

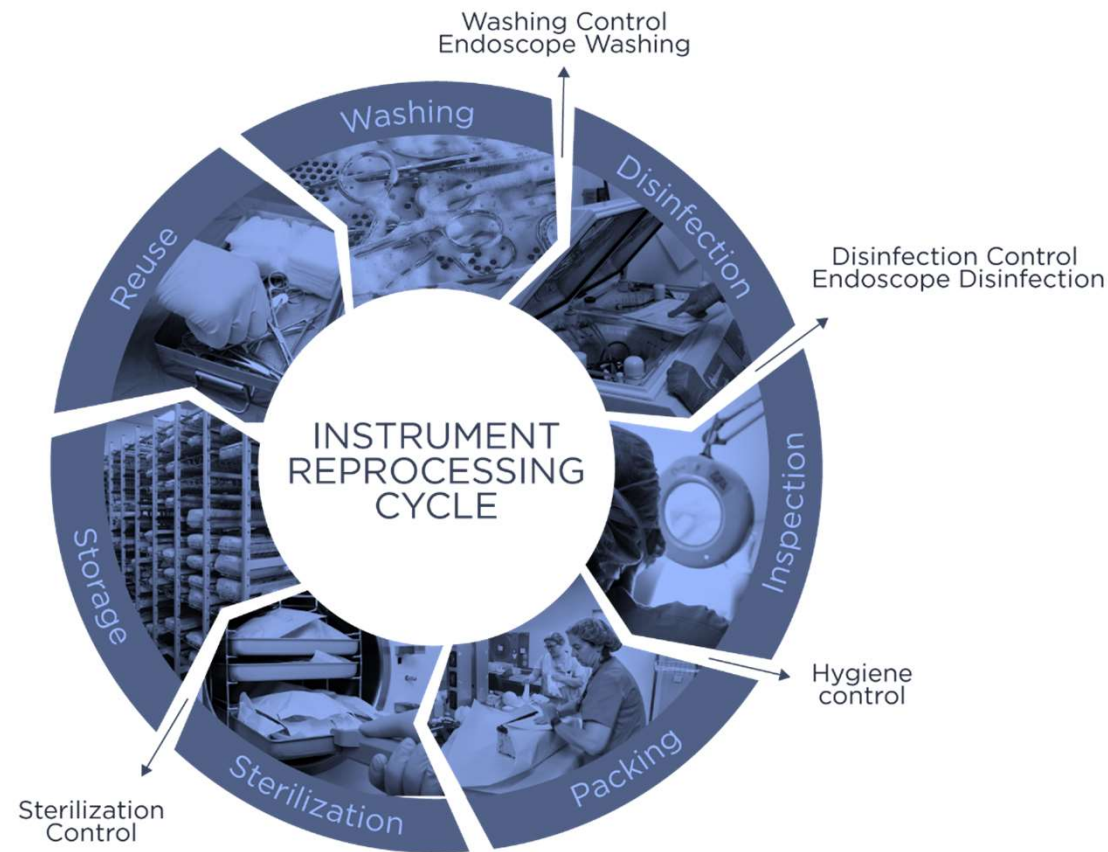
Advanced Technologies for enhancing routine testing

Quantitative Protein Testing and Ultra Rapid
Biological Indicators



Washing and Sterilization

The two main steps in the MD reprocessing cycle



Washing, Disinfection and Inspection



Washing, Disinfection and Inspection

Basic concepts and different ways to measure its efficiency

Not clean



Not sterile

Without efficient cleaning, posterior disinfection and sterilization will be compromised



Monitoring the effectiveness of these 3 steps, helps reducing the risk of an infectious incident



Washing, Disinfection and Inspection

Basic concepts and different ways to measure its efficiency

Washing main purpose:

Total elimination of organic residues

Disinfection main purpose:

Inactivation of living cells, especially microorganisms

Inspection main purpose:

Visual confirmation of absence of organic residues



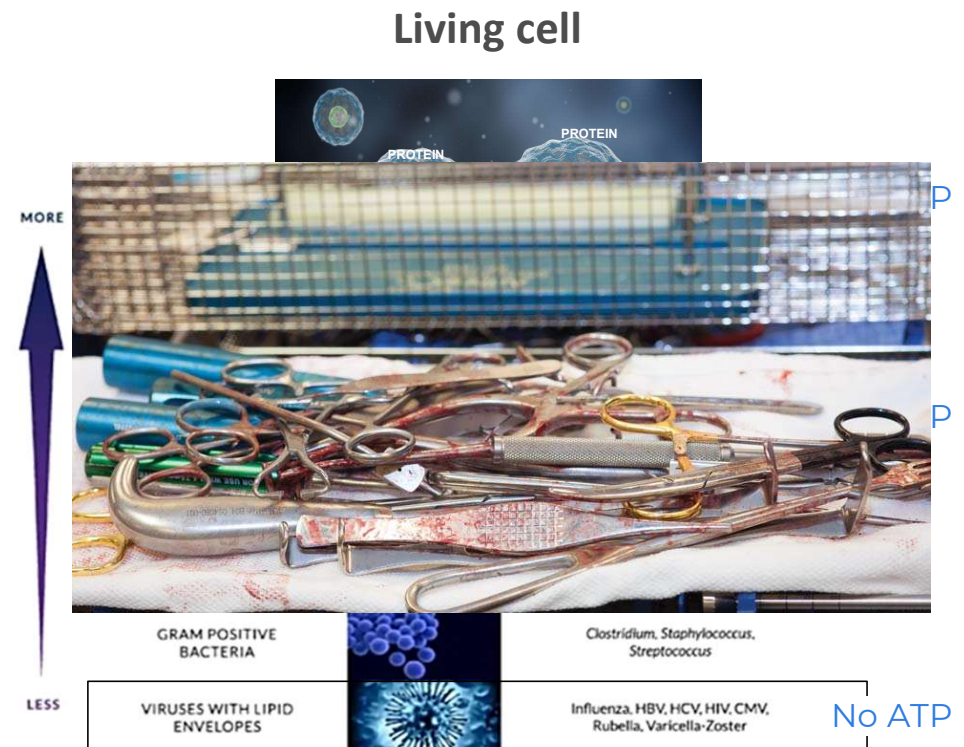
Is not enough



Quantitative protein test

Why is so important to test protein?

