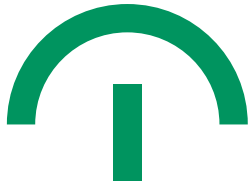




Let's work together
to create a better future

Solutions to guarantee safety in Dental Clinics

Rev. 6 | August 2021



Let's work together
to create a better future

What we do?

At Terragene® we offer a range of effective, simple-to-handle products to accurately control every step of instrument reprocessing in dental clinics. Available in a variety of formats, these high-performance control devices provide fast and consistent results in order to protect what you care the most, your patient.

terragene.com



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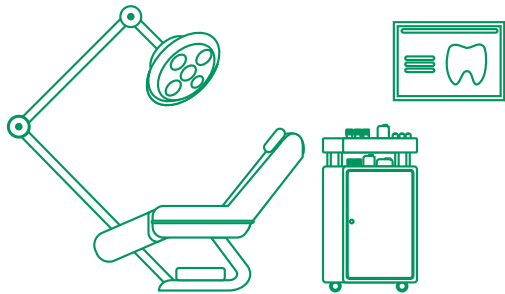
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Washing, Disinfection & Hygiene

It is vital to control the cleaning processes of instruments and devices since the result influences the success of the subsequent processes for sterilization. This control is crucial, particularly in automatic washing machines like washer-disinfectors and ultrasonic washing machines. The process parameters in the washing procedure may deviate from the acceptable limits. This can directly impact on the cleaning performance and affect negatively the final reprocessed materials. Moreover, the international Standards ISO 15883 (part 1 and 5), HTM-01 (part 01 and 05) and ANSI/AAMI (ST79:2017) require the monitoring of this process with a specific regime, through weekly or even daily check-ups.



Indicators for Cleaning efficiency monitoring

Controlling cleaning and washing processes of dental instruments and materials is highly important since its outcome affects the success of subsequent disinfection and/or sterilization processes.

Chemdye® Splat

Chemdye® Splat indicators consist of a synthetic support, which is stable at disinfection temperatures. Each indicator contains a mixture of specially combined colored organic components. Splat indicators formulation allows monitoring of all factors that affect the cleaning/washing process outcome. Splat indicators can be used for routine monitoring of cleaning/washing processes in washer-disinfectors and ultrasonic washing machines.

Chemdye® Splat CDWA indicators should be used along with Chemdye® Splat CDWAH (washer disinfectors) and CDWAH-U (ultrasonic washing machine) Holders. This accessories can be fixed on the tray, which allows reproducible location of the indicator inside the chamber. Also, CDWAH Holder poses a challenge to the washing process emulating shadowed or occluded surfaces of the instruments to be processed.

Chemdye® Splat CDWA cleaning indicators along with Chemdye® Splat CDWAH and CDWAH-U Holders allows to detect possible failures of a washing cycle.

2 challenge levels



CDWAH Holder

BASKET ZONE



COVERED ZONE

Helps to evaluate: Water pressure, spray system performance, location inside the washer and mechanical functions.

Helps to evaluate: Detergent chemistry and concentration, water quality, temperature, cycle duration, etc.

CDWAH-U Holder

For ultrasonic cleaning performance test.



Indicators for Ultrasonic Cavitation performance test

CDWU

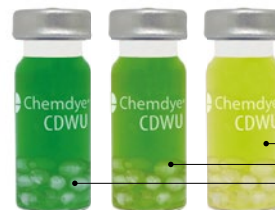
Chemdye® CDWU indicators consists of a transparent vial, with a blue-colored reactive solution and glass beads immersed in it. The formulation of the solution contained in the vial allows the monitoring of cavitation capacity of the ultrasonic washer.

When cavitation functions properly, vibration of the glass beads triggers a color change in the solution, from blue to yellow, through a range of green color intermediates.

The CDWU indicators can be used for routine monitoring of ultrasonic washing machines with different ultrasonic washing configurations. It should be noticed that the CDWU indicators were developed to monitor the cavitation performance of the ultrasonic washing machine with an empty tank, that is, without any load.



