Zoë-CM2[™] User Guide







Zoë® Culture Module

Zoë means life. The Zoë-CM2 Culture Module is designed to sustain the life of cells within Organ-Chips.

The instrument automates the precise conditions needed for simultaneous cell culture of up to 12 Organ-Chips. It supplies the dynamic flow of media and recreates the mechanical forces of breathing motions or peristalsis that help Organ-Chips recreate the microenvironment cells experience in the body.

Zoë-CM2 gives users the ability to independently control the flow rate of media through both the top and bottom channels of Organ-Chips. It also allows users to determine stretch parameters—including frequency and amplitude—of the Organ-Chip membrane. What's more, the Zoë-CM2 Culture Module has automated algorithms to prime the fluidic channels of Organ-Chips with media and remove any bubbles from the fluidic channels. Zoë-CM2 can be operated with controls located on the instrument or remotely monitored and controlled with the Zoë Manager web application.

This user guide has essential instructions for how to safely and effectively operate Zoë-CM2. Please ensure all users thoroughly read and understand this guide before operation.

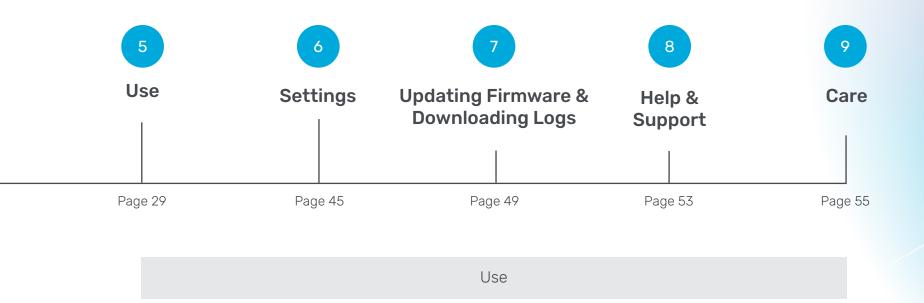
This product is for research use only.

Zoë Culture Module

Table of Contents



Introduction





1 Introduction

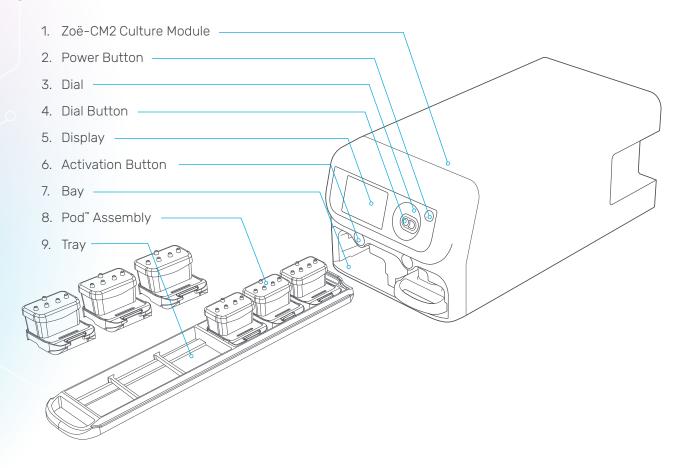
This section provides an overview of Zoë and its functions.

Equipment (what's in the box)

- 1. Zoë-CM2 Culture Module
- 2. Chip Cradles
- 3. Gas & Vacuum Supply Line
- 4. Zoë Core Update Cable
- 5. SensorPush HT1 Temperature and Humidity Smart Sensor
- 6. Metal Spudger Pry Tool
- 7. Ethernet Cable
- 8. 24V Power Supply

Zoë-CM2 Culture Module

Components



Power Button – Used to power the device on and off.

Dial – Used for selecting elements on the display, basic navigation, and adjusting values.

Dial Button – Used to confirm selections, parameters, and other edits to system settings.

Display – Shows the current Zoë parameters, displays system status, and provides alerts and messaging to the user.