1. PROTEINS are fundamental components of cells (scaffold proteins) and carry out important biological functions (enzymes).
2. Blood and human tissues contain PROTEINS.
3. PROTEINS are the most difficult to remove residues during a cleaning process.
4. PROTEIN residues represent a direct measure of organic/microbial contamination.
5. A dead cell will lose the ATP content, but proteins will remain, i.e., there is still a contamination in the instrument.
6. Not all microorganisms contain ATP.
7. With protein tests we reduce and monitor the Prion Risk.



Protein Detection Systems

Systems in the market

Colorimetric (qualitative) systems

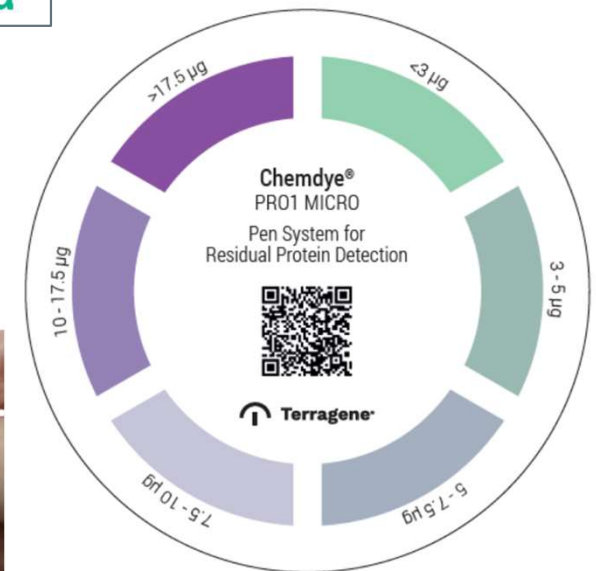


Quantitative systems



Quantitative protein test

PRO1MICRO



Quantitative protein test

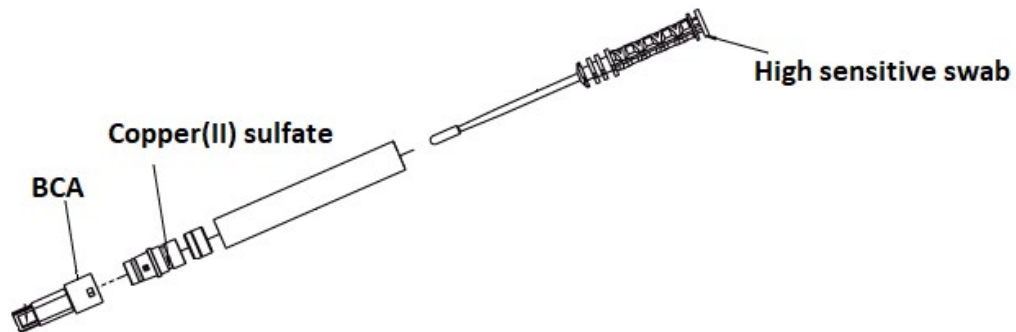
PRO1MICRO

Colorimetric reaction

When proteins are present, peptide protein bonds reduce the **Cu²⁺** ions of copper(II) sulfate to **Cu⁺** (copper I).

The amount of **Cu²⁺** reduced is proportional to the amount of protein present in the solution.

Bicinchoninic acid (BCA) reacts with each Cu⁺ ion, forming a **purple-colored complex** that strongly absorbs light.



Quantitative protein test

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Using Bionova® Auto-Reader Incubators

MINIPRO



4 minutes

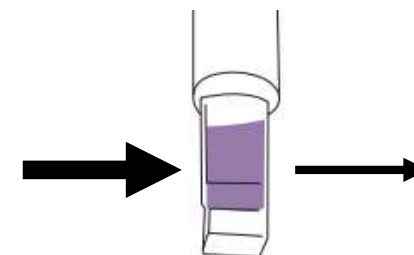
IC1020FR LCD



IC1020FR



7 minutes



Quantification range: 1 - 50 μg



Quantitative protein test

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Frequency and Threshold

Frequency

Threshold

HTM 01-01 (UK)

50 test Quarterly

5 μg per instrument
side

ISO 15883-5:2021

We offer a Digital Solution
for the two regulatory
approaches

Alert level $\geq 3 \mu\text{g}/\text{cm}^2$.
Action level $\geq 6,4 \mu\text{g}/\text{cm}^2$



Quantitative protein test

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Software Bionova Cloud – ISO 15883-5

The screenshot displays the Bionova Cloud software interface. On the left is a dark sidebar with a menu containing options like HOME, COMPANY, AUTO READERS, BIOLOGICAL INDICATORS, HYGIENE MONITORING, TRAZANTO RESULTS, EQUIPMENT, LICENSE, DASHBOARD, CONFIGURATION (highlighted in green), PARAMETERS, LOG, CHANGE PASSWORD, SUBSCRIPTIONS, and DATABASE MIGRATION. The top header is black with the BIONOVA cloud logo on the left and "Terragene Specialists, Product" on the right. The main content area is white and contains a form for configuration. At the top of the form is a box for "UPLOAD COMPANY LOGO" with a green button. Below this are "SAVE" and "DELETE" buttons. The "Working Mode" section is circled in blue and includes a "Mode" dropdown menu set to "ISO 15883-5", a green "SAVE" button, and two input fields: "Protein alert threshold [µg/cm²]" with the value "3" and "Protein action threshold [µg/cm²]" with the value "6,4". A second green "SAVE" button is at the bottom of this section.



