



Renvo™ Dock Operator's Guide

Part Number 121971-00
07Dec2021

Preface

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Any questions regarding the contents of this Operator's Guide may be directed to the address below, or to your local Thermo Fisher Scientific representative.

Thermo Fisher Scientific
Customer Support
27 Forge Parkway
Franklin, MA 02038
1-800-209-8763



i. Warranty

Thermo Fisher Scientific™ warrants that the Thermo Scientific™ Renvo™ Dock is purchased through Thermo Fisher Scientific or from an authorized distributor shall be free from defects in material and workmanship for a period of one year from the date of purchase or 3,000 tests, whichever comes first. The warranty shall not extend beyond three years from the date of shipment to an authorized dealer. Misuse of the Renvo™ Dock, including exposure to harmful chemicals, environmental extremes beyond the equipment ratings in this Guide, or mishandling may render the warranty null and void.

ii. Intended Use

The Renvo Dock is a reusable platform, used in conjunction with a Thermo Scientific™ Renvo™ Test Cassette to run rapid PCR tests for environmental surveillance use only and not for diagnostic purposes.

Testing should be conducted by a trained operator (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the product used under his or her supervision, (2) who is responsible for enforcing appropriate methods of using the product to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the storage, use, and disposal of the product and wastes as may be appropriate or required within the scope of using the product.

Testing should be conducted on a surface that can be easily disinfected. Disposable gloves, face covering and safety goggles should be worn throughout the process.

iii. Trademarks and Patents








This product may be covered by one or more U.S. and/or foreign patents or pending patents applications. See www.mesabiotech.com/patents for details.

KimWipe™ is a trademark of Kimberly Clark Corporation.

CaviWipes™ is a trademark of Metrex Research, LLC.

iv. Symbols and Abbreviations

The following symbols are used throughout this manual:

Symbol	Definition
	Alternating Current.
	Direct Current.
	WEEE – Electronic equipment marked with this symbol are subject to European Union Directive 2002/96/EC (@EEE) and cannot be disposed of in the municipal waste system.
	Biohazard – Potentially infectious materials. Precautions must be observed.
	This symbol indicates the name and location of the product manufacturer.
	Consult the instructions for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Informational note.

The following symbols are used throughout this manual:

AC – Alternating Electrical Current

DC – Direct Electrical Current

A – Amperes

V – Electrical Voltage

v. Warnings and Precautions



Do not block the air vents located on the rear and sides of the Renvo Dock. A minimum of two inches (5 cm) of clearance must be maintained.



Do not place the Renvo Dock in the vicinity of equipment that generates heat. The Dock must be maintained in an ambient temperature range of 15° C to 30° C (59° to 86° F) to operate properly.



To reduce the risk of damage to the unit, avoid using sprays near the Renvo Dock.



Use only the supplied power adapter with the Renvo Dock (MeanWell Part Number GSM25B12-P1J). This component has been tested and certified for use. If you need a replacement power supply, contact your Thermo Fisher Scientific distributor.

vi. Disposal and Shipping

All electronic products must be disposed of separately from the municipal waste system.



The Renvo Dock may become biologically contaminated during use. Before disposing or shipping the Dock for service, it must be decontaminated.



The Renvo Dock is covered under European Directive 2002/96/EC (WEEE) and must therefore be disposed of at collection facilities designated by government or local authorities. For more information about disposing of the Dock, contact your Thermo Fisher Scientific distributor.

To decontaminate the dock before disposal:

- Unplug the DC power connector from the back of the Renvo Dock.
- Open the lid of the dock by pressing the lid latch button and pulling the lid to the open position.
- If a Cassette is in into the Dock, remove it by firmly grasping and pulling it upward.
- Soak the entire Dock in a 10% bleach solution for at least 10 minutes. Ensure that the Dock is fully submerged in the solution and that the entire interior of the Dock is flooded. Keep the Dock upright to allow entrapped air to escape through the cassette slot.
- Remove the Dock from the bleach solution. Turn the Dock upside down to drain the solution from the interior. Allow the Dock to dry.
- Dispose of the Dock as electronic waste according to local regulations.

