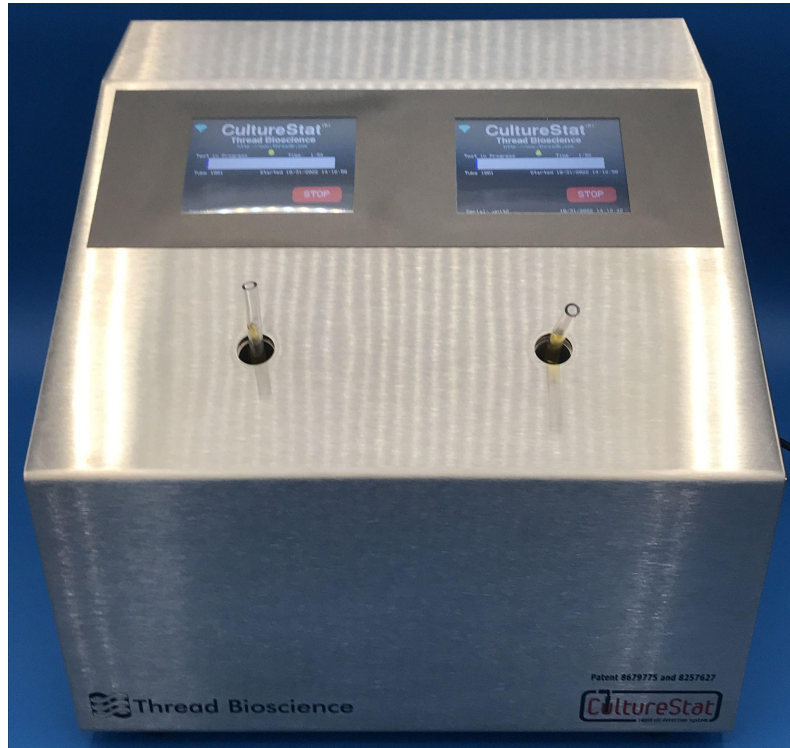


CultureStat Owner's Manual

Thread Bioscience, INC.
CultureStat Rapid UTI Detection Device



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Introduction

Thank you for selecting Thread Bioscience, Inc. for your equipment needs. For maximized product performance and ease of use please proceed as follows:

1. Inspect the carton and unit for shipping damage. Notify the carrier immediately if damage is found.
2. Use the “Accessory Checklist” when unpacking to verify that all parts of the unit have been received. Do not discard packing materials until everything has been accounted for.
3. Read this operation Manual thoroughly before deciding on an appropriate location for the unit. You must consider the availability of power and other equipment requirements, as well as user convenience in operation.
4. Carefully follow directions in the “Installation” section of the manual.
5. Insist that each operator be familiar with the “Operating Procedures” section of this manual.
6. Follow the required preventive maintenance schedule for long equipment life.
7. Keep this manual in a safe location for ready reference to the “Operations Procedures” and “Maintenance” sections when needed.

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The information contained in this manual is the exclusive property of the manufacturer and has been provided solely to enable the users of the equipment described herein to operate and maintain such equipment. Any other use of this information, or reproduction or transmission of all or any portion of this manual, without prior written consent of the manufacturer, is expressly prohibited.

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Model Description (1)

CultureStat is a rapid test to accurately determine the absence or presence of bacteriuria and differentiate between lag phase and log phase growth stage.

CultureStat can distinguish between infectious (log) and non-infectious (lag) state microbial growth

CultureStat samples are examined in-situ, preventing genetic mutation from sample's source state

CultureStat does not promote environmental microbial adaptation (from wet state to a dry environment as in agar plates)

CultureStat sample size is 7,000 times greater than other culture techniques

CultureStat ***is a culture methodology*** utilizing broth media

CultureStat results are objectively achieved utilizing spectrophotometric and algorithmic analysis

CultureStat is a multi-layered test incorporating several input sources to compile data

CultureStat testing environment is controlled

CultureStat results are digitally recorded

CultureStat is completely automated, eliminating human error and subjectivity

CultureStat results are available in less than 2 hours

CultureStat requires less than a minute of operator time per test

CultureStat allows accurate timely negative results preventing unneeded antibiotic prescriptions

CultureStat significantly reduces false positives and provides faster positive result times

CultureStat low incidence of false negative and false positive results support use as an accurate negative screen

CultureStat provides rapid test results preventing incorrectly prescribed antimicrobial drugs

CultureStat allows a Provider to more accurately prescribe for actual infections

CultureStat can be used in conjunction with Antimicrobial Sensitivity Testing (AST) to target specific bacterium

CultureStat does not require additional software to purchase or install

CultureStat ampoules are the only disposable component

CultureStat test ampoules have a shelf life of five years

CultureStat ampoules do not require refrigeration for storage

CultureStat use as a negative screen device reduces healthcare testing cost

CultureStat promotes efficient testing by identifying negatives and reducing false positives

CultureStat reduces the total cost of antimicrobial prescriptions

CultureStat is used by Providers to accurately diagnose infection reducing untreated infection cost

Unit Specifications (2)

Overall Dimensions and Materials of Construction

The overall dimensions are listed below. The materials of construction include stainless steel (outside case), mylar (screen covering), and SBR rubber (foot mounts).

