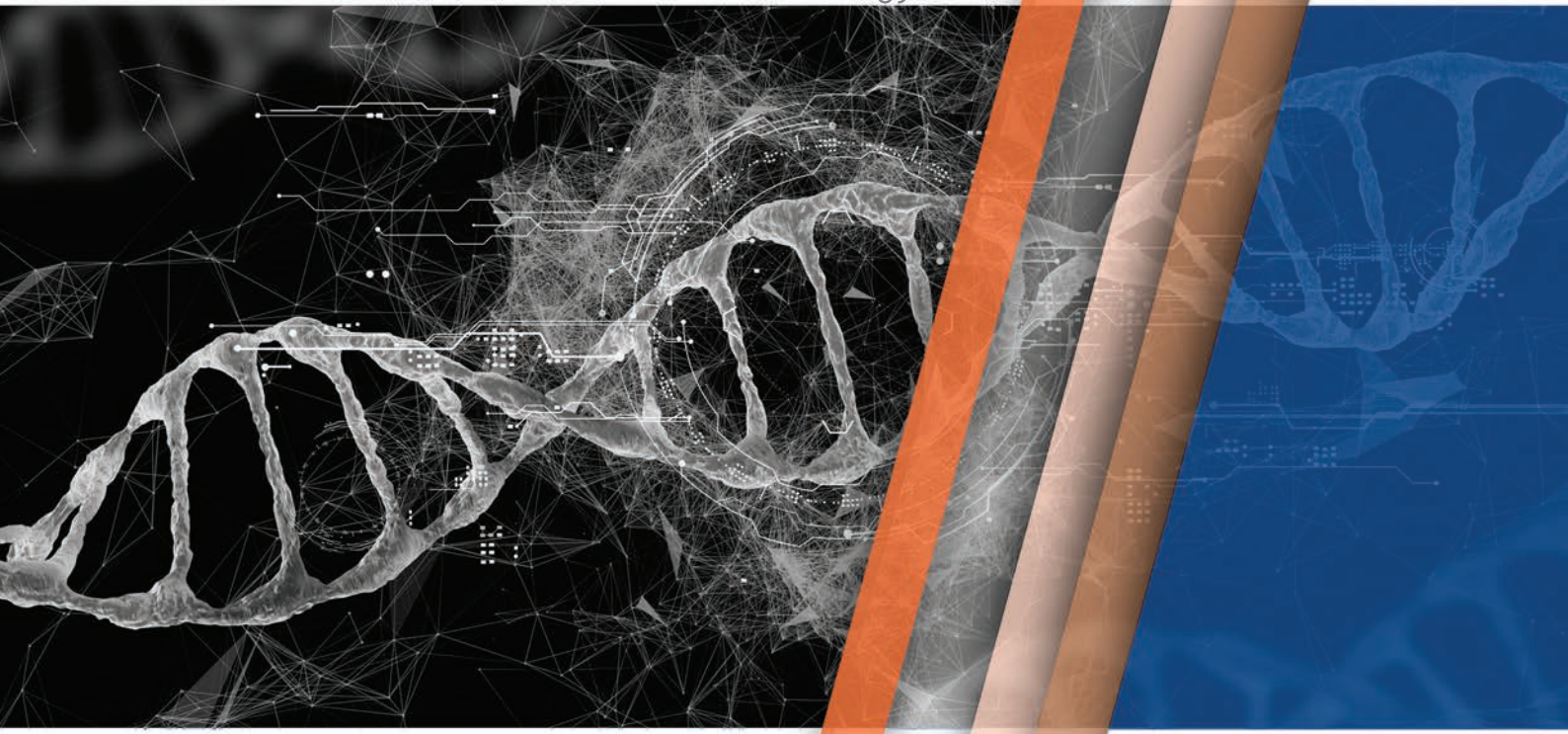
E-BEAM, Fast and reliable, chemical-free decontamination technology



How can we meet the ever-increasing health and safety requirements both with regard to consumers as well as operators, while at the same time reducing the environmental impact and space requirements for packaging production lines?

It is because industrialists in the agricultural food sector are increasingly faced with this difficulty, that manufacturers such as Serac have developed decontamination solutions based on E-Beam technology.
The capability of the electron beams to efficiently destroy micro-organisms has been well known for decades and its reliability when used in a high-speed industrial production context has been confirmed in numerous applications, in particular for surface cross-linking of plastic materials.
Their use for the decontamination of packaging lines is however far more recent. It is associated with the development of a new generation of emitters, which are more compact and longer lasting, as well as the ground work undertaken by equipment manufacturers in the qualification of processes specific to this field of activity.

Without water or chemical products, E-Beam decontamination has a very low environmental impact. Once the process has been validated, this technology is far easier to control than the decontamination processes using hydrogen peroxide (H2O2) or peracetic acid. It is also a lot faster which enables a reduction in the space required for the decontamination module.
It thus offers all the advantages necessary to meet the needs and expectations of industrialists.

