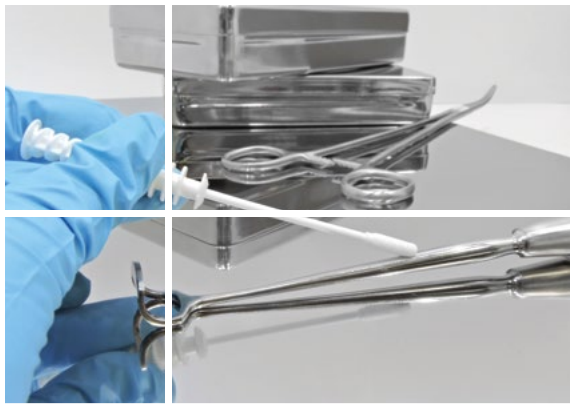
*Innovation in technologies for sterilization and disinfection control*

# Terragene®
# solutions to guarantee safety in Medical Diagnostic Laboratories

TERRAGENE®

Rev. 1 | May 2018

Terragene® offers a range of effective and easy-to-handle products to control the washing, hygiene, disinfection and sterilization processes in medical diagnostic laboratories. Available in a wide variety of formats, these high-performance control devices provide fast and consistent infection control results.



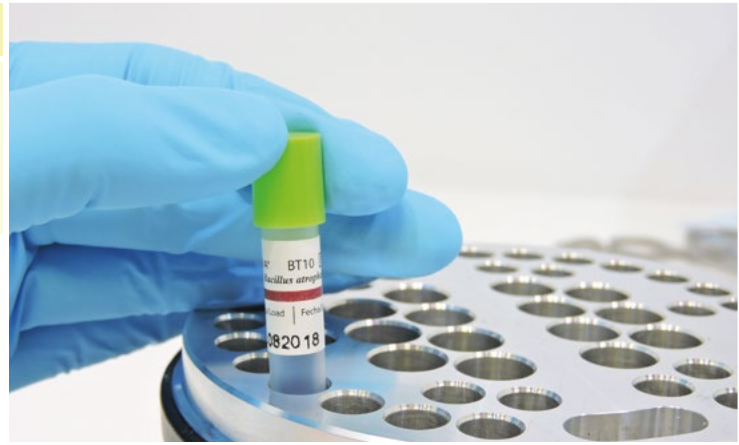
# System
# for surface proteins and allergens detection



The Chemdye® PRO1 MICRO Hygiene Monitoring System has been designed to detect proteins, allergens and reducing agents in instruments after cleaning, in real time.
The system has a high absorption swab that allows the sampling of different surfaces with high efficiency. A visual reading of color change indicates the presence of detectable levels of protein.

Using any of the Bionova® IC10/20FR, IC10/20FRLCD or MiniPro Auto-Readers, the Chemdye® PRO1 MICRO system can be incubated and a quantitative result with a sensitivity of 0.3 µg can be obtained.

# Self-Contained Biological Indicators for sterilization processes



Biological Indicators (BIs) are the only devices accepted worldwide as direct evidence of microbiological lethality after a sterilization cycle. Terragene® offers its line of Bionova® Conventional Self-Contained BIs to control the sterilization processes of materials and instruments. Its innovation technology allows obtaining results within 24-48 hours.

For the incubation of Conventional Self-Contained BIs, Terragene® has the Bionova® IC10/20 Dual Incubator that provides optimal conditions for accurate reading of a wide range of biological indicators (both at 37 °C and 60 °C). This incubator has a hole for external temperature control (Bionova® thermometer code: TB-IC1020).

EO **BT10**

STEAM **BT20**

Conventional Self-Contained

DRY **BT30**


# Rapid, Super Rapid and Ultra Rapid

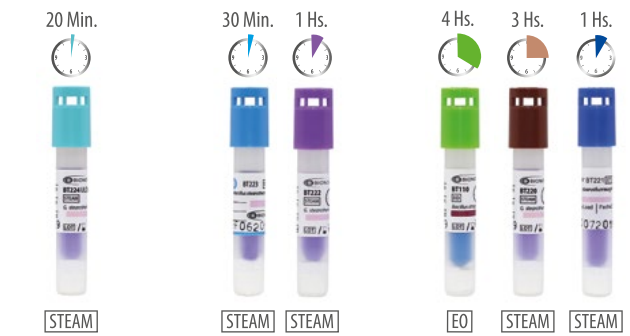
## Self-contained Biological Indicators

### for Steam sterilization processes


The demand in the delivery of sterile instruments in less time can now be satisfied with the Fluorescence Rapid Readout System of Terragene®. The new Bionova® Rapid, Super Rapid and Ultra Rapid Self-Contained Biological Indicators allow to release sterile loads in 20 minutes or in just a few hours.
Terragene® offers the Ultra Rapid Biological Indicators (BT224), Super Rapid (BT222 and BT223) and Rapid (BT220 and BT221) for Steam and Ethylene Oxide (BT110) sterilization processes. Its innovation technology allows to obtain reliable results in record times, accelerating the workflow.

