

Accula™

DOCK

mesabiotech™



Accula™ Dock Operator's Guide

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 Mesa Biotech representative.

Mesa Biotech, Inc.
Customer Support
6190 Cornerstone Court East, Suite 220
San Diego, CA 92121
858-800-4929

I. Contact Information



Manufacturer

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6190 Cornerstone Court East,
Suite 220
San Diego, CA 92121
858-800-4929



EU Authorized Representative

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



Distribution



For a complete listing of distributors, contact Mesa Biotech, Inc. or visit www.mesabiotech.com/distributors

II. Warranty

Mesa Biotech™ warrants that Accula™ Docks purchased through Mesa Biotech 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 3 years from the date of shipment to an authorized distributor. Misuse of the Accula™ Dock, including exposure to harmful chemicals, environmental extremes beyond the equipment ratings in this Guide, or mishandling may render the warranty null and void.

III. Intended Use

The Accula Dock is a reusable platform, used in conjunction with an Accula Test Cassette to run *in vitro* diagnostics assays.

IV. Trademarks and Patents










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

KimWipe™ is a trademark of Kimberly Clark Corporation.

CaviWipes™ is a trademark of Metrex Research, LLC.

V. Symbols and Abbreviations

The following symbols are used throughout this manual:

Symbol	Definition
	Alternating Current
	Direct Current
	Manufacturer
	Authorized representative in the European Community.
	WEEE – Electronic equipment marked with this symbol are subject to European Union Directive 2002/96/EC (WEEE), and cannot be disposed of in the municipal waste system.
	Biohazard – Potentially infectious materials. Precautions must be observed.
	Consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	For <i>In Vitro</i> Diagnostic Use
	Informational note.

The following symbols are used throughout this manual:

AC – Alternating Electrical Current

DC – Direct Electrical Current

A – Amperes

V – Electrical Voltage

VI. Warnings and Precautions



Do not block the air vents located on the rear and sides of the Accula™ Dock. A minimum of 2 inches (5 cm) of clearance must be maintained.



Do not place the Accula™ 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 use of sprays in the vicinity of the Accula™ Dock.



Use only the supplied power adapter with the Accula™ Dock (MeanWell Part Number GSM25B12-P1J). This component has been tested and certified for use. If a replacement power supply is needed, please contact your Mesa Biotech distributor.

VII. Disposal and Shipping

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



A used Accula™ Dock may be biologically contaminated. Prior to disposal, or shipping for service, the Dock must be thoroughly cleaned.



The Accula™ 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 regarding disposal of the Dock, please contact your Mesa Biotech distributor.

To decontaminate the Dock prior to disposal:

1. Unplug the DC power connector from the back of the Accula™ Dock.
2. Open the lid of the Dock by depressing the lid latch button and pulling the lid to the open position.
3. If there is a Cassette inserted into the Dock, remove it by firmly grasping and pulling it upward.
4. 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. It is recommended to maintain an upright orientation of the Dock in order to allow entrapped air to escape through the cassette slot.
5. Remove the Dock from the bleach solution. Turn the Dock upside down to drain the solution from the interior. Allow the Dock to dry.
6. Dispose of the Dock as electronic waste in accordance to local regulations.

If for any reason, it becomes necessary to return a Dock to Mesa Biotech or one of its distributors, prior to packaging please carefully follow the exterior cleaning procedure detailed in section D. Maintenance, Cleaning the Accula™ Dock.

A. System Description and Specifications

The Accula™ Dock is an electronic module which executes *in vitro* diagnostic tests on compatible Accula Test Cassettes. It consists of an electro-mechanical interface to a single Test Cassette. The Dock contains all electrical systems, controls and logic necessary to orchestrate *in vitro* diagnostic tests within the inserted Test Cassette.

Upon insertion of a Cassette, the Dock will detect and identify the Cassette type. After the user transfers a clinical test sample into the Test Cassette and closes the Dock lid, embedded firmware in the Dock will control fluid flow of the sample into the various chambers of the Test Cassette, apply controlled voltage signals to the various Cassette heaters (monitored by sensors within the Dock), and provide visual status to the user with critical information such as estimated time to read, and various error states, should they be encountered.

Dock Specifications

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



The Accula™ Dock is not to be used in direct sunlight.

- Acceptable tilt – The Dock must be installed on a level surface, with an incline not to exceed 10 degrees.
- Dimensions: 5.7 in (14.5 cm) H x 3.9 in (9.9 cm) W x 3.8 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 Mesa Biotech type H03VWH2-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 located on the rear and sides of the Dock. A minimum 2 inches (5 cm) of clearance must be maintained.



Do not place the 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.

1. Place the Accula™ Dock on a level, stable table or laboratory bench. To ensure proper function, allow at least 2 inches (5 cm) of clearance around the Dock. Do not place it near equipment that will give off heat.
2. Insert the round DC connector of the adapter into the Dock as shown below. Connect the power cord to the AC 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, there may be an unused ground pin showing. This is normal and expected.

- Once the Accula™ Dock is connected to power, it will initialize automatically. The unit will beep, followed by a series of brief messages on the display. (The image below is for illustration purposes only. Your firmware P/N, version, and ambient temperature may differ.)

- | | | | |
|----|-------------------------------------|----|-------------------------------|
| 1. | MESA BIOTECH, INC.
MOLECULAR POC | 3. | AMBIENT
TEMPERATURE: 25C |
| 2. | FIRMWARE
P/N 210405 V2.7 | 4. | DOCK READY
INSERT CASSETTE |

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

C. Operation

This section provides detailed instruction pertaining to the operation of the Accula™ Dock only. It is not intended to be a comprehensive instruction for performing diagnostic tests. Such instructions are found packaged with the specific test kits.

