

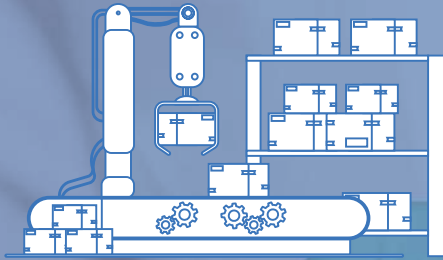


Terragene®



Let's work together
to create a better future

Solutions to guarantee safety in Pharmaceutical Industry



Sterilization Monitoring

Sterilization procedures should be monitored using biological and chemical indicators. Biological indicators, or spore tests, are the most accepted means of monitoring sterilization because they assess the sterilization process directly by killing known highly resistant microorganisms.

Chemical indicators do not guarantee sterilization; however, they help detect procedural errors (e.g., overloaded sterilizer, incorrect packaging) and equipment malfunctions. On the other hand, some chemical indicators should be used inside a package to verify that the sterilizing agent has penetrated it and reached the instruments inside.

Spore Strips, Spores Coupons & Culture Medium



BT40

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.

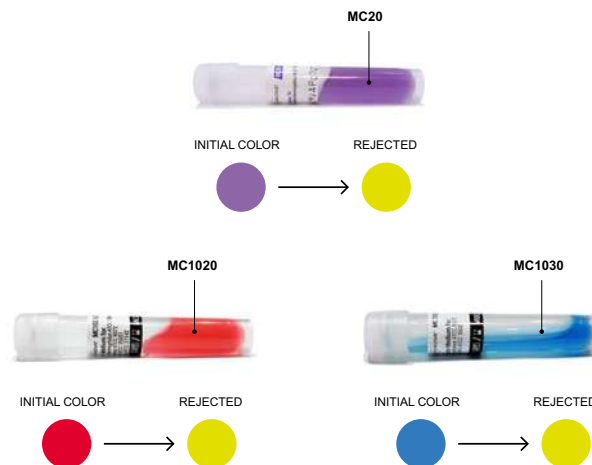
Conversely, if the sterilization process has been successful, the culture medium will remain its original color.

Code	Use	Spore	Compatible Culture Media	Conditions
BT40		Bacillus atrophaeus	MC1020 MC1030	48 hs at 37 °C
BT50		Geobacillus stearothermophilus	MC20 MC1020	24 hs at 60 °C 48 hs at 60 °C
BT70		Bacillus pumilus	MC70	48 hs at 37 °C
BT92		Geobacillus stearothermophilus	MC1020	24 hs at 60 °C
BT93		Geobacillus stearothermophilus	MC1020	24 hs between 55-62 °C



BT93

Bionova[®] BT93 consists of an envelope containing a stainless steel coupon soaked with a Geobacillus stearothermophilus ATCC 7953 spore population. Spore Coupon is specifically designed to control VH2O2 sterilization processes. Spore coupon should be incubated in Bionova[®] MC1020 Growth Medium tube or other medium appropriate for Geobacillus stearothermophilus ATCC 7953 growth.



Steam Sterilization Spore Ampoules

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 after 48 hours of incubation at 60 °C (BT21, BT22, BT23) or 37 °C (BT24).

Advantages

- ✓ Easy to use and interpret.
- ✓ Does not require activation.
- ✓ Evidence of growth with direct visual confirmation.
- ✓ For liquid load sterilization monitoring.
- ✓ Available in packages refrigerated at 4 - 8 °C, includes negative controls.



Code	Conditions	Sterilization
BT21 BT22 BT23	121-134 °C	Steam
BT24	110-121 °C	Steam

Self-Contained Biological Indicators for Sterilization processes



IC10/20

For the incubation of Conventional 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 position for external temperature control (Bionova® TB-IC1020).

Bionova® Conventional SCBI



EO BT10



STEAM BT20



DRY BT30



VH202 BT91



FORM BT100

Ultra Rapid, Super Rapid & Rapids Biological Indicators



Their innovative technology allows you to get reliable results in record time and speed up your workflow.

With increasing demands for faster sterile instruments turnaround in healthcare facilities, sterilization results need to be available as soon as possible to verify the sterility of the load. To fulfil these needs, Terragene® offers a broad portfolio of fluorescence biological indicators for sterilization monitoring.

