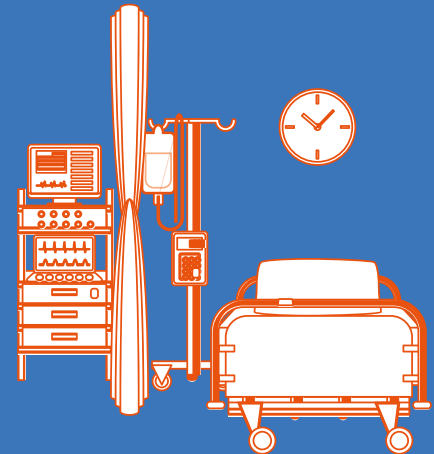




Sterilization Monitoring



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.

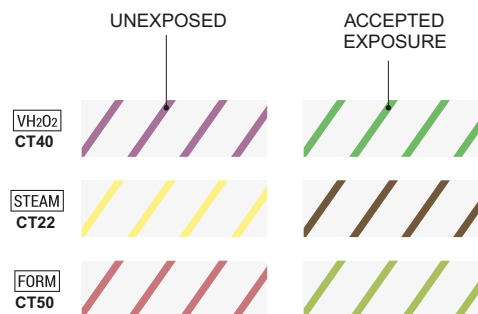
Label Gun

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 sterilization processes from those that have not.



Cintape® CT22 and CT40 are FDA Cleared.

Bowie-Dick Test Packs

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.

Helix Indicators

Helix Indicators for Steam, EO, LTSF & VH2O2 PCD-A3.5Y, PCDA-E1, PCDA-F1, PCDA-P1

Chemdye® Test strips for use in Helix-PCD System. Load release.
Varnished self-adhesive strips printed with indicator Type-2.
Chemical strips (Type 2 Chemical Indicator according to ISO 11140-1:2014) for use with Helix-PCD in the control of sterilization processes.
Indicators are 100% free of toxic heavy metals.



Steam Sterilization



EO Sterilization



VH2O2 Sterilization

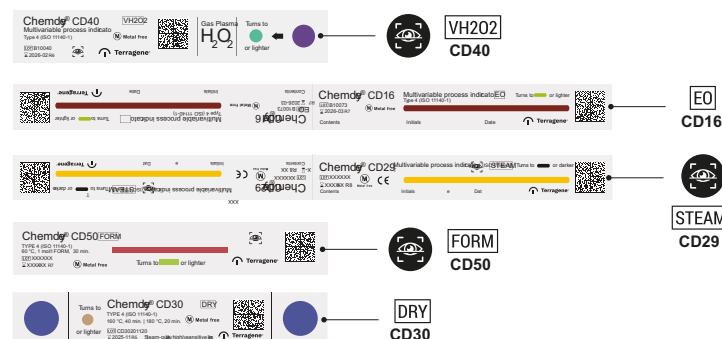


LTSF Sterilization

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.



Learn more and check the related products
terrargene.com

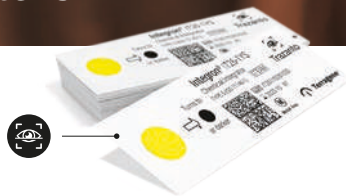
Chemdye® CD16, CD29 and CD40 are FDA Cleared.

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 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.



Emulators for Steam



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

Emulators for Dry Heat



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

Conventional Biological Indicators



Bionova[®] Conventional SCBI



IC10/20

Biological indicators are the only internationally accepted indicators that provide a direct measure of a sterilization cycle lethality.

By using Bionova[®] Dual Incubator, Bionova[®] Conventional SCBIs produce visible results within 24 h (Steam, VH2O2) or 48 h (Ethylene Oxide, Formaldehyde and Dry Heat).

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.

The fastest VH2O2 Sterilization Process Monitoring System

Hyper System

It is composed of a Self-Contained Biological Indicator with a 5 minute readout time based on fluorescence technology and a dedicated fluorescence Auto-reader. It is designed for monitoring plasma or vaporized Hydrogen Peroxide sterilization processes.

Bionova® Hyper Auto-reader has been designed for the incubation and automatic readout of Hyper Bionova® Self-contained Biological Indicators (BT98).



100% Biological

The fastest 100% biological monitoring system for plasma or vaporized Hydrogen Peroxide sterilization.



Compact design

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



Easy & hyper rapid

In their two positions it automatically detects the SCBI and delivers a readout result after 5 minutes using advanced fluorescence techniques.

5'
Hyper Rapid
Readout



VH202



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



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.

- BT224, BT222 and BT220 for Steam.
- BT96 and BT95 for VH2O2.
- BT102 for Formaldehyde.
- BT110 for Ethylene Oxide.