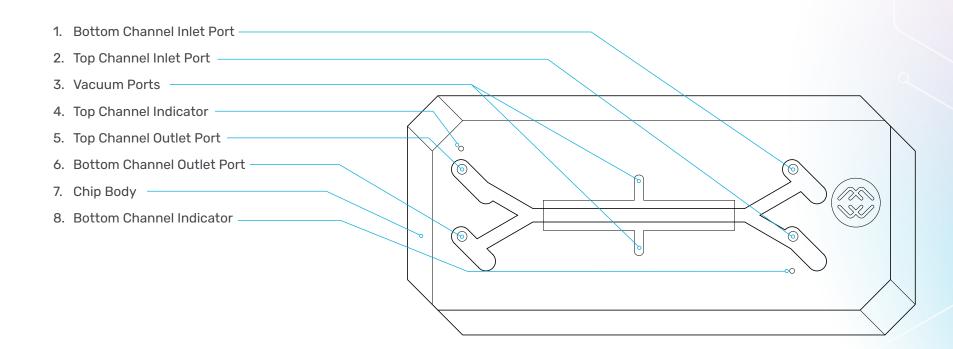
Bays – Zoë has a left and right Bay. Each Bay holds up to six Pod® Portable Modules, or 12 total.

Bay Activation Buttons -

Each of the two Bay Activation Buttons can be pressed to raise or lower the manifolds to engage the Pods and resume or pause flow independently in each Bay.

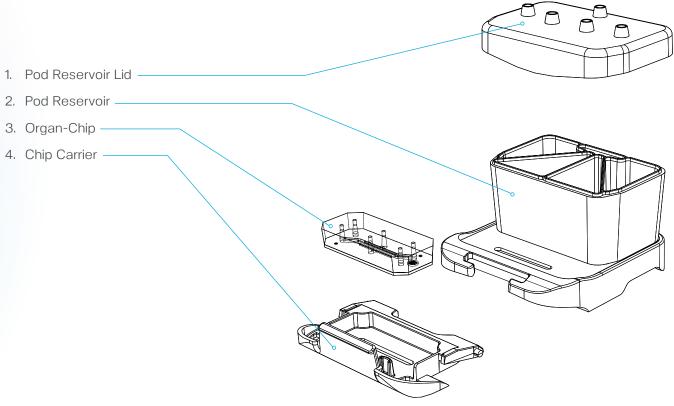
Organ-Chip

Configuration

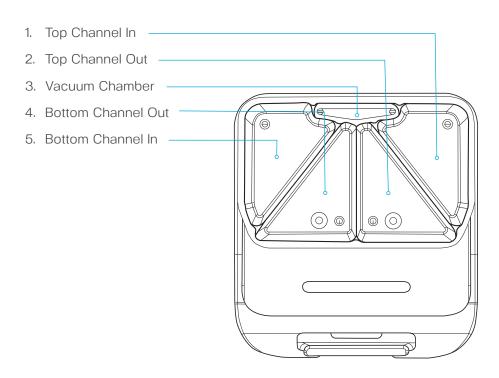


Pod

Configuration



Pod Components





2 Specifications

This section provides specific technical information and operational requirements. Included are system dimensions, thermal and gas requirements, and modes of operation.

Specifications

Manufacturer Emulate, Inc.

27 Drydock Avenue Boston, MA 02210

Assistance Contact

support@emulatebio.com

Use The Zoë-CM2 Culture Module is

for research use only

emulate 7.0 in

8.6 in

General Model: CM2

Weight: 10.9kg (24 lbs.)

