

ReddyPort™ Microphone and Controller

Instructions for Use (IFU)

The information in this document is required for the operation of the ReddyPort™ Microphone and Controller.

ReddyPort Microphone and Controller empower patients to speak up and share their needs. For clinicians and family members, it helps reduce the frustration that comes from not being able to hear the patient behind the mask, especially during a life-threatening illness.

- Microphone with integrated speaker seals with ReddyPort Elbow.
- System uses (DSP) digital signal processing to remove breathing noises and naturalize the patient's voice.
- Controller adjusts the volume of the patient's voice.
- Allows patients to communicate with clinicians and family without mask removal.
- Helps improve clinician and patient satisfaction.



Patient using microphone to communicate



Microphone with integrated speaker and Controller

The ReddyPort Microphone and Controller system is **NOT** a medical device as it is not intended for diagnosis, mitigation, treatment, or prevention of disease and does not affect the structure or any function of the body. Despite this, the ReddyPort Microphone and Controller System has been tested to medical standards (electrical safety and biocompatibility).

Instructions on how to safely work with the ReddyPort Microphone and Controller system include:

- General information on the indications for use, contraindications, potential complications, and mechanisms of action
- Description of the ReddyPort Microphone and Controller System
- Installation and operation guide
- Maintenance and servicing guide
- Technical data
- Warranty information

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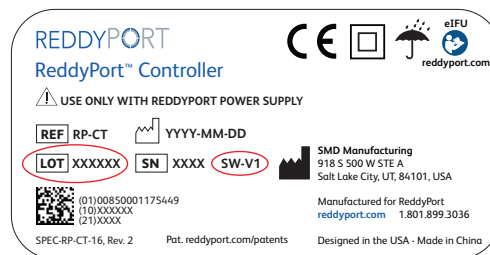
1. Customer support and information

If you have any questions regarding the operation or maintenance of the ReddyPort Microphone and Controller System, please contact customer support online or call **801.899.3036**.

Before You Call

In order to expedite your call, please have the following information available: Lot numbers for the ReddyPort Controller (RP-CT) and ReddyPort Microphone Module (RP-MM).

- Software version (found on the back sticker of the ReddyPort Controller). This number is listed in the format “SW-VX”
- Short description of the problem and circumstances under which the problem occurred.



2. General safety

This section provides information to help ensure safe and proper use of the ReddyPort Microphone and Controller system.

2.1. Requirements for the operator

The ReddyPort Microphone and Controller system should be used under the supervision of a clinician who is familiar operating it. While patient families or the patient themselves may be able to operate the ReddyPort Controller (RP-CT) for volume control and on/off functionality, the initial system setup should be installed and supervised by a trained clinician.

2.2. Warnings, cautions, notes, and tips

Naming conventions for warnings, cautions, and notes that are used throughout this document are described below:

WARNINGS inform of actions that could result in injury to the patient, the operator, or third parties.

CAUTIONS inform of actions that could result in damage to any equipment.

NOTES Provide general information for standard operations.



WARNING!

Potential danger
Description of potential danger.
» Action to be taken or avoided.



CAUTION!

Potential risk
Description of potential risk.
» Action to be taken or avoided.



NOTE

General information
for standard operation.

2.3 General precautions

Heed the following Warnings, Cautions, and Notes at all times when using the device.



WARNING!

Risk of cross-contamination.

The ReddyPort Microphone (RP-MM) is for single patient use only.

» **DO NOT** reuse the ReddyPort Microphone.



WARNING!

Risk of product damage.

Do not force the magnetic connector on the ReddyPort Data Cable (RP-DC) onto the ReddyPort Microphone. When the orientation of the data cable is correct, the magnets will “snap” together.

» Read this document for instructions on how to properly attach the data cable.



CAUTION!

Risk of leachable materials entering lungs.

The ReddyPort Patient Microphone Module has not been assessed for drug contact.

» **DO NOT** leave the ReddyPort Microphone in the ReddyPort Elbow when it is not being used.

» **DO NOT** nebulize drugs into the circuit while the ReddyPort Microphone is in the ReddyPort Elbow.



NOTE

This device, if it were classified as a medical device, would be classified as Class II Type BF medical electrical equipment and complies with specified safety levels for electrical isolation and leakage current. The ReddyPort Power Supply (RP-CT) has no connection to earth ground because the necessary level of protection is achieved using double insulation.

3. Introduction and operating principles for the ReddyPort Microphone and Controller system

The ReddyPort Microphone and Controller System consists of four components:

- A. The ReddyPort Controller (RP-CT) contains the central processing unit that receives the signal from the microphone and powers the speaker.
- B. The ReddyPort Microphone (RP-MM) contains a microphone module that records the patient's voice and the speaker that plays out the patient's voice.
- C. The ReddyPort Data Cable (RP-DC) transmits signals between the ReddyPort Controller and ReddyPort Microphone.
- D. The ReddyPort Power Supply (RP-PS) attaches to the ReddyPort Controller to provide power.