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01

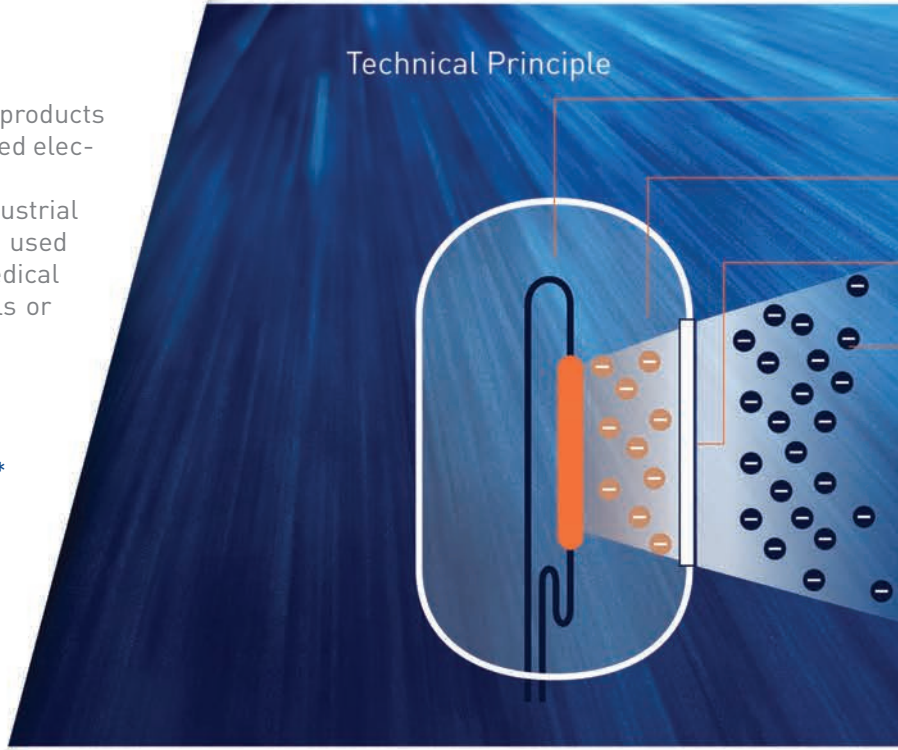
A technology based on the emission of a beam of electrons

E-Beam stands for "electron beam"

E-beam treatment consists of exposing the products to be decontaminated to a beam of accelerated electrons.
This technology is nothing new to the industrial sector; it has been perfectly mastered and used for over fifty years for the sterilisation of medical equipment, cross-linking of plastic materials or drying of resins or inks

Creation of the beam

The beams are generated in an ultra-vacuum* chamber by heating a cathode* under the effect of an electrical current. Subjected to a very high electrical voltage, they are then accelerated and directed towards a "window" through which they leave the emitter.



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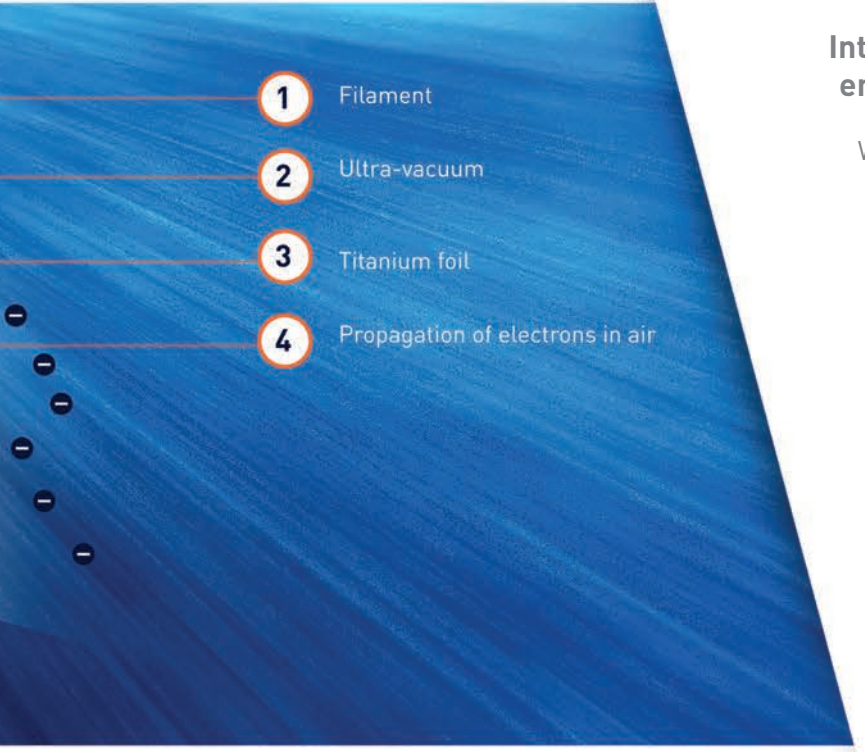

Interaction with the surrounding environment

When they leave the emitter, the electrons pass through the air before entering into contact with the material to be treated.

