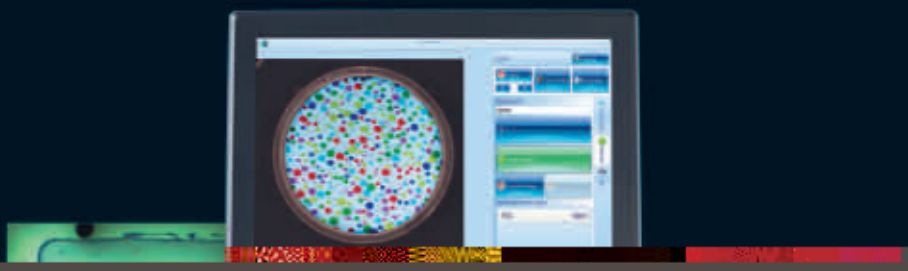
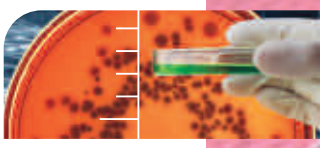


# ADVANCED AUTOMATION

Synbiosis is the manufacturer and supplier of the world's most popular automated microbiological colony counters and zone measurement systems. With over 25 years of experience, Synbiosis systems provide dedicated solutions for a wide range of applications. **ProtoCOL 2** is the number one choice in the automated colony counting and zone measurement market.



With the introduction of the **ProtoCOL 2** series, a new generation of colony counting and zone measurement has been reached. This ground breaking instrument takes the technology to a new level with its unique functionality and performance.

- Ergonomic design for comfortable use and easy access
- Sensitive touch screen for rapid input and intuitive control
- Unique lighting (patent pending) configuration for exceptional illumination of all sample types
- Fully automatic reading for time savings of over 80% when compared to any manual method
- Highly reproducible and consistent results
- Extensive results and data output facilities
- Meets the most demanding requirements for 21 CFR Part 11, GLP and QA
- Has full audit trail and user permissions log

# PROTOCOL 2 FLEXIBILITY IS THE KEY

The ergonomic design of **ProtoCOL 2** makes it very comfortable and easy to use.

## Camera

The high resolution CCD camera captures high definition images and detects colonies as small as 43 microns

## Design

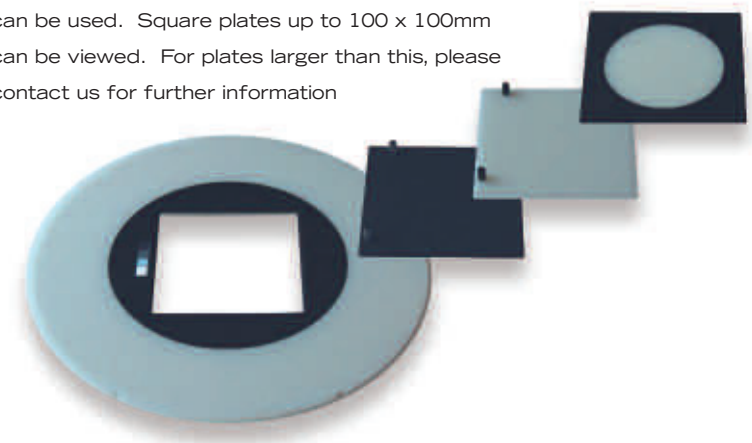
The ergonomic design gives a small footprint and looks good in any laboratory or production environment

