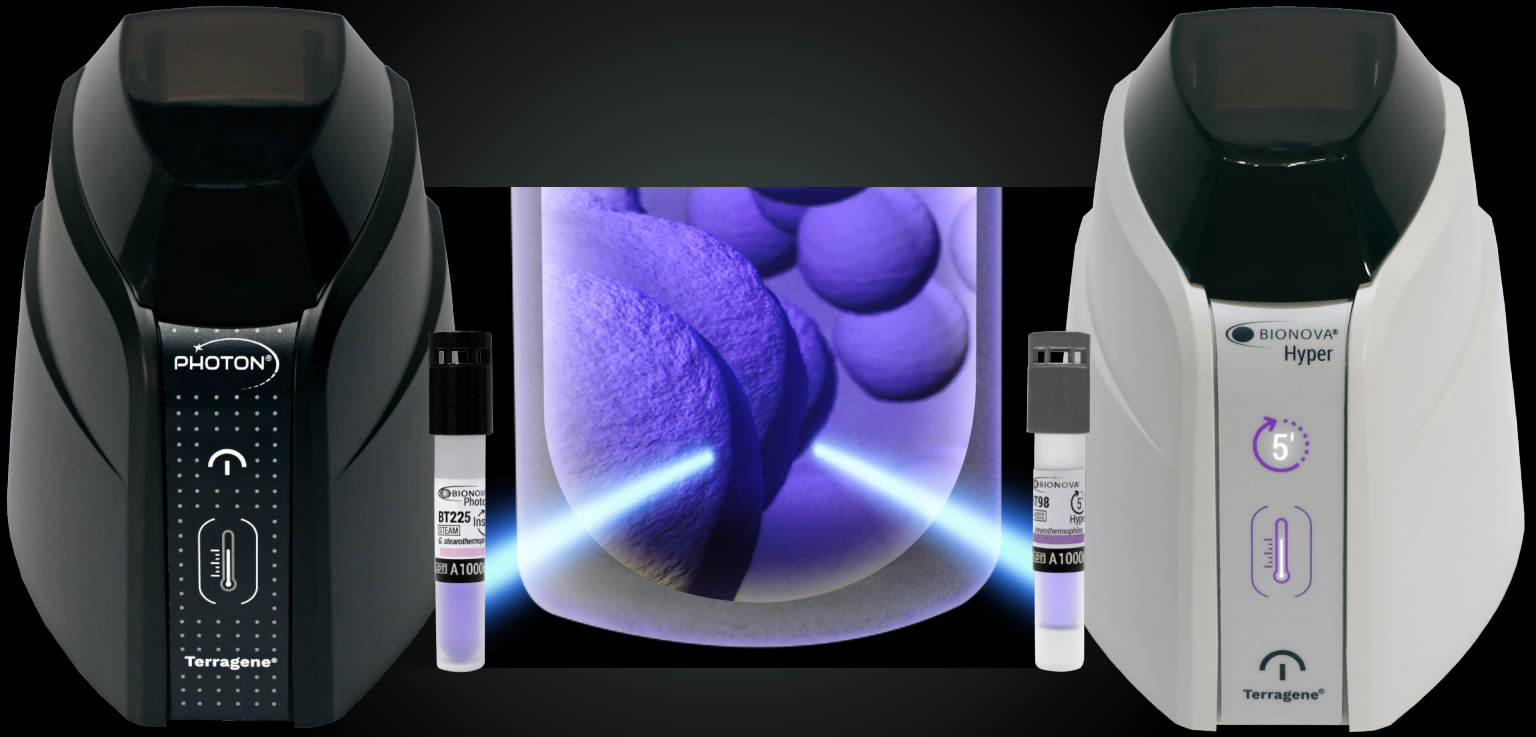
Bionova®
Photon & Hyper

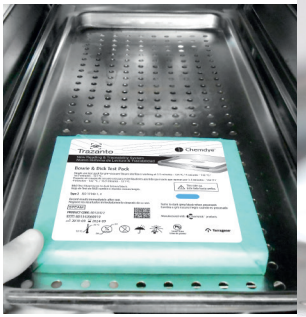
Revolutionise the market for Biological Indicators



