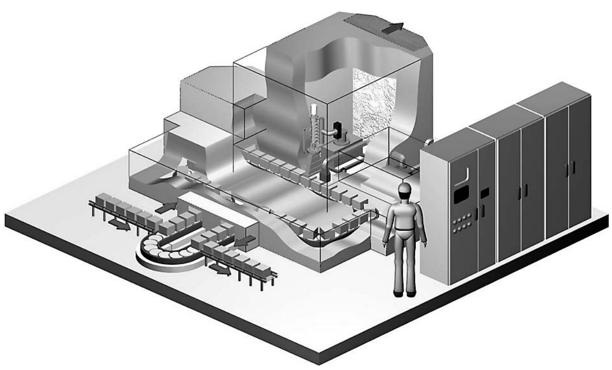

Electron Beam Sterilization System

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Nowadays, electron beam (EB) irradiation method is attracting attentions as useful medical tools sterilization, which has the advantages such as safety, zero emission and high speed processing. In this trend, in addition to present main object (the low-density medical tools: ex. operation dress), other various objects are strongly desired that will be applied of EB sterilization method. Mitsubishi Heavy Industries, Ltd. (MHI) has succeeded in realization of high efficiency continuous EB sterilization processing for high-density medical tools, vessel surface, and so on. Further, compact EB systems are also developed, which can also be applicable for above mentioned objects.

1. Introduction

Conventional sterilizing method of medical tools is mainly the use of ethylene oxide gas (EOG), gamma ray, high-pressure steam etc. However, the sterilization industry is undergoing drastic changes because of the strict regulations trend for EOG which is main method now, and the mounting demands for zero emission and high-speed treatment. Accordingly, recent attentions are turned to electron beam (EB) method which has the excellence for above mentioned subjects.

MHI started various research and development, and has manufactured various electron beam sterilization systems since 1996[1]. They are designed to sterilize mainly low-density disposable medical tools (such as operation dress), which are strongly requested at the beginning. Subsequently, the requests for suitable system about various other objects (e.g. other medical tools) have been increasing as the recognition of this means spread.

In order to correspond to this trend, the efficient irradiation technology for each object and the downsized system so as to replace the existing sterilization apparatus are required. This paper reports MHI's new technology and system of EB sterilization for such demands.

2. Electron beam irradiation characteristics

Electron beam irradiation characteristics depend on the absorbed dose and the acceleration energy.

2.1 Absorbed dose

As a result of the interaction between electrons and generated radicals, microorganisms are dead by a process of DNA chain cleavage. The amount of interaction between electron beam and object is called the absorbed dose, defined as the energy absorbed per unit mass ([J/kg] = [Gy]). The logarithmic value of survival fraction is proportional to the absorbed dose. The absorbed dose required to reduce the survival fraction to 1/10 is called the D value, and a specific value is set for each microorganism. So, the required absorbed dose increases in proportion to the target reduction level.

2.2 Acceleration energy

Fig. 1 shows the depth dose curve. Relations between

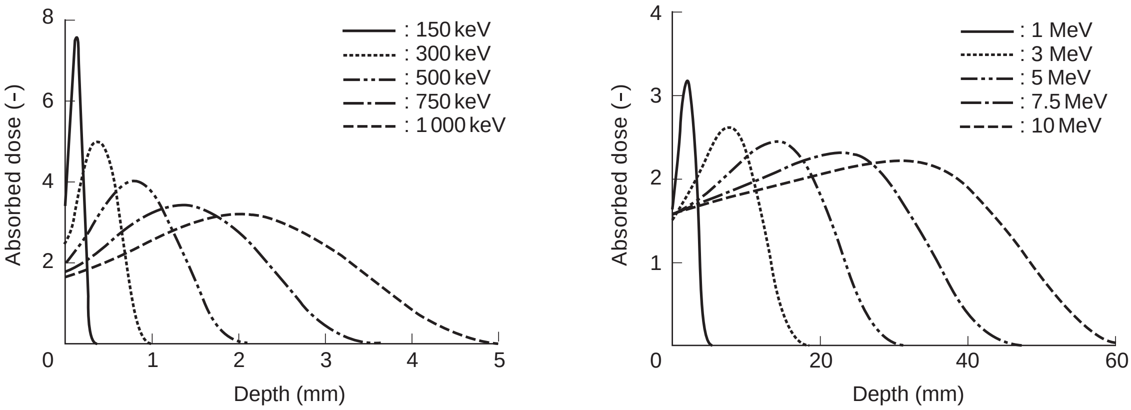

Fig. 1 Depth dose curve
Depth is converted to specific gravity of 1. Relations between depth and dose depend on acceleration energy.

