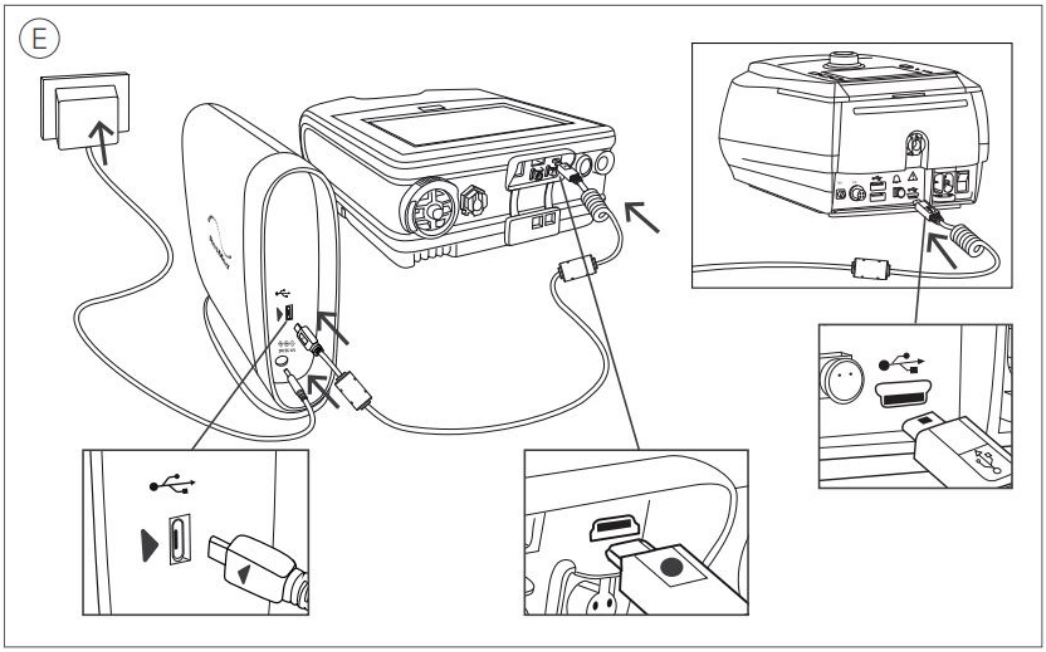
CAUTION

- Do not leave the plug blade attachment in a power outlet alone.

- Do not plug the PSU upside down into a power outlet. Ensure that the power cord extends downward.

Setup

Refer to illustration



RCM can only be connected to one ventilation device at a time.

1. Connect the RCM to the power using the PSU. Ensure that the Power indicator illuminates.
2. Position RCM where the Signal indicator shows that you have network reception, and ensure that RCM is:
    - more than 0.8″ (2 cm) away from the body during operation.
    - in an area that will not be affected by moisture.
    - ideally 12″ (30 cm) away from the ventilation device or other electrical equipment and 3’3″ (1 m) from mobile communication devices.
3. Ensure that the RCM is secured with the stand or wall mount. Refer to the Using the stand/wall mount section.
4. Connect one end of the USB cable to the micro USB port of RCM, and the other end to the mini USB port at the rear of the powered-on ventilation device (refer to the illustration). Ensure that the Vent. Input indicator illuminates.
5. To ensure correct times are shown in AirView, ensure that the clock on the ventilation device is correct (change if appropriate).

Notes:

- For further assistance, contact your care provider or ResMed representative.
- To stop RCM, unplug the power cord from the power outlet.