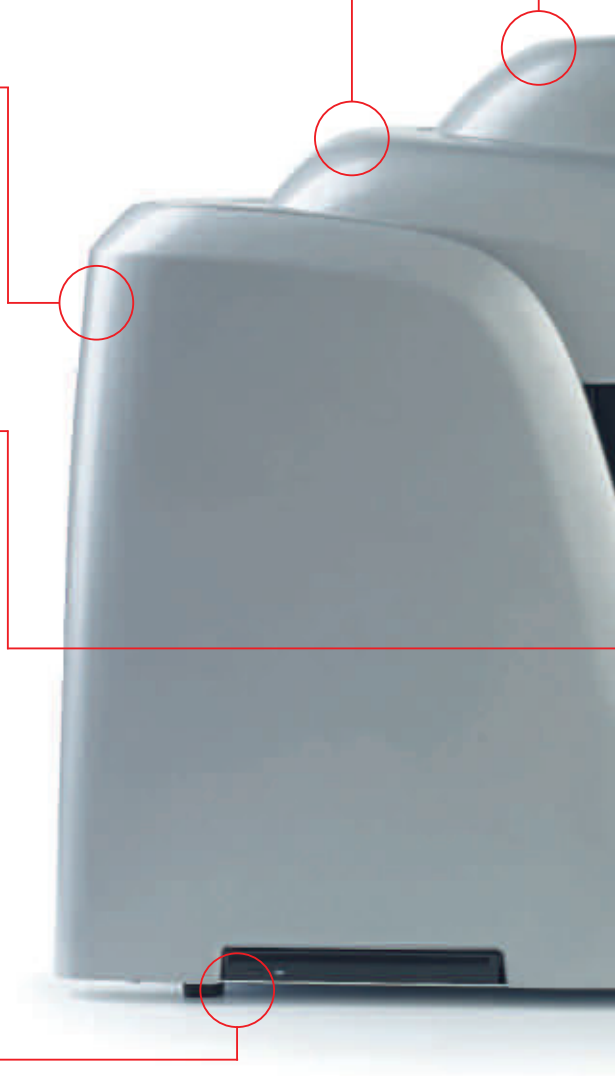
## Processor

- An integral processor eliminates the need for an expensive external computer
- A large capacity integral hard disk drive allows storage of images
- Uses Windows XP operating system
- Network capability included

## Platform

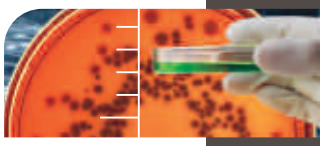
The sample platform has interchangeable backgrounds (black, white and clear) for effective brightfield and darkfield exposure. Round plates from 55 - 100mm can be used. Square plates up to 100 x 100mm can be viewed. For plates larger than this, please contact us for further information





## Peripherals

- A DVD R/W allows for both input and output of data
- Spare USB ports (x6) for mouse, keyboard and memory sticks



## Touch screen

- A 17", sensitive touch screen monitor allows for easy control. The software uses large navigation buttons which are intuitive and easy to follow
- The viewing position can be adjusted to suit users whether seated or standing. (The monitor can also be bench mounted if required)

## Lighting

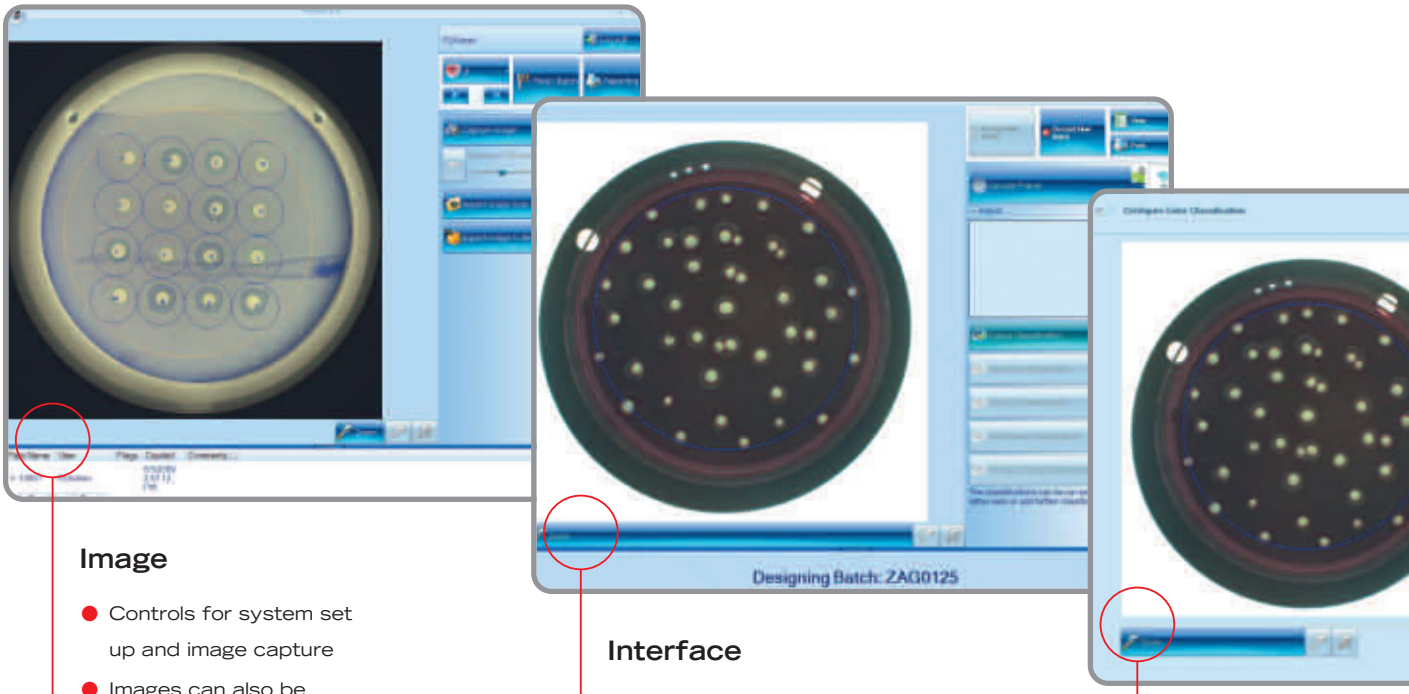
- A unique lighting configuration using red, green and