- BT225, BT224, BT222 and BT220 for Steam.
- BT96 for VH202.
- BT102 for Formaldehyde.
- BT110 for Ethylene Oxide.

Instant	Hyper Rapid	Ultra Rapid	Super Rapids		Rapids			
								
								
STEAM BT225	VH202 BT96	STEAM BT224	VH202 BT96	STEAM BT222	VH202 BT95	FORM BT102	STEAM BT220	EO BT110

Automatic Readers for Bionova[®] Biological Indicators



MINIBIO



IC1020FR



IC1020FRLCD

Bionova[®] Auto-readers are automatic systems for incubation and readout of Bionova[®] Biological Indicators. IC10/20FR and IC10/20FRLCD also allow incubation and readout of Hygiene Monitoring Systems (Chemdye[®] Pro1 Micro).

The auto-readers allow to work at 2 temperatures (37 or 60 °C) and to select and execute incubation programs in parallel, allowing simultaneous incubation of BIs with

different reading times. They have a thermal printer for the record keeping of results.

The devices can be connected to a PC, which will be able to continuously obtain information about the incubation process and record the results through the Bionova[®] Cloud Traceability Software.

Bowie-Dick Test Packs & Cards

Bowie-Dick Test Pack BD125X/1 | BD125X/2

Chemdye® Bowie-Dick Test Pack was developed to control air removal and steam penetration performance in vacuum-assisted steam sterilizers. They are single-use devices that consist of a lead free chemical indicator, BD Test Sheet, placed between porous sheets of paper, wrapped with crepe paper, with a Steam indicator label on the top of the package. Product BD125X/1 also has a Warning Sheet which contains a circular lead free chemical indicator, thus allowing an early detection of air removal failures before they appear on the central chemical indicator.



Bowie-Dick Test Cards BD8948X | BD8948X/1 | BD8948H

Chemdye® Bowie-Dick Test Card has been designed to monitor the effectiveness of air removal in vacuum-assisted steam sterilizers at 132 °C, 4 min and at 134 °C, 3.5 minutes. Chemdye® Bowie-Dick Test Card consists of a Type 2 metal free chemical indicator printed on one side of the card. Chemical indicator changes from purple to green when processed. Non-uniform color change indicates presence of an air pocket during the sterilization cycle thus indicating sterilizer malfunction.

BD8948H is a stainless steel re-usable Holder for keeping BD8948X and BD8948X/1 Test Cards in place for proper assessment of sterilization cycle.

Chemdye® BD125X/1 and BD8948X/1 are FDA Cleared.

Process Indicators



Double adhesive labels

TYPE 1

Automatic record system labels have been designed to monitor Ethylene Oxide (CD13), Steam (CD23), Dry Heat (CD33), Plasma or Vaporized Hydrogen Peroxide (CD43) and Formaldehyde (CD53) sterilization processes. These self-adhesive labels are used in the outer part of the sterilization packs, 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.

Label Gun

Chemdye[®] CG3 is a Three-line Automatic Labeler that allows a quick and easy labelling of sterilization packages through the use of special documentation labels. Chemdye[®] CG3 labeler has three printing lines of twelve alphanumeric digits per line.



Tapes

TYPE 1

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).

	UNEXPOSED	ACCEPTED EXPOSURE
EO CT10		
VH₂O₂ CT40		
STEAM CT22		
FORM CT50		

Cintape[®] CT22 and CT40 are FDA Cleared.

Single and double strips

Chemdry® CD40
Multicatalytic process indicator
Type A (ISO 11446-1)
ISO 11446-1:2005
© 2008-02-06

CD40

Chemdry® CD16
Multicatalytic process indicator
Type A (ISO 11446-1)
ISO 11446-1:2005
© 2008-02-06

CD16

Chemdry® CD29
Multicatalytic process indicator
Type A (ISO 11446-1)
ISO 11446-1:2005
© 2008-02-06

CD29

Chemdry® CD50 FORM
Multicatalytic process indicator
Type A (ISO 11446-1)
ISO 11446-1:2005
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FORM
CD50

Chemdry® CD30
Multicatalytic process indicator
Type A (ISO 11446-1)
ISO 11446-1:2005
© 2008-02-06

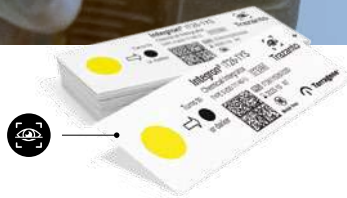
CD30



Chemdye® CD16, CD29 and CD40 are FDA Cleared.