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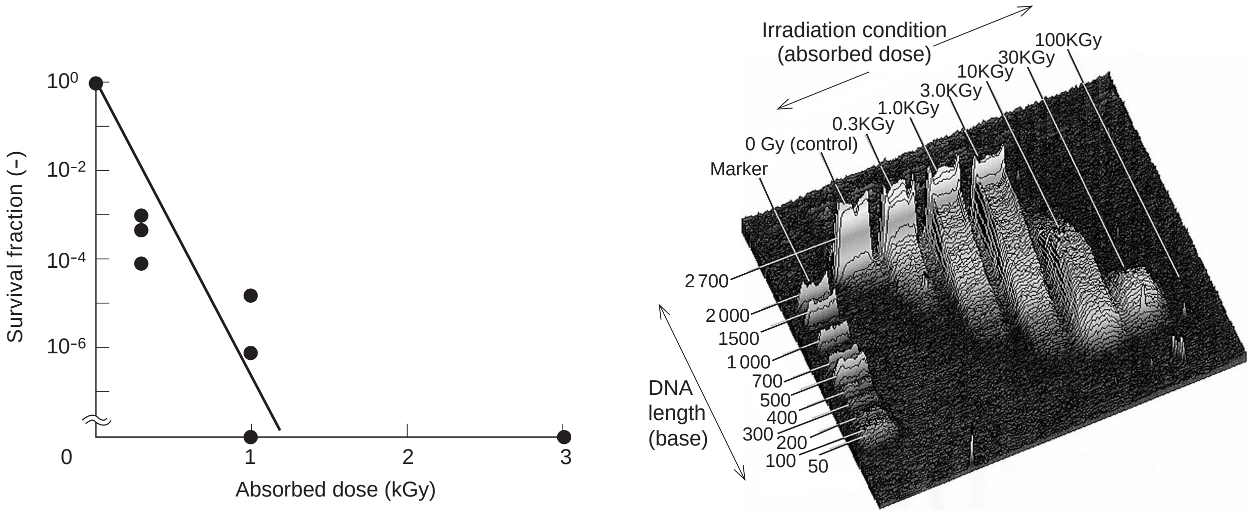
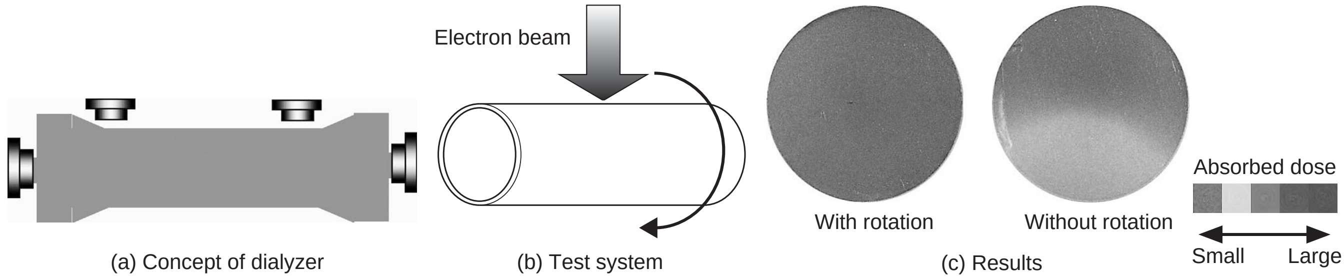


(a) Survival curve (b) DNA chain shortening

Fig. 2 Correlation between survival fraction and DNA chain shortening
Correlation between survival fraction and DNA chain length on absorbed dose has been confirmed with E.coli irradiated by electron beam.