Quantitative protein test

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Software Bionova Cloud – ISO 15883-5

The screenshot displays the BIONOVA cloud web application interface. On the left is a dark sidebar with a menu. The "EQUIPMENT" menu item is highlighted in green. Below it, the "INSTRUMENTS" menu item is highlighted with a blue box. The main content area shows a table with the following data:

CODE	INSTRUMENTS	AREA	SWAB BOTH SIDES	CREATION DATE
ESPÁTULA	VER ERRORES	21.1 cm ²	<input checked="" type="checkbox"/>	11/29/2022 11:41 AM
CLAMP ANTO	PINZA	10.3 cm ²	<input checked="" type="checkbox"/>	11/29/2022 10:50 AM
SCISSOR ANTO	DESK SCISSOR	19.7 cm ²	<input checked="" type="checkbox"/>	11/29/2022 10:40 AM
123123	CONTROL	21.3 cm ²	<input type="checkbox"/>	11/18/2022 9:24 AM
INSTRUMENT1	ALIEN TEST	5.8 cm ²	<input checked="" type="checkbox"/>	6/23/2022 12:53 PM
S1	SCISSOR 1	11.8 cm ²	<input checked="" type="checkbox"/>	6/15/2022 5:38 AM
C	BROCHE	4.4 cm ²	<input type="checkbox"/>	5/20/2022 2:57 PM
LAPICERA	LAPICERA LIMPIA	7.3 cm ²	<input type="checkbox"/>	5/13/2022 12:27 PM
PUNTERO	PUNTERO LÁSER	26.6 cm ²	<input type="checkbox"/>	5/11/2022 3:53 PM
USB	CABLE USB	25.5 cm ²	<input type="checkbox"/>	5/11/2022 2:01 PM

At the bottom of the table, there is a pagination bar showing "ROWS PER PAGE 10" and "(1-10/16)". Below the table, a blue box contains the text "To generate measurements you must download the Surface Eye App" and two buttons: "GET IT ON Google Play" and "Download on the App Store".



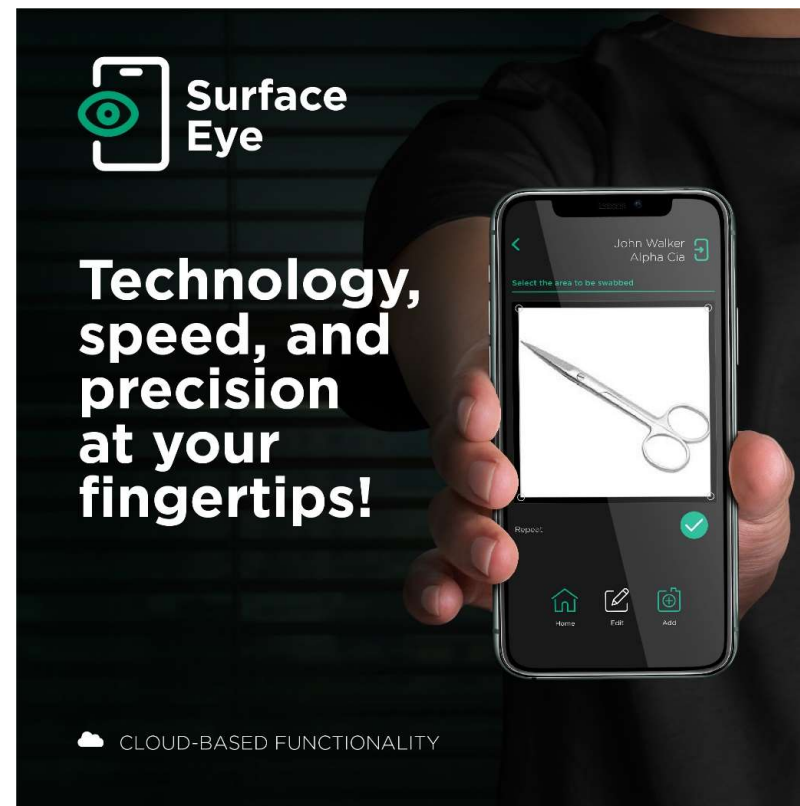
Quantitative protein test

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Software Bionova Cloud – ISO 15883-5



[Surface Eye video](#)



Quantitative protein test

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Software Bionova Cloud – HTM 01-01 (IQAS)

A screenshot of the Bionova Cloud web application interface. The left sidebar contains a menu with items: HOME, COMPANY, AUTO READERS, BIOLOGICAL INDICA..., HYGIENE MONITORI..., TRAZANTO RESULTS, EQUIPMENT, LICENSE, DASHBOARD, CONFIGURATION (highlighted in green), PARAMETERS, LOG, CHANGE PASSWORD, and SUBSCRIPTIONS. The main content area has a top header with the BIONOVA cloud logo, a Terragene logo, and the text "Specialists, Product". Below this, there is a "Company Logo" section with a text input field, a file size limit of "< 1 MB", an aspect ratio limit of "3:1", and a green "UPLOAD COMPANY LOGO" button. Below that are "SAVE" and "DELETE" buttons. The "Working Mode" section is circled in blue and contains a "Mode" dropdown menu set to "HTM-0101" with a green "SAVE" button below it. Below that is a "Protein Threshold [µg]" input field set to "5" with a green "SAVE" button below it.

Quantitative protein test

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Software Bionova Cloud – HTM 01-01 (IQAS)

What do you need for implementing the IQAS?

- Bionova® Cloud account
- Hygiene Monitoring System Chemdye® PRO1MICRO
- Bionova® Autoreader: IC1020FR, IC1020FRLCD or MINIPRO

Steps:

- 1- Baseline development
- 2- Control Analysis



Quantitative protein test

PRO1MICRO



Software Bionova Cloud – HTM 01-01 (IQAS)

There are two main approaches to instrument sampling:

- If a **single measurement** is to be made at each time point. Baseline: 20 readings
- For measurements that fall naturally into **groups** established by the user (for example, five instruments per week). Baseline: 30 readings



Quantitative protein test

PRO1MICRO



Software Bionova Cloud – HTM 01-01 (IQAS)

If you proceed your IQAS implementation with SINGLE instrument sampling (measurement grouping = 1):

“Graph I”: (Individual Graph) log10 protein residues vs. measurement number.

