

LECTOR DE ZONA DE ANTIBIÓTICOS

TRINITY™ V3

TRINITY V3* utiliza imágenes digitales para automatizar la lectura de zonas y los cálculos para los ensayos de potencia de antibióticos. Está disponible un módulo de recuento de colonias opcional. Este completo sistema de microbiología industrial se utiliza a menudo en laboratorios de microbiología QA/QC farmacéuticos.

TRINITY V3 cumple estrictamente con los requisitos de firma electrónica 21 CFR Parte 11 y sigue los métodos de ensayo de difusión en agar USP 81, EP, BP y JP. Los documentos de validación de IQ OQ PQ se incluyen con la compra de cada sistema.

También se suministran cilindros peni y dispensadores de cilindros peni para ensayos de potencia de antibióticos.



DISPENSADOR DE CILINDRO DE PENI Y CILINDROS DE PENI

El dispensador de cilindros de peni incluye una tolva que contiene más de 300 cilindros de peni de acero inoxidable (cara plana o borde biselado) y puede dispensar 4 o 6 cilindros de peni con un solo tirón de la palanca. Los cilindros Peni se dejan caer con precisión sobre placas redondas de 90-100 mm. Todos los productos están diseñados y fabricados en los Estados Unidos.

El lector de zona antibiótica TRINITY V3 automatiza los ensayos de potencia antibiótica siguiendo los métodos USP 81, EP, BP, JP.



Dispensador de cilindro Peni

Dispensador de cilindro Peni

Material :

Acero inoxidable y aluminio

Dimensiones :

Ancho: 13 cm / 5,25 pulg.

Alto: 31 cm / 12,25 pulg.

Profundidad: 13 cm / 5,25 pulg.

Fabricado en EE . UU.



Cilindro de pene de cara plana



Cilindro Peni de borde biselado

Cilindros Peni (cara plana o borde biselado)

Material : acero inoxidable

Dimensiones :

diámetro interior: 6 mm
 Diámetro exterior: 8 mm
 Longitud: 10 mm

Tolerancia: ± 0,1 mm

Fabricado en EE . UU.

TOP CAMERA READER – HARDWARE

Dimensions (Unit / Shipping):

Width: 54 cm (21 in) / 63 cm (25 in)
 Height: 53 cm (21 in) / 63 cm (25 in)
 Depth: 35 cm (14 in) / 48 cm (19 in)

Weight (Unit / Shipping):

Weight: 14 kg (32 lbs) / 21 kg (47 lbs)

Voltage:

100 – 240 Volts
 50 – 60 Hz

Loading System for Test Plates:

Drawer fits test plates up to 150mm round
 Adapter rings available for unique test plate sizes

Image Capture:

Full color digital camera
 High Resolution 2592 x 1944 pixels (5.0 megapixels)
 Unlimited number of test plate images may be saved and printed

Image Precision:

0.05 mm for colony size detection and zone diameter reading
 0.08 mm for colony size discrimination

Lighting:

Non-breakable LED light source
 Lifespan 50,000+ hours
 Over sample lighting
 Under sample lighting
 Darkfield illumination
 Brightfield illumination

Cabinet Design:

Closed cabinet
 No ambient light interference

Monitor:

24 inch widescreen
 Touch Screen
 Mounted to reader cabinet with tilt capability
 CE, UL, and FCC certified

Calibration:

Zone diameter measurement
 Colony size and count verification
 Color verification
 Calibration required after software installation and if system is physically moved

Environmental Requirements:

Temperature: 10-45°C
 Humidity: 0-90%
 Similar to requirements for personal computer operation

Maintenance:

No routine maintenance required
 Contains no motors, no scanners, no mirrors, no moving parts, no breakable light source

US FDA, United States of America Food and Drug Administration:

510(k) Reviewed - K944319 and K932122

HARDWARE ACCESSORIES AND DOCUMENTS

Bar Code Reader (optional)

Electronic Caliper (optional):