Bionova® Rapid, Super Rapid and Ultra Rapid BIs should be incubated in Bionova® Auto-Readers: IC10/20FR, IC10/20FRLCD or MiniBio.

Bionova® BT220, BT221, BT222 y BT223 Biological Indicators are FDA cleared.



# Bionova®
# Automatic Readers

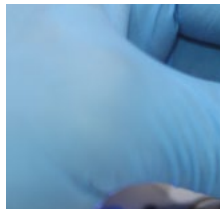
## IC10/20FRLCD

The Bionova® IC10/20FRLCD Auto-reader is an automatic system with 12 positions for the incubation and reading of Rapid, Super Rapid and Ultra Rapid Biological Indicators and a reading position for Hygiene Monitoring Systems (Chemdye® PRO1 MICRO). The Bionova® IC10/20FRLCD Auto-readers have an innovative 3.5 " LCD touch screen, which not only allows reading to be configured, but also provides visual information regarding the incubation process in progress. The Bionova® IC10/20FRLCD Auto-readers support working at 2 temperatures (37 or 60 °C) and the selection and execution of different reading programs in each of the 12 positions, allowing simultaneous incubation of BIs with different reading times. It has a thermal printer for the documentary record keeping of results.
The Bionova® IC10/20FRLCD Auto-reader can be connected via Ethernet to a PC or any mobile device, through which you can continuously obtain information from the incubation process and record the results through the Bionova® Traceability Software.

Bionova® IC10/20FR Auto-reader is FDA cleared.

## IC10/20FR

The Bionova® IC10/20FR Auto-reader consists of an automatic system with 12 positions for the incubation and reading of Rapid, Super Rapid and Ultra Rapid Biological Indicators and a reading position for Hygiene Monitoring Systems (Chemdye® PRO1 MICRO). The state-of-the-art technology of the Bionova® IC10/20FR Auto-reader allows to work at 2 temperatures (37 or 60 °C) and to select and execute two incubation programs in parallel, allowing simultaneous incubation of BIs with different reading times. It has a thermal printer for the record keeping of results.
The Bionova® IC10/20FR Auto-reader can be connected via USB to a PC, which will be able to continuously obtain information about the incubation process and record the results through the Bionova® Traceability Software.




## MiniPro

The Bionova® MiniPro Auto-reader consists of an automatic system with three positions for reading Hygiene Monitoring Systems (Chemdye® PRO1 MICRO). Its compact design makes it ideal for small spaces.
The Bionova® MiniPro Auto-reader has a thermal output printer and a USB port, which allows it to be connected to a PC and to record and store the readings through the Bionova® Traceability Software.

## MiniBio

The Bionova® MiniBio Auto-reader consists of a compact automatic system, which makes it an ideal equipment for small spaces. Its innovative configuration allows you to incubate 3 Rapid, Super Rapid or Ultra Rapid Biological Indicators simultaneously, with 3 different programs, thus contributing to an increasingly fast and efficient result analysis. The auto-reader has a thermal printer and a USB port, which allows to connect it to a PC and record and store the results through the Bionova® Traceability Software.

# Performance control of the autoclave

TYPE 2



## Bowie & Dick Test Pack

The Chemdye® Bowie & Dick Test Package was developed to control air removal and steam penetration in vacuum-assisted steam sterilizers. The Chemdye® BD125X/2 is a single-use device, consisting of a lead-free chemical indicator, arranged between permeable sheets of paper, wrapped with crepe paper, with a label indicating exposure to steam (Type 1) on top of the package. This test pack should be used routinely, in the first cycle of the day, in order to check if the sterilizer can be used in the remaining cycles with loads, provided that the result is accepted.

## Bowie & Dick Test Card

The Chemdye® Bowie & Dick Test Card has been designed to monitor the effectiveness of air removal in vacuum-assisted steam sterilizers at 132 ºC for 4 minutes and at 134-135ºC for 3.5 minutes. This card consists of a metal-free Type 2 indicator, which turns from purple to green when processed. A heterogeneous color change, i.e. the presence of purple/gray color, indicates a remnant of air during the sterilization cycle, which indicates a malfunction of the sterilizer. This warns the user that it is not advisable to use the sterilizer to process the load.
Chemdye® BD8948H is a reusable stainless steel stand for the Bowie & Dick test card. The stand keeps the BD8948X test card firmly in place for a correct assessment of the Bowie & Dick cycle.

TYPE 1

# Sterilization process exposure control

## Self-adhesive tapes

Cintape® self-adhesive tapes have been designed to wrap and seal sterilization packages, as well as to distinguish between packages that have been exposed to sterilization processes from those that have not. For the medical diagnostic laboratories, Terragene® has tapes for: Ethylene Oxide (CT10), Steam (CT22) and Dry Heat (CT30).

