

Innovation in technologies for sterilization and disinfection control



Terragene®
solutions to guarantee
safety in
Pharmaceutical Industry



TERRAGENE®

Rev. 1 | May 2018



Terragene® offers a range of effective, easy-to-handle products to accurately control cleaning, disinfection, hygiene, and sterilization processes in pharmaceutical industries. Available in a variety of formats, these high-performance control devices provide fast and consistent results in infection control.



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 the Bionova® Conventional Self-Contained Biological Indicators to control the sterilization processes of materials and instruments of the pharmaceutical industry. Its innovation technology allows obtaining results within 24 to 48 hours.

In addition, Terragene® offers Bionova® Rapid Colorimetric BIs, which guarantee reliable results in shorter times of 8 hours: BT90 (Hydrogen Peroxide), BT200 (Steam) and BT101 (Formaldehyde).

For the incubation of Conventional and Colorimetric Rapid Self-Contained BIs, Terragene® offers the Bionova® IC10/20 Dual Incubator that provides optimal conditions for the incubation of a wide range of biological indicators (37 °C and 60 °C). It consists of a heating block that also allows to incubate culture media and biological ampoules for sterilization of liquid loads. This incubator has a hole for external temperature control (Bionova® TB-IC1020).



EO BT10

Conventional
Self-Contained



STEAM BT20



DRY BT30



VH₂O₂ BT91



FORM BT100



FORM BT101



STEAM BT200



VH₂O₂ BT90

Rapid
Colorimetric
Self-Contained

Rapid, Super Rapid and Ultra Rapid Readout Biological Indicators for sterilization processes



The demand for sterile instruments in less time can now be met by the Bionova® Rapid Readout Fluorescence System. Bionova® Rapid, Super Rapid and Ultra Rapid Self-Contained Biological Indicators allow the release of sterile loads between 20 minutes to a few hours.

Terragene® offers Ultra Rapid (BT224), Super Rapid (BT222 and BT223) and Rapid (BT220 and BT221) Biological Indicators for Steam sterilization processes, Ethylene Oxide (BT110), Plasma or Vaporized Hydrogen Peroxide: Super Rapid (BT96) and Rapid (BT95) and Formaldehyde (BT102). Its innovative technology allows to obtain reliable results in record times, accelerating the workflow.



Ultra Rapid

20 Min.



STEAM

Super Rapids

30 Min.



VH₂O₂

30 Min.



STEAM

1 Hs.



STEAM

Rapids

2 Hs.



VH₂O₂

2 Hs.



FORM

4 Hs.



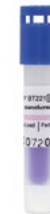
EO

3 Hs.



STEAM

1 Hs.



STEAM

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



Bionova[®] Automatic Readers

IC10/20FRLCD

Bionova[®] IC10/20FRLCD Auto-reader is an automatic system with 12 positions for the incubation and reading of Rapid, Super Rapid and Ultra Rapid BIs and one reading position for Hygiene Monitoring Systems (Chemdye[®] PRO1 MICRO).

Characteristics

- Innovative 3.5" LCD touch screen, which not only allows you to configure the reading, but also provides visual information regarding the incubation process in progress
- Allows the user to work at 2 temperatures (37 or 60 °C) and to select and execute a different reading program in each of the 12 positions, allowing simultaneous incubation of BIs with different reading times.
- Thermal printer for the documentary record of the results.
- 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

Bionova[®] IC10/20FR Auto-reader is an automatic system with 12 positions for the incubation and reading of Rapid, Super Rapid and Ultra Rapid Biological Indicators and one reading position for Hygiene Monitoring Systems (Chemdye[®] PRO1 MICRO).

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. 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

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.

Bionova® MiniPro Auto-reader has a thermal output printer and a USB port, which allows connection to a PC and recording and storing the readings through the Bionova® Traceability Software.



Final readout



MiniBio

Bionova® MiniBio Auto-reader is a compact automatic system, ideal for small spaces. Its innovative configuration allows you to incubate 3 Rapid, Super Rapid or Ultra Rapid Indicators simultaneously, with 3 different programs, thus contributing to an increasingly fast and efficient result analysis.

This auto-reader has a thermal printer and a USB port, which allows connecting it to a PC and storing the results through the Bionova® Traceability Software.

Performance control of the autoclave



TYPE 2



Bowie & Dick Test Pack

The Chemdye® Bowie & Dick test pack was developed to control air removal and steam penetration in vacuum-assisted steam sterilizers. 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) in the 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 load, provided that the result is accepted.