Linked to the computer by USB cable
 Measuring range: 0-150mm
 Resolution: 0.01mm
 Precision: 0.02mm
 Repeatability: 0.01mm
 Measurement unit: millimeter

Calibration Template

Test Plate Adapter:

90 mm Test Plate Adapter Ring

Power Supply with Cord:

12 Volt Power supply
 UL and CE certified

USB Cable

Product Manual

Software CD

Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) validation protocol documents

ANTIBIOTIC POTENCY SOFTWARE MODULE (AA-MOD)

Test Plates Read:

90-100 mm round

Reading Time:

Less than 1 second per test plate

Methods:

US Methods – USP <81> (United States Pharmacopoeia), US-FDA, CFR (Code of Federal Registry), AOAC (Association of Analytical Communities)
EP (European Pharmacopoeia)
BP (British Pharmacopoeia)
JP (Japanese Pharmacopoeia)
CP (Chinese Pharmacopoeia)
Meets GLP (Good Laboratory Practices) requirements

Zone Measurement Accuracy:

Displays 1 or 2 decimal places
0.05 mm precision for measurements
Threshold and sensitivity settings for difficult plates

Log Options:

Natural Log
Base 10 Log

Calculation Features:

Instant concentration and potency calculation upon completion of reading all plates
Plate to plate variation automatically accounted for in calculations
Display up to 5 decimal places on calculated values

USP Method Features:

Option to check zone measurements for outliers
Option to plot concentration on y-axis or x-axis
Option to use corrected reference to calculate unknowns
Option to display standard curve before reading unknowns
Option to calculate concentration as a percentage of reference
Displays raw data and graph on-screen to review, save and print

<p>Plots standard curve with unknown and known concentrations, and outlying points clearly displayed</p> <p>Calculates correlation coefficient, standard deviation, sample concentrations and original concentration values</p> <p>Calculation / Display of Relative Standard Deviation for each measurement set</p> <p>Generates Combined Sample Potency Report</p> <p>Checks for Outliers in combined sample potency values</p> <p>Calculates Log based Combined Average Potency</p> <p>Calculates Confidence Interval for Average Potency</p>
<p>EP Method Features:</p> <p>Reads and calculates results up to 16 plates</p> <p>Performs ANOVA (Analysis of Variation) calculations</p> <p>Calculates Statistical Weight for individual assays</p> <p>Generates Combined Sample Potency Report</p>
<p>JP Method Features:</p> <p>Reads and calculates results up to 15 plates</p> <p>Includes potency calculation options</p>
<p>Electronic Records:</p> <p>Meets 21 CFR Part 11 (Code of Federal Registry) for electronic signature requirements</p> <p>Classified as a closed system.</p> <p>Results and system information are stored in a proprietary, locked database.</p> <p>User ID and Password verify electronic signatures:</p> <ul style="list-style-type: none"> - System access is logged, including unsuccessful attempts at access. - The number of unsuccessful login retries before system lockout can be set by the System Administrator. - The number of retries is reset with a successful login. If lockout occurs, an administrator must log in to unlock the system. - User ID and passwords are stored and classified as active or inactive. Previously used IDs and passwords are stored so that they cannot be reused. <p>System Administrator can set minimum User ID length, minimum password length, and password expiration time:</p> <ul style="list-style-type: none"> - All changes to Users, configuration, and system settings are logged. - Three Levels of system access: Administrator, User, and Read-Only. - Read-only rights include viewing and printing of completed assay results only. - User rights include above plus reading, saving, and printing of assays. - Administrative rights include read-only rights plus password/User ID assignment, deletion of assay results, and system backup restoration. <p>Software is designed to enforce proper assay reading sequence. Plates cannot be read until minimum assay information is entered.</p> <p>All results are marked with User ID, time and date when saved:</p> <ul style="list-style-type: none"> - Password is verified to save result and a note is displayed that indicates the electronic signature is being attached to the result. - Results must be saved before they can be printed. - Printed results include User Name, User ID and Assay ID on all pages. <p>Changes to reading values after the results have been viewed are marked on-screen and on printouts. Original values are saved and shown creating an audit trail of changed values.</p> <p>After a result has been saved and the assay is closed, it can be re-opened and printed, but is read-only.</p> <p>User activities are logged including: Starting an Assay, Saving a Format, Reading Plates, Previewing the Standard Curve, Viewing Results, Saving the Assay, and Exiting the Assay as applicable.</p>
<p>Data Export:</p> <p>Test results including raw measurements may be exported in text or binary format to be read by other software programs</p>