“MR Graph”: (Moving Range Graph) Absolute differences between log10 protein residues vs. the number of differences.

If you proceed your IQAS implementation with GROUPS instrument sampling (measurement grouping > 1):

“XBAR Graph”: Group average vs. group number.

“R-Graph”: (Range graph) Group range vs. group range number



Quantitative protein test

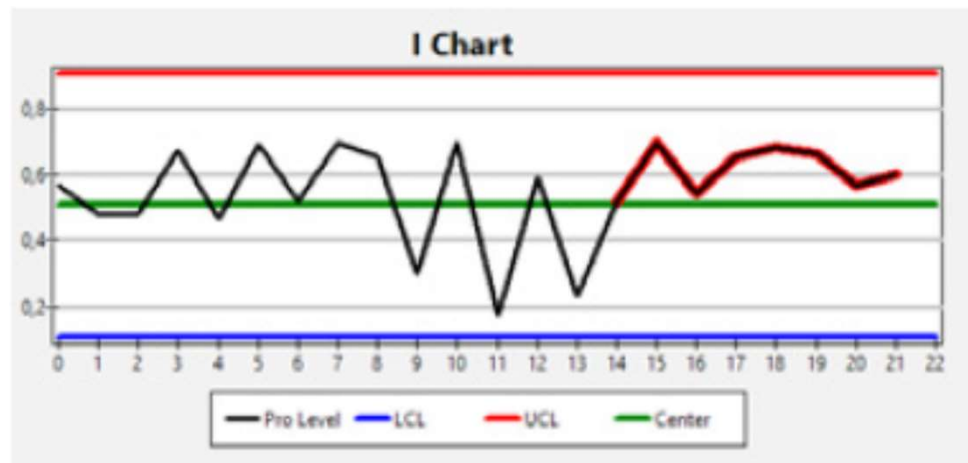
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Software Bionova Cloud – HTM 01-01 (IQAS)

Trends analysis

Example 1: Out of control type 1: **Instability**. In this case, 8 or more consecutive measurements are on the same side of the average.



Quantitative protein test

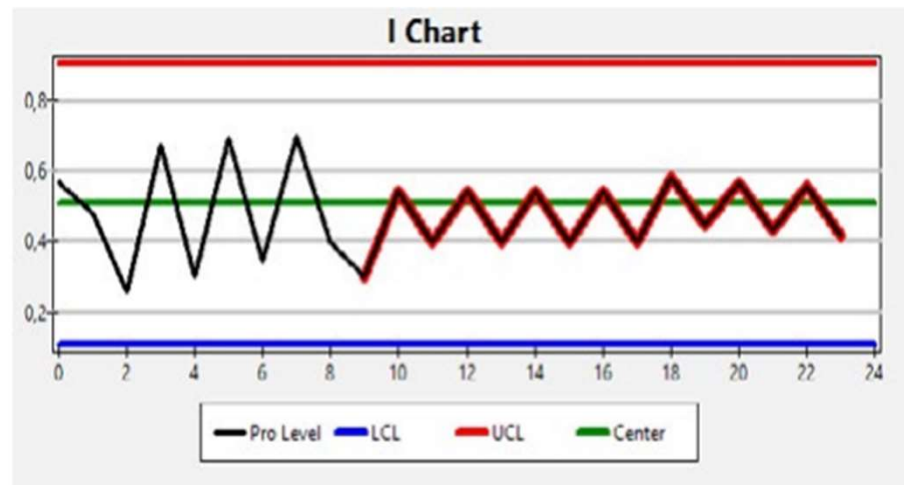
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Software Bionova Cloud – HTM 01-01 (IQAS)

Trends analysis

Example 2: Out of control type 2: **Alternating**. In this case, there are 14 measurements where there is an alternating pattern.



Quantitative protein test

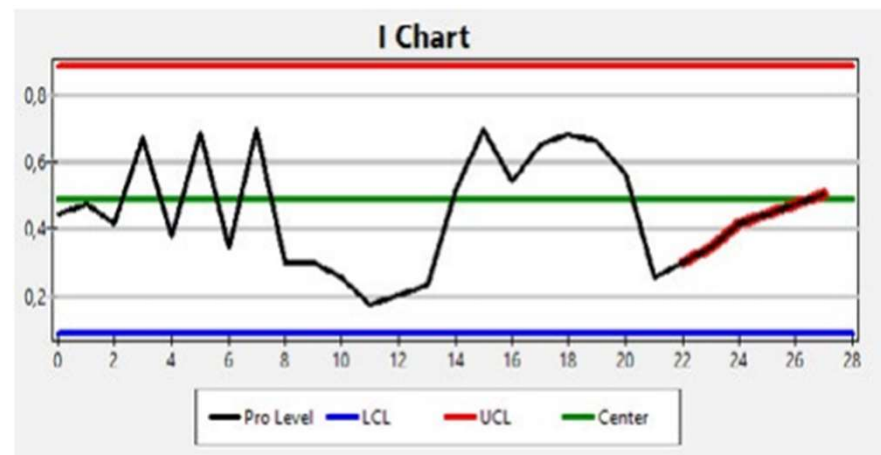
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Software Bionova Cloud – HTM 01-01 (IQAS)

Trends analysis

Example 3: Out of control type 3: **Monotonous**. In this case, 6 consecutive measurements show a monotonous trend (all rising or falling).