Rev. 0

Terragene®

Some background information



In the field of healthcare, sterilization processes are critical within the workflow of healthcare providers. This is not only because of the amount of surgical material that needs to be reprocessed every day, but mainly because of the need to have safe equipment to be used with patients. Let us think that not many years ago one of the greatest risks associated with surgery was not related to complications of surgery itself, but to infections acquired during surgical practices by using elements that had not been properly sterilized. The development of technologies to control these processes was a key factor for changing this complex reality. Among the most used and safest sterilization processes, both for the patient and for the SPD/CSSD Staff member we can highlight high pressure steam sterilization (or autoclave) and H2O2

steam sterilization. The latter is the main alternative when the material to be sterilized is thermo sensitive. The choice of each method depends on various factors such as: nature of the load to be sterilized, time available, load volume and overall costs.

There are different ways to control these processes. One of them is chemical monitoring using chemical indicators. These are composed of specially calibrated inks to change color when the critical parameters of the corresponding sterilization process are reached. The universe of these indicators is varied and heterogeneous. One of their main advantages is how quickly they provide results. Some of these are used prior to the process itself to release the sterilizer for later use (e.g., Bowie-Dick Test). Some chemical indicators are placed outside the sterilization packets to identify non-sterile packages from which they were subjected to the process (Type 1 chemical indicators) and others are included in the sterilization packages that will subsequently be opened in the operating room. They will be evaluated by the corresponding staff as a second point of control beyond the one carried out forward in the sterilization department (Type 4 and 5 chemical indicators).

Another important control methodology is biological monitoring of the whole process using biological indicators (BIs). These indicators can be considered the "true sterility indicators" since their composition includes living organisms that will have to be inactivated by the process. These microorganisms are bacterial spores and we must remember that there is no microorganism or pathogen in nature more difficult to destroy or inactivate than bacterial spores. This is why in many countries the usage of these indicators is required for releasing the previously sterilized load. Let's go deeper into the use (or lack of use) of biological indicators in different territories. In many countries BIs should be used to release the load. What do we mean by "load release"?: When the sterilization process is completed the "load" (all the material that was inside the sterilizer) is removed from the sterilizer and kept in quarantine ("yellow" or alert zone) until having the result of the BI that was included in each sterilization cycle or in the first cycle of the day. We will list below different realities that have been observed in different countries that are naturally established practices or are led by local regulations:

Frequency of use:

• BI for steam: It is usually at least one BI per day and per sterilizer. Many countries have already evolved to use at least one BI per cycle
• BI for H2O2: One in each sterilization cycle (one of the most widespread forms of usage frequency throughout the planet)

How to use:

In many countries, for both BIs, these are not used alone inside the chamber, but within a PCD package (process challenge device) or a pouch (which would fulfill the function of PCD itself).

Particular situations are:

• The USA follows the regulations set out in AAMI ST79 for steam. This regulation states that the BI must be used within a PCD package. The release of the load will be subject to the type of load: the "non-implantable" load can be released by the result of the CI also included in the PCD package while the release of the "implantable" load requires an "accepted" result granted by the BI included in the PCD. In fact many countries, beyond The USA, have coupled to the directions set in AAMI ST79.
• European territory: Several European countries perform for steam sterilization the so called "parametric release". This means that the load is released by the sum of the Bowie-Dick start-of-the-day test and the physical parameters reported by the sterilizer. Fortunately, several countries are changing this reality and adding biological monitoring into their steam processes.

Added to all or mentioned above there is a particular situation. "Unscheduled" sterilization processes that require "last-minute" sterilization for an immediate need for surgical material. This situation has boosted the development of fast, super-fast and ultra-fast BIs that use fluorescence technology and deliver results in times between 15 and 20 minutes.