Bowie & Dick Test Card

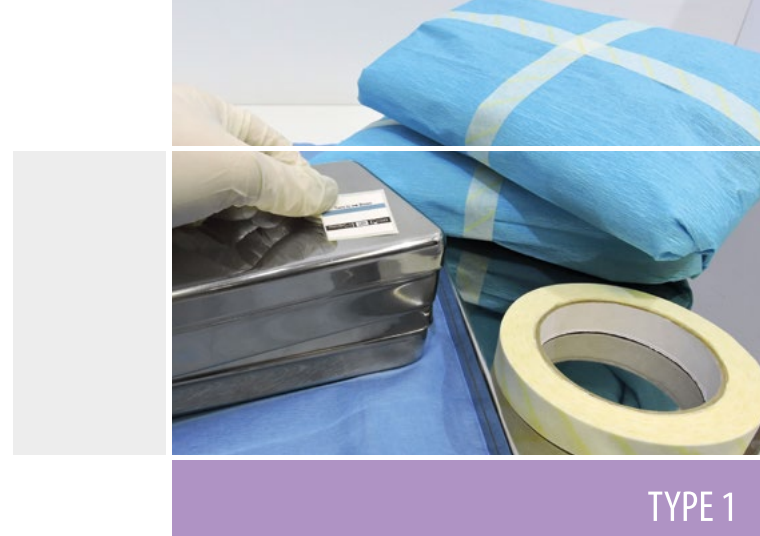
Chemdye® Bowie & Dick Test Card has been designed to monitor the effectiveness of air removal in vacuum-assisted steam sterilizers at 132°C, 4 minutes and at 134°C, 3.5 minutes. This card consists of a Type 2 Metals-free chemical indicator that changes from purple to green when processed. A heterogeneous color change, i.e. the presence of purple/grey color, indicates presence of an air pocket during the sterilization cycle thus indicating sterilizer malfunction.

This warns the user that it is not advisable to use the sterilizer to process the load. BD8948H is a stainless steel re-usable Holder for Bowie & Dick Test Card. The holder keeps BD8948X Test Card in place for proper assessment of the sterilization cycle.

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 items that have been exposed to Steam sterilization processes from those that have not. Terragene® has tapes for every sterilization process: Steam (CT22), Ethylene Oxide (CT10), Plasma or Vaporized Hydrogen Peroxide (CT40), Formaldehyde (CT50) and Dry Heat (CT30).



Self-adhesive labels for automatic record system

Chemdye® Automatic record system labels have been designed to monitor Ethylene Oxide (CD13), Steam (CD23), Dry Heat (CD33), Plasma or Vaporized Hydrogen Peroxide (CD43) or Formaldehyde (CD53) sterilization processes. These self-adhesive labels are usually placed out of the plate, stuck to packages or pouches, allowing differentiation between processed and unprocessed items.

Their double-adhesive technology allows easy label removal from the sterilization package for data documentation.

Chemdye® CG3 is a Three-line Automatic Labeler that allows a quick and easy labeling of sterilization packages through the use of special documentation labels, preventing the traceability errors of the packs.

Sterilization process control

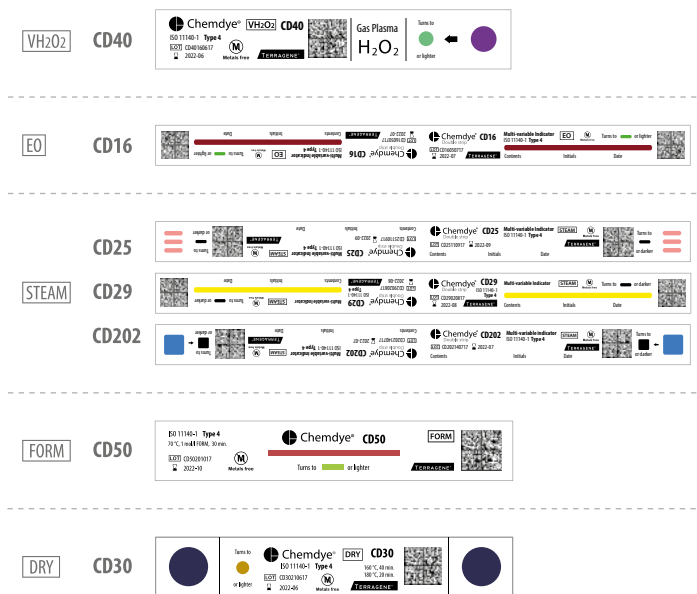
TYPE 4

Multivariable indicators for internal use

Simple and double strips

Chemdye® Type 4 Internal control strips are Multivariable Indicators that rapidly show if critical parameters of the sterilization process have been reached, besides ensuring sterilizing agent appropriate penetration of the items inside the packages. This chemical indicators show a significant color change when exposed to the stated values (SVs) of the critical process variables.