Instant	Hyper Rapid	Ultra Rapid	Super Rapids		Rapids			
INSTANT	5'	20'	30'	1 h	2 h	2 h	3 h	4 h
STEAM BT225	VH2O2 BT98	STEAM BT224	VH2O2 BT96	STEAM BT222	VH2O2 BT95	FORM BT102	STEAM BT220	EO BT110

Fluorescence-based Process Challenge Device for Steam Sterilization

Steam PCDs

Process Challenge Devices are designed to simulate a biological indicator (BI) placed in a large hospital pack and emulate the 16 towel pack PCD described in AAMI-ST79. Bionova® PCD pre-assembled disposable test packs consists of a SCBI, a Type 5 Integrator Indicator and a self-adhesive Record Card, held within a stack of porous cards that poses resistance to steam penetration. The whole ensemble is contained within a cardboard box with a Type 1 Process Indicator that changes color when exposed to steam.



KPCD225-2
UNPROCESSED



NEGATIVE



POSITIVE



KPCD225-C
UNPROCESSED



REJECTED



ACCEPT



Code	Readout	SCBI
KPCD220-2	3 hs at 60 °C	BT220
KPCD220-C	3 hs at 60 °C	BT220
KPCD222-2	1 hour at 60 °C	BT222
KPCD222-C	1 hour at 60 °C	BT222
KPCD224-2	20 min. at 60 °C	BT224
KPCD224-C	20 min. at 60 °C	BT224
KPCD225-2	7 sec. at 60 °C	BT225
KPCD225-C	7 sec. at 60 °C	BT225



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.

Touchscreen Fluorescence Auto-reader

for Rapid, Super Rapid & Ultra Rapid Biological Indicators



IC10/20FRLCD



Touchscreen

Bionova® IC10/20FRLCD has a 3,5" LCD touchscreen.



Workflow optimization

Bionova® IC10/20FRLCD has 12 positions to simultaneously incubate all different Bionova® SCBI and 1 position for incubating and quantifying Protein Pen (Hygiene Monitoring System). Furthermore, remaining incubation time at each position is displayed on the screen.



Automatic readout

Bionova® IC10/20FRLCD automatically reads the results of the incubation, displaying icons corresponding to each BI position when the final result is obtained.



Bionova® Cloud Reading & Traceability software system

USB, Wi-Fi & Ethernet connection for PC record keeping through Bionova® Cloud Reading and Traceability software.



Remote access

Remote display of each reading status in PC and Smartphones.



Result recording

The device automatically records the last 208 reading results. Remote viewing on the computer through the Embedded Web Server.



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® IC10/20FRLCD Auto-reader is FDA Cleared.

Fluorescence Auto-reader

for Rapid, Super Rapid & Ultra Rapid Biological Indicators



IC10/20FR



Multiple positions

12 positions for incubating Rapid, Super Rapid and Ultra Rapid Fluorescence Readout SCBIs. 1 position for incubating and quantifying Protein Pen (Hygiene Monitoring System).



Diferent reading programs

Bionova® IC10/20FR allows to simultaneously incubate biological indicators with diferent incubation times.



Automatic readout

Bionova® IC10/20FR automatically reads the results of the incubation, showing specific led color lights corresponding to each BI position when the final result is obtained.



Bionova® Cloud Reading & Traceability software system

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



Result recording

The device automatically records the last 12 reading results. Remote viewing on the computer through the Embedded Web Server.



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.

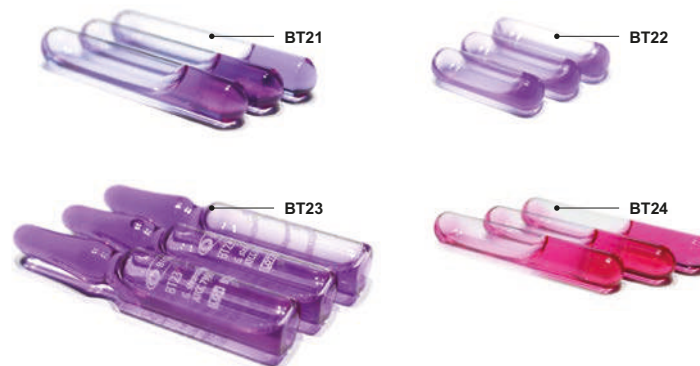
Steam Sterilization Spore Ampoules

BT21 | BT22 | BT23 | BT24

Bionova® Spore Ampoules are self-contained biological indicators for monitoring steam sterilization processes of liquid loads. Consists of different volumes of culture medium inoculated with a specific spores population: *Geobacillus stearothermophilus* ATCC 7953 (BT21, BT22 and BT23) and *Bacillus subtilis* DSM 5230 ATCC 35021 (BT24) within an hermetically sealed borosilicate glass. The culture medium is specially formulated to turn to yellow when spores grow. Bionova® spores ampoules provide visual confirmation of sterilization within 48 hs 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

Spore Strips, Spore Ampoule & Culture Medium

Bionova® Spore Strips consists of an envelope, permeable to the sterilizing agent, containing a paper strip inoculated with a spore population. BT31 BI consist of a sand type carrier with specific spores inside of a glass ampoule designed to monitor very high temperature dry heat sterilization processes.