## Self-adhesive labels for automatic record system

The labels for the Chemdye® automatic record keeping system have been designed to monitor sterilization processes by Ethylene Oxide (CD13), Steam (CD23) and Dry Heat (CD33). These labels are generally placed outside the tray, attached to packages or bags, allowing to differentiate between processed and unprocessed loads. Its double-adhesive technology allows easy removal of the sterilization package for record keeping.

The Chemdye® CG3 Three-Line Automatic Labeller has 3 alphanumeric lines allowing quick and easy labeling of sterilization packages through the use of double-adhesive labels, also avoiding traceability errors in the packages.

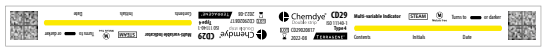
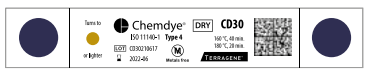
# Sterilization process control

TYPE 4

## Multivariable indicators for internal use

### *Simple and double strips*

Chemdye® Type 4 internal control strips are multivariable indicators that quickly show if the critical parameters of the sterilization process have been reached, ensuring an adequate penetration of the sterilizing agent into the packages. These chemical indicators show a significant color change when exposed to the stated values (SVs) of the critical process variables.
Terragene® offers a diverse presentation of Type 4 strips, according to the needs of the users.


| | | |
|---|---|---|
| EO | CD16 |  |
| | CD25 |  |
| STEAM | CD29 |  |
| | CD202 |  |
| DRY | CD30 |  |


## Moving front integrators for Steam
Integron® IT26-C

Developed to monitor steam sterilization processes between 118 ºC and 138 ºC, the Integron® IT26-C indicator ensures an adequate control of all the critical parameters of steam processes (temperature, time and steam quality). Its chemical pellet melts and migrates like a dark bar along a transparent window. The migration occurs through an area marked as ACCEPT (accept) or REJECT (reject), indicating whether the sterilization conditions were reached or not. The result "ACCEPT" is achieved when a theoretical population of spores reaches its kill time, which means that the condition of integration has been reached.

## Unique point integrator for Steam
Integron® IT26-1YS

The Integron® indicator IT26-1YS allows the verification of steam sterilization cycles between 121°C and 135°C, ensuring that all critical parameters (temperature, time, steam quality) of the process have been reached.


TYPE 5

## Two-level integrator for EO
Integron® IT12

Integron® IT12 integrator has been developed to control sterilization processes by Ethylene Oxide. It is a two-level indicator: level 1 is the level of exposure, which indicates that the indicator was exposed to Ethylene Oxide, while level 2 is the level of integration. This second level consists of a point of purple/brown ink that turns to green when integrating all the critical parameters of the sterilization process (time, temperature, humidity and concentration of Ethylene Oxide).

## Emulators for Dry Heat

Integron® IT31

Designed to react to Dry Heat sterilization processes at 160 ºC, 40 minutes. Its blue color indicating ink has been developed to turn to brown when the stated values of the critical process variables for which it has been designed are reached.

## Emulators for Steam

Integron® IT27-3YS / IT27-4YS / IT27-5YS / IT27-7YS

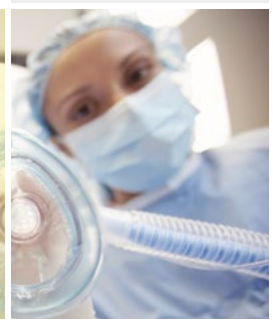
Designed to monitor steam sterilization processes. They control all the critical parameters of the sterilization process at their position in the chamber, ensuring an adequate control of the effectiveness of the sterilization processes (temperature, time, steam quality).

| | | |
|---|---|---|
| IT27-3YS | 3 min | 134 ºC |
| IT27-4YS | 4 min | 134 ºC |
| IT27-5YS | 5 min<br>15 min | 134 ºC<br>121 ºC |
| IT27-7YS | 7 min<br>20 min | 134 ºC<br>121 ºC |
| IT27-18YS | 18 min | 134 ºC |

# Spores Strips and Culture Medium

Bionova® spore strips consist of an envelope, permeable to the sterilizing agent, which contains a paper strip inoculated with a population of spores.
After being exposed to the sterilization process, the strips are transferred aseptically to the tube of culture medium and incubated in the Bionova® IC10/20 Dual Incubator according to the respective incubation conditions. If the sterilization has failed, the culture medium will turn to yellow. Otherwise, if the sterilization process has been successful, the culture medium will remain the original color.

| Code | Use | Spore | Culture medium | Incubation conditions |
|---|---|---|---|---|
| **BT40** | EO / DRY | *Bacillus atrophaeus* | MC1030 | 37 ºC - 48 hs. |
| **BT50** | STEAM | *Geobacillus stearothermophilus* | MC1020 | 60 ºC - 24 hs. |



Chemdye® BIONOVA® one by one T-Matrix® Integron® Cintape® Chemink® BIONOVA® Humidigene®

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