Quantitative protein test

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Conclusion: The best option to control your cleaning process

- 1- Identification and quantification of proteins, highly challenging molecules for the washing process
- 2- Swab system that allows testing areas of difficult access
- 3- Quantifiable system with high sensitivity and detection limits according to the highest standards
- 4- Quality Control and Traceability Software for digital storage of results and analysis



Sterilization



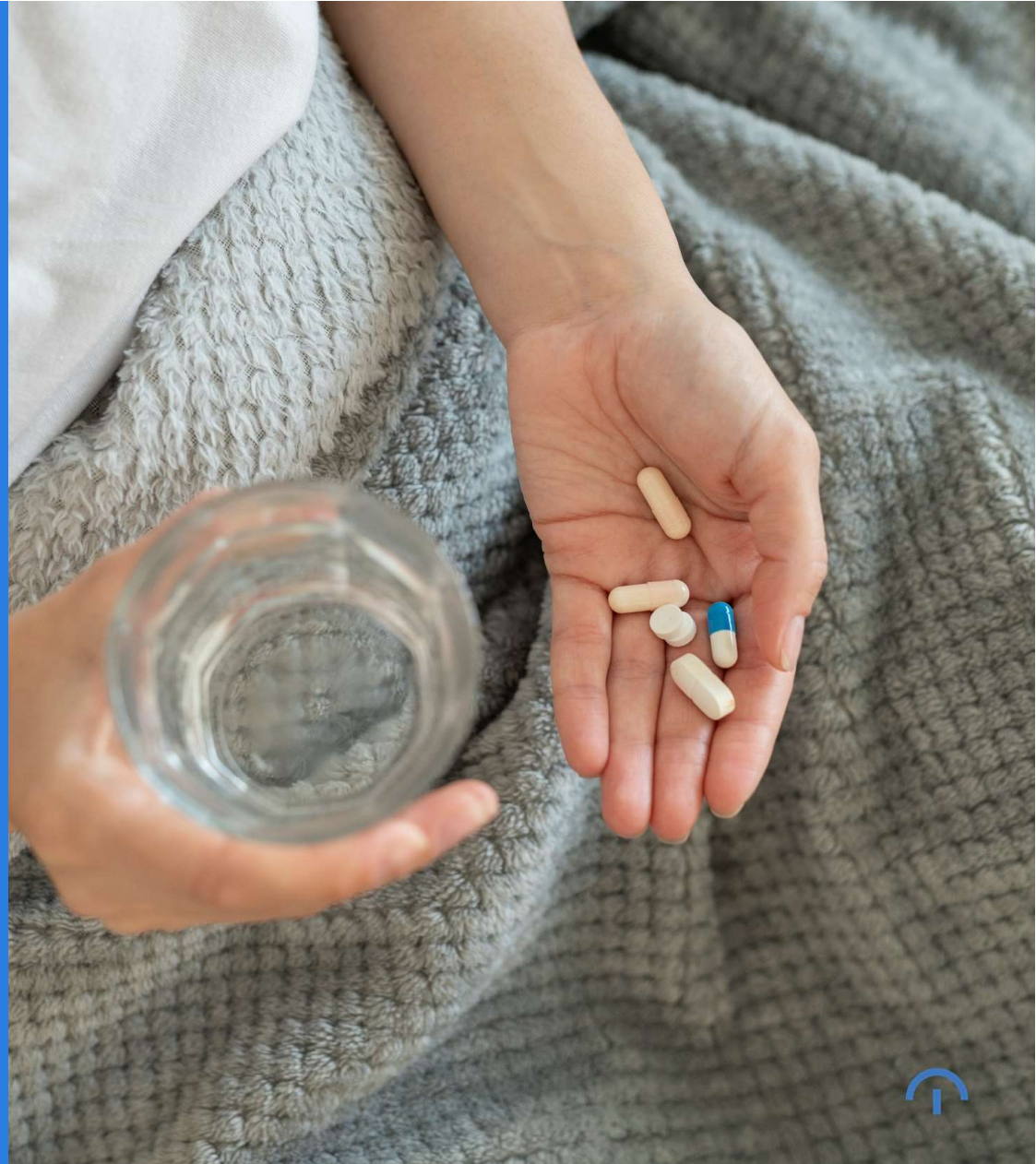
New challenges for infection control

Population growth:
overcrowded hospitals, increased need
for operating rooms → Increased rotation
speed of reusable materials