Power Consumption: 2.16 kW/day

Capacity: 12 Pods

Operating Requirements

Instrument Rating: 24 VDC, 3.5 A, 50-60 Hz **Gas Input Pressure:** 276 kPa +/- 35 (40 psig +/- 5)

Gas Input Composition: 5% CO₂, balance air **Vacuum Input Pressure:** -70 kPa (-10.2 psig)

Environmental Operating Temperature: 20–38°C (68–100. 4°F)

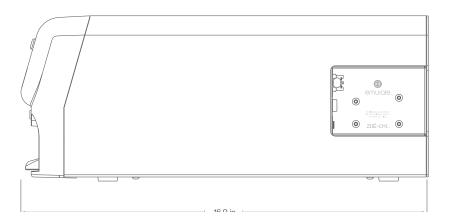
Relative Humidity: 0-90%

Max Altitude: 2,000 meters (6,562 feet) Storage Temperature: -5-40°C (23-104°F) Storage Humidity: 30-85%, non-condensing

Technical Flow Rate Ranges: 0 µL / h or 10–1,000 µL / h

Stretch: 0-12%

Stretch Frequency: Min: 0.01 Hz Max: 0.4 Hz



Zoë-CM2 Operation

Zoë-CM2 has two different modes of operation. It can operate:

- 1) Offline (not connected to the internet)
- Connected to the Emulate Cloud and operated via Zoë Manager (recommended)

The table to the right outlines the basic functionality and benefits of each mode.

We take data privacy seriously. For more information, please reference our Data Privacy & Security Policy for Emulate Software Applications.

Mode of Operation	Description (Basic Functionality)	Advantages
Offline	Zoë-CM2 is not connected to the internet.	No internet connection needed.
	Zoë-CM2 can only be operated using the screen on the instrument.	
Cloud-Connected via Ethernet	Zoë-CM2 has access to the internet.	Remotely monitor Zoë status and parameters as well as pause and flow functions.
	Zoë-CM2 can be operated by using either the screen on the instrument or the web.	Run commands on Zoë, such as Flush and Regulate, remotely. When Emulate is given permission, Emulate field engineers can pull diagnostic data from an instrument for streamlined support.
		When a software update is available, Zoë can be updated over the air.



3 Safety

This section includes recommended precautions when handling and using Zoë-CM2. The information here describes how users can minimize the chance of harming themselves or the module during operation.

Zoë-CM2 Safety



The Instructions Symbol

The product is marked with this warning symbol where it is necessary for the user to refer to the instructions in the user guides.

Regulatory Compliance and Testing

This product has been tested to the requirements of:

61010-1 (IEC, EN, UL, CSA)

IEC 61010-2-10 Safety Requirements for Electrical Equipment for measurement, control, and laboratory use

EMC Testing to EN61326-1:2013, FCC Part 15 Subpart B:2021, ICES-003 Issue 6, EN 55032:2015/AC:2016

Caution Statements

It is essential that all instructions are followed, and all warnings are understood. Failure to adhere to the instructions or operate the equipment within the stated specifications may cause injury, damage to the instrument, or issues with chip performance.

Zoë-CM2 is not sterile out of the box. Clean thoroughly with 70% ethanol before placing in the incubator to decrease the risk of contamination.

Never attempt to maintain or sanitize Zoë without first disconnecting from the power source.

Vent and disconnect all Gas Supply Lines before moving, sanitizing, or maintaining Zoë.

Zoë is heavy, so exercise care when moving it. Incubator shelving may not support Zoë when it is partially pulled out of the incubator. Make sure the instrument is placed on a secure and sturdy surface.

Never insert fingers or foreign objects into the Bays. Injury or instrument damage may result.

Always follow in-house safety protocols before handling compressed gas.

Users are responsible for the proper disposal of any single-use components that encounter biological material.

Service and maintenance should only be completed by Emulatecertified personnel. Never attempt to disassemble or repair Zoë without assistance.

Please be considerate of the instrument temperature range. Do not attempt to operate Zoë-CM2 in a temperature range outside of the one presented in this manual.

To power Zoë-CM2, only use the 24V Power Supply and Power Cord provided with the instrument. Note that this Power Cord is different from those of Orb and Zoë-CM1. Do not plug in the Power Supply provided with the Orb or Zoë-CM1 into Zoë-CM2.

If two Zoës are being placed in an incubator, arrange them on the bottom shelf alongside each other to ensure a balanced temperature in the incubator.