If you need to return a Dock to Thermo Fisher Scientific or one of its distributors, before packaging, carefully follow the exterior cleaning procedure detailed in Section D. Maintenance, Cleaning the Renvo Dock.

A. System Description and Specifications

The Renvo Dock is an electronic module that executes tests on compatible Renvo Test Cassettes for environmental surveillance purposes. It consists of an electro-mechanical interface to a single Test Cassette. The Dock contains all electrical system, controls, and logic necessary to orchestrate tests within the inserted Test Cassette.

When you insert a Cassette, the Dock detects and identifies the Cassette type. After you transfer a test sample into the Test Cassette and close the Dock lid, embedded firmware in the Dock controls fluid flow of the sample into the chambers of the Test Cassette, applies controlled voltage signals to the Cassette heaters (monitored by sensors within the Dock), and provides visual status with critical information such as estimated time to read and any error states encountered.

Dock Specifications

- Power input: 12VDC \pm 1VDC, 1A maximum
- Environmental (operating temp, altitude, humidity)
 - Ambient Temperature: 15° C to 30° C (59° F to 86° F)
 - Relative Humidity: 20-80%, non-condensing
 - Altitude: Sea level to 8,000 feet

Do not use the Renvo Dock in direct sunlight.

- Acceptable tilt – Install the Dock on a level surface, with an incline not to exceed 10 degrees.
- Dimensions: 5.7 in (14.5 cm) H x 3.9 in (9.7 cm) D
- Weight (including dock, Power Adapter, and US Power Cord): <1.4 lbs. (619 g)
- Useful Life: 3,000 tests.

AC Adapter Specifications

Power input: 100-240VAC, 50/60Hz

Power Output: 12VDC, 2.08A, 25W maximum



Use only power cords provided by Thermo Fisher Scientific type H03VVH2-F, 2 x 0.75mm² or type SPT-2, 2 x 18AWG, 60°C, with connector type C7 and approved plugs from EU, US, Canada, and other countries as may be applicable.

B. Installation



Do not block the air vents on the rear and sides of the Dock. Maintain a minimum two inches (5 cm) of clearance.



Do not place the Dock near equipment that generates heat. The Dock must be maintained in an ambient temperature range of 15°C to 30°C (59°F to 86°F) to operate properly.

1. Place the Renvo Dock on a level, stable table or laboratory bench. To ensure proper function, allow at least two inches (5 cm) of clearance around the Dock. Do not place it near equipment that gives off heat.
2. Insert the round DC connector of the adaptor into the Dock as shown below. Connect the power cord to the AD adapter, and then insert the power cord plug into the electrical outlet.



This system does not use a ground connection. Depending on your type of AC outlet, an unused ground pin may be visible. This is normal and expected.

3. After you connect the Renvo Dock to power, it initializes automatically. The unit beeps, and a series of brief messages appears on the display. (The image below is for illustration only. Your firmware P/N, version, and ambient temperature may differ.)

•

MESA BIOTECH, INC.
MOLECULAR POC

AMBIENT
TEMPERATURE: 25C

•

FIRMWARE
P/N 210405 V2.7

DOCK READY
INSERT CASSETTE

Immediately after displaying the final message, the unit beeps twice, which indicates that the Dock is ready to use.

C. Operation

This section provides detailed instruction about operating the Renvo Dock only. It is not intended to be a comprehensive instruction for performing environmental surveillance tests. Such instructions are found packaged with the specific test kits.

Inserting the Test Cassette



You can use each Test Cassette only once. Sensors in the Dock do not allow the assay to run if the Cassette has already been inserted.