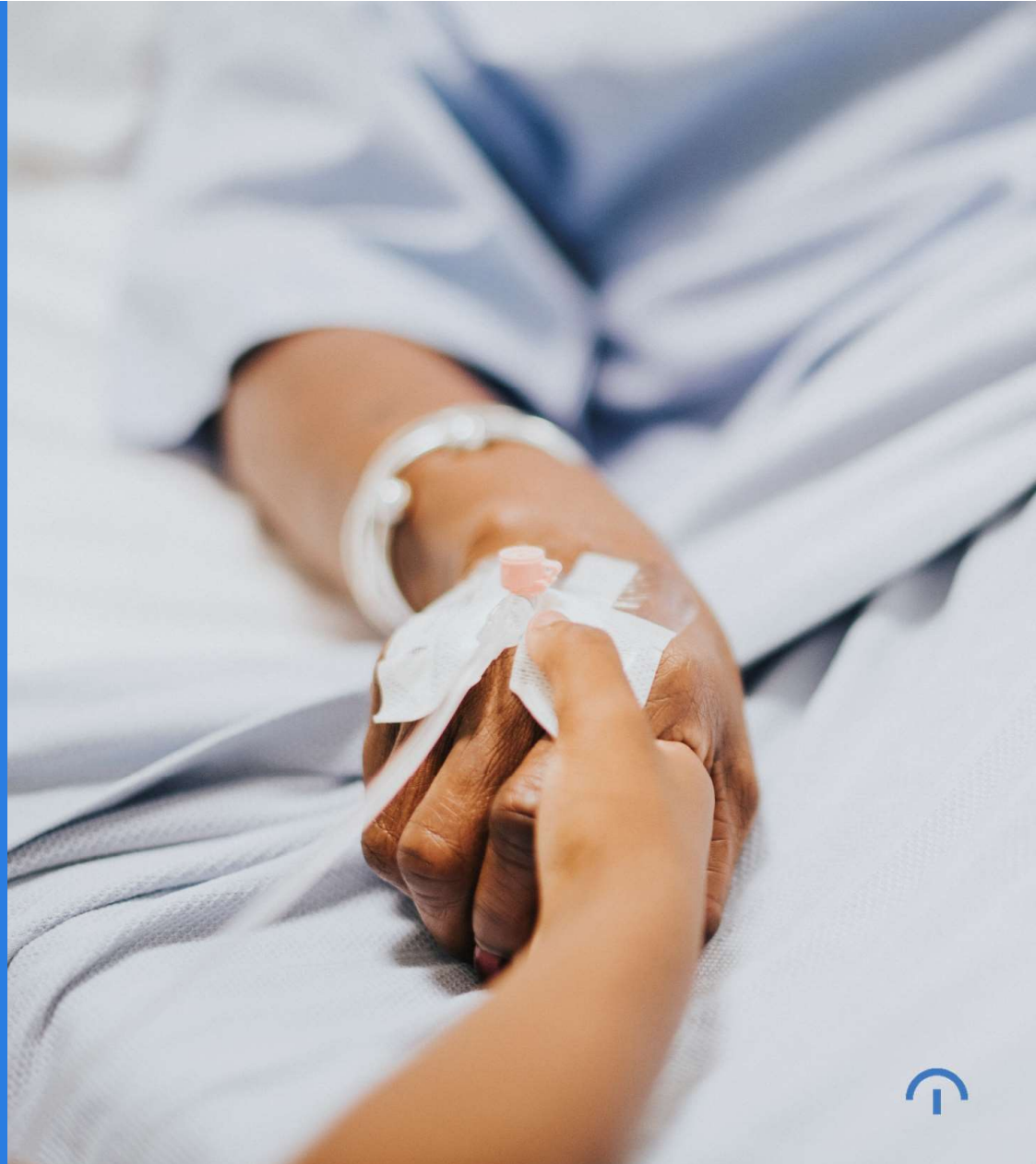
New challenges for infection control

Incorrect use of antibiotics: increases the resistance of pathogenic bacteria; increases the rate of hospital acquired infections.



New challenges for infection control

New threats:
diseases caused by Prions; new
pathogens.



New challenges for infection control

New medical devices:
New technologies in the reprocessing of instruments (washing, disinfection and sterilization) and inappropriate indicators for monitoring these processes.



New challenges → New concepts

Medical devices
manufacturers

Equipment,
facilities,
training and
hospital
protocols

Regulatory
authorities

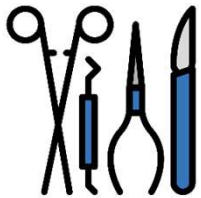
Standards

THEY HAD TO ADAPT QUICKLY TO INNOVATIONS AND THE
MODERN MARKET



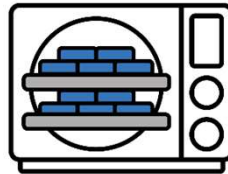
Routine Challenges

Steam sterilization is one of the most recommended and used sterilization methods and therefore, it is wrongly considered as an easy method.



Instruments have different temperature profiles

A good understanding of the instruments and products is needed.



Loading pattern might affect the sterility assurance

Each load configuration must be validated.



Accurate measurement of the parameters

Temperature probes are located in the drain.



Water quality

- _ Pure steam.
- _ Non-condensable gases (Temperature and pressure relationship might not be the appropriate in presence of NCG).



Complete and effective quality assurance program

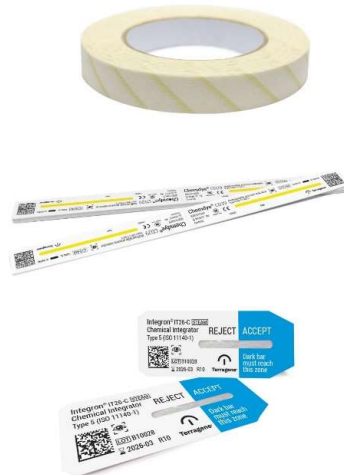
Physical controls

Thermometer | Manometer
Printer ticket | LCD Display



Chemical controls

Chemical indicators



Biological controls

Biological indicators



Load release | Biological Indicators

Bls basic concepts

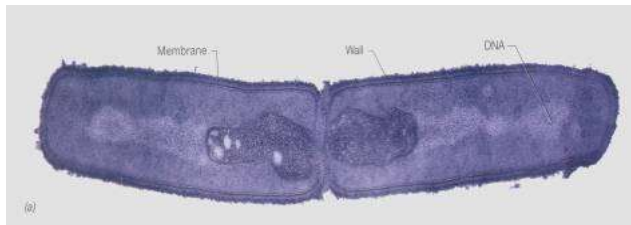
The most reliable sterilization control system
THE GOLDEN STANDARD

A system that uses highly resistant microorganisms (spores) in order to control the death of pathogenic and non pathogenic organisms (less resistant)



Load release | Biological Indicators

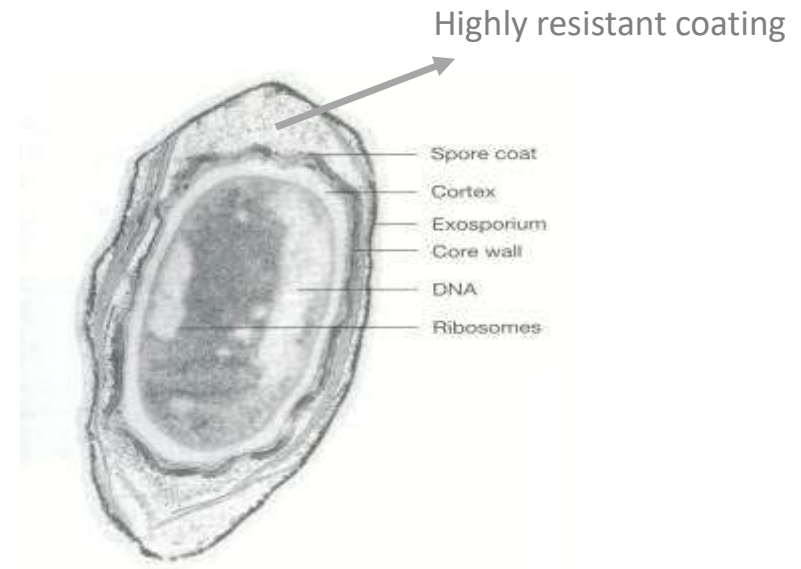
Bls basic concepts



Bacterial cell
(active)