## Sliding doors

Two sliding doors can be positioned to eliminate external light

# PROTOCOL 2 SOFTWARE EASE OF USE

The new **ProtoCOL 2** software brings advanced levels of control and functionality to all applications.
**ProtoCOL 2** is available as either a colony or zone counter but both software modules can be purchased together to provide a multifunctional system.




### Image

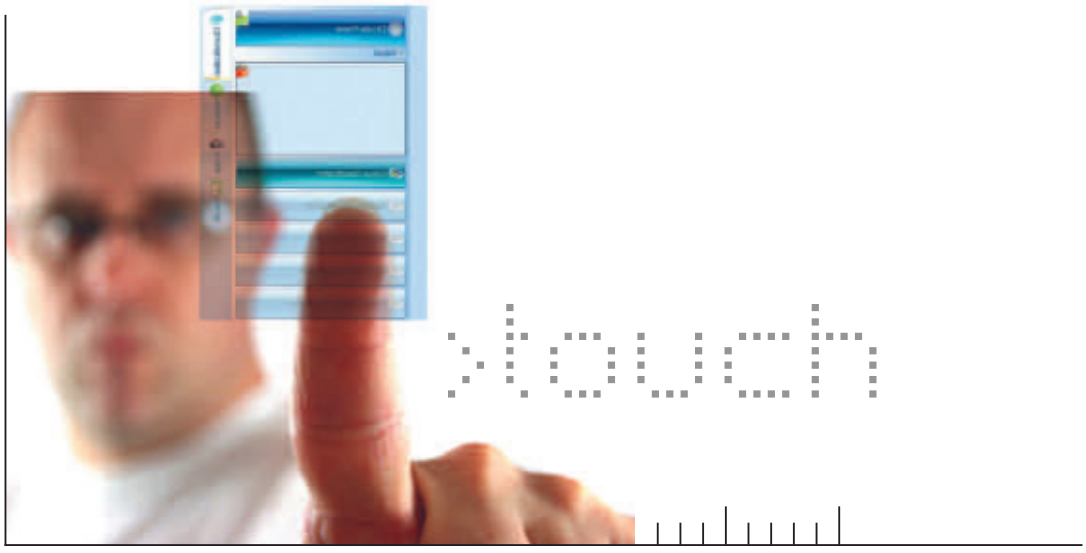
- Controls for system set up and image capture
- Images can also be exported or imported

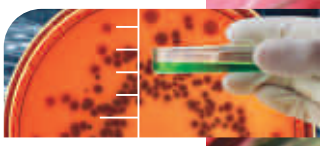
### Interface

Intuitive navigation with large touch button control for ease of use

### Classification

Set up batches and define parameters (colour, size, shape, grid removal)





### Password security

Different levels of users are governed by password control, maintaining system security and ensuring the batches of results cannot be changed or deleted in error. Such features are designed to follow compliance with quality procedures and GLP.