UNPROCESSED



FAILURES



**PROCESSED
AND CORRECT**



Protein-based quantitative Hygiene Monitoring System

PRO1 MICRO

Terragene® has developed the Chemdye® Pro1 Micro Hygiene Monitoring System which not only detects but also quantifies proteins, allergens and reducing agents on the surfaces of instruments, after the cleaning and disinfection process.

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 at 15 minutes of incubation at 60 °C (using Bionova® IC10/20FR and IC10/20FRLCD) or 4 minutes at 60 °C (in Bionova® MiniPro Auto-Reader). By its given final quantitative result, it is possible to determine whether reprocessing and/or retesting of the tested surface is necessary.

Chemdye® Pro1 Micro system can obtain a quantitative result with a sensitivity of 0.3 µg.

Advantages

- ✓ Unique absolute total protein quantification system.
- ✓ High sensitivity.
- ✓ Rapid test results in 4 minutes with Bionova® Minipro.



 **4'**
Ultra Rapid
Readout

- ✓ Alternatively provides qualitative data. Comparison of the final color against a color pattern included within the device allows estimation of cleanliness.
- ✓ It does not require handling dangerous chemical substances in specialized laboratories.
- ✓ Quick results that allow taking immediate remedial action and avoiding healthcare-acquired infections.
- ✓ Manufactured under ISO 15883-1 standard and follow recommendations set in the HTM01-05 and HTM 01-01 guidelines.
- ✓ Traceability with Bionova® Cloud Software.



Auto-reader for Pro1 Micro Hygiene Monitoring System



4'
Ultra Rapid
Readout



Quantitative analysis

Bionova® MiniPro is an advantageous and very sensitive tool for incubation and reading of Pro1 Micro 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

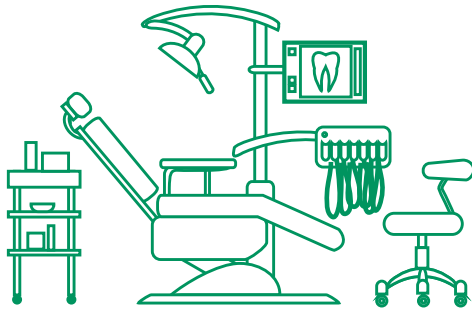
The device has an opening on its side to insert a thermometer, which allows temperature calibration control.



Compact design

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





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.

Biological Indicators



Check out our Biological Indicators available here
terragine.com

The first Instant Biological Monitoring System

Photon System

It is composed of a Self-Contained Biological Indicator with Instant Readout based on fluorescence technology and a dedicated fluorescence Auto-reader. It is designed for monitoring vacuum assisted and gravity air-displacement steam sterilization processes.

Bionova® Photon Instant Auto-reader has been designed for the incubation and automatic readout of Photon Bionova® Self-contained Biological Indicator (BT225).



100% Biological

The first and only 100% biological instantaneous monitoring system for steam sterilization processes.



Compact design

Allows to operate quickly, in tight spaces and without problems.



Easy & immediate

In their two positions it automatically detects the Photon BI and delivers a readout result after a few seconds using advanced fluorescence techniques.



STEAM



USB, Wi-Fi & Bluetooth®

The electronic tickets created can be accessed using compatible devices like smartphones. Record keeping through Bionova® Cloud Reading and Traceability software.



Ultra Rapid, Super Rapid & Rapids Biological Indicators



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 steam-sterilized loads between 20 minutes to a few hours.

Rapid, Super Rapid and Ultra Rapid BIs for sterilization in autoclaves should be incubated in the Bionova® Automatic Fluorescence Auto-readers IC10/20FR, IC10/20FRLCD or MiniBio at 60 ± 2 °C. These devices provide accurate, rapid, reliable and easy detection of positive and negative indicators, offering final results in short times. All this information can be recorded and stored in the Bionova® Cloud Traceability Software, available on our website.