Differentiation



Spore
(inactive)



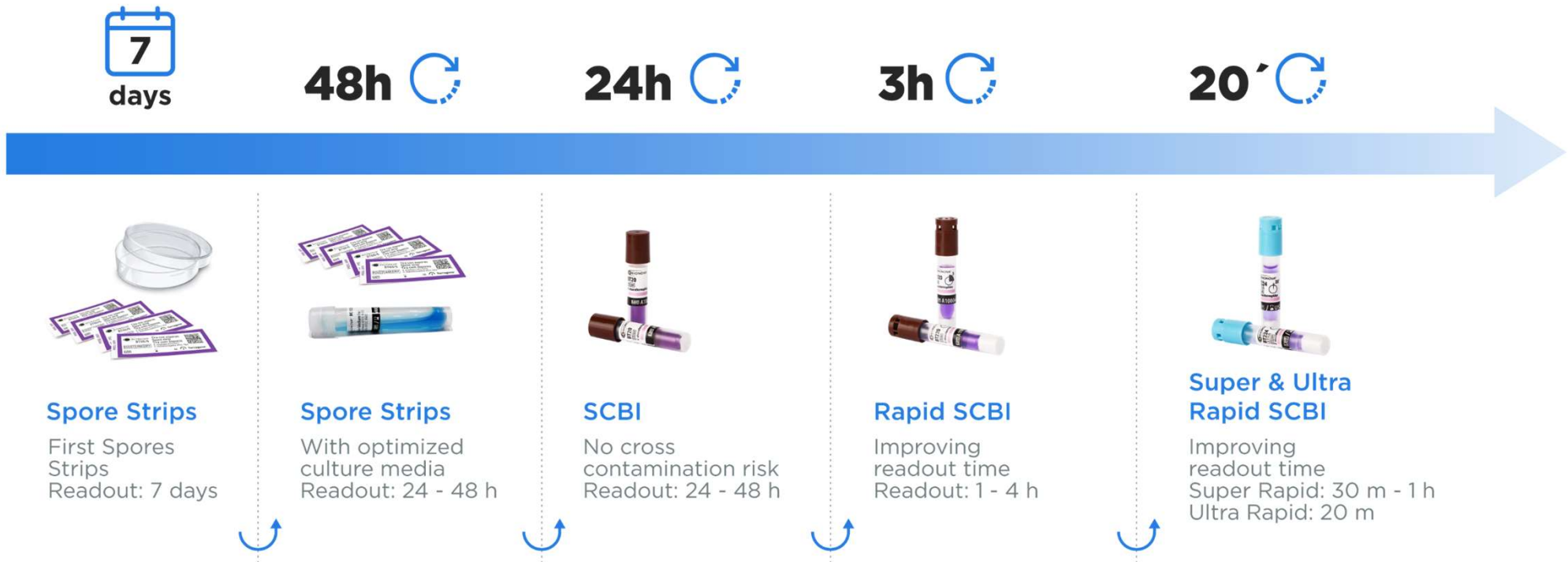
Biological Indicator

They are biological structures highly resistant to heat, desiccation, chemical agents and radiation.



Load release | Biological Indicators

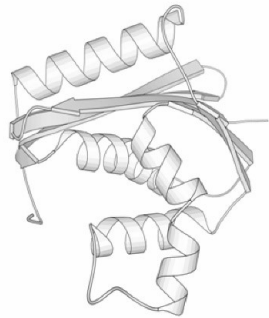
BIs evolution



Load release | Biological Indicators

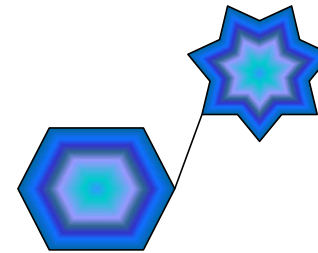
How does the fluorescence readout work?

ENZYMATIC REACTION: Prediction of
Spore viability



α -glucosidase
(*G. stearothermophilus*)

Spore-associated enzymes



Non-fluorescent substrate

Incorporated in the culture medium



Load release | Biological Indicators

How does the fluorescence readout work?

ENZYMATIC REACTION: Prediction of
Spore viability



Load release | Biological Indicators

Dedicated Auto-Readers



Bionova® MiniBio



Bionova® IC1020FR

Bionova® IC1020FR LCD



Ultra Rapid

20'



STEAM
BT224

Super Rapids

30'



VH202
BT96

30'



STEAM
BT223

1h



STEAM
BT222

Rapids

2h



VH202
BT95

2h



FORM
BT102

4h



EO
BT110

3h



STEAM
BT220

1h



STEAM
BT221



Load release

Biological Indicators | Bls evolution





First Instant Biological
THE UNIQUE INSTANT
Monitoring System
AUTO-READER IN THE MARKET