### Validation

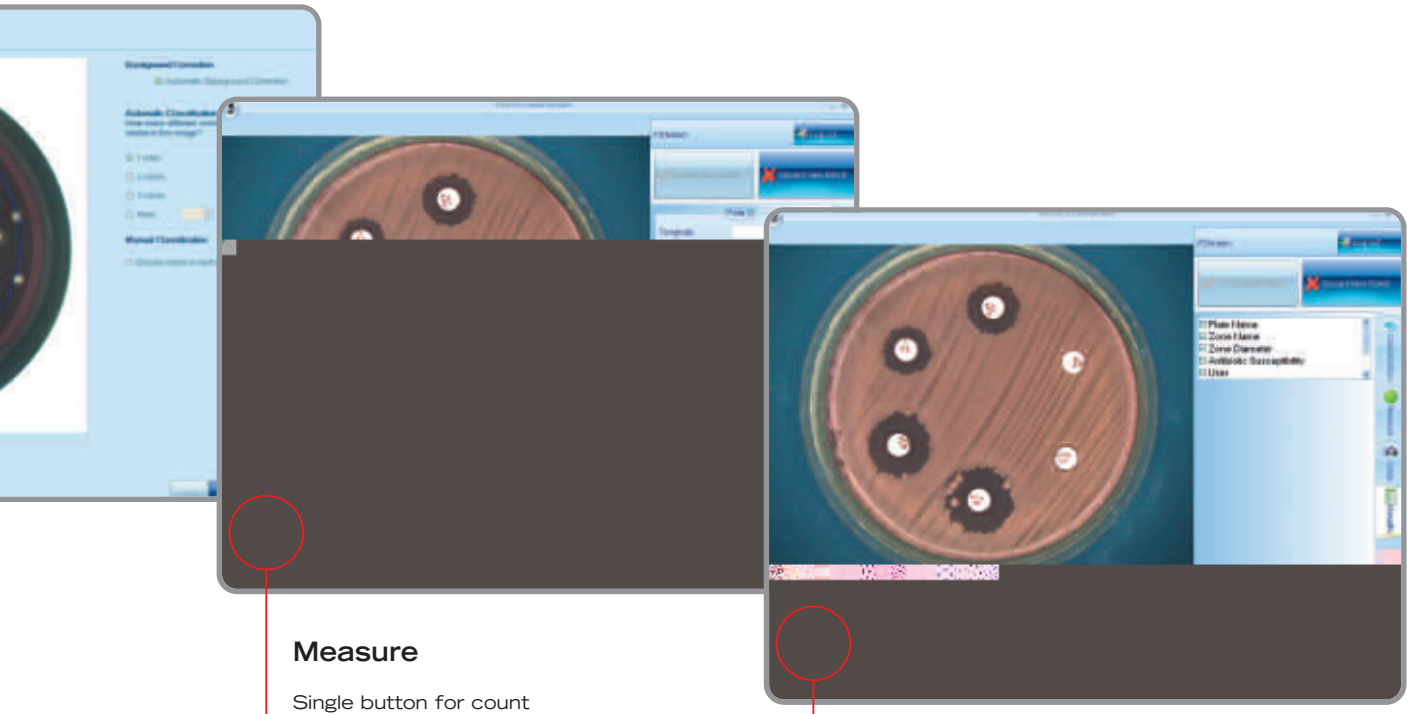
A Validation Certificate is issued with every **ProtoCOL 2**, guaranteeing each system has been checked against validation standards before shipment. A Validation Kit is provided to check system performance.

### Audit trail

When users adjust a setting or re-read previously analysed samples by automatic or manual methods, **ProtoCOL 2** automatically creates a copy of the original result in addition to the new result. This ensures a comprehensive audit trail for all results. Users can configure **ProtoCOL 2** to request a 'reason for change' free text comment that is recorded in a comments field. Data is maintained in a secure format, as directed by Good Laboratory Practice.