PHOTON®
The Instant Steam Biological Monitoring System
STEAM
BIONOVA®
CONFIGURE NEW DEVICE
PHOTON
MODEL: Photon Auto-Reader
IP: 192.168.111.220
NAME: Juancito
Green
PHOTON®
Terragene®


BIONOVA® Hyper
The fastest VH2O2 Sterilization Process Monitoring System
VH2O2
Red
Green
Terragene

Changing paradigms thanks to the new immediate indicators Photon & Hyper

100%

BIOLOGICAL

SENSITIVITY

AUTOMATIC

DIGITAL

Photon
INSTANT

Hyper
5’

Photon is the first and only 100% biological instantaneous monitoring system to control steam sterilization processes between 132 and 135 °C. On the other hand Hyper is the fastest H2O2 sterilization process monitoring system in the world, with a readout time up to 5 minutes. Due to their very short readout time, Photon and Hyper are positioned as the great revolution in biological monitoring for the most relevant sterilization processes.

Both systems work with dedicated or specific auto-readers: Photon and Hyper auto-readers.

PHOTON®

Compact and easy to handle design.

Associated traceability software Bionova® Cloud.

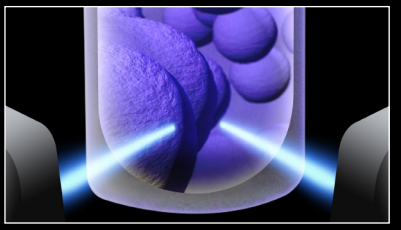
Virtual ticket generation with Bionova® App Wireless assistant.

Results indicated by colored LEDs and alarm sounds.

PC or mobile connectivity via USB, Bluetooth or Wi-Fi.

Two simultaneously reading positions.

Temperature control: using LED light, via App or Traceability Software and/or position for external thermometer.



Fluorescence reading: radial configuration of light source and detectors that optimize the excitation of the fluorochrome and its subsequent detection.

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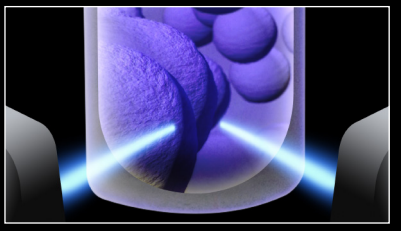

Fluorescence reading: radial configuration of light source and detectors that optimize the excitation of the fluorochrome and its subsequent detection.