(a) Concept of dialyzer (b) Test system (c) Results

Fig. 3 Evaluation result of absorbed dose in cylindrical container
Dose uniformity is confirmed by rotating the cylindrical container.

depth and dose depend greatly on the acceleration energy, and hence adequate setting according to the individual object is necessary.

2.3 Necessity of optimum system

Surplus dose leads to the decrease of irradiation efficiency and of strength and the coloring of object. Excess energy, e.g. high energy electron beam for sheets surface sterilization, leads to the decrease of irradiation efficiency and the increase of size and cost. Besides, upper limitation of energy (up to 10 MeV) to avoid activation must be considered.

So, construction of optimum irradiation system is greatly important, which can apply a necessary dose uniformly to individual items with adequate electron beam energy.

3. Example of optimum irradiation technology

MHI has studied the electron beam sterilization characteristic, e.g. the correlation between survival fraction and DNA chain shortening (**Fig. 2**). Examples of developed optimum irradiation technology, for highly requested objects, are shown below.

(1) High density medical tools

Most dialyzer contains physiological saline with hollow fibers inside. Therefore, the density is higher than present main objects for EB sterilization, and then uniform irradiation is difficult by previous EB irradiation technique that irradiated from one or both direction.

Noticing that dialyser is rotation symmetry, MHI developed a uniform irradiation technology inside it with the combination of EB irradiation from peripheral direction and the rotation them around the axis under conveyance. To confirm the validity of this method, an acrylic cylindrical container modeling dialyzer is irradiated by EB which was filled with agar containing a sensitive pigment which color changes depending on the absorbed dose, and then the degree of discoloration on the cross-section was evaluated. **Fig. 3** shows that the evaluated result of absorbed dose in the cylindrical container is uniform. The validity of this method has been also verified by the evaluation of absolute values of absorbed doses by film dosimeter, and of the fluidity of liquid in a cylindrical container.

Henceforth, MHI intends to apply this for high-density medical tools sterilization system with our various physical distribution technologies.

(2) Inner surface of vessel

To sterilize the inner surface of vessel, such as storage containers of medicine or the like, the electron beam trajectory must be controlled suitably for

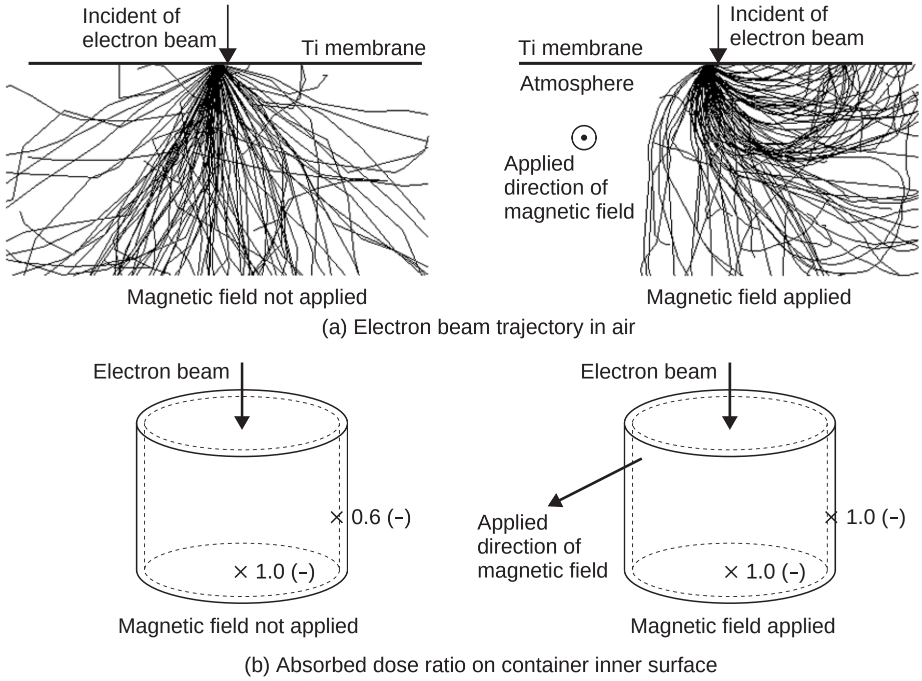


Fig. 4 Magnetic field deflecting effect of electron beam in air
Uniformity of absorbed dose at inner surface of vessel can be improved by controlling electron beam trajectory with applied magnetic field.