The impact of the electron beam on the molecules of the material they hit modifies the latter by means of an ionisation* reaction.

The ionisation process draws away electrons from the material which, due to this, is no longer electrically neutral and it reacts in turn to create new stable molecules.

It is the consequences of these ionisation reactions which enable us to destroy the micro-organisms, dry the monomers or cross-link the plastic materials depending on the use made of the E-Beam technology.

* See glossary on page 29

01

A technology based on the emission of a beam of electrons

High and low energy electron beams

An electron beam is characterised by its energy, expressed in electron-volts*, and its power, expressed in watts.
The energy of the beam characterises its capacity to penetrate the materials it encounters, whereas the power defines its treatment capacity.

It is common these days to separate the electron beams in two main categories: High-energy beams (several million electron-volts*) and low energy beams, which do not exceed a few hundred kilo electron-volts* (keV).

For packaging decontamination applications, some solutions require high energy beams, whereas other systems function perfectly well with low energy beams depending on the shape of the product and the way it is placed in the radiation field.

The choice of energy and power levels of a beam are defined according to the intended application and process to ensure the electrons arrive at the correct point and in sufficient quantity to destroy the micro-organisms present. This quantity is expressed in the absorbed dose, the unit value of which is the Grey (Gy), representing the unit of energy in relation to the mass of the material irradiated.

* See glossary on page 29

The future of ionising treatment processes

E-Beam and gamma rays are today the two main ionisation* treatment methods used in industry.
But the trend is clearly leaning towards the development of E-Beam technology which offers advantages both from an environmental as well as an industrial viewpoint.

A solution without a radioactive source

The electron beams are produced from a neutral material (generally tungsten) whereas gamma rays are produced from a radioactive isotope* of cobalt (cobalt 60).
The use of E-Beam technology therefore avoids the presence of a radioactive source inside the factory, presence which is particularly restrictive from a health and safety viewpoint, has a serious environmental impact (waste) and is increasingly frowned upon in terms of company image.

Shorter treatment times

The dose rate* based on is a key notion in ionising treatment methods It corresponds to the time required by the product to absorb a defined dose of radiation.
Furthermore, electron beams have a far greater dose rate* than gamma rays (in the order of kiloGray per second for the first and up to 10,000 times less for the second).

This means that with E-Beam technology it is possible to considerably reduce the time the product is exposed to the radiation. A positive point with regard to productivity most certainly, but also for quality as over-exposure may in certain applications cause oxidation with a subsequent drop in the organoleptic properties of foodstuffs as well as the physical properties of some materials.

* See glossary on page 29

The future of ionising treatment processes

Unavoidable for individual treatment in a production line

Gamma rays have a far greater material penetration capacity as opposed to electron beams; They are therefore often used for the decontamination of products in their packaging by complete pallet load.

On the other hand, however, their low dose rate * excludes their use for high speed treatment; This explains why in most industrial applications for the cross-linking of plastic materials E-Beam technology is used and why this technology is being used today for individual decontamination in a production line.

* See glossary on page 29

A double action on micro-organisms

Breaking of the DNA chains

The ionisation* reactions caused by the electron beams have an influence on the DNA of the micro-organisms and cause them to break (single or double strand) at the chain link points. These breaks are irreparable and have an immediate and fatal effect on single-cell organisms (bacteria, yeast, mould).

Dissociation of water

Micro-organisms contain a large quantity of water. The collision between the electron and a water molecule results in the dissociation* of the latter in extremely active free radicals (OH, H, O2). These free radicals, in the same way as ozone which is created by their re-combination, participate in the oxidation reactions which also damage the DNA of the micro-organisms. They prevent, in particular, the pairing of nucleo-tides* affected with those of the other strand.

* See glossary on page 29

01

Proven treatment already used in numerous sectors

Sterilisation of medical equipment

E-beam treatment has been used for almost 50 years in the medical sector for the sterilisation of textiles, plastic elements (syringes, tubes, pouches) or implants.
Often contracted out to specialised service companies equipped with large-scale installations, E-beam decontamination is in this particular case usually carried out with high energy beams. This enables the electrons to pass through packaging in order to sterilise the product contained therein. However, mini-sterilisers using a low energy beam are also now becoming available on the market.
These sterilisers are used for individual sterilisation of products in a packaging line.
E-beam treatment is recognised by the AAMI (Association for the Advancement of Medical Instrumentation)

Sterilisation of pharmaceutical products and reactive substances

Sterilisation of active substances is a delicate matter; The process must be perfectly mastered in order to deliver a sufficient dose of electrons without modifying the properties of the product. Electron beam sterilisation is also used for this type of application (sterilisation of freeze-dried vaccines, syringes filled with vaccine or blood sampling tubes containing a reactive agent).