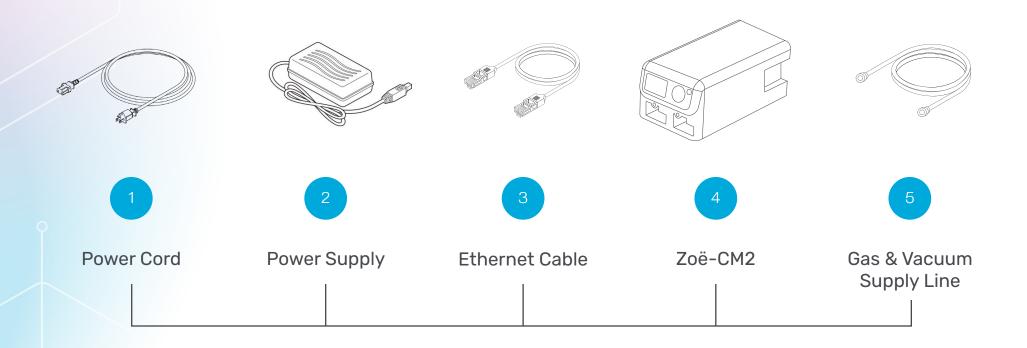


4 Installation

This section covers the basic installation of Zoë-CM2. Please reach out to Emulate Field Support for detailed installation guidance and support if needed prior to proceeding with installation. Ensure Orb and all hubs are connected before installing Zoë-CM2.

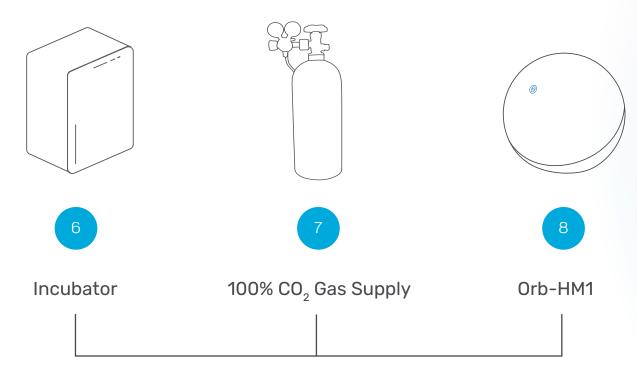
Items for Installation

Zoë-CM2 comes with the following items for installation:



Items for Installation

The user will need to provide the following equipment for installation:



Note: Contact Emulate for guidance on user-provided equipment.

Installation Procedure

Preinstallation

Setup

- 1. Before commencing installation, ensure that incubators are fully operational.
- 2. Unpack Zoë-CM2 with its accessories. Sanitize them with 70% ethanol prior to bringing them into the chosen operating environment.
- 3. Make sure the box is not missing any accessories or parts (see page 7).
- 4. Remove the SensorPush HT1 Temperature and Humidity Smart Sensor from the Zoë-CM2 box. This will be used to check the incubator temperature prior to Zoë-CM2 installation.
- 5. To set up SensorPush HT1:
 - a. Download the SensorPush app to a smartphone (available on App Store and Google Play).
 - b. Turn on the smartphone Bluetooth capability and open the SensorPush app.
 - c. Click "Add Sensor" in the top right corner of the screen.
 - d. Place the SensorPush HT1 on the screen and follow the instructions.
 - e. Give the SensorPush HT1 a name corresponding to the incubator in use.
 - f. Click "Back" in the top left corner of the screen.

Installation Procedure

Incubator Temperature Check

- Place the SensorPush HT1 in the center of the top shelf in the incubator and make sure the incubator door is closed securely.
- 2. Monitor the SensorPush app until it indicates that the incubator temperature has stabilized:

Note: Zoë-CM2 and the SensorPush HT1 should be turned on and placed into the incubator for stabilization. Emulate recommends leaving them for four hours to enable accommodation of temperature and humidity settings.

- a. Open the SensorPush app and monitor the temperature over time.
- b. Wait until the temperature of the incubator is stable and is within the acceptable range of 36°C to 38°C. Once it is within this range,
 Zoë-CM2 is ready to be installed. If the temperature falls outside of this range, the incubator needs to be recalibrated before installation of Zoë.