The Accula™ Dock is capable of running any of a number of *in vitro* diagnostic tests offered by Mesa Biotech. For the purpose of illustration, this section includes Dock messages specific to the Flu A/Flu B Test.

Inserting the Test Cassette



Each Test Cassette may only be used once. Sensors in the Dock will not allow the assay to run if the cassette has already been inserted.

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



- Insert the Test Cassette into the slot with the cassette label facing toward the front of the Dock. The sample port (covered with a foil tab) on the top of the cassette should be accessible to the user. Fully depress the Test Cassette into the Dock until it 'clicks' into position. The Accula™ Dock will measure the temperature of the cassette and display it as shown in the example below:

CASSETTE
TEMPERATURE: 24C

If the cassette has been properly inserted, the display will identify the type of test that is supported by the cassette, for example:

FLU A/FLU B
CASS. INSERTED



If the display shows an error, refer to *Section E - Troubleshooting* for additional information.

- After a few seconds the display will prompt the user 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 Accula™ Dock, as this may cause the test to abort.

- Per the test kit instructions, remove the foil tab from the Test cassette and immediately add the sample to the cassette sample port. The Accula™ Dock will beep upon sensing the sample, and display:

SAMPLE LOADED
CLOSE LID

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

- 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 display:

SAMPLE LOADED
LID CLOSED

The Dock will verify that the Test Cassette has been sealed. Once verified it will initiate the test and display:

CASSETTE SEALED
TEST STARTED

During the test, the Dock will display 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 a number of factors, including ambient temperature, altitude, and the type of assay being run.



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

3. Allow the assay to run to completion before moving or disturbing the Accula™ Dock. The internal fan will turn on periodically during the assay. This is normal and expected. When the assay is finished, the remaining time will be 00:00, and the Accula™ Dock will display:

TEST COMPLETE
READ RESULTS

4. The Dock will beep every two seconds until the Test Cassette is removed.
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, please refer to the test kit instructions.

Once the Test Cassette has been removed, the Dock will display 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 Accula™ Dock will beep three times, and the display will remind the user to replace the unit. For example:”

REPLACE DOCK
IN 56 TESTS

7. After a few seconds, the Dock will display:

DOCK READY
INSERT CASSETTE

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

Reading the Test Results

Please refer to instructions provided with each assay test kit.

Re-programming the Dock

Periodically new tests are developed which require new programming for the Accula™ Dock. In order to support these new tests, the Dock firmware must be updated. This is a very simple process, by following these easy steps:

1. Apply power to the Accula™ Dock as indicated in Section B – Installation. The Dock will automatically initialize and display:

DOCK READY
INSERT CASSETTE

2. Insert the latest Programming Cassette (denoted by red top) into the Dock as instructed in Section C above (Inserting the test cassette). The Dock will sense the Programming Cassette and display:

PROGRAMMING
CASSETTE READY

Followed by:

**PROGRAMMING
WAIT FOR REBOOT**

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

**FIRMWARE P/N
210438-EN REV A**

4. The display will prompt you to remove the Programming Cassette:

**REMOVE PROGRAM-
MING CASSETTE**

Once the Programming Cassette is removed, the Accula™ Dock will restart with the new firmware installed.

D. Maintenance

Cleaning the Accula™ Dock

Regular cleaning of the Accula™ Dock is recommended. The Dock should be cleaned every day that it is used, and prior to disposal or shipment or servicing.



A used Dock may be biologically contaminated. Prior to disposal, or shipping for service, the Dock must be thoroughly cleaned.



To reduce the risk of damage to the unit, avoid use of sprays in the vicinity of the Dock.



Prior to cleaning the Accula™ Dock, disconnect the power supply. This will help to prevent damage to the unit.

Mesa Biotech 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% and
- Diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride: 0.28%.

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

If Cavi Wipes are unavailable, other cleaning solutions may be used 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. Follow 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 prior to re-connecting 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 prior to cleaning.

Troubleshooting

The Accula™ Dock performs a number of different environmental tests before and during an assay run to ensure that the conditions will allow a successful assay. If any of these 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 will be displayed for several seconds:

ERROR! CODE 05

This screen will be followed by a brief message describing 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 will check the altitude on its initial power up and not continue if the altitude range has been exceeded. To continue, the Dock must be re-located 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 5 minutes to acclimate.
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. Insure 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 for this would be that the latest program revision has not been installed into the Dock. See section C: Operation, Re-programming the Dock above. 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 may 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 inserting the Test Cassette into the Dock, it must be pressed 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, the Test Cassette must not be removed until the test is complete. See section C: Running the Assay above.

Error Code	Displayed Error Description	Cause/Remedy
08	INADEQUATE SAMPLE	This error will occur 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. Ensure sufficient sample volume is added to the Test Cassette.
09	REMOVE UNATTENDED CASS.	Each Test Cassette must be used in a timely manner when removed from its protective pouch. If the Test Cassette has been sitting in the Dock for more than 5 minutes, the test will abort and the Test Cassette must be discarded.
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.
15	TEST ABORTED! FLOW ERROR	The Dock is not heating properly during temperature cycling. This is indicative of 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.

**CLOSE LID
REMAINING: 21:15**

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

**REPLACE DOCK
IN 99 TESTS**

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