It is incorporated into the good manufacturing practice guide in the pharmaceutical industry (GMP) and it is particularly interesting for heat-sensitive substances; Indeed, when per-

fectly controlled, the exposure to this radiation does not significantly increase the temperature inside the product.

Reduction of microbial content in foodstuffs

On the international stage, E-beam technology also replaces gamma rays in more and more foodstuff or phytosanitary applications (decontamination of meat, or fruits and vegetable, disinsectisation of cereals...).
The primary arguments in favour of this change of technology are the elimination of a radioactive source and reduction of the footprint of decontamination units. However, the use of E-Beam technology often requires redesigning of the processing line in order to incorporate the decontamination unit upstream of the packaging line. E-beam treatment is recognised and approved by the FDA (Food and Drugs Administration).

Decontamination of water and effluents

E-Beam technology has also been used for around twenty years in pilot projects for the treatment of industrial water and effluents as well as slurry from waste water treatment plants (reduction of chemical contaminants in the drinking water in Austria, treatment of effluents from dying processes in Brazil or, more recently in China, treatment of slurry and waste water in South Africa and USA...).
Its effect destroys the organic pollutants, or increases their biodegradability in order to render their elimination in the receiving medium easier.
It is the environmental aspect of the E-Beam treatment which gave rise to this project; Indeed, contrary to conventional de-pollution systems, E-Beam treatment requires no chemical product and produces no toxic by-products.

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A new field of application for a proven technology

Conscious of the advantages of E-Beam technology, its environmental impact, user safety and running costs, manufacturers of aseptic filling and packaging lines have closely examined the use of this technology in their trade.
The initial operational solutions appeared on the market very recently and were in particular rendered possible thanks to the miniaturisation of emitters. They combine the well-known efficiency of E-Beam technology on micro-organisms with its capacity to be incorporated into high-speed industrial processes; It is this aspect which renders them particularly innovative

High-speed, individual decontamination on production line

The effectiveness of ionisation* treatment in decontamination applications has long been proven; It has been used for this purpose for over fifty years. Moreover, the electron beams are often used on high-speed, non-stop production lines (cars, cables, ducting) and have therefore proven beyond doubt their industrial reliability.
Application of this technology in the decontamination of packaging lines however is a very new arrival on the scene. The appearance of these innovative solutions was rendered possible by recent developments in the design of ultra-vacuum* chambers and the miniaturisation of low-energy beam emitters.

Now much more compact, less expensive and longer lasting, these new generation emitters may easily be incorporated into a production line.

* See glossary on page 29

In-depth groundwork on the qualification of processes

The main challenge in developing solutions for decontamination of packaging lines is adapting the E-Beam treatment process to this use:
- ensuring the wide variety of applications encountered in this sector (decontamination of films, pre-formed and formed packaging elements),
- comply with the hygiene standards required.

This prerequisite demands extensive groundwork in areas such as size, power, positioning and the number of emitters, all of which are validated with dosimetric studies which guarantee that each packaging element has been sufficiently exposed to the electron beam in a uniform manner.

Targeted markets and technical approaches

Primarily for liquids in cartons and bottles

E-Beam decontamination is primarily used for the aseptic packaging of liquids. Although trials have been carried out on flexible packaging elements (pouches, bag-in-box), the units presently in operation are only used for cartons and bottles.
Where bottles are concerned, the E-Beam decontamination solutions were initially developed for the treatment of PET. Indeed, with this new technology it is possible to avoid certain phenomena relative to the migration of hydrogen peroxide or peracetic acid in the plastic. This having been said, E-Beam treatment is not limited exclusively to this material and the treatment of PEHD, PP, aluminium and even glass is now possible.
Electron beam treatment is used for aseptic packaging of a wide variety of acidic or basic products: fruit juices, dairy products, vegetable milks, waters, teas...

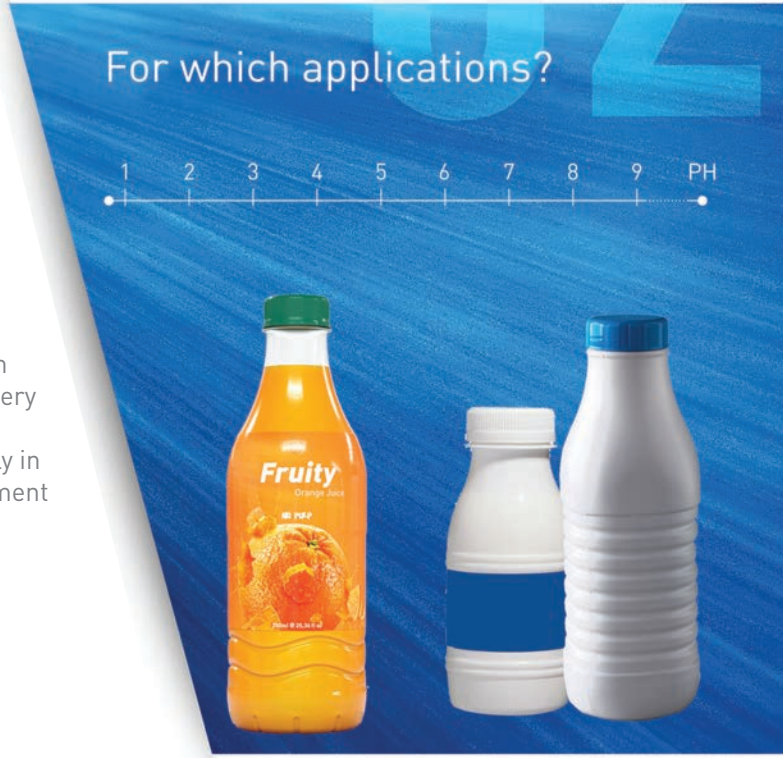
Decontamination of films, pre-formed packaging or bottles