Integrator Indicators

IT26-1YS Unique point Integrator TYPE 5



It was developed for verification of Steam sterilization cycles between 121 °C and 135 °C. These products ensure an adequate control of the effectiveness of sterilization processes (temperature, time, steam quality).

The accepted final color is reached when a theoretical spore population reaches its kill time, indicating integration condition has been reached.

IT12 EO Two level Integrator TYPE 5



It was developed to control Ethylene Oxide sterilization processes. It is a two-level indicator: Level 1 is the exposure level, which indicates exposure to Ethylene Oxide, while Level 2 is the integration level. This second level consists of a purple/brown ink dot that turns to green as it integrates all critical parameters of the sterilization process (time, temperature, humidity and Ethylene Oxide concentration). This indicator mimics the death curve of a theoretical *Bacillus atrophaeus* spore population.



IT26-C Moving front Integrator TYPE 5

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). 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.

Emulators for Steam

Emulators for Dry Heat



IT28 | IT27-5YS | IT27-7YS | IT27-18YS TYPE 6

Designed for monitoring Steam sterilization processes. They fulfil 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 efficacy of the sterilization processes (temperature, time, steam quality).

Code	Conditions
IT28	3.5 min. 134 °C 15 min. 121 °C
IT27-5YS	5 min. 134 °C 15 min. 121 °C
IT27-7YS	7 min. 134 °C 20 min. 121 °C
IT27-18YS	18 min. 134 °C

IT31 TYPE 6

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

Code	Conditions
IT31	40 min. 160 °C



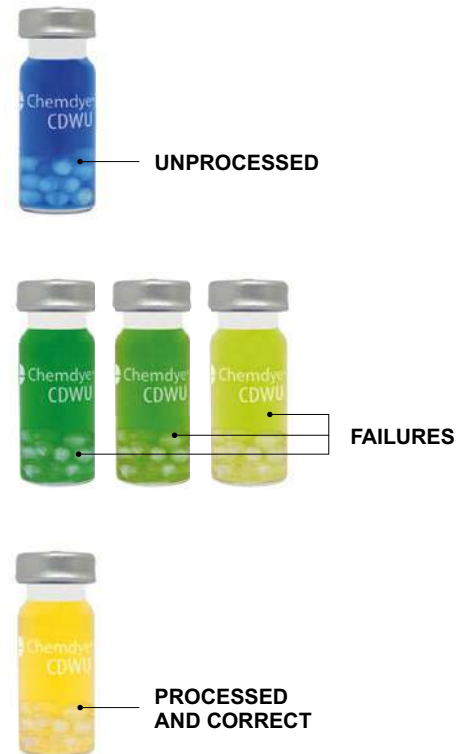
[Learn more and check the related products](https://www.terrargene.com)
terrargene.com

Indicators for Ultrasonic Cavitation performance test

CDWU

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 bluecolored 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.



System for surface residual Protein quantification



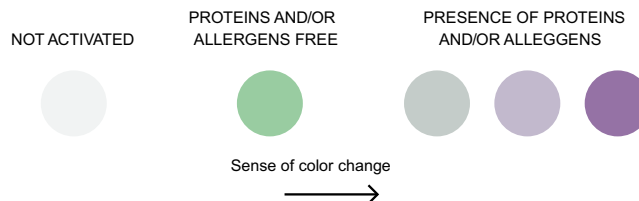
 4'
Ultra Rapid
Readout

Pro1 Alert

Terragene® has developed the Chemdye® Pro1 Alert Hygiene Monitoring System which not only detects but also quantifies proteins, allergens and reducing agents from different surfaces. The system consists of a pen that has a high absorption swab and two separate reactive solutions contained within the same device. After taking the sample from the selected surface, the swab is returned to the pen, activated and the result is then obtained with 4 minutes of incubation at 60 °C in Bionova® MiniPro Auto-Reader. Chemdye® Pro1 Alert system quantifies with a sensitivity of 0.3µg of total proteins.. The validation of this system reduces the use of multiple and time-consuming specific allergen tests. Its high sensitivity allows to alert the presence of residual proteins from different sources like milk, nuts, gluten, soy, egg, fish and seafood. The system is used along with Bionova® MiniPro auto-reader for analytical analysis.