After exposure to the sterilization process, strips and BT31 ampoule content are aseptically transferred to the culture media tube and incubated in the Bionova® Dual Incubator according to the specific conditions. If sterilization has failed, culture medium will show a significant color change. Conversely, if the sterilization process has been successful, the culture medium will remain its original color.



INITIAL COLOR

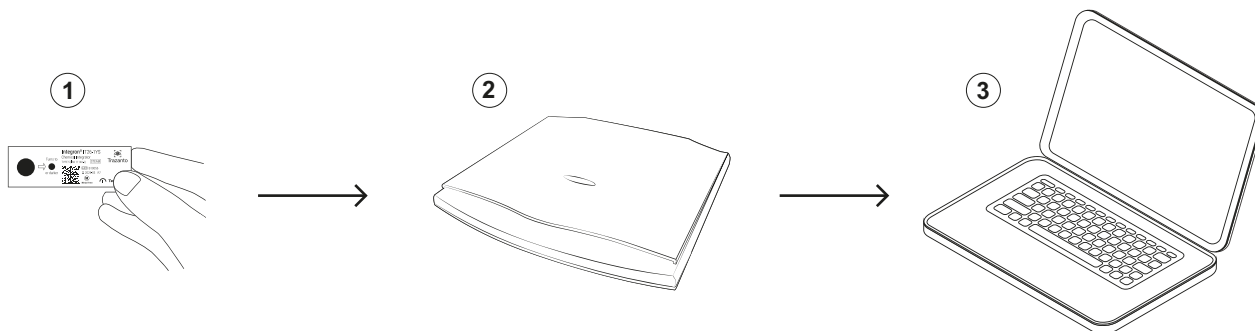


REJECTED



Code	Use	Spore	Compatible Culture Media	Conditions
BT40	EO DRY	Bacillus atropheus	MC1020 MC1030	48 hs at 37 °C
BT50	STEAM FORM	Geobacillus stearothermophilus	MC20 MC1020	24 hs at 60 °C 48 hs at 60 °C
BT60	EO DRY STEAM	Geobacillus stearothermophilus and Bacillus atropheus	MC20 MC1020 MC1030	24 hs at 60 °C 48 hs at 37 °C
BT31	DRY	Bacillus atropheus	MC1030	72 hs at 37 °C

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
	LUMENIA	For Washing Efficiency control in flexible endoscopes' hollow internal channels

Sterilization

	CD29	For Steam
	CD40	For Hydrogen Peroxide
	CD42	For Hydrogen Peroxide
	CD50	For Formaldehyde



PCD20-2 | PCD20-C
PCD220-2 | PCD220-C
PCD222-2 | PCD222-C
PCD224-2 | PCD224-C
PCD225-2 | PCD224-C

For Steam processes



PCD26-2 | PCD26-C

For Steam processes



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-SBL

Unique point Steam Type 5 CI
For Steam processes
between 121-135 °C



IT26-SAD

Unique point Steam Type 5 CI
For Steam processes
between 121-135 °C



IT26-C

For Steam processes
between 118-138 °C

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.




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 according to the HTM 01-01 guidelines.

Auto-reader for Pro1 Micro Hygiene Monitoring System



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.



4'
Ultra Rapid
Readout



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.

ATP based Hygiene Monitoring System

Indicators for Ultrasonic Cavitation performance test



Surface ATP Test

Chemdye® ATP surface test ATP-s1 hygiene monitoring system has been designed for the detection of ATP on hard-to-reach surfaces that have been subjected to cleaning/disinfection processes.

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.



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.

Indicators for Cleaning efficiency monitoring

Thermodisinfection Indicators



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 allow to detect possible failures of a washing cycle.



After cleaning, surgical instruments must be disinfected to ensure safe subsequent handling and processing. Thermal disinfection with moist heat is the most common method for disinfection of medical devices when using washer disinfectors.

Disinfection efficiency is reached with a combination of temperature and time ranging from 90 to 93 °C and 1 to 10 minutes (or more), respectively.

IT27W-1 | IT27W-5 | IT27W-10

Integron[®] Indicators have been designed to react in moist heat disinfection processes in washer-disinfectors, providing an accurate, convenient method of routine control, and assuring disinfection efficiency. The green indicating ink was developed to turn to purple when temperature and time conditions are met.

Code	Time	Temperature
IT27W-1	1 minute	90 °C
IT27W-5	5 minutes	90 °C
IT27W-10	10 minutes	93 °C

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