Three solutions are currently proposed on the market, each with its own treatment process. The simplest case is flat treatment of the sheet before forming the carton packaging. This is followed by the treatment of pre-formed elements with a small volume and relatively simple shape. E-Beam treatment of formed bottles is, bearing in mind the complexity and diversity of shapes available on the market, more delicate. It is therefore this solution which requires the most research to guarantee the minimum exposure to the electron beam in every part of the packaging.

E-Beam treatment may also be used for the decontamination of caps when necessary.

2 methods for interior decontamination

Presently two methods of E-Beam treatment are proposed for bottles and pre-formed packaging:
Sterilisation from the exterior only, or exterior/interior sterilisation.
The first method requires an electron beam with an energy level sufficiently high to pass through the packaging; The second uses ultra-miniaturised emitters, which may be introduced via the neck of the packaging, with a very low energy beam.
It is this second method, more reliable and easier to apply in production, that Serac has retained for its E-Beam treatment ßluStream.



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Reduction of environmental impact at the workstation
Acceleration and safety of the decontamination process

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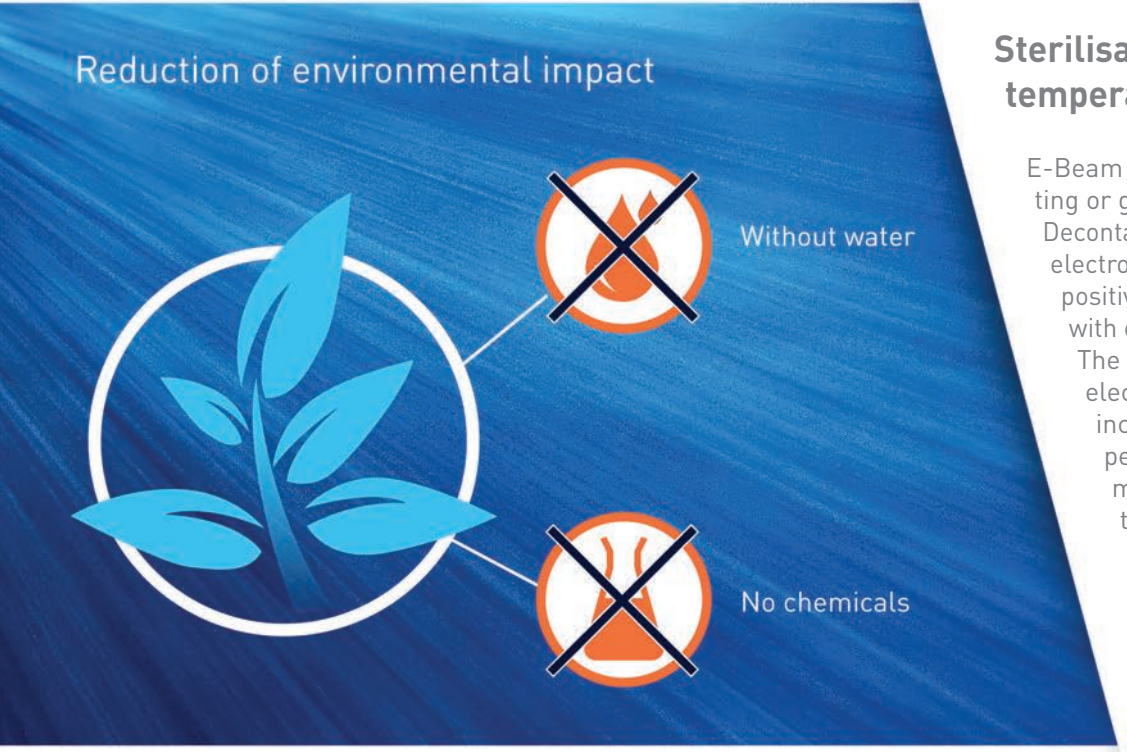
Reduction of environmental impact at the workstation

"zero chemicals" sterilisation

Electron beam sterilisation is a physical treatment method which requires no chemical products. The process therefore generates no toxic waste requiring treatment before evacuation into the natural environment, and for which the company may potentially face payment of duty or taxes. Savings are therefore both economical as well as environmental and concern the installations, purchasing of consumables and management of waste.
The absence of chemical products is also interesting for manufacturers wishing to present their customers with a production process which is both responsible and natural, or where the target consumers are particularly sensitive (babies, immunodeficient persons.