Table 1 Line-up of microwave acceleration type electron beam system

Item			Small model	Medium model	Large model
Concept			Compact	On-line	High power
Performance	Energy	(MeV)	1 - 10	1 - 10	10
Performance	Power	(kW)	2 - 4	3 - 6	14 - 31
Performance	Scanning width	(cm)	30 - 50	30 - 50	30 - 80
Performance	Estimated throughout	(kg/h)	130 - 230	200 - 350	1 000 - 1 800
Others	Acceleration system		C-band standing wave type	S-band standing wave type	S-band traveling wave type
Others	Required area	(m^2)	50 - 300	70 - 350	550

Note: Estimated throughout is converted to 25 kGy application in low density medical tools.

each object.

Seeing that the trajectory of an electron beam in air can be controlled by a magnetic field, MHI developed a technology for applying a magnetic field simultaneously with irradiation.

Fig. 4 shows the deflection effect of a magnetic field on an electron beam in air. This Monte Carlo simulation results show that the spread of the electron beam trajectory in air caused by scattering with gas can be controlled by magnetic field. Actual ratio of measured absorbed dose in inner surface of vessel also shows the uniform irradiation. The outer surface can also be irradiated uniformly by this technology.

In Future, MHI will be developing sterilization system for various vessels of medicines, foods and beverages along with appropriate objects handling technology above mentioned. Also, electron beam handling technology will be further developed for gas treatment such as air sterilization, exhaust gas treatment (e.g. VOC decomposition), and so on.

4. Electron beam sterilization system

MHI is promoting development of a compact EB system to meet the space-saving demands of users.

4.1 Microwave acceleration system

Table 1 is a line-up of EB products for using LINAC type acceleration guide and microwave electric field. Development in the high-energy region (1 to 10 MeV) has already been completed, and the line-up will be further expanded over a wide energy range depending on demands. A high-power model has already been reported(2), so more recent models are briefly described below.

(1) On-line type

The on-line type electron beam irradiation system is intended for use in irradiating intermediate packaged products in mid process on the productions line.

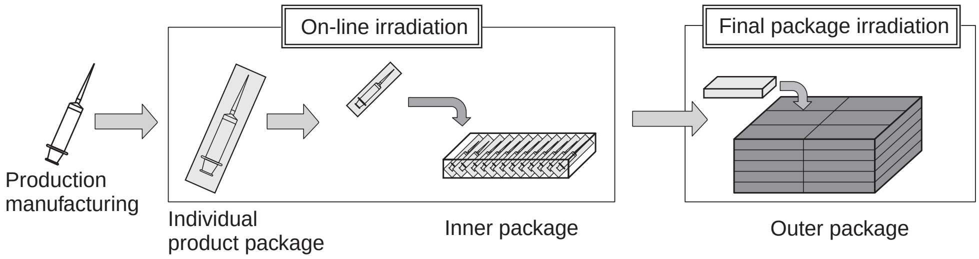


Fig. 5 Electron beam irradiation systems for use at various stages of production
Suitable irradiation systems can be selected depending on the type of product and stage of manufacture.