1. Remove the Test Cassette from the foil pouch by tearing off the top of the pouch starting at the notches in the pouch.
2. Open the lid of the Dock by pressing the black lid latch button and pulling the lid to the open position.



3. Insert the Test Cassette into the slot with the cassette label facing the front of the Dock. The sample port (covered with a foil tab) on the top of the cassette is accessible to you. Fully press the Test Cassette into the Dock until it 'clicks' into position. The Renvo Dock measures the temperature of the cassette and displays it as shown in the example below:

**CASSETTE
TEMPERATURE: 24C**

If the cassette is properly inserted, the display identifies the type of test that is supported by the cassette, for example:

**SAR-CoV-2
CASS. INSERTED**



If the display shows an error, see Section E - Troubleshooting.

4. After a few seconds the display prompts you to add the sample to the cassette sample port:

**ADD SAMPLE
THEN CLOSE LID**

The Test cassette is now ready to accept the sample.



To avoid contamination, do not remove the foil tab covering the cassette sample port until you are ready to add the sample.

Running the Assay



After starting the test, avoid bumping, tilting, or otherwise disturbing the Renvo Dock, as this may cause the test to abort.

1. Following the test kit instructions, remove the foil tab from the Test cassette and immediately add the sample to the cassette sample port. The Renvo Dock beeps when it senses the sample and displays:

SAMPLE LOADED
CLOSE LID

The Dock then beeps once every second until the lid is closed.

2. Close the lid, pressing it into place over the top of the Test Cassette until it clicks into its locked position. The Dock will then displays:

SAMPLE LOADED
LID CLOSED

The Dock verifies that the Test Cassette is sealed. After verification, the Dock initiates the test and displays:

CASSETTE SEALED
TEST STARTED

During the test, the Dock displays an estimated time to completion. For example:

TEST RUNNING
REMAINING: 25:15



The remaining time is an estimate of the time required to run the assay. The actual time remaining is determined by several factors, including ambient temperature, altitude, and the type of assay being run.



During a test run, you hear the whir of a fan and flow of air through the Dock. This is normal behavior and does not indicate a Dock malfunction.

3. Allow the assay to run to completion before moving or disturbing the Renvo Dock. The internal fan turns on periodically during the assay. This is normal and expected. When the assay is finished, the remaining time is 00:00, and the Renvo Dock displays:

TEST COMPLETE
READ RESULTS

4. The Dock beeps every two seconds until you remove the Test Cassette.
5. Remove the Test Cassette by pressing the latch button and pulling the lid open. Firmly grasp the top of the Test Cassette and pull straight up until the Test Cassette is removed from the Dock. The results of the assay may be immediately read. For instructions interpreting results, see the test kit instructions.

After you remove the Test Cassette, the Dock displays the number of tests that have been run and the number remaining. For example:

RUN COUNT: 1113
REMAINING: 1887

6. If fewer than 100 tests remain, the Renvo Dock beeps three times and the display reminds you to replace the unit. For example:”

REPLACE DOCK
IN 56 TESTS

7. After a few seconds, the Dock displays:

DOCK READY
INSERT CASSETTE

8. This indicates that the Renvo Dock is ready to run another assay.

Reading the Test Results

See the instructions provided with each assay test kit.

Re-programming the Dock

Periodically new tests are developed that require new programming for the Renvo Dock. To support these new tests, you need to update the Dock firmware.:

1. Apply power to the Renvo Dock as indicated in Section B – Installation. The Dock automatically initializes and displays:

DOCK READY
INSERT CASSETTE

2. Insert the latest Programming Cassette (indicated by red top) into the Dock as instructed in Section C above (Inserting the test cassette). The Dock senses the Programming Cassette and displays:

PROGRAMMING
CASSETTE READY

followed by

PROGRAMMING
WAIT FOR REBOOT

3. The Dock’s display turns off for a few seconds while the unit reboots and reprograms its embedded firmware. When the display turns on, verify that the new firmware revision is correctly reported. (The image below is for illustration only. Your firmware P/N and version may differ):

FIRMWAREP/N
210438-EN REV A

4. The display prompts you to remove the Programming Cassette:

REMOVE PROGRAM- MING CASSETTE

After you remove the Programming Cassette, the Renvo Dock restarts with the new firmware installed.