ANTIBIOTIC POTENCY SOFTWARE MODULE - LARGE PLATE METHOD

REQUIRES ELECTRONIC CALIPER

Recording Device:

Electronic caliper records zone diameters via USB port directly into software

Plate Layout Options:

Latin Square
 Random
 Sequential
 User Defined

All known and unknown test samples are located on one large plate

Plate Sizes:

All plate sizes including 243mm bioassay dishes (NUNC in Denmark)

Plate Format Options (Standard Curve Large Plate Assay):

Standards 2-8
Replicates 1-8
1-100 Unknown Samples

Calculation Features (Standard Curve Large Plate Assay):

Correlation coefficient
Standard deviation
Sample concentrations
Original concentration values

Plate Format Options (EP/BP Large Plate Assay):

2 or 3 Point Assay
1-5 Unknown Samples
1-16 Replicates

Calculation Features (EP/BP Large Plate Assay):

Performs ANOVA (Analysis of Variation) calculations
Options for Completely Randomized, Randomized Block and Latin Square assay designs
Calculates Statistical Weight for individual assays
Generates Combined Sample Potency Report

COLONY COUNT SOFTWARE MODULE (CC-MOD)

Plate Samples/Media:

Bacteria
Yeast
Transparent
Opaque
Colored
Blood Agar
3M™ Petrifilm™
Spiral Inoculated
Ames
Phage/Plaque
Pour Plate
Filter Membrane/Grid

Chromogenic Agar:

Reads and interprets colonies of bacteria and yeast on various commercial brands of chromogenic agar plates

Define Plate Area for Reading:

Entire Plate
Half Plate
Quadrants
Custom defined

Accuracy:

Smallest detectable colony diameter: 0.05 mm
Smallest colony size discrimination: 0.08 mm

Counting Options:

Differentiate by size (up to 10 size ranges may be defined and counted simultaneously)
Differentiate by color (up to 256 colors or shades may be defined and counted)
Automatically separate touching colonies into multiple counts
Divide large colonies into multiple counts
Adjust sensitivity, exposure, and lighting parameters
Recall common counting formats
Adjust counted area to exclude plate rims and ridges
Calculates end concentrations on spiral inoculated plates
Colonies are marked on-screen by color
Manual include and exclude colonies

Guidelines:

Follows Aerobic Plate Count Guidelines in the US-FDA Bacteriological Analytical Manual (BAM), the US-FDA preferred laboratory procedure for microbiological analysis of food and cosmetics

Meets 21 CFR Part 11 electronic signature requirements with multi-level access controls and full audit trails
Meets GLP (Good Laboratory Practices) requirements

COMPUTER REQUIREMENTS

COMPUTER TYPICALLY NOT INCLUDED WITH TRINITY™ V3

Operating System:

Windows 10 & 11
All Microsoft® Service Packs and Critical Updates must be applied

USB ports:

3 available (minimum)

Internet Connection:

Recommended

Surge Protector

CERTIFICATIONS

ISO Certifications for Giles Scientific:

ISO 13485: 2016

Council Directive 98/79 EC for "in vitro" diagnostic medical devices:

Conforms

SERVICE CONTRACT AND WARRANTY

RENEWABLE ANNUALLY (YEAR 1 INCLUDED WITH PURCHASE)

Live technical support:

7 days per week via telephone and email

Hardware Warranty:

One Year

Customer Support Center:

Access to online training videos and product and validation manuals

Software updates via website download:

New TRINITY V3 product features

www.heedding.com