Advantages

- ✓ Unique absolute total protein quantification system.
- ✓ High sensitivity.
- ✓ Rapid test results in 4 minutes.
- ✓ Dangerous chemical substances in specialized laboratories.
- ✓ Quick results that allow taking immediate remedial action.
- ✓ Manufactured under ISO 15883-1 standard.
- ✓ Whole traceability using Terragene® Bionova® Cloud Software.
- ✓ Alternatively provides qualitative data. Comparison of the final color against a color pattern included within the device allows protein/allergen level estimation.



Auto-reader for Pro1 Alert Hygiene Monitoring System



MINIPRO



Quantitative analysis

Bionova® MiniPro is an advantageous and very sensitive tool for incubation and reading of Pro1 Alert hygiene monitoring systems since it offers the user the unique benefit of performing a quantitative analysis of small quantities of protein and allergens, thus providing an exclusive and convenient way to keep results recording and traceability of every surface checked for contaminants. This exclusive feature makes Bionova® MiniPro an innovative device to keep objective track of surface cleaning process monitoring unparalleled on the current market.



Time Optimization

Bionova® MiniPro has 3 incubation positions, thus allowing the incubation of 3 Protein Detection System Pens at the same time.



Built-in Thermal Printer

A thermal printer delivers a ticket showing the final result of each active readout position. This allows to register each result in a record keeping book.



Reading & Traceability system

USB connection for PC record keeping through Bionova® Cloud Reading and Traceability software.



No maintenance required

The device does not need any kind of routine maintenance.



Temperature calibration

The device has an opening on its side to insert a thermometer, which allows temperature calibration control.



Compact design

Bionova® MiniPro is a compact table-top incubator that can be placed anywhere in your facility thanks to its small size.

Pen system for surface Protein semi-quantification

Pro1 RT

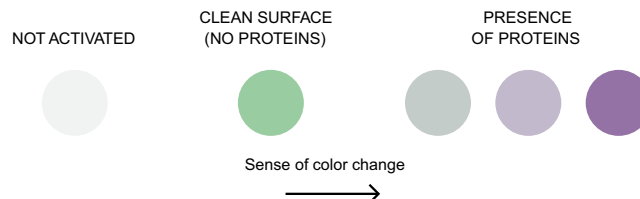
Surface cleaning and disinfection are processes applied on regular basis on different working environments like medical centers, bio-pharmaceutical industry, food industry, retail and gastronomy sectors. Residual protein levels on surfaces and rinsing water are an indicator of cleaning efficiency. This is because proteins represent the greatest challenge due to its high surface adhesion, especially when they undergo a denaturation process after being exposed to high temperature. The Chemdyne® Pro1 RT Hygiene Monitoring System was designed for the fast and simple protein level determination on instrument's surfaces, hard-to-access areas or in the rinsing water of instruments after cleaning.

The system includes a high absorption swab, which allows the collection of samples from different types of surfaces or solutions with high efficiency. A visual readout of a color change indicates the presence of detectable levels of protein in only 10 minutes allowing to take fast corrective decisions in the presence of contaminants. This system is highly sensitive, detecting from 15 µg of total protein (0.3 mg/ml in solution).



Rapid
Readout

Incubation Room
Temperature
20 to 30 °C



ATP based Hygiene Monitoring System



Surface ATP Test

Chemdye® Pen system for ATP quantification used on any surface for hygiene monitoring after the washing or disinfection procedure.

ATP is a molecule present in all living organisms, so it is a good indicator of the presence of microorganisms or residues that may promote their growth. When monitoring begins, the reagent in the test pen vial reacts with the ATP collected on the swab to produce luminescence. The intensity of the light emitted is proportional to the amount of ATP, and, therefore, it is also proportional to the degree of contamination.

Characteristics

- The system has a highly absorbent swab that allows the collection of samples from different surfaces, and a reactive solution.
- The swab is pre-moistened and is capable of releasing the ATP present inside living cells.
- Detection limit: 0.5 femtomol of ATP.
- Quantitative analysis using a specific Luminometer.

SRS STERISURE PRIVATE LIMITED

229, HARE KRISHNA VIHAR, NIPANIA,
INDORE, M.P., INDIA-452010

+91-8103888844, +91-9826914157

WWW.SRSSONS.COM, INFO@SRSSONS.COM