D. Maintenance

Cleaning the Renvo Dock

Regular cleaning of the Renvo Dock is recommended. Clean the Dock every day that it is used, and before disposal or shipment or servicing.



The Renvo Dock may become biologically contaminated during use. Before disposing or shipping the Dock for service, it must be decontaminated.



To reduce the risk of damage to the unit, avoid using sprays near the Dock.



Before you clean the Renvo Dock, disconnect the power supply. This helps to prevent damage to the unit.

Thermo Fisher Scientific recommends cleaning the Dock each day it is used with CaviWipes™ germicidal disposable wipes, (EPA Registration No: 46781-8). The cleaning procedure below has been validated using these wipes.

CaviWipes™ germicidal disposable wipes contain the following active ingredients:

- Isopropanol: 17.2%
- Diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride: 0.28%

For information about purchasing CaviWipes™ germicidal wipes, contact your authorized distributor.

If Cavi Wipes are unavailable, you can use other cleaning solutions such as 10% bleach or 70% ethanol.

Procedure:

1. Unplug the power cord from the Dock.
2. Close the Dock lid.
3. Using a CaviWipes™ germicidal disposable wipe, gently wipe the outer surfaces of the Dock, removing any gross debris. Do not press the wipe against the open vents of the back or sides of the Dock.
4. Using a new CaviWipe, wipe the front of the Dock twice top to bottom, then twice left to right. Repeat this procedure for the back, top and bottom of the Dock.
5. Do not let liquid accumulate near any opening. Make sure no liquid enters the dock.
6. Leave the Dock "wet" for at least 3 minutes.
7. With a fresh dry cloth (like a Kimwipe™) remove any residual moisture.
8. Allow the unit to dry for at least 10 minutes before you re-connect the power cord for the AC Adapter.



Do not open the Dock lid during the cleaning procedure.



Do not insert the cleaning wipe into the cassette slot. This may cause damage to the unit.



Do not use solvents other than those recommended above.



Do not let liquid accumulate in or around Dock vents.



Ensure that the Dock lid is closed before cleaning.

Troubleshooting

The Renvo Dock performs multiple environmental tests before and during an assay run to ensure that the conditions will allow a successful assay. If any tests fail, an error code is displayed along with a brief notification of the type of failure. For example, if the Dock detects that a used Test Cassette has been inserted, an error code is displayed for several seconds:

ERROR! CODE 05

This screen is followed by a brief message that describes the error:

**CASSETTE ALREADY
USED! REPLACE!**

Listed below are the different error codes with an explanation of the causes and remedies for each.

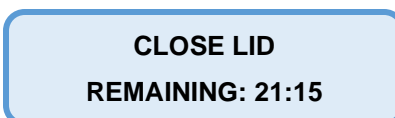
Error Code	Displayed Error/Description	Cause/Remedy
01	ALTITUDE OUT OF VALID RANGE	The maximum operational altitude is 8000 feet (2438 meters) above sea level. The Dock checks the altitude on initial power up and does not continue if the altitude range has been exceeded. To continue, relocate the Dock to an altitude below 8000 feet.
02	TEMPERATURE OUT OF VALID RANGE	DOCK: The valid ambient operating temperature range of the Dock is 59°-86°F (15° – 30°C). This is checked during power up and whenever the Dock is reset. Move the Dock to an acceptable ambient temperature environment and let it sit for at least five minutes to acclimate.