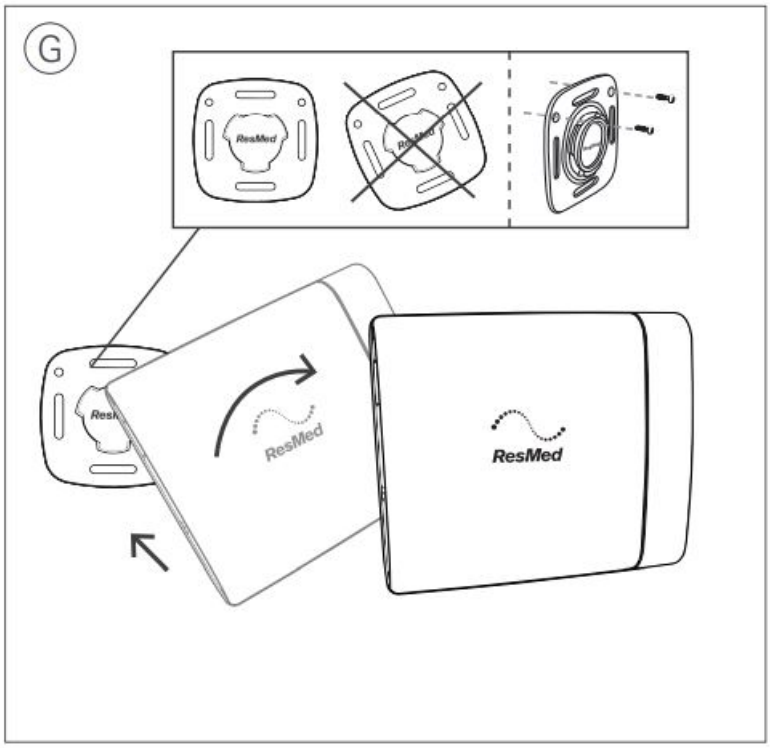
Using the stand/wall mount

Stand
Refer to illustration

1. Place the stand on a stable level surface.
2. Insert the longer edge of the stand into RCM, ensuring that it clicks into place.
3. To remove the stand, release the clip on the stand.

Wall mount

Refer to illustration



Use appropriate fittings to attach the wall mount. For example, use the round holes or the slots of the wall mount for screws or cable ties (not provided).

WARNING

Ensure that the wall mount is securely fixed in place.

1. Hold RCM at an angle and push it onto the wall mount. Adjust the angle to fit RCM in place.
2. Turn RCM clockwise until it clicks into place.
3. To remove RCM from the wall mount, turn it counterclockwise.

Sending data to AirView
RCM automatically sends the previous 24 hours of data to AirView once a day from approximately 12 pm (based on the clock of the connected ventilation device).
If automatic data transmission is missed or interrupted, it will resume when the connection is re-established. No data will be lost.
To ensure daily automatic data transmission, ResMed recommends you to connect RCM once a day for one hour, with the Vent. Input and Signal indicators on.
Note: Data more than seven calendar days old will not be sent to AirView.

Cleaning and maintenance

The exterior of RCM and the PSU can be cleaned with a damp cloth and an approved mild cleaning solution.
The following cleaners and disinfectants are compatible for use when cleaning external surfaces of RCM:

- isopropyl alcohol
- bleach (1:10) (may also be known as ‘diluted hypochlorite’).

Always follow the manufacturer’s recommended cleaning instructions.

WARNING

Ensure that the RCM and PSU are dry before reconnecting to the power outlet and ventilation device.

Troubleshooting

Problem/possible cause	Solution
The Power indicator does not illuminate.	Check that the PSU is connected correctly to the power outlet and the rear of RCM. Check that the plug blade attachment is inserted into the PSU correctly. Check that the PSU is the one provided with RCM.
The Vent. Input indicator does not illuminate.	Check that the ventilation device is turned on. Check that the USB cable is connected correctly to the rear of RCM and the ventilation device.
The Signal indicator does not illuminate.	Change the position of RCM. Check that you have network reception. Ensure that RCM is ideally 12″ (30 cm) away from the ventilation device or other electrical equipment.
The Error indicator is on.	Switch RCM off, then on again, to see if this removes the error. If the Error indicator displays again, contact your care provider or ResMed representative.
Automatic data transmission was interrupted or missed at 12 PM (eg, no signal, RCM/ventilation device disconnected or powered off).	Re-establish the connection between RCM, ventilation device, and AirView (refer to the Setup section). Automatic data transmission will resume to send any outstanding data.

If the problem cannot be solved, contact your care provider or ResMed representative.