### Database

The software is built around a SQL database so that all data can be shared and integrated with other systems and software packages. The system meets all 21 CFR Part 11 requirements.



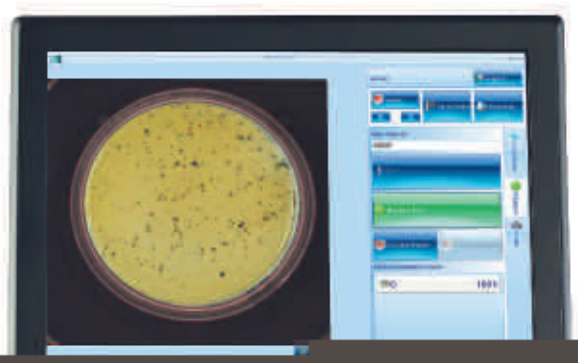
## Measure

Single button for count or measurement

## Results

Define results tables, calculation methods and output modes. **ProtoCOL 2** automatically saves all results for full traceability. Images can be saved for a complete digital record of every plate and can be exported to Excel. Results can be linked to a calculation module for the statistical analysis of data from assays. Data is automatically transferred to customer defined templates. These templates and subsequent calculations follow the requirements of USP, EP and BP. The module includes parallel line analysis, slope ratio analysis, probit analysis, ED50 determination, 4-parameter logistic curve fitting, limit testing of single dose assays and combination of assays

# PROTOCOL 2 COUNT
# COLONY COUNTING



**ProtoCOL 2 Count** is a complete system for all automatic colony counting applications.

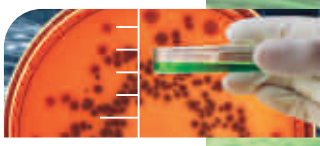
Once a plate is inserted, the locating pins centre the sample. Assays are treated in batches which are defined before counting or measuring. Designing a batch includes assay type, colour, size and shape classification. After the 'measure' button is touched to activate counting, colonies are immediately detected and the count is displayed on screen.

With the standard system:

- Count coloured colonies, plaques and perform microbial limit tests

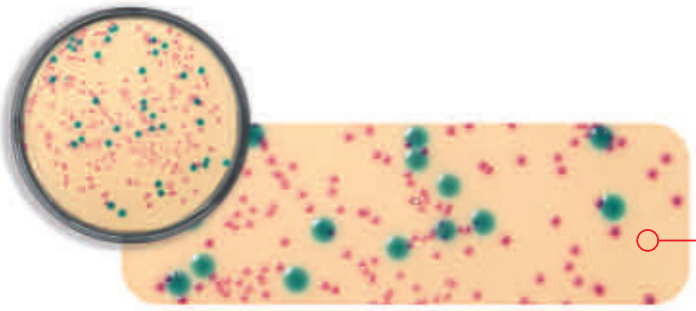
Add optional software modules for:

- Spiral plates
- OPKA (Opsonophagocytic Killing Assay)
- SBA (Serum Bactericidal Activity)
- Ames assay and mouse lymphoma test
- Multi-sector plates e.g. air sampling and multiwell plates



# Applications

**ProtoCOL 2 Count** is the perfect system for multiple applications, including food, water, dairy, beverage, hygiene, clinical microbiology, environmental monitoring, toxicology, sterility testing, pharmaceuticals and fungal contamination.

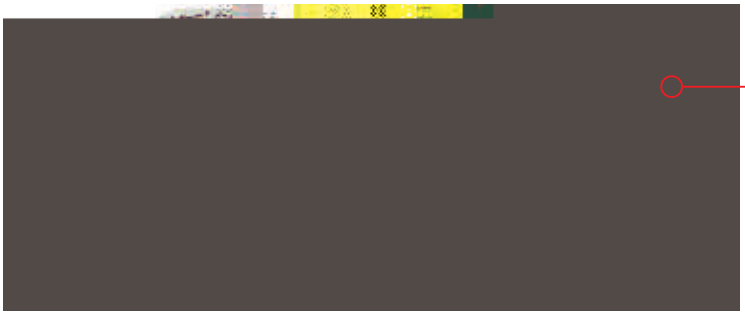


### Colony counting

**ProtoCOL 2** can count both colonies and plaques with a single button press. Multiple different coloured colonies are easily detected and counted simultaneously. Size and shape discrimination can also be used.