Error Code	Displayed Error/Description	Cause/Remedy
03	TEMPERATURE OUT OF VALID RANGE	CASSETTE: The valid operating temperature range of the Test Cassette is 59°-86°F (15° – 30°C). This is checked as soon as a Test Cassette is inserted into the Dock. Make sure that the Test Cassette temperature is valid and re-insert it into the Dock.
04	UNKNOWN TYPE OF CASSETTE	This error is caused when the Test Cassette is not recognized by the Dock. The most likely reason is that the latest program revision has not been installed into the Dock. See Section C: Operation, Re-programming the Dock. It is also possible that the Test Cassette is not firmly seated into the Dock. In this case, remove the Test Cassette, wait a couple of seconds, and re-insert it, pressing it firmly into position.
05	CASSETTE ALREADY USED! REPLACE!	Each Test Cassette can only be used one time. Even if a test does not complete, that Test Cassette may not be used again if the previous test was started or if the lid was closed.
06	CASS. NOT SEATED PROPERLY. RESEAT	When you insert the Test Cassette into the Dock, press it firmly into place. If this error occurs, remove the Test Cassette, wait a couple of seconds, and re-insert it, ensuring that the Test Cassette has come to a firm stop. If this error continues after trying multiple Test Cassettes, contact your distributor to replace the Dock.
07	TEST ABORTED! CASSETTE REMOVED	This error occurs when a Test Cassette has been removed before the assay test has been completed. To avoid this error and guarantee accurate testing, do not remove the Test Cassette until the test is complete. See section C. Running the Assay.
08	INADEQUATE SAMPLE	This error occurs if the lid is closed before the sample is loaded into the Test Cassette. To avoid this error, never close the lid before sample addition. If a sample was added but not detected, discard that Test Cassette and insert a new Test Cassette. Ensure the sample is at room temperature. Make sure sufficient sample volume is added to the Test Cassette.
09	REMOVE UNATTENDED CASS.	Each Test Cassette must be used promptly after you remove it from its protective pouch. If the Test Cassette has been sitting in the Dock for more than five minutes, the test aborts and the Test Cassette must be discarded.

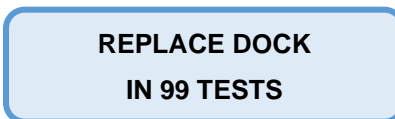
Error Code	Displayed Error/Description	Cause/Remedy
10	CASSETTE SEAL FAILED. REPLACE	If this error occurs, replace the Test Cassette and run the test again. If this failure repeats, contact your distributor and replace the Dock.
11	DOCK EXPIRED REPLACE DOCK	When the Dock has completed 3,000 runs, this error will appear. Contact your distributor to purchase a replacement Dock.
12	TEST ABORTED! TILT ERROR!	The Dock must be kept level at all times when operating. Do not bump, lift, or tilt the Dock during operation. If this error occurs the test is aborted and must be re-run with a new Test Cassette.
13	TEST ABORTED! POWER IS LOW!	The Dock's power supply voltage has fallen below acceptable limits. The run is aborted, and another run is not allowed to start until the power supply voltage is within acceptable limits.
14	TEST ABORTED! FAN/COOLING FAIL	The Dock is not temperature cycling as expected. This may be caused by a fan malfunction, or a problem with the liquid flow inside the Test Cassette. The run is aborted and must be re-run with a new Test Cassette. If this error happens repeatedly, the Dock must be replaced.
14	TEST ABORTED! FLOW ERROR	The Dock is not heating properly during temperature cycling. This indicates a problem inside the Test Cassette with fluid flow. The test is aborted and must be re-run with a new Test Cassette.

Other Warnings

The following messages are informational and do not indicate an error in the Dock or test.



Opening the lid during a test does not pause or abort the test, but it is not recommended. If this warning occurs, close the lid and let it remain closed until the completion of the test.



When 100 or fewer tests of the recommended lifetime usage of 3,000 tests remain, this warning is displayed after every completed test. Contact your distributor to purchase a new Dock before this number approaches zero.

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Find out more at thermofisher.com/renvo

ThermoFisher
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