Technical specifications

Dimensions (H x W x L)	RCM only: 5.28″ x 1.73″ x 5.91″ (134 mm x 44 mm x 150 mm) The stand will add 0.12″ (3 mm) to the height and 0.24″ (6 mm) to the width.
Weight	RCM only: 0.62 lb (280 g) The stand will add 0.07 lb (30 g) and the wall mount will add 0.02 lb (10 g).
Power supply unit (PSU)	AC 100–240 V, 0.35–0.70 A, 50–60 Hz DC 24 V, 1.25 A Cable length 5’10” (1.8 m) Class II, suitable for continuous operation Typical power consumption; <3 W Maximum power consumption: <5W
Housing construction	Flame retardant engineering thermoplastic and silicon

Environmental conditions Operating temperature: Operating humidity: Operating altitude: Storage and transport temperature: Storage and transport humidity:	+32oF to +104oF (+0oC to +40oC) 10%–95% non-condensing Sea level to 9842.5 ft (3000 m) -13oF to 158oF (-25oC to +70oC) 10%–95% non-condensing
Electromagnetic compatibility	Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments. It is recommended that mobile communication devices are kept at least 3’3″ (1 m) away from the device.
IEC 60601-1 classification	Non-transit operable, portable equipment
Compatible software versions	AirView: 4.1 or higher Astral: SX544-0401 or higher Stellar: SX483-0250 or higher
Wireless module	Technology used: 3G/2G
FCC ID: 2ACHL-RCM3G	The RCM device complies with FCC Rules. Additional information regarding the FCC Rules for this device can be found on **www.resmed.com/downloads/devices.**
IC ID: 9103A-RCM3G	The RCM device complies with Industry Canada Rules. Additional information regarding the Industry Canada Rules for this device can be found on **www.resmed.com/downloads/devices.**
Declaration of Conformity to 1999/5/EC (DoC to the R&TTE Directive)	ResMed declares that the RCM device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. A copy of the declaration of conformity (DoC) can be found on **www.resmed.com/downloads/devices.**
Separation	The RCM device should be used at a minimum distance of 0.8” (2 cm) from the body and ideally 12″ (30 cm) from the ventilation device during operation.
Design life	5 years The RCM and PSU do not contain any serviceable parts.

Guidance and manufacturer’s declaration electromagnetic emissions and immunity
Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Guidance and manufacturer’s declaration—electromagnetic emissions
IEC60601-1-2:2007
These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The device 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	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage 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	

WARNING

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of cables other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

Guidance and manufacturer's declaration – electromagnetic immunity
These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment — guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	100V 240V	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	Recommended separation distance $d = 0.35 \sqrt{P}$ $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.70 \sqrt{P}$ 800 MHz to 2.5 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, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Notes:

- Ut is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 0.35 √P	80 MHz to 800 MHz d = 0 .35 √P	800 MHz to 2.5 GHz d = 0.7 √P
0.01	0.035	0.035	0.070
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12″ (30 cm) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Symbols
The following symbols may appear on the product or packaging:

- Follow instructions for use.
- Manufacturer.

- European Authorized Representative.
- Batch code.
- Catalog number.
- Serial number.
- Direct current.
- Humidity limitation.
- Temperature limitation.
- Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician).
- European RoHS. Protection against insertion of fingers and against vertically dripping water.
- Keep dry.
- Fragile, handle with care.
- RCM certification.
- Canadian Standards Associations.
- Non-ionising radiation.
- USB connector.
- Power indicator.
- Vent.
- Input (Ventilator Input) indicator.
- Signal indicator.
- CE labelling in accordance with EC directive 93/42/EEC and Radio Equipment Directive 2014/53/EU. Polarity of DC power connector. Indicates a warning or caution.

Environmental information
This device should be disposed of separately, not as unsorted municipal waste. To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment.
If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your ResMed device please contact your ResMed office, local distributor or go to **www.resmed.com/environment**.

warranty

Limited warranty
ResMed Pty Ltd (hereafter 'ResMed') warrants that your ResMed product shall be free from defects in material and workmanship for a period of 12 months from the date of purchase by the initial consumer. This warranty is not transferable.
If the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components.
This Limited Warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs; c) any damage or contamination due to cigarette, pipe, cigar or other smoke; and d) any damage caused by water being spilled on or into an electronic device.
Warranty is void on product sold, or resold, outside the region of original purchase.
Warranty claims on defective product must be made by the initial consumer at the point of purchase.
This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.
ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or limitation of

incidental or consequential damages, so the above limitation may not apply to you.
This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

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Documents / Resources

	**ResMed RCM1 Connectivity Module for Ventilators** [pdf] User Guide RCM1 Connectivity Module for Ventilators, RCM1, Connectivity Module for Ventilators, RCM1 Connectivity Module, Connectivity Module, Module

References

- **Sleep apnea and COPD - learn about symptoms and treatment | ResMed**
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