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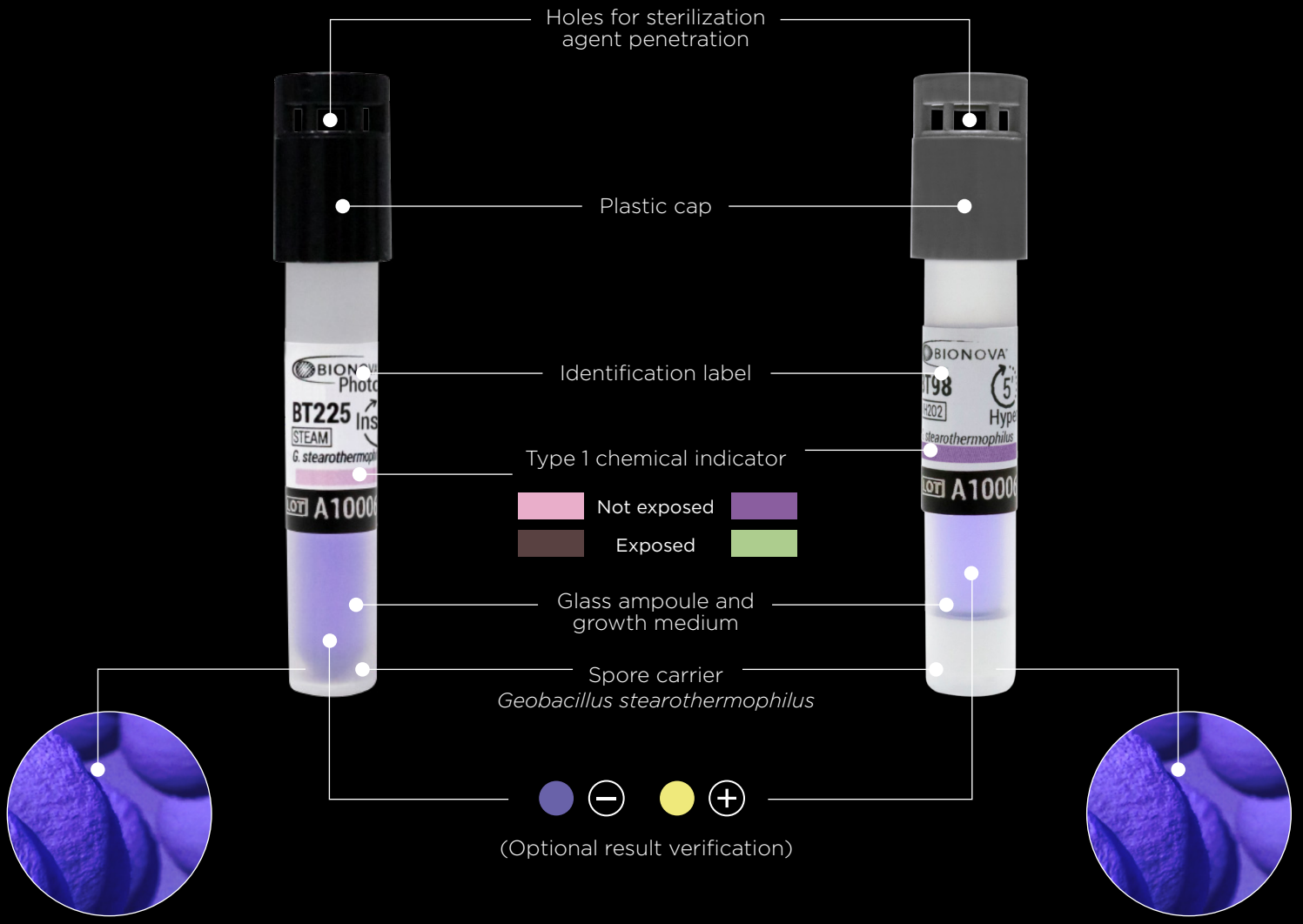
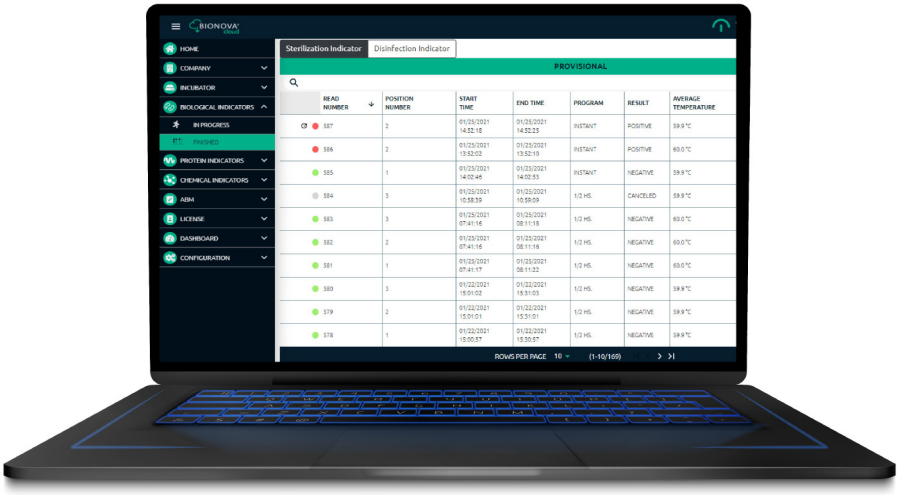
Photon INSTANT

Hyper 5’



Both auto-readers can be connected to any mobile device (e.g., smartphone) via Bluetooth or Wi-Fi connection. This allows the use of the Bionova® Wireless Assistant App. It is a very simple app that is basically designed to generate virtual tickets that can be printed or shared in a very simple way. In general, this application allows:

- Auto-reading status display: connection and temperature
- Online display of results obtained
- Online and real-time notifications
- Virtual ticket generator: easy and direct display, printing and sharing
- Track record



The last, but not least, component of the Photon and Hyper systems is the traceability software Cloud-Based Bionova® Cloud. This traceability software is developed for the monitoring of all indicators and systems developed within the "Infection prevention" division of Terragene®. Among the most noteworthy features we can mention:

- Traceability software designed for reading and tracking:
  - Biological Indicators: disinfection and sterilization
  - Chemical indicators
  - Washing indicators
  - Hygiene monitoring system by protein absolute quantification
  - Washing efficacy control in AERs (endoscope reprocessing machines)
- Located in the cloud. Easy access through any Web browser
- Auto Reader Settings: calibration, threshold, etc
- Statistical and general analysis: general results, HTM01-01, efficiency, etc
- Results history and report/report generator.
- Allows direct communication with the most common management and traceability softwares available in healthcare effectors.