Note: The SensorPush app has three different statuses for the temperature: "Rising", "Falling", and "Steady". The temperature of the incubator can be considered stable when the SensorPush app reads "Steady".

c. Once finished, the SensorPush HT1 can be removed from the incubator and set aside for later use.

Installation Procedure

Installation

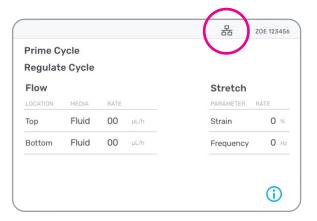
- 1. Run the Gas and Vacuum Supply Line through the incubator access hole.
- 2. Plug the Power Supply into an APC UPS or grounded wall outlet, mount the Power Supply transformer to the back of the incubator, and run the Power Cord through the incubator access hole.
 - **Caution:** Ensure the 24V Power Supply and Cord that came with Zoë-CM2 are being used. Do not use a Zoë-CM1 Power Supply since these output 12V and will not work with Zoë-CM2.
- 3. Connect the Ethernet Cable to an active network port and run it through the incubator access hole.
- 4. Connect the Gas and Vacuum Supply Line, Power Cord, and Ethernet Cable to the Zoë Bulkhead.
- 5. Connect the Gas Supply Line to the gas hub and connect the Vacuum Supply Line to the vacuum hub.
- 6. Power on Zoë-CM2 by pushing the Power Button on the front of the unit.
 - **Note:** The Power Cord may disconnect from the module during installation. It may also disconnect if the module or incubator is moved. It is recommended to minimize any tension/strain on the Power Cord. A magnet is provided to help minimize cable tension in the back of the incubator.

Installation Procedure

Connecting to a Network

Zoë-CM2 can be connected to the internet via the ethernet port on the back of Zoë.

- 1. To connect to a wired network, plug the supplied Ethernet Cable into the network port on Zoë, and connect the other end to an active ethernet port.
- 2. The system will connect automatically once an active connection is detected. After this, the network icon will appear in the title bar on the Zoë screen.





5 Use

This section describes proper interaction with, and operation of, Zoë-CM2. The instrument should always be used in an incubator while following aseptic procedures.

Use

Getting Started

Zoë-CM2 Interface

- a. Display
- b. Dial
- c. Dial button
- d. Bay Activation Buttons
- e. Power Button -

Powering On

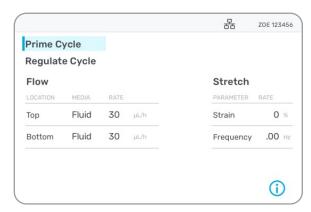
To power Zoë on, push the Power Button located on the upper-right corner of the faceplate. Zoë will then go through its startup routine until it displays the status screen.

Use

Running the Prime Cycle

The Prime Cycle perfuses media through the Pod before it is connected to a seeded chip to ensure no air is trapped when a chip is connected to the Pod.

- 1. Prepare Pods per desired organ-specific protocol.
- 2. Insert Tray with up to six Pods into a Zoë Bay.
- 3. Repeat Step 2 in the opposite Bay if priming more than six Pods.
- 4. Using the Dial, hover over "Prime Cycle" on the display. Press the Dial Button to select.
- 5. Rotate the Dial to bring up the "Start" option.

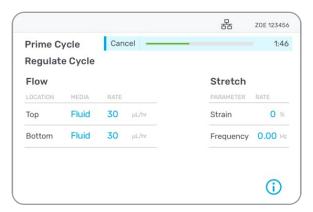


Use

Running the Prime Cycle (Continued)

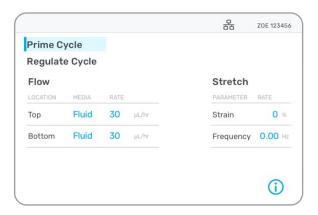
6. Press the Dial Button to select "Start," which will initiate the Prime Cycle. This will cause the manifolds to lower.