Dry sterilisation

The absence of chemical products also means no need to rinse the packaging. Foodstuff industries which use a great deal of water in their processes, are particularly sensitive to the environmental impact of this consumption. Water is therefore often one of the first items concerned by improvement plans. E-Beam treatment offers the factory the possibility to reduce water consumption at the workstation to practically zero and to present a considerable improvement in their environmental balance. Water is also potentially a major source of contamination; another reason to reduce its use in foodstuff processes.



Sterilisation at ambient temperature

E-Beam technology requires no heating or generation of steam. Decontamination with low-energy electron beams therefore presents a positive energetic balance compared with conventional technologies. The energy transmitted by the electrons does no significantly increase the packaging temperature. Thanks to the elimination of heating, E-Beam treatment may be used on thinner packaging resulting in a reduction of raw materials consumption.

Acceleration and safety of the decontamination process

Shorter treatment times

The electrons interact very quickly with the material onto which they are beamed. This is what enables them to offer a high useful dose rate*. With this property, a microbiological reduction compliant with aseptic requirements (5 log for Bacilus pomelos) is possible in only a few seconds.Thanks to this duration in treatment time, electron beam decontamination enables increasing of the aseptic production line work-rates or reduction of the production line footprint for a given work-rate.

Limited cleaning

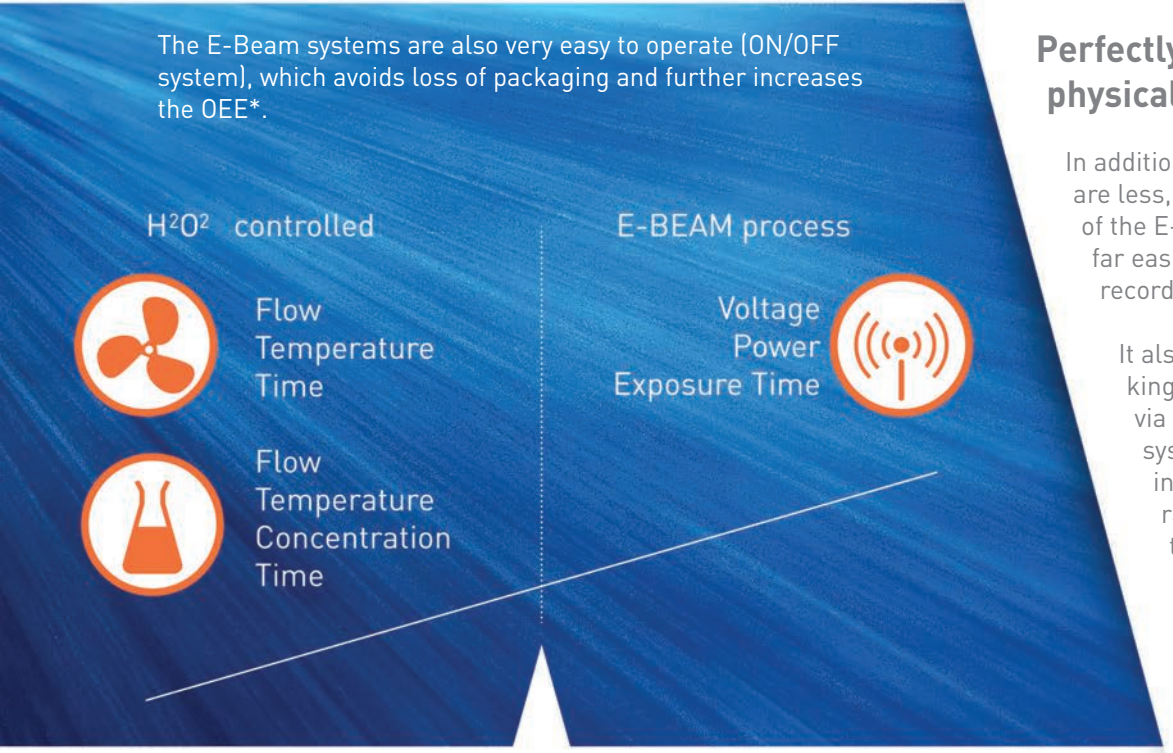
As the E-Beam decontamination systems require no circulation of water or chemical products and do not enter into contact either with the packaging or soiled solutions, they require very little cleaning.

For this reason, they have no negative impact on the OEE* (Overall Equipment Efficiency) of the line and stoppage times are set according to the filling machine cleaning cycles.