Learn more and check the related products
terragene.com



Ultra Rapid

20'



STEAM
BT224

Super Rapids

1h



STEAM
BT222

Rapids

3h



STEAM
BT220

Code

BT220
BT222
BT224

Conditions

121-135 °C
121-135 °C
132-135 °C

Sterilization

Steam
Steam
Steam

Bionova® BT220, BT222 and BT224 are FDA Cleared.

Compact Fluorescence Auto-reader

for Rapid, Super Rapid & Ultra Rapid Biological Indicators



MINIBIO



Easy to use

Allows quick, accurate and reliable detection of positive and negative BIs, providing results in short times.



Compact design

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



Automatic readout

Bionova® MiniBio Auto-reader detects when a BI is placed in an incubation position and automatically starts a readout.



One Auto-reader for every process monitoring

Bionova® MiniBio allows to simultaneously incubate with different incubation times. 3 positions, 3 incubation times.



Bionova® Cloud Reading & Traceability software system

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



Built-in Thermal Printer

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



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.

Bionova® MiniBio Auto-reader is FDA Cleared.

Conventional Self-contained Biological Indicators

Terragene® offers its line of conventional Self-Contained Biological Indicators (SCBI) for sterilization processes control of dental materials and instruments. Its innovative technology allows obtaining results within 24 hours (Steam) or 48 hours (Dry Heat).

Bionova® Conventional SCBI



IC10/20 BI Incubator

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



Biological Indicators & Incubators compatibility chart

	 IC10/20	 PHOTON	 MINIBIO
 BT20	✓		
 BT30	✓		
 BT220			✓
 BT222			✓
 BT224			✓
 BT225		✓	

Chemical Indicators



Check out our Chemical Indicators available here
terrargene.com

Process Challenge Devices for Hollow Material Sterilization Monitoring



PCD-A-3.5Y



KIT HELIX

Advantages

- ✓ Easy interpretation of results.
- ✓ The adhesive on the back of the indicator strip facilitates recording of results.
- ✓ Manufactured with highly resistant and durable materials.
- ✓ Different Chemical Indicators strips for monitoring different steam sterilization cycles.
- ✓ Manufactured with Chemink® inks, 100% Metals Free.

HELIX KITS

Chemdye® PCD-A Chemical Indicators were designed to be used in Helix-PCD Systems to monitor Steam sterilization processes operating at 134 °C.

PCD-A Chemical Indicators may be packed as a Kit version along with a Chemdye® Helix PCD for a safe load release of hollow material in large and small sterilizers.

PCD-A-3.5BD Test Strips along with a Chemdye® Helix Process Challenge Device have been designed to monitor Bowie-Dick test cycles at 134 °C, 3.5 minutes, assessing air removal and steam penetration in large and small vacuum-assisted steam sterilizers.

Code

Conditions

KH2X15-3Y	3 min. 134 °C
KH2X15-3.5Y	3.5 min. 134 °C
KH2X15-5.3Y	5.3 min. 134 °C
KH2X15-7Y	7 min. 134 °C
KH2X15-3.5BD	3.5 min. 134 °C Bowie-Dick cycle



Bowie-Dick Test Packs

Bowie-Dick Test Packs 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 (ISO11140-1,4) and BD8948X/1 (ISO11140-1,5) 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 Steam (CD23) and Dry Heat (CD33) 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 sterilization processes from those that have not.



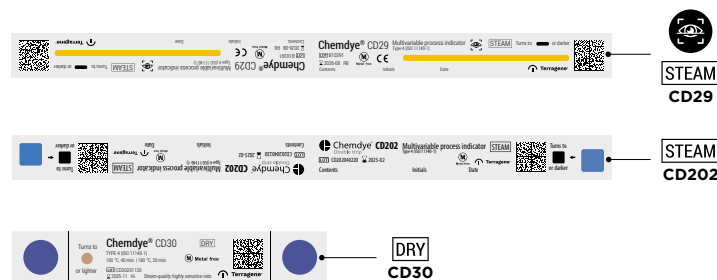
Cintape® CT22 is FDA Cleared.