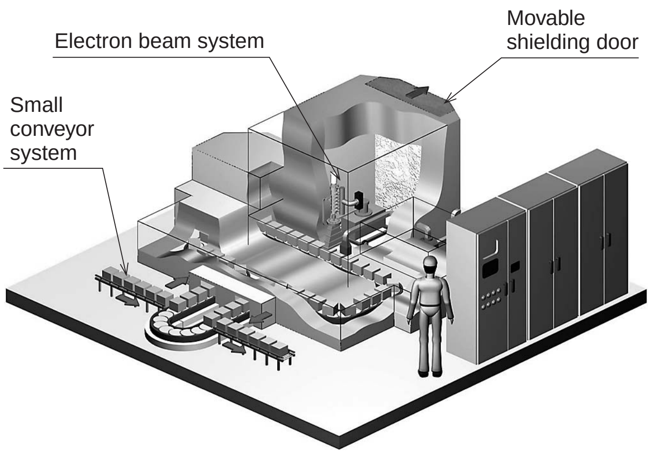


Fig. 6 On-line type electron beam irradiation system
Electron beam is irradiated in shielding to individual items which is transferred by conveyor system directly connected to productions line.

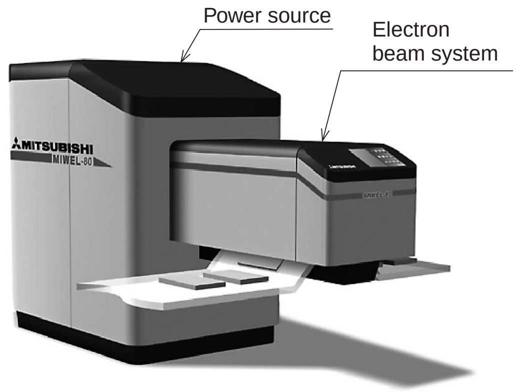


Fig. 7 Wide-range electron beam irradiation system
Compact structure containing all components in shielding is realized.

Table 2 Line-up of electrostatic acceleration type electron beam system

	Item		Ultra-low energy	Low energy
	Concept		Surface layer treatment	Surface treatment
Perform-ance	Energy	(keV)	80 - 120	120 - 300
	Output	(kW)	15	36 or less
	Irradiation width	(cm)	200 or less	200 or less
	Processing speed	(m/min)	40 or less (at 100 keV)	68 (at 300 keV)
Others	Accelerating system		Electrostatic type	Electrostatic type
	Required area	(m^2)	8	15

Note: Processing speed is converted to 25 kGy application.

Fig. 5 shows methods of irradiation at various stages of production. This system is intended to treat in minimum packaged state as required by end users. Therefore, this system requires relatively less acceleration energy and less power compared with previous methods which treat final package.

Fig. 6 shows the system configuration. Significantly small required area is realized with newly developed item, the standing-wave type acceleration guide (suited for less power) and the low curvature conveyor. Further, all the components, including the shielding walls, are incorporated in a combined structure, so it is easy to adapts the modification of the production lines. This system will be supplied mainly to users manufacturing sterilized products, as a substitute for their existing facility.

(2) Ultra-small C-band accelerator

By applying the super-precision MHI processing technology, the world's first commercial systems have been developed using C-band (5.7GHz) acceleration guide, which are much smaller than the existing S-band ones(3). In this system, maximum 10 MeV EB is realized in about 60 cm length acceleration guide. In future, in addition to application in EB sterilization for smaller scale users, it is planned to other applications, e.g. radiation therapeutic equipment, by taking advantages of small size and light-weight.

4.2 Electrostatic acceleration system

Table 2 is a line-up of EB products using an electrostatic field(4).

In this system, wide electron exposure unit has already been developed. **Fig. 7** shows the product image.

The feature of this system is as follows that miniaturization is realized by installing all components in its own shielding, long-life is attained with our original double-window structure and conservativeness is improved using cartridge type maintenance parts.

In future, it is planned to apply this system in gas disposal and surface modification, in addition to the sterilization of packaging and others.

5. Conclusions

Efficient uniform irradiation technology has been established with the optimum object handling technology and/or suitable EB trajectory control technology, which are applicable to so-called upcoming objects, e.g. high-density medical tools, pharmaceutical and food containers and gases.

Further, compact EB sterilization systems are developed, which can also be applicable for above- mentioned technology. So, MHI line-up of EB sterilization system is fully realized for various demands, now.

In future, applications of this technology will be further promoted in the field of crosslinking, environmental, medical engineering, etc. in addition to sterilization, so as to contribute to widespread technical innovation.

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