7. A status bar and timer will appear to show the progress of the Prime Cycle.



Use

8. Once the Prime Cycle is complete, the status bar and timer will disappear, the manifolds will rise, and the Bay(s) will be deactivated.

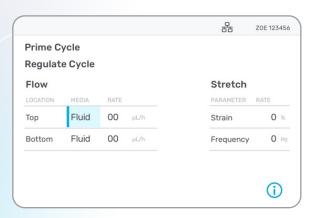


9. Remove the primed Pods from Zoë and attach the prepared chips to the Pods. Reference organspecific protocols for instructions on chip preparation prior to attachment.

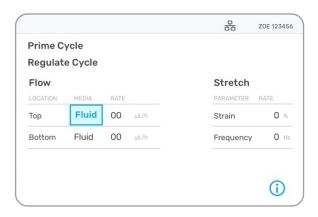
Use

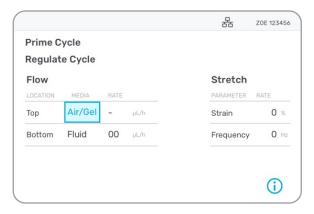
Selecting Media Type

 Using the Dial, hover over the areas below "Media" denoting the "Top" and "Bottom" channels.



2. Press the Dial Button to edit the "Media" type.
Rotate the Dial to select between Fluid and Air/Gel:

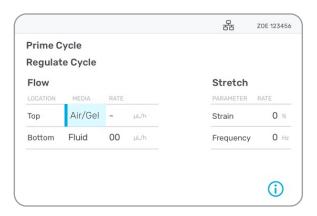




Use

Selecting Media Type (Continued)

- 3. After hovering over the desired media type, press the Dial Button to confirm.
 - a. Note: If selecting Air/Gel, the flow rate will automatically be set to 0 to prevent media flow, as there is no flow in the channel when "Air/Gel" is selected.

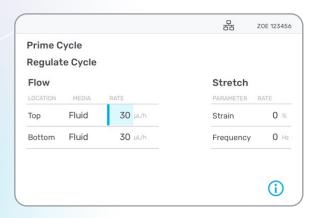


4. These settings will now take effect on Zoë.

Use

Programming Flow Rate

 Using the Dial, hover over the areas below "Rate" denoting the "Top" and "Bottom" channels.



2. Press the Dial Button to begin editing flow rate. Rotate the Dial to adjust the flow rate between 10 and 1,000 μ L / hr.

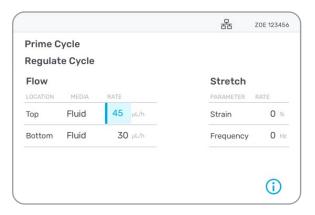




Use

Programming Flow Rate (Continued)

3. After rotating to the desired flow rate, press the Dial Button to confirm.

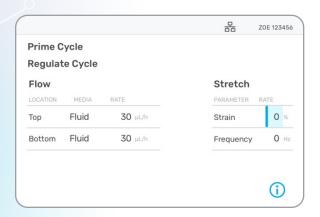


4. These settings will now take effect on Zoë.

Use

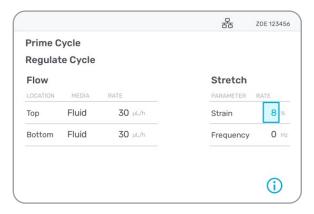
Programming Stretch Parameters

Using the Dial, hover over the "Strain" parameter.
 This option allows you to set the amount of stretch on the chips.