Only 3 parameters to be set

Electron beam treatment is controlled with 3 parameters (voltage, current and exposure duration), whereas decontamination systems using hydrogen peroxide or peracetic acid require the setting of respectively 7 and 6 parameters to ensure efficient decontamination.
This is why E-Beam systems are presently the easiest aseptic decontamination solutions to manage during production.

* See glossary on page 29



Perfectly controllable physical parameters

In addition to the fact that there are less, the critical parameters of the E-Beam systems are also far easier to control, monitor and record in the quality system.

It also enables individual tracking of packaging elements via a continuous monitoring system. They also offer industrialists more guarantees in relation with treatment continuity and conformity of results obtained.

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Initial dosimetric study
Equipment: The key points taken into consideration
What are the implications during production?

Initial dosimetric study

In order for E-Beam decontamination to be perfectly reliable, it is important to ensure the entire surface of the packaging receives the dose of radiation defined and required. If homogeneous exposure of a flat film or carton to an electron beam is relatively simple, this operation becomes a lot more delicate in a bottle filling line, both due to the complexity of the packaging shape as well as the diversity of the formats which may be processed in this production line

Definition and validation of treatment times

The treatment times are defined for each packaging format according to the level of decontamination required. Validation is carried out with dosimeters* placed at critical points in various zones of the bottle. The dosimeters the most commonly used for this purpose change colour more or less intensely depending on the dose of radiation received and thus enable mapping of the dose dispersion inside as well as outside the bottle. It is indeed impossible to apply a perfectly uniform dose to packaging with such complex shapes;

* See glossary on page 29

Inspection during production

Once the application has been validated, routine inspections may be carried out in a fast and easy manner. A single dosimeter* on a single "sample bottle" is all it takes to confirm that the dose is correct.

This operation only takes a few minutes per day.

* See glossary on page 29

Equipment: The key points to be taken into consideration

Working life and maintenance of emitters

E-Beam emitters are obviously key operating components in the system; their working life, as well as possible maintenance operations required have an impact on the OEE* and TCO* (Total Cost of Ownership) for the entire line.

The maintenance times will be considerably reduced if the emitters may be replaced in the same way as a light bulb; Indeed, replacement of an internal component (window, cathode) is not a simple operation.

The new generations of hermetically sealed emitters offer a double advantage: their working life is considerably increased compared with emitters of the previous generation and they are practically maintenance-free.

System redundancy

The number of emitters used is a key safety factor for the decontamination process. A system using only one or two emitters may fail to function entirely if one of the two emitters is defective. In the case of a system using multiple emitters however, the line may continue to operate in downgraded mode.

Booth design

The booth design form must take into account the X-ray* interference emitted by the E-Beam treatment, even if this interference is extremely low. Protection screens must be

* See glossary on page 29

incorporated into the treatment chamber and the booth casing must be reinforced.

This reinforcement is calculated according to the maximum beam energy and power; it is much lighter for low-energy beams which represents a considerable cost saving compared to high-energy beams.

What are the implications during production?

Adopting an innovative technology is always a potential source of industrial risk and legitimate questions are asked concerning the incidence this change may have on production.
If E-Beam technology is considered a potentially interesting decontamination solution, the following 3 points must be considered:
- This technology benefits from decades of experience feedback in other sectors (see intro part 1),
- The reliability of the latest generation of miniature emitters is also beginning to be well documented as these devices have been in use for around 8 years already and have also been used in several other activity sectors,
- E-Beam decontamination is much easier to use than currently available decontamination methods (H2O2 and PAA).

Incorporation in existing production lines

All industrialists wishing to benefit quickly from the advantages offered by E-Beam technology with regard to the environmental impact and safety in aseptic processes will have to ask the question about how to incorporate it into an existing production line.
In fact, even if this change requires adaptation of the machine interfaces upstream and downstream which represents a major modification, incorporation of the E-Beam into an existing line remains perfectly feasible. The E-Beam modules pose no problem as far as space requirement is concerned as they are more compact than other decontamination modules, and their installation is by no means complicated as they are "Plug and run" modules which simply require an electrical supply.

Production work-rate

As presented above, thanks to its high dose rate*, E-Beam treatment enables reduction of individual treatment times for packaging elements and therefore offers a promising perspective with regard to increasing production work-rates.

The operating simplicity of the system will enable a rapid rise in work-rate capacity. Based on the experience feedback from existing E-Beam sterilisation applications, several weeks is sufficient to allow perfect control of this technology during production and use of the decontamination module to its full capacity.

Of course, obtaining of the promised work-rate increase also depends on the capacity of the filling machine to adapt to this change. This will be that much easier if the latter is not already working at its maximum capacity, or if it has been designed to enable an easy upgrade to higher work-rates.

Training of operators

The operators must understand all parameters to be taken into consideration with this new process, the new safety precautions to be taken, and the new cleaning procedures. But here again, this learning curve is fast and easy for persons experienced in the use of the complex decontamination methods used today in aseptic filling processes.