Terragen® offers various presentations of Type 4 Strips, according to the needs of the users.





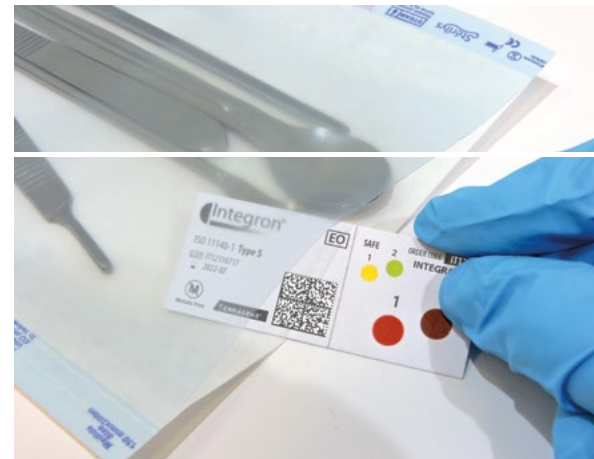
Moving front integrators for Steam Integron® IT26-C

It was developed for monitoring Steam sterilization processes between 118 °C and 138 °C and to ensure an adequate control of the effectiveness of sterilization processes by monitoring all critical parameters of steam sterilization (temperature, time, steam quality). Its chemical pellet melts and migrates as a dark bar along the paper wick. Migration occurs through a zone marked as ACCEPT or REJECT, thus indicating whether sterilization conditions were met or not. The “ACCEPT” result is reached when a theoretical spore population reaches its kill time, indicating integration condition has been reached.



Unique point integrator for Steam Integron® IT26-1YS

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



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 in a point printed with 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

Integron® IT31 is designed to react to sterilization processes by Dry Heat at 160 °C, 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 for monitoring Steam sterilization processes. They fulfill the requirements for Type 6 indicators monitoring all the critical parameters of the sterilization process at their position in the chamber and ensuring an adequate control of the effectiveness of the sterilization processes (temperature, time, steam quality). The wide range of emulators allows the selection of the most suitable indicator for the sterilization process to be controlled, since they are cycle-specific indicators.



IT27-3YS	3 min	134 °C
IT27-4YS	4 min	134 °C
IT27-5YS	5 min 15 min	134 °C 121 °C
IT27-7YS	7 min 20 min	134 °C 121 °C
IT27-18YS	18 min	134 °C

Liquid loads Sterilization

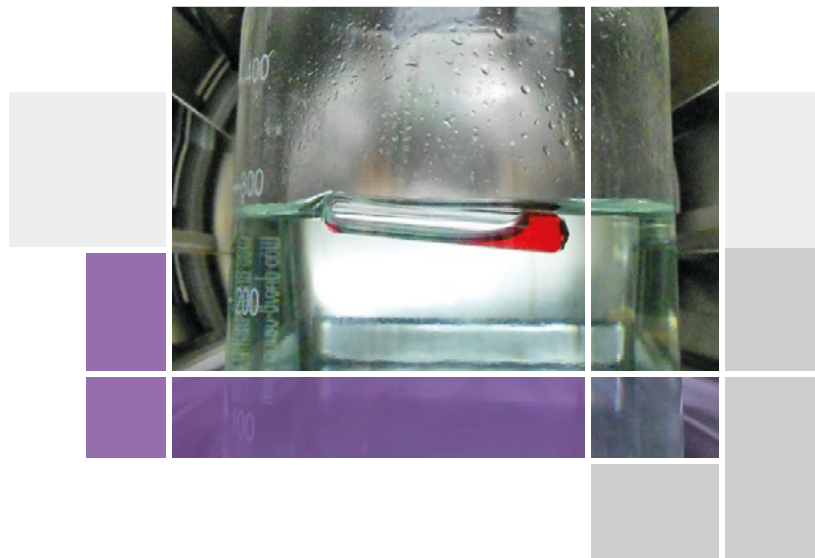
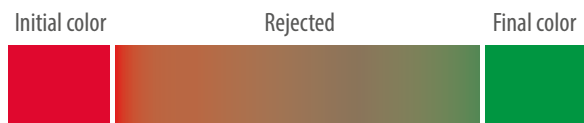