10" W x 8" H x 9" D
(25.4 cm W x 20.3 cm H x 22.9 cm D)

Ampoule Well Capacity

Each CultureStat device is outfitted with two ampoule wells that operate individually of one another. Each well is designed to house one singular ampoule at a time.

Well Diameter
0.5" (12.8cm)

Electrical Requirements

All electrical parts are UL listed/approved. The CultureStat operates internally at 12 VDC, which can be supplied with the included power supply unit and a power source of 110 to 240 VAC (50-60 Hz). Power consumption of the device is less than 100 watts and the unit has a resettable circuit breaker on the rear panel which limits the internal current of each individual well to 3 amps at 12 VDC.

Suggested Cleaning

General Cleaning of the outside case is recommended after use. See the "Maintenance" section for further recommendations and procedures.

Shipping Weight

The shipping weight of the CultureStat is approximately 9 lbs/4 kg.

Installation (3)

The CultureStat should be installed on a flat, solid surface with easy access to required electrical supplies. The CultureStat should be placed in an area that has proper equipment to clean and dispose of medical fluids properly.

Use a power source easily accessible to the unit to avoid stretching the power cord.

Operating Procedures (4)

1. Unpacking and Assembly

The CultureStat contains the Culturestat unit and a 12 volt power supply unit.

2. Power Requirements

The CultureStat is supplied with a 2 prong, 12 volt power supply unit that requires a power source of 110 to 240 VAC (50-60 Hz). This power supply unit can be plugged into a normal wall outlet and then plugged into the power supply port on the back of the CultureStat.

3. Powering the Unit On/Off

Once the power supply unit is plugged into the power source and the CultureStat device you may power each well on individually by flipping the corresponding power switch to the “On” position. The red tab on the switch will be visible when the power is turned on. To turn each well off you will need to turn each individual power switch to the “Off” position. The red tab will no longer be visible when the power is turned off.



(Image displaying power switches, circuit breakers, and power supply port on rear of device)

4. Running a Test

To run a test on the CultureStat you will place your filled ampoule into one of the two wells. After the ampoule is in the well completely (no part of the ampoule should be visible other than the Tygon tubing at the top) (See image below) you will press the green “Start” button on the

screen corresponding to the well your ampoule is located. The test will now run its course and provide you with your results for your sample.



(Example of how ampoules should be placed in device)

5. Ending a Test

If you need to end a test after it has already been started you will press the red “Stop” button on the screen corresponding to the well your ampoule is located in. This will give you an incomplete result for your current sample and put that well back into standby mode so that you may use it to begin a new test at any time.

6. After a Test is Complete

Once a test has run its course the screen will display your test result. Once you have your results recorded you should properly dispose of the ampoule. You may now use the device for another test by inserting a new ampoule into the well and pressing the green “Start” button.

Maintenance (5)

Maintenance Recommendations

You may perform a General Cleaning of the CultureStat Reader device while it is plugged in and powered on. A Deep Cleaning disinfection procedure should be performed at the conclusion of the testing for that day or following 24 hours of continuous use. The CultureStat Reader device must be powered down and unplugged to perform a Deep Cleaning.

Deep Cleaning includes all sides, including the bottom, of the outer case using a disinfectant of significant strength to ensure any contamination is eradicated. General Cleaning of the outside case is recommended after each use. To perform a General Cleaning use isopropyl alcohol and a clean rag or alcohol wipes to clean the top and sides of the outside case and screens of the CultureStat Reader device.

Preventive Maintenance Schedule

Following the preventive maintenance schedule will help ensure that CultureStat continues to function properly and that there are no unintended interruptions in service from the unit.

The CultureStat can run tests 24 hours a day without having to be powered off.

Every 12 Months

The CultureStat will go into a manual lockdown and tell you it must be returned to the manufacturer for factory recertification.

Troubleshooting Guide (6)

Problem	Possible Causes
CultureStat does not turn on	Unit is not plugged in or not plugged into a working outlet Power supply unit/cord is not securely plugged into the device Power switch is in the “Off” position
“Malfunction - Return for Service”	The device has reached its 12 month return for service date A software malfunction has occurred