### Spiral plates

**ProtoCOL 2** counts spiral colony plates by counting colonies in the outer sector of the upper half of the spiral and the outer lower sector of the spiral. If this count is less than the minimum count rule value, **ProtoCOL 2** will automatically count the whole plate.

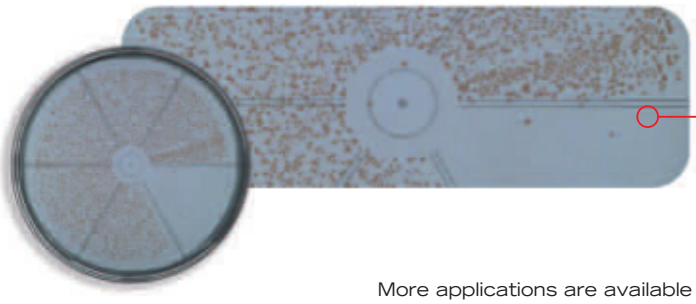


### OPKA - Opsonophagocytic-killing assay

*Streptococcus pneumoniae* is a major cause of pneumonia in young children and the elderly. New vaccines against this bacterium are required because conventional antibiotics are becoming less effective due to the increasing numbers of multi drug-resistant *S. pneumoniae.* The OPKA is a useful test for measuring antibody function and is a good surrogate assay for immune protection.

### Ames assay

Ames is a reverse mutation assay used to test whether samples are mutagenic and are therefore more likely to be carcinogenic. A genetically altered bacterium is put on to the plate along with the test sample. If the bacterium grows it means that the sample has reverse mutated the bacterium and is therefore likely to be mutagenic.



### Multi-sector air plates

Multi-sector plates are often used for environmental monitoring, specifically air sampling. The plate is placed into an air sampler so that only one sector of the plate is exposed at a time as air is drawn through the air sampler. Each sector is then counted in turn.

More applications are available

# PROTOCOL 2 ZONE ZONE MEASUREMENTS

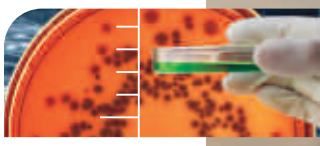
**ProtoCOL 2 Zone** is ideally suited to the demanding application of zone measuring.

Every antibiotic manufacturer is required to demonstrate that the potency of their finished products meet the required specifications. One of the most common but time consuming methods is based on inhibition zones.

Manual measurements are often unreproducible and cannot meet the majority of published standards for accuracy and repeatability.

**ProtoCOL 2 Zone** is ideal for:

- Inhibition zones
- Antibiotic susceptibility testing
- Single radial immunodiffusion assays