Chemical Tubes

Chemdye® Chemical tubes have been developed to monitor Steam (CD210, CD220) and Dry Heat sterilization of liquids (CD230, CD240, CD250) in the pharmaceutical industry. These are easy-to-use multivariable indicators, consisting of borosilicate glass tubes of 40 x 7 mm, sealed at both ends. One end is coded by colors to facilitate the identification of the indicator when outside its package. The tube contains 0,25 ml of a thermosensitive red liquid that turns to green when the stated values of the critical process variables of the sterilization process have been reached. The color tubes are calibrated to respond to the specific temperature and time parameters during Steam and Dry Heat sterilization cycles.

A permanent color change occurs when the proper parameters have been met at the position of each control tube.

Code	Description	Conditions	Sterilization
CD210	Black spot	15 min. 121 °C / 10 min. 126 °C	Steam
CD220	Yellow spot	3-3.5 min. 134 °C	Steam
CD230	Green spot	60 min. 160 °C / 30 min. 170 °C	Dry Heat
CD240	Blue spot	12 min. 180 °C	Dry Heat
CD250	White spot	120 min. 160 °C / 35 min. 180 °C / 60 min. 170 °C	Dry Heat



Self-contained Spore Ampoules

Bionova® Self-contained Spore Ampoules have been designed for monitoring sterilization of liquids in the pharmaceutical industry. Spore ampoules are made of hermetically sealed type I borosilicate glass, containing a specific population of *Geobacillus stearothermophilus* or *Bacillus subtilis* spores and a specially formulated synthetic culture medium that turns to yellow when spores grow.

Bionova® Self-contained Spore Ampoules provide visual confirmation of sterilization within 24 hs (BT21, BT22, BT23) and 48 hs (BT24).



Spores Strips and Culture Medium

Bionova® Spore Strips consist of an envelope, permeable to the sterilizing agent, containing a paper strip inoculated with a spore population.

After exposure to the sterilization process, strips are aseptically transferred to the culture medium tube and incubated in the Bionova® IC10/20 Dual Incubator according to the specific conditions. If sterilization has failed, culture medium will turn to yellow.

Conversely, if the sterilization process has been successful, the culture medium will remain its original color.



Code	Use	Spore	Culture medium	Incubation conditions
BT40	EO DRY	<i>Bacillus atrophaeus</i>	MC1030	37 °C - 48 hs.
BT50	STEAM FORM	<i>Geobacillus stearothermophilus</i>	MC1020	60 °C - 24 hs. (Steam) 60 °C - 48 hs. (Form)
BT70	IRRAD	<i>Bacillus Pumilus</i>	MC70	37 °C - 48 hs.
BT92	VH ₂ O ₂	<i>Geobacillus stearothermophilus</i>	MC1020	60 °C - 24 hs. (Steam)

Indicators for Cleaning efficiency test



For controlling the cleaning processes of instruments and materials in the pharmaceutical industry, Terragene® offers Chemdye® CDWA indicators whose formulation allows detecting all the factors that affect the final result. Chemdye® CDWA indicators can be used for routine control of cleaning processes and allows monitoring the effectiveness of washing in automatic machines with different configurations.

The Chemdye® CDWA indicators should be used together with the Chemdye® CDWAH holder, which represents a realistic challenge to the washing process especially in areas of difficult access.