3.1 Intended use

The ReddyPort Microphone and Controller system is intended to be used to amplify the patient's natural voice out to their surroundings while undergoing non-invasive ventilation. It is **NOT** a medical device and is **NOT** intended to diagnose, cure, treat, alleviate, or prevent any disease or health condition. It is **NOT** intended to affect the structure or any function of the body. The device is intended to be used for patients undergoing non-invasive ventilation with a circuit containing the ReddyPort Elbow.

3.2 Operating principle

The ReddyPort Microphone and Controller system operates using a three-step process. First, the patient's natural voice signal is recorded on the Microphone Module (RP-MM) from inside of the mask and is transmitted along the Data Cable (RP-DC) to the ReddyPort Controller (RP-CT). The ReddyPort Controller then removes breathing noise, naturalizes the voice, and amplifies the patient's voice. Finally, the amplified voice of the patient is transmitted back to the ReddyPort Microphone along the Data Cable and is played out to the room from the integrated speaker.

4. ReddyPort Microphone and Controller system installation

4.1 Parts list

The following components are used with the ReddyPort Microphone and Controller

- A) ReddyPort Controller
- B) ReddyPort Microphone
- C) ReddyPort™ Data Cable
- D) ReddyPort™ Power Supply

Other components (*not show in rendering*):

- Mounting bracket
- Mounting strap
- Tubing clips (4)
- Screw (1)
- Screwdriver



The ReddyPort Microphone and Controller system view showing connections.

4.2 System overview

A) ReddyPort Controller (RP-CT) contains a central processing unit that allows the user to control the volume of the patient's voice. The device removes breathing noises within the circuit and naturalizes the patient's voice.

B) ReddyPort Microphone (RP-MM) contains the microphone that records the patient's voice and a speaker that plays out the patient's voice after cleanup and amplification.

C) ReddyPort Data Cable (RP-DC) transmits signals between ReddyPort Microphone (RP-MM) and ReddyPort Controller (RP-CT).

D) The ReddyPort Power Supply (RP-PS) powers the control unit using 5 VDC.

E) The ReddyPort Controller Mounting Bracket allows the ReddyPort Controller to be mounted to various ventilator rails or poles (*not show in rendering*)

F) The Tubing Clips allow the ReddyPort Data Cable to be mounted to standard 22mm tubing (*not show in rendering*)

4.3 Installing strap and mounting bracket to ReddyPort Controller

1. Locate screw provided in the box.
2. Align hole in strap to screw thread (*figure 1*).
3. Align and press mounting bracket through strap with “fork” towards strap (*figure 2*).
4. Screw in mounting bracket with provided screwdriver (*figure 3*).

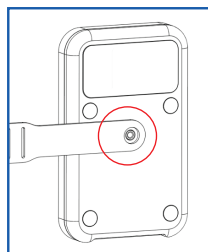


Figure 1

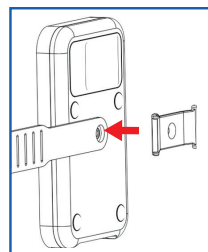


Figure 2

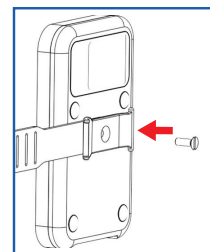


Figure 3

4.4 Setting up the ReddyPort Controller and Data Cable

Connect the ReddyPort Power Supply to the power jack on the back of the controller.



WARNING!

Risk of Improper Use

The Control Unit requires a 5 VDC Power Supply. Attachment of a higher voltage power supply could lead to controller and microphone damage.

» Only use the ReddyPort Power Supply. If a replacement is needed, contact the Distributor.

Attaching ReddyPort Data Cable and Power Supply to ReddyPort Controller



The end of the data cable that connects to the controller is black. Instructions for connecting the data cable to controller are listed below. *Refer to page 5 for rendering of ReddyPort Microphone and Controller system.*

1. Locate black end of data cable which inserts into controller **(B)**.
2. Before inserting data cable into bottom of controller, hold black end of data cable pointing away and turn rotating outer sleeve counterclockwise to open the locking mechanism.
3. Press and rotate black end of data cable into corresponding connector on controller until pins align and it slides into place.
4. Once inserted completely, rotate locking collar on black end of data cable clockwise one quarter turn to secure and lock into place.
5. If inserted correctly, you will hear it “click” and lock into place.
6. Insert power supply jack **(C)**, into controller and plug into power outlet.