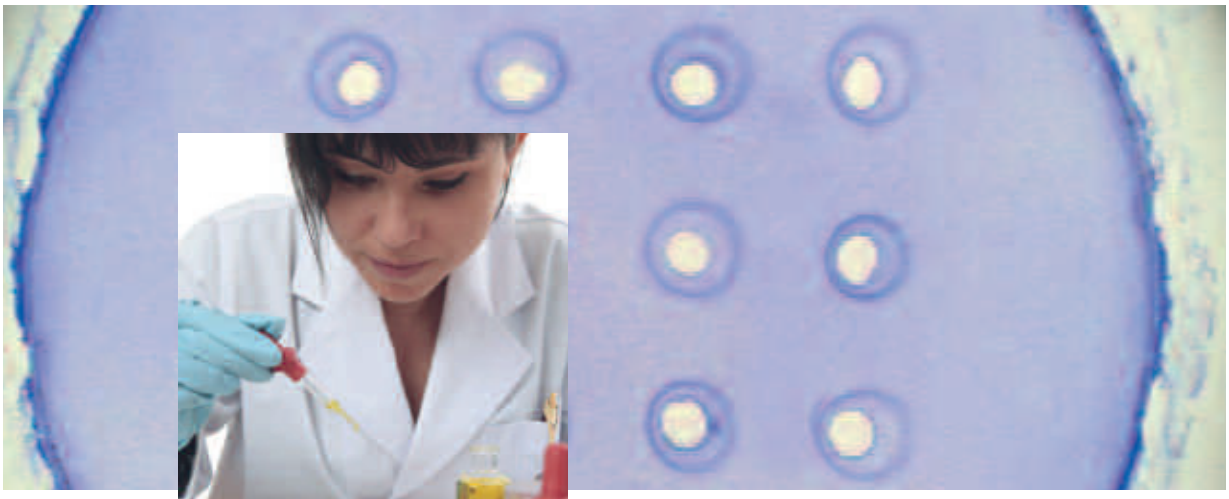
## Antibiotic susceptibility testing

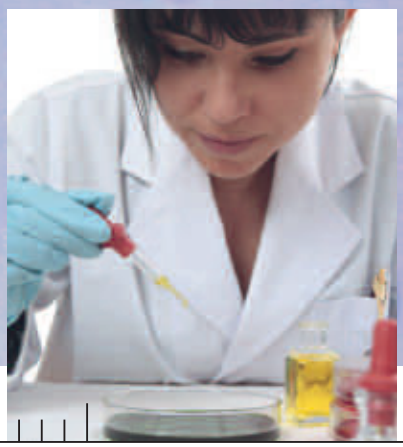
Antibiotic susceptibility testing (AST), is used to determine whether a bacterium is sensitive or resistant to a specific antibiotic so that the patient, human or animal, can be treated most effectively. The bacterium in question is grown on the appropriate medium and different antibiotic disks or disks containing different strengths of the same antibiotic are placed on the surface of the agar. If the bacterium is sensitive to the antibiotic on the disk, a zone is cleared around the disk. The larger the zone of clearance, the more sensitive the bacterium is to the antibiotic. **Protocol 2 Zone** can be configured to measure these zones quickly and accurately, whatever disk format is used. Results can be exported in Excel format or automatically uploaded to a calculations module for statistical analysis.

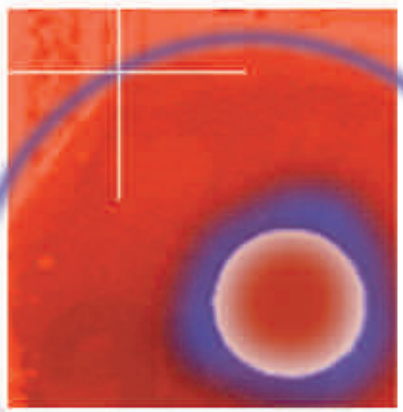
## Inhibition zones

Automatic sizing of zones surrounding disks or multipoint innoculations is simplified with **ProtoCOL 2 Zone**. The size of each zone is accurately measured and the results are calculated.

Zones of inhibition are used as a measure of the effectiveness of antibiotics and vaccines in drug development. The manual method for measuring these zones requires the technician to measure the diameter in six different places which is very time consuming and short cuts are often taken. **ProtoCOL 2 Zone** carries out this process automatically in a fraction of a second.



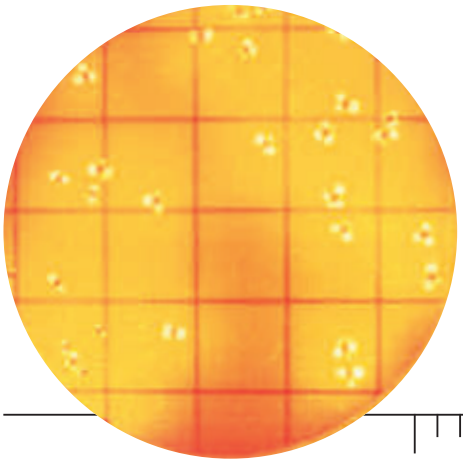




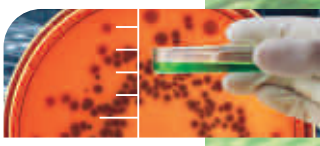
## Single Radial Immunodiffusion (SRD) assays

The SRD assay is a simple yet powerful technique that is routinely used in many laboratories.
SRD assays are used to quantify all classes of immunoglobulin, as well as various complement components, and can be used to test the potency of viral vaccines, such as the influenza vaccine.
**ProtoCOL 2 Zone** software can measure the reaction zones of SRD plates in a fraction of the time taken by manual methods, export the data for statistical analysis, and record an image of the plate, thus saving many hours of highly repetitive work.