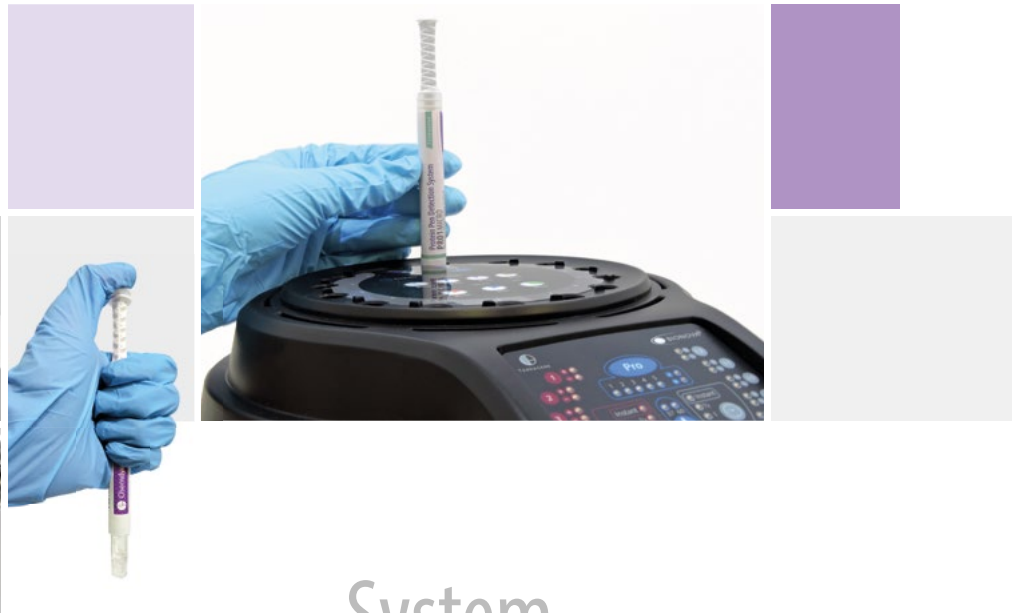
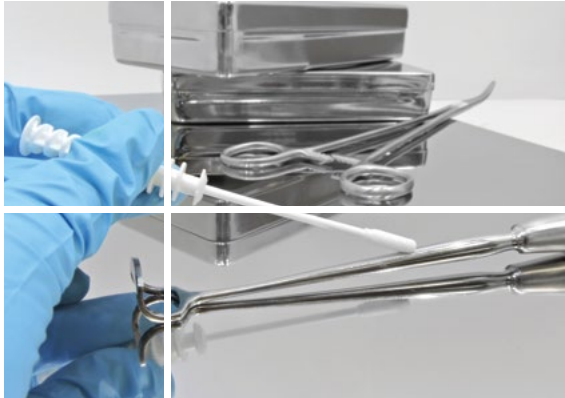


CDWAH Holder

BASKET ZONE: water pressure, spray system performance, detergent chemistry and concentration, temperature.

COVERED ZONE: detergent chemistry and concentration, water quality, temperature, cycle duration, etc.

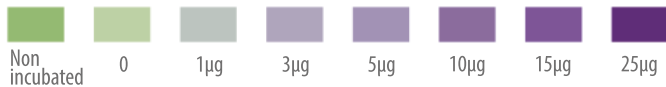




System for surface protein and allergens detection

The Chemdye® PRO1 MICRO system has been designed to detect proteins, allergens and reducing agents on surfaces after a cleaning process in difficult access areas, 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 proteins.

For incubation of Chemdye® PRO1 MICRO, Terragene offers the Bionova® Auto-Readers IC10/20FR, IC10/20FRLCD or MiniPro, allowing the user to obtain a quantitative result with a sensitivity of 0.3 µg.





Indicators for cavitation capacity testing of ultrasonic washers

Terragene® offers the Chemdye® CDWU indicator for evaluating the efficiency of the cavitation process from ultrasonic washers. Chemdye® CDWU indicator consists of a transparent vial, with a blue-colored reactive solution and glass pearls immersed on it. During cavitation, the vibration of the glass pearls triggers a color change in the solution, from blue to yellow, through a range of green color intermediates. When cavitation energy is high enough to guarantee a correct washing of the instruments, the final result will be a yellow coloration, otherwise the indicator will remain greenish, which will show a weak cavitation zone located in that area of the washing machine.





IT400

Specially designed for disinfection processes at temperatures of 50-60 °C.



IT401

Developed for disinfection processes in equipment that work at temperatures of 35-43 °C.

Control for High Level Disinfection Processes with liquid Peracetic Acid

Integron® IT400 / IT401 chemical indicators have been designed to control the effectiveness of high-level disinfection processes using liquid peracetic acid (PAA) as a disinfecting agent, ensuring that the critical parameters of this process are reached (temperature, time and concentration of PAA). They consist of an indicator strip printed with specific reactive ink for PAA, contained inside an envelope of non-absorbent material, which avoids the direct contact of the reactive ink with the aqueous medium.





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