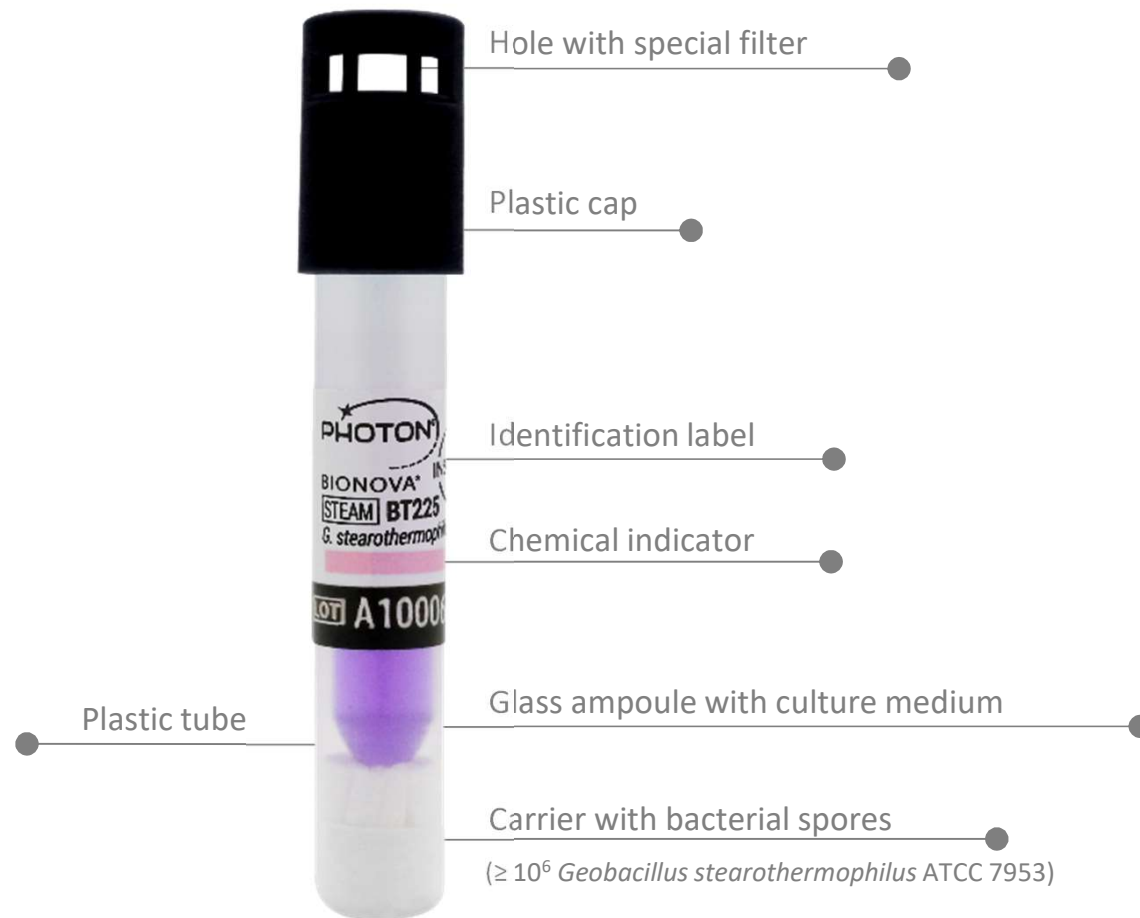


Instant SCBI



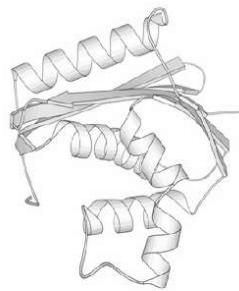
132-135°C

Gravity and Pre vacuum



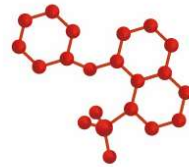
Instant SCBI

Positive
fluorescence
readout:
Unexposed or
living spores

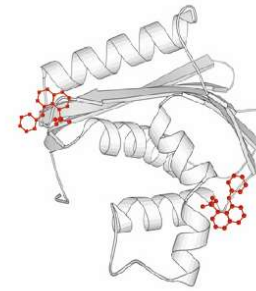


Native
Spore protein

+



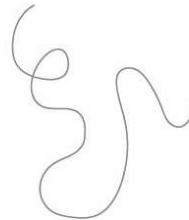
ANS incorporated
in the culture medium



HIGH FLUORESCENCE
EMISSION

Interaction protein-
sensor

Negative
fluorescence
readout: Sterilized

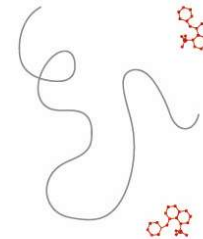


Unfolded
Spore protein

+



ANS incorporated
in the culture medium



LOW FLUORESCENCE
EMISSION

No
interaction
allowed, no
fluorescence signal





Instant, Microbiological and
Safe, your load release has
never been more realible



WASHING
MONITORING

Chemdye® Splat
CDWA4 / CDWA3 /
CDWAH Holder



HYGIENE
MONITORING

Chemdye®
PRO1 MICRO



Bionova® MiniPro



STERILIZATION
MONITORING

Bionova® Biological Indicators and
Auto-reader Incubators



Chemdye® / Integron®
Chemical Indicators (Type 4, 5 or 6)

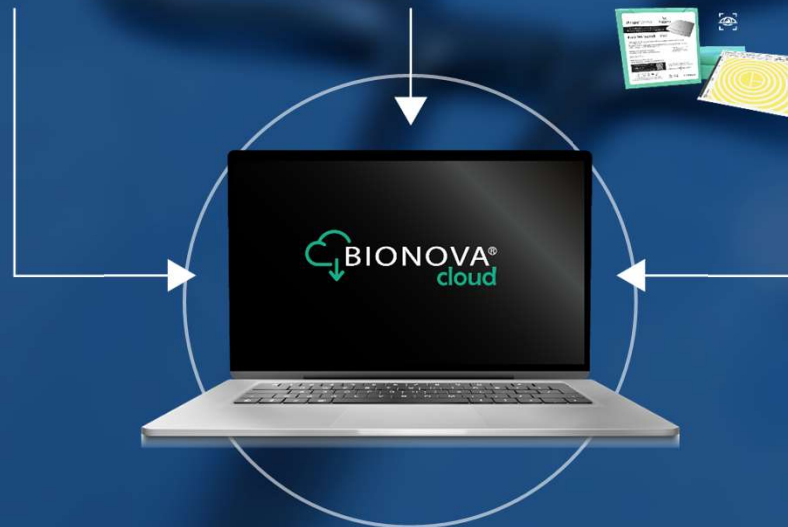


Trazanto Scanner



Products manufactured by Terragene

Chemdye® Chemical Indicators
(Type 2)



Bionova Cloud Ecosystem



*Bionova Cloud
makes the workflow
reliable and secure*



Video





Thank you