* See glossary on page 34

Glossary

Cathode
The electrode connected to the negative pole of the electrical supply, point of exit or emission of electrons

Dose rate
Dose of radiation absorbed per unit of time, measured in Grays per second (Gy/s).

Dissociation (reaction):
Reaction by which the molecules separate into smaller particles (atoms, ions or radicals), often in an irreversible manner.

Dosimeter
A device placed on the product and designed to measure the dose of radiation it receives. When irradiated, this device presents a quantifiable modification of one of its properties according to the dose absorbed. This change is measured using appropriate analysis techniques and instruments.

Electron-volt (eV)
Kinetic energy acquired by an accelerated electron from rest with a potential difference of one volt

Ionisation
Phenomenon resulting in addition or loss of electrical charge in an atom or molecule. Ionisation may be obtained with the impact of an electron, photon, by applying thermal energy or by means of a chemical reaction.

Isotope
The isotopes of a chemical element are atoms which contain the number of protons characterised by this element, but a different number of neutrons.

The core of cobalt 59, stable isotope of the element contains for example 27 protons and 32 neutrons, whereas that of cobalt 60, radioactive element, contains 27 protons et 33 neutrons.

Nucleotide

An organic molecule, basic element of a nucleic acid such as DNA or RNA.

OEE

Overall Equipment Efficiency. It is obtained by multiplying the synthetic efficiency (operating rate x efficiency rate x rate of compliant products) by the load rate (working time on workshop opening time).

Reticulation

Reaction of linking macromolecular chains in three-dimensional grids.

X-ray

Electromagnetic radiation composed of photons, used in a wide range of applications such as medical imagery

TCO (Total Cost of Ownership)

Total cost of ownership of an item which represents the total sum spent by the owner over the entire life cycle of the item.

Ultra-vacuum

A very high vacuum, characterised by pressures generally below 10-7 Pa or 100 nPa

Use of electron beams (E-Beam) for the decontamination of packaging lines is a true innovation. It has all the elements necessary to be perfectly controlled

" Even though E-Beam technology is still very new for the treatment of packaging lines, it is well proven in other industrial sectors. We have been working for over thirty years with companies using this technology. Ionising treatments are presently the most effective solution for decontamination purposes whereas E-Beam is the green technology with no source of radioactivity and no chemical products; It therefore offers all the advantages necessary to become the standard in aseptic packaging.
We are extremely pleased to have accompanied Serac in the validation of its process. This is a key component in the success of a project for which resource centres such as ours have the experience and means necessary to offer a secure approach to industrialists.
We hope that this white paper will help convince industrialists to use E-Beam treatment in their aseptic packaging applications."

Alain Strasser
Head of the Aérial Technologies Resources Centre

About Aérial

Founded in 1985, Aérial, Technologies Resources Centre and Agricultural Food Industry Technical Institute, started out as part of an applied research programme into the ionisation of foodstuffs.

Since the early 90's, Aérial has been independently offering its specific know-how to agricultural food industries as well as all other industrial sectors using ionisation techniques.

Aérial is equipped, in its various laboratories, with highly-efficient analytic instruments (dosimetric, microbiological, physico-chemical, sensory analysis, freeze-drying), as well as an electron beam ionisation experimental station.
Aérial accompanies industrialists in the calibration and development of dosimetric systems in a wide range of industrial activity sectors (agricultural foodstuff, medical and para-medical, para-pharmaceutical, packaging).

Safer and better for the environment, I am absolutely convinced that E-Beam decontamination technology has a promising future ahead of it in the aseptic packaging sector

"Serac has perfectly controlled decontamination of its packaging elements for the last 35 years in its ultra-clean and aseptic filling lines.
Over the last decade, we have noted that our customers wish to make true progress in matters such as environmental impact, but also want to render their decontamination process safer in order to avoid any potential health hazard.
As all we offered at the time were chemical treatment processes, we turned our attention to physical, dry decontamination alternatives. It is with this in mind that we co-developed (with Claranor) the pulsed light treatment process for ultra-clean applications.
With ßluStream, our E-Beam decontamination module, we now propose a solution which required neither water, nor chemicals for aseptic packaging applications.

E-Beam technology is still in the teething stage in the packaging sector, but is well proven in other activity sectors.
In our business, it offers the double advantage of simplicity and reliability. This is why I am convinced of the fact that it will soon seduce industrialists in the agricultural food sector.
I am extremely pleased to have participated in the development of ßluStream, which undoubtedly bears the Serac trademark: This is a reliable and versatile solution which anticipates the needs and expectations of our customers."

Delphine Gueguen
Head of the Aseptic Equipment Division

Publisher: Serac
12 route de Mamers
72400 La Ferté-Bernard

Designer : Nexteo Conseil

Writer: A Fond les Bases

Completed in September 2017
by printing ITF Imprimeurs
ZA Le Sablon – CS40051
72230 Mulsanne

Copyright Serac : September 2017