Multivariable Indicators

Single and double strips TYPE 4

Chemdye® Type 4 internal control strips are multivariable indicators that rapidly shows if critical parameters of the sterilization process have been reached, ensuring appropriate penetration of the sterilizing agent inside the packages. These chemical indicators offers a distinct color change when exposed to the stated values (SVs) of the critical process variables.



Chemdye® CD29 is FDA Cleared.



Learn more and check the related products
terragene.com



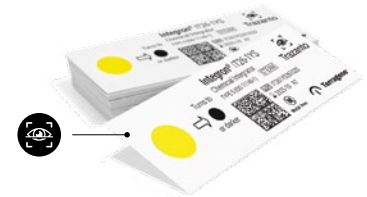
Integrator Indicators



IT26-C with and without extender 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.

IT26-1YS Unique point Integrator TYPE 5

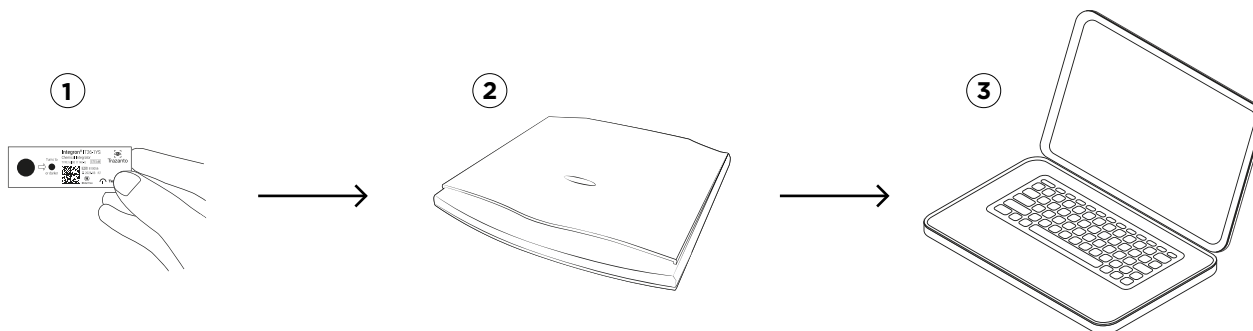


It was developed for verification of Steam sterilization cycles between 121 °C and 135 °C. These products ensure an adequate control of the effectiveness of sterilization processes (temperature, time, steam quality).

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

Integron® IT26-1YS and IT26-C are FDA Cleared.

Automatic System for Quality & Traceability Control of Washing & Sterilization processes



This innovative and unique system consists of a highly sensitive scanner associated to Bionova® Cloud Traceability Software and in conjunction with Trazanto®, which is our scanner. The scanner along with our traceability software are capable of analyzing and interpreting the results of Chemdye® and Integron® Cleaning and Sterilization Chemical Indicators. In this way, the user is able to collect the results of all the chemical indicators used in all the packs of the same sterilization cycle, or those used in different locations in a cleaning cycle, and to digitally store that information.

Trazanto® System interprets the results in a sensitive and reliable way, thus avoiding possible failures in the operator's visual interpretation. The recording of such results, through the usage of Bionova® Cloud Traceability Software, supports and protects them, by optimizing the results' traceability and availability, generating reports alerts if there are failures in the performance of certain cleaning or sterilization cycles and/or equipment.

Advantages

- ✓ Artificial intelligence reading system.
- ✓ Automatic recognition of product code and lot number.
- ✓ Highly sensitive and easy-to-use scanner.
- ✓ Associated with Bionova® Cloud Traceability Software that allows the registration and monitoring of results, and the generation and printing of reports.
- ✓ Prevents possible failures in the operator's visual interpretation.