2. Press the Dial Button to begin editing the strain. Rotate the Dial to adjust the level of strain between 0% and 12%.

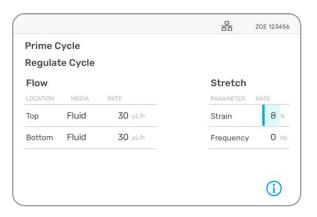




Use

Programming Stretch Parameters (Continued)

3. After reaching the desired level of strain, press the Dial Button to confirm.



4. Using the Dial, hover over the "Frequency" parameter. This option allows you to set the frequency of stretch.



Use

Programming Stretch Parameters (Continued)

- 5. Press the Dial Button to begin editing the frequency. Rotate the Dial to adjust the frequency between 0.00 and 0.40 Hz.
 - ZOE 123456 **Prime Cycle** Regulate Cycle Stretch Flow LOCATION MEDIA Fluid 30 µL/h Strain 8 % Top Bottom Fluid 30 µL/h Frequency

6. After reaching the desired frequency, press the Dial Button to confirm.

Use

Running Regulate™ Cycle

The Regulate Cycle is designed to remove any microbubbles that may have been introduced during the activation and seeding steps.

Note: If modeling ALI or filling the top/bottom channel with gel, be sure to select "Air/Gel" for the "Media" field on the main screen prior to running the Regulate Cycle. This ensures that Regulate will run properly and will not disrupt gel or ALI conditions. To avoid drying out the reservoir during the Regulate Cycle, ensure there is sufficient media in all pods. Reference the relevant cell culture protocol for more details.

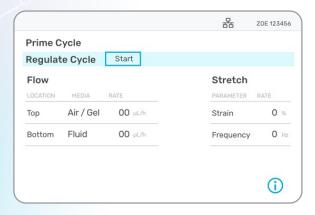
 If no connected Pods or chips are present in Zoë, insert the desired quantity into each Bay of Zoë.
 Press the Bay Activation Buttons to lower the manifolds and activate the Bays. 2. Using the Dial, hover over "Regulate Cycle" on the display. Press the Dial Button to select.



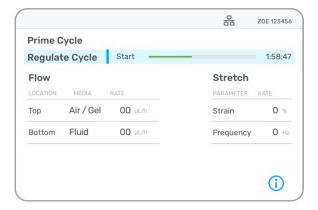
Use

Running Regulate™ Cycle (Continued)

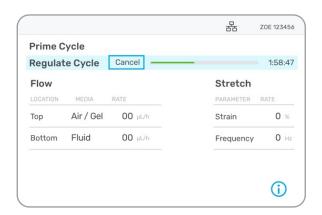
3. Rotate the Dial to bring up the "Start" option. Press the Dial Button to select "Start," initiating the Regulate Cycle.



4. A status bar and timer will appear and show progress of the Regulate Cycle.



To cancel the Regulate Cycle, rotate the Dial to bring up the "Cancel" option. Press the Dial Button to select.



Use

Running Regulate™ Cycle (Continued)

5. Once the Regulate Cycle is complete, the status bar and timer will disappear, and the system will revert to the preset flow and stretch parameters.



Shutting Down

Press the Power Button on the front of Zoë.

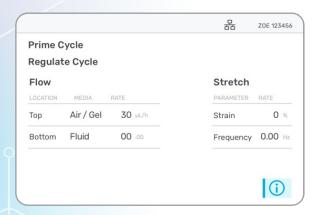


6 Settings

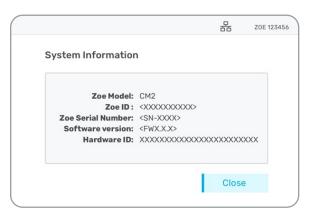
Settings

System Information

The "System Information" screen provides details on Zoë Model, Name (ID), Serial Number, Software Version, and Hardware ID. This screen can be accessed by hovering over and selecting the ① icon on the lower right of the screen.



To close the "System Information" screen, hover over and select the "Close" option.



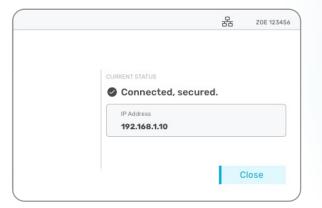
Settings

Network Connection

To check the status of the network connection, use the Dial to hover over the "Ethernet" icon in the top bar of the display. Press the Dial Button to bring up the "Network Connection" screen.