4.5 Mounting ReddyPort Controller to a ventilator

1. Orient mounting bracket horizontally or vertically
Loosen screw (*if necessary*).
2. Stretch strap around rail or handle.
3. Insert “prongs” of mounting bracket into appropriate strap opening to securely attach controller.

Attaching ReddyPort Data Cable to circuit

1. Run data cable along top of circuit and using tubing clips provided, “snap” data cable into place.

It is recommended that final tubing clip be placed ~ 3-5” from distal end of the circuit.

4.6 Connecting the ReddyPort Microphone

1. Insert the ReddyPort Microphone into the ReddyPort Elbow making sure it is fully inserted.



WARNING!

Risk of product damage

DO NOT force the ReddyPort Data Cable magnetic connector onto the ReddyPort Microphone. When the orientation of the Data Cable is correct, the magnets will “snap” together.

» Read this document for instructions on how to properly attach the Data Cable

2. Attach the magnetic connector side of the ReddyPort Data Cable to the ReddyPort Microphone. The connector will only attach one way. If it is not connecting, simply switch its orientation.



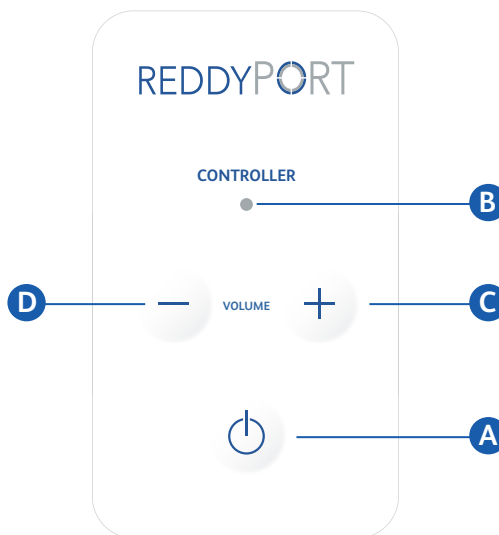
The end of the cable that connects to the ReddyPort Microphone is blue and the proper orientation of the connector has the ReddyPort Logo facing outward (*photo to the left*). To remove, simply pull down and the magnet will release, disconnecting the cable.

4.7 Using the ReddyPort Microphone

1. Power up the ReddyPort Controller by pressing the power standby button. The green LED will illuminate when the power is on.
2. Instruct the patient to talk and adjust the volume of the system utilizing the plus symbol and minus symbol buttons. Upon startup of the controller, the volume will be set on the middle setting, adjust the setting up/down as needed (the LED will blink when a volume input is received). When the volume is adjusted to the maximum/minimum volume, the LED will blink rapidly 2 times.
3. After the patient is done talking, remove the ReddyPort Microphone from the ReddyPort Elbow and place it somewhere safe from contamination. **DO NOT** leave the Patient Microphone Module in the Elbow while not in use. **DO NOT** nebulize drugs into circuit while the Microphone is in use.

The following components are located on the ReddyPort Controller membrane:

- A) Power standby button
- B) LED power indicator (*green light means device is on*)
- C) Volume up button
- D) Volume down button



CAUTION!

Risk of leachable materials entering lungs

The ReddyPort Microphone has not been assessed for drug contact.

» **DO NOT** leave the ReddyPort Microphone in the ReddyPort Elbow when it is not being used.

» **DO NOT** nebulize drugs into the circuit while the ReddyPort Microphone is in the ReddyPort Elbow.

4.8 Cleaning instructions

1. If the ReddyPort Microphone gets dirty during use, wipe it down with a mild liquid detergent and sterile water. **DO NOT** apply significant pressure to the mesh on the microphone module.
2. The ReddyPort Controller and Data Cable should be cleaned between patients. Unplug the controller and cable prior to cleaning the device. Wipe clean with an alcohol based disinfectant wipe or a quaternary ammonium compound based disinfectant wipe. Check for exposed wiring, damaged connectors, or other defects and replace if any are visible.



WARNING!

Risk of Product Damage

Unplug the controller prior to cleaning. Do not spray liquid directly onto the controller and **DO NOT** immerse the controller in liquid.

» ReddyPort Microphone Module is single use only. **DO NOT** reuse.

4.9 After-use instructions

When finished, dispose of the contaminated device as per your facility's protocols. **DO NOT** reuse ReddyPort Microphone on multiple patients.



CAUTION!

Risk of patient infection

The ReddyPort Patient Microphone Module is not intended for multi-patient reuse. The ReddyPort Patient Microphone Module is single use only.

» ReddyPort Microphone Module is single use only. **DO NOT** reuse.