# PROTOCOL 2 A PERFECT SOLUTION



| Features | Benefits |
|---|---|
| Built-in processor, hard disk and DVD | No need to use a separate PC - saving both cost and space |
| High resolution camera | Can read colonies as small as 43 microns |
| Unique LED lighting system (patent pending) | The best high contrast lighting - better than fluorescence or halogen types - for reflection free images and improved contrast leading to better detection |
| Touch screen monitor | Enables rapid data input at the touch of a fingertip |
| Counts coloured colonies | Many ISO standard methods are now using chromogenic media |
| Sliding doors | Eliminates ambient light |
| New software and algorithms | Enhanced results and ease of use |
| Integrated SQL database | Data access and sharing by multiple users simultaneously<br>Greater data security and easier back-up<br>Customisable reports and queries<br>Easy LIMS connectivity |

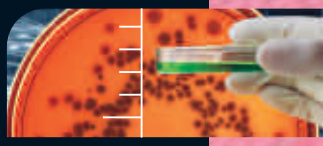


т/ф (495) 980-29-37, 781-21-58, 311-22-09, 319-22-78

# PROTOCOL 2

## Specifications

| | |
|---|---|
| Construction | Ergonomic housing constructed in high density foam<br>Integral microprocessor<br>Integral CCD camera and lens<br>17" mounted touch screen monitor |
| Light shield | 2 sliding doors to prevent excessive ambient light |
| Camera | 1.4 m pixel scientific grade CCD camera<br>USB integral camera with f1.2 lens |
| Monitor | 17" mounted touch screen |
| Resolution | For standard 90mm Petri dish, smallest detectable colony is 43 microns |
| Imaging | 3 channel capture for colour images |
| Lighting | Unique 3 channel (red, green, blue) LED lighting (patent pending)<br>Multi-array LED lighting (computer controlled)<br>Lower lighting with upper reflective lighting for all applications |
| Processor | Integral microprocessor<br>Operating system Windows XP embedded |
| Storage | 120GB minimum internal hard disk |
| External connections | DVD RW<br>USB ports for mouse, keyboard, camera<br>USB ports x 2 additional<br>External monitor connection<br>Ethernet<br>Sound output<br>1394 firewire connection |
| Detection mode | Fully automatic with manual over-ride |
| Measurement modes | **PC2 Count:** Colony counting, pour plates<br>**PC2 Zone:** SRD zone sizing, inhibition zones, antibacterial susceptibility |
| Count modes | Separation of touching colonies, discrimination by area, exclude areas, colour mode, shape mode |
| Software | Integral **ProtoCOL 2** software<br>Touch screen input |
| Database | SQL database stores all data and images |



## Ordering

| | |
|---|---|
| PROC2-COUNT | **ProtoCOL 2** for colony counting on pour plates |
| PROC2-ZONE | **ProtoCOL 2** for zone sizing |
| PROC2-SPIRAL-MOD | Colony counting software module for spiral plates |
| PROC2-OPKA-MOD | OPKA (Opsonophagocytic killing assay) software module |
| PROC2-AMES-MOD | Ames assay software module |
| PROC2-SECTOR-MOD | Multi sector plate software module |
| PROC2-SBA-MOD | SBA (Serum bactericidal assay) software module |
| PROC2-ZONE-MOD | Zone sizing software module |
| PROC2-COUNT-MOD | Colony counting software module for pour plates |

**Synbiosis Europe and International Headquarters:**
Beacon House Nuffield Road
Cambridge CB4 1TF UK
Tel: +44 (0)1223 727125
Fax: +44 (0)1223 727101
email: sales@synbiosis.com

**Synbiosis USA Headquarters:**
5108 Pegasus Court Suite M
Frederick MD 21704 USA
Tel: 800-686-4451/301-662-2863
Fax: 301-631-3977
email: ussales@synbiosis.com

**Website: www.synbiosis.com**

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