Trazanto® Compatible Indicators

Washing



CDWA3

For Cleaning performance tests



CDWA4

For Washing Efficiency tests

Sterilization



CD29

For Steam



BD125X/1

Bowie-Dick Test Pack
for 3.5 min at 134 °C



BD125X/2

Bowie-Dick Test Pack for 4 min
at 132 °C & for 3.5 min at 134 °C



IT26-1YS

For Steam processes
between 121-135 °C



IT26-C

For Steam processes
between 118-138 °C



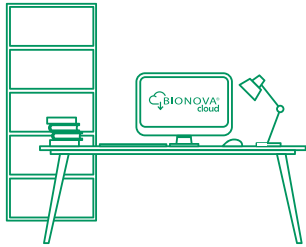


Terragen

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SHOWING PAGE: 1



Bionova® Cloud

At Terragene® we have developed a complete traceability system for monitoring reprocessing procedure in your facility processes in sterilization departments. You can now have access to a complete solution associated with Terragene's disposables. Streamline and automate the traceability associated with washing tests, chemical indicators (including the Bowie-Dick test), quantitative protein-based hygiene monitoring tests, and for any Bionova® fluorescence readout biological indicator.



Digital workflow solutions for the Sterile Processing Department



Get full Quality Control & Traceability!

Advantages

✓ Get a full and automatic traceability system for all your monitoring processes: washing, hygiene, chemical monitoring and biological monitoring all together.

✓ Avoid human error.

✓ Instant online results.

✓ Speed up all your processes: agile workflow and less time-demanding activities.

✓ Monitor the historical performance of every equipment inside your facility the SPD independently.

✓ Accuracy and efficacy.

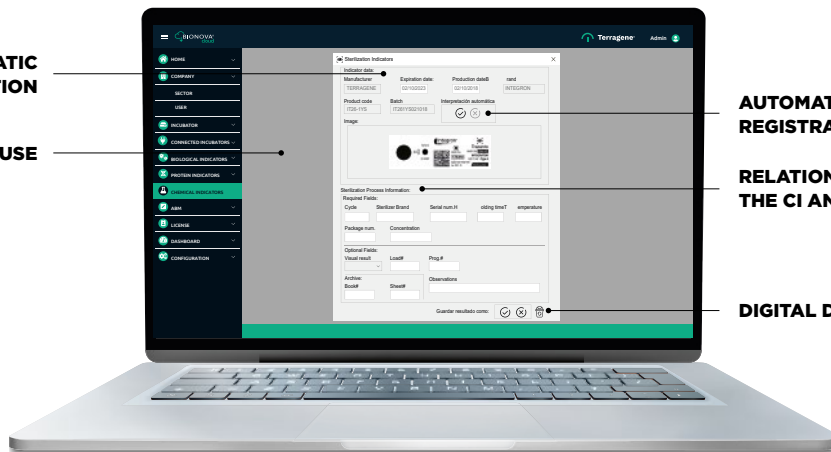
**AUTOMATIC
INTERPRETATION**

EASY TO USE

**AUTOMATIC
REGISTRATION**

**RELATIONSHIP BETWEEN
THE CI AND THE STERILIZER**

DIGITAL DATABASE



Bionova® Cloud Compatible Products

Sterilization

BOWIE-DICK TEST



BD125X/1



BD125X/2

BIOLOGICAL INDICATORS



BT220 | BT222 | BT224 | BT225

CHEMICAL INDICATORS



IT26-C



IT26-1YS



CD29

AUTO-READER INCUBATORS



PHOTON



MINIBIO

INDICATORS ANALYZER



TRAZANTO*

Washing

WASHING INDICATORS



CDWA3



CDWA4

INDICATORS ANALYZER



TRAZANTO*

Inspection & Hygiene

PROTEIN DETECTION



PRO1 MICRO

AUTO-READER INCUBATOR



MINIPRO

Let's work together
to create a better future.