CAUTION!

Sterilization may damage the ReddyPort Microphone and ReddyPort Controller

DO NOT sterilize the ReddyPort Microphone or ReddyPort Controller using an autoclave or gas.

» Follow the cleaning instructions in **Section 4.8**.

5. ReddyPort Service and warranty information

5.1 ReddyPort Microphone and Controller system service

Only ReddyPort approved personnel can service the ReddyPort Microphone and Controller System. ReddyPort personnel will service the ReddyPort Controller as needed throughout the life of the product.



WARNING!

Risk of improper use and injury

No modification of this equipment is allowed, except by authorized personnel.

» **DO NOT** open, tamper with, or modify the ReddyPort Microphone or ReddyPort Controller.

5.2 Limited warranty

ReddyPort Inc. warrants that the ReddyPort Microphone shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by ReddyPort to the dealer. If the product fails to perform in accordance with the product specifications, ReddyPort, Inc. will replace – at its option – the defective material or parts. This warranty does not cover damage caused by accident, misuse, abuse, alteration, water ingress, improper storage, improper cleaning, and other defects not related to material or workmanship.

ReddyPort Inc. warrants that the ReddyPort Controller, Power Supply, and Data Cable shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by ReddyPort to the facility. If the product fails to perform in accordance with the product specifications, ReddyPort, Inc. will repair or replace – at its option – the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration, water ingress, improper storage, improper cleaning, and other defects not related to material or workmanship. The ReddyPort Controller can only be used with the ReddyPort Power Supply. Using power supplies other than the included ReddyPort Power Supply will nullify the warranty.

5.3 Lifetime of the device

The expected lifetime of the ReddyPort Microphone is 100 hours. This represents two (2) hours a day of talk time for 50 days. The expected lifetime of the ReddyPort Controller is 1,500 operating hours. This represents two (2) hours of talk time per patient, per day, for two (2) years.

Contact the distributor for assistance with disposing of the device.

5.4 Repairing the ReddyPort Controller

Should you need to return the controller for repair, please follow these steps:

- 1) Obtain a Return Material Authorization (RMA) number from ReddyPort directly.
- 2) Pack the ReddyPort Controller in the original packaging containers.
- 3) If original packaging is not available, contact ReddyPort for instructions at **801.899.3036**

6.0 Troubleshooting









If this happens	It could mean:	Try this
There is no audio output from the speaker when inserted and powered on.	The magnetic connector is not fully connected.	Re-attach the ReddyPort Connector to the ReddyPort Microphone and try again or try switching the orientation of the magnetic connector.
There is leak coming from the ReddyPort Elbow when the ReddyPort Microphone is inserted	The ReddyPort Microphone is not fully inserted into the ReddyPort Elbow.	Press the ReddyPort Microphone further into the ReddyPort Elbow.

7. ReddyPort technical specifications

Overview of the ReddyPort Microphone System

Technical specifications	
Power supply input	90-264 VAC 47-63 Hz, 1 amp @ 115VAC, .5A at 230VAC
Power supply output	5VDC, 2.4 amps
Power supply cable length	15ft
Data cable length	8ft
Controller dimensions	6.08" L x 6.27" W x 1.55" H (154mm x 159mm x 39mm)
Controller weight	0.9 lbs (.41 kg)
Patient Microphone dimensions	3.1" L x 1.77" W x 1.95" H (79mm x 45mm x 49.5mm)
Patient Microphone weight	45g
Controller power input	5 VDC, .730A when in use standard, 5VDC 1.88A maximum peak power estimate
Controller consumption	3.65W
Operating environment	Temperature: 15°C - 45°C Relative humidity: 15 – 95% non-condensing Altitude: 0 – 4000 meters (0 – 13,000 Ft) Atmospheric pressure: 450 – 1100 hPa
Storage / shipping environment	Temperature: -40°C - 70°C Relative humidity: 10 – 100% Atmospheric pressure: 450 – 1110 hPa
Water ingress protection	IPX1
Model	RP-CT, RP-MM
Applied parts	None – Parts that could contact the patient or contact the gas pathway were considered applied parts for testing, but are not classified as applied parts.

8. Symbols Glossary

Symbols	Meaning
	Alternating current
	Direct current
IPX1	The device offers no special protection from water.
	Attention, consult ACCOMPANYING DOCUMENTS
	Power standby button
	Manufactured by
	Do not reuse
	Class II Equipment
	Keep dry

9. Manufacturer Information



SMD Manufacturing
918 S 500 W STE A
Salt Lake City, UT, 84101, USA

Manufactured for ReddyPort
reddyport.com 1.801.899.3036

For any inquiries contact ReddyPort at **1.801.899.3036**
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