If there is an active ethernet connection, "Connected" will automatically be displayed along with the IP address. If there is no ethernet connection, "Disconnected" will be displayed.



To pause network connection, unplug the Ethernet Cable.



7 Updating Firmware & Downloading Logs

Updating Firmware & Downloading Logs

Updating Zoë Firmware

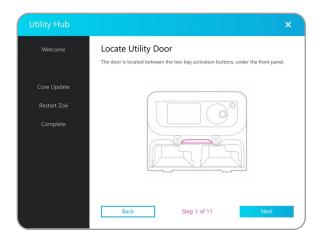
To update the Zoë firmware, download the "Utility Hub" application from emulatebio.com/utility-hub.

The application is compatible with computers running Windows 7 or a later version.

1. Once Utility Hub has been downloaded, open the application and select "Update Firmware".



2. Follow the instructions displayed on Utility Hub to update the Zoë firmware.



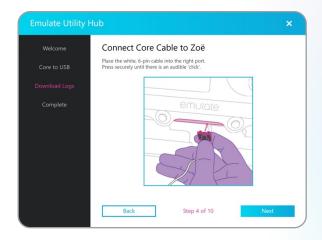
Updating Firmware & Downloading Logs

Downloading Logs

1. Open Utility Hub and select "Download Logs".



2. Follow the instructions displayed on Utility Hub to download the logs from Zoë-CM2.





8 Help & Support

Contact Emulate Support for any issues with Zoë-CM2.

Email: support@emulatebio.com

Website: https://emulatebio.com/contact-support/

Phone: +1 844-902-4477 (Toll Free)

+1 781-583-3515



9 Care

Care

Cleaning & Maintenance

Care for Zoë includes periodic cleaning. Preventative maintenance should be performed by a qualified Emulate Field Engineer at least once per year.

<u>Contact Emulate Support</u> for additional details and to request an appointment. Regular checks and recordkeeping provide helpful information should any troubleshooting be required.

Zoë does not require significant maintenance. However, it is necessary to clean the exterior of the module and Trays with 70% ethanol prior to each use. The module should be cleaned in place and not removed from the incubator. All maintenance activities should be recorded in a lab notebook or equivalent.

Troubleshooting

Problem	Possible Reason	Recommended Solution
Zoë Culture Module will not power on	The Power Cord has become unplugged from the Zoë Culture Module.	Confirm the Power Cord is fully connected to rear of Zoë Culture Module.
	There is an unknown internal error with Zoë.	Contact Emulate for troubleshooting.
	The Power Cord is damaged.	Replace Power Cord; contact Emulate for replacement.
Bay will not activate	Bay is empty or Tray is not fully inserted into the Bay.	Insert Tray until the Tray snaps into place.
	Gas & Vacuum Supply Line is not connected to Zoë or is not connected to the gas hub	Connect the Gas & Vacuum Supply Line to rear of the Zoë Culture Module and the other end of the Gas Connector Line to the gas hub.
	The Orb Hub Module is powered off.	Refer to the Orb User Guide.
Bay will not de-activate	Bay was activated with empty Tray inserted, and empty Tray was removed before de-activating Bay.	Insert empty Tray and press the Activation Button Refer to the Orb User Guide.
Zoë is frozen or unresponsive	N/A	Power Zoë off and back on again.
		IMPORTANT: If problem persists, contact Emulate support.
Pods stuck in Zoë	Pod lid not secured on Pod.	Wiggle the Tray to the right and left while sliding it out, making sure to keep it level.
		IMPORTANT: If problem persists, contact Emulate support.
Pods not flowing properly or evenly	If there are large fluctuations in flow rates, bubbles are the likely cause.	 Remove the chip from the Pod Flush the chip with media Re-prime the Pod with degassed media Connect the chip to the Pod, and Run the Regulate Cycle
Internet connection is interrupted	Bad internet connection.	Power Zoë off and back on again. Check ethernet connection.
	Ethernet Cable has become disconnected.	Check cable connection at Zoë and port on wall.



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