What are the main functional benefits of these two new technologies?

1 Speed: because we have managed to bring the response time of minutes to immediacy (7 seconds for Photon and 5 minutes for Hyper).

This has a direct impact on both patients and health care providers' staff. Almost instantaneously you can count on the highest level of microbiological safety in all situations where time is pressing and demands are increasing.

2 Precision: since these are biological indicators, now more accessible, the levels of certainty are total and that makes it much more powerful than chemical indicators.

In the last stage of the sterilization efficiency control, the surgical staff controls the packages (containing the surgical material to be used with the patients) by means of the result given by the chemical indicator contained in said package. The reason for this choice is mainly due to questions of time and simplicity. However, this method lacks the rigour and security that only biological monitoring can provide, something that is now achievable with the implementation of Photon and Hyper.

3 Convenience, because when used with a reasonably sized incubator, allows to operate fast, in small spaces and without problems.

Intimately linked to the previous point. Basically the result is obtained simply by placing the indicator in the auto-reader. To this is added the improvement in the traceability of the information process that is generated, stored and shared automatically with the entire Bionova® Cloud platform.

4 Related to speed, it accelerates the workflow of sterilization departments: It helps to improve their overall performance.

The implementation of these technologies changes the paradigm of the processes within the sterilization department. The release of the load can be done without the need to leave the load that was sterilized in a quarantine zone since at the time when the sterilizer is opened the user can count on the corresponding release result given by a biological monitoring with Photon or Hyper. This implies a positive impact not only on the processes carried out at the department but, also on the operators and managers involved in these tasks. No more "early release" protocols or sheets in sterile departments.

> *In the end, "time is money". Anything that can help reduce time and add health certainties results in efficiencies that affect the "bottom line".*


SPEED
PRECISION
CONVENIENCE
EFFICIENCY
PHOTON
PHOTON
Terragene
BIONOVA
Hyper

Photon & Hyper revolutionise the market for biological indicators: providing accurate and instantaneous information

• These are unprecedented innovations that create a new global threshold for sterilization processes: they combine biology, electronics and software; resulting in the fastest and most accurate performance assurance of sterilization processes within health effectors.

• Photon and Hyper provide practicality, speed, safety and result certainty. Accelerating the workflow in the sterilization department by helping to improve its performance.

• With these products, Terragene® revolutionizes the use of biological indicators: combining the safety of the biological indicator with the immediacy of chemical indicators.

• With these technologies, Terragene® surpasses the universe of “Sterilization Control” to move into the universe of “Information Generation and Management”: Information and traceability systems that are integrated from cell phones, PCs and other electronic devices into the hospital control systems. They provide clear and accurate information to ensure the highest quality in the monitoring of the most used sterilization processes.

Photon and Hyper systems mean:

POPULARIZATION
Because anyone can monitor a sterilization process with the maximum possible security and extreme simplicity.

EVOLUTION
Because they combine the immediacy of the result of a chemical indicator with the safety that only a biological indicator can provide.

ACCELERATION
Because you get safety results for patients with the speed required by current demands.

MAXIMIZATION
Because it optimizes reprocessing processes in healthcare settings.

SAFETY
Because they manage to guarantee the maximum safety of the surgical equipment used with patients.

INTEGRATION
Because it is a complete system composed of indicators, associated autoreaders and traceability software that meet current needs: generation of accurate and secure information.

DIGITALIZATION
Together with Bionova® Cloud and Bionova® Wireles Assistance all the results can be recorded and managed in a digital